European Food Safety Authority

External Evaluation of EFSA

Final Report

ERNST & YOUNG
Quality In Everything We Do

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List of abbreviations

ABB	Activity Based Budget
ADoI	Annual Declaration of Interest
AF	Advisory Forum (Risk Assessors)
AFCWG	Advisory Forum Working Group on Communication
Cons.	Consumer Organizations
DG BUDG	Directorate General for Budget
DG HR	Directorate General Human Resources and Security
DG RTD	Directorate General for Research and Innovation
DGs	Directorates General
DG SANCO	Directorate General for Health and Consumers
DoI	Declaration of Interest
EC	European Commission
ECHA	European Chemicals Agency
ED	Executive Director
EFSA	European Food Safety Authority (hereinafter as well referred to as "the Authority")
EMA	European Medicines Agency
EP	European Parliament
FIR/A	Food Industry Representatives/Applicants
FP	Focal Points
FSA	Food Standard Agency
IEP	Information Exchange Platform
ILSI	International Life Sciences Institute
IOs	International organizations
JC	Judgment Criteria
MB	Management Board
MEP	Member of the European Parliament
MS	Member States
NGOs	Non-Governmental Organizations (other than Consumer Organizations)
NRM	National Risk Managers
NRA	National Risk Assessors
SC	Scientific Committee
SCP	Stakeholder Consultative Platform
SDoI	Specific Declaration of Interest
Scient. Org.	Scientific organizations
SOP	Standard Operating Procedure

1. Executive summary

1.1 Main findings

EFSA deals with the provision of scientific outputs and technical support, the communication of risks associated with the food chain and the scientific cooperation with organizations operating in the food and feed safety fields. It operates with the principles of independence, openness and transparency. This report evaluates these tasks and EFSA's principles, considering also EFSA stakeholders' point of view, for the period January 2006 to December 2010, sometimes extending to 2012 to take into account significant recent developments.

Provision of scientific outputs

Changes in recent years have made the context in which EFSA operates increasingly complex. New legislations (e.g., health claims) have assigned to EFSA new areas of responsibility; science innovation has requested the Authority to adopt new risk assessment methodologies and to consider risks with a wider integrated approach. In this changing context, the Authority has faced an increasing demand for scientific advice and namely for regulated products, with a subsequent need to align its structure. EFSA's structure has indeed adapted to changes and activity evolutions in terms of both structural reorganizations and consistent allocation of resources, even though both weak internal processes (i.e., the monitoring process) and the various workflows envisaged in the fragmented legislative framework (for regulated products) limit its efficiency. Anyway, EFSA's reorganization, together with quality procedures and highly qualified experts, seems to have been effective in supporting a process of **provision of outputs** that can be considered of good quality and useful for policy making. Some concerns persist and counterbalance the effectiveness of the process in relation to the efficiency and sustainability in the allocation of tasks between internal staff and experts and on the relation with the industry to enable safe innovation in the EU.

Risk Communication

EFSA's activity in **risk communication** is considered useful and clear enough to inform and support decision-making processes. The points of strength in EFSA's communication relate to its content, quality and relevance. Nonetheless, EFSA's communication still lacks of clarity; while messages may be adequate for a well informed target audience, they are not readily accessible for a broader public, in particular due to language barriers. EFSA should focus on improving the effectiveness of existing tools (especially the website) in order to better meet the different information needs of its stakeholders, with greater tailoring and targeting of its messages and tools. There is an opportunity to strengthen the role given to EFSA in supporting the EC and risk managers in Member States in facilitating coherent risk communications when urgent scientific advice is needed, making more effective the support provided by members of the Advisory Forum Working Group on Communications.

Cooperation

The current system of **cooperation** and networking is adequate and allows EFSA to have high quality expertise from different MS, that on their side benefit of EFSA's support in terms of Pan-European assessment, creating an opportunity to streamline the overall costs of high quality assessment by building on synergies and by the availability of forefront methodologies or support tools for all. Still, cooperation with MS remains an area of improvement in order to better share responsibilities, priorities and future workloads –avoiding duplications and misalignments- and to better harmonize methodological approaches and IT systems for data collection.

While at an EU level EFSA's role is appreciated and its opinions are respected, at an **international level** is still to be built. Relying on a widespread recognition as an attractive place to work, EFSA should take advantage of its strong EU positioning to further develop data exchange with International Organizations and promote the convergence of international risk assessment standards with the EU approach.

EFSA's key principles

EFSA has performed its tasks in an **independent** way, thanks to the progressive consolidation of one of the most advanced and robust system for independence.

The positive framework emerging from the evaluation is also the result of the high level of **transparency and openness** achieved in its activities. Indeed, EFSA went far beyond the compliance with the requirements of the Founding Regulation, making public more and more documents and creating ad-hoc tools for the involvement of external stakeholders. Still, the risk assessment process is questioned in its transparency and openness. EFSA should capitalize the expertise gained while choosing the most effective and efficient tools and monitor the ongoing Pilot Project to open up Panels to observers as a tool to enhance the transparency and openness of its scientific decision making process.

1.2 Findings per thematic areas

Provision of scientific outputs and technical support

The provision of outputs originated from external requests is effective -as it meets EFSA main stakeholders' needs, in terms of high quality, accessibility and reliability of outputs- and provides added value, through the use of an integrated approach and the development of tools and procedures to support risk managers. Also in emergency situations, outputs are appreciated, specifically for their clarity and timeliness, even if produced as an answer to an external request for urgent advice, whereas an enhanced capacity of EFSA to anticipate risks before they become an emergency/crisis would be desirable.

When dealing with the provision of outputs originated from internal mandates and self-tasking function EFSA's performance is less effective, when considering that the food system is not aware of this function.

The following recommendations are provided to improve the effectiveness, quality and added value of the provision of outputs:

- Address the concern of **timeliness**, *i)* improving the user friendliness of the RoQ in order to allow requestors and other interested stakeholders to follow the process and *ii)* improving the dialogue with partners to limit bottlenecks;
- Improve the **usability** of guidance documents, enriching them with practical examples of implementation and identify specific point of contact;
- Promote the **harmonization of outputs**, *i)* controlling the compliance of Panels and Committee to the guidance documents detailing scientific and procedural aspects of the risk assessment workflow and *ii)* simplifying SOPs related to the scientific decision-making process and encourage their use;
- Increase the external **awareness of internal mandates and self-tasking** activities on emerging issues, better communicating outputs and activities.

Data Collection

EFSA's data collection activity is compliant with the requirements set in the Founding Regulation and allows the Authority to adequately respond to requests for advice, even in crisis situations, and to support decision-making processes of risk managers and national risk assessments. Indeed, data are of good quality and support EFSA in the provision of reports

that are also appreciated for their quality and for the useful overview on the main trends they provide. Also the level of accessibility and availability of data is quite good, especially for data related to Food Consumption, where EFSA has invested a lot through different initiatives, but still the consultation of data is very much limited by the presence of filters, the weak query function and the limited user-friendliness of the databases.

In order to increase its performance in the data collection activity, EFSA should take into account the following recommendations:

- Improve the **compatibility of the Data Collection Framework** with national IT systems for data collection, revising the Data Collection Framework in order to make the formats for data submission more flexible and usable for all MS;
- Improve the **accessibility to data and information** *i)* making the databases more user-friendly and intelligible and improving the query function; *ii)* identifying strategies to harmonize EFSA's data collection requirements with non European ones;
- Strengthen the role given to EFSA in assisting risk managers on continuous pro-active risk monitoring in areas not specifically identified by the Founding Regulation (e.g., GMOs).

Risk Communication

EFSA's communication has proved to be effective and of high quality, especially in terms of content, relevance and timing, and usefulness to improve knowledge and awareness of existing food-chain risks. Indeed, EFSA has succeeded in building awareness, trust and reputation for the overall food safety system and for itself, contributing to the harmonization and coherence in risk communication. Still, though, some weaknesses are present and can be addressed taking into account the following recommendations:

- Bring more **clarity** in EFSA's communication, *i)* adapting the communication language taking into account the targets and *ii)* further increasing the use of other languages (other than English) for publications and communication on the website;
- Make the **website** more effective, reducing the complexity of the navigation on the website and strengthening the search engine;
- Strengthen the role given to EFSA in supporting the EC and risk managers in MS in ensuring coordinated and **coherent communications when urgent scientific advice is required** to address risks associated with the food chain *i)* defining clear responsibilities in risk communication as soon as a crisis arises and *ii)* making more effective the support of AFCWG in crisis situations.

Cooperation and networking

EFSA's scientific cooperation system is effective and adequate, allowing EFSA to benefit in terms of availability of high quality expertise.

More specifically the level of cooperation has continuously improved over the years with the EC but can still improve with MS. Cooperation with MS relies on a wide portfolio of instruments, but still represents an ongoing concern, both because of an unclear sharing of responsibilities, a weak work programme sharing and communication and a limited effectiveness of the Advisory Forum, and also because of the highly differentiated contribution of MS, due to differences in risk assessment capacity among MS.

The main areas of improvement as regard EFSA's cooperation activity are therefore the reduction of misalignments and duplication of work among MS and between MS at the European level, and the contribution of external experts to EFSA's work through improved procedures of mobilization.

International role and recognition

While EFSA's role is clearly recognized and appreciated at a European level, its positioning in the international scene is still to be built, despite EFSA's organization and participation to international scientific events and agreements with third countries agencies and international organizations.

Still, EFSA's scientific opinions form part of the references that are used by policy-makers to set standards (Codex Alimentarius, FAO, WHO, OIE and national agencies), even though they are not considered as a main element in the European policy decision-making process.

EFSA is globally considered as **an attractive place to work** for external leading experts, above all as relates to the high quality of the scientific work undertaken, the international and multi-cultural environment and the public recognition of the good reputation of the EFSA.

The following recommendations are addressed to improve EFSA's international role and recognition:

- Strengthen **agreements/scientific partnerships** with other agencies and IOs for the exchange of information and the use of data fostering the convergence of international risk assessment standards with EU approach in a globalizing economy;
- More actively participate in international discussions on **risk assessment methodologies**;
- Monitor the **professional attractiveness** of EFSA for external experts to maintain a high quality of scientific outputs, limiting the travelling time for experts by promoting the use of IT tools (interactive video-conference, webinars, etc.).

The organizational structure, its operational efficiency and its adaptability to change

EFSA's MB and the organizational structure allow the Authority to fulfil its mandate.

EFSA's structure, processes and allocation of resources are globally appropriate to the type of work entrusted to it, even though the distribution of work among staff and experts seems to be unbalanced to adequately face future challenges, internal processes (specifically as relates the monitoring system) still need to be improved, and the limited standardization of the workflows, mainly in relation to the evaluation of regulated products, limits efficiency.

Anyhow, EFSA's organizational structure has proved to be flexible enough to adapt to the progressive changes in tasks, specifically in reaction to the increasing applications.

In order to increase its performance, EFSA should take into account the following recommendation:

- Improve the **monitoring system**, *i)* improving the readability of reporting documents by using a uniform nomenclature; *ii)* using the same indicators in strategic and reporting documents over the years; *iii)* inserting a column in the budget reconciling budget lines with activities; *iv)* limiting changes in budget, reporting documents, indicators, activity repartition and explaining them whenever they occur, enabling comparison across years; v) establishing a system to reconcile mandates received, the questions produced and the outputs provided. *vi)* increase the level of reliability and integrity of data used.

Independence

EFSA has fulfilled its obligation to operate in an independent manner, having one of the most advanced and robust systems in place for ensuring the independence. Despite criticisms, no major changes in EFSA's structures, governance and procedures are needed and the current

situation is considered as a satisfying infrastructure also if compared with other European Agencies and relevant international standards, like OECD ones[1].

More transparency and an improved communication are needed in relation to:

- EFSA's links with industry and industry-affiliated bodies;
- Screening procedures and decisions on conflicts of interests;
- Mitigation of criticisms towards EFSA's experts independence.

Policies and procedures have evolved over the years coherently with the new challenges and work areas the Authority had to manage. Even though these policies have proven to be effective in preventing and dealing with conflicts of interest, the current level of regulation of this issue is critical as well as the absence of a complete EU specific regulatory framework, and this risks to impact negatively on experts' willingness to work for the Authority. Any additional effort to further introduce rules should be adequately counterbalanced with different complementary initiatives in order to be effective.

Openness and transparency

EFSA has fulfilled its obligations to operate in an open and transparent manner, widening the portfolio of public documents of its decision-making bodies and progressively increasing the level of inclusion of external stakeholders in its decision-making process through a variety of instruments.

Although much has been done to make the principles of openness and transparency part of EFSA's work and activities, the risk assessment process is still too closed. Indeed, the Panel system functioning and decision-making is not open to public scrutiny and comments and, despite the recent Pilot Project to open up Panels to observers represents an important shift towards a higher level of transparency, it seems not enough.

The principles of openness and transparency are part of EFSA's work today but should continue to increase their relevance to face future challenges linked to the changing legal context pushing up the minimum requirements and to meet the increasing stakeholders' expectations of transparency and inclusion.

[1] The OECD standards are made for public officials and leave uncovered 75% of the population of the EFSA that do not enter in this contractual category, namely the Management Board members, the scientific experts members of Panels and Working Groups, the Advisory Forum members and the Stakeholders Consultative Platform members.

1.3 Transversal/strategic recommendations[2]

EFSA should **further increase the level of openness/transparency in some processes** and namely in risk assessment/scientific decisions making, data collection, screening interests. As regards the process of risk assessment, EFSA should increase the level of transparency on how external scientific studies, as well as suggestions and comments coming from stakeholders are taken into account (especially the diverging ones). For specific scientific decision-making processes, IT platforms/points of contacts to exchange information and updates in meetings on how comments/studies have been taken into account can help. The procedure to update opinions once new evidence is available should be improved in terms of timeliness. The impact on the external perception of transparency of the Pilot Project to open up Panels to external observers should be seriously evaluated. Lastly, EFSA should assess the cost-benefit of the tools of involvement of stakeholders in order to prioritize them and focus efforts on the most efficient and effective tools.

Also the data collection process can be improved in terms of transparency, providing feedbacks to data providers on the quality, quantity, relevance and use of collected data and making clearer reference to the sources of data, to conflicting data, assumptions and uncertainties in scientific outputs. The issues of the ownership and of the final level of accessibility of data should also be addressed. Last but not least, to increase the level of transparency, EFSA should evaluate the opportunity to give stakeholders the possibility to get access to documents related to the screening procedures and decisions on conflict of interests.

EFSA should **further strengthen the cooperation with Member States**, in order to gain in effectiveness and efficiency, avoid duplications and enhance EFSA's role in all Member States. This can be done with different actions involving a more effective functioning of the Advisory Forum and with an enhanced role of Focal Points: *i)* improving the integrated system of exchange of information (IEP) giving the possibility to signal to EFSA new risk assessment, divergent opinions, etc.; *ii)* increasing the diffusion and communication of EFSA's risk assessment in MS; *iii)* sharing agenda and work plans (including priorities) to make the most of existing and on-going works and develop joint activities; *iv)* stimulating exchanges and the participation of each MS at AF meetings and a better matching between meetings' agenda items and participants.

Although the quality of data is generally satisfying, some improvements can be done to promote a higher quality: EFSA should evaluate to allocate funds to the implementation of a project aimed at establishing/improving data quality provision by MS and promoting assurance systems according to a harmonized approach for data collection. Difficulties faced by MS in providing data (both in terms of available resources and IT interface) should be taken into account.

EFSA should **increase its planning and prioritization capacity**. EFSA works in a very complex context, where the workload is increasing, not easily foreseeable and becoming more and more challenging. From one side, it is important that EFSA and all its clients increase the level of information exchange in order for EFSA to tackle the increasing workload in an efficient way; from the other side EFSA should strengthen its internal capacity to anticipate challenges and emerging risks and prioritize its activities/tools. A formal recognition that EFSA's mandate has been de facto extended over the years to address the changing needs and expectations of risk managers (i.e., environmental risk assessment) could also help EFSA in the adequate identification of priority areas of intervention.

[2] The transversal/strategic recommendations were not assessed in terms of impact on the actual resources or in terms of EFSA's potential necessity for additional resources.

The consultation of EFSA during the EU legislative process should be more effective, to anticipate impacts of new legislations on EFSA's work and allow EFSA to organize at best. Regular meetings to report on progress in the work plan implementation and review the work plan, in case of new regulations or emerging issues, should be established and an increase in the number of EC's feedbacks on the usefulness of the outputs should be provided, also to allow EFSA to identify priority work areas and focus available resources (including an efficient use of outsourcing).

As regards future challenges and emerging risks, EFSA should continue strengthening its "Intelligence capacity" to study the global context, be aware of the international trends and regularly monitor evolutions and changes. An increase of exchanges/partnerships with public research institutions and MS to have inputs in terms of knowledge and innovation is recommended, as well as a better use of stakeholders meetings to identify emerging issues and future work areas.

EFSA should **take into account different stakeholders' needs and better customize its services**.

One main issue relates to MS needs, that are differentiated according to the specific MS characteristics. In order to better meet MS expectations and needs, EFSA should organize bilateral meetings and evaluate the opportunity to insert specific national context details when dealing with opinions, and to provide an additional service consultancy for NRM to interpret/adapt the opinion to a specific national context. The opportunity to integrate meetings with complementary projects developed in cooperation with specific MS should be considered to take benefit of MS expertise and increase the value of their contribution.

Also the capacity of EFSA to meet the industry needs should be improved, balancing the need to respond effectively to industry needs with its independence and taking into account that applications cover more than 60% of EFSA's outputs. The change in the organization, with the creation of a specific Unit and an Application Desk for applicants goes in this direction, but effects are not perceived yet and the process seems to be still too complex and inefficient, considering the heterogeneity and innovative nature of some requests and the time needed to provide opinions. The Application Desk should work as a platform for discussion between EFSA and applicants, and EFSA should evaluate the cost opportunity of introducing hearings and pre-submission meetings (even with fees), to streamline the application process and allow EFSA and firms to gain efficiency.

Lastly, as regards EFSA communication, EFSA should evaluate whether the general public represents a priority target for communication and thus, in case, design adequate tools of information.

EFSA should **increase its capacity to deal with criticism on its independence**.

EFSA has already implemented effective procedures to deal with independence and their additional reinforcement is not recommended, not to introduce additional burdens to experts' participation to EFSA's activities. Rather, EFSA should focus the communication on independence, specific aspects of implemented rules, procedures and results that address still existing criticisms. It should also analyse criticisms, keeping track of "scientific" and "political" ones and defining strategies to deal with both. One specific point of attention relates to NGOs: EFSA should conduct a survey focused on NGOs to better understand the obstacles to a fruitful cooperation, identifying expectations and areas of potential cooperation.

2. Introduction to EFSA and the independent external evaluation

2.1 EFSA

The regulatory context

EFSA's legislative framework finds its roots in the Founding Regulation of the European Parliament and the Council, Regulation (EC) No 178/2002 *"laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety"*, which, in chapter 3, establishes the European Food Safety Authority.

According to Article 6 of Regulation (EC) No 178/2002, "*food law shall be based on risk analysis*" which is defined by the Regulation as "*a process consisting of three interconnected components: risk assessment, risk management and risk communication*". In accordance with the Regulation, the risk assessment is *"undertaken in an independent, objective and transparent manner*" and EFSA was created to perform this function.

In particular, Article 22 declares the mission of the Authority, by stating that "*The Authority shall provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct impact on food and feed safety. It shall provide independent information on all matters within these fields and communication on risks*".

Given the interconnection between the different components of risk analysis, the Regulation also specifies that EFSA, the Commission and Member States shall cooperate to promote the effective coherence between risk assessment, risk management and risk communication functions.

Table 1 shows the objectives and tasks of EFSA defined in the Founding Regulation.

Table 1: EFSA's objectives

GLOBAL OBJECTIVES (REG. 178/2002 ART. 22)	TASK (REG. 178/2002 ART. 23)
1- Provide independent scientific advice	1.1 Provide the Community institutions and the Member States with the best possible scientific opinions in all cases provided for by Community legislation – art.23 a)
	1.2 Provide scientific and technical support to the Commission and in the interpretation and consideration of risk assessment opinions – art.23 c)
	1.3 Commission scientific studies necessary for the accomplishment of its mission – art.23 d)
	1.4 Search for, collect, collate, analyze and summarize scientific and technical data – art. 23 e)
	1.5 Undertake actions to identify emerging risks – art. 23 f)
	1.6 Provide scientific and technical assistance in the crisis management procedures implemented by the Commission – art. 23 h)
	1.7 Express independently its own conclusions and orientations – art. 23 k)
2- Provide independent risk communication	2.1 Ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information – Art. 23 j)

3- Promote scientific cooperation	3.1	Establish a system of networks of organizations operating in the fields within its mission - Art. 23 g)
	3.2	Provide scientific and technical assistance, requested by the Commission, with a view to improving cooperation between the Community, applicant countries, international organizations and third countries – art.23 i)
	3.3	Promote and coordinate risk assessment methodologies Art. 23 b)

The procedures applied by EFSA in response to the requests for scientific opinions are outlined in Commission Regulation (EC) No 1304/2003, while Regulation (EC) No 2230/2004 defines the rules and criteria concerning the cooperation with Member States and the scientific partner network creation.

Thus, the Founding Regulation, along with its implementing measures, outlines **level I** of EFSA's regulatory framework.

Beyond this first level of regulation, we find the sector-specific regulations, which are related to the different processes the Authority has to follow depending on the products or scientific areas of involvement. In particular, these regulations define the areas where the Authority shall be involved and the specific steps of the processes it has to follow **(level II).**

Besides the above mentioned regulation levels, EFSA is subject to some cross-cutting laws regarding:

- EC regulation (e.g., access to documents, management of private information, etc) – **level III**;
- Internal policies and self-regulatory rules (e.g., functioning of EFSA's units, procedures to be followed, SOPs, etc) – **level IV**.

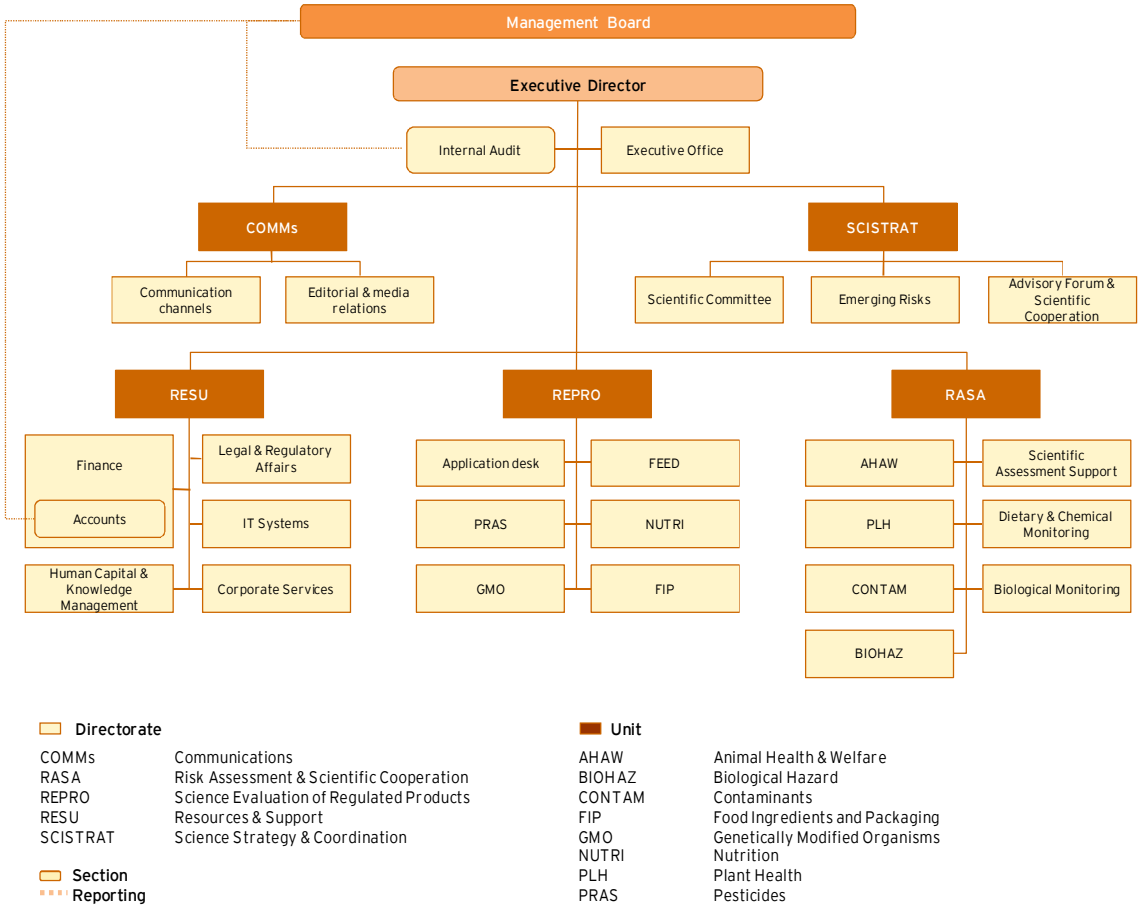
Annex 4 provides a structured list of regulations.

EFSA's structure

The organizational structure

The current structure (Figure 1) is in place since May 2011, and reflects the strategic direction EFSA undertook in 2009 with the definition of the Strategic Plan 2009-2013. For a description of the functions of each Directorate, see Annex "EFSA's Executive Director and Directorates".

Figure 1: Current organizational structure



(Source: EY elaboration on EFSA's website)

As per article 24 of its Funding Regulation, beside the Executive Director and her staff, the Authority is comprised of:

- a Management Board;
- an Advisory Forum;
- a Scientific Committee and Scientific Panels.

Management Board

Since its establishment in 2002, the European Food Safety Authority has been governed by a Management Board whose members are mandated to act in the public interest. The Board is responsible for the effective and efficient delivery of EFSA's mandate as defined in the Founding Regulation. The Board also plays a significant role in EFSA's governance, ensuring that EFSA acts independently.

The Management Board has no influence on the content of EFSA's scientific advice.

All Management Board meetings are held in public and can be followed on demand over the Internet, with the exception of confidential administrative issues (such as security). Moreover, the Board's documents are published on EFSA's website prior to the start of the meetings.

Advisory Forum

The Advisory Forum connects EFSA with the **National Food Authorities** of the Member States, Iceland and Norway. It encourages networking, cooperation and pooling of expertise. The Forum is composed of one representative from each of the 27 EU MS, one from Iceland, one

from Norway and observers from Switzerland and the EC. Each MS is responsible for appointing its representative. The Forum is chaired by EFSA's Executive Director.

Members have committed to:

- exchange scientific data;
- coordinate risk communication activities and messages;
- address contentious issues and diverging opinions;
- set up working groups to focus collectively on specific issues;
- coordinate work and avoid duplication.

Through the Forum, the MS can advise the Authority on the work programme, on priorities to address and other relevant matters. Moreover, the Forum helps National Authorities in sharing information and coordinating activities among themselves.

Scientific Committee and Scientific Panels

The Scientific Committee is (along with the Scientific Panels) **responsible for adopting EFSA's scientific opinions**, supported by EFSA's staff. It carries out its work either in response to requests for scientific advice from risk managers or on its own initiative. The Committee prepares guidance documents for the Scientific Panels and it prepares scientific opinions both on cross-cutting subjects – issues that do not fall within the competence of any of the scientific panels – and on multi-sector issues, falling within the remit of more than one panel.

Its main tasks consist in:

- developing, promoting and implementing the harmonization of integrated approaches for exposure hazard and risk assessment;
- ensuring consistency among the opinions of the Scientific Panels;
- ensuring the consistency of the scientific opinion procedure, in particular with regard to the adoption of working procedures and harmonization of working methods;
- providing advice on EFSA's scientific work programme and on scientific cooperation and networking.

The Scientific Panels are (along with the SC) **responsible for adopting EFSA's scientific opinions** and implementing the work programme within their specific areas of expertise. EFSA has ten Panels[3].

EFSA's stakeholders/partners

To carry out its mandate, EFSA has to deal with a **complex network of actors** comprising Member States (NRM and NRA), European bodies (e.g., Parliament Committees, the EC, other decentralized authorities and agencies), other scientific and research organizations active at national, European and international level and with other non-institutional stakeholders. The interaction with its stakeholders is particularly significant in view of the fact that one of the main objectives of the Authority is to provide effective communication of scientific advice and the facilitation of dialogue with and between interested parties.

Article 36 of Regulation (EC) No 178/2002 and, in particular, paragraphs 1, 2 and 3, emphasize the importance of EFSA promoting **European networking** between competent organizations operating within the fields of the Authority's mission, in view of facilitating a

[3] Additives and products or substances used in animal feed (FEEDAP); Animal health and welfare (AHAW); Biological hazards (BIOHAZ), including BSE-TSE-related risks; Contaminants in the food chain (CONTAM); Dietetic products, nutrition and allergies (NDA); Food additives and nutrient sources added to food (ANS); Food contact materials, enzymes, flavourings and processing aids (CEF); Genetically modified organisms (GMO); Plant health (PLH); Plant protection products and their residues (PPR).

scientific cooperation framework, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices. Given this priority, Commission Regulation (EC) No 2230/2004 lays down the rules regarding the network of organizations operating in the fields within EFSA's mission and provides for a list of competent organizations required to meet specific quality and competency criteria.

Therefore, in addition to the actors such as the Management Board, the Executive Director, the Advisory Forum (within which Member States' National Food Safety Authorities are represented), the Scientific Committee, the Scientific Panels and the various Directorates, the following set of stakeholders play an important role in relation to EFSA and its activities:

European bodies / Institutional stakeholders:

- EC DGs: DG Sanco, DG Env, DG Agri and the Joint Research Centre (JRC) have common areas of interest with EFSA both in terms of requesting scientific opinions (particularly in the case of the first three) and in terms of sharing findings and developments in the food safety domain (more specifically, JRC's research area "Food and feed safety and quality" is common also to EFSA, and the two collaborate closely on a regular basis, also through formal cooperation agreements).
- European Parliament Committees: some of the Committees of the European Parliament (such as European Parliament Committees ENVI and AGRI) also share areas of interest with EFSA and represent a key source of the demand for scientific opinions and risk assessments. In addition, European Parliament Committee COBU is a key stakeholder because it is responsible for the budget of decentralized bodies such as EFSA.
- Other decentralized authorities / European agencies: EFSA collaborates closely with EU Agencies that operate in similar or related fields. Interaction is of particular importance in the case of:
    - The **European Chemicals Agency (ECHA)**, which has an interest in sharing work and data with EFSA in the areas of risk and hazard assessment of chemical substances, including scientific advice, risk assessment methodology and risk communication;
    - The **European Centre for Disease Prevention and Control (ECDC)**, which, for example, also focuses on zoonotic diseases and publishes a joint annual report on animal infections transmissible to humans with EFSA. Indeed, EFSA and ECDC have a formalized cooperation agreement;
    - The **European Medicines Agency (EMA)**, as its mandates include veterinary drugs, meaning that there is a common area of interest and associated opportunity for collaboration with EFSA in terms of food safety.

Other stakeholders

The Stakeholders Consultative Platform: the Platform, composed of EU-wide stakeholder organizations working in areas related to the food chain, assists EFSA in the development of its overall relations and policy with stakeholders. It comprises, for example, consumer associations, food and drink confederations, NGOs involved in the protection of the environment as well as animal health and welfare, etc.

Network of competent organizations as per Commission Regulation (EC) No 2230/2004: competent organizations designated by Member States (with input from the Advisory Forum) and required to meet specific eligibility criteria, collaborate with EFSA to carry out a set of tasks such as disseminating best practices, collecting and analyzing specific data in response

to a common priority and in view of facilitating and contributing to the Authority's risk assessment procedures, etc.

Applicants: individual firms or groups of firms submitting dossiers (requests for authorizations) to EFSA through the MS or the EC.

International Organizations (e.g., OIE, WHO, FAO, FDA): international organisms and food agencies of different parts of the world that are concerned with protecting and promoting public health and food safety.

Media: representatives of news agency, newspaper or online news services, that care of inform food industries, regulators and citizens about food safety issues.

2.2 The independent external evaluation

Evaluation context

As per Regulation (EC) 178/2002, Article 61, every six years starting from the 1st of January 2005, EFSA has a legal obligation to *commission an independent external evaluation of its achievements*.

In December 2005, the **first external evaluation of EFSA** was carried out in compliance with Article 61 of EFSA's Founding Regulation. The main results from this exercise were positive. The evaluation showed that EFSA was delivering its mandate adequately: the provision of scientific advice to the European Community's legislative process was delivered within the agreed deadlines and communication on food and feed safety was increasing across the European Institutions and Member States. Nevertheless, the Report identified some issues and set specific priority areas to be addressed by the Management Board in order to improve the Agency's performance, such as: a better definition of the Agency's internal structures and working practices; the development of EFSA networking with Member State organizations and other key players.

A second evaluation exercise was carried out in 2009: the European Commission commissioned an **evaluation of the EU decentralized agencies** that included EFSA.

The present evaluation is therefore the second independent external evaluation EFSA is subject to according to Regulation (EC) 178/2002, Article 61.

Main stakes and emerging challenges

In recent years, the context in which the Authority operates has changed significantly due to different political, social and economic phenomena:

- **The EU Enlargement.** Since 2002 the EU has faced two important enlargements, especially towards Eastern Europe. The number of MS has passed from 15 to 27 and several other countries (e.g., Iceland, Turkey, Republic of Macedonia, etc.) are expected to enter in the years to come. EFSA has to deal with a more variegated range of countries with different food consumption habits, different vulnerability and exposure of the population to risks, and different risk assessment capacity. *The EU enlargement carries with it the responsibility for the Authority to acquaint new countries and involve them appropriately*.
- **The demographic trends of the population.** The declining birth rate and the subsequent aging of the population, the strong increase of immigration and urbanization, the changes in life style leading to different consumption habits, and the longer life expectancy are the main trends that have characterized the recent

demographic evolution. This new demographic context has already determined and will probably determine in the future *new problems related to the spread of diseases directly or indirectly linked to food consumption,* such as diabetes, allergies, obesity, hearth diseases, thus significantly influencing EFSA's risk assessments.

- **Globalization.** This is a phenomenon that has considerably affected the food sector; worldwide imports and exports of food are increasing, breaking down geographical barriers and creating a single world market. Food safety risks, like food, do not respect international borders, forcing EFSA to carefully *consider what may have been a regional or national problem in the past, as a potential Europe-wide or even global issue if it arises in a widely traded or used food/ingredient*. Consequently, the harmonization between national and international standards becomes increasingly important, and a wider range of information and data should be collected to better assess risks and take appropriate measures to protect consumers. Thus, EFSA is demanded to enlarge the data collection pool, to increase the cooperation with international stakeholders, and to enhance its contribution to debates on food hazards at international level.

The EU enlargement and the globalization will likely affect the activity of cooperation of EFSA, in terms of a wider mix of Institutional stakeholders to adequately understand and satisfy in terms of risk assessments needs. Cooperation will be strategic for the assessment of future emerging risks that will be more and more transnational thus requiring the cooperation of both Member States and third countries for a sound data collection and analysis. The new demographic context and the rising of new emerging issues linked to food consumption, could on the other side, be the object of future self-tasking mandates or internal studies of the Authority.

In addition to the dimensions described above, it is important to consider the economic context in which the Authority has to work. Indeed the **economic crisis** that has hit the financial world before and the real economy afterwards, is having harmful impacts on the European Institutions and on the various national authorities, including those operating in the area of food safety. The scarcity of resources made available by the NRM to their national agencies, indeed, could lead EFSA to face the future with less MS collaboration and participation in its activities (lower data collected, decrease in the number of experts involved, limited participation to events or meetings).

Within this context, EFSA has to face a foreseen increase in the workload (especially in the fields of regulated products) with a stable budget and staff. For doing this, it is important that the Authority continues to improve its organizational structure and its management systems to gain efficiency and to meet the evolving needs of its clients, allocating resources across its main areas of responsibility and increasing its ability to recruit the best scientific experts and the best staff.

Not only is the Authority required to meet an increasing demand for scientific opinions but it has also to face the **increasing complexity of risk assessment** as identified in the Science Strategy 2012-2016. This complexity is mainly related to the following dimensions:

- The institutional risk assessment environment is differentiated and fragmented. If at the beginning risk assessment was one of the possible tools that risk managers could use to better support political decisions, now, after the food/feed outbreaks that have occurred in Europe over the years, risk assessment has became a condition sine qua non the political decision could neither be taken nor accepted by the public opinion. As a consequence, some Member States have progressively developed their national expertise creating several institutional patterns where risk assessments and risk management activities are differently combined. Thus, in Europe, it is possible to find big Member States with a sound national risk assessment capacity (and sometimes a

specialized Agency established before EFSA's creation) as well as small ones and new entrants with a weaker or absent risk assessment expertise.

- Public awareness has increased. An increasing number and type of stakeholders have progressively developed their awareness of food related risks, as confirmed by the Eurobarometer study. Consumers are better informed and more empowered than in the past and more and more interested in environmental issues and animal welfare.
- New technologies and science innovation increasingly characterize the food and feed production. In line with the Lisbon Treaty and the EU's 2020 Agenda, which identify science and innovation as key drivers of the EU competitiveness, the agricultural sector has been transformed in recent years through the use of intensive methods of production, disease-free raw materials and the application of agrichemicals. This has brought EFSA to deal with new issues in its risk assessments. Equally, as stated in the Strategic Plan 2009-2013, advancements in genetics (above all GMOs), genomics, proteomics, system biology and bioinformatics will have an important impact on the Authority's future work.
- Climate change has greatly influenced food and crop production practices and patterns, and has lead to the use of new chemicals in agriculture that could increase the risk of an outbreak of new diseases and pandemics, as happened in the past (e.g., avian influenza).

The above listed trends let assume that in the future **risk assessment will be potentially more complex** and characterized by uncertainty. For this reason, the Authority should:

- Be constantly up to date with developments in food and feed technologies and with all the innovations, in order to be able to assess their implications and to be at the forefront in risk assessment methodologies and to support adequately all the different risk managers' needs;
- Provide information to the general public on new and emerging trends in the field of food/feed safety;
- Address, through a proactive monitoring, new areas of intervention not originally envisaged in the Founding Regulation, like GMO, and integrate risk assessments with additional dimensions (e.g., environmental impacts, occupational health, post-market monitoring, risk comparisons and health benefits) through an integrated approach;
- Capitalize the expertise collected during the first 10 years of activity and thus prioritize further developments and take clear strategic decisions to cope efficiently with the complexity of the risk assessment and to deal with the different expectations through a strengthened system of cooperation and harmonization able to involve new Member States, and an international perspective.

Evaluation objectives, scope and process

The evaluation aimed at *assessing the working practices and the impact of the Authority* on the food safety system.

Specifically it focused on an assessment of EFSA's performance based on the following criteria and questions:

- **Effectiveness**: To what extent has the agency achieved its mission and tasks (established by the legal framework founding the agency)?
- **Efficiency**: To what extent have the agency's internal organization and operations been conductive to its efficiency?
- **Sustainability**: To what extent is the EFSA putting the appropriate resources, planning and prioritisation activities to sustain its outputs and meet the requirements of its

mandate in the long term?

- **Independence**: To what extent has EFSA fulfilled its obligations to operate in an independent manner?
- **Transparency/openness**: To what extent has EFSA been transparent in its scientific, communications, and other work, its decision-making and priority setting and to what extent has it been open to relevant input, scrutiny and dialogue in its work including its networks?
- **Scientific quality**: To what extent does EFSA ensure the quality of its scientific outputs and excellence in science to produce a robust scientific basis for the EU risk manager?
- **Added value**: To what extent has EFSA provided added value to the European Community and other stakeholders?

In compliance with the Founding Regulation, the scope of the study covers the period **starting 2005** (date of the previous evaluation report) and ending at the **beginning of 2011**. In order to take into consideration significant recent changes and developments in EFSA's structure and activities, the timeline has been sometimes extended (even to 2012).

The external evaluation has been entrusted to Ernst & Young through a tendering process. Table 2 shows the phases of the evaluation.

Table 2: Phases of the evaluation

PHASES OF THE EVALUATION	TIMEFRAME
Inception phase	June 2011 – December 2011
Data collection phase	January 2012 – April 2012
Reporting phase	May 2012 – July 2012

A Steering Committee has been established to comment and advise on the work done during the whole process of the evaluation, meeting 5 times with the evaluation team.

The evaluation team acknowledges the helpful comments received by the Steering Committee.

The evaluation framework

The evaluation logic, as described in more details in the Inception report, has a hierarchical structure defined by a main question and related sub-questions, as illustrated in Table 3.

Table 3: Evaluation logic

QUESTION (PER TOR)	RELATED SUB-QUESTIONS
Q1. To what extent has the Authority achieved its mission and tasks (established by the legal framework founding the Authority)?	Q1.1 - Is the process of provision of scientific advice and technical support put in place by EFSA (from the data collection phase to the production of outputs) effective in providing qualified advice and support, including support to emergency situations?
	Q1.2 – Is the process put in place by EFSA to communicate effective and open?
	Q1.3 – Is the process put in place by EFSA to promote scientific cooperation effective?
Q2. To what extent have the Authority's internal organization and operations been conductive to its efficiency?	Q2.1 – Is the organization of EFSA appropriate and adequate to its workload?
	Q2.2 – Are processes efficiently planned and managed?
	Q2.3 – Is there a balance in the resource allocation?
Q3. To what extent is the EFSA putting the appropriate	Q3.1 – What is the impact of the evolving expectations placed on EFSA on the legislative framework?

QUESTION (PER TOR)	RELATED SUB-QUESTIONS
resources, planning and prioritisation activities to sustain its outputs and meet the requirements of its mandate in the long term?	Q3.2 – What is the impact of the evolution in workload and work areas on EFSA's ability to fulfil its mandate?
	Q3.3 – What is the impact of the evolution in workload and work areas on EFSA's ability to fulfil its overall remit?
Q4. To what extent has EFSA fulfilled its obligations to operate in an independent manner?	Q4.1 – To what extent have EFSA's overall structures, governance and procedures been effective in ensuring that the Authority can operate without undue influence as required by its Founding Regulation?
	Q4.2 – What lies behind the criticisms on independence and are the developed procedures mitigating them?
Q5. To what extent has EFSA been transparent in its scientific communications, and other work, its decision-making and priority setting and to what extent has it been open to relevant input, scrutiny and dialogue in its work including its networks?	Q5.1 – Are the procedures to assure transparency effective and efficient?
	Q5.2 – Are the procedures to assure openness effective and efficient?
	Q5.3 – Are the principles of transparency and openness relevant to EFSA's mission, taking into account the costs for their implementation?
	Q5.4 What has been the impact of communications on perceptions regarding food related risks and trust in EFSA within the overall food safety system?
Q6. To what extent does EFSA ensure the quality of its scientific outputs and excellence in science to produce a robust scientific basis for the EU risk manager?	Q6.1 – Are inputs used to produce scientific outputs adequate to assure a high standard of quality?
	Q6.2 – Are the processes and procedures put in place adequate to assure a high standard of quality?
	Q6.3 What is the perception of the quality of EFSA scientific outputs compared to other similar organization?
	Q6.4 –To what extent is EFSA at the forefront of scientific knowledge, risk assessment methods, and aware of innovation?
Q7. To what extent has EFSA provided added value to the European Community and other stakeholders?	Q7.1 - Has the creation of the Authority provided tangible improvements to the provision of scientific advice and the coherence of communications in the areas of its remit and are these proportionate to the cost?
	Q7.2 - To what extent has the Authority contributed to food safety and nutrition and to confidence in the EU Agro-food sector and, if so, are these proportionate to the cost?
	Q7.3 - To what extent is EFSA contributing to common scientific views throughout the EU? (Divergent scientific opinions minimized, scientific reference body at a European and international level)?
	Q7.4 - To what extent does EFSA reduce the duplication of risk assessments throughout the EU therefore diminishing the costs of risk assessments for national food safety systems?
	Q7.5 - To what extent have EFSA's activities in times of emerging threats to the safety of the food chain assisted risk managers in developing appropriate risk mitigation activities?
	Q7.6 - To what extent have EFSA's work and actions contributed effectively to the development of the EU's objectives, legislation and policy within its fields of competence?

(Source: EY)

For each evaluation question, specific evaluation grids (included in the Inception Report) have been defined, presenting all the elements of the methodology necessary to answer a specific question (i.e., Judgement Criteria, type of analysis, indicators and sources of information).

In accordance with the Steering Committee, this evaluation has focused on the external perception of EFSA by main stakeholders (see details of selected target groups in Annex

"Questionnaire and supporting documents" and Annex "Interviews and supporting documents").

Given the high number of questions and issues involved in the evaluation, and with the aim of facilitating stakeholders' understanding of the issues, the 7 evaluation questions and related sub-questions have been aggregated in the following thematic areas of evaluation (see Annex "List of Judgment Criteria" for further details on the aggregation of questions):

- provision of scientific outputs and technical support;
- data collection;
- risk communication;
- cooperation and networking;
- EFSA's international role and recognition;
- organizational structure, its operational efficiency and its adaptability to change;
- independence;
- openness and transparency.

Data collection tools

In order to assess EFSA's performance, the evaluation team has analyzed relevant documents (see Annex 6) and implemented the following primary data collection tools:

- an on-line survey submitted to 165 stakeholders;
- in depth interviews with 51 stakeholders;
- direct observation of 8 EFSA's key meetings;
- a benchmark with selected organizations.

A synthetic description of the tools, including their use and the related results, is provided below.

eSurvey and interviews

eSurvey

The eSurvey has been used to collect information on the level of satisfaction and on the expectations towards EFSA of different types of stakeholders (related to three target groups: institutional stakeholders, external stakeholders and EFSA's bodies). The questionnaire, sent through the EY eSurvey© tool to 165 stakeholders, covered all the evaluation criteria and all the evaluation thematic areas, and it envisaged both open and closed questions[4] (see Annex 1 for the template of the questionnaire and the list of stakeholders).

The questionnaire has been completed by 104 stakeholders, as shown in Table 4 (see Annex 1 for the complete list of respondents).

[4] In questions with a rating,1 is to be considered as the minimum and 4 the maximum.

Table 4: Target groups and types of stakeholders involved in the eSurvey

TARGET GROUP	TYPE OF STAKEHOLDER	QUESTIONNAIRES COMPLETED	RATE OF RESPONSE
Institutional Stakeholders	European Commission[5]	8	80%
	EP	3	60%
	National Risk Managers	11	38%
	National Risk Assessors	23	79%
External Stakeholders	Scientific Org. (Art 36)	12	50%
	Food Industry/Applicants	13	50%
	NGOs	3	38%
	Consumer Organizations	5	83%
	Media	3	75%
EFSA's bodies	MB	13	93%
	SC	10	100%
Total		104	63%

(Source: EY)

Interviews

Face-to-face interviews and phone interviews have been performed with the main objective to collect qualitative information, to enrich the global perception gathered through the eSurvey or to deepen and interpret information collected from the eSurvey and from secondary sources (i.e., existing documents, publications, reports). Interviews guidelines are reported in Annex 2.

Interviews have involved 41 stakeholders[6], belonging to one of the three main target groups: institutional stakeholders, external stakeholders or EFSA's bodies, and selected according to their strategic importance/role for specific evaluation criteria (see Annex 2 for a detailed list of subjects involved).

The types of stakeholders involved in interviews are reported in the following table.

Table 5: Target groups and types of stakeholders involved in interviews

TARGET GROUP	TYPE OF STAKEHOLDER	INTERVIEWS DONE
Institutional Stakeholders	European Commission	2
	EP	4
	National Risk Managers	6
	National Risk Assessors	8
External Stakeholders	Scientific Org. (Art 36)	2
	Food Industry/Applicants	6
	NGOs	3
	Consumer Organizations	4
	International Organizations	4
EFSA's bodies	MB	2
Total		41

(Source: EY)

Final sample of stakeholders

Together, the eSurvey respondents and the stakeholders involved in the interviews, represent the final sample of the evaluation. The following table and graph show its composition.

[5] In the report European Commission stands usually for DG SANCO, and DG BUDG when included in the questionnaire.

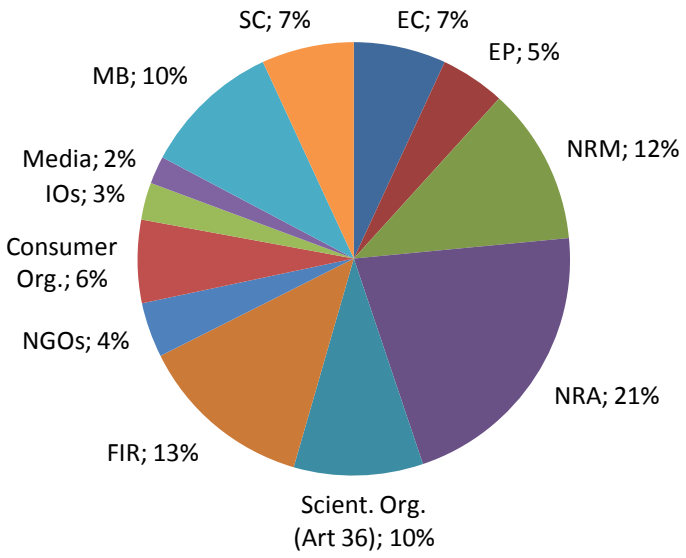
[6] 10 more interviews have been conducted with 8 representatives of EFSA and 2 of DG SANCO in the inception phase and their results have been considered in the evaluation.

Table 6: Distribution of questionnaires and interviews per target group and type of stakeholder

TARGET GROUP	TYPE OF STAKEHOLDER	COMPLETED QUESTIONNAIRES	COMPLETED INTERVIEWS	WEIGHT PER TYPE OF STAKEHOLDER	WEIGHT PER TARGET GROUP
Institutional Stakeholders	European Commission	8	2	7%	45%
	EP	3	4	5%	
	National Risk Managers	11	6	12%	
	National Risk Assessors	23	8	21%	
External Stakeholders	Scient. Org. (Art 36)	12	2	10%	38%
	Food Industry/Applicants	13	6	13%	
	NGOs	3	3	4%	
	Consumer Organizations	5	4	6%	
	International Institutions	0	4	3%	
	Media	3	0	2%	
EFSA's bodies	MB	13	2	10%	17%
	Scientific Committee	10	0	7%	
Total		104	41		

(Source: EY)

Chart 1: Evaluation sample composition



(Source: EY)

Comparing the final sample of stakeholders with the original sample

The original sample has been selected in order to be representative of all the main EFSA's stakeholders, i.e., institutional, externals and members of two specific EFSA's bodies: the Management Board and the Scientific Committee. Identified types of stakeholders cover the main interests linked to EFSA's activities, from direct clients (EC, EP, NRM) to other stakeholders impacted by EFSA's activity (e.g., FIR/A, NGOs, Cons.).

The selection of specific stakeholders has been done with a "reasoned sampling methodology", responding to different criteria:

- coverage of MS (as in the case of NRM and NRA);
- coverage of different areas of expertise/interests/sectors (as in the case of SCP, Scient. Org. (art. 36), FIR, NGOs, Cons.);
- coverage of key informants (as in the case of EP, EC);
- balance between members being Chairs of the Panels and external experts (in the case of the SC).

The distribution of the final sample per type of stakeholder is different from the one envisaged in the original sample due to differences in the rate of response (see the following Table 7).

Table 7: Global rate of response for stakeholders

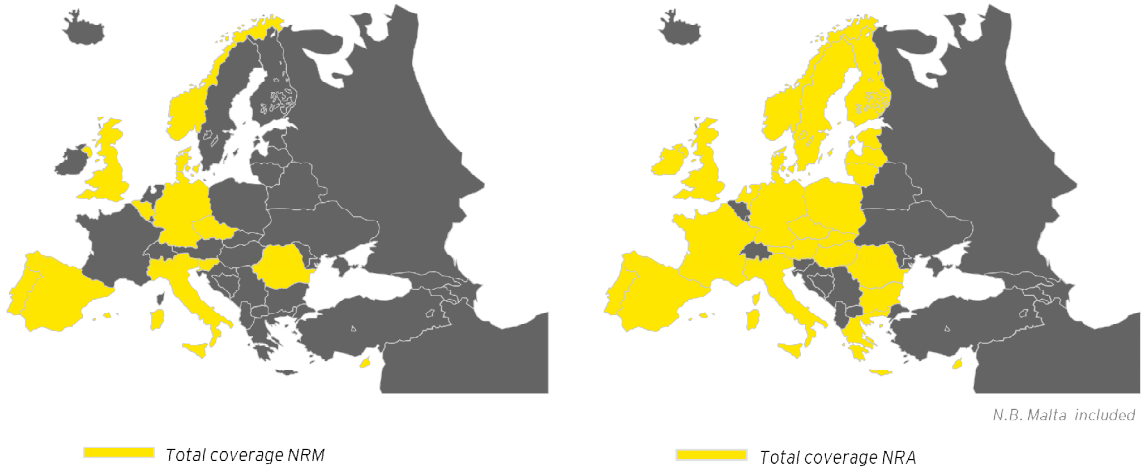
TARGET GROUP	STAKEHOLDER	GLOBAL RATE OF RESPONSE
Institutional Stakeholders	European Commission	83%
	European Parliament	78%
	National Risk Managers	44%
	National Risk Assessors	84%
External Stakeholders	Scient. Org. (Art 36)	52%
	Food Industry/Applicants	59%
	NGOs	46%
	Consumer Organizations	82%
	International Organizations	100%
	Media	75%
EFSA's bodies	Management Board	94%
	Scientific Committee	100%
Total		68%

(Source: EY)

More specifically, the rate of response has been much lower for NRM and NGOs, although significant follow up has been done, as for all the other stakeholders. The evaluation team has addressed this issue to assess the representativeness of the information collected by these stakeholders for the evaluation results, concluding that as long as evidence was available on convergent and homogeneous opinions even from few respondents, these should be taken into account in the evaluation. Isolated opinions have not been taken into account.

The Figure 2 shows the geographical coverage of the final sample as regards NRM and NRA.

Figure 2: Geographic distribution of NRM and NRA involved in eSurvey and interviews



(Source: EY)

Use of information collected from stakeholders

Evidences on the stakeholders' point of views are presented in a specific paragraph ("Stakeholders' point of view") illustrating for the main issues related to each thematic area of evaluation, the global level of satisfaction, perceived strengths and weaknesses and, when appropriate, suggestions for areas of improvement.

Issues coming from stakeholders are weighted along the text according to their intensity for different stakeholders, and references in brackets indicate the different stakeholders raising the issues. The presence of the acronym for stakeholders stands for two or more stakeholders of the same category sharing the same opinion. Nonetheless, when relevant for the analysis, information coming also from one single stakeholder has been taken into account, with clear reference to the specificity.

Specific criticisms pointed out by stakeholders along the text are sometimes indicated in the conclusions as areas of improvement. This happens when evaluating the effectiveness/suitability of EFSA's activities to clients' needs for which the stakeholders' satisfaction represents a key indicator, or in case additional factual evidences confirm the validity of the perception and strengthen the need for improvement.

Direct observation of EFSA's key meetings

To gather important information and analyse directly some of the decision processes involved in the evaluation questions, a direct observation of some of the EFSA's key meetings has been performed.

Four kinds of meetings have been observed: Management Board meetings, Scientific Committee meetings, Scientific Panel meetings and an Advisory Forum meeting (see Table 8).

Table 8: List of meetings observed

TARGET GROUPS	TYPE OF MEETING	DATE
Management Board	51st Management Board Meeting *"Broadcast"*	15-12-2011
	52nd Management Board Meeting	15-3-2012
Advisory Forum	43rd Meeting of the Advisory Forum	7-3-2012
Scientific Panels	GMO	25-1-2012
	Food Contact materials, Enzymes, Flavourings (CEF)	1-2-2012
	Animal Health/Welfare	9-2-2012
	Biological Hazards	25-1-2012
Scientific Committee	Meeting of the Scientific Committee	7-2-2012

(Source:EY)

The direct observation of the above listed EFSA's key meetings has allowed to have a better understanding both of the interactions between all the actors involved and of the functioning of the specific bodies/Panels. When appropriate, evidence collected with direct observation has been provided along the text, together with the reference to the specific meeting.

The observation has been focused on:

- the global arrangement of the meeting;
- the independence policy;
- the decision-making process;
- the Chair: role and attitude;
- the involvement of participants;
- support of/interactions with EFSA's staff.

Benchmark

The benchmark aims to provide thematic insights on the functioning of similar organizations in comparison with EFSA. The objective is to identify best practices in the compared agencies and confront EFSA's practices. A list of objective indicators was developed in order to obtain comparable information between organizations, covering various dimensions:

- the composition and the working methods of the Management Board;
- the process to mobilize the network of experts;
- the resources allocation;
- the distribution of work between the panels, Authority's staff and external bodies;
- structures, governance and procedures to assure independence;
- systems and procedures for quality assurance;
- the legislative framework;
- the openness of procedures;
- the cost-effectiveness of the implementation of the principles of openness and transparency;
- validity/reliability of scientific outputs;
- international recognition.

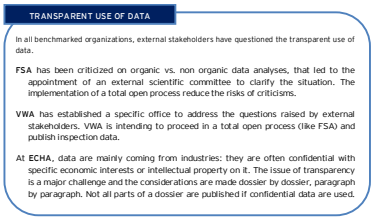
Four agencies form part of the benchmark analysis including:

- two EU agencies: European Medicine Agencies (EMA) and European chemicals agency (ECHA);

- two national food safety agencies: Food Standards Agency in the UK (FSA), and the Netherlands Food and Consumer Product Safety Authority (VWA).

The benchmark analyses consisted of an interview with a staff from the agency in a management position, with additional information coming from identified documentation (Annual report, Founding Regulation or any other suggestion from our contact in the agency). After interviewing the agencies, an interview was planned with DG SANCO to provide a more global approach on agencies' strengths and weaknesses.

At the end of the evaluation exercise, additional interviews were conducted to deepen several aspects of the analyses.


TRANSPARENT USE OF DATA

In all benchmarked organizations, external stakeholders have questioned the transparent use of data.

FSA has been criticized on organic vs. non organic data analyses, that led to the appointment of an external scientific committee to clarify the situation. The implementation of a total open process reduce the risks of criticisms.

VWA has established a specific office to address the questions raised by external stakeholders. VWA is intending to proceed in a total open process (like FSA) and publish inspection data.

At **ECHA**, data are mainly coming from industries: they are often confidential with specific economic interests or intellectual property on it. The issue of transparency is a major challenge and the considerations are made dossier by dossier, paragraph by paragraph. Not all parts of a dossier are published if confidential data are used.

Blue boxes along the text highlight the inclusion of a benchmark analysis in different paragraphs. They provide insights on the way of functioning in other agencies.

Methodological limits:

- The benchmark does not aim at assessing other agencies, being the data collection based on existing information sources and on a limited number of interviews.

Structure of the report

The core part of the report is structured along the above mentioned 8 thematic areas; the applicable evaluation criteria (as illustrated in Figure 3) are reported along the text.

Figure 3: Matrix of thematic areas and evaluation criteria

		Evaluation Criteria						
		Effectiveness	Efficiency	Sustainability	Independence	Openness Transparency	Scientific quality	Value Added
Thematic Areas	Provision of scientific outputs and technical support	✓					✓	✓
	Data collection	✓					✓	
	Risk communication	✓						✓
	Cooperation and networking	✓	✓	✓				✓
	International role and recognition			✓			✓	✓
	Organizational structure, operational efficiency and adaptability to change		✓	✓				
	Independence				✓			
	Openness and transparency					✓		

(Source: EY)

Each thematic area is structured as follows:

- **Facts & Figures**: presenting the main evidence related to EFSA's procedures or activities, coming from secondary sources, direct observation and the benchmark.
- **Stakeholders' point of view**: illustrating the global stakeholders' perspective as well as

more specific points of view as emerged from the eSurvey and interviews.

- **Analysis of evidences**: presenting a comprehensive analysis of findings taking into account the context of the organization and the results coming also from other parts of the report.
- **Evaluation results**: presenting the results of the analysis.

Specific and transversal **recommendations** are provided at the end of the report. Recommendations are presented with addresses and the associated level of priority that has been defined according to the following criteria:

- the impact of the recommendation on the general performance of EFSA;
- the relevance of the recommendation for EFSA's mission;
- the intensity of the issue for stakeholders.

3. Evaluation results

3.1 Provision of scientific outputs and technical support

3.1.1 Introduction to the results for the thematic area of evaluation

EFSA's provision of scientific outputs[7] and technical support comes from both external requests (mandates and questions from EC, EP, MS) and EFSA's self-tasking function, and relates to either ordinary or emergency situations. This area of evaluation relates to the following evaluation criteria that are analysed in details in the following paragraphs through the use of secondary and primary sources:

- **Effectiveness and scientific quality**, the main questions being whether *i)* EFSA meets its clients' needs in a timely manner *ii)* the self-taking function is effective in keeping abreast of emerging issues *iii)* outputs are considered to be of high standard of quality and reliability.
- **Added value,** the main question being whether the process of provision of outputs uses an integrated approach and supports the development of new tools in Member States.

3.1.2 Effectiveness and scientific quality

Coherently with the evaluation framework, the effectiveness and quality of the provision of scientific outputs and technical support by EFSA is analyzed according to the following dimensions, starting with an analysis of EFSA's procedures and activities, followed by the stakeholders' point of view:

- suitability of outputs to clients' needs;
- timeliness of outputs provision;
- quality of scientific outputs: adequacy of the quality assurance procedures and comparison with other organizations;
- effectiveness and scientific quality of EFSA's self-tasking function to keep abreast of emerging issues.

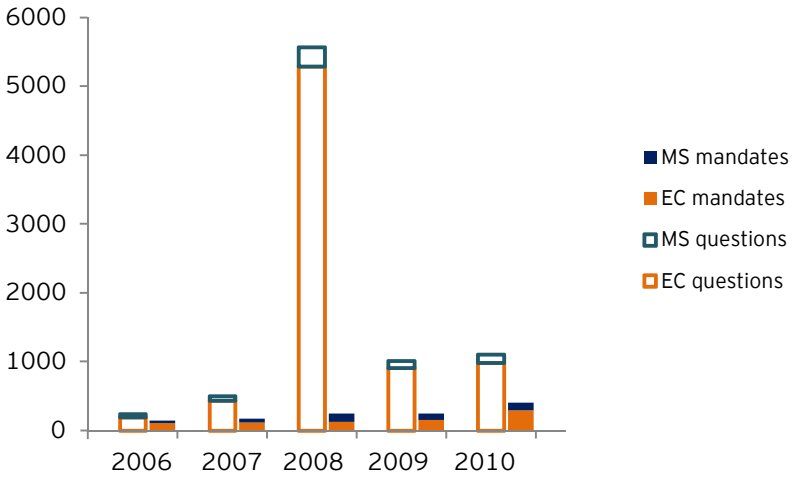
3.1.2.1 Facts & Figures

Suitability of outputs to clients' needs

The demand of outputs by the EC and the MS (in terms of mandates and questions) has constantly increased[8] (see Figure 4): risk managers continue to ask EFSA for advice.

[7] Scientific outputs include: scientific opinions (generic/on applications), statements and guidance of EFSA, scientific reports of EFSA, reasoned opinions, conclusions on pesticides peer review.
[8] The 2008 peak of requests (in terms of questions) is due to the implementation of the EU Regulation on Nutrition and Health Claims (Regulation EC No 194/2006) that has required the evaluation of a high number of claims submitted by Member States to the European Commission.

Figure 4: Annual mandates and questions received by requestor 2006-2010



(Source: EY elaboration on EFSA's data, 2012)

More specifically scientific opinions inform the EU policy decisions, as reported also in a recent study[9]. 100% of dossier-related opinions and outputs (i.e., applications) were taken up by the Commission services in developing their proposals or taking forward discussions with Member States. For non-dossier related opinions and outputs, there was also a 100% uptake[10].

To align scientific outputs to stakeholders' needs and expectations, **EFSA has progressively developed a set of procedures to identify client needs** and to allow clients to communicate their expectations, developing a continuous exchange of information to improve the efficiency and effectiveness of its risk assessment workflow.

PROCEDURES TO IDENTIFY CLIENTS' NEEDS

- The involvement of the European Commission, the European Parliament and Member States (through the Advisory Forum members) in the **drafting of mid-long term objectives of the Strategic Plan 2009-2013** in order to set EFSA's future goals coherently with their future needs.
- The strengthening of the **specific dialogue phase in the risk assessment workflow between EFSA and the requestor,** to ensure that requests are clear, complete and a common understanding is reached on what is expected. This step enables EFSA to ask for clarifications or revisions of the proposed Terms of Reference, deadlines or scientific information provided in order to get to a suitable outputs for both parties.
- **The inclusion of representatives of the European Commission in Panels and working groups meetings** to clarify the Term of Reference and provide additional information if needed.
- The receipt on a regular 6 monthly basis of a **tabulated feedback from the Commission on its utilization of EFSA's opinions and other scientific outputs.**

(Source: EY elaboration on secondary sources)

In addition, EFSA has also launched in 2008 a three-part quality review system to assess EFSA's scientific work (see the following par. "Quality of scientific outputs" for more details).

[9] As shown in the Case study carried out by the External Consultants on the utility of 12 opinions conducted in 2011 in the context of the impact indicators progresses.
[10] Progress report on the implementation of the MB decision to further develop Impact Indicators within EFSA as appropriate tools for measuring the effectiveness of EFSA (MB 16.06.11).

Delivery procedures have also been the object of increasing improvements over time and they are now standardized through specific standard operating procedures[11].

DELIVERY PROCEDURES

- Once the scientific opinions/reports are adopted, their delivery consists of three major steps: preparation of the publication, sending opinions/reports to requestor and at the end publication of opinions/reports and summaries on EFSA's webpage.
- The process normally starts with an editorial review of the document quality and the provision of the opinion to the requestor 24 hours before its publication in order to allow interested parties to adopt measures to support EFSA's communication.
- After this "embargo" the work is made available to the public on EFSA website, EFSA Journal and the Register of Questions where the scientific output can be searched by keyword, Panel, adoption or publication date.
- For some specific opinions that EFSA identifies as particularly important, the Authority develops a different communication approach, involving the media, profiling the issue on the EFSA website or in EFSA publications, or discussing it during scientific events.

(Source: EY elaboration on secondary sources[12])

As relates **emerging risks** in the field of food safety[13], the Authority has implemented various actions from 2008 to nowadays to support its clients in their **identification,** like the creation of a dedicated Unit (EMRISK), the establishment of a working group on data collection for emerging risks and of a Member States network and a stakeholder consultative group (see the following box).

EFSA'S ACTIONS TO KEEP ABREAST OF EMERGING RISKS

- The creation in 2008 of a dedicated **Unit** (EMRISK Unit) to monitor relevant information sources, collect and evaluate data, develop procedures of analysis, share information with stakeholders and Member States to identify new emerging fields of interest.
- The establishment of a **working group on data collection** to identify emerging risks (DACO WG) and support the EMRISK Unit in defining a list of priority sources of information and suitable strategies and tools to gather relevant signals.
- The establishment in 2010 of a Member States **network** and a **stakeholder consultative group** on emerging risks.

(Source: EY elaboration on secondary sources)

Timeliness of outputs provision

The percentages of scientific outputs respecting deadlines, as shown in Table 9 are positive, although not in line with the target, that indeed has been reduced from 95% in 2009/2010 to 85% in 2011[14].

[11] SOP 25 (Finalizing, endorsing and publishing other scientific outputs), SOP 28 (Preparing a scientific output for publication).
[12] EFSA website, Workflow for scientific opinions.
[13] Having regard to Articles 23 and 34 of Regulation (EC) 178/2002, an emerging risk to human, animal and/or plant health is understood as a risk resulting from a newly identified hazard to which a significant exposure may occur or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard. An assessment of emerging risk is characterized by the early detection of facts related to that risk derived either from research and/or from monitoring programs or episodic observations. Assessment of emerging risks is distinct from the assessment of risks under emergency (or crisis) conditions, as the latter are dealt with through established Commission procedures (Definition and description of "Emerging risks" within the EFSA's mandate, July 2007).
[14] Source: Annual Activity Report.

Table 9: Percentage of EFSA's outputs issued within deadline requested

	2006	2007	2008	2009	2010	2011
% of total scientific outputs and supporting publications	59%	65%	87%	80%	79%	81%

(Source: EY elaboration on EFSA's data, 2012)

EFSA has introduced specific procedures to better deal with the difficulty to respect deadlines coming from the complexity of the requests and the unforeseen workload (e.g., for most of EC mandates). Main actions undertaken relate to the **renegotiation of deadlines** in the past 10 years[15] and the implementation of **the "stop-the-clock" procedure**[16].

STOP-THE-CLOCK PROCEDURE

- A procedure by which the deadline for the adoption of the scientific output is suspended due to the request for additional information sent to the applicant/requestor in order to better understand the Term of Reference. The clock starts running again when the requested information is provided, according to the relevant sectorial law. This mechanism has been thought mainly for applications with legal deadlines where renegotiations are not usually possible.

(Source: EY elaboration on secondary sources)

As relates **outputs provided in food/feed emergency situations**, all urgent requests sent to EFSA over the years got a response within 30 calendar days (see Table 10). The story shows that EFSA has usually activated its urgent procedures after receiving an official request from institutional stakeholders.

Table 10: List of requests for urgent advice, per year and requestor, and number of days to respond

REQUEST	YEAR	REQUESTOR	NUMBER OF DAYS TO DELIVER
Melamine in food and feed	2007	EC	30
Mineral oil in sunflower oil	2008	EC	29
Melamine in infant milk	2008	EC	3
Dioxins in Irish pork meat	2008	EC	2
Inks for food packaging in breakfast cereals	2009	EC	13
Nicotine in wild mushrooms	2009	EC	14
Chlormequat in table grapes	2010	EC	2
Volcanic ash	2010	EC	6
STEC 0104	2011	EC	8
STEC 0104	2011	EC	27

(Source: EY elaboration on EFSA's data, 2012)

Quality of scientific outputs

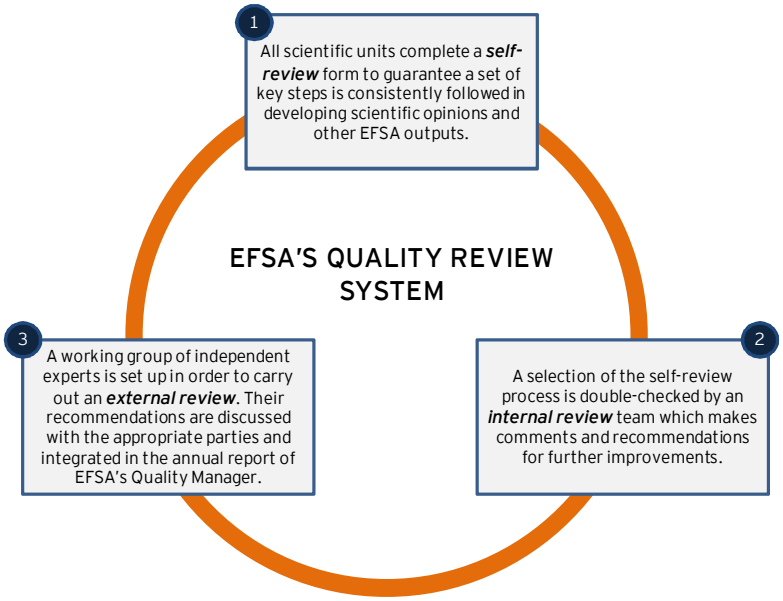
Starting from 2007, EFSA has progressively **implemented a quality management system**, which includes the **three-part quality review system**[17] described in Figure 5.

[15] The Quality Self reviews undertaken by Panels and Working Groups indicate that deadlines have been frequently renegotiated during the process of scientific opinions, although not when legal provisions establish a deadline, as for most of the applications (see Reports of the Quality Manager 2008, 2009, 2010, 2011).

[16] This procedure is envisaged in some sector-specific regulations related for example to GMO, plan protection products and health claims.

[17] The proposal for the quality system has been adopted by the Scientific Committee in 2007.

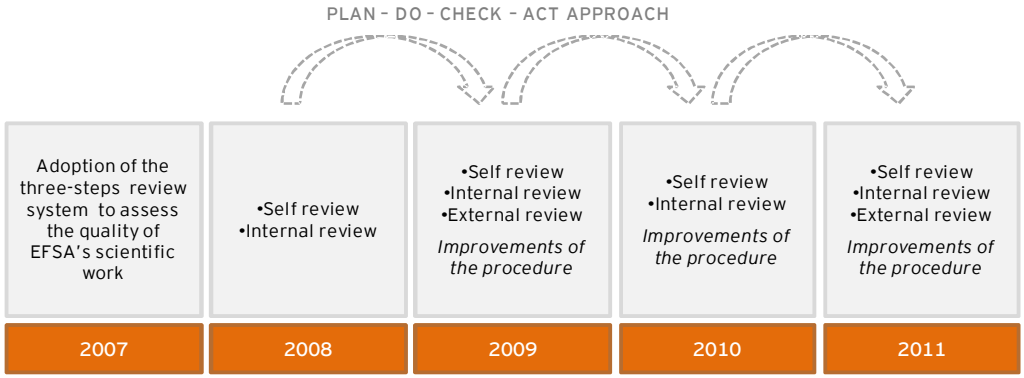
Figure 5: EFSA three-part quality review system



(Source: EY elaboration on secondary sources)

EFSA has in place the main elements of a quality system, including policies, procedures and guidance documents. However, those have not been implemented in a coherent and integrated way and the implementation has not been monitored on an ongoing basis. The quality of EFSA outputs is reviewed through the EFSA quality review system. To improve the quality, clarity and consistency, all EFSA's outputs are (1) checked during their development as regards their compliance with best scientific practice. After adoption by the Scientific Panel or Committee, (2) a sample of EFSA's draft opinions or other scientific documents is reviewed by senior scientific staff not involved in the preparation or adoption of the opinion. At the end, (3) a number[18] of adopted and published scientific outputs are reviewed by independent scientists[19]. The system has been developed over the years by meeting specific targets, as shown by the key performance indicators contained in the Annual Activity Reports and is subject to continuous improvements to meet the organization's and clients' needs: Figure 6 shows that the procedures have been revised every year since 2008, also taking into account evidences coming from the external review performed in 2009[20].

Figure 6: The approach in the development of EFSA Quality Review System



(Source: EY elaboration on secondary sources)

[18] In the 2011 External Quality review, 49 scientific outputs out of approximately 525 EFSA's scientific outputs (2010) were randomly selected.
[19] Report of the Quality Manager 2009.
[20] Before 2011 the external review was planned every 3 years, from 2011 it is planned on a yearly basis.

The last review of outputs performed under the Quality External Review[21], conducted in 2011 by an independent and external group of experts (ERWG) taking into account a sample of 49 EFSA's scientific outputs, provided evidence that 40% of the outputs were well constructed, transparent and easily understandable (receiving only high scores, A or B) and the number of negative findings (D scores) was limited to 1,4% (with a reduction of 4,6 points in comparison with 2009)[22].

Nonetheless, the Quality External Review[23] pointed out some aspects that still limit the quality of EFSA's outputs:

- a lack of clarity of databases used for the identification of reference material for the generation of opinions, as well as a non exhaustive explicit reference in the summary and conclusions of the case where the only source of data came from the applicant;
- weak conclusions, presented without concrete support;
- deficiencies in referencing and availability of original documentation;
- deficiencies in synthesis and analysis;
- limited consideration of uncertainties and limitations at the level of both the parameter estimates and the integrated final risk estimates;
- inadequate summaries including missing important critical parameters.

Even if EFSA's quality review system is not like a traditional peer review process[24], the system in place envisages a review process so that quality checks before and after publication are done on EFSA's outputs.

EFSA Insight Survey[25] that involved internal staff, besides, shows there is an issue related to the **complexity** of some procedures: in EFSA people are committed to quality in their work, but they do not link it to a quality policy, SOPs, common procedures etc, because of their complexity. The issue of complexity was beginning to be addressed in 2011.

The quality of the outputs is also supported by the Panel system, that, in itself, can be considered an additional form of review: outputs are adopted, following a documented review, by experts with a wide range of complementary skills and experiences, and according to the new Policy on Independence[26], the decision-making process does provide room for contradictory debates, both at the working group level and during the plenary session, so that the risk of one viewpoint exerting an undue influence over the other members of the group is limited and EFSA's advice does not represent the views of any single expert or school of thought.

[21] Report of the Quality Manager 2011.
[22] The remaining outputs (58,6%) were not homogeneously evaluated by the external group of experts.
[23] Report of the Quality manager 2011.
[24] The process of subjecting an author's scholarly work, research or ideas to the scrutiny of others who are experts in the same field, before a paper describing this work is published in a journal. The work may be accepted, considered acceptable with impartial revisions, or rejected.
[25] EFSA Insight Survey – Written feedback provided by EFSA staff, 2011.
[26] Policy on Independence and Scientific Decision-Making Process of the European Food Safety Authority (mb 15-12-11).

CLARITY OF SCIENTIFIC OUTPUTS

The clarity of scientific ouputs is a permanent challenge for all benchmarked organizations and is linked to both:

- **The quality of expertise hold by experts: ECHA** assigned the responsibility of selecting the best experts to Member States. A review of performance is implemented each year at FSA, at committee and individual levels.
- **The validation of work**: at **FSA** the homogeneity in documents presentation is based on the review of all documents by a chief scientist. The unit dedicated to coordinate the different committees plays a central role in the homogeneity of documents at ECHA. The secretariat also plays a key role in the language quality.

In order to release opinions in line with the most recent developments, the Authority disposes of a **procedure to take new data into account** and correct published outputs[27], in case EFSA is aware of evidences questioning the safety of a substance, product or claim undermining the validity of an adopted opinion.

To improve the **structure** of scientific opinions and enhance the harmonization, EFSA has progressively implemented various initiatives like:

- the advice from the EFSA Scientific Committee on a **general format for scientific opinions of the EFSA**[28]. According to this decision, in each scientific opinion, a summary summarizes which questions are addressed, which information is evaluated, the key issues that result in the opinion, the conclusions and, if any, recommendations based on the assessment;
- two **guidance documents**[29] (in 2006 and 2009), detailing respectively **transparency in risk assessment procedural aspects and scientific aspects** and general principles (see par. "Openness and Transparency" for further details).

EFSA recognizes, as shown in the 2011 Declaration of Intent signed by the Management Team[30], the need to continuously invest in the improvement of the system, to guarantee the quality of its scientific outputs and maintain its world-class reputation. Some ambitious objectives have indeed been fixed: by 2016, EFSA has planned the implementation of a fully integrated system[31] (compatible with the ISO 9001:2008 system) covering all the Authority's activities.

This is in line with the quality assurance procedures implemented by ECHA. As regards in general the comparison with other organizations, the following boxes, describing the main characteristics of the quality assurance procedures of FSA, EMA and ECHA, show that some of the points envisaged in EFSA's planning, are considered in the systems of these organizations, like the compliance of the system to ISO 9001.

[27] Business Process mapping, Draft Pilot Report for Science. Deloitte, 2011.
[28] Technical Report 2003.
[29] Transparency in risk assessment carried out by EFSA: Guidance document on procedural aspects (EFSA Journal 2006 353, 1-16) and Transparency in risk assessment – Scientific aspects. Guidance of the Scientific Committee on transparency in the Scientific aspects of risk assessment carried out by EFSA. Part 2: General principles. (EFSA Journal 2009 1051, 1-22).
[30] EFSA Integrated Quality Management System Declaration of Intent, EFSA Management Team, September 2011 (Report of the Quality Manager 2011).
[31] Integrated Quality Management System as a single integrated system used by an organization to manage the totality of its processes in order to meet the organization's objectives and to satisfy its staff, beneficiaries and other stakeholders.

QUALITY ASSURANCE PROCEDURES

- To appreciate the quality and reliability of **FSA** work, the fact that the Parliament and Government give an external point of view is important. FSA, like EFSA, publishes each year a report on assurance of scientific quality.

QUALITY OF SCIENTIFIC OUTPUTS

- In the United Kingdom, specific quality assurance procedures to ensure the quality of **FSA**'s scientific advices and impartiality of scientific expertise have been implemented. Notably:
  - A peer-review assurance by the Chief Scientist Advisor and publication of everything FSA does with a risk assessment procedure.
  - An own internal science government check list to carry out proper procedures.
- **EMA** has implemented specific procedures to ensure the quality of selected experts. There is a list of criteria of quality standards shared and approved by the European Commission. When MS propose experts, they must comply with those criteria. The committees are also free to choose experts but according to the same criteria (highest possible standards). When it is difficult for small MS to cover the full range of expertise, there is support from another MS.
- **ECHA** has developed its management standards based on the Commission's Internal Control Standards for effective management and the internationally recognised ISO 9001 standard for quality management systems.

Evidence on the quality of EFSA's scientific outputs is provided by the increasing trend of **EFSA's outputs citations** in key relevant scientific journals[32] (Table 11): Food science and technology represents the most important thematic area in which EFSA's outputs are cited, followed by Toxicology and Veterinary Science.

As an additional evidence of the quality of EFSA's outputs, EFSA Journal is now indexed into 4 bibliographic databases[33].

Table 11: Number of citations of EFSA's publications

	2006	2007	2008	2009	2010	2011
N. of citations of EFSA publication in scientific papers	13	19	35	132	293	487

(Source: EY elaboration on EFSA Annual Activity Reports)

Effectiveness and scientific quality of self-tasking function to keep abreast of emerging issues

EFSA normally undertakes scientific work on its own initiative in fields where scientific knowledge and approaches are continually evolving. Over the period 2006-2011 two distinct processes have been used. Firstly, self-tasking occurs when EFSA, identifying a particular issue that requires further analysis and research, requests a self mandate directly to a Panel to produce a guidance, an opinion or data collection. Secondly, internal mandates could be used to assign tasks to Units, including outsourcing. These activities in general provide support to the work of the Panels in the form of exploratory or background work, and have been the principal processes used to task the EMRISK Unit to develop a procedure for the

[32] Progress report on the implementation of the MB Decision to further develop Impact Indicators within EFSA as appropriate tools for measuring the effectiveness of EFSA (MB 16-06-11).
[33] Annual Activity Report 2011.

formal identification of emerging risks. This procedure has been developed starting from recommendations made by the Scientific Committee in 2006 through a pilot study carried out in 2010-11.

Internal mandates and Self-tasking mandates have progressively increased their relevance in EFSA's activities, passing from 6% of EFSA's outputs (in terms of questions) in 2007 to 12% in 2011[34].

Self-tasking mandates represent a valuable instrument for EFSA to rapidly undertake on its own initiative, specific studies/activities on emerging issues or future challenges, in order to be able to anticipate future legislative works and to play an active role within the food safety system.

Around half of the self-tasking activities related to emerging issues and future challenges including developing methodologies, collection and analysis of experiences, technical specifications and risk assessment, as shown in **Error! Reference source not found.**.

Table 12: Scientific works undertaken under EFSA self-tasking function, 2007-2010

EFSA SELF-TASK QUESTIONS
Questions related to emerging issues
Blue Tongue Self mandate
The role of the tick vectors in the epidemiology of African Swine Fever and Crimean-Congo Hemorrhagic Fever in Eurasia
Bovine Besnoitiosis: an emerging disease in Europe
Self-tasking mandate on risk based control of biogenic amine formation in fermented foods
Assess the public health significance of meticillin resistant Staphylococcus aureus (MRSA) in animals and foods
Food borne antimicrobial resistance as a biological hazard
Surveillance and monitoring of Toxoplasma spp. In humans, food and animal
Monitoring and identification of human enteropathogenic Yersinia spp.
Monitoring of verotoxigenic Escherichia coli (VTEC) and identification of human pathogenic VTEC types
Food borne viruses
Mandate proposed to EFSA by the ANS Panel for a self-tasking safety assessment as a food additive of lutein preparations other than lutein with high concentrations of total saponified carotenoids at levels of at least 80 %.
PET recycling processes- evaluation criteria
Assessment of the use of cobalt compounds as additive in animal nutrition
Scientific Opinion on clustering and ranking of emissions of plant protection products from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments
Scientific Opinion on Risk Assessment for a Selected Group of Pesticides from the Triazole Group to Test Possible Methodologies to Assess Cumulative Effects from Exposure through Food from these Pesticides on Human Health
Cumulative and synergistic effects of pesticides
Questions related to future challenges
Geographical distribution of ticks with proven involvement in the transmission of animal diseases and zoonosis in Eurasia
Self-mandate on "Good Practice in Conducting Scientific Assessments in Animal Health Using Modelling
Risk Assessment Guidelines for Animal Welfare
Question for Scientific Opinion on the development of risk ranking tool on biological hazards
Question for Scientific Opinion on Reflecting the experience and lesson learnt from modelling on biological hazards
Future prospects that the BIOHAZ panel is facing
Self-tasking Working Group on the assessment of potential impacts of genetically modified plants on non-target organisms

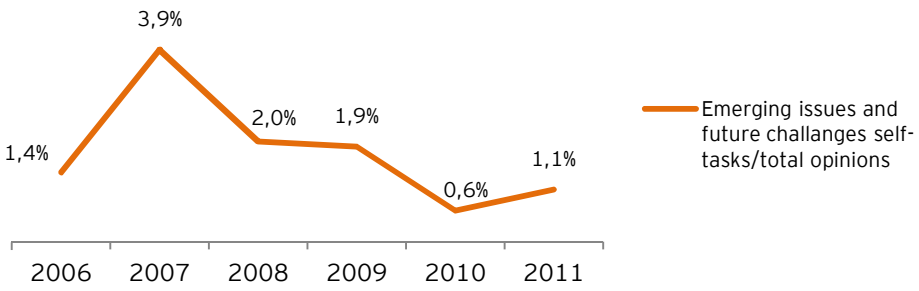
[34] Data provided by EFSA, 2012.

EFSA SELF-TASK QUESTIONS
Scientific Opinion on the science behind the guidance for scenario selection and scenario parameterisation for predicting environmental concentrations of plant protection products in soil.
Scientific Opinion on the importance of the soil litter layer in agricultural areas
Scientific Opinion on Proposal for scenario development and risk assessment of PPP use in protected crop systems
Scientific Opinion on emissions of plant protection products from greenhouses and crops grown under cover: outline for a new guidance
Scientific Opinion on the identification of pesticides to be included in cumulative assessment groups on the basis of their toxicological profile
Scientific Opinion on outline proposals for assessment of exposure of organisms to substances in soil
Scientific Opinion on the evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for dietary risk assessment
Opinion on FOCUS report on landscape and mitigation factors in ecological risk assessment
Exploring options for providing preliminary advice about possible human health risks based on the concept of Thresholds of Toxicological Concern (TTC).

(Source: EY elaboration on EFSA's data, 2012)

Despite Internal mandates and self-tasking mandates progressively increased their relevance in EFSA's activities, the production of scientific works on emerging issues and future challenges through self-task mandates is characterized by a decreasing trend (both in absolute terms and as a percentage of total opinions, see Chart 2).

Chart 2: Trend of emerging issues and future challenges self-tasks/Total opinions



(Source: EY elaboration on EFSA's data, 2012)

3.1.2.2 Stakeholders' point of view

Suitability of outputs to clients' needs

EFSA's outputs are globally suitable to the needs of its clients and more specifically complete and clear according to 88% of respondents (Q1.1). This positive evaluation is also confirmed by several interviewees (NRM, NRA, IOs, Cons., EP, EC[35]).

As regards the **needs of risk managers** (EC and NRM), information and comments received by these stakeholders show how scientific opinions are globally considered clear and well structured. In addition, the majority of European risk managers (EC, EP) think that EFSA's scientific outputs usually fully fit their needs to inform EU policy decisions[36].

Given that outputs are generally suitable to the needs of EFSA's clients, some differences emerge when looking at the variety of perception by MS: information collected during interviews (NRM, NRA) highlights that in countries with a strong risk assessment capacity (like Germany, UK or France), risk managers mainly rely on national agencies when dealing with

[35] This opinion is supported also by one FIR and one NGO.
[36] Progress report on the implementation on the MB decision to further develop impact indicators within EFSA as appropriate tools for measuring the effectiveness of EFSA (mb 16 06 2011).

national-specific issues and on EFSA for crisis situations/transnational issues or big studies. Smaller countries/new entrants or countries with a weaker national risk assessment capacity rely instead more on EFSA's opinions.

As emerged from interviews, the general positive assessment of EFSA's outputs is not completely shared by **Food Industry Representatives**, who find the process of opinions, specifically on health claims and procedures, inefficient, costly and highly bureaucratic and thus entailing a significant burden, as well as lacking of **clarity and transparency** (e.g., the process of the Food Additive Panel in dealing with data gaps). The absence of a **direct channel of communication** with EFSA both before the submission of the dossier and after an opinion is adopted[37] is one of the main issues raised by these stakeholders, as it generates mistakes in the dossiers as well as misunderstanding of EFSA's additional requests for data. A more direct contact with EFSA's scientists/experts and a refinement of the role of the Secretariat are thus requested by the majority of Food Industry Representatives. In addition, the 24 hours before publication to communicate the final opinion to the requestor are considered as not sufficient when EFSA's outputs determine negative effects, as they do not allow implementing a business continuity plan to adequately face the potential crisis.

Some **horizontal concerns regarding the suitability of scientific outputs still persist** and have been raised by some direct clients (EC, EP, NRM, *NRA*[38]) and external stakeholders (Cons., FIR) even if NRM and NRA usually recognise the difficulties of the context in which EFSA normally performs, mentioning the limited availability of data on certain issues due also to the unwillingness/difficulties of stakeholders to provide them, the sometimes strict deadlines that EFSA sets to provide outputs (both for regulations and in case of emergencies), the increasing level of complexity of risk assessment.

The main criticisms refer to:

- **The structure of opinions and their usability** (EC, NRA, EP, Cons.[39]). Terms of Reference are not always completely respected and it is sometimes difficult to interpret opinions from a legislative perspective (one EC). Opinions are too long and difficult to understand (NRA, Cons., one EP): more simplicity and clarity are requested.
- The **theoretical nature of guidance documents** that undermines their concrete implementation (few NRM). Guidance documents on data collection are the most discussed (see also par. 3.2 "Data Collection" for further evidences) as well as guidance for applications even if for different reasons (FIR[40]).
- **The adequacy of opinions for different national context** (NRM, NRA). EFSA's outputs do not adequately consider national details (e.g., EU food habits diversity, etc.): Member States need to consequently integrate EFSA's output by asking their national agency. In addition, the presence of recommendations to Risk Managers is a controversial issue: whereas some NRA think that additional and clearer recommendations should be present in all outputs, other stakeholders (e.g., one NRM, one FIR) think that EFSA should stay in its role of risk assessor.

[37] Indeed, generally the application is submitted to a National Risk Manager that forwards it to EFSA. The information flows with the requestor are mediated by the Risk Manager.
[38] Even if NRA are not direct clients, they represent a key stakeholder in the provision of scientific outputs of EFSA.
[39] This opinion is supported also by one NRM.
[40] Food Industry representatives' comment do not relate to the theoretical nature of guidance documents but mainly to the limited involvement in EFSA decision-making process related to these outputs, confirming, once again, their need to increase the communication with EFSA.

The following thematic areas have been pointed out by a few respondents[41] as possible priority areas to further improve the suitability of outputs to clients' needs.

THEMATIC AREAS OF IMPROVEMENT (Q1.2) *Suggested once*	- GMO (NRA) - Nanotechnologies (NRA) - Additives (NRA) - Food supplements (NRA) - Contamination of foods with micro-organisms, chemical substances of physical contaminants relationship to the limits of acceptability. (NRM) - Procedures based on the HACCP principles with regard to the application of such procedures by food business operators. (NRM) - Animal health and welfare (NRM) - Risk benefit analysis of foods (FIR) - Report on zoo noses trends (FIR) - Tolerable intake reports (FIR)	NRA, NRM, FIR

(Source: EY survey)

During **food/feed emergency situations**, considering the limited time to provide the opinion and the limited available data – as Member States are not always able to provide data within the fixed deadline -, EFSA's opinions are globally considered useful to NRM and NRA. More specifically, NRM highly appreciate EFSA's capacity to provide clear and synthetic risk assessments in user-friendly formats as a basis for their political decisions.

Nonetheless some stakeholders (EP, NRM, Cons.)[42] think that EFSA is **not proactive enough** in supporting risk managers in the **timely** identification of emerging risks and in dealing with them before they become an emergency. Despite the implemented activities to keep abreast of emerging issues (e.g. EMRISK Unit), there is a limited awareness of EFSA's role in this context. Indeed, EFSA usually reacts to external requests (as better illustrated in the previous paragraphTable 10) and does not seem to be able to act on its own or to anticipate critical situations (NRA, FIR). Legal boundaries, the increasing workload and the limited critical mass of expertise and resources to deal with emerging issues are recognised as the principle limits to EFSA's potential role (NRM, FIR, Cons.)[43].

Timeliness of outputs provision

Timeliness in the provision of outputs has raised controversial evidences from stakeholders.

Whereas 80% of stakeholders consulted through the survey[44] are satisfied with timeliness (Q1.3) of scientific outputs – with an increase to 94%[45] as regards technical advice and a value of 79% for opinions for applications (Q1.4) – interviews highlighted some criticisms.

Despite the increasing respect of deadlines illustrated before, criticisms come from EC, EP, NRA, FIR, complaining about the slowness in the delivery of EFSA opinions and **perceiving the scientific workflow for opinions as too long.** As regards specifically FIR, the criticism relates to the **gap between regulatory deadlines and industry needs:** industries do not work on the same timing scales, and processes of approval are too slow compared to the need of commercialization of products. FIR also complain about EFSA's presumed attitude to privilege European Commission's requests and some of them perceive a reluctance of the Authority to provide answers to specific requests coming from the industry regarding the application process.

[41] Acronyms of stakeholders in brackets mainly refer to one respondent.
[42] This opinion is also supported by one Scient. Org. and one NRA.
[43] This opinion is also supported by one Scient. Org. and one NRA.
[44] NA included.
[45] NA excluded.

At the same time, there is a widespread recognition, mainly among institutional stakeholders (NRM, NRA), of EFSA's ever-increasing amount of outputs as well as of the limited availability of financial and human resources. The Authority is not always blamed for the **delays, often considered as an effect of external and irregular request flows.**

On the contrary, as for the opinions provided in food/feed emergencies, timeliness of EFSA support is the most appreciated aspect (82% of respondents have given a rate equal or higher than 3 out of 4 Q3.6), confirming the low average time of response described above.

Quality of scientific outputs

Also the scientific quality and the reliability of outputs have been investigated with reference to the provision of outputs. As for the suitability of outputs to clients needs, also as relates reliability the stakeholders' perspective is of outmost importance.

Most stakeholders (namely, NRM, NRA, Cons., and some FIR) appreciate the **quality of outputs**, considering EFSA's outputs as the main reference not only for European Institutions but also for other National Authorities. The quality of outputs is specifically appreciated for guidance documents. These documents are among the most known by stakeholders (NRM, NRA, FIR) and are considered of high scientific quality (even if lacking of practical examples of implementation according to few NRM). This quality is considered to be the result of EFSA's capacity to gather the best knowledge and high level experts on the specific issues treated in the guidance documents.

Also **in food-feed emergency situations** the quality of EFSA's scientific outputs is globally positively evaluated by respondents (on average 79% of stakeholders in the survey, giving a 3-4 rate out of 4 - Q3.6 and EC, EP, NRM, NRA in the interviews), specifically as regards clarity and relevance (with respectively 79% and 76% of respondents giving a positive rate 3 or 4 out of 4 - Q3.6).

Nonetheless, some stakeholders criticize the following issues:

- **Transparency** (NRA, NRM, FIR, NGOs)[46]. Coherently with the last evidences coming from the External Quality Review presented before (see par. 3.1.2.1), the scientific soundness of opinions does not appear to be clear enough, especially with regard to the consideration of other relevant schools of thought. Once data are provided to EFSA, it is not always clear if and how they are used for the provision of final outputs (see also par. "Data Collection" and "Openness and Transparency"). Outputs do not always contain all the details needed to adequately follow and trace the risk assessment (data – especially industry's ones, methodologies, rationales, uncertainties, minority views). There is no clear demonstration of the expertise used to deal with a specific issue nor of the independent and unbiased views of experts involved (EC).
- **Update/integration of a scientific decision-making process** (NRA, FIR): despite the existence of a specific procedure for the update of published opinions, the long time taken by EFSA to update[47] as well as the lack of openness towards external scientific

[46] This opinion is also supported by one EC.

[47] EFSA's procedure to integrate/update published opinions is quite bureaucratic and long according to some stakeholders. Here follows some examples provided by stakeholders at this regard: for BSE data collection, a National Agency submitted data with an error, neither the MS or EFSA detect this error and EFSA came out with an opinion with significant negative aspects for the Country. It has taken 2/3 months, and the intermediation of the EC to convince EFSA to make a new evaluation (NRA). In 2005 EFSA launched a call for data on poppy seeds. One of the main producers of poppy seeds in Europe was not able respond to the call. Thus, EFSA came out with an opinion without trying to ask again for data coming from that country. Once the opinion was published, this country tried frequently to ask EFSA to reconsider the output without any result. Finally, the opinion was not completely relevant for the national market and this country will wait for the next official updating of the opinion to send its contribution

inputs during the drafting of an opinion and after its publication, once new evidences become available, are criticised (see also par. 3.8 "Openness and Transparency"). One NGO has also pointed out EFSA's lack of consideration of independent studies and its unawareness of their existence[48].

- **The lack of internal homogeneity and harmonization** (NRM, FIR, IOs)[49]. Despite EFSA's implementation of common formats for opinions and guidance documents detailing scientific aspects for all risk assessments, different Panels use different approaches and provide different types of scientific outputs (i.e., formats, terminology, level of detail, methodology[50], etc.). Improvements are strongly requested by stakeholders[51].
- **Lack of a peer review system** in the procedures to assure the quality of EFSA's outputs (by few NRA and NGOs), despite the existence of the three steps quality review system described before.
- (limited to NGOs) **EFSA's industry-friendly attitude**. Criticisms are focused[52] on the use that EFSA makes of "industry science" to judge whether products are safe[53]. A stronger cooperation with research institutions and universities is then desired by NGOs (as well as by 2 out of 4 MEPs interviewed), in order to better deal with the most controversial risk assessment and to commission independent safety testing.

Connected to quality is the **reliability** of outputs: scientific outputs are considered reliable by the majority of stakeholders (89% of respondents have given a rate equal or higher than 3 out of 4 - Q1.5) and the most reliable if compared with EMA, ECHA, FSA, VWA[54]. FSA's outputs are considered to be the most reliable after EFSA's ones (83% have given a 3-4 score out of 4 - Q1.5)[55].

The reliability of EFSA's scientific outputs is particularly relevant for institutional stakeholders (90% gave a rate equal or higher than 3 out of 4 - Q1.5), and specifically for the **EC,** that usually fully relies on scientific opinions and advice provided by EFSA[56]. It is also appreciated by external stakeholders (86% gave a rate equal or higher than 3 out of 4 - Q1.5), mainly by Consumer Organizations, that consider EFSA's outputs valid and well put, even in comparison with the outputs of other Food Safety Organizations, and by Scientific Organizations (art.36),

(NRA). Another example: once on the level of biotoxins on metals a NRM provides comments together with other NRM and EFSA takes approximately 10 months to came up with an updated opinion (NRM).

[48] Conflict on the menu. CEO, 2012. (e.g.,, EFSA's opinion on gliphosate, 2012).

[49] This opinion is also supported by one Scient. Org. and one EC.

[50] (FIR) vertical model for additives and a probabilistic model for food contact materials.

[51] E.g., in Feed Additives Panel it seems there is no uniform approach on the management of risks and the way to handle data gaps. There are a lot of published guidelines (how to submit dossiers) but no guidelines available on the work of the Panel in the situation of data gaps that lead to different approaches to handle these data gaps (FIR).

[52] Conflicts on the menu, CEO, 2012.

[53] Those dossiers are often not available because of their unpublished status and/or commercial confidentiality rules and cannot be replicated. Through a set of evidences (e.g.,, Bisphenol A and Aspartame) one NGO pointed out how EFSA has repeatedly ignored or dismissed independent studies, giving as an explanation that those studies were not carried out according to the norms for industry tests for regulatory purposes (Good Laboratory Practice). (Source: Conflict on the menu. CEO, 2012).

[54] The high percentage on NA (>50% of stakeholders) limits the scope of the comparison that should be integrated with evidences coming from the benchmark analysis. The high level of satisfaction regarding EFSA's outputs could be explained, according to some EP and Cons., with the high level of transparency and openness that characterizes the Authority's activities. "EFSA has been under public scrutiny since it was created and it difficultly can afford to make many mistakes" (EP).

[55] ECHA, VWA and EMA get similar rates by respondents, respectively 81%, 79% and 75% have given a 3 or 4 rate to the reliability of their outputs. The low level of reliability concerning EMA (25% of respondents have given negative rates) is linked (EP, NRA) to the recent postponement of the discharge 2010 due to conflicts of interests.

[56] As shown also in the Case study carried out by the External Consultants on the utility of 12 opinions conducted in 2011 in the context of the impact indicators progresses.

evaluating EFSA's opinions and scientific basis usually well described, with details on assumptions made and source of data.

Also **at international level**, EFSA's opinions are considered as reliable and in some issues even as a reference (see par. 3.5 "EFSA's International role and recognition" for more details). Nonetheless, its opinions are often considered as European-based (IOs), respecting the high levels of food safety defined by the European Commission. For this reason, EFSA's opinions are sometimes conflicting with international ones (e.g., JECFA, WHO, FAO, OIE, etc.) that should provide opinions potentially applicable to all countries. An enhanced cooperation with international institutions, even at an early stage of an opinion development, is suggested (IOs) in order to provide EFSA's opinions with increased international validity.

The following points are considered as relevant in supporting the good quality and reliability of EFSA's outputs:

- **EFSA's independent and European nature** (NRA, Scient.Org., Cons.). Without being influenced by national, financial or political interests like national authorities, EFSA gathers information from all Member States and acts for the European Union and not in favour of a specific interest.
- The Authority's capacity to have **excellent experts** in the Scientific Committee and Panels (NRM, FIR).
- The progressive efforts of the Authority to develop a **quality review system** for its scientific outputs and to guarantee the use of the best scientific methodology (NRM, NRA[57], FIR).
- The possibility to **easily consult EFSA's outputs** on the website or through the newsletter (NRA, FIR).

Effectiveness and scientific quality of self-tasking function to keep abreast of emerging issues

Despite the scientific works undertaken by EFSA illustrated before, there is a **limited awareness and recognition of EFSA's self-tasking activities for emerging issues among stakeholders** (NRM, NRA)[58], that hardly identify those activities or distinguish them from externally requested activities. As a consequence, according to one NRA, there is a weak external consideration on EFSA's specific contribution in detecting and dealing with emerging issues and sometimes EFSA's activities duplicate national activities (NRA). The lack of awareness on EFSA's self-tasking function has emerged quite clearly from interviews, contrasting the high level of satisfaction on the self-tasking function emerged from the survey, that should be therefore taken with some caution.

Outlier in this context is an International Organization that recognizes EFSA's positioning in the development of new processes and methodologies for the identification of emerging food safety risks (also thanks to the availability of resources allocated to develop new models) and considers the cooperation with the Authority as fruitful in this respect.

In this context, it is still **controversial for some stakeholders whether EFSA should continue to invest resources on self-tasking activities,** as suggested by one Cons., and one NRA or whether it would be more effective to reallocate financial and human resources to the increasing number of requests for scientific outputs (NRA, FIR), avoiding also in this way to overlap with national activities (NRA).

Whatever is the development of the self-tasking function, stakeholders have expressed the **need to better focus its aim to enhance its future utility and to better report on it** (NRA,

[57] A few NRA, questioned EFSA's current quality assurance system as not fully adequate to ensure the highest expected quality in EFSA's scientific outputs.
[58] This opinion is also supported by one FIR.

NRM, Scient.Org.). This could be done for example by identifying new issues of interest on which EFSA could play a more significant role without overlapping with National Authorities tasks[59].

3.1.2.3 Analysis of evidences

Evidences collected from the desk analysis and stakeholders support a positive evaluation of the effectiveness and quality of EFSA's outputs, in terms of their capacity to meet clients' needs, timeliness and quality.

As far as the capacity to meet clients' needs is concerned, there is evidence on the fact that outputs meet clients' needs, both because clients express satisfaction on their suitability to their needs and on their usefulness also in food/feed emergency situations, and also looking at the constantly increasing demand for them and on the positive results of a study conducted in 2011 on the usefulness of EFSA's outputs to inform EU policy decisions. As a matter of fact, 100% of both dossier and non–dossier related opinions and outputs were indeed taken up by the Commission services in developing their proposals or taking forward discussions with the Member States.

The actions undertaken by EFSA, and namely the procedures to identify clients needs and to deliver outputs, seem therefore to have been effective in achieving these positive results, given that they have provided the basis to better share expectations (through the involvement of the EC and the NRM in drafting objectives of the Strategic Plan and of the EC in Panels and working groups), to enforce the dialogue with requestors in the risk assessment workflow and before publication of the output, and to receive feedbacks on the utilization of EFSA's outputs. Though, there are still areas of improvement to be taken into account to meet all expectations, as some NRM think that guidance documents have a theoretical nature that undermines their concrete implementation and that outputs are not always addressing their specific national context. Food Industry Representatives, moreover, find the process of opinions inefficient, costly and highly bureaucratic, as well as lacking of clarity and transparency and ask for a direct channel of communication with EFSA and for more than the 24 hours envisaged in the delivery procedure before publication of outputs in order for them to implement a business continuity plan to adequately face potential crisis. As further detailed in par. 3.8 "Openness and Transparency" and in par. 3.6 "Organization", EFSA has already implemented different instruments of dialogue with FIR (the main initiative being the creation of the Application Helpdesk in 2011) and further developments are still ongoing in this relationship, but at the moment it is too early to evaluate the impact of these initiatives and FIR still ask for a better dialogue, also to better understand the complex workflows that characterize EFSA's activities in the evaluation of regulated products (see also par. 3.6.3.3).

It is also to be noticed that the general positive evaluation on the suitability of outputs to meet clients' needs is not extended to the case of emerging risks: in this case, indeed, the actions undertaken by EFSA to support clients in the identification of emerging risks (i.e., the creation of a dedicated Unit (EMRISK), the working group on data collection, the Member States network and the stakeholder consultative group) have not yet brought results that can be significantly appreciated by stakeholders, who indeed think that EFSA should be more proactive in the timely identification of emerging risks.

As regards self-tasking, stakeholders are not completely aware of the added value coming from this function and do not recognize a dominant role of EFSA in tackling emerging issues and future challenges. Whatever is the development of the self-tasking function, stakeholders have expressed the need to better focus its aim to enhance its future utility and to better report on it.

[59] E.g., international risks – one NRA, or consumer sensitive issues – one Cons.

Timeliness does not represent a major issue in terms of effectiveness of the provision of outputs. Although the process of provision is not yet 100% compliant with deadlines, and despite some interviewees have complained on the length of the process, the survey to stakeholders shows a high level of satisfaction on the timeliness and does not provide a basis to evaluate the presence of a general problem on this criteria, but rather a specific problem related to industrial needs, compared to which the processes of approval are considered too slow for the needs of commercialization of products.

The effectiveness of the provision of outputs in terms of quality is also satisfactory: evidences from the Quality External Review and from opinions of stakeholders show indeed that outputs have a good and increasing quality (with a strongly decreasing trend of negative comments emerging from the Quality External Review), also when considering food-feed emergency situations, and that they are considered reliable even at an international level (as a matter of fact also citations of EFSA's outputs show an increasing trend, especially as regards Food science and technology and Toxicology and Veterinary Science). Provided that in general terms countries with a stronger risk assessment capacity do not rely on EFSA's outputs as much as countries with a weaker risk assessment capacity, the vast majority of stakeholders appreciate the completeness and clearness of outputs provided by EFSA. This is the result of both the availability of the best knowledge and of high level experts (as highlighted by stakeholders) as well as of EFSA's independent nature, and of the procedures put in place by EFSA. These procedures, although considered a bit too complex, have indeed put the basis to improve the quality of outputs, in terms of structure, clarity, transparency, update to take new data into account, independence and review.

In this context, of course, there are some elements in the quality of outputs that can still be improved, emerging from both the Quality External Review and stakeholders, like their length, their simplicity and clarity, their scientific soundness and the transparency in the use of data; the process of update, their format -that despite the procedures put in place to improve and harmonize the structure of outputs, still determines a lack of harmonization.

The **lack of harmonization** of outputs is indeed an issue that has emerged from different sources, as well as from the direct observation of EFSA's meetings performed by the evaluation team. Even if this diversity could be partially explained by the historical vertical approach of the food legislation and by the highly different regulatory framework of each sector, this aspect needs to be better approached.

The analysis that the evaluation team has performed on the completeness of the quality management system, also shows that some areas need to be further developed, as shown in the following table, listing key elements identified by the evaluation team and the correspondent state of implementation in EFSA's Quality Management System.

Table 13: EFSA Quality Management System completeness

ELEMENTS OF THE QUALITY MANAGEMENT SYSTEM	EVIDENCES ON EFSA'S SYSTEM
Key outputs defined	(*2008 and 2010*) Definition of EFSA scientific outputs.
Key processes defined	(*2008*) Development and publication of the Risk Assessment Workflow[60]. (2008 *ongoing*) Development and Implementation of Standard Operating Procedures now under revision. (*2010*) Introduction of Work Instructions[61].

[60] A description of the flow of activities from the moment a mandate is received until the publication of the scientific output.

[61] Step-by-step instructions for the accomplishment of a task by one person or team retained in the Directorate or Unit where the work is performed.

ELEMENTS OF THE QUALITY MANAGEMENT SYSTEM	EVIDENCES ON EFSA'S SYSTEM
Key parameters describing quality defined	(*2011*) Quality defined as the degree of adherence to EFSA's core values. The quality attributes are: Science, Timeliness, Transparency, Independence and Clarity in communication. For each attribute, relating measures are identified.
Procedural compliance with policies and procedures monitored (includes control of documents; control of records, control of non-conforming product, corrective actions, preventative actions)	(*ongoing*) Indicated among the priorities for the "Vision EFSA Integrated Quality Management System 2010-2015"
Organization's performance in terms of quality assessed and reviewed	(*2008-2010*) Implementation of measures aimed at assessing the quality of EFSA's scientific outputs and at harmonizing and documenting procedures and practices regarding its scientific activities. (*ongoing*) Harmonization, measurement and control of activities other than scientific ones.

(Source: EY elaboration on secondary sources)

3.1.2.4 Evaluation results

The provision of outputs originated from external requests is effective and of good quality.

The **process meets EFSA clients' needs**: despite the evolution in workload and work areas, crisis situations and the difficulty to foresee changes in the legislative framework, EFSA has maintained its capacity to fulfil its overall remit, providing its main stakeholders the support they needed. As discussed in par. 3.1.2.3, the global stakeholders' satisfaction should be added to the implementation by EFSA of specific procedures to identify clients' needs and deliver outputs according to the specific target and content of the communication.

The effectiveness in the provision of outputs is especially appreciated in **emergency situations**, when EFSA is able to provide clear and timely risk assessment, used by risk managers as a basis for their political decisions.

Nonetheless, EFSA does not anticipate crisis/emergencies and normally reacts to EC requests for urgent advice, as demonstrated by the past crisis/emergency situations. Despite EFSA has created in 2008 a dedicated Unit (EMRISK), activities aiming at identifying emerging risks before they become a crisis/emergency need to be further improved, and a more proactive behaviour is also expected by some stakeholders. (see par. 3.1.2.2 and 3.1.2.3)

EFSA's clients appreciate the high **quality, accessibility and reliability of outputs**. Quality has progressively improved, with the result that negative comments reported in external experts' reviews have reduced more and more (reaching 1,4% in 2011), and EFSA's outputs are definitely considered as reliable, even more than those of other organizations according to some stakeholders. (see par. 3.1.2.2 and 3.1.2.3)

EFSA is at the forefront of scientific knowledge and risk assessment methods as shown by the increasing trend of EFSA's outputs citations in key relevant scientific journals. Food science and technology represent the main area of recognition followed by Toxicology and Veterinary science.

The stakeholders' global positive assessment of EFSA's scientific outputs is quite homogeneous. Nonetheless, Food Industry Representatives question the limited exchange of scientific information with EFSA as they assume it is at the origin of some misunderstandings

with specific issues applicants have to deal with. Coherently with the Founding Regulation[62], EFSA should continue to dialogue with applicants, ensuring that all parties share a common understanding. Nonetheless, risk managers remain the Authority's main clients and, despite the increasing weight of the applications on the total amount of requests received annually, all further efforts (if considered necessary) towards a greater inclusion of FIR in the decision-making process, should be adequately balanced with EFSA's duty to act independently (see also par. 3.1.2.2, 3.6.3.2, 3.8.2.2).

In this global positive context, there are though some **areas of improvement** that EFSA might take into account to better align its outputs to clients' needs and increase their quality:

- *usability*: opinions are considered by some risk managers to be too long and not immediately usable from a legislative perspective or from a MS's point of view in so far they do not take into account national contexts. As far as guidance documents are concerned, while considered of high scientific quality, they are too theoretical and difficult to be implemented (par. 3.1.2.3);
- *update/integration*: according to some stakeholders, opinions are not quickly updated once new evidences becomes available or following critics, and a need to increase the effectiveness of the existing process has emerged (par. 3.1.2.2);
- *timeliness*: although there is a substantial compliance with formal deadlines and a general satisfaction on timeliness, the process is considered long if looking at applications and the need to take into account Industry needs of commercialization. Urgent advices instead globally satisfy stakeholders as EFSA has always provided a response within 30 calendar days (par. 3.1.2.3);
- *transparency*: the scientific soundness of opinions does not appear to be clear enough, as far as it concerns the use of data, the integration of different schools of thought (including industry dossiers), methodologies, rationales, uncertainties and last but not least independence of experts (par. 3.1.2.3);
- *harmonization*: outputs are heterogeneous as regard formats, terminology, level of detail, methodology, etc. and do not adhere to predefined templates. In addition SOPs, as confirmed by internal staff, are too complicated to be followed (par. 3.1.2.3).

The **provision of outputs originated from internal mandates** and self-tasking function, to investigate on emerging issues and/or future challenges, is less effective: although looking at the type of works undertaken, it is possible to say that EFSA is definitely active in its self-tasking function and internal mandates, the food system is not aware of the added value coming from this function and does not recognise a dominant role of EFSA in tackling emerging issues or future challenges. It emerges quite clearly that there is need to better focus the aim of self tasking and internal mandates to enhance their future utility and to better report on them.

3.1.3 Added value

This part illustrates the added value linked to the provision of scientific outputs and technical support by EFSA. To analyze this aspect, the following issues will be detailed firstly through an analysis of EFSA's procedures and implemented activities and then presenting the stakeholders' point of view:

- Existence of an integrated approach in scientific output and technical assistance provision;
- Relation with risk managers in the provision of scientific advice.

[62] Art. 42 " The Authority shall develop effective contacts with consumer representatives, producer representatives, processors and any other interested parties".

3.1.3.1 Facts & Figures

Existence of an integrated approach in scientific output and technical assistance provision

The added value provided by EFSA through the provision of outputs has been evaluated in terms of integrated approach[63]. Indeed, as stated in EFSA's Strategic Plan 2009-2013, it is expected that risk assessments considering risks in a wider integrated manner will be increasingly required (see also par. 2.2), in order to provide risk managers with comprehensive advice on which to base their decisions[64]. Through the system of Scientific Committee, Panels and Working Groups, EFSA can bring together a wide range of knowledge that spans the entire length and breadth of the food chain including animal health and welfare, plant health and crop protection rights all the way to nutrition and diet.

The portfolio of expertise mapped for Panels is indeed wide (see Table 14), and enables the Authority to face the increasing complexity of risk assessment and to provide scientific outputs considering different issues related to a specific theme.

Table 14: Number of fields of expertise per Panel

Panels		2009 8 SP+SC call + ANS-CEF call	2011 Ext RL call(8SP/SC)+ ANS-CEF call	2012 8 SP+SC call
RASA + SC	AHAW	17	16	17
	BIOHAZ	12	12	11
	CONTAM	18	18	20
	PLH	16	16	16
	SC	18	18	17
REPRO	ANS	11	16	16
	CEF	11	13	13
	FEEDAP	14	14	4
	GMO	13	13	11
	NDA	9	9	10
	PPR	14	19	12

Highly differentiated mix of expertise to face generic opinions and horizontal issues.

Sector specific expertise to manage applications of regulated products.

(Source: EFSA's elaboration on application forms, 2012)

For risk assessments that require a broader range of skills than available in one single Panel, EFSA has established joint work between Scientific Panels, as stated in the Science Strategy 2012-2016, to ensure the full range of disciplines is available to build the risk assessment[65].

Until now, EFSA has published a limited number of scientific opinions, in total 28[66], where two or more Scientific Panels were adopting joint opinions. Nonetheless, in the future, the number of scientific issues that fall within the competence of more than one Scientific Panel is expected to raise significantly, possibly 100-400 per year in 2013-2015, in the area of enzymes originating from genetically modified microorganisms, CEF-GMO, according to the medium term planning endorsed by EFSA and the DG SANCO.

Also the new rules of procedures of Scientific Committee, Panels and Working Groups approved by EFSA in 2012 allow greater flexibility in the multidisciplinary composition of the working groups[67].

[63] The Authority should provide a comprehensive independent scientific view of the safety and other aspects of the whole food and feed supply chains, which implies wide ranging responsibilities for the Authority. These should include issues having a direct or indirect impact on the safety of the food and feed supply chains, animal health and welfare, and plant health. (Founding Regulation (36).
[64] Science Strategy 2012-2016.
[65] Science Strategy 2012-2016.
[66] Decision of the Executive Director of the European Food safety Authority regarding multisectoral issues, 2012.
[67] The chairmanship of the working groups would be possible for members of any EFSA Panels and no longer be limited to the members of the Panel that decided to set up the working group. (52 Management Board Meeting minutes).

In scientific opinions on multisectoral issues, a crucial role is assigned to the Scientific Committee through the Founding Regulation Art. 28(2). It is formally responsible for scientific opinions falling within the competence of more than one Scientific Panel, and on issues which do not fall within the competence of any of the Scientific Panels. In order to reinforce the Scientific Committee, EFSA has recently approved[68] an approach that the EFSA Mandates Review Committee[69] shall implement, based on a case-by-case assessment when assigning mandates, so as to ensure timely and efficient delivery of integrated scientific advice in full compliance with the legal framework.

Relation with risk managers in the provision of scientific advice

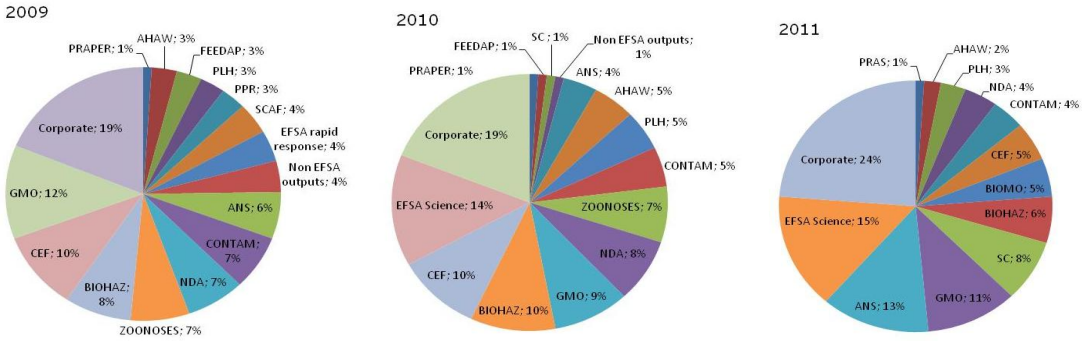
The European Food Safety Authority works closely with risk managers throughout the European Union. The European Commission, European Parliament and EU Member States are the key risk managers in the EU system. They are responsible for making European policies and taking decisions to manage risks associated with the food chain. In the context of the provision of scientific outputs, EFSA's relation with risk managers is analyzed according to the Authority's capacity to ensure business continuity and the development of tools and procedures to support national risk managers in crisis situations.

In order to **provide continuity of support** to risk managers, **the Authority has implemented different measures:**

- Improvements in the **exchange of information** with risk managers through, for example, the consultation on annual and multiannual working plans, with the Advisory Forum Members[70] and the recently approved roadmap 2010-2015 with DG SANCO. The roadmap, in particular, has represented an important step in this direction, allowing EFSA to anticipate and better manage future EC workload and allocate staff and financial resources consequently (see par. 3.4 "Cooperation and networking" for further tools and activities implemented by the Authority to enhance the exchange of information with risk managers and get relevant inputs to plan priorities adequately);
- adoption, since 2009, of a **business continuity strategy**[71] for recovering and continuing business in the event of an unforeseeable business disruption;
- **changes in the adaptability of the organization:** mobility and flexibility in the allocation of posts have also been put into motion for general scientific competences. A recent example is the temporary transfer of two scientific officers for 9 months from PPR, AMU and SCO Units to the PREPeR unit as the latter unit is facing a particularly high workload as a result of the resubmission of pesticide applications[72] (see par. 3.6 "Organization" for further details);
- increase of **communication activities**: the increasing trend in the number of press releases/web stories (from 73 in 2009 to 78 in 2011) and in the variety of topics treated (Figure 7).

[68] Decision of the Executive Director of the European Food safety Authority regarding multisectoral issues, 2012.
[69] The EFSA's Committee responsible for screening all requests sent to EFSA on a weekly basis. It considers the type of scientific output required and allocates the requests to the suitable Scientific Panel(s) or Scientific Committee.
[70] EFSA website.
[71] Annual Activity Report 2009.
[72] Multiannual Staff Policy Plan 2011-2013.

Figure 7: Percentage of press releases/web stories per type



(Source: EY elaboration on EFSA's data, 2012)

Regarding the **support provided by EFSA during food/feed crisis situations**, Member States have never asked for EFSA's advice[73] despite, according to EFSA's procedures for responding to urgent advice needs, they have a notification procedure at their disposal as described in EFSA's Procedures for responding to urgent advice needs 2011.

Over the years, EFSA has developed a mix of tools and procedures to assist risk managers in developing appropriate risk mitigation activities in times of crisis situations. The recent E.Coli case in 2011 (see box below) can provide a good example of EFSA's portfolio of services during this kind of situations.

E.COLI OUTBREAK

E. Coli outbreak in 2011 (STEC O104:H4) is the most significant urgent request of scientific support to the EC and MS that EFSA has been involved in, in terms of immediate human health risk, duration of the assistance and implication of EFSA resources.

The urgent response of EFSA took place in three different phases:

1. The drafting of a report as a response to a demand for background information on the internalisation of enteric pathogens in plant material. Additionally, and on EFSA's initiative, a report summarising available data on STEC was compiled jointly with the ECDC.
2. The placement of EFSA's staff with the German authorities following a request from the EC and the German Federal Ministry of Food, Agriculture and Consumer Protection. This was the first time a request for placing staff with a MS in a context of a crisis has been made and EFSA sent people with specific expertise to address the specific case.
3. EFSA's coordination at EU level of the traceback process between MS to find the common source of the outbreak. Representatives from the German food safety authorities were sent to EFSA to cooperate on the cluster tracing mapping. This phase ended with the publication of the report on tracing of fenugreek seeds.

This response lasted 6 weeks and involved staff from 10 Units as well as a Task Force involving representatives from impacted MS, the EC, ECDC and the EU reference laboratory on E. Coli, WHO and FAO as well as external experts.

(Source: EY elaboration on secondary sources[74])

Tools activated in the E.Coli outbreak are only part of the **wider portfolio of tools that EFSA can provide to support risk managers,** like the Crisis Room, emergency meetings of Scientific

[73] Data provided by EFSA, 2012.
[74] Editorial: EFSA's Food and Feed Crisis Preparedness and Response, Tobin Robinson and Hubert Deluyker, EFSA, 2012.

Panels of the Steering Committee, setting up of a specific task force, urgent meetings of the Advisory Forum, urgent scientific studies, and urgent translations[75].

The Authority has undertaken over the years increasing efforts to be prepared to react and support the EC and MS during crisis and other urgent situations. Indeed, it has drawn up its in-house procedures to complement the Commission Plan, for use within EFSA and to guide EFSA's staff in case of an urgent request for scientific advice (the 2011 Emergency Manual[76]). The procedures are regularly updated following experience gained during crisis responses and through crisis preparedness training and simulation exercises[77] involving staff and stakeholders (e.g., MS, EC)[78]. The recently settled (2008) EMRISK Unit is responsible for coordinating EFSA responses and activities during urgent situations as well as for cooperating with relevant key players and EFSA has introduced and progressively improved an impact indicator looking at how EFSA reacted in a crisis[79] is a demonstration of the increasing interest towards this area of activity.

Until now, crisis have occurred only in bigger countries where a sound risk assessment expertise was already in place and where structured national risk assessment agencies (e.g., BfR Germany) have primarily managed the emergency situation, and EFSA has offered an additional support and coordination.

3.1.3.2 Stakeholders' point of view

Existence of an integrated approach in scientific output and technical assistance provision

Over time, the Authority has been able, according to the majority of stakeholders (83% rate 3-4 out of 4 to Q1.7), to implement **a multi-disciplinary and integrated approach**, providing comprehensive scientific advice to risk managers (as also described in the previous par. 3.1.3.1).

Although the wide range of expertise available for Panels illustrated before can support the multi-disciplinary and integrated approach, for a few stakeholders (EP, NRA and experts during the direct observation of a Panel meeting[80]) this **represents also a limit to the sustainability of this approach**, in so far it:

- determines difficulties in effectively managing resources;
- implies some difficulties of cooperation among experts belonging to different Panels and dealing with transversal issues, and namely safety of the food and feed chain, animal health and welfare and plant health;
- brings the Authority to deal also with tasks that are not strictly focused on food safety.

According to the EP, an integrated approach could rather be pursued cooperating more with other specialized agencies that could complete EFSA's core thematic areas of responsibility.

T**he support of the relevant upstream stakeholders** (producers, manufacturers, etc.) **is also slightly criticized,** especially by some FIR (58% gave a rate equal or below 2 out of 4 - Q1.8*)*,

[75] EFSA Procedures for responding to urgent advice needs, 2011.
[76] EFSA Procedures for responding to urgent advice needs, 2011.
[77] EFSA has developed and implemented a multi-annual crisis preparedness training programme to provide technical training for staff aimed at rehearsing and evaluating the current procedures. The broad goal of this training is to improve EFSA crisis preparedness and to develop an effective coordination framework for internal and external cooperation with EFSA's units and stakeholders.
[78] Annual Report on EFSA's food and feed safety crisis preparedness and response in 2010.
[79] The dimensions analyzed are: the reaction time in collecting and providing data and the ability to support key risk management decisions. (Source: Progress Report on the implementation of the MB Decision to further develop Impact Indicators within EFSA as appropriate tools for measuring the effectiveness of EFSA).
[80] Opinion collected during the 63 Plenary meeting of Animal Health and welfare Panel.

that express concerns on the way the Authority has to deal with their dossiers (see also par. 3.1.2.2). It seems that some EFSA's requests for clarification on an application submitted have sometimes revealed that EFSA was not deploying the right expertise to deal with the specific issue[81].

On the other side, the support of **downstream stakeholders** (retailers, consumers, etc.) **seems enough** in delivering scientific advice associated with the food chain (as confirmed by 66% of respondents Q1.9).

Relation with risk managers in the provision of scientific advice

Evidences collected show a general satisfaction on EFSA's capacity to guarantee **business continuity to risk managers**.

Despite the evolution in workload and work areas (see par. 3.6 "Organization" for details on the increased workload), crisis situations, and the difficulty to foresee changes in the legislative framework[82] (MB, NRM), EFSA has maintained its capacity to fulfil its overall remit and more specifically to guarantee business continuity to risk managers and its main stakeholders for the 77% of respondents (giving a rate equal or higher than 3 out of 4 - Q3.3), who have always obtained the support needed from EFSA within assigned resources (77% rate 3 or 4 out of 4 – Q3.4).

Although the capacity to guarantee business continuity is quite satisfactory, some areas for improvements are indicated by few stakeholders:

- the provision of details, within risk assessments, related to the **national needs** expressed by NRM. An effort to know the different realities of different countries and to try to adapt their opinions on these realities is expressed (NRM) (see also par. 3.1.2.2);
- an improved **cooperation with NRA and other national scientific institutions** in order to allow EFSA to collect all the necessary data and to dispose of the widest portfolio of expertise (NRM, FIR, EP) (see also par. 3.2 "Data Collection");
- (only few NRM) the implementation of **targeted trainings** as well as customized channels of communication targeted for NRM needs (e.g., Newsletter, focused meetings).

Regarding **food/feed crisis situations**, there is a widespread consensus among NRM that the Authority's tools and activities previously described, have been useful and all MS have benefited indirectly from EFSA's risk mitigation activities (all NRM giving a rate equal or higher than 3 out of 4 – Q3.1).

Despite no one has directly asked, National Risk Managers are aware that, during food crisis, they have the possibility, through an ad hoc procedure, to ask for EFSA's intervention and no formal barrier prevents them from asking. Nonetheless, they could receive support also from other organizations *(Q3.2)* and most of the times, when a crisis outbreaks, they prefer to address directly to their National Food Safety Agencies or to specialized National Research Institutes, since national institutions are more aware of the specific political, social and scientific context. A limited number of NRM indicated international institutions as a reference point and among them only OIE has been mentioned.

[81] A FIR stated that from the questions he received from the ANS Panel it was clear that data included in the dossier had been not adequately understood.

[82] The health claims regulation is the most mentioned example (MB, NRM) of an unforeseeable change in legislation for which EFSA had to adapt its organization and reallocate resources to deal with the increasing number of requests resulting from the new regulation entered into force with a small notice and without an adequate assignment of resources.

E. Coli outbreak (2011), is mentioned by the majority (NRA, NRM)[83] as the reference example to argue on the effectiveness of EFSA's support to the safety of the food chain in times of crisis situations, further confirming its relevance in EFSA's history. Globally, EFSA's resolution to the contribution of the crisis is widely acknowledged. During the E. Coli outbreak, as well as in previous crisis situations, **the most appreciated form of support** is EFSA's capacity to quickly establish a **European network of cooperation** between national risk managers and risk assessors, the European Commission, EFSA's staff and other supporting experts. Recurrent conference calls and video conferences, the organization of meetings with National Risk Assessors and the presence on the field of the EFSA-EC task force have reassured Risk Managers and national stakeholders as well.

Nonetheless NRM agree on the need to further enhance EFSA's response capacity in urgent situations and suggest to better capitalize previous experiences in order to identify proper areas of improvement and to strengthen the discussion on how to address crisis situations in peace times.

3.1.3.3 Analysis of evidences

Evidences collected through the desk analysis and the stakeholders show that EFSA is providing added value in terms of both integrated approach and tools and procedures to support risk managers.

As regards the **integrated approach**, besides of course the role assigned by the Founding Regulation to the Scientific Committee in case of multisectoral issues, the system put in place seems to be effective in supporting an integrated approach: both the availability of a **wide range of expertise** and the **procedures** put in place by EFSA, like the assignment of mandates related to multisectoral issues, the joint work envisaged in the Science Strategy between Scientific Panels, the new rules approved in 2012 to support a greater flexibility in the multidisciplinary composition of the working groups, provide the basis to activate an integrated approach whenever it is needed. Also stakeholders think that EFSA is effective in providing comprehensive scientific advice, through a multi-disciplinary and integrated approach, that involves also upstream and downstream stakeholders (although some criticisms on the relation with FIR are present).

An integrated approach can be therefore considered to be a reality in EFSA's risk assessment. The issue remains, though, whether the actions undertaken to support this integrated approach are the most efficient ones, or whether, specifically as regards the availability of a wide range of expertise, there are no other options (like a stronger cooperation with specialised agencies, as suggested by the EP) to reach the same results in terms of integrated approach with fewer efforts to manage resources and cooperate among experts. Difficulties associated with this system might indeed undermine its sustainability.

The analysis of evidences supports the conclusion that EFSA has been able to provide added value also as regards the **support to risk managers**, and specifically the development of tools and procedures.

EFSA has invested in both an improvement of information and communication with risk managers (enhancing the exchange of information, with the consultation on annual and multiannual working plans, with the Advisory Forum Members and the roadmap 2010-2015 with DG SANCO and increasing communication activities on all areas of activity) and in tools to support specifically business continuity (with the business continuity strategy adopted in 2009 and changes in the organization that support more flexibility to manage with risk managers' requests).

[83] This opinion is also supported by one EP, one Cons. and one IO.

As a result, stakeholders do appreciate EFSA capacity to guarantee business continuity to risk managers, even though NRM are not completely satisfied on the capacity of EFSA to consider their national needs (see also par. 3.1.2.2) and NRM, FIR and the EP think that an improved cooperation with NRA and other national scientific institutions might improve the support EFSA provides through a better availability of data and expertise (as emerged also as relates the integrated approach).

No major issues emerge from the analysis of the support provided by EFSA in crisis situations. The mix of available tools and procedures, the 2011 Emergency Manual and the EMRISK Unit settled in 2008, seem to have been effective in this area of support, considering that both the results on the impact indicator on the reaction of EFSA in these situations and the widespread consensus emerging from stakeholders support this conclusion.

3.1.3.4 Evaluation results

EFSA's provision of outputs provides added value, in terms both of use of an integrated approach covering the entire food chain and of development of tools and procedures to support risk managers.

The **integrated approach** of EFSA's opinions is globally recognized by stakeholders and is further sustained through the availability of a wide range of expertise in EFSA's Panels and through improved rules allowing greater flexibility in the multidisciplinary composition of Working Groups.

The support coming from downstream stakeholders (retailers, consumers, etc.) through, for example, the Stakeholder Consultative Platform, further contributes to strengthen the integrated approach.

An issue remains on whether the system put in place is sustainable.

EFSA provides a **continuous support to risk managers** and a recently approved business continuity strategy guarantees the continuity of business in the event of unforeseeable business disruption. The exchange of information with Member States has continuously improved (e.g., with consultations on annual and multiannual working plans with the Advisory Forum Members and inviting risk mangers to share their future priorities). Nonetheless, more cooperation with national risk assessors and other national scientific institutions to dispose of a wider portfolio of expertise should be taken into account.

Various tools and activities are developed by EFSA to support risk managers **in times of crisis situations** (e.g., crisis room, specific task force, meetings and teleconferences, etc.) and globally EFSA's support is appreciated by risk managers.

3.2 Data collection

3.2.1 Introduction to the results for the thematic area of evaluation

The evaluation of EFSA data collection activities is focused on the accomplishment of the tasks described in art. 33 of (EC) Reg. 178/2002[84], on the actions of harmonization and cooperation with all subjects involved in data collection and, ultimately, on the quality and reliability of data collected and made available.

This area of evaluation relates to the following evaluation criteria:

- **Effectiveness**, the main questions being whether *i)* the existing system for cooperation and networking with national bodies provides an appropriate basis to support EFSA's work *ii)* EFSA fulfils its mandate to collect and analyze data relevant for the safety of the food chain *iii)* data collection activities ensure EFSA's ability to respond to requests for advice in times of emerging threats.
- **Scientific quality**, the main question being whether data collected support high quality scientific outputs.

3.2.2 Data collection effectiveness

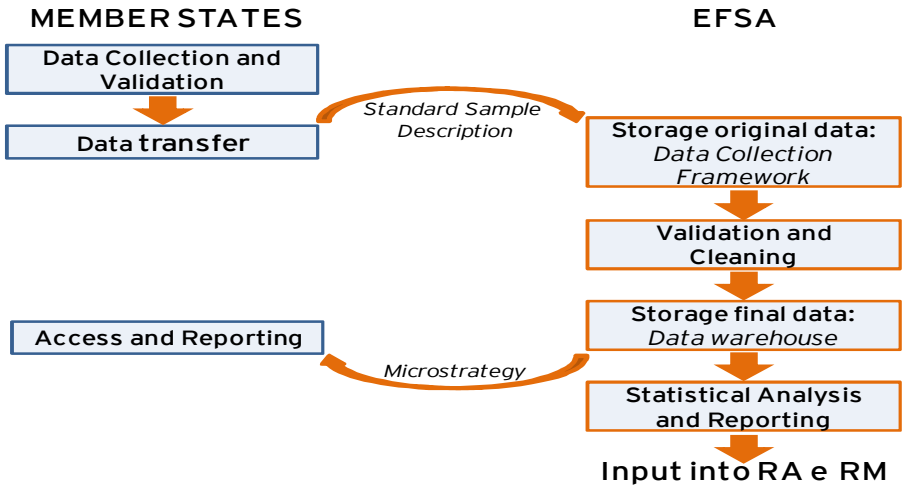
The data collection activity is composed of **several processes of collection, validation, storage and analysis of data, in the four main sectors identified by the Founding Regulation** (zoonoses, chemical contaminants, pesticides residues, food consumption), involving the most relevant data providers (National food, feed, veterinary Institutes, local and regional competent authorities, Industries, competent laboratories, etc.). EFSA, indeed, does not produce data but rather collects them from Member States and companies often signing confidentiality agreements with data providers. Once the collecting activity is completed by Member State Institutions, data are submitted through EFSA's Data Collection Framework (DCF)[85]. Once data have been validated, cleaned and collected in a specific data warehouse by the Authority, they are ready to become the inputs for:

- Risk Assessment processes;
- Annual Reports that aim at providing an overview of the monitoring results and at informing the Commission, the EP and MS about the trends in EU related to the main thematic areas foreseen by the Founding Regulation.

[84] Founding Regulation 178/2002 art. 33 "The Authority shall search for, collect, collate, analyse and summarize relevant scientific and technical data in the field within its mission. Sub 4 (The Authority shall forward to the Member States and the Commission appropriate recommendations which might improve the technical comparability of the data it receives and analyses, in order to facilitate consolidation at Community level), sub 6 (The Authority shall forward the results of its work in the field of data collection to the European Parliament, the Commission and the Member States)".This activity shall involve, in particular, the collection of data relating to:
- food consumption and the exposure of individuals to risks related to the consumption of food;
- incidence and prevalence of biological risks;
- contaminants in food and feed;
- residues.

[85] A web interface accessible by web browsers through which data providers transfer their files.

Figure 8: Data collection and exchange process



(Source: EY elaboration on EFSA Report on Data Collection: Future Directions – Technical Report of EFSA, 2010)

The process described in general terms above, and shown in Figure 8, involves various steps of monitoring, harmonization, quality assurance, reporting and data transfer[86].

The evaluation of the effectiveness of data collection activities starts from factual evidences and presents then the stakeholders' point of view, related to the three main steps of data collection and exchange process:

- Cooperation for data collection;
- Data collection tools and activities;
- Reports on EFSA's data collection activity.

3.2.2.1 Facts & Figures

Cooperation for data collection

The task of working in close cooperation with all organisations operating in the field of data collection, including those from applicant countries, third countries and also international bodies, is assigned to EFSA by its Founding Regulation.

As represented in Figure 8, it is clear that the effectiveness of EFSA's **data collection activity highly relies on the commitment of MS** to provide and share data. Indeed, EFSA intervened, in 2002, in a fragmented context where each MS had a different food safety system and where EFSA had no power to enforce NRM, NRA and other data providers to collect certain data in a certain format. If EFSA needs to cooperate with MS to get data, MS benefit from EFSA's activities given that, starting from local data sources, EFSA combines[87] them into a harmonized European-level dataset that allows risk managers to be informed about the current situation and trends in EU when taking decisions or making policies, and the scientists and researchers to perform the necessary analyses for risk assessments. Indeed, the collection of reliable data is a pre-requisite for informed risk assessment and risk management. Both risk assessors and risk managers need up to date and comparable data across MS on hazards in the food chain and on food consumption.

[86] All these processes and activities are described in EFSA's documents and summarized, in particular, in the Technical Report - Activities, Processes and Quality Assurance Elements on Data Collection Programmes with Member States (March 2011).
[87] Technical report - Activities, Processes and Quality Assurance Elements on Data Collection Programmes with Member States (March 2011).

EFSA cooperates also through the provision of **recommendations** to the MS and the EC on how to improve the technical comparability of the data it receives and analyses[88]. In this regard it is important to notice the increasing trend over the years of recommendations for the harmonization of data collection methodologies presented in the reports issued by EFSA (as illustrated in Table 15), namely those directed to MS: 65 out of 86 reports include recommendations to EC or MS or both for appropriate data collection methodologies.

Table 15: Number of reports on databases, with and without recommendations to MS and EC, per year

RECOMMENDATIONS INCLUDED	2006	2007	2008	2009	2010	2011	TOTAL
Total reports	**3**	**11**	**9**	**19**	**19**	**25**	**86**
Reports with recommendations to MS	1	6	6	6	7	8	34
Reports with recommendations to EC	1	1	3	1	2	1	9
Reports with recommendations to MS and EC	0	0	0	6	7	9	22
Total of reports with recommendations	**2**	**7**	**9**	**13**	**16**	**18**	**65**
Total of reports without recommendations	**1**	**4**	**0**	**6**	**3**	**7**	**21**

(Source: EY elaboration on EFSA's data, 2012)

With the goal of establishing efficient technologies and processes of exchange of information and better data harmonization, the Authority has operated on two different levels:

- **Data entry, transfer and validation**: the "*Guidance on Data Exchange*" prescribes procedures to efficiently transmit and exchange data between MS and EFSA, including specific file formats for data transmission (e.g., XML, Microsoft Excel etc.) and specific data transmission protocols to support electronic data exchange; the "*Guidance on Standard Sample Description for Food and Feed*" provides the harmonized description of data on analytical measurements in food and feed samples[89].
- **Harmonization across different data collection domains**. In this context, EFSA is working on an ontology system as a basis of a computer classification system. The goal that the Authority would like to achieve in the future with this system is to provide users (internal and external) with web accessible systems to create, use, maintain and share the terminologies[90].

EFSA has done many efforts in recent years to harmonize the activities of data collection in the areas identified by the Founding Regulation. In this context, **Food consumption** is the area where the Authority has mainly worked on, implementing activities like[91] :

- creation of several **Data Collection experts Groups**: "Expert Group on food consumption data" in 2007 (where MS representatives are included), "Food Consumption and Exposure Working Group" in 2008, "Working Group for Food Classification" in 2009;
- publications of **Guidelines** to harmonize food consumption data collection;
- **The EU menu**: a project aiming at harmonizing data collection on food consumption across Europe (ongoing pilot studies started in 2011). Coordinated by EFSA, and in close cooperation with MS, this project will allow the collection of comparable food consumption data across the EU and will assist policy makers in assessing the

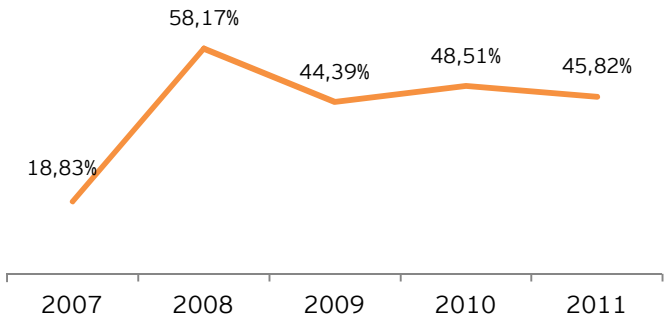
[88] "EFSA Report on Data Collection: Future Directions – technical report of EFSA", 2010.
[89] "Standard sample description for food and feed – Guidance of EFSA", 2010 – "Guidance on Data Exchange – Guidance of EFSA", 2010.
[90] "EFSA Report on Data Collection: Future Directions – Technical Report of EFSA", 2010.
[91] "EFSA Report on Data Collection: Future Directions – Technical Report of EFSA", 2010.

nutritional status of population groups, setting targets regarding healthy diets and monitoring progress over time.

Even in other areas (biological risks, residues and contaminants) the Authority has implemented a series of activities to foster the harmonization of data, like: the publication of guidance documents, guidelines and harmonized specifications for monitoring and reporting (e.g., for antimicrobial resistance data, E-coli, Salmonella, etc.), creation of Working Groups (e.g., Expert Group for Chemical Occurrence Data) and ad-hoc meetings (e.g., Future Data Collection of Pesticide Monitoring Data)[92].

To reinforce the link with MS, EFSA has also implemented **new mechanisms of cooperation** with specialized organizations of MS, such as grants and procurements (Chart 3), calls for data on emerging and innovative issues and agreements on access to databases.

Chart 3: Percentage of data collection activities entrusted to competent organizations out of the total EFSA data collection activity



(Source: EY elaboration on EFSA's data, 2012)

With regard to **international cooperation on data collection**, as underlined by EFSA's Science Strategy[93], although the Authority already cooperates with third countries and international food safety bodies, there is a need to strengthen data sharing and data access agreements with other key national and European agencies (e.g., EMA, ECDC) and IOs (e.g., WHO, FAO, OECD).

Another critical aspect to work on, that emerges from the documents published on the future strategy of EFSA in the field of data collection, concerns **data ownership** and **how data provided to the Authority by the MS are used and managed**. In this field much remains to be done and, for this reason, EFSA will continue to increase the level of transparency on the use of data, and in parallel provide MS with a wider access to data as well as with analysis charts and reports on data provided[94].

[92] See note 90.
[93] "Science Strategy 2012-2016", EFSA, 2011.
[94] See note 90 and 93.

TRANSPARENT USE OF DATA

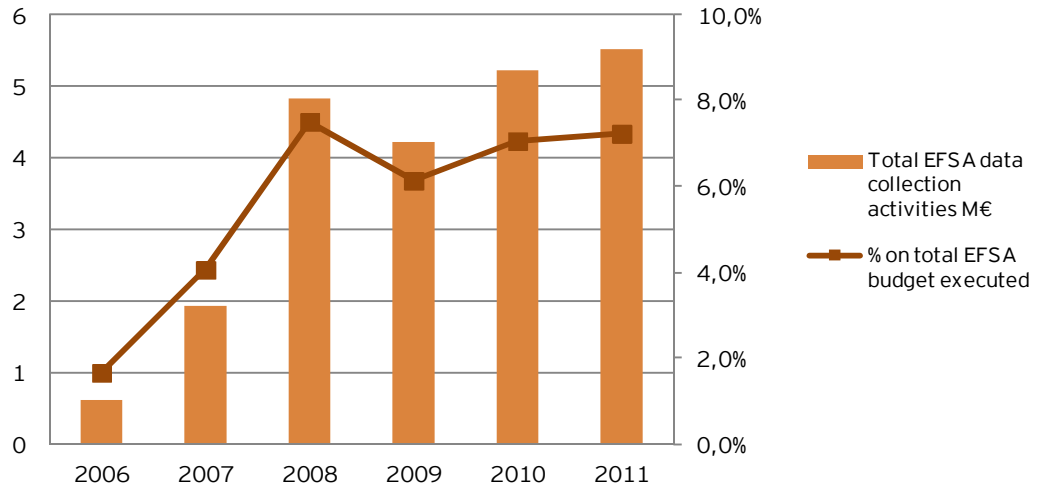
In all benchmarked organizations, external stakeholders have questioned the transparent use of data.

- **FSA** has been criticized on organic vs. non organic data analyses, that led to the appointment of an external scientific committee to clarify the situation. The implementation of a total open process reduce the risks of criticisms.
- **VWA** has established a specific office to address the questions raised by external stakeholders. VWA is intending to proceed in a total open process (like FSA) and publish inspection data.
- At **ECHA**, data are mainly coming from industries: they are often confidential with specific economic interests or intellectual property on it. The issue of transparency is a major challenge and the considerations are made dossier by dossier, paragraph by paragraph. Not all parts of a dossier are published if confidential data are used. There is a constant balancing between the need for transparency and the protection of economic interests. It is a crucial issue in deliberation process.

Data collection tools and activities

In order to sustain the data collection process, EFSA has progressively increased its commitment, **increasing resources allocated to these activities** (Chart 4). In 2011, EFSA has allocated 7,23% of the total budget (€ mil. 5,5) for the data collection activities, a percentage 1,8 times higher than in 2007 (and more than 4,3 times compared to 2006).

Chart 4: Total EFSA data collection activities/total budget executed per year



(Source: EY elaboration on EFSA's data, 2012)[95]

A significant number of actions have been undertaken over the years to further enhance EFSA's data collection capacity. Among the most relevant: the creation of **specific databases** and of an **integrated IT system** for data collection and the establishment (2011) of three **specific units** (i.e., DCM, BIOMO and SAS) to collect useful data and inputs for all scientific opinions centralizing the activities of data collection previously implemented separately by each Panel/Unit.

[95] Data collection activities include: DCM/BIOMO/SAS total basic average salary plus DCM/BIOMO/SAS payments for Grants and Procurements plus IT development and maintenance costs for data collection.

In the field of data storage, EFSA has already defined the IT requirements for the creation of a single Data Warehouse with standardised transfer and access for the different types of data it receives. In relation to this project the Authority has created an **IT Working Group on Data Warehousing and Web Reporting** with the goal to explore the priorities for the deployment of (web) reporting technologies that would be most beneficial to MS competent authorities and other EU stakeholders[96].

EFSA **data collection tools cover all four major thematic areas** identified by the Founding Regulation. In Table 16 it is possible to appreciate the main results (activities, tools and databases) achieved by EFSA[97] in data collection over time[98].

Among these, it is important to underline what EFSA has done regarding the **food consumption** data collection activity: the Authority has implemented "*EFSA's Comprehensive European Food Consumption Database*" (completed and updated from 2010), a source of information on food consumption in the European Union, containing the most up to date detailed data for a conspicuous number of EU countries. On EFSA's website, the general public can directly access statistics related to the **Concise Database**, a reduced version of the Comprehensive Database.

EFSA's data collection activity and the availability of up-to-date data are key to provide a rapid response during food and feed crisis. For this purpose, EFSA has developed procedures for responding to urgent requests[99] (see also par. 3.1 "Provision of scientific outputs and technical support"). For example **during the E. Coli crisis,** EFSA was asked by the EC to support Member States and coordinate activities to investigate the source of the outbreaks in France and Germany in order to allow risk managers to take the appropriate measures. Data concerning the trace back and trace forward were exchanged through the RASFF[100], allowing MS and European institutions to receive up to date information[101]. According to the Annual report on EFSA's food and feed safety crisis preparedness and response 2011[102], data exchange was fairly rapid and access to all data was assured to all MS, thanks to the day-to-day interaction and the networking culture established by EFSA with Member States and the Commission. This crisis pointed out the importance of networking to put in place a successful exchange of information.

EFSA'S DATA COLLECTION PROCEDURES/TOOLS IN CRISIS SITUATIONS

- **EFSA's data gathering tasks**: Data availability at short notice has been greatly enhanced through the Comprehensive Food Consumption Database, chemical occurrence data, and trends and sources of zoonoses and zoonotic agents and food borne outbreaks.
- **EFSA's expertise:** it is available at short notice through EFSA's staff and the experts of EFSA's Panels. Further support is available through the networks developed by EFSA, both in specific areas, but also at a more general level through the AF and the Focal Points. To supplement this, EFSA maintains a list of experts volunteering their assistance to EFSA, the Expert Database. EFSA has also developed contacts with food chain stakeholders through its SCP, and has regular collaboration with IOs. (see also par. 3.1.3.1)

Source: EY elaboration on" EFSA's Food and Feed Safety Crisis Preparedness and Response", 2012

[96] "EFSA Report on Data Collection: Future Directions – Technical Report of EFSA", 2010.
[97] Technical report of EFSA - Activities, Processes and Quality Assurance Elements on Data Collection Programmes with Member States.
[98] Annual Activity Report (2007 – 2011).
[99] "EFSA's Food and Feed Safety Crisis Preparedness and Response", 2012
[100] The Rapid Alert System for Food and Feed (RASFF) is a tool that aims to provide to food and feed control authorities an effective exchange of information about measures taken responding to serious risks (EC website).
[101] E. coli (STEC) O104:H4 2011 outbreaks in Europe, EFSA Journal 2011.
[102] Annual report on EFSA's food and feed safety crisis preparedness and response 2011, p. 14.

Table 16: Data collection activities and tools implemented by EFSA per thematic area, 2007-2011

THEMATIC AREAS	2007	2008	2009	2010	2011
FOOD CONSUMPTION	Creation of the "Expert Group on Food Consumption Data" (EGFCD) The EGFCD co-operated in the establishment of the "Concise European Food Consumption Database".	DATEX Unit finalized the Concise European Food Consumption database. A Guidance Document for the use of the Concise European Food Consumption Database in Exposure Assessment was published. A Working Group was formed to further harmonize collection of food consumption information in future studies. A call for proposals focused on children was launched.	A Comprehensive food consumption Database has been populated with information at the most detailed level available in each collaborating Member State for children and adults. Guidelines to further harmonize food consumption data collection were issued during the year.	The EFSA Comprehensive European Food Consumption Database was completed and validated.	The Food Classification and Description System for exposure assessment was implemented. The EU Menu project is progressing with ongoing pilot studies for children, adolescents, adult and elderly. EFSA published a report giving an overview of the Comprehensive Database and providing guidance for its use to assess dietary exposure. Summary statistics from the database have been made available to the public on the EFSA web site.
ZOONOSES	A revised web reporting system and reporting manual were launched and the national datasets were received by the end of May.	A revised reporting system for food borne outbreaks was applied in 2008 Guidelines were issued for the reporting of antimicrobial resistance in commensal bacteria from animals and food.	A pilot project aimed to test a web based reporting system and a data warehouse for zoonoses has been carried out successfully.	A new web application for data reporting was successfully deployed and three reporting manuals and an internal report were provided to Member States specifying the agreed amendments to the application. A plan to modernise the automatic data transfer was agreed with Member States and an internal report on a survey on the possible introduction of the XML format was issued.	
CHEMICAL		Expert Group for Chemical		Guidance on Standard	Continued data collections,

THEMATIC AREAS	2007	2008	2009	2010	2011
CONTAMINANTS		Occurrence Data was established A Working Group on Left-censored data was established.		Sample Description and the Guidance on Data Exchange were published.	with periodical reporting, started for many groups of contaminants.
PESTICIDES		PRAPeR organised a meeting on Future Data Collection of Pesticide Monitoring Data with all Member States.	A pilot project was launched to test the suitability of the SSD 87 data model with real pesticide monitoring data.	All the 29 reporting countries were able to implement the SSD.	
GENERAL	IT Working Group met to discuss the state of the art of the project "Data Collection Framework"[103]. EFSA has produced a technical architecture, a process model for launching data collection campaigns and a prototype for ad-hoc Data Collection.		A draft guidance document on how to best handle left-censored data was developed by a Working Group coordinated by the DATEX unit. A database on bioactive compounds from plants was delivered through an outsourced project.	Systems for the routine monitoring of data submitted to the Rapid Alert System for Food and Feed and the collection and analysis of import data for the identification of emerging risks were introduced.	Initiatives for revision and improvement of the Standard Sample Description (SSD) were launched.

(Source: EY elaboration on secondary sources)[104]

[103] Data Collection Framework: a set of standards and technologies allowing scientists to quickly compose reliable and cost-effective data collection applications with minimal assistance from the IT Unit. DCF was used to generate a first version of data collection applications with a simple scheme.
[104] "EFSA Report on Data Collection: Future Directions – Technical Report of EFSA", 2010; Annual Activity Report 2007 – 2011; EFSA's web site.

Reports on EFSA's data collection activity

EFSA issues a variety of reports on data collection activities, some of which are published annually, while others are written on ad hoc topics (e.g., chemical contaminants and microorganisms[105]).

From 2006 to 2011, an increasing number of reports on data collection activities have been published by EFSA passing from 3 in 2006 to 25 in 2011 for a total amount of 86 (refer to Table 15 for further details).

As already detailed in Table 16, EFSA has produced thematic reports for all the thematic areas identified by the Founding Regulation. More specifically, with regard to **zoonoses**, **antimicrobial resistance** and **food-borne outbreaks**, EFSA publishes, in collaboration with the European Centre for Disease Prevention and Control (ECDC), annual Community Summary Reports based on data gathered; in addition EFSA issues specific reports that include analyses of different sets of data received, mainly for Salmonella.

Regarding **contaminants**, since 2009, data collected are used by the Authority to release an Annual Report on veterinary medicinal residues in food from animals. In addition, data gathered support risk managers in setting legislative limits and monitoring food chain levels of persistent organic pollutants.

Finally, with regard to **pesticides,** since 2007, data collected during the year are used to produce the Annual Report on Pesticide Residues[106].

3.2.2.2 Stakeholders' point of view

Cooperation for data collection

EFSA's system of cooperation for data collection is positively evaluated. The efforts made by EFSA in this field **are recognized** by most stakeholders (above all EC, NRM, NRA in interviews and 84,6% of respondents giving a rate equal or higher than 3 out of 4 in the survey – *Q5.1*). More specifically, NRA have expressed great satisfaction on what EFSA has done until now on the collection of scientific data and information, that they consider as a key priority for the EU citizens (3,35 average rate).

The adequacy of EFSA's **system of cooperation for the exchange of data is overall positive** (78% of respondents rated 3 or more out of 4 – *Q5.1*), although lower than for data collection.

Still, **EFSA data collection harmonization is one of the biggest challenges** (NRM, NRA, Cons.)[107] being the cooperation with MS more important than ever. The main priorities of stakeholders, as they stated, are to improve and make more objective and fast the data collection processes in Europe. All NRA and NRM involved in the analysis are used to share data with EFSA and are willing to participate to as many calls as they can, but **some obstacles still limit their cooperation in data collection:**

- **Difficult interface between EFSA IT Data Collection Framework and national IT systems for data collection** (NRM, NRA). As stated by some stakeholders and previously illustrated, EFSA requires that National Authorities (or other data providers) send their data according to detailed requirements and formats. For national entities, in particular for the smallest ones, fulfilling these requirements is hard, because their IT systems are often not easily compatible with EFSA's ones. As they underlined, the format of national data is different from the format required by EFSA; moreover, the standard description table used by the Authority changes

[105] "EFSA Report on Data Collection: Future Directions – Technical Report of EFSA", 2010.
[106] "EFSA Report on Data Collection: Future Directions – Technical Report of EFSA", 2010; EFSA's web site.
[107] This opinion is also shared by a member of MB.

frequently and it is difficult for data providers to follow the requirements.

- **Lack of national resources to collect data according to EFSA's requirements and methodologies** (NRM, NRA). Despite the wide recognition of the usefulness of having a common format of data, there are many complaints on the specific requirements requested by EFSA to MS, requiring efforts and financial resources that often NRA and NRM do not have. In addition EFSA, according to some stakeholders (NRA, FIR), seems to ask for too many data from MS, even beyond the minimum requirements of law.
- **Lack of clarity on the ownership of data and on the final level of accessibility of data once in EFSA databases.** According to some stakeholders (NRA, FIR, IOs)[108], the agreements signed by EFSA with data providers limit the Authority's ability to share and treat data; EFSA has not made it clear enough the level of accessibility of stakeholders and this aspect limits Member States' willingness to share data.
- In addition, **a lack of transparency on the use of data sent to EFSA** has also been pointed out (NRA, FIR, Cons.). No feedback is given to data providers once data are submitted (NRA, FIR) and no sufficient indications on the sources of data are provided in the published scientific opinions (Cons.). (See also par. 3.1 "Provision of Scientific outputs" and par. 3.8 "Openness and Transparency").

Most stakeholders (59% - Q5.2) are ready to support EFSA[109] in improving data collection, identifying specific areas of improvement/contribution as listed in the Table 17.

Table 17: Activities proposed to support EFSA's data collection

SUPPORT ACTIVITIES *Q5.2*	- National data as part of the EREN[110]-networking. - Building up an operative System for Data Transfer. - Defining the processes between EFSA and MS. - Harmonisation of Data submission. - A database of collected scientific information. - Increase the number of Working Groups and extend the network of opinion and feedback's to entire world. - Sending data when there is a call and exchange of scientific information and networking. - Double checking some data used. - Data quality assessment integration of lab data. (LIMBS) prioritisation of data exchange regarding actual MS problems. - More comprehensive and coherent program on scientific cooperation for procurement/grants at the European level.	NRA
	- Streamlining national systems in order to fit into the EFSA systems.	NRM

(Source: EY survey)

Despite EFSA already cooperates at an international level, as previously pointed out, the data collection activity is perceived as mainly limited to Europe and **a lack of an international harmonized approach** is pointed out, by few stakeholders (Scient. Org., FIR)[111], as a limit to international cooperation as well as an obstacle to improvements in risk assessment. According to some IOs, it would be desirable to have a closer relationship between the Authority and the IOs in order to encourage a more constructive and integrated sharing of data.

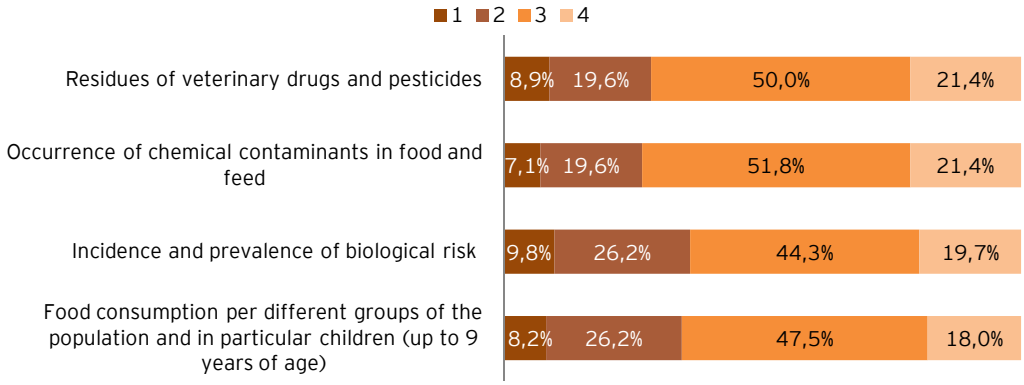
[108] This opinion is also supported by one Scient. Org.
[109] Respondents to this question belong to only 5 categories of stakeholders (RM, RA, FIR/A, Cons., NGOs).
[110] Emerging Risks Exchange Network
[111] This evidence is also supported by one NRM.

Data collection tools and activities

Globally, EFSA is perceived as effective in data collection and the activities it implemented in this field, as described before, **are widely appreciated**. All stakeholders have highlighted the importance of sharing data for a better risk assessment system, better policies and a safer food/feed chain. 68,5% of respondents[112] have rated positively the level of **accessibility** of the EFSA's databases (rate 3 or more out of 4) and 61,5%[113] are satisfied with the **availability** of data in those databases (giving on average a rate equal or higher than 3 out of 4 - *Q4.1 – Q4.2*). The results achieved and planned for the future **are globally appreciated.** Nonetheless, the high number of stakeholders who have not expressed any rate (approximately 30% of NA answers *Q4.1-Q4.2*, and more specifically 30% among NRM and 52% among EC) reveals the presence of some uncertainties and the existence of areas of improvement, that have been confirmed with interviews.

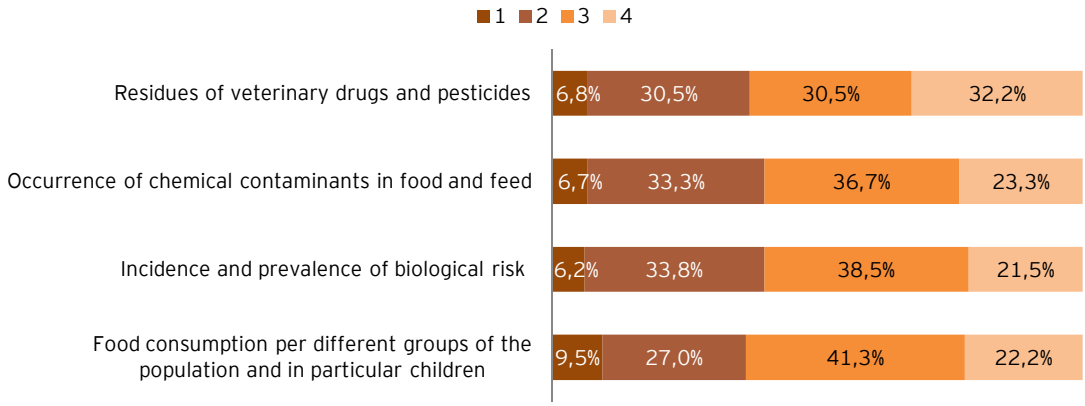
Availability of data and access to databases related to the four thematic areas identified by the Founding Regulation are globally satisfying (Chart 5, Chart 6), but with a high percentage of NA answers (around 30%), confirming again the overall controversial perception illustrated before.

Chart 5: Level of satisfaction on the accessibility to databases related to the 4 thematic areas identified by the Funding Regulation



(Source: EY survey)

Chart 6: Level of satisfaction on the availability of data related to the 4 thematic areas identified by the Funding Regulation



(Source: EY survey)

[112] If NA are included the percentage drops to 45,97%.
[113] If NA are included the percentage drops to 43,67%.

The activity of **data collection in food consumption is highly appreciated**, as shown by the highest level of satisfaction on the availability of data (Chart 6), and by some stakeholders' statements (FIR and one IOs), pointing at this field as the area in which EFSA has achieved the best results in the last years as well as an international recognition. The availability of data is only one aspect contributing to the positive evaluation of this thematic area; indeed, according to the above mentioned stakeholders, EFSA is doing well also in the harmonization of MS collection and reporting activities on food consumption data.

Analyzing more specifically the perceived availability and accessibility of data, despite the good rate on **accessibility** coming from the survey, some interviewees pointed out that the existent filters (defined to differentiate the access according to roles) and the limited effectiveness of the query function limit the possibility to consult all the data (NRM, FIR, Cons., IOs), determining a **confused perception on the actual availability of data within EFSA's databases.**

According to the majority of stakeholder (54,7%[114] - *Q4.3*) there are significant **data gaps** and 39,1% of them have not answered to the question, (above all FIR, Cons., NRA). There is not always visibility on the data actually available and this leads one to consider EFSA's databases as being incomplete (FIR, NRA)[115]. Stakeholders in the survey (*Q4.3*) suggested the thematic areas where there are main data gaps (see Table 18[116]).

Table 18: Main gaps in data availability

THEMATIC AREAS	STAKEHOLDERS
Chemical and microbiological contaminants (also unregulated) (NRA, Scient. Org.); Food consumption database (FIR, NRA, NRM); Veterinary drugs residues (NRA); Certain specific food groups (SC); Animal health (NRA, SC); Nanotechnology (NRA); Zoonotic agents (NRA); Food additives (NRA).	FIR; NRA; SC; Scient. Org.; NRM

(Source: EY survey)

Some **suggestions** have been proposed by few respondents to the survey (*Q4.3*)[117] in order to solve the questioned lack of data, like:

- more detailed data or consumption patterns to make quantitative assessments (EC);
- consideration of individual diet survey data (FIR);
- link to human health data – ECDC (NRA);
- improvement of EFSA's consumption database to enhance the accuracy, the updating and the harmonization of data included (NRA);
- availability of data on sensitivity, consumption and exposures for specific populations (e.g., pregnant women, children under 6, elderly people…) (NRA);
- less relevance to those adverse effects that are not justified by a real biological risk (FIR).

As stated by some NRA, EFSA's data collection activities support its **ability to respond to requests for advice, even in crisis periods**. As illustrated in par. 3.1 "Provision of scientific outputs and technical support", EFSA's opinions during emergencies have been globally considered useful to NRA and NRM, receiving a strong consensus. According to few NRA,

[114] If NA are included the percentage drops to 33,3%.
[115] To point out that 12 out of 17 NRA respondents consider that there are data gaps.
[116] Acronyms of stakeholders in brackets mainly refer to one respondent.
[117] Each statement has been suggested by one stakeholders.

EFSA quickly collects data and produces good scientific opinions/reports (e.g., E. Coli, Schmallenberg) considering the limited amount of time and the limited availability of data at disposal. In crisis situations, more than in peace times, the cooperation with MS is and will continue to be necessary in order to deliver high quality outputs and respond adequately to requests for advice.

Reports on EFSA's data collection activity

The **quality of EFSA reports on data collection is very high** (NRM, NRA, Scient. Org., 92% of respondents giving a 3-4 out of 4 rate - *Q4.4*). Reports contain a good level of aggregation of all data collected and allow Member States to have a useful overview on the trends in EU related to the main thematic areas foreseen by the Founding Regulation (as listed in Table 16 and in par. 3.2.3.1. point "Reports on EFSA's data collection activity"). It is meaningful to underline the great satisfaction of the NRM, all of which voted 3 or 4 out of 4.

Besides quality, the reports issued by EFSA are also recognized for their contribution to the harmonization of data collection methodologies. As already seen in par. 3.2.3.1. under the point "Cooperation for data collection" (Table 15), the majority of the reports contain recommendations to MS and EC on data collection activities. These recommendations are **highly appreciated** for their **clarity** by all respondents (NRM, NRA, EC), 61% of whom have expressed maximum satisfaction (rate 4 out of 4 - *Q4.5*).

3.2.2.3 Analysis of evidences

EFSA's data collection activities has been analyzed taking into consideration the following dimensions: the cooperation, EFSA's tools and activities and reports on EFSA's data collection activities. The first level of analysis performed relates to the compliance of the above mentioned activities with the Founding Regulation requirements, and the second to their effectiveness for direct clients (NRM, NRA) and for stakeholders in general.

Given that EFSA does not produce data but rather collects them from stakeholders in MS, **cooperation with MS** is critical in evaluating the effectiveness of EFSA's data collection activities.

As emerged from the desk analysis and from stakeholders, much has been done by EFSA to foster cooperation to collect relevant data to support the Authority in the provision of high quality outputs and in meeting increasingly complex data collection needs (e.g., increasing trend of applications on new products). Indeed the Authority has activated **incentive mechanisms for a coordinated data collection activity involving both MS** (e.g., involvement of MS representatives in thematic experts groups, co-implementation of thematic projects like the EU Menu) and competent organizations (e.g., grants and procurements, calls for data) and the international bodies (even if there is room for improvement in this area, provided that IOs and Scient. Org perceive the data collection activity as mainly limited to Europe and lacking of an international harmonized approach). All these efforts are globally recognized by stakeholders, and especially by NRA, that consider the current system for cooperation as adequate for the exchange and the collection of data.

Nonetheless those mechanisms are just one aspect of EFSA's cooperation for data collection.

Indeed, EFSA cooperates with MS and competent organizations also through the definition of procedures for the **harmonization** of data collection methodologies. As emerged from the desk analysis, in compliance with the specific requirement of the Founding Regulation (art. 4), the Authority has provided over the years an increased number of recommendations to the EC and MS to improve the technical comparability of the data it receives and analyses in order to facilitate consolidation at Community level. The high appreciation of stakeholders for the clarity of these recommendations, together with the development of additional guidance documents defining specific data transmission protocols to support data exchange and the

ongoing creation of an ontology system as a basis for an harmonized computer classification system, let us conclude that the role of EFSA in the harmonization of data collection methodologies is quite relevant.

Though some evidences show that the results of these activities are not completely satisfying: the EFSA IT interface (Data Collection Framework) seems indeed not to be compatible with national IT systems for data collection and not all the data providers are able to respect EFSA's format requirements, in so far they are different from national formats and require a high amount of resources (human and financial). The commitment of Member States seems to be necessary also for an effective harmonization of data collection formats and systems. Despite the difficulties previously described, their involvement will allow both risk managers to be informed about the current situation and trends in EU for the policy making process, and the scientists and researchers to perform the necessary analyses for the conduct of risk assessments.

Provided that EFSA is cooperating and supporting MS in the harmonization of data collection methodologies, the **capacity of EFSA to collect data** seems adequate as the Authority has implemented, coherently with the Founding Regulation requirements, specific tools and activities for all the four main thematic areas, and stakeholders do think that data collected are adequate, representing a good base for the country specific outputs /studies. This is particularly true for Food Consumption. Indeed, as a matter of fact, this is the area where EFSA has invested the most in the collection of data (e.g., creation of the comprehensive and the concise European Food Consumption Database) as well as in the harmonization of data collection methodologies (e.g., EU Menu project, publication of guidance documents). Due to the increasing number of emerging issues that can potentially have an impact on the food/feed safety chain (see par 2.2.), EFSA is progressively widening its data collection activities including additional thematic areas (e.g., GMOs) not explicitly foreseen in the Founding Regulation in order to adequately support risk managers' information needs. A formal recognition of EFSA's role in the risk monitoring of these new issues could positively support the Authority to adequately face future challenges.

In general terms EFSA's data collection activity seems quite effective in providing access to databases and in creating an increasing number of **reports** that allow NRM to have a useful overview on the trends in EU related to the main thematic areas foreseen by the Founding Regulation thus supporting their decision-making process. This is true even in **crisis situations**, where data collection activities have supported the capacity of the Authority to respond to urgent requests for advice. Indeed, EFSA has shown (e.g., supporting activities for data sharing with MS during the E.Coli case) to be able to collect data in a short time and to use them effectively in providing high quality and widely appreciated scientific outputs (as already pointed out in par. 3.1 "Provision of scientific outputs").

EFSA's data collection is effective and is improving in its effectiveness (even though data gaps are signaled), thanks to different actions that EFSA has undertaken in the last years and it is still developing:

- The creation of three organizational units dedicated to collect useful data and inputs for all scientific opinions together with the creation of an integrated IT system and the future development of a single Data Warehouse, are streamlining the activity of data collection previously conducted separately by different Units/Panels;
- The creation of an IT working group on Data Warehousing and Web Reporting will further contribute to the effectiveness of data collection activities developing reporting technologies suitable to MS competent authorities and other EU stakeholders' needs.

While, as said before, data aggregated by EFSA in specific reports are widely appreciated, the direct use of EFSA's data by stakeholders is less effective. Indeed, the presence of filters and

the weak query function (e.g., access limits linked to the ownership of data and to the membership of stakeholders) that limit the possibility to consult data, the limited user-friendliness of the databases (as also experienced by the evaluation team) and the high number of NRM and EC that do not express any rate on the level of accessibility and availability of data, show a lack of transparency and awareness of data included in EFSA's databases. This, together with the limited transparency on the use of data pointed out in the par. 3.1 "Provision of scientific outputs" where we have highlighted that no feedback is given once data are submitted by data providers and that more clarity is needed in the identification of the specific sources of data in scientific outputs, draws attention to the **level of transparency in data collection activities** as a priority area of improvement. Similarly to other EU agencies like ECHA and other national agencies like FSA and VWA the issue of transparency is a major issue to be faced. (See also par. 3.8 "Openness and Transparency" for a more comprehensive analysis).

The analysis performed shows that globally EFSA has fulfilled its mandate to collect, collate, analyze and summarize relevant scientific and technical data for the safety of the food chain as foreseen in the Founding Regulation.

The effectiveness of EFSA's data collection activities is good as globally stakeholders recognize their usefulness and appreciate efforts. Though it could be further improved through an enhanced collaboration.

3.2.2.4 Evaluation results

EFSA's data collection activity is compliant with the requirements set in the Founding Regulation and is effective and adequate to support the Authority in responding to requests for advice even in crisis situations.

EFSA's system of cooperation for data collection is positively evaluated by most stakeholders, recognizing the efforts made by EFSA in this field and thinking that data collected are adequate for country specific studies and to support decision-making processes. A widespread awareness of the strategic importance of this activity clearly emerges from the several activities implemented by the Authority over the years (e.g., increased number of reports with methodology recommendations, use of new mechanisms of cooperation – grants and procurements, calls for data – harmonization activities).

Nonetheless, the complex implementation and the limited availability of resources at national and EFSA level make the cooperation with MS and the harmonization in data collection methodologies one of the biggest challenges.

In this regard, the main areas of improvement are linked to:

- *IT interface:* despite the efforts made by EFSA in this field (e.g., publication of guidance on Data Exchange and Standard Sample Description, use of ontology system to harmonize different data collection domains), EFSA IT Data Collection Framework is not easily compatible with national IT systems for data collection and national format requirements are different from EFSA's ones; according to some stakeholders it is difficult and requires a high amount of resources for data providers to follow the expected requirements.
- *Transparency of the process*: no feedback is given to data providers once data are submitted to EFSA and the final outputs do not always contain enough information on how data have been used. In addition, a lack of clarity on the ownership and on the final level of accessibility of data limits MS willingness to share data. Stakeholders' perception is confirmed also by the Authority, who has considered this aspect as one of most critical ones on which work on in the future.

Beyond the European borders, EFSA's data collection activity is limited by the lack of an international harmonized approach, confirming the need, already pointed out in EFSA's Science Strategy, to strengthen data sharing and data access agreements with other key national, European agencies (e.g., EMA, ECDC) and IOs (e.g., WHO, FAO, OECD).

Data collection is properly carried out by EFSA. Data are globally perceived by the majority of stakeholders as accessible and available in the four thematic areas identified by the Founding Regulation, and mainly in Food Consumption, where indeed a significant number of actions have been undertaken by the Authority over the years (see below). Due to the increasing number of emerging issues that can potentially have an impact on the food/feed safety chain (see par. 2.2) EFSA has de facto widened data collection activities including additional thematic areas. This situation should however be adequately regulated to be sustainable.

The general effectiveness of accessibility and availability of data is mainly due to:

- The increasing trend of resources allocated by EFSA (in 2011 more than 4,3 times compared to 2006);
- The implementation of a portfolio of initiatives to rationalize EFSA's expertise (e.g., creation of specific databases, development of an integrated IT system, establishment of three specific units – DCM, BIOMO, SAS – to collect useful data and inputs for all scientific opinions, creation of an IT Working Group on Data Warehousing and Web Reporting, etc.);

Nonetheless, the survey reveals the presence of some uncertainties among stakeholders, pointing out that the level of accessibility to databases could be further improved. Too many filters, indeed, limit the consultation of all data, this together with the weak query function and the limited user friendliness of databases distort the stakeholders' perception on data availability.

EFSA issues a variety of report on data collection activities (e.g., Annual Report on veterinary medicinal residues in food from animals, Annual Report on Pesticide Residues, others specific technical reports, etc.). **The quality of these reports** on data collection **is very high**. Reports contain a good level of aggregation of all data collected, allow Member States to have a useful overview on the trends in EU related to the main thematic areas foreseen by the Founding Regulation and provide clear recommendations for appropriate data collection methodologies.

In crisis situations, despite the limited amount of time and data at disposal, EFSA's data collection activities support the capacity of the Authority to respond to urgent requests for advice, as EFSA has shown to be able to collect data in a short time and to use them effectively in providing specific outputs (e.g., supporting activities for data sharing with MS during E-coli crisis).

3.2.3 Scientific quality of data

3.2.3.1 Facts & Figures

As previously detailed, data are collected mainly in relation to the four main thematic areas foreseen by the Founding Regulation (food consumption, biological risk, contaminants in food and feed and residues), that represent the core fields of activity of EFSA. Over the years, coherently with the evolution of food safety needs, EFSA has identified additional thematic areas to answer to new and emerging data collection needs, like Salmonella, E-coli, PAH[118].

In this changing context, as described in the introduction to this paragraph, EFSA has implemented a **process for data collection, validation, transfer and storage** by which data

[118] "EFSA Report on Data Collection: Future Directions – Technical Report of EFSA", 2010.

are transferred from the data provider to the Authority and subsequently cleaned and validated: data are submitted to EFSA through the **Data Collection Framework system (DCF)**, that controls for the structure of the database and for the compliance with the controlled terminology; a further check is also performed afterwards in **SAS**[119] using ad hoc procedures.

The issue of the quality of data collected and used by EFSA for its outputs has always been crucial. In order to obtain data of good quality it is important that data collection is planned over the medium and longer term; indeed all the main EFSA's planning documents identify the data quality check as fundamental:

- the Strategic Plan 2009-2013 identified the long-term need for EFSA to have access to high-quality scientific data;
- the Science Strategy 2012-2016 considers that a regular review of data collection activities in terms of representativeness, accuracy and compatibility to sustain the quality of the data (e.g., in data collection for human exposure assessment) is necessary.

In several instances EFSA has been tasked by the EC to establish, in cooperation with the competent MS institutions, a **study protocol**[120] which is then implemented consistently across the EU. Data collection based on such pre-defined uniform methodology provides EFSA with **high-quality data** that could be easily analyzed and used for its reports[121].

HETEROGENEOUS QUALITY OF DATA

Among the benchmarked organizations, VWA experienced difficulties in the quality of data, notably as regards consumption data. They are working on this issue, through the appointment of an independent institute in charge of controlling VWA data. ECHA mainly collect data from industries without encountering difficulties in the quality.

3.2.3.2 Stakeholders' point of view

The majority of stakeholders have confidence in the quality and reliability of EFSA's data (respondents to the questionnaire have expressed a rate equal or greater than 3 out of 4 in 87% of cases – *Q6.1* and 90% - *Q6.2*). According to them, t**he quality of data is satisfying**; EFSA is doing a good job and its data usually provide a good overview of the leading topics/issues that the data are collected for. In addition, thanks to EFSA's quality management system, the data represent a good base to be used for the country-specific outputs/studies (NRA)[122].

Nonetheless, the **quality of data is also questioned** by some stakeholders (NRM, NRA, NGOs)[123] recognizing that it strongly depends on the initial data quality (only 25%[124] of data providers clearly stated to have a data quality system in place - *Q6.3*). The main issue of criticism is the limited quality of data collected by the national data providers **and then sent to EFSA, and in particular as regards data coming from smaller countries** that usually do not have a Data Quality System to validate data sent to EFSA.

The reliability of industry analysis when the Authority deals with application dossiers is questioned by NGOs, that suggest developing EFSA's own capacity to perform its analysis and reduce the impact of methodologies that they consider biased in favour of industry interests,

[119] Statistical Analysis System.
[120] A methodology for collecting data of several nature from different MS.
[121] "EFSA Report on Data Collection: Future Directions – Technical Report of EFSA", 2010.
[122] This opinion is also supported by one FIR and one Scient. Org.
[123] This opinion is also supported by one FIR.
[124] Percentage raises to 35,8% without considering NA answers.

at the expense of public health (e.g,, guidance documents on the new pesticide regulation and on GMO risk assessment)[125].

3.2.3.3 Analysis of evidences

The increasing importance given by EFSA to the quality of data, as demonstrated by its planning documents, and the multiple checks performed on incoming data (e.g.,, DCF, SAS) are effective in making stakeholders globally confident in the quality and reliability of EFSA data. Evidences show that EFSA usually provides data of good quality and has progressively improved the process of validation and cleaning of initial data provided by MS.

Nonetheless, some concerns emerge as regards the quality data provided by MS. Although no clear evidence is available on their quality, some comments coming from stakeholders involved in the evaluation exercise draw the attention on the limited quality of data provided by some MS, especially the smallest ones. This, together with the limited number of data providers having clearly stated to have a data quality management system in place, shows that the cooperation of EFSA with MS for the improvement of their quality assurance systems is crucial for the overall EFSA's data quality given that it is primarily a MS responsibility to take the necessary measures to enable the data they collect to be transmitted to the Authority.

3.2.3.4 Evaluation results

EFSA usually provides data of good quality.

EFSA provides a complete overview of the leading topics/issues that the data are collected for, mainly in relation to the thematic areas foreseen by the Founding Regulation but also to emerging specific topics identified over the years. Stakeholders have confidence in the quality and reliability of EFSA's data.

Nonetheless the quality of EFSA's data still strongly depends on the initial data quality, that seems to be limited for many data providers and namely for smaller countries. A higher commitment of some national data providers to improve the quality of data seems to be necessary.

[125] Conflicts on the menu, CEO, 2012

3.3 Risk Communication

3.3.1 Introduction to the results for thematic area of evaluation

One of EFSA's key responsibilities according to its Founding Regulation is to communicate food and feed safety advice to its principal partners, stakeholders and the public at large, to help bridging the gap between science and consumers[126].

This area of evaluation relates to the following evaluation criteria:

- **Effectiveness,** the main question being whether EFSA communicates effectively and openly on risks in the food chain;
- **Value Added,** the main questions being whether *i)* EFSA activities have been effective in enhancing trust in the Authority within the overall food-safety system *ii)* EFSA has contributed to scientific homogeneity and coherence in the field of food safety and namely to the reduction of divergent scientific opinions.

The evaluation has taken into account information coming from different types of stakeholders (institutional, external, EFSA's bodies), enriched with that of citizens and consumers assessed through the Eurobarometer analysis commissioned by EFSA.

3.3.2 Risk communication effectiveness

The objective of the evaluation is to analyze whether EFSA communicates effectively and openly on risks in the food chain in a timely manner and, in detail, to evaluate the quality of EFSA's communication and related tools in terms of content, clarity, timing, relevance, outreach and also targets.

3.3.2.1 Facts & Figures

EFSA has significantly **changed its approach in communicating risks** over the years. In 2010, the Authority has moved from the communication of single scientific opinions to the communication of a thematic area (e.g., Zoonoses. Salmonella, etc.) with different levels of details (from the 3 min videos "Understanding science" to the more technical scientific opinions linked to the thematic area), in order to satisfy the heterogeneous information needs of stakeholders.

In addition, as relates the publishing activity, besides the publication of its scientific opinions and of a high number of documents and texts on the EFSA's website, EFSA has developed several new on-line sections (e.g., FAQs, EFSA's answers and videos) aimed at improving the clarity, visibility and awareness on the main EFSA's areas of work.

EFSA's scientific outputs have been published on the EFSA's website since its inception in 2003, and in December 2009 a new web area for the EFSA Journal has been launched. Since January 2011 the EFSA Journal is the single repository and unique access point for EFSA's scientific outputs.

In general, the newly implemented contents have had great success and a substantial increase in the use of such instruments has been noticed (Table 19).

[126] Ensuring that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission (Article 23); Communicating in the fields within its mission without prejudice to the Commission's competence to communicate its risk management decisions (Article 40); Acting in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk communication process (Article 40); Providing, at the request of the Commission, assistance concerning communication on nutritional issues within the framework of the Community health programme (Article 22).

Table 19: Main indicators of EFSA's publishing activity

	2006	2007	2008	2009	2010	2011
Publications	n.a.	58	63	139	198	125
EFSA-related media coverage[127]	4.638	7.194	11.652	9.038	8.330	9.397
Web news stories and press releases	n.a.	63	69	71	75	78
Web-site visits	1,3 mln	1,4 mln	2,1 mln	2,4 mln	3 mln	Over 3,5 mln
Newsletter subscriptions	12.500	17.500	21.140	25.690	26.934	27.993

(Source: EY elaboration on EFSA Annual Activity Reports)

EFSA's main efforts in recent years have been focused on some of the priority areas identified in the 2010-2013 Communication strategy[128], and more specifically on timing, clarity and outreach of the communication.

The timing of EFSA communication is improving. Indeed, EFSA has enhanced the timeliness of the communication: in 2011 82% of outputs without press releases/web stories are published on time (within 15 working days)[129]. A point of attention remains on outputs with press releases/web stories, where the results achieved are still insufficient as only 50% of them are communicated on time (compared to 35% in 2009) (Table 20).

Table 20: Percentage of outputs communicated within fixed deadlines

INDICATORS	2009	2010	2011
Outputs without press releases/web stories (within 15 wd)	75%	70%	82%
Outputs with press releases/web stories (within 20 wd)	35%	25%	50%

(Source: EY elaboration on EFSA's data, 2012)

In order to improve **clarity,** EFSA has undertaken visible efforts to make its communication more understandable, with executive summaries of opinions, newsletters, press releases, etc., and the production of new outputs explaining the underlying scientific concepts behind its work (e.g., new *Understanding Science* video series)[130]. In addition to summaries, for all scientific outputs there is also an abstract that makes it possible for all readers to understand, in a limited number of lines, the content of the document[131]. While EFSA's opinions are available only in English, EFSA's key corporate publications (Annual Report Summary, Work Plan, Strategic Plan) have been available since 2009 in all 23 official EU languages[132] (25 including Norwegian and Icelandic), and press releases are available in the four languages of EFSA's website (English, French, German and Italian). Additionally, on key publications including country-specific information (e.g., press releases and fact sheets on Eurobarometer 2010), EFSA makes available its communications and relevant documents in all 23 languages.

Concerning the **outreach**, **EFSA has progressively increased the volume of initiatives** of communication over time and **has developed an articulated mix of online and offline**

[127] Number of articles related to EFSA and EFSA's activities.
[128] According to the 2010-2013 EFSA Communication Strategy EFSA should "simplify its messages, making them clearer, relevant and more meaningful to the target audience and expand its public outreach".
[129] Deadlines are defined by EFSA in Standard Operating Procedures.
[130] The advice from the EFSA Scientific Committee on a general format for scientific opinions of the EFSA, technical report 2009.
[131] The advice from the EFSA Scientific Committee on a general format for scientific opinions of the EFSA, technical report 2009.
[132] In 2012 EFSA will not translate the work plan in all languages.

communication tools including the corporate website, webcasting, participation in events and conferences, a variety of hard copy publications and information materials, press events and information for the media such as press releases and news alerts.

The institutional website remains the main tool of communication of the Authority. Its visits have increased over the last few years (Table 19) from 1.3 million in 2006 to over 3.5 million in 2011, with an increase of 2.7 times. Table 21 summarizes the main changes occurred over the years on the website, and the recent "EFSA 2012 web user survey", available on the web site, is a further action taken by EFSA to improve this tool.

In addition, EFSA has recognized the growing use of social media and considered these as part of its integrated approach to communication[133]. It has, therefore, developed social media guidelines for use by EFSA's staff and a social media strategy; the recent introduction of Twitter (2011) witnesses EFSA's engagement in this direction.

Table 21: Main changes implemented to improve EFSA's website

2006	- The Authority decided to initiate steps to support a redesign of the EFSA website; - Implementation of new software, through which EFSA was able to track the use of individual web pages and documents; - Implementation of a number of new content sections as well as several webcastings of major events; - Survey of website users to understand if the EFSA website was meeting users' needs.
2007	- EFSA launched a completely redesigned and rebuilt website with new features (simpler navigation, events and meeting calendar, all documents searchable by title, date and category, etc); - New "key topic" sections were published to allow users easy access to information on topical issues.
2008	- Online database for Declarations of Interest is launched; - Graphical presentation of risk assessment workflow is published on EFSA website.
2009	- New EFSA Journal web-area is launched; - A new web-based subscription service for all EFSA newsletters; - Better access to key topics from other areas of the site; - Single entry points and search functions for scientific documents and events; - Survey of website users to understand if the EFSA website was meeting users' needs.
2010	- Created better contextualisation of website content by adding related links between scientific and media material, between the website, and the Register of Questions and Declaration of Interests databases; - Documents and directly related organisational/thematic homepages; - New design which included a new navigation model and homepage; - Better page titles and navigation labels; - Improvements to existing search facilities; - Memorable URLs; - Survey of website users to understand if the EFSA website was meeting users' needs; - Enhanced the use of multimedia by embedding videos on web pages and extending webcasting to a new range of events.
2011	- Top-level dedicated web area "Applications helpdesk", with new user-friendly FAQs in each scientific area; - New scalable model for thematic communication (A-Z topics) and more theme-based search options; - Improved usability of EFSA website by incorporating the EFSA Journal into the core

[133] Annual Activity Report 2011.

	of the website.

(Source: EY elaboration on secondary sources)[134]

As regards targets, EFSA's Communication Strategy defines the primary targets of communication as "those who commission work from the Authority and/or have a particular involvement in areas covered by EFSA's remit. EFSA's key target audiences include: the European institutions who can task EFSA to carry out scientific work (i.e., the European Commission, European Parliament and Member States); national food safety authorities; stakeholders with a specific interest in the food chain (including consumer organisations, industry, environmental and other NGOs); stakeholders from the scientific and academic communities; and other audiences with a particular interest in food, food safety and nutritional issues (e.g., health professional groups), but opens as well to the public at large, stating that communication "must nevertheless be understandable to non-scientists and, within a broader public audience".

RISK COMMUNICATION

In comparison with EFSA, benchmarked agencies do not have the same amount of targets for communication. FSA and VWA communicate towards a wide range of stakeholders in their country, whereas ECHA and EMA communicate towards a smaller range of stakeholders in 27 countries.

- FSA adapts the communication messages to a very fine level of targets.
- At VWA, the risk manager (Ministry) is responsible for the communication in case of a crisis. In the recent months, they have strengthened their communication to accelerate the dissemination of information to mitigate a risk. Most of the time, they focus their communication on answering a criticism they may receive.
- 30 people are working for the communication unit within ECHA (including internal and external communication). The communication towards stakeholders is mainly done through the web site. **The agency is only responsible for providing guidance** for the communication of information on the risks and safe use of chemicals with a view to coordinate MS on these activities. Competent authorities in MS are responsible for informing the general public on the risks arising from substances when this is considered necessary for the protection of human health or environment (Article 123, R 2006/1907).

In recent years, EFSA has made **many significant efforts** to improve the effectiveness and the efficiency of its communication activities **even under an organizational perspective**. The main changes are summarized in the box below.

[134] EFSA's Annual Activity Report 2006 - 2011.

EFSA'S ORGANIZATIONAL CHANGES

- The creation of the new structure of the **Communication Directorate** in May 2011, divided into two units: the Editorial Unit and the Communication Channel Unit. The first one sets communication approaches, key messages and content for dissemination, the second one develops integrated communications activities across all communications channels and tools.
- The establishment in 2005 of the **Advisory Group on Risk Communications (AGRC)** to support the Executive Director in the development of appropriate risk communication strategies, in the identification of appropriate channels and in the evaluation of the impact of risk communication on public perception. *(Decision Concerning the establishment and operations of the Advisory Group on Risk Communications, Executive Director 2011)*
- The creation in 2003 of the **Advisory Forum Working Group on Communication (AFCWG)** working with the communications departments of the National Food Safety Agencies to build a more collaborative and informed approach to communicate risks in the food chain and to promote coherence of messages across the Community (See par. 3.3.3 for further details on AFCWG role and effectiveness).

(Source: EY elaboration on secondary sources)[135]

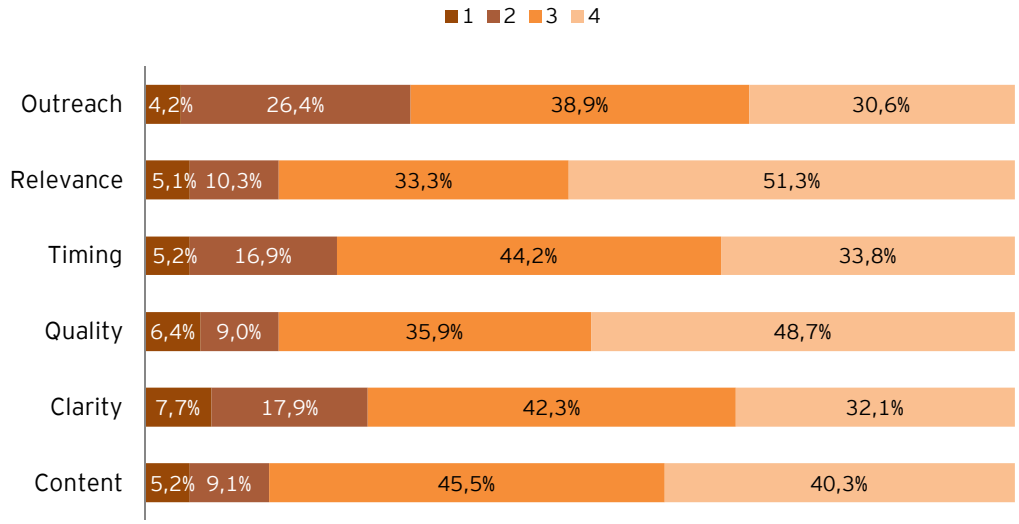
3.3.2.2 Stakeholders' point of view

Globally, **EFSA's risk communication activity is of high quality,** according to the majority of stakeholders (79% of respondents – total average rate – have expressed a positive rate, 3 or 4 out of 4, on the criteria of communication quality Chart 7 – *Q7.1*). This evidence further confirms the Image Survey 2010 results, where EFSA was considered "*a good communicator with massive output*". EFSA's communication system is appropriate, adequate and exhaustive (NRA, NRM, Cons.). Over the years the Authority has increased the volume and the quality of communication and has improved its capacity to communicate, even to the general public (NRA, Cons.)[136].

Chart 7 summarizes the level of satisfaction of stakeholders regarding content, clarity, quality, timing, relevance and outreach of EFSA's communication *(Q7.1)*.

[135] "*Description of the scope of Directorates and Units within EFSA's new organizational model*"; EFSA's Annual Activity Report 2011; "Advisory Forum Working Group on Communication – Terms of reference", EFSA 2007; EFSA's website.
[136] This opinion is also supported by one Scient. Org.

Chart 7: Level of satisfaction on EFSA's communication



(Source: EY survey)

Content is the most satisfactory aspect with 86% of stakeholders expressing a good rate (3 or 4 out of 4). This positive appraisal is equally distributed among the different types of stakeholders; institutional and external stakeholders have stated an average score well above 3 out of 4.

Nonetheless, **content** remains a debatable issue (namely NRA and NRM). It is still **controversial whether EFSA should provide more detailed recommendations to NRM** as suggested by some NRA, or care about not going beyond its role of risk assessor, communicating only the risks and leaving the political decisions (e.g., recalls, consumer advice and recommendations on avoidance of food safety risks) to risk managers (one NRM[137] and one FIR)[138].

Quality and relevance of EFSA's communication largely satisfy stakeholders. Indeed about 50% of stakeholders have given a rate of 4 out of 4 with an average rate well above 3 for both institutional and external stakeholders *(Q7.1)*. EFSA's activities **have been useful** to improve knowledge and awareness of existing food-chain risks, as confirmed by the high percentage of stakeholders (74%) who have rated 3 or 4 out of 4 in the survey *(Q7.2)*.

Coherently with previous evidences, timing is good, even in crisis situations, according to NRM (average rate of 3,16 out of 4) and NRA (average rate of 3,22 out of 4) *(Q7.1)*: possible delays between an opinion and its communication exist due to the contingent urgent situation and not to structural problems in EFSA's communication process (one NRA). Among external stakeholders, FIR demand for a more rapid publication of agenda and minutes of meetings, as sometimes they are published months after the meetings.

The two aspects that deserve more attention, according to stakeholders, **are clarity and outreach** of EFSA communication. Both have raised the higher percentages of negative comments respectively with 26% and 30,6% of respondents giving a rate of 2 or below out of 4. *(Q7.1)*

As regards clarity, EFSA's communication is considered adequate only for a well educated public and has **some language barriers,** considering that English is not understood

[137] The E. Coli outbreak has been mentioned as an example in which EFSA's communication went too far away informing how to deal with the crisis (NRM).
[138] See paragraph 3.7 "Independence" for further evidences on this aspect.

everywhere (NRA, Cons., FIR). This is further confirmed by the unavailability of many EFSA's documents (mostly opinions) in several EU languages, as shown before.

Concerning the **outreach**, it is important to underline that, among EFSA's **communication tools**, the website is the most mentioned one. There is a strong agreement among stakeholders that this tool has improved over time, now including all the main documents, both institutional and scientific (NRM, Scient. Org., FIR, Cons., IOs), recognizing all the efforts, previously described, made by EFSA to improve the website. Nonetheless, further improvements are needed according to some stakeholders. The **navigation is still too complicated**, it is sometimes difficult to look for thematic information (Cons.), the search engine seems too weak and it is often easier to find a document using an external research tool (e.g., Google) (FIR).

As regards the **targets** of the communication, it is **controversial whether EFSA's communication should be oriented to the general public**, as also dealt in the Authority's Communication Strategy[139]. The majority of institutional stakeholders (NRM, NRA) agree on the fact that EFSA should primarily communicate to NRM and NRA, providing them and other national stakeholders with the adequate tools to communicate to the public. EFSA's efforts to make its communication easier to understand (e.g., short movies posted on EFSA website, summaries) are considered good and enough for them to communicate with the general public.

On the other side, stakeholders supporting EFSA's engagement in communicating to the general public (Cons. Org., Media, FIR, IOs)[140] and those asking for an increased effort to improve communication towards this target, raised different issues. The Authority should not be the only one responsible for communicating with general public, but it is important that it does it, because some National Authorities are not prepared or do not have enough staff to communicate to the general public (one MB). Moreover, even if Consumer Organizations are trusted by consumers, they often do not have enough scientific background and their communication risks to be not always reliable. EFSA, thanks to its scientific body-nature, should be more educational towards the general public explaining the context of the decision in order for people to understand it (Cons.).

The communication to Member States is perceived as **adequate** and **clear** enough to inform and support decision-making processes (NRM, NRA). However, there is a need to further strengthen cooperation between EFSA, NRM and NRA (NRA), through a continuous and routinely speaking, in order to better understand national needs and produce valuable guidelines, harmonize the outputs, reduce the possibility to have a duplication of activities and better address criticisms coming from national NGOs or national public opinion.

As for the provision of scientific outputs, there are few stakeholders (NRM, NRA) asking for:

- **a more active role** by EFSA in communicating risks.
- **a more contextualized communication**. The communication of EFSA is not always adequate to different national contexts and often it does not take into account their specificities.

Although there is a strong recognition among all stakeholders of the efforts that EFSA has undertaken since its inception to openly and effectively communicate its activities and achievements, there are still some **criticisms** coming from few stakeholders:

- sometimes EFSA's communication is **overwhelming** (Scient. Org., and IOs): too much information is sent to stakeholders and not always in the most adequate format;
- an important amount of resources are allocated to the communication, but **there is a lot of waste** too: too many copies of the same documents sent to the same

[139] Key strategic priorities for 2010-2013 in its Communications Strategy.
[140] This opinion is also supported by one member of MB.

stakeholder (IOs), additional white-page hard copies, a badly conceived newsletter neither interesting for experts nor understandable for the general public (one member of MB);

- **media** (expressing an average negative judgment under 2 out of 4) **criticise all aspects of EFSA's communication activity**, questioning the complexity of the messages. Underpinning reasons can be found in the previous 2010 Image Survey: EFSA's relationships with media and press are underestimated and EFSA prefers to communicate via National Agencies.

Some interesting **suggestions to improve EFSA risk communication effectiveness** come from some stakeholders (Q7.3), including[141]:

- improving communication on results of consultations where changes are made (Media);
- improving communication on answers to requests for scientific opinions (Scient. Org.);
- putting real risks in context (FIR);
- raising consumer awareness of high safety in regulatory frameworks where it exists (FIR);
- communicating more effectively a risk where it is present along with the lack of risks or benefits (FIR);
- communicating EFSA's feedback in case a MS has contributed to a study/an opinion (NRA).

Some thematic areas of improvement are suggested as well (Q7.3).

THEMATIC AREAS	*Suggested more than once*	- Genetically modified organisms (NRA, Media); - Zoonoses (NRA); - Bisphenol (NRA, Scient. Org.); - Health claims (NRA, Scient. Org.);	NRA, Media, Scient. Org.
	Suggested once	- Antimicrobial resistance (NRA); - G Flavourings assessment (Media); - Carcinogenicity (Scient. Org.); - Acrylamide (NRA).	

(Source: EY survey)

3.3.2.3 Analysis of evidences

Information collected both from the desk analysis and from stakeholders provides evidence for a general positive evaluation on the effectiveness and timeliness of EFSA's communication. The different actions that EFSA has undertaken in the last years to improve the communication's effectiveness, increasing the portfolio of on and offline communication tools to effectively reach different targets, publishing all outputs, respecting deadlines and moving to an approach based on thematic areas seem indeed to have brought to positive results, when considering on the one side that most stakeholders recognise that communication has improved and find the system to be appropriate, adequate, exhaustive, of high quality and useful to improve knowledge and awareness of existing food-chain risks, and on the other side that all major indicators on the effectiveness of communication (i.e., number of visits on the website, number of subscriptions to the newsletter, media coverage) have increased in the period under evaluation, with a convergence also on the results of the Image Survey of 2010 where EFSA emerged as "*a good communicator with massive output*".

[141] Each statement has been suggested by one stakeholder.

More specifically, the analysis of evidences coming from the desk analysis and stakeholders shows that that the points of strength in EFSA's communication relate to its content, quality and relevance, that are indeed highly appreciated by stakeholders.

There are though some issues that emerge as weaker points in EFSA's communication.

Some of them have already been addressed by EFSA in its Communication Strategy that indeed identifies priorities in timing, clarity and outreach of the communication. Whereas as regards timing, efforts done by EFSA have already produced effects in terms of both timely publication of outputs without press release and stakeholders' satisfaction, who indeed find timing of communication good (with the exception of FIR who demand for a more rapid publication of agenda and minutes of meetings), as relates clarity, the actions undertaken with the provision of summaries and of abstracts of scientific outputs, have not brought significant results yet, at least as regards stakeholders satisfaction. Although communication is considered useful and clear enough to inform and support decision-making processes, it still lacks of clarity, being targeted to a well educated public and not accessible to anybody for language barriers. The strongest criticisms on this point come from the media, who find communication too complex. Indeed, only key corporate documents are published in 23 languages, whereas scientific opinions are published only in English.

Also the use of the communication tools has some room for improvement: despite the development and the improvement of different tools and specifically of the **web site**, this tool does not seem to be completely effective. Provided that, as already mentioned, the number of visits has constantly increased over the years, and documents are available and organized in thematic areas to help their search, still the navigation of this tool is far from being completely satisfying and does not seem to be user-friendly enough (this limit has also been experienced by the evaluation team). These limits can be particularly relevant for those stakeholders that are not directly involved in EFSA's activities (i.e., external stakeholders and the general public) that do not have familiarity with EFSA's activities and outputs.

This latter point, related to the general public, remains an issue to be addressed: how EFSA should **communicate to the general public** is indeed still unclear both in EFSA's strategic documents and in stakeholders' perception.

In addition, no evidence is available on whether the actions defined in the communication strategy that imply a close cooperation with MS to promote harmonized communication to consumers, are properly working to pursue this objective. Some more detailed understanding of the actions to be taken to meet information needs of consumers seems then to be necessary in order to optimize the use of resources, given that EFSA's communication, still characterized by a technical and difficult style, remains mainly targeted to European and national risk managers and to NRA.

From the analysis of the information collected, two transversal issues emerge:

- the relation with the **media**: this relation remains a weak point of EFSA's communication, and media do not appreciate EFSA's communication at all;
- the cooperation with NRA and NRM: this is demanded in order to both better understand national needs and define harmonized actions towards other stakeholders (and namely the general public).

As a concluding remark, it seems that more than on the development of new communication tools, that are abundant and sometimes even overwhelming for stakeholders, it seems that EFSA should focus on improving the effectiveness of existing tools in terms of a better matching between information needs of different stakeholders and targeted messages and tools, at the same time keeping on improving communication **simplicity, clearness** and **outreach**.

3.3.2.4 Evaluation results

EFSA's communication is effective and of high quality.

EFSA's stakeholders mainly appreciate the **content** of the Authority's communication. **Quality**, **relevance** and **timing** of the messages are also satisfying and communication outputs are useful to improve knowledge and awareness of existing food-chain risks.

Notwithstanding, the following areas of improvements are identified to improve EFSA's communication effectiveness:

- *clarity*: despite the Authority's efforts to make its communication more understandable (e.g., executive summaries of opinions, newsletters, press releases, etc), messages are still conceived as adequate for a well educated public. Language barriers related to the use of English further undermine this objective, indeed EFSA's opinions are still mainly written in English and only key corporate documents are available in other languages.
- *outreach*: navigation on the website is still too complicated – even if visible improvements have occurred over the years (e.g., redesign of the website, implementation of new software, new content sections, new search functions, etc.) – and the search engine is not effective, as also stated by some stakeholders.
- *target*: despite the efforts accomplished by EFSA to communicate to the general public (e.g., videos, summaries, etc.), and despite its engagement in the Communication Strategy to expand its public outreach, EFSA's communication to the general public remains questioned by some stakeholders in terms of both effectiveness and efficiency. A clear position of the Authority is therefore necessary to optimize the effectiveness of its future communication activities, taking into account a better dialogue and cooperation with MRA and NRM.

3.3.3 Added value of risk communication on public trust and coherence

Coherently with the evaluation framework, the added value of the EFSA's Risk Communication is analyzed in terms of its impact on:

- public trust and reliability;
- coherence of the food safety system.

3.3.3.1 Facts & Figures

Trust and reliability

According to EFSA's vision "EFSA's goal is to be globally recognised as the European reference body for risk assessment on food and feed safety, animal health and welfare, nutrition, plant protection and plant health"[142]. To pursue this goal and bring the Authority closer to all the interested parties (both the direct clients and the general public), starting from 2005, EFSA has developed a various portfolio of activities and tools for inclusion and public scrutiny (see also par. 3.8 "Openness and Transparency" for further details). The Authority has also recently undertaken the following activities:

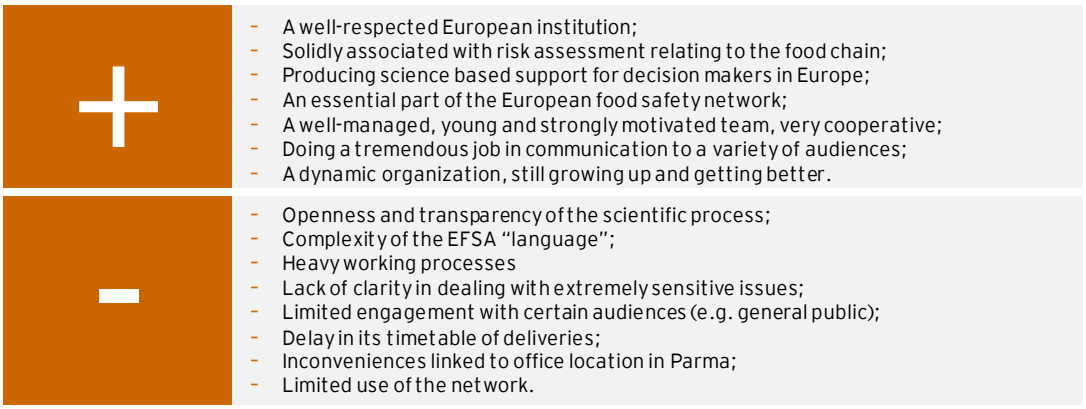
- new **networks of expertise** on several topics, managed by EFSA with the participation of all MS (e.g., Animal health, welfare, GMOs);
- publications of risk assessment guidance and guidelines (e.g., the environmental risk

[142] EFSA's Vision.

assessment guidance on GMO plants);

As shown in the already mentioned Image Survey of 2010[143], whose main evidences are summarized in Figure 9, **the Authority is progressing through efforts in various areas to improve public trust** like: reduction in time to produce opinions (achieving the results described in the previous paragraphs), openness and improved attitude to take discussions, improvement of the Communication process, longer and wider perspective of development including the extra EU Members States as key stakeholders of a globalized food safety system.

Figure 9: EFSA's strengths and weaknesses as evidenced by the 2010 Image Survey



(Source: EY elaboration on 2010 Image Survey)

Regarding EFSA's **reliability** among European consumers, results of the Eurobarometer[144] (presented in the following box) found that **globally citizens feel that public authorities are doing well to protect them from unsafe food** and consider National and European Food Safety Agencies among the most reliable information sources.

[143] Image of the European Food Safety Authority, Qualitative research report, February 2010.

[144] To keep pace with the evolution of its stakeholders' perceptions and adapt consequently its communication, in order to plan it adequately and better focus on the most sensible target, EFSA has demonstrated a constant commitment in the observation of the evolution of public perception. After a first study carried out in 2005, EFSA has commissioned another study in 2010 to gain deeper insight into consumer concerns related to food and risks associated with the food chain and to establish a higher level of consumer confidence in public authorities (among which EFSA) on food safety-related issues.

EUROBAROMETER: MAIN RESULTS

- As an information source on possible risks associated with food, **Europeans have confidence in:**
  - **National and European food safety agencies (EFSA)**: 64%
  - European Institutions: 57%
  - National Governments: 47%
- The percentage of Europeans concerned with risks linked to food is progressively increasing (+3% since 2005) attaining 11% of the respondents.

- In the future, an **increased attention** will be paid by external stakeholders to EFSA's activities and opinions and the Authority **should enhance trust** in the food safety system not only through communication activities, but also through its routine working practices that will become more and more observed.
- There is a broad agreement that public authorities do a lot to ensure that food is safe in Europe and that they do a good job in informing people about food-related risks. The level of agreement has increased compared to 2005, but, from the results, it is clear how confidence varies quite widely across EU. There is high confidence in Finland (84%), Slovakia (78%) and

(Source: EY elaboration on Eurobarometer research)

Coherence

There are various **risk communicators across Europe and the risk of highly differentiated messages is present**.

One of EFSA's priorities for 2010-2013, according to EFSA's Strategic Plan, is to "further increase the coherence of risk communications across the EU and beyond".

To foster the harmonization and reduce the negative impact of potential conflicting opinions, **EFSA has implemented the procedure** envisaged in Art. 30 of the Founding Regulation 178/2002, in **case of controversies and discrepancies** emerged at European level on scientific issues.

ARTICLE 30 PROCEDURE

- EFSA normally exercises vigilance in order to identify divergent scientific opinions. When a potential source of discrepancy is located, the Authority should contact the interested body to ensure that all relevant data and information are shared. When a substantive divergence is identified, EFSA and the interested body have to cooperate to solve the divergence or to publish a joint document clarifying the scientific issues and uncertainties about the data. The document has to be presented to the EC if the body in question is a Community agency or one of the Commission's Scientific Committees (not in case of a MS body).

(Source: EY elaboration on Funding Regulation 178/2002)

As observed during direct observations[145], this procedure is applied to find, when appropriate, a common agreement among the parties and, when applied, it has almost always brought to a satisfying conclusion, as shown in Table 22.

[145] Scientific Committee Plenary, as relates the draft opinion on "Threshold of toxicological concern (TTC)

Nonetheless, difficulties have been encountered in the application of this procedure at an international level (see also par.3.5.2.1 for further details).

Table 22: Results of the application of the procedure for divergent opinions art.30

YEAR	TOPIC OF THE CONTROVERSIAL ISSUE	UNIT RESPONSIBLE	RESULT OF DIVERGENCE
2006	QRA tallow	BIOHAZ	solved
2008	MON 810	GMO	solved
	Threshold of Toxicological Concern	Scientific Committee	solved
2009	Risk assessment of lycopene	ANS	confirmed
2011	Sweeteners	ANS	solved
	Coumarin	NDA	solved
	Bisphenol A	CEF	confirmed[146]

(Source: EY elaboration on EFSA's data, 2012)

To reduce the natural diversity given by the presence of several risk communicators across Europe, EFSA has established in 2003 the **Advisory Forum Working Group on Communication (AFCWG)** (see also par.3.3.2.1). Through this platform of exchange, EFSA keeps a close relationship with national Food Safety Organizations, in order to support timely and consistent diffusion of risk communication messages. It also co-operates with institutional stakeholders, such as the EC, to support a coordinated and coherent approach to risk communication across risk assessment and risk management[147].

As regards EFSA's communication during **crisis situations**, its Communication Strategy[148] does not provide any formalized procedure to be implemented, as confirmed during **E-coli crisis in 2011**. Throughout this emergency, indeed, EFSA, after notifying all interested parties that it was monitoring the outbreak, tried to align its communication efforts with other organizations and MS. Recognising the variety of communications that were circulating in different MS, EFSA set up a table to get an overview of who was communicating what and since when. After discussions with the MS, it was clear that some of them were better informed about ongoing events than others, and that a common knowledge of the situation had not been achieved.

This outbreak highlighted the importance of EFSA's risk communication mandate, and the need to coordinate communication between NRM and NRA. As stated in the Annual Report on EFSA's food and feed safety crisis preparedness and response 2011, in order to improve information exchange in future crisis, EFSA has decided to **use the Advisory Forum Communications Working Group** to ensure that there is equal access to information.[149]

In addition to the activities of the AFCWG with MS, EFSA has implemented in 2009 its international strategy, recognising **international co-operation in risk communication** as key to build coherence in an increasingly global communication environment. EFSA has established cooperation agreements with the U.S. Food and Drug Administration, the Food Safety

[146] No formal confirmation received from the Unit about the result of this divergence.
[147] Updated in its Terms of Reference in 2007 the AFCWG has the ambitious goal of sharing communication best practices and skills among Member States and developing an overall approach and outline for risk communications guidelines to help support coherence in risk communication across the EU ("Advisory Forum Working Group on Communication – Terms of reference", EFSA 2007). The AFCWG section is referred to in the judgment criteria "The processes related to the AF are efficient (the AF is able to assist and advise EFSA and EFSA is able to make the most efficient use of this advice and assistance)".
[148] EFSA's Communication Strategy: 2010 – 2013 perspective, EFSA 2010.
[149] Annual Report on EFSA's food and feed safety crisis preparedness and response 2011, EFSA 2012.

Commission of Japan and is liaising closely with agencies outside the EU (e.g., Australia, Canada, New Zealand, etc.) as well as with international organizations (WHO, FAO, OIE, OECD, etc).

3.3.3.2 Stakeholders' point of view

Trust and reliability

EFSA has succeeded in building trust and awareness for itself and the overall food safety system according to 87% of respondents (rate 3 or 4 out of 4 – *Q8.1*) and to 74% of respondents (rate 3 or 4 out of 4 – Q7.2). Moreover, the majority of stakeholders (NRM, NRA, Scient. Org., IOs, FIR) have underlined EFSA's high **recognition and positive reputation** in the food safety system (see also par. 3.5 "International role and recognition" for further details). The Authority is relatively well known, understood, and perceived as useful. Moreover EFSA's activities in the field of food safety are now recognized by the majority of stakeholders, as confirmed by the high trust that they pour on the Authority (an overall average rate of all respondents of 3,40 – *Q8.1*), with the exception of the **Media** who have expressed a lower recognition (rate of 2,6 out of 4). A remark comes also from a NGO representative who claims that EFSA, in some areas, does not respond in a promptly and adequate manner, not managing to enhance trust and confidence (e.g., GMOs area).

The reliability of EFSA in the European system of risk assessment is certainly significant: 86% of respondents said they trust the risk assessment system of EFSA (rate 3 or 4 out of 4[150] - *Q8.2*). EFSA's transparency and independence contribute to further strengthen the reliability of its assessments and methodologies (one NRA and one NRM).

Nonetheless, the globally positive evidence coming out from the survey requires further evaluation. Indeed, the perception of NRA and NRM on EFSA's reliability is often influenced by the institutional system of the MS of origin and its expertise in risk assessment. As emerged from interviews (NRA and a member of Cons.) all MS have confirmed their attitude, often embedded in historical and political reasons, to make primarily reference to their national expertise before asking EFSA's intervention when a food/feed safety issue emerges. However this should not be seen as a lack of confidence in the work of EFSA, as demonstrated by the good results of the survey, but rather as the result of a practice still in use in the majority of MS.

EFSA is highly committed to dialogue to reinforce trust and confidence according to 78% of stakeholders (Q8.3). EFSA is doing a good job in scientific risk assessment, listening and commenting on external inputs adequately (FIR), and in the dialogue with all the National Authorities, that since EFSA's birth, feel more trustful and confident in delivering clear and complete messages to consumers (one NRM and one NRA), considering the Authority as free from national political or financial interests.

Nonetheless, interviews have underlined that national **consumers are often unaware of EFSA's existence and utility for the food safety chain** and do not perceive any improvement since EFSA's creation (NRA)[151], partially contradicting the above mentioned findings of the Eurobarometer. EFSA has an indirect impact on public awareness, always mediated by other institutions: only few people see EFSA as a scientific body protecting consumers, but it is mainly seen as an instrument of the EC to support its political decisions (NRM). A big gap still exists in the relationship between EFSA and the citizens (NRM and NRA).

[150] Respondents to this question belong to only 4 categories of stakeholders (EC, EP, RM, RA).
[151] This evidence is supported also by one FIR.

Coherence

EFSA's communication on risks in the food chain is coherent according to the majority of stakeholders (88% of respondents have expressed a rate of 3 or 4 out of 4 – Q7.4).

As regards the impact of EFSA's communication activities on **divergent opinions**, EFSA is recognized by most stakeholders as a **contributor to the coordination and harmonization of the different scientific positions** in the field of food safety (NRM, NRA). The survey shows that 60%[152] of the respondents believe that the activities of EFSA contributed to the reduction of divergent scientific opinions in Europe (rate 3 or 4 out of 4)[153], even if the previously described procedure implemented to solve divergent opinions (art. 30 procedure) is considered long and bureaucratic by some stakeholders (one NRM, one IOs). Although much has been done to reduce divergent opinions, **divergent opinions still exist**[154]**.**

Indeed, interviewees reveal that **further improvements are still needed** (NRM, NRA)[155] although in a context where **a total coherence** in risk communication in Europe **is simply not feasible** (NRA)**.**

In addition to MS with different cultures, in the EU there is a large number of organizations working in food safety, whose views are often taken into account and considered relevant by stakeholders. 46 out of 59 respondents said they consider other opinions besides EFSA's ones (Q7.5). Among those who are more often considered: WHO and FDA (among international organizations), FSA and the BfR (among national agencies) (Table 23).

Table 23: Others organizations taken into account for risk communication

INTERNATIONAL ORGANIZATIONS	EUROPEAN ORGANIZATIONS	NATIONAL ORGANIZATIONS
WHO *(EC,NRA, EC, NRM, Scient. Org.)*; FAO *(NRA, NRM)*; US FDA *(EC, NRA, NRM, Scient. Org.)*; Health Canada *(NRA, Scient. Org.)*; Codex *(NRA,NRM)*; JECFA *(NRA, Scient. Org.)*; JMPR *(NRA)*, OECD *(NRA)*; IARC *(Scient. Org.)*, OAI *(NRA)*, JEMRA *(NRA)* *(once suggested)*.	EMA *(NRA)*; ECDC *(NRA, NRM)*.	BFR *(NRA, NRM)*; FSA *(NRA, NRM)*; ANSES *(NRA)*; RIVM *(NRA, Cons.)*; All other MS Authorities *(EC, NRA, EP, Cons., NRM)*; NVWA *(Cons.)* *(once suggested)*.

(Source: EY survey)

Slightly different and more worrying, according to the perspective of an International Organization[156], is the **divergence of EFSA's opinions from the ones produced by international fora** (i.e., JECFA, WHO, FAO, etc.)[157]. There are various underpinning reasons raised by International Institutions, from differences in the methodologies[158] to differences in the data set used and in the data gaps (EFSA produces mainly European opinions based on European data whereas International Institutions widen their perspective to deliver international opinions). In addition, when EFSA's opinions are diverging from international opinions, it seems to be difficult to re-evaluate hazards, due to EFSA's limited provision of data and details of the risk assessment (IOs), and despite EFSA's international strategy

[152] Percentage of satisfied respondents rises to 73,7% without considering NA answers.
[153] The remaining 40% splits fairly between those with a negative judgment and who is unable to express an opinion on the impact of the work of EFSA (Q8.4- EC, RM,RA, FIR/A).
[154] e.g., the activities of some National Authorities have been based recently on different positions than those of EFSA, making it possible to predict a future risky trend - a member of MB.
[155] This opinion is also supported by one member of MB, one EP, one Cons.
[156] This evidence is supported also by one NRM and one NGO.
[157] i.e. genetically modified potato case (NGO).
[158] Regarding food additives and contaminants EFSA's Panel considered different end points and used different methodologies (one IO).

mentioned above. According to some stakeholders, EFSA should play a more active role in the harmonization of risk assessment methodologies at an international level, participating more frequently in international discussions (i.e., FAO and WHO).

As regards the effectiveness of the activities carried out by **AFCWG**, a **controversial judgment** is expressed by stakeholders on its role. The AFCWG is considered by the majority of stakeholders as **an ongoing platform of exchange of best practices and skills**, and its expected positive impacts on the coherence in risk communication across EU are **discussed**. 51%[159] of stakeholders are satisfied by the activity of AFCWG (rate 3 or 4 out of 4), but about 1/3 (29%) did not express any rate[160] (Q8.5 – EC, NRM, NRA).

There is a wide recognition among stakeholders of the importance of cooperation in risk communication activities. Nonetheless, different countries raise different needs according to their specific expertise and those needs do not seem to be completely satisfied by the actual portfolio of instruments deployed by EFSA. During the four annual meetings of the AFCWG, representatives of countries with a limited risk assessment expertise and without a dedicated unit for risk communication, might be inspired with new ways to communicate to the public and might rely on EFSA guidance for risk communication during crisis situations (one NRM, NRA), whereas representatives of countries with a solid communication department might find the AFCWG meetings not useful and of limited pragmatism and power of action (e.g., during crisis situations – NRA, MB)[161].

The heterogeneous profiles of the AFCWG participants seem to be an additional reason of its limited effectiveness, according to a member of the MB, as people chosen by MS do not always have the necessary competences and the different background of participants may have an impact on the quality of the discussion.

In the heterogeneous context described above, where each Member State has a different experience and expertise as well as different public sensitivity, NRA suggest that EFSA **should seek to establish a routinely dialogue** with MS, in order to provide solid common grounds, shared by main policy makers; moreover it should **continue to implement coordination tools, guidelines and dictionaries** with useful scientific terms (NRA), to support different stakeholders in communicating the risks in the food sector in a more coherent way, even in crisis situation. EFSA's resolution to the contribution of the crisis, indeed, is widely acknowledged, although a few stakeholders (EP, NRM) find that EFSA's communication lacks of harmonization in emergency situations, as clearly showed during the E.Coli crisis, where EFSA should have reacted more quickly and should have centralized the communication, being not acceptable that each MS communicates autonomously during these situations with the risk of creating panic.

3.3.3.3 Analysis of evidences

Information collected from the desk analysis and from stakeholders shows the added value that EFSA is providing in terms of both trust and coherence in risk communication. Stakeholders recognize EFSA's commitment to dialogue to reinforce **trust and confidence**, consistently with the results of the Eurobarometer, even if EFSA is not necessary the only voice they listen to, provided that some international and national agencies are also very well considered, especially in those countries with a strong risk assessment capacity. Involved stakeholders do indeed trust the risk assessment system of EFSA, especially as they recognise the independent position of EFSA. Though, no clear evidence is available on the added value of EFSA' communication on trust of citizens; rather, some comments coming from stakeholders involved in the evaluation exercise draw attention on a limited awareness of citizens about

[159] NA included.
[160] Percentage of satisfied respondents rises to 72,4% without considering NA answers.
[161] This evidence is also supported by one NRM.

EFSA's existence and role in enhancing public trust. Also as regards trust, like for the effectiveness of communication, the general public remains at the margin of EFSA's activities, even if most NRM believe that thanks to EFSA they can provide their national consumers with clearer messages.

As regards **coherence** and the reduction of divergent opinions, EFSA is using both formal (procedure article 30 and the AFCWG) and informal instruments. Despite the recognition of a significant role of EFSA in promoting coherence and of its effectiveness in reducing divergent opinions (although mainly in Europe, considering that coherence with international fora seems to be weak), these results are not straightforward connected to the formal instruments put in place by the Authority, especially as regards the AFCWG, provided that more than few stakeholders do not express any opinion on its role. As a consequence, it seems that the added value that EFSA is providing on coherence is due more to informal instruments and to its communication activity than to this instrument. The analysis of the information collected suggests that the use of this instrument should be improved, also in support of coherence of communication in crisis situation (as also envisaged by EFSA), where no clear procedure is available and a lack of harmonization is present.

Another issue that should be taken into account to improve the added value of risk communication on coherence relates to the dialogue with MS. Again, as already pointed out in par. 3.1 "Provision of scientific outputs" and 3.4 "Cooperation and Networking", also for risk communication there is a demand to better dialogue with MS, considering also the different national contexts, the different recognition of the importance of cooperation in risk communication activities by different MS and the practise of some NRM to rely on their national agencies and on other national specialized organizations with a subsequent risk for duplication and overlapping of opinions.

3.3.3.4 Evaluation results

EFSA has succeeded in building awareness, trust and reputation for itself and the overall food safety system and has contributed to the harmonization of different scientific positions.

The Authority is relatively well known and understood, and perceived as **a reliable system** in the European system of risk assessment. This positive evaluation is also the result of several efforts made by the Authority over the years like:

- EFSA's high commitment to dialogue with partners and stakeholder to reinforce trust and confidence, as confirmed in the Science Strategy 2010-2016;
- EFSA's efforts to improve public trust, for example in terms of reduction of the time needed to produce opinions, increased level of openness and transparency, improvement of the communication process, adoption of a longer and wider perspective including extra EU MS.

Nonetheless, to further improve public trust, the Authority should address the following challenges:

- *the highly differentiated recognition of MS*: according to the specific institutional system and the risk assessment expertise, each MS differently perceives EFSA's role and reliability and holds different expectations. This trend is highlighted by some stakeholders and has also emerged from the direct observation of interactions between the MS representatives during the 43rd AF meeting[162]. Countries with a limited risk assessment capacity usually rely more on the work of the Authority than more experienced ones.

[162] 43th Advisory Forum, 7-8 March 2012, Parma.

- *The communication to the general public*: EFSA has usually an indirect impact on public awareness, being mainly mediated by other institutions.

EFSA is recognized by most stakeholders as a contributor to the coordination, harmonization and decrease of the divergent scientific opinions, as further confirmed by the limited number of cases of implementation of the "reconciliation" procedure ex art.30 of the Founding Regulation. Nevertheless, divergent opinions still exist, at both EU and international level.

To further contribute to the coherence of risk communication, the following areas of improvement have been identified:

- *AFCWG*: this WG does not satisfy the different expectations of MS representatives as it answers in the same way to different needs and expectations. Its support could be further improved especially in crisis situations.
- *communication in crisis situations:* communication activities lack of harmonization in the European system, as emerged for example during the E-coli crisis, where no clear responsibilities were defined as for the communication and different MS started to communicate separately, as interviews have revealed. Further cooperation among MS is needed to effectively face the communication during crisis situations.
- *cooperation with NRM-NRA*: it seems impossible to prevent NRM to rely on their national agencies, but the increasing credibility of EFSA should ensure that MS, in the future, before beginning a risk assessment activity, will address the Authority to verify the existence of similar studies, thus avoiding the risk of duplication and overlapping opinions.
- *international cooperation*: procedures to deal with divergent scientific opinions with IOs are perceived as difficult by some stakeholders due to EFSA's limited provision of data and details of risk assessments, notwithstanding EFSA has implemented an international strategy for cooperation in risk communication.

3.4 Cooperation and networking

3.4.1 Introduction to the results for the thematic area of evaluation

This part focuses on EFSA's cooperation and networking with EU partners and stakeholders, either institutional (MS, EC, EP) or scientific organizations. Interactions with the international community and civil society stakeholders are analyzed in other sections (respectively: par. 3.5 "International role and recognition"; par. 3.8 "Openness and transparency").

This area of evaluation relates to the following evaluation criteria:

- **Effectiveness, efficiency and sustainability,** the main questions being whether *i)* EFSA cooperates with the Commission and MS to promote coherence between risk assessment, risk management and risk communication in an effective manner; *ii)* EFSA acts in close cooperation with the competent bodies in the MS, *iii)* whether EFSA is able to make the most efficient use of the AF advice and assistance, *iv)* whether the cooperation in place allows for a sustainable quality of work.
- **Value Added,** the main question being whether the cost for national food safety authorities has reduced thanks to EFSA's activities.

Partners involved in the cooperation and networking activities of EFSA are described in the following box.

COOPERATION AND NETWORKING FRAMEWORK

One of EFSA's key responsibilities, according to its Founding Regulation, is to strengthen scientific cooperation and networking between EFSA and Member States. To accomplish its mission, EFSA works closely with partners and stakeholders, and is a proactive member of important networks.

- **The Advisory Forum (AF)** defined in the article 27 of the founding regulation and Scientific Cooperation Unit have been created in that perspective to ensure work sharing and exchange of scientific data and information. The aim of the AF is to facilitate, by four meetings per year, the dialogue between national food safety authorities and EFSA.
- In line with **Article 36** of EFSA's Founding Regulation and its implementing rules, EFSA's Management Board approved a list of **organizations operating in the fields within the Authority's mission** capable of assisting the Authority in its tasks (data collection, preparatory work, scientific and technical assistance). Networking with these competent organizations enables EFSA to use a wider spectrum of scientific excellence in Europe.

In order to support the cooperation between RA institutes, the AF appointed in December 2006 a network of focal points.

- **Focal Points** act as an interface between EFSA and the national food safety authorities, research institutes, consumers and other stakeholders. The Focal Point network support their AF members in the practical implementation of activities related to networking and scientific cooperation including the exchange of scientific information through the Information Exchange Platform (IEP), the support of competent organizations under Article 36 of EFSA's founding regulation, the promotion of the experts database at national level and the raise of EFSA's scientific visibility.
- Starting from 2010, EFSA units benefits from the support of 9 networks of nationally appointed. scientific organizations, nationally appointed. Their aim is to facilitate scientific cooperation in the fields of EFSA's mission by coordinating activities, exchanging information, developing and implementing joint projects and exchanging expertise and best practices.
- With a view to deliver timely scientific advice of the highest standards to support the policies and decisions of Europe's risk managers (EC, EP and MS), **external scientific experts are invited to cooperate with EFSA for two types of assignments**: (i) EFSA assignments: provision of scientific advice to EFSA's scientific committee, Scientific panels, EFSA networks and respective working groups. (ii) Assignments to scientific projects by direct invitation of Member States, EEA/EFTA countries or the European Commission. The experts can apply to be part of the expert database that gathers the pool of experts that are willing to participate.

(Source: EY elaboration on secondary sources)

EFSA is committed to deliver the best expertise to provide risk assessments for food and feed safety in the European Union. To accomplish its mission, EFSA works closely with partners and stakeholders based in the MS and the EC. The opinions provided are based on sound science involving Europe's leading experts in regulatory risk assessment.

3.4.2 Effectiveness, efficiency and sustainability

3.4.2.1 Facts & Figures

a) *EFSA cooperation with institutional stakeholders in Member States (National risk assessors and risk managers)*

There are two types of cooperation between EFSA and Member States with different aims:

- **cooperation of EFSA with risk managers** which aim is the coherence of the risk analysis process as foreseen in recital 17 , Article 22 (8), Article 28 and Article 40 of EFSA's Founding Regulation: EFSA, European Commission and Member States must cooperate to promote the effective coherence between risk assessment, risk management and risk communication. Risk managers in MS can send their request for scientific advices to EFSA and EFSA provides scientific technical support to risk managers through data collection programmes.
- **cooperation of EFSA with risk assessors**: EFSA shall act in close cooperation with competent bodies in the Member States carrying out similar task (Article 22 (7) of the Founding Regulation). The Founding Regulation foresees the creation of dedicated tools to facilitate the cooperation with risk assessors, including the Advisory Forum and Article 36 networks.

The cooperation with **national risk managers** is limited as the main client for EFSA is the European Commission (EU risk manager). Figure 4: Annual mandates and questions received by requestor 2006-2010 recalls the limited number of questions and requests sent by MS to EFSA in comparison with those sent by the EC (108 MS requests vs. 293 EC requests in 2010). NRM often form part of the same institution as NRA, considering the presence of 7 members from ministries (NRM) in the AF.

As regards the cooperation with NRA, in order to exchange information on potential risks and pool knowledge created in MS on risk assessment, the Founding Regulation sets up the Advisory Forum gathering the national food safety authorities in Europe. According to the Founding Regulation (article 27), the primary mission of this Advisory Forum is to ensure close cooperation between the Authority and competent bodies in the MS in particular on the following items:

- avoidance of duplication of the Authority's scientific studies with Member States;
- in case of divergent opinions, where the Authority and a national body are obliged to cooperate;
- in the promotion of the European networking of organizations operating within the fields of the Authority's mission;
- where the Authority or a Member State identifies an emerging risk.

ADVISORY FORUM

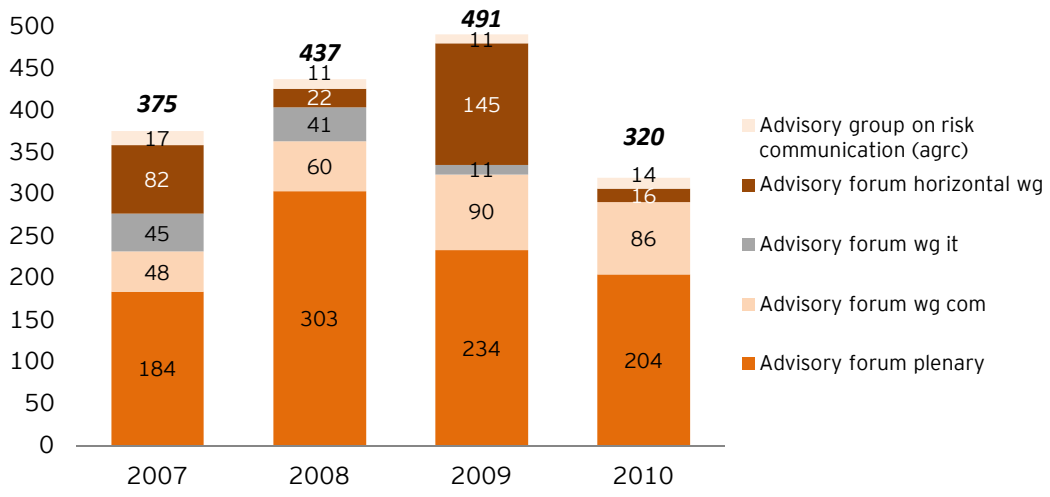
- The EFSA's Advisory forum connects EFSA with the national food safety authorities of:
  - All 27 EU Member States;
  - Iceland;
  - Norway;
  - Representatives from National Food Safety Authorities of Switzerland and of the Candidate Countries and European Commission as observers.
- Members use the Forum to advise EFSA on scientific matters, its work program and priorities, and to address emerging risk issues as early as possible. They have implemented a strategy for closer networking which focuses on sharing scientific information, pooling resources and coordinating work programs. They have committed to
  - Exchange scientific data;
  - Co-ordinate risk communication activities and messages;
  - Address contentious issues and diverging opinions;
  - Set up working groups to focus collectively on specific issues;
  - Co-ordinate work and avoid duplication;
  - The Forum also helps national authorities share information and co-ordinate activities between themselves

(Source: EY elaboration on secondary sources)

Regarding the setting up of advisory forum working group to focus collectively on specific issues, one working group has been set up in the field of communication.

The Advisory Forum is at the heart of the cooperation scheme between Member States and EFSA. The **four meetings per year** give NRA the opportunity to advise EFSA in its activities. The trend of increasing costs of AF activities stopped in 2010 and should further decrease thanks to the decision of organising more meetings in Parma.

Chart 8: Cost of Advisory Forum in K€



(Source: EY elaboration on secondary sources).

In addition to the AF meetings, cooperation between NRA and EFSA relies on additional instruments like **training sessions for experts from National Authorities** (e.g., training program on Food Safety "Better Training for Safer Food" targeting staff from national competent authorities in Member States and Candidate Countries that focuses on risk

management and control), training sessions conducted by National experts coming from National bodies, new rules of the independence policy which are more favourable to the inclusion of National bodies' experts in EFSA's activities. In line with the strategy priorities, these instruments actively contribute to the sharing of best risk assessment practices, the harmonization in methodologies and the promotion of coherence.

EFSA evaluation in 2005 pointed out the need to "develop cooperation/active networking with MS bodies"[163], being the first recommendation listed in the final report. As a consequence, the MB took stock of this recommendation and recommended the development of greater cooperation and networking between EFSA and its counterparts in the Member States as a key priority over the next five years, in June 2006. This recommendation led to the establishment of a **strategy for cooperation and networking between the EU Member States and EFSA in December 2006** prepared by an ad hoc working group set up by the Advisory Forum (in consultation with the Scientific Committee), that, in order to enhance the effectiveness and efficiency of EU risk assessment, led to **the establishment of Focal Points and proposition of cooperation projects.**

The creation of **Focal points** (established in 2006 and made operational in 2008) confirms the importance given to cooperation and networking with Member States. This network acts as an **interface between EFSA and the National Food Safety Authorities,** research institutes, consumers and other stakeholders. They support Advisory Forum Members in the practical implementation of activities related to networking and scientific cooperation and more specifically they[164]:

- facilitate the exchange of scientific information through the Information Exchange Platform (IEP);
- support organizations under Article 36, notably to increase their support to EFSA;
- support the population of EFSA's Expert Database;
- raise the visibility of EFSA's scientific work and EFSA's outreach at national level.

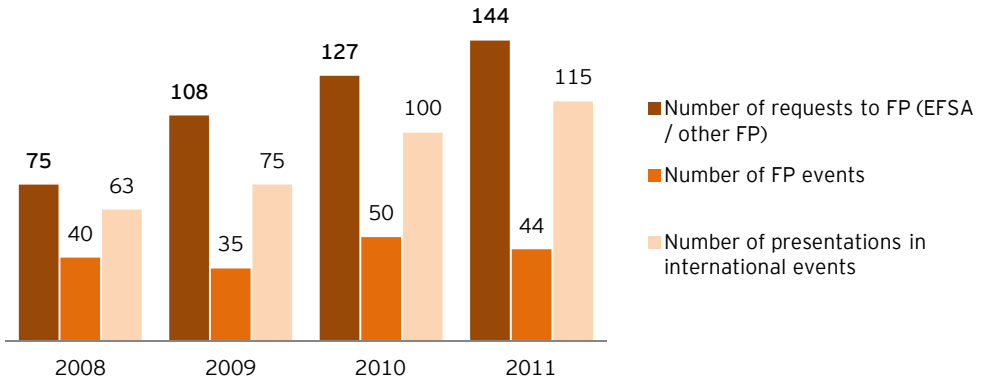
The Focal Point network is composed of one member per MS, generally based in the National food safety authority (NRA) or the National administration in charge of supervising food safety issues (NRM), one member from Norway, one from Iceland, as well as six observers from Switzerland, Candidate and Acceding Countries.

The number of requests sent to Focal Points (by EFSA or other FP) has doubled since its creation in 2008. Over the three years, Focal Points activities were mostly directed **to foster the list of competent organizations and further strengthen these national networks**[165]. In addition they have been encouraging and assisting the organizations in their country to submit proposals for Article 36 calls published on EFSA's website. They have been also active in supporting experts through promotion activities in the form of:

- presentation of the Expert Database at national scientific events;
- distribution of EFSA leaflets on the Expert Database to members of the national Focal Point Networks;
- publication of information about the Expert Database on national Focal Point web pages, newsletters, newspapers or national scientific journals.

[163] Evaluation of EFSA, Final report. Bureau van Dijk Ingénieurs Conseils, with Arcadia International EEIG. 2005.
[164] Focal Point Activities report.
[165] Focal point activities 2011, EFSA.

Chart 9: Evolution of Focal Points activities



(Source: EY elaboration on Focal Points Activities Report 2008, 2009, 2010, 2011)

An interim review of the strategy in 2008 highlighted the positive feedback from MS on the actions implemented under the strategy and the need to further strengthen some of the existing initiatives, notably to harmonize the risk assessment guidance (identified as a high priority by MS). This review also gave the opportunity to identify the need for training expressed by MS, targeting MS with less experience in risk assessment. In early 2011, EFSA issued a new report on the strategy[166], highlighting the importance given to cooperation with MS, in a context of increasing workload for EFSA.

b) EFSA cooperation with the European institutions (European Commission, European Parliament and European agencies)

According to article 22 of the Founding Regulation, EFSA' primary mission is "to provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on all matters within these fields and communicate on risks." In order to fulfil its mandate, it has to work in close cooperation with the European institutions in order to identify the current and future needs regarding the scientific and technical support it can provide for risk analysis.

In the European food safety system, risk assessment is done separately from risk management. The EC, EP and EU Member States are the key risk managers in the EU safety system whereas the Authority is the risk assessor. EC sends their questions and requests on food safety to EFSA that provides an answer based on its own risk assessment. EC is by far the first requestor for EFSA, as the national risk manager requests remained limited in the last years, as previously discussed (see Figure 4). The question of cooperation between the EC and EFSA is crucial in order to adequately respond to EC needs.

EFSA's Founding Regulation provides for close cooperation between Commission's services and EFSA with the presence of Commission' representatives in several bodies, including the followings:

- one representative of the European Commission forms part of the Management Board (Art. 25) with a supervision role;
- EC departments' representatives participate in the work of the AF (Art. 27) to act as an interface between EFSA and MS;
- EC departments' representatives can be entitled to be present in the meetings of the Scientific Committee, the Scientific Panels and their working groups (Art. 28). If

[166] Scientific Cooperation between EFSA and Member States: taking stock and looking ahead (report), EFSA, 2011.

invited to do so, they may assist for the purposes of clarification or information but shall not seek to influence discussions.

For these reasons, EFSA maintains an active collaboration with the European Commission and operates in structured co-operation with the Directorate-General for Health and Consumers. Accordingly, **regular bilateral meetings** take place at all levels of seniority, including between the Executive Director of EFSA and the Director-General for Health and Consumers. An interface unit has been set up in this Directorate-General of the Commission to liaise with EFSA. Its representatives regularly attend key EFSA meetings as observers, including those of the Scientific Committee and Panels, expert working groups, the Advisory Forum and the Stakeholder Consultative Platform. Strong relationships have also been forged with other Commission services including DG Environment, DG Research, DG Enterprise and the Joint Research Centre[167].

EFSA is committed to maintain an active cooperation with the European Parliament, and its Executive Director is regularly auditioned by the Environment, Public Health and Food Safety (ENVI) Committee of the EP to share its expertise on food safety issues. The Executive Director can punctually attend meetings of other committees (agriculture, internal market) when a specific issue falls within EFSA' remits. An EFSA liaison officer serves as a contact point between EFSA and the European Parliament.

Members of the EP are looking carefully at EFSA activities and efforts to promote independence and efficiency: recent examples attest that members of the EP are not yet fully satisfied with EFSA procedures, considering the recent postponement of 2010 discharge for EFSA budget in May 2012: they pointed out excessive Management Board costs (in 2010[168]) and conflict of interests as the chair of the Management Board was reported to have direct links to the food industry, and to be a member of the Board of Directors of the International Life Science Institute (ILSI) – Europe[169] (in the meantime, EFSA announced her resignation the day before Parliament voted).

EFSA has regular contacts also with other EU agencies, as it works with other EU agencies active in closely related fields, by exchanging information and cooperating on matters of mutual interest. In order to reinforce relations with EU agencies working in closely related fields, EFSA signed memoranda of understanding with ECDC (2008), EMA (2012) and ECHA (2009), to foster cooperation in areas of mutual interests, facilitate exchange of information, etc. The current cooperation implies joint production of scientific outputs on topics with shared interests between agencies (Zoonoses, food borne outbreaks, communicable diseases). The majority of joint scientific outputs were issued in cooperation with ECDC.

c) EFSA cooperation with scientific organizations and stakeholders

EFSA scientific activities strongly rely on the participation of external experts through various procedures:

- **recruitment of experts to participate in Scientific Committee and Panels**, every 3 years;
- **recourse to external scientific experts** to assist EFSA Scientific Committee, Scientific Panels, EFSA networks and respective working groups to contribute to EFSA assignments (provision of scientific advice) or assignments to scientific projects;
- **allocation of grants and procurements** to competent organizations in order to support EFSA in the following tasks: data collection, preparatory work for scientific opinions, other scientific and technical assistance.

[167] Source: EFSA web site.
[168] See par. 3.6 "Organization" for further details.
[169] See par. 3.7 "Independence" for further details.

Cooperation with competent organization (Art. 36 list and others)

One of the most important structures EFSA has implemented in order to act in close cooperation with competent organisations in Member States is **Art. 36 Network**. This network is composed of organizations designated by Member States, followed by an assessment of EFSA and a final decision by the Management Board, based on criteria provided in Commission Regulation (EC) No. 2230/2004. According to Art. 36 "the Authority shall promote the European networking of organizations operating in the fields within the Authority's mission". More specifically art. 36 Network shall facilitate in:

- collecting, analysing and sharing specific data in response to a common priority: about 50% of data collection activities are entrusted to Competent bodies, out of the total EFSA data collection activities (list as per Art. 2 Reg. 2230/2004);
- preparing the Authority's scientific opinions, including preparatory work related to the assessment of authorization dossiers: a very low rate (ranging from a minimum of 0,43% in 2008 to a maximum of 6,31% in 2009) of preparatory work entrusted to competent organizations out of the total EFSA preparatory activities;
- preparing the harmonization of risk assessment methods: around 10% of all scientific tasks that are performed during preparatory work are entrusted to competent organizations, out of the total EFSA's preparatory activities.

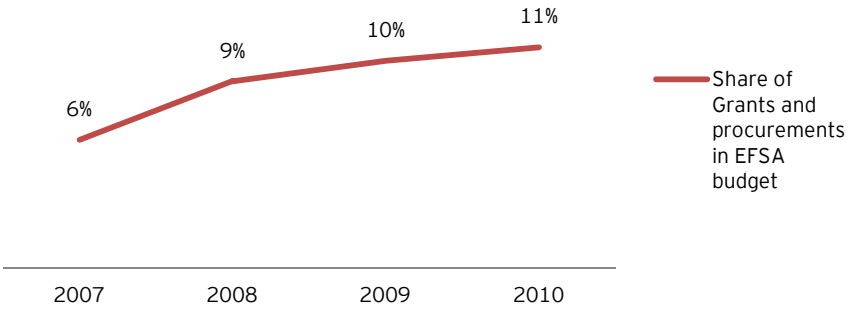
Table 24: Percentage of activities entrusted to competent organizations out of the total EFSA activities

	2007	2008	2009	2010	2011
% of data collection activities entrusted to competent organizations out of the total EFSA data collection activities	18,83%	58,17%	44,39%	48,51%	45,82%
% of preparatory work entrusted to competent organizations out of the total EFSA preparatory activities*	2,75%	0,43%	6,31%	3,36%	3,25%
% of all scientific tasks entrusted to competent organization out of the total EFSA preparatory activities	4,40%	11,73%	12,14%	10,30%	10,22%

(Source: EY elaboration on EFSA's data, 2012)

The share of EFSA budget allocated to grants and procurements has been steadily increasing between 2007 and 2010, from 6% of EFSA total budget in 2007 to 11% in 2010 (Chart 10). This trend of outsourcing more activities is also perceived in other benchmarked agencies (ECHA and FSA).

Chart 10: Share of EFSA budget to grants and procurements



Source: EY elaboration on data from (i) Annual report on Article 36 activities – Follow-up to the 2009 evaluation report of EFSA's grant and science procurement schemes and (ii) financial reports

The list of competent organizations (Art. 36 Network) has been established in 2006 and amended several times since then. Currently the number of organizations that compose Art. 36 network has increased over time arriving at nearly 400 names in 2010[170]. All the 27 countries are represented with a highly variable number of institutions. Italy registers the highest number with 40 competent organizations; United Kingdom is the second provider with 36 designated organizations and Portugal the third with 30. In addition the list of competent organizations is adjusted every two years to meet the needs of the Authority and the Member States[171], also identifying new areas of competence.

Many members of the Scientific Panels, Scientific Committee and Working Groups work for the organizations of the Art. 36 list, but they are not the only ones as pointed out during the 43rd Advisory Forum meeting in March 2012. Composition and participation to the list is increasingly criticized by Member States[172] for various reasons (NRA):

- **Unequal participation**: one of the main criticisms is that a lot of competent organizations are registered in the list but a limited number are effectively involved and sends experts to EFSA. 90 out of 416 have participated in at least one grant or procurement project (2007-2011)[173].
- **Lack of feedback**: EFSA does not always report to Institutions under Article 36 the level and impact of their experts' participation on EFSA's overall performance, even though these institutions renounce to part of their working force to support EFSA. EFSA does not provide any feedback when national institutions are not selected to be part of art. 36 list. For example, 7 Italian institutions passed last selection whereas 13 other ones failed without obtaining explanations from EFSA (NRA).
- **Limited representativeness**: the list does not represent exhaustively the scientific community as there are 105 organizations that send Panel/SC experts that are not on the list. The analysis of the listed organizations reveals the compliance of the list structure with the regulation laying down the detailed rules regarding the network of organizations. Indeed, governmental founding organizations (75% - 100%) represent the highest percentage, in line with article 1 indicating that network organizations must be legal entities pursuing public interest objectives, and their organizational arrangements must include specific procedures and rules ensuring that any tasks entrusted to them by the Authority will be performed with independence and

[170] Annual report on Article 36 activities. Follow-up to the 2009 evaluation report of EFSA's grant and procurement schemes. EFSA, 2011
[171] Review of the work carried out under Article 36 and proposed contract and grant activities for 2009.
[172] As witnessed in the 43rd Advisory Forum Meeting. The Article 36 List. 7-8 March 2012.
[173] Evaluation of EFSA's Science Grants and Procurement Schemes, EFSA, 2010.

integrity[174]. Increasing private funding organizations would bring complex issues of conflict of interest.

To review the role and the functioning of this list, EFSA has proposed the establishment of a Working Group of Advisory Forum members to reflect the review of the list of competent organizations.

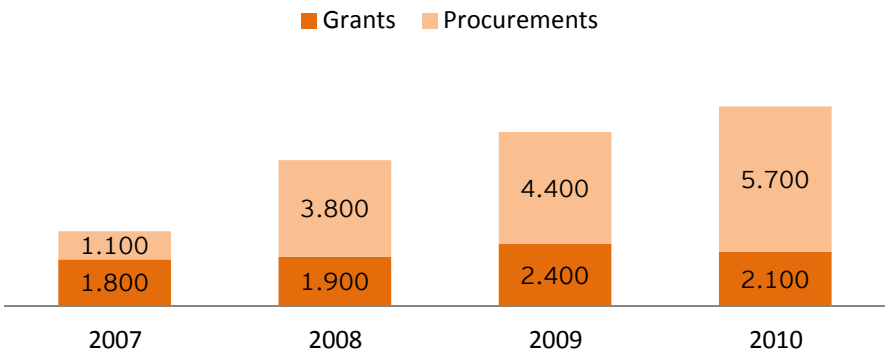
Competent organisations from the list can be awarded grants whereas procurements are open to other organisations. **Grants and procurement schemes** have been implemented in 2007 to carry out scientific cooperation projects with Member State organizations. The overarching objective of these schemes is to support the scientific work of EFSA (see also par. 3.6 "Organization").

Their purposes are regulated by Regulation (EC) 2230/2004 and Article 32 of EFSA's Founding Regulation[175], more specifically[176]:

- support for the examination of authorization dossiers;
- preparatory work for risk assessment;
- data collection and analysis supporting risk assessment;
- horizontal issues and scientific cooperation.

The Authority amount spent for cooperation projects with institutions and organizations in Member States to support EFSA in its scientific tasks has considerably increased between 2007 and 2010 especially for procurements. This statement is similar in comparable EU agencies (ECHA, EMA).

Chart 11: Total amount spent for procurements/agreements and grants in K€, 2007–2010



(Source: Annual report on Article 36 activities – Follow-up to the 2009 evaluation report of EFSA's grant and science procurement schemes)

In 2007 dedicated resources were €2.9 million, in 2010 they reached €7.8 million (for 2011 EFSA planned to spend almost €8.3 million). It is important to note that for grant projects a financial contribution is provided by the awarded organizations with a minimum of 20% of the

[174] Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organizations operating in the fields within the European Food Safety Authority's mission

[175] In addition grant and procurement projects are planned on the basis of an Annual Work Programme and are implemented through calls relating to specific tasks. The planning activity for grants and procurements usually takes place the year before its implementation and follows a cycle in which:

- the scientific and budgetary needs for grants and procurement are identified by the EFSA scientific committee, scientific panels and units (preliminary plan);
- the EFSA Advisory Forum and Scientific Committee are consulted on the preliminary Work-Programme to identify priorities and avoid duplication (intermediate plan).

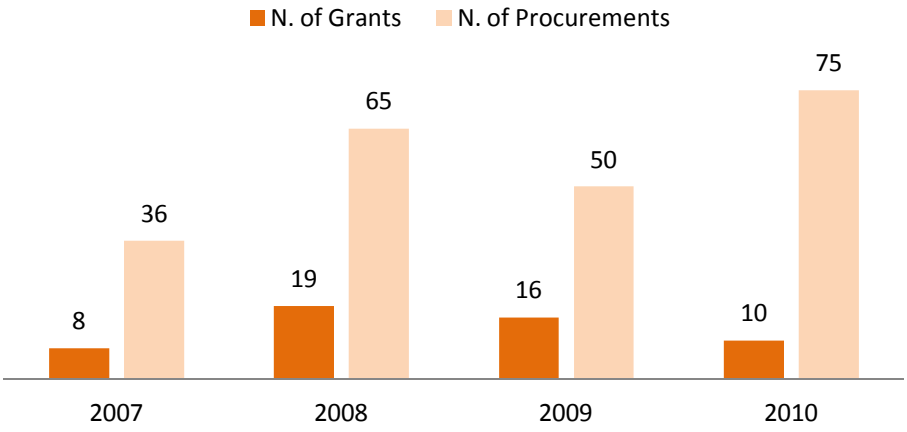
The final Work-Programme is proposed for adoption by the EFSA Management Board.

[176] Follow-up to the 2009 evaluation report of EFSA's grant and science procurement schemes, 2011.

total project costs. Taking this contribution into account, the total budget allocated to grant projects further increases by a factor of at least 1.25 to a total of € 8.4 million.

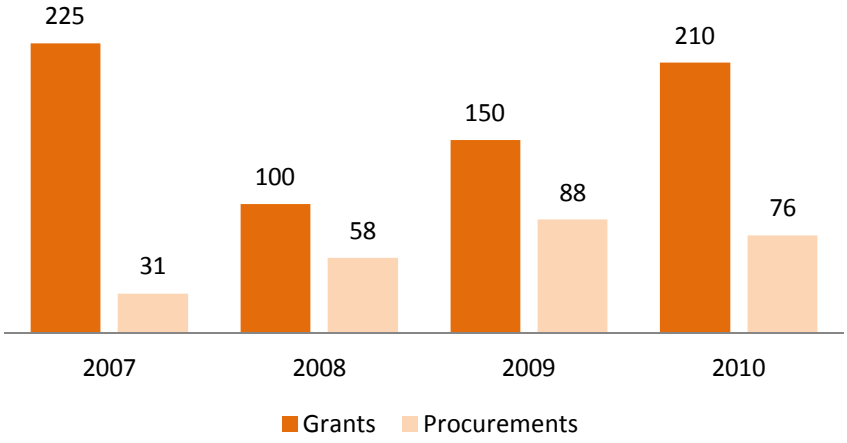
In the past few years the total amount of EFSA workload has increased[177] mainly in the number of procurements.

Chart 12: Number of grants and procurements



(Source: EY elaboration on EFSA's Science Grants and Procurement Schemes)

Chart 13: Average amount for a single grant/procurement in K€



(Source: EY elaboration on secondary sources)

The evaluation of EFSA's grants and procedures schemes pointed out that, despite the improvements registered, some elements still seem to limit Member State organizations capacity to participate in grant and procurement projects and the application rate of Members State organizations is still limited (14% of grants between 2007 and 2009 remained unsuccessful[178]) even if these activities are recognized by the majority as a good strategy to cope with the increasing Authority's workload. Their level of openness is still questioned because of[179]:

- the difficulty to find partner organizations within the timing of a call;

[177] Follow-up to the 2009 evaluation report of EFSA's grant and science procurement schemes. 2011.
[178] Evaluation of EFSA's Grants and Science Procurement Schemes, 2009.
[179] Annual Report on Article 36 activities. Follow up to the 2009 evaluation report of EFSA's grant and science procurement schemes, 2011.

- the complexity of the application process;
- the limited knowledge and communication of this scheme towards Member States;
- the maximum ceiling of overheads too low as well as EFSA share of co-financing;
- the rigidity of the instruments which involve participants in a high administrative burden;
- the complexity and length of the designation process of competent organizations by Member States and their subsequent evaluation by EFSA.

The drawbacks and the limits of these programmes could also explain the constant and significant difference between appropriations and commitments regarding Grants and procurements (e.g., in 2011 85% committed).

Despite the measures adopted by the Authority to improve the efficiency and effectiveness of this programme[180] a lot of work is still to be done. The analysis of the recommendations coming from previous evaluations reveals some difficulties of EFSA in the implementation of the programme. The main critical issues are constantly repeated over the years. Some improvements demonstrate, however, the engagement of the Authority to better plan and simplify the implementing rules of the programme[181]:

- setting of a minimum budget for grants at €60,000;
- increasing the use of multi-annual and framework contracts;
- introducing medium-term planning;
- updating the guidance and training provided to application;
- foreseeing calls on the website and increasing the time available for applicants to apply to EFSA calls.

Cooperation with EFSA networks

Established in 2010[182], **EFSA Networks are 12 nationally appointed groups of EU Member State organizations with expertise in specific fields**, which aims at contributing to the scientific cooperation. Networks are created by EFSA in consultation with the Advisory Forum and Scientific Committee to work on specific areas within EFSA's remit. They shall be dissolved as soon as the remit has been completed[183]. The specific level of openness in this case should be referred to the capacity of involving the best expertise without prejudice towards particular countries or institutions.

Networks are chaired by EFSA and supported by the relevant EFSA Unit. Their aim is:

- coordinating activities;
- exchanging information;
- developing and implementing joint projects;
- exchanging expertise and best practices.

13 networks are active in 2012 on 9 different areas (Animal health and welfare, Biological hazards, Dietary and Chemical Monitoring, Emerging risks, GMO, Plant health, Pesticides, Scientific Committee, Biological Monitoring).

Tools to enhance cooperation : the Information Exchange Platform and the Expert Database

[180] In 2009, the Authority carried out the first evaluation of the grants and procurement schemes to assess the efficiency and the effectiveness of the process for the years 2007-2009. In 2011 a follow up was released and the review was extended to the years 2009-2010.
[181] Follow-up to the 2009 evaluation report of EFSA's grant and science procurement schemes, 2011.
[182] Rules of Procedures of EFSA Networks.
[183] Decision concerning the establishment and operation of European Networks of scientific organization operating in the fields within the Authority's mission, MB 18-03-10.

In the last few years, EFSA has implemented two IT tools to enhance the cooperation and networking among Members States and the European Commission:

- The Information Exchange Platform;
- The Expert Database.

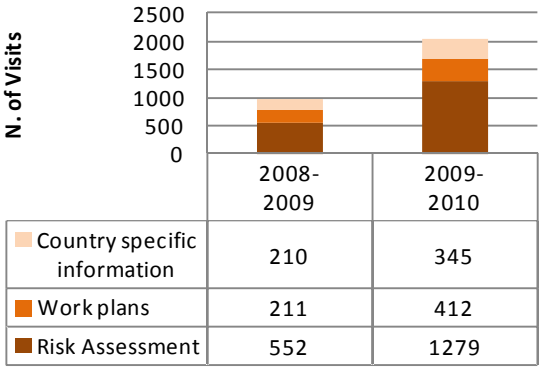
As anticipated in the previous paragraphs, the **Information Exchange Platform** is an extranet website created in 2008 to provide a platform for the Advisory Forum/Focal Point members and EFSA to facilitate the exchange of risk assessment outputs undertaken by official bodies in the different Member States. In addition, the site allows linking a risk assessment mandate/request to its outputs thereby providing details on the process of a risk assessment.

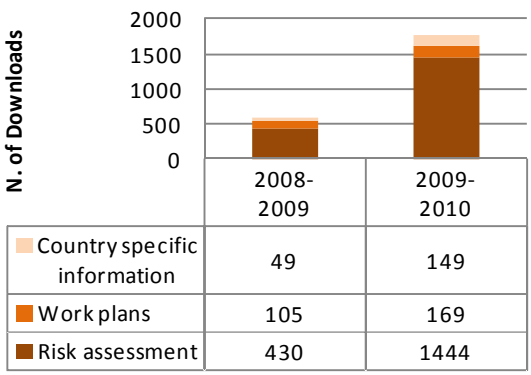
A 2010 evaluation of the Internal Exchange

- sharing risk assessment activities or outputs. Platform[184] outlined that the main uses of the Platform are:
- keeping informed on risk assessment activities or outputs in a particular scientific area and/or other countries.

Although the IEP was only launched three years ago, it has already been positively received and has the potential to enhance the exchange of risk assessment activities between Member States and EFSA. More specifically, the Platform since its creation has registered a number of visits that has steadily increased since its launch, most notably when access was broadened to: Advisory Forum (2009), Scientific Panels (2009) and Networks (2010).

Chart 14: Number of IEP visits and downloads per section





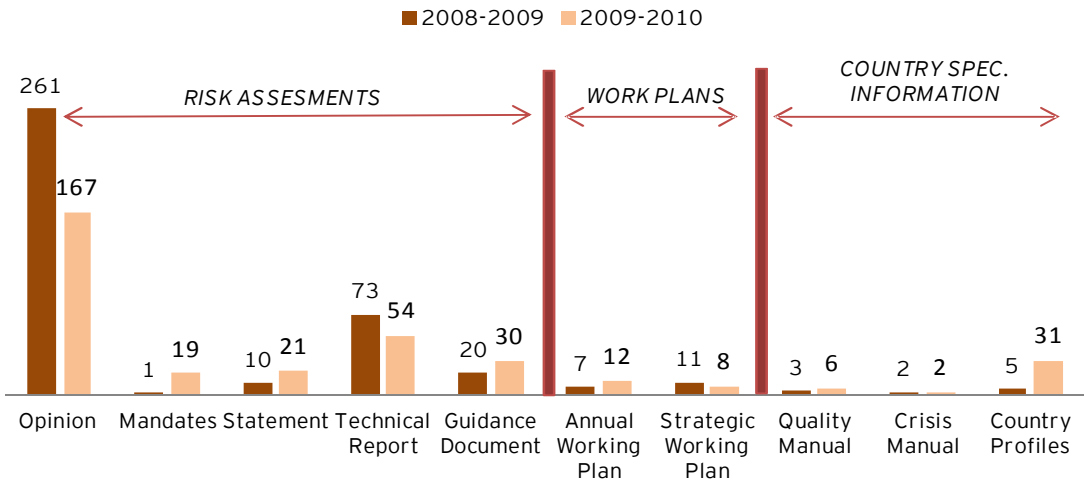
(Source: EY elaboration on data of IEP Evaluation Report)

Visits to the homepage have shown an increase from both readers and EFSA's staff over the past two years. Focal Points and Advisory Forum members showed[185] the highest percentage of active use of the IEP site. The overall main purpose identified for using the IEP was to keep informed on risk assessment activities in a particular scientific area. The risk assessment section is the most viewed and downloaded section and the monthly reports are viewed as the most important feature of the IEP. Feedback from users shows that further dissemination of the monthly reports and broadening access to the site would be beneficial. In addition a number of improvements to the site were identified and need to be addressed. These include the search function and features to download and view documents.

[184] In 2010 the Working Group on the Information Exchange Platform was asked to evaluate the first two years of the platform, with particular attention to assess its usability. In 2011 main findings came up in the evaluation report: Information Exchange Platform (IEP) Evaluation Report.
[185] Information Exchange Platform (IEP) - Evaluation Report, EFSA, 2010.

Every section almost doubled the number of visits[186]. The Risk Assessment section, which stores documents on risk assessment outputs and requests, is the most visited[187] and documents included in this section are the most downloaded followed by the sections "Work Plans" and "Country Specific Information". Total downloads almost tripled during the two year activity.

Chart 15: Number of IEP uploads per section



(Source EY on data of IEP Evaluation Report)

Cooperation with experts from the database

Launched in 2008, experts can apply to be part of **the expert database** that gathers external experts that are willing to contribute to EFSA assignments. Every time EFSA needs the support of external expert, it will use the database to identify the profiles that match the requirements, contact them to check their availability and interest in participating in the assignment. They receive a compensation for travel and subsistence and an indemnity for their contribution.

The database currently holds information on 2.597 experts (of which 645 included in 2010).

Table 25: EU and EEA/EFTA experts' geographic distribution

COUNTRY	# OF EXPERTS	COUNTRY	# OF EXPERTS
ITALY	346	UNITED KINGDOM	332
GERMANY	253	FRANCE	193
NETHERLANDS	171	SPAIN	160
BELGIUM	101	DENMARK	87
GREECE	76	SWEDEN	73
AUSTRIA	73	PORTUGAL	59
IRELAND	56	FINLAND	53
SWITZERLAND	49	NORWAY	48
ROMANIA	45	POLAND	34
BULGARIA	33	HUNGARY	31
SLOVAKIA	27	SLOVENIA	25
CZECH REPUBLIC	21	LITHUANIA	14

[186] As specified by the Evaluation Report it should be considered that the number of visits to the site is underestimated. Data on visits were only taken from those who access the IEP from the homepage. The site can also be accessed from other routes i.e. through the monthly report links or a document link, therefore, it is likely visits to the site are higher.
[187] Information Exchange Platform (IEP) - Evaluation Report, EFSA, 2010.

COUNTRY	# OF EXPERTS	COUNTRY	# OF EXPERTS
CYPRUS	9	LATVIA	6
LUXEMBOURG	6	MALTA	6
ESTONIA	5	ICELAND	1
OTHERS	204		

(Source: EY elaboration on Expert Database 2010 Annual Report of Activities)

By the end of 2010[188], **experts from 60 different countries were included** in the Expert Database, and all the Member States and European countries have been represented, with the single exception of Liechtenstein, along with 30 third-countries. Experts from these third countries amount to 7.9% of all included experts. Italy, United Kingdom, Germany, France, Netherlands and Spain are the countries presenting the highest number of experts, corresponding to 56% of all included experts.

Table 26: Non-EU and non-EEA/EFTA experts geographic distribution

COUNTRY	# OF EXPERTS	COUNTRY	# OF EXPERTS
UNITED STATES	71	CANADA	27
TURKEY	20	CROATIA	11
SERBIA	10	NEW ZEALAND	10
AUSTRALIA	9	ISRAEL	6
THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA	6	INDIA	4
SOUTH AFRICA	3	CHINA	3
RUSSIAN FEDERATION	2	CUBA	2
JAPAN	2	THAILAND	2
MOROCCO	2	ARGENTINA	2
SAUDI ARABIA	1	PAKISTAN	1
MEXICO	1	UKRAINE	1
EGYPT	1	CHILE	1
BRAZIL	1	BOTSWANA	1
BANGLADESH	1	ALBANIA	1
URUGUAY	1	SUDAN	1

(Source: Expert Database 2010 Annual Report of Activities)

With regard to non-EU countries, United States, Canada and Turkey are the best represented in the Expert Database with 57.8% (i.e., 34.8%, 13.2% and 9.8% respectively). Candidate countries (Croatia, Former Yugoslav Republic of Macedonia and Turkey) are relatively well represented as third countries, amounting to approximately 20% of all third countries' experts.

Experts recorded in the database belong to **different fields of expertise** to support EFSA in the development of opinions for main areas of expertise that fall within EFSA's remit. According to the Expert Database 2010 Annual Report of Activities experts, are distributed among the following areas of expertise:

- new technologies (12,4%);
- plant health (15,8%);
- genetically modified organisms (19,9%);
- food production and food supply (22,3%);
- toxicology (22,7%);

[188] Expert Database 2010 Annual Report of Activities.

- feed (23,3%);
- exposure assessment (23,6%);
- plant protection products (27,5%);
- animal production, health and welfare (28,5%);
- biological hazards (29,8%);
- food including nutrition (53,6%);
- other areas – general areas e.g., food safety, statistics, agronomy, etc (63,7%).

The most common areas of expertise are the generic area, food including nutrition and biological hazards. In addition the main areas of expertise observing higher growth rates during 2010 (i.e., a higher increase on the proportion of experts selecting such expertise as compared to their proportion by end of 2009) were "Plant Health" (2.4% increase), the so called "Other Areas" (1.4% increase) and "Exposure Assessment" (1% increase).

3.4.2.2 Stakeholders' point of view

a) EFSA cooperation with institutional stakeholders in Member States (National risk assessors and risk managers)

Globally, EFSA's efforts to promote coherence between risk assessment, risk management and risk communication are well-perceived (79% of respondents give a rating equal or higher than 3 in the online survey – EC, NRA, NRM, Q9.1). In particular, EFSA guidelines are coherent with national risk assessment methodologies for 86% of NRA (Q9.2). Nevertheless, despite the high number of instruments developed by EFSA to cooperate with institutional stakeholders (NRM, NRA, EC, EP), the complexity and fragmentation of the European Food Safety system make cooperation being one of the main present and future challenges repeated in nearly all the meetings, according to a high number of stakeholders (notably NRA). NRM are used to firstly rely on their own risk assessment system when it is effective.

From the National Risk Assessors' point of view, the AF functioning is quite satisfying: 91% of them (Q9.4) declare that they benefit from taking part to the EFSA Advisory Forum when they deal with specific requests from their national risk managers and 74% of them recognize (NRA, Q9.5) **the AF as a facilitator to share work programs outputs, risk assessment practices or methodologies**.

This point of view is shared by 66%[189] of all respondents who declare that EFSA benefits from the presence of the AF (EC, NRA, NRM, Q9.8). Nevertheless, there are still areas of improvement to ensure better effectiveness and efficiency. When AF activities are evaluated separately (Chart 16), about 30% of respondents (EC, NRA, NRM, Q9.9) ask for improvements in four main areas:

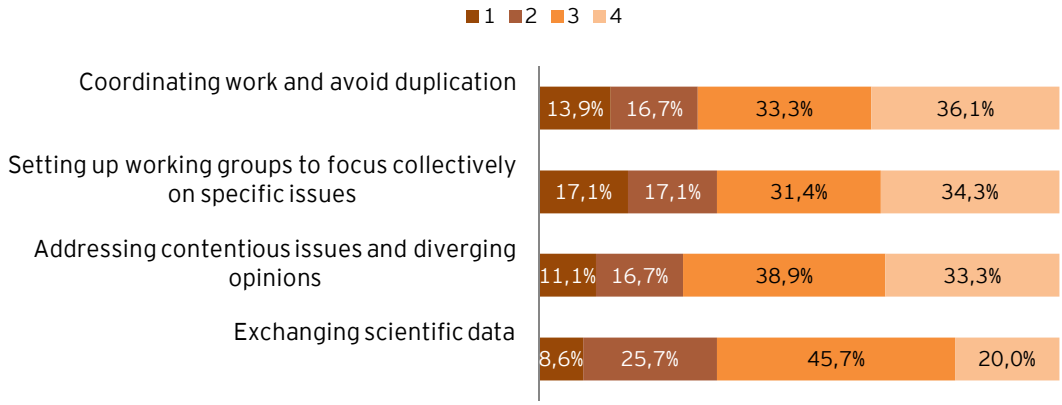
- **The coordination of work to avoid duplication**: there are still duplications of work between more experienced national risk assessment agencies[190] and EFSA mainly because, in the areas where the competencies are not yet centralized some NRA continue to do their own assessments upon NRM requests. Agendas and respective work plans are not totally shared. The Focal point network is a key to improve this axis. The AF could also help NRA defining common priorities at the European level to develop joint activities.
- **The development of working groups to focus collectively on specific issues**: 34% of the respondents do not consider the AF as effective on these specific topics.
- **The resolution of controversial issues and divergent opinions**: the AF reinforces the

[189] NA included.
[190] Recent examples with Isoflavones or Biosphenol A.

dialogue between MS and EFSA both on risk assessment methodologies and specific case studies but it is sometimes difficult within the AF to find a convergent solution because of differences of expertise between NRA.

- **The exchange of scientific data** between and among MS and EFSA has been intensified (notably through Focal Points and the Information Exchange Platform) (NRA), but efforts should continue to ensure the best quality and reliability of data.

Chart 16: Level of satisfaction on the effectiveness of the Advisory Forum



(Source: EY survey)

The different seniority of participants at the AF (from top managers to staff) as well as **the high diversity of their expertise seems to limit the quality of the plenary discussion** where some interests dominate (i.e., from largest Countries with a strong internal expertise). The benefit NRA get from EFSA varies with countries' expertise. EFSA should consider this difference of expectations between NRA and develop a more tailored approach to better address all expectations.

The cost of the Advisory Forum should decrease with the decision to organize all meetings in Parma, although some stakeholders fear that this decision may bring drawbacks for cooperation and networking among NRA (Scient. Org.).

Nonetheless about 48% of respondents NRA (Q9.3) declared in the survey that they had **situations of misalignment with EFSA's advice** (see par. 3.3 "Risk Communication" for further details). When EFSA and national agencies publish or express divergent opinions, the divergence must be well-managed by EFSA in order to avoid confusion of citizens and industries that can conduct to a lack of trust in EFSA's outputs. (FIR)

On this aspect, cooperation with MS carrying out similar tasks is really perceived as essential: sharing and alignment of work plans as well as definition of common priorities between NRAs at the European level to develop joint activities shared with EFSA should be further developed (EP, NRM).

Focal points are perceived as a very important network (NRA, Scient. Org.) to ensure a good channel of communication between EFSA and EU Countries. Through Focal Points and the AF there is a strong exchange of scientific information and opinions; namely, the Information Exchange Platform (IEP) is very useful to develop better food risk assessment, as each MS can be better informed on similar risk assessment activities in a particular scientific area in Europe by consulting information shared on the platform. Nevertheless, Focal Points' degree of connection to EFSA depends on the Member State and the field of expertise.

b) EFSA cooperation with the European institutions (European Commission, European Parliament and European agencies)

The quality of communication with the EC is recognised and considered as a strong asset to guarantee EFSA's effectiveness in addressing EC requests (EC). EC representatives in EFSA events play a strong role in recalling the legal framework of EFSA to make them focus on the activities of its remit, even though some stakeholders (NRA, MB) think that the EC should be less present.

The cooperation with the EP has improved recently thanks to the efforts made by EFSA on transparency and openness. EP criticisms towards EFSA are generally in line with those coming from civil society: clearer independence management rules and more transparency on the decisions taken. The regular bilateral meetings between EFSA and the Environment, Public Health and Food Safety committee (ENVI) tend to improve the quality of cooperation between both institutions. EFSA now has close contacts with EP members that contribute to improving its image.

However, considering the recent events (postponement of 2010 discharge for EFSA budget in May 2012), additional time is needed for Members of the EP to trust EFSA as an independent scientific opinions' provider.

EU Institutions (EP, EC) underline the necessity for EFSA to **better cooperate with other EU Agencies**, including EMA, ECHA and ECDC to deliver to the EC and the EP more transversal approaches on emerging issues. Stakeholders do not have a clear view on the separation of tasks between agencies (IOs), pointing the fact that additional efforts are required to clarify the landscape for external stakeholders.

c) Cooperation with competent organization (Art. 36 list and others)

Member States pointed out the difficulty for their experts (art. 36 experts as well as experts from food safety authorities) to be involved in EFSA's activities (NRA, MB, EP). Independent scientific experts that compose Panels have a major role in EFSA's activity but National Authorities and research institutions, which provide experts point out the issue of sharing resources. The more experts spend time on EFSA's activities, the less they have time to do their usual work for their original institutions. There are also important differences of workload for Panel members among Panels. It is important that the time spent by experts of the panel is optimized in order to concentrate the time they spent for EFSA on added value activities. Additional preparatory work and restitution could be further handled by EFSA's staff with a high technical experience to limit panel members' contribution to added value activities (EP, NRA, Scient. Org.).

Scientific organizations pointed out that they would like to have a return benefit when contributing to EFSA (data sharing or preparatory work). The use of data by MS is not fully operational so far.

The role of network is unclear for stakeholders (Scient. Org): their added value in comparison with Focal Points is not clear. The multiplication of networks can hamper the effectiveness of cooperation.

The Information Exchange Platform is also perceived as a useful instrument of exchange of information (NRA, Focal points) and best practices as witnessed by the increasing number of documents among stakeholders over the years.

3.4.2.3 Analysis of evidences

a) EFSA cooperation with institutional stakeholders in Member States (National risk assessors and risk managers)

Cooperation with MS relies on a wide portfolio of instruments but still represents an ongoing concern for stakeholders and a clear sharing of responsibilities with EFSA is not yet achieved, partly due to weak work programme sharing and communication.

The **cooperation of EFSA with risk managers** is differentiated if looking at NRM or the EC: **while cooperation with NRM** is limited, the one with the EC is more developed: this seems to be related to the fact that the number of requests or questions they receive from MS is low if compared with those received from the EC and NRM often rely on their own national food safety authority to address their needs.

Cooperation with NRA has increased over time, even if the balance on share of work between EFSA and MS is still to be found and a need to maintain efforts to strengthen rapprochement between EFSA and NRA emerges especially from stakeholders. Cooperation has increased also thanks to the AF and the Focal Points, that directly contribute to foster exchange of information (facilitating the sharing of work programmes, practices and methodologies, etc.), but some issues related on the effectiveness and efficiency of this cooperation emerge from the evidences collected:

- the AF is not completely effective in avoiding duplications and the possibility to set up working groups to focus collectively on specific issues (only one group has been set up on the issue of communication) is limited;
- the Focal Points effectively contributed to developing communication between EFSA and NRA, to the sharing of information and to the promotion of EFSA activities that require active MS participation (i.e., grants, procurements and experts' contribution): Their activity has indeed almost doubled since 2008 and is considered to be a complement of the AF.

b) EFSA cooperation with the European institutions (European Commission, European Parliament and European agencies)

Evidences collected show that the cooperation between **EFSA and the European Commission** is effective, thanks to regular formal and informal contacts between both institutions. Although from an external stakeholders' perspective, the frequent exchange of information could be seen as a lack of independence between risk assessment and risk management, the presence of the EC is considered as essential to help to EFSA better fulfil its mandate and to help the EC better anticipate on future legislative work and facilitate the process of risk assessment.

With regard to the European Parliament, there is a shared feeling among EP members, external stakeholders and EFSA that the cooperation has strongly evolved in the recent years, due to the commitment of the Executive Director to better address their needs as well as develop a dedicated liaison officer at EFSA with the EP. However, EP members are still very cautious about trusting EFSA in order to encourage independence and reliability.

EFSA is committed to foster **cooperation with EU agencies as** illustrated by the signatures of memoranda of understandings with EMA, ECHA and ECDC, but the perceptions of stakeholders attest that the cooperation is not yet fully effective and requires additional efforts so that stakeholders have a clear understanding of the tasks separation between agencies.

c) Cooperation with competent organization (Art. 36 list and others)

Evidences show that, despite the work done by the Focal Points to communicate with competent organizations (Art. 36 or individual experts), EFSA networks established in 2010

and the increased outsourcing of data collection and preparatory activities (e.g., EFSA's expenditures dedicated to grants and procurements have almost tripled between 2007 and 2010), the cooperation with these organisations is not fully operational. The composition of the art. 36 list is criticised regarding the effective participation of members (less than 25% of the registered organisations in the list of competent bodies (Art. 36) have been involved at least once in the process), the limited representativeness and the lack of feedback for MS. The percentage of unsuccessful calls for grants (14% between 2007 and 2009) illustrates the lack of efficiency in the process. To facilitate involvement of research organisations, ECHA has implemented framework contracts to speed up the process to involve external organisations in their activities, once the contract is open.

Recently, new decisions have been taken by EFSA to demonstrate the willingness to foster this kind of cooperation. The new implementing rules of the Policy on independence 2011 go in this direction, lightening the conditions for Food Safety Organizations to participate to EFSA's activities. The results are still to be observed.

Considering the limited comments on the quality of cooperation with research organisations and experts, there is a clear need to improve the provision of feedback to organisations and MS that send experts working for EFSA. There is an issue concerning the resources sharing between EFSA and research organisations or national authorities.

3.4.2.4 Evaluation results

66%[191] of respondents (EC, MB, Scient. Org., *Q9.11*) recognize the high quality of the support (in terms of expertise) provided by MS Agencies to EFSA's work. Nevertheless interviewed people have pointed out some criticisms and underlined areas of improvement for cooperation and networking.

Globally EFSA's scientific cooperation system is effective.

The quality of the **cooperation of EFSA with the EC** is good, and even if the EC involvement in EFSA's activities may be perceived negatively by some external stakeholders, the presence of EC's representatives to EFSA meetings, as per the Founding Regulation, is essential to help EFSA better fulfil its mandate and to help the EC better anticipate on future legislative work. They participate to bilateral meetings and are involved in EFSA's activities (presence in the MB, participation in AF meetings and frequent participation in panels and scientific committees' meetings).

Cooperation with MS relies on a wide portfolio of instruments but still represents an ongoing concern and a clear sharing of responsibilities with EFSA is not yet achieved, partly due to weak work programme sharing and communication. The stable level of requests sent by MS reflects their difficulty to entrust EFSA instead of their national agencies (if any). The sharing of responsibilities between national agencies and EFSA is often listed as a main challenge for EFSA by interviewed stakeholders.

The cooperation with MS is based on the use of networks contributing to EFSA's activities:

- The Advisory Forum is a facilitator to share work programmes outputs, risk assessment practices and methodologies for the NRA. The previous evaluation pointed out the limit of the AF meetings and underlined the need to develop additional tools to foster cooperation between EFSA and MS.
- The appointment of a network of Focal points in all MS in 2006 effectively contributed to developing communication between EFSA and National Food Safety Authorities and to the sharing of information. Focal points have been actively involved in the

[191] NA included.

promotion of EFSA activities that require active MS participation (grants, procurements and experts' contribution). The activity of focal points almost doubled since 2008 (sent requests and participation to events – see Chart 9: Evolution of Focal Points activities) reflecting the utility of these networks. They appropriately complement the existing tools according to stakeholders.

- The outsourcing of activities to Article 36 organisations or individual experts in MS has significantly increased in the recent years (e.g., EFSA's expenditures dedicated to grants and procurements have almost tripled between 2007 and 2010, see Chart 10). They are actively involved in data collection activities and preparatory activities (preparatory work and scientific tasks – see Chart 3).

There are though some areas of improvement to ensure better effectiveness and efficiency in the coordination of work:

- *The situations of misalignment*: situations of misalignments are still pointed out by stakeholders, including duplication of work on specific national sensitive issues (the strong links between NRA and NRM still limit the number of requests directly sent to EFSA by NRM) (see par. 3.4.2.1).
- *The procedures to involve external expertise*: they must be adjusted in order to improve the effectiveness of external experts' contribution, notably through the increase of application rates to procurements, the diversification of participants and the renewing of the pool of expertise. 14% of the procurements remain unsuccessful between 2007 and 2009 and less than 25% of the registered organisations in the list of competent bodies (Art. 36) have been involved at least once in the process (see par. 3.4.2.1).

The use of AF advice and assistance can be improved to be more efficient.

Stakeholders underlined the need to further improve the use of AF advice. Four main areas have been identified to improve EFSA use of AF:

- the definition of common priorities and sharing of work programme among AF members to improve coordination of work and avoid situations of misalignments;
- a stronger use of the possibility to set up AF working groups to focus on a specific issue;
- a harmonization of AF members expertise to facilitate the resolution of contentious issues associated to targeted trainings;
- efforts to promote the best quality and availability of scientific data.

The actual system for cooperation and networking is adequate also considering the high quality of the support (in terms of expertise) provided by MS agencies to EFSA's work.

The quality of scientific outputs relies on the contribution of experts sent by the MS. MS with stronger risk assessment capacity are perceived to participate more significantly to the EFSA's decision-making process. This is confirmed by the over representativeness of a few Member States in the expert database (see Table 25): Italy, United Kingdom, Germany, France, Netherlands and Spain are the countries presenting the highest number of experts, corresponding to 56% of all included experts. A more balanced contribution between MS is required to adequately involve national expertise.

Considering the reliance of EFSA on external expertise, the professional attractiveness of EFSA is a key aspect to ensure sustainable quality of work. The careful monitoring of EFSA's professional attractiveness will contribute to maintaining a high level of expertise within EFSA.

3.4.3 Added value of EFSA for national food safety authorities

3.4.3.1 Facts & Figures

The number of EFSA's mandates received by Member States to perform risk assessments has doubled between 2007 and 2008 and remained steady (about 100 mandates/year) since 2008.

Table 27: Number of EFSA solicitations by Member States for risk assessments

	2006	2007	2008	2009	2010	2011
Number of mandates from MSs	38	51	114	88	108	93

(Source: EY elaboration on EFSA's data, 2012).

WORK SHARING BETWEEN EFSA AND NATIONAL AGENCIES

Not all MS have their own food safety agency, limiting the risk of duplication. FSA is very clear about avoiding doubloons in work sharing: they will not work on a specific issue if EFSA does.

ECHA is one step further in the relation with national agencies: they are now experiencing the alignment of work programmes. Divergent opinions are handled during committees. This closer relation must also be linked to the way ECHA involves external experts, as per its Founding Regulation. ECHA committees are composed by national experts appointed by MS. In this regard, ECHA experts act as MS rapporteurs whereas EFSA relies on independent experts.

3.4.3.1 Stakeholders' point of view

As regards the **impact of EFSA's activity on national risk assessors**, 29% of respondents (NRA, Q9.12) consider that EFSA activities did not always lead to a reduction in the number of risk assessments across EU (rate lower or equal 2 out of 4). Indeed, the number of EFSA's mandates received by Member States to perform risk assessments has doubled and remained steady (about 100 mandates/year) since 2008.

One of the reasons for that is the historical links between NRM and NRA: NRM are used to send their requests to NRA rather than to EFSA, as shown by the number of mandates they receive from MS below. **Some mechanisms could help incentivizing NRM to directly send their request to EFSA when relevant**. However, sometimes the weak communication between EFSA and National Authorities before the launch of a scientific workflow for the delivery of an opinion has been responsible for duplications (e.g., Isoflavones, NRA).

A few stakeholders are willing to see EFSA, in a mid-long term, to act as the unique European Food Safety Agency whereas National Bodies would act as regional food controllers (EP, FIR). The introduction of a common European strategy would considerably facilitate the cooperation between MS. The precise role of EFSA and the National Agencies' contribution to EFSA must be discussed to reach this goal.

77% of national risk assessors and risk managers (Q9.13) consider that their National Food Safety Authority benefits from EFSA's activities in terms of **costs**: due to EFSA inputs and sharing of expertise as well as operational support (risk assessments, communication support, methodologies and trainings), national authorities can reduce some of their expenses. For

example, costs related to finding the best methodology are reduced. However, a 23% share considers that EFSA's activities do not benefit to their agencies' costs.

The impact on National Agencies' budget and activities highly depends on the Agency's expertise. For countries where there is no Risk Assessment Agency, the impact of EFSA is significantly positive (it develops works that the country would not be able to develop alone). For larger western countries, the impact is controversial and sometimes brings duplication and an increase of work to "translate" EFSA's opinions to a national level to support risk managers.

EFSA sometimes causes a problem to the efficiency of National Authorities because it engages National Authorities' experts (NRA), even for 50% of their time. They are paid by National Authorities, but with increased time spent for EFSA that only provides travel and subsistence costs and a fee for participation.

3.4.3.2 Analysis of evidences

Several figures underline the need to stress the added value of EFSA for national food safety authorities: the stable number of mandates sent by MS, the 23% of respondents declaring that EFSA did not lead to a reduction in costs in the national food safety authorities, the 48% having experienced situations of misalignments, etc.

According to stakeholders, the reduction of costs has been observed on certain activities (finding methodologies, communication support, trainings) but the core activities (risk assessment) have not necessarily decreased. Although there are no proofs on the evolution of costs for national authorities, opinions converge to state that for MS with stronger risk assessment capacities, the creation of EFSA brought additional costs for the national authority (notably due to internal experts' contribution to EFSA and translation of EFSA's opinions to a national level).

The alignment of work programmes implemented at ECHA is a satisfying tool to improve coordination between national food safety authorities and ECHA and reduce the risk of duplication of work. Stronger efforts to facilitate the alignment of work programmes would benefit to the added value of EFSA in comparison with national agencies.

3.4.3.3 Evaluation results

National food safety authorities benefit from EFSA's activities in terms of streamline of expenditures.

MS declare that their expenditures related to finding best methodologies, communication support or trainings have been reduced in national food safety authorities (see par. 3.4.3.1).

However, the benefits vary from one MS to another. The impact of EFSA on National Agencies' expenditures highly depends on MS risk assessment capacities:

- for MS with limited own internal risk assessment capacities, EFSA provides an activity that they would not provide by themselves;
- for MS with strong internal risk assessment capacities, EFSA's activities are perceived to bring additional costs through the involvement of internal staff on EFSA's activities as well as entailing translation of EFSA opinions to a national level.

3.5 International role and recognition

3.5.1 Introduction to the results for thematic area of evaluation

This part aims at assessing the role of EFSA in Europe and at international level and the recognition and involvement of the Authority in the scientific community. Three aspects are analyzed: the international role of EFSA, its international recognition from a European and international point of view and the professional attractiveness of EFSA for international experts (both Europeans and international), as a sign of recognition.

This area of evaluation relates to the following evaluation criteria:

- **Scientific quality and sustainability** the main questions being whether *i)* EFSA is involved in the international scientific community, *ii)* events organized by EFSA contribute to the exchange of scientific data and information, *iii)* the participation of EFSA to international events contribute to sustain the quality of its scientific outputs.
- **Added value** the main questions being whether *i)* Member States trust EFSA risk assessment system, *ii)* EFSA is internationally recognized and *iii)* EFSA outputs contribute to a more science based legislation.
- **Scientific quality** the main question being whether EFSA professional attractiveness ensures high quality scientific outputs.

Since most of the respondents to the survey and interviewees are based in Europe (NRA, NRM, EC, EP, NGOs, Scient. Org.), the answers provide their perception on the international visibility of EFSA. The additional interviews conducted with international organizations like FAO, WHO, OIE or national authorities outside Europe (FDA) contribute to assessing the positioning of EFSA from an international perspective.

3.5.2 Scientific quality and sustainability: the international role of EFSA

3.5.2.1 Facts & Figures

As a major global trader of food and feed, the Community has entered into international trade agreements and contributes to the development of international standards. The Founding Regulation of the Authority states that it should contribute, through the provision of support on scientific matters, to the Community's and Member States' role in the development and establishment of international food safety standards and trade agreements[192]. For this purpose, the Founding regulation (Article 31) states that the Authority shall work in close cooperation with all organizations operating in the field of data collection, including those from applicant countries, third countries or international bodies.

EFSA strategy to support the Community in the development and establishment of international food safety standards and trade agreements relies on an international strategy developed in 2006[193].

[192] Recital 39 of the Founding regulation of EFSA, 2002/178.
[193] International activities – a strategic approach, EFSA, 2009.

EFSA'S STRATEGIC APPROACH TO ITS INTERNATIONAL ACTIVITIES

- Following EFSA' external evaluation in 2005, the management board considered international activities as one of the key recommendations arising from the report. In this regard, combined with globalization challenges, they adopted in 2009 a document describing EFSA's strategic approach to international activities based on four axes:
  - To support the EU in its international commitments;
  - To ensure access to international scientific data and information to provide a strong basis for risk assessment and the identification of emerging risks;
  - To participate to risk assessment at the international level;
  - To promote coherence in risk communications and build awareness of EFSA's activities at the international level.
- For each objective, the document describes the main initiatives and actions to implement. This strategy is a key element to strengthen EFSA's international role and recognition.

(Source: EY elaboration on secondary sources)

EFSA plays a role in the international scientific community to promote risk assessment. This role relies on three types of activities targeting the scientific community:

- **organization and participation to international scientific events**;
- **production of scientific outputs** and utilization of these outputs by the international scientific community;
- **scientific cooperation** with third countries agencies and international organizations[194].

Scientific colloquia organized by EFSA contribute to bringing the best expertise to support EFSA activities, as well as EFSA participation to international projects and events.

In 2011, EFSA contributed to several international events, including 3 sessions of the Codex Alimentarius[195], video-conferences with US Environmental Protection Agency (EPA), and various OECD working groups. They are liaised with the Joint FAO/WHO Expert Committee on Food Additives (JECFA) secretariat on food safety issues and have regular contacts with FAO and OIE (World Organization for Animal Health), and they invite their experts to participate in plenary meetings.

The analysis of EFSA's activities, with particular regard to its participation to international programmes and cooperation with international organizations contribute to sustainably place EFSA on the international scientific landscape[196].

The table below (Participation to congresses and scientific events by Scientific Committee members) attests that EFSA Scientific Committee members have increased their participation to congress and scientific events in the last three years, although the number is still low. It shows the commitment of EFSA to maintain the quality of scientific expertise among EFSA's staff. This participation contributes to maintaining the level of expertise within the scientific committee. These congresses form part of the different scientific events where EFSA participates. Other events contribute to the visibility and outreach of EFSA on the international scientific community, like in 2011: 13 events were organized including **one scientific colloquium** on emerging risks in plant health; **two consultative workshops** with stakeholders (GM plant comparators, Independence); **a joint EFSA-European Commission-**

[194] JC Q 7.C: EFSA is internationally recognized.
[195] Other contributions not listed in the 2011 annual report.
[196] JC Q 3.f: EFSA's structure (Panels and Committee) and the actual system for cooperation and networking are adequate to sustain the quality of work, both in terms of scientific outputs and needed expertise.

ECDC event on zoonoses and **an EU Agencies** exhibit at the European Parliament; and the local Festa dell' Europa.

Table 28: Participation to congresses and scientific events by Scientific Committee members197

	2006	2007	2008	2009	2010	2011
Participation to congresses[198]	-	2	5	9	12	10

(Source: EY elaboration on EFSA's data, 2012)

The table below (Number of scientific outputs and quotations of EFSA publication (i.e., outputs) in scientific papers) on EFSA scientific outputs shows that the number of scientific outputs has increased, notably in recent years. A direct consequence is the **stronger contribution of EFSA to scientific community**, as illustrated through the increasing number of quotations based on EFSA publications.

Table 29: Number of scientific outputs and quotations of EFSA publication (i.e., outputs) in scientific papers

	2006	2007	2008	2009	2010	2011
# Scientific outputs	174	283	486	636	565	658
# Quotations	13	19	35	132	293	487

(Source: EY elaboration on EFSA's data, 2012)

Considering the importance of sharing scientific data and methodology to perform risk assessment, EFSA is committed to develop partnerships with other agencies, illustrated by the two agreements signed between EFSA and non-EU agencies. EFSA signed an **agreement with FDA in 2007** designed "to facilitate the sharing of confidential scientific and other information between EFSA and the FDA". FDA is now exchanging staff with EFSA on a regular basis that clearly strengthens communication between both organizations ("Liaison Exchange Agreement"). In addition to that, EFSA signed a **Memorandum of Cooperation with the Food Safety Commission of Japan (JFSC)** in 2009 for the promotion of scientific cooperation on data collection and data sharing related to risk assessment.

The cooperation with other agencies in the world is steadily increasing as mentioned in the EFSA annual report 2011: several third countries delegations invited EFSA, including the Republic of Korea, China, Australia, USA, Colombia, Kazakhstan, Kyrgyzstan, Uzbekistan and Japan in 2011[199].

In comparison with other EU Agencies (EMA, ECHA), EFSA partnerships with other Agencies remain limited: EMA has signed 6 agreements with the largest regulatory bodies, versus 4 for ECHA. The relative delay of EFSA in establishing agreements with third countries' Agencies must be linked to the fact that Founding Regulations of EMA and ECHA both describe their international roles, whereas there is no specific role in EFSA Founding Regulation, apart from "the provision of support on scientific matters to the Community and Member States' role in the development and establishment of international food safety standards and trade agreements."

[197] JC 3.f. Absence of publications.
[198] Participation of Scientific Committee members to congresses and scientific events is known only when they attended on behalf of EFSA.
[199] Brazil and Argentina, not listed in the 2011 annual report (EFSA communication).

INTERNATIONAL COOPERATION OF EMA AND ECHA

- INTERNATIONAL COOPERATION AT **EMA**: The European Medicines Agency co-operates with many of the world's largest regulatory bodies outside the European Union (EU) on issues of mutual concern (USA, Canada, Japan, New Zealand, Switzerland, Australia). The cooperation is based on agreements and confidential arrangements to promote exchange of information. They also support the European Commission' pharmaceuticals collaboration with China, Russia and India. EMA has a specific International relations and Cooperation Department with a desk for EU and an extra international relations desk.
- INTERNATIONAL COOPERATION AT **ECHA**: the European Chemicals Agency has developed partnerships with four third countries (USA, Canada, Japan, Australia) based on memorandum of understanding and statements of intent to promote the scientific dialogue and the cooperation on technical matters.

Besides regular contacts with international organizations, EFSA has no agreements or formalized partnerships with international organizations.

In theory, the Founding Regulation (Article 30, Paragraph 1) indicates that EFSA shall "exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks." This encompasses the solving of divergence in scientific opinions issued by international organizations.

Divergent opinions between international organizations have proved to be difficult to handle, such as the conflict on GM potatoes that opposed EFSA and WHO in 2007 on the human relevance of the antibiotic resistance marker gene *nptII*, which confers resistance to two families of antibiotics: kanamycin and neomycin. WHO and EFSA had a divergent opinion, and EMEA eventually had the final word, stating in favour of WHO.

However, as a risk assessor for the European Commission, the cooperation with international organizations, notably policy makers like OIE, FAO or CODEX ALIMENTARIUS, should be limited to the provision of scientific inputs to support EC discussions. Cooperation must take place in the framework of EC cooperation activities.[200]

3.5.2.2 Stakeholders' point of view

EFSA's events (e.g., scientific colloquia, scientific networks meetings) obtain on average positive feedbacks from stakeholders on the quality of the discussions and its usefulness. 83% of the respondents to the survey gave a rate equal or above 3 out of 4 to the question relating to the usefulness of events organized by EFSA (Q10.10). [201]

From European participants' point of view, these events are considered as very rich notably in terms of networking for risk managers. They take this opportunity to enhance the networking between Member States and third countries, during which they better understand other European countries' positions and choices. EFSA's events also gather high level experts whose contributions are appreciated. It is a good opportunity to identify and discuss the future challenges that food safety has to face, as well as aligning risk assessment strategies.

Several respondents suggest that EFSA could strengthen its international visibility by increasing its participation and contribution to international meetings, notably outside Europe (SC, EP). The majority of respondents indicate that they **have poor visibility on EFSA's participation to international programmes** (71% versus 29% that have a good visibility, *Q10.11*). According to EC and EP members, these contributions should form part of

[200] JC Q 3.f
[201] JC Q 1.f & Q 3.g.

international cooperation strategy of the community, or be limited to scientific events (i.e., excluding policy makers' events).

The quality of scientific outputs is appreciated by interviewed stakeholders (see par. 3.1 "Provision of scientific outputs" for further details).

The efforts made to collaborate with other national agencies than FDA and JFSC through staff exchange and share of studies should be renewed with other agencies and go beyond the paper level. EFSA does not seem fully committed in the development of cooperation and partnerships considering the various reminders coming from RA to establish international networks as soon as new issues rose or to harmonize methodologies.

EFSA's international role is already acknowledged by peer Agencies. Scientific opinions published by one Agency including EFSA are taken into account by others, (FIR, EC, IOs), sometimes leading to same decisions (made with delay) in the main Agencies. However, decisions are not transposable from one Agency to another without taking into account the local specificities (geographical and cultural differences may influence the degree of exposure).

Cooperation between agencies is also a request from industries (FIR). From an industry point of view, since food and feed products are international commodities, they are willing to see a greater harmonization in risk assessments methodologies between countries to facilitate the marketing of their products, as observed in other EU agencies.

INTERNATIONAL ROLE OF EMA AND ECHA

- **EMA** and **ECHA** opinions are recognized outside Europe. Countries are basing their legislation on their opinions because they are seen as leaders worldwide. ECHA is recognized to have the primacy to set standards worldwide: industrials based their development on ECHA standards. International companies that send applications to ECHA or EMA are willing to see homogeneous standards worldwide.
- EMA and ECHA are well established from an international point of view, but this must also be linked to other factors (longer existence for EMA, absence of international comparable agency for ECHA, etc.)

In spite of this procedure, several stakeholders (including IOs) highlight the **lack of cooperation of EFSA with other international organizations.** Several stakeholders mention that the cooperation between organizations on this aspect would be relevant (NRM, NRA, IOs). WHO and FAO are discussing to align their RA methodologies and the participation of EFSA to this discussion would be valuable.

The cooperation to share data with other international organizations is a priority but **there are still some rooms for improvements (NRA, Scient. Org.)**. As mentioned in the paragraph on data collection, IOs data sharing is not fully operational. On a technical aspect, the data that international organizations require from MS are the same, but the way MS must present them differ, which leads to time consuming work reformatting data for RA bodies. The templates that international organizations are using to collect data could be harmonized.

3.5.2.3 Analysis of evidences

EFSA international activity is based on its participation to events of recognised quality, as well as its rich and increasing contribution to the scientific literature, and steadily developing scientific cooperation with third countries agencies and international agencies.

Stakeholders still have a poor vision on what EFSA does to play an international role, in line with the criticisms received during the previous evaluation. This vision must be counterbalanced by several aspects:

- first: as per its Founding Regulation, EFSA is not supposed to play a specific international role, apart from close cooperation for data collection. This is the reason why EFSA is lagging behind in comparison with other agencies like ECHA or EMA whose international role is part of the Founding Regulation.
- second: the international strategy developed in 2009 following the 2006 evaluation only became operational very recently and its effects will only be perceived later on by stakeholders.

EFSA is now putting efforts to improve cooperation with third countries, staying in the field of its remit. The implementation of the strategy performed in the last two years (new agreements, discussion with third countries and participation to international scientific events) is the first step to an effective international cooperation, although it is hardly perceivable for stakeholders so far.

Opinions from stakeholders converge on the fact that cooperation with international organisations is not sufficient. EFSA task to exercise vigilance in order to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks, including international organizations, is not fully operational considering the recent divergences with WHO. This issue could form part of the international strategic approach of EFSA for the coming years.

3.5.2.4 Evaluation results

EFSA plays a role in the international scientific community to promote risk assessment.

This role relies on three types of activities targeting the scientific community:

- Organization and participation to international scientific events. EFSA's events receive a good feedback from stakeholders and the participation of EFSA Scientific Committee members to international scientific congress has slightly increased in the recent years. A stronger commitment in international scientific events would increase EFSA international recognition as well as keep it abreast of scientific research outputs on the area of its remits. Colloquia organized by EFSA with international scientific experts contribute to bringing the best expertise to support EFSA's activities. The increasing participation of EFSA's Scientific Committee members to congresses attests its commitment to maintain the quality of the scientific expertise among EFSA's staff (although its participation remains at a low level).
- Production of scientific outputs and use of these outputs by the international scientific community. With a growing number of scientific outputs, the number of quotations of EFSA papers has considerably risen in the scientific literature (from 13 in 2006 to 487 in 2011). This statement strongly supports the contribution of EFSA to the international scientific community.
- Scientific cooperation with third countries agencies and international organizations. EFSA is developing partnerships with national agencies in third countries in order to facilitate the sharing of data and the harmonisation of methodologies.

Since the drafting of "EFSA strategic approach to international activities" in 2006, the sustainable positioning of EFSA in the international community is steadily increasing but additional efforts (participation to events, formal cooperation with third country agencies and international organisations) are required to enhance the international role of EFSA.

3.5.3 EFSA added value from a European and international perspective

3.5.3.1 Facts & Figures

The international role of EFSA can be measured through its capacity to support the evolution of the EU legislation framework and as a consequence the evolution of international standards. **At European level**, EFSA is committed to provide support to the legislation process leading to the development of food safety standards for the community. **At international level,** the community risk manager (EC) discusses with international organisations in charge of setting food and feed safety standards in the world for trade purposes. EC participates in these meetings with the support of EFSA to lighten the issues that EC should be aware of before making a decision.

In terms of recognition of EFSA by national bodies, the added value of EFSA in comparison with national agencies can be found:

- in the provision of pan European scientific opinions on specific products.
- in the capacity of EFSA to hire the best experts to address new challenges and propose a scientific opinion that may take into account a minority opinion. For international stakeholders, it provides a synthesis of major opinions in Europe on a specific product.
- in the increase of visibility of Europe for external stakeholders, notably in the formulation of a European position.

3.5.3.2 Stakeholders' point of view

European added value of EFSA

There is a large consensus on the fact that EFSA is a **leader to perform risk assessment**. Two thirds of the respondents to the survey[202] considers that EFSA is at the forefront of the risk assessment methodologies in Europe, and this figure rises to 91% of the respondents when including those who gave a rate equal or higher than 3 out of 4 *(Q10.1)*[203].

MS have different opinions on the utility of EFSA's existence and work. As previously described in the paragraph on cooperation, the perception of EFSA's role varies a lot according to the food safety national system in place in the MS: as a consequence, the expectations towards EFSA vary a lot from one MS to another (See par. 3.4 "Cooperation and networking" for further details).

In terms of recognition of EFSA by national bodies, a few stakeholders (NRA, Scient. Org.) states that EFSA does not have the primacy: scientific opinions of EFSA still rely on volunteers coming from MS, undermining the role of EFSA. EFSA also relies on data produced by industries, which limit the autonomy of EFSA to produce a scientific opinion. They are highly dependent of external organizations, experts and laboratories. This is the major difference between national agencies and EFSA.

At European level, EFSA opinions are taken in a strong consideration at the EC working groups (e.g., plant protection, contaminants, etc.) and it has a proven role in standard settings in Europe. The EC is also satisfied with the quality of information they receive from EFSA upon requests. The close cooperation between EFSA and EC ensures an appropriate understanding of EC requests. EFSA independent opinions are always considered when preparing a new legislation.

[202] Mostly European respondents.
[203] Indicator of the JC Q7.D: EFSA risk assessment is reliable and trusted in EU.

EFSA inputs to EP committees are appreciated by EP members. The communication is now fully effective and EFSA is very reactive to EP requests. EFSA contribution has been more and more valuable in the recent years (EP), thanks to a stronger anticipation of EP needs by EFSA (although there is still some room for improvements on this aspect). The new Director has been committed to deliver the right expertise to appropriately throw light on an emerging food safety issue to EP members (EP, EC).

Without reconsidering the quality of the communication between EP, EC and EFSA, several stakeholders (NRA, NRM, FIR, Consumers) report that EFSA's scientific inputs have difficulties to compete with other aspects taken into account in the EU decision-making process (economic, social and political aspects). The capacity of EFSA to provide inputs and suggestions for the improvement of the food safety system, in a proactive and independent manner, is questioned by stakeholders (See par. 3.1 "Provision of scientific outputs" for further details on self-tasking activities and internal mandates).

International added value of EFSA

When considering third countries outside Europe, the opinion of respondents regarding the involvement of EFSA in the international scientific community and the added value of EFSA is less enthusiastic as the rate 3 out of 4 obtains the largest number of answers (Q10.2, *Q10.3*).

The three questions regarding the positioning of EFSA on the international scientific community (*Q10.2, Q10.3, Q10.4*) obtains an average rate of 3.16 out of 4 highlighting the fact that **some improvements can be made to position EFSA as a leader outside Europe**.

The section above develops the contribution of EFSA to improvements in providing scientific advice to the international scientific community. This contribution is mainly based on the quality of scientific outputs produced by its internationally recognized experts. 84% of the respondents to the survey consider that EFSA involvement in the international scientific community provides added value (*Q10.3*).

EFSA's capacity to recruit the best experts is recognized internationally, but the consequence is that EFSA is sometimes seen as a board that manages scientists' activities instead of providing its own position on specific issues (NRA), as opposed to FDA for instance.

EFSA's international positioning highly depends on issues treated (FIR) and on sector-specific regulations. For those (e.g., flavourings) where the EU regulations require EFSA for an opinion before a new component enters the market, the Authority does not compete with National Authorities. It is recognized as the reference and could more easily play a role at an international level. Other areas where EFSA's contribution is considered as significant by the respondents to the survey are the following: biological hazards, zoonoses, animal welfare and pesticides.

In terms of timeliness to produce a scientific advice, there are some criticisms towards EFSA, considered as being slower than other agencies (including non EU agencies), to be linked with the fact that they are working with 27 MS: the time spent in reducing divergent opinions and finding consensus among MS is not taken into account in national agencies. A recent example with bisphenol A shows that several agencies gave their opinion before EFSA (France and FDA for instance): they were quicker to acknowledge the analyses performed and limit the use of the products (FIR).

At international level, EFSA's scientific outputs contribute to the international development of food safety standards. EFSA's opinions are always taken into consideration in international discussions. For instance, EFSA results are fully integrated into working groups of OIE and Codex Alimentarius to prepare international standards (IOs, EC). In the past, JECFA opinions used to be the reference point. Recent examples (flavourings) have shown that EFSA can take the lead over JECFA on specific issues, thanks to the quality of its work.

EFSA is known to set the highest standards in the world (SCP, FIR, IOs). Consumers' associations consider that these high standards have a positive influence in food safety system outside Europe.

The European Commission attests that third countries show great interests in EFSA scientific opinion considering the increasing number of requests they receive from them to better understand EFSA methodologies and opinions.

However, the European-based opinions are sometimes criticized because the high standards that are accepted in Europe are not always relevant in other areas of the globe, notably in poorest countries where food safety is currently focusing on the application of basic hygienic rules, or in other continents where the environment is different (IOs). In this regard, EFSA's opinions can be inapplicable at a larger scale. If the toxicity can be compared, the levels of exposure vary significantly from one region of the world to another. The acceptable risk set by EFSA is often criticized by other international bodies including international organizations.

Since EFSA is a younger structure than the other international organizations (notably UN structures), its role in the international community still remains to be found (NRA). The recent effort made with the implementation of an international strategy for EFSA contributes to better positioning EFSA in the international landscape.

3.5.3.3 Analysis of evidences

EFSA'S contribution to feed European institutions on scientific aspects of a discussed policy is operational: regular contacts contribute to the quality of the scientific opinions provided by EFSA. Without reconsidering the quality of the cooperation, stakeholders point out that EFSA opinions are eventually poorly included in policy decision making. This cannot be linked to EFSA's activities as it fully plays its role vis-à-vis European institutions, but rather to the fact that the scientific aspect provided by EFSA represents only one of the aspects to consider when drafting a policy.

From an international perspective, EFSA scientific opinions form part of the references that are used by policy-makers to set standards (Codex Alimentarius, FAO, WHO, OIE and national agencies). Recent examples show that EFSA took the leadership over JECFA on specific issues like flavourings. Several third countries show great interest in EFSA opinions, considering the number of visits they receive as well as requests sent to the European Commission in relation to EFSA outputs. EFSA's weak international role is also the result of the limitative EFSA's mandate in international cooperation on risk assessment (see also par. 3.2 "Data Collection"). EFSA's capacity to foster the convergence of international risk assessment standards with EU approach should thus be strengthened in order to let EFSA play a major role in a globalizing economy.

3.5.3.4 Evaluation results

There is a large consensus by European Member States on the fact that EFSA is reliable.

EFSA gathers the best experts across Europe and its opinions are respected by all Member States. 91% of respondents indicate that EFSA is at the forefront of risk assessment methodologies in Europe. In terms of European positioning, considering that its expertise relies on MS contribution, the leadership of EFSA competes with largest agencies that provide experts to EFSA.

Its added value can be found in the capacity to provide pan-European opinions, to attract the best experts to address new challenges, to increase the visibility of European position vis-à-vis third countries.

Further improvements are still needed regarding EFSA's recognition outside Europe.

The strategic approach to international activities of EFSA set up in 2009 is the first step to improve the international recognition of EFSA outside Europe, but is still not visible.

Two partnerships with third countries national agencies (USA in 2007 and Japan in 2009) to share scientific data and perform risk assessment contribute to increasing the recognition of EFSA outside Europe. Several other countries are interested in scientific opinions produced by EFSA and have approached EFSA to foster cooperation, considering the number of invitations they received from third countries in 2011 (Korea, China, Australia, Colombia, etc.).

Divergent opinions among NRA, EFSA and IOs (ex: conflict on GMO potato with WHO) and obstacles in data sharing still limit the Authority's fruitful involvement in the international scientific community. EFSA is considered as one (not the only one) source of information taken into account by IOs when dealing with specific issues. In addition, the strict European food safety standards on which EFSA's scientific outputs are based, are often criticized by IOs because they are not always relevant neither consistent with those used in other areas of the globe. This makes EFSA's opinions sometimes inapplicable at a larger scale. More efforts should be put into the identification at an early stage of any potential source of divergence and a more coordinated approach, in order to fully achieve its mission defined in article 30 of the Founding Regulation. Moreover, EFSA's international role could be further strengthened through the broadening of the Authority's mandate in international cooperation on risk assessment that is actually limitative, thus reducing the influence that the EU can achieve in the definition of international standards.

EFSA's contribution to the EU legislation and policies is still perceived as too weak.

Despite the fact that Members of the European Parliament underline the strong support provided by the Authority in informing the legislative process, several external stakeholders have the feeling that EFSA's scientific point of view is not enough considered in comparison with other factors taken into consideration in the decision-making process (economic, social, political) (see par. 3.5.3).

From an international perspective, EFSA scientific opinions form part of the references that are used by policy-makers to set standards (Codex Alimentarius, FAO, WHO, OIE and national agencies). Recent examples show that EFSA took the leadership over JECFA on specific issues like flavourings.

3.5.4 EFSA scientific quality: professional attractiveness for best experts

3.5.4.1 Facts & Figures

The professional attractiveness of EFSA is an indicator of its international recognition for administrative and scientific staff and experts. The section below details the capacity of EFSA to attract the best experts and staff in the world.

The capacity of EFSA to keep its experts is measurable through the analysis of the turnover among Panel members, after their three-year mandate (renewable). The levels of turnover in Panel members (indicated in Table 30) seem to be high. Without considering the reasons for leaving a Panel (i.e., end of mandate, unwillingness to apply again), the increase in turnover between 2006-2009 and 2009-2012 can be questioned. The renewing of Panels in 2012 will

provide more information on the willingness of experts to extend their participation in a Panel. EFSA has no other elements on the reasons for relative high level.

Table 30: Turnover in Panel members

PANELS	MANDATE YEAR	TURNOVER
8 SP+SC	2006-2009	42%
8 SP+SC	2009-2012	58%
ANS+CEF	2008-2011	21%

(Source: EY elaboration on EFSA's data 2012[204])

The 2005 external evaluation identified a recruitment difficulty not in the mobilization process itself, while in the location of the Authority in Parma[205]. Indeed, if compared with Brussels the location of EFSA in the Italian city is more expensive, entailing higher travel expenses and time. That, alongside with the pressure in external experts' full-time jobs, was pointed out as reducing their willingness to work for the Authority. In order to overcome this difficulty, since 2010 EFSA has developed tele-meetings, allowing experts participation through call conferences to SC, Panels and Working Groups meetings. In addition, an attendance indemnity per hour was fixed in line with the daily indemnity of a physical meeting[206]. The use of tele-meetings in EFSA's scientific work continues to be promoted, to reduce the travel burden of experts and the associated costs[207]. Nevertheless, as noticed during Direct Observations[208], call conferences are not always well performing. EFSA's staff representatives are not able or do not always take the responsibility to explain to experts the Authority's policy or procedures[209].

3.5.4.2 Stakeholders' point of view

The professional attractiveness of EFSA for leading experts from MS (and globally) to participate as an external expert or work for EFSA on a permanent basis, is satisfying: 85% of respondents (Q11.1) declared that the attractiveness, in terms of professional development, is satisfying (rate equal or above 3 out of 4).

Several elements are often listed as attractive in terms of professional development (NRM, NRA, IOs):

- **the quality of work**: EFSA's staff produces high quality scientific outputs and has regular contacts with highly qualified experts. They work on future challenges that the society has to face. The high level of expertise in EFSA's network is a strong asset.
- **The international environment of EFSA**: EFSA's staff and experts have the opportunity to work in a multi-cultural environment and EFSA opinions are considered by risk managers and similar agencies over the world. Working for EFSA gives the

[204] These figures must be balanced by the fact that they do not reflect the overall turnover of experts at EFSA: experts could leave a Panel to apply for another one. This internal turnover is not considered in the table above.
[205] Evaluation of EFSA, final report, 2005, p. 15.
[206] Decision concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their working groups (MB 17 12 2009). Presentation on the decision concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their working groups - MB meeting, 17th December 2009, Stockholm.
[207] Annual Management Plan 2012, p. 3.
[208] Reference to 63rd AHAW plenary (9th February 2012, Parma), 25th CEF plenary (1st February 2012, Parma), 71st GMO plenary (25th February 2012, Parma) and 53rd Scientific Committee plenary (7th February 2012, Parma).
[209] As observed in Panels' meetings, where EFSA's representatives do not always take the responsibility to explain to experts the Authority's policies or procedures. Reference to the Direct Observations of 63rd AHAW plenary (9th February 2012, Parma), 25th CEF plenary (1st February 2012, Parma), 53rd Scientific Committee plenary (7th February 2012, Parma).

opportunity to measure the different approaches to carry out risk assessment. Even for administrative staff, this international organization is highly valuable on their CV.

- **The career development:** the participation to a panel brings important benefit on the CV of a scientist. Considering the number of issues dealt by EFSA, there is a large range of opportunities for EFSA's staff. Several respondents insist on the EFSA's multidisciplinary activities. The salary is also considered as an attractive element for EFSA's staff.

On the other hand, several limits remain to attract highly qualified staff as well as experts including (NRM, NRA, IOs):

- **the location of EFSA in Parma,** because of the poor accessibility of Parma for European experts. It is listed as a first limit to professional attractiveness by different profiles of interviewees and respondents to the survey (NRM, NRA, IOs, EC,). If external experts may accept to occasionally travel to Parma, it becomes eliminatory for permanent staff. For experts, online meetings (webinars) and meetings in other European capitals would make their contribution easier. Travelling to different MS for meetings, like the Advisory Forum does, is also considered as a very effective way to promote cooperation between MS.
- **The internal bureaucracy**: as it is the case for European institutions in general, EFSA must comply with numerous obligations before producing an opinion and work on finding a consensus between divergent opinions. Some independent scientific experts can be reluctant to this and do not bear the administrative burden it requires.
- **The transparency and independence**: the continuing issues on conflicts of interest that target EFSA's staff and experts can discourage some experts to take part to the scientific work. The attack on transparency and independence make experts reluctant to participate.
- **The small compensation fees** together with the increasing barriers imposed by the new implementing rules of independence and the widespread perception that EFSA is not protecting its experts enough, are progressively decreasing EFSA's level of attractiveness.
- **The lack of internal scientific research capacities**: EFSA is not a research centre and except for self-tasking studies and internal mandates, it relies on external scientific research institutes to get data and information (through grant and procurements) and analyses existing studies to develop its own opinions. Some experts prefer working in an institution with its own research capacities.
- **The lack of international visibility**: the international dimension of EFSA (i.e., extensive contacts with EU and third countries Authorities) is not always visible for European experts. Some experts recognized the prestige of working for EFSA, but more cooperation with MS could help increasing the diversity of applications.

The limits to professional attractiveness of EFSA can hamper its advantages leading to a possible lack of very specific expertise from top scientists. The internal rules of EFSA must be proportionate to the involvement of scientists: in any case, the rules shall not be a barrier for top scientists with the right profile to contribute to EFSA activities. A monitoring of experts' willingness to work for EFSA is needed to ensure a high quality in scientific outputs.

3.5.4.3 Analysis of evidences

Stakeholders' point of view on the professional attractiveness of EFSA is worrying considering the recurrent and convergent limits listed by interviewees and respondents. The potential side effect is a reduction in very specific expertise provided by top scientists, which constitutes the strength of the overall system. The factual information on professional attractiveness is not

satisfying to draw conclusions on this basis. The high turnover rate could be judged as alarming but it does not reflect the real turnover as experts frequently decide to work for a different panel.

Considering the potential risks of a reduction of EFSA professional attractiveness, there is a strong need to develop factual information through appropriate collection tools to monitor this aspect, crucial for a high recognition of EFSA activities.

3.5.4.4 Evaluation results

EFSA is globally considered as an attractive place to work for external leading experts.

Among the main strengths of working for EFSA the high quality of the scientific work undertaken, the international and multi-cultural environment and the public recognition of the good reputation of the EFSA are considered very valuable for external experts working for EFSA.

Among the main limits that are often listed:

- the location in Parma: if compared with Brussels the location of EFSA in the Italian city is more expensive, entailing higher travel expenses and time. This aspect, alongside with the pressure in external experts' full-time jobs, was pointed out as reducing their willingness to work for the Authority in the 2005 evaluation;
- the heavy burden of internal bureaucracy: independent scientific experts can be reluctant to the process that leads to the production of scientific opinions;
- the frequent external attacks to the independence of experts working for the Authority;
- the limited financial compensation considered not sufficient if compared with the increasing workload of experts;
- the lack of EFSA's internal scientific research capacities that limits EFSA's possibility to develop its own researches/testing.

These limits must be seriously considered and monitored in order to avoid a possible lack of scientific expertise. As an example, the high level of turnover in panels should be carefully watched to differentiate voluntary leaves from internal turnover.

3.6 Organizational structure, operational efficiency and adaptability to change

3.6.1 Introduction to the results for thematic area of evaluation

This area of evaluation relates to the following evaluation criteria:

- **Efficiency,** the main questions being whether *i)* EFSA's organization is appropriate and adequate to its workload *ii)* the processes are efficiently planned and managed *iii)* there is a balance in the resource allocation.
- **Sustainability,** the main questions being whether the evolution in workload and work areas affect EFSA's ability to fulfil its overall remit both in terms of *i)* the organization and *ii)* the legislative framework.

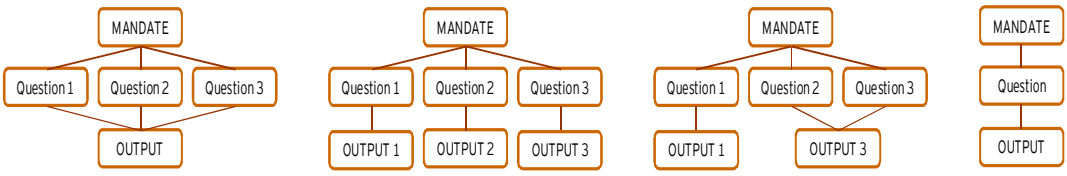
The evaluation is mainly based on stakeholders' opinions as gathered in the questionnaire and during interviews. In order to present the issue and support or right-weight questionnaire and interviews results, a section collecting inputs coming from desk analysis, direct observations of EFSA's key meetings and benchmark is provided before the presentation of the stakeholders' perspective.

Despite the significant improvements made by the Authority in the development of integrated monitoring and reporting systems, data related to the evaluation period are not always comparable, due to the limited level of details of the 2006-2009 reporting documents limiting the analysis.

Indicators have been calculated taking as a reference point the current organizational chart (May 2011 – Figure 1). Thus, financial and human resources related to the period under evaluation (2005-2011) have been re-aggregated according to the current structure and nomenclature of the Units and Directorates. This exercise required some approximations, highlighted and explained in the footnotes.

In order to evaluate the Authority's activity evolution and operational efficiency, the trends of scientific outputs requested to and released by EFSA have been taken into consideration and compared, The monitoring system, not configured to reconcile mandates and questions with outputs[210], has limited the analysis (Figure 10).

Figure 10: Possible correspondences between mandates, questions and outputs



(Source: EY elaboration on RoQ, Register of Questions User Guide)

[210] The workflow begins with a mandate, which may come from the EC or MS, or may be internal. Every mandate contains one or more questions, afterward processed by one or more Panels/Units. At the end, an output (e.g.,, opinion, statement, guidance, report) is produced and may be related to one or more questions, whereas it is impossible to have several outputs for the same question.

3.6.2 The Authority's structure efficiency

The efficiency of the Authority's structure is analyzed according to the following dimensions:

- The Management Board;
- The organizational structure;
- The internal processes.

3.6.2.1 Facts & Figures

EFSA's organization has been designed and restructured over the years in order to reflect the Authority's main priorities, mission and tasks as established in the Founding Regulation[211].

The Management Board

The Management Board: role and composition

Since its inception in 2002, EFSA is governed by a Management Board, whose function and role have evolved over time, shifting from an initial focus on the adoption of rules and procedures to the current emphasis on evolving EFSA's strategy and future direction[212]. In particular, as stated in 2007 Annual Activity Report, **the MB ensures the Authority functions effectively and efficiently**[213], carries out its mission and performs its tasks as defined in the Founding Regulation[214] and acts independently[215]. More specifically, as also noticed in Direct Observations[216] and read in reporting documents, it establishes EFSA's budget and work programmes, and monitors their implementation; it ensures appropriate financial management and accountability; and it appoints the Executive Director and members of the Scientific Committee and the Scientific Panels[217]. In addition, as required in the Board's Code of Conduct[218] the MB should have **no influence on EFSA's experts or on scientific advice** that are under the sole responsibility of EFSA's Panels and Scientific Committee. Indeed, as noted observing its meetings, the MB does not exert influence.

MB'S ROLE

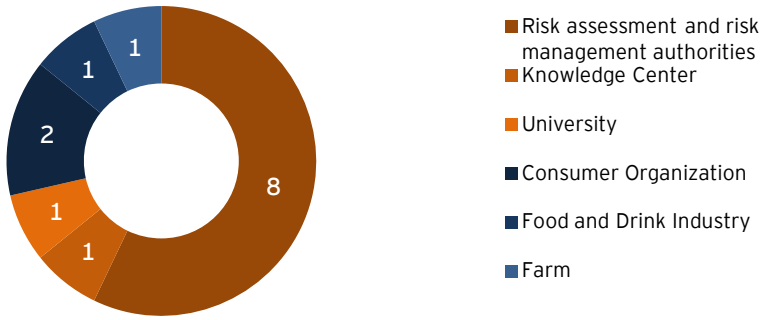
- In **FSA, VWA and EMA** the MB has a strategic role. Similarly to EFSA, in **EMA**, among others, it adopts the budget and the work program, it appoints the Executive Director and it validates the Annual Report. Whereas, in **ECHA** the MB is also involved in operational execution.

Coherently with Art. 25 of the Founding Regulation, **the MB is composed by 14 members** and a representative of the EC. **No posts are reserved for representatives of MS** (unlike other EU Agencies' MB), organisations or sectors. As shown in Chart 17, the current MB members have a broad range of expertise related to the food chain[219], and four members have their background in organisations representing consumers and other interests in the food chain, such as food and drink industry and farm[220]. Moreover, as required by the Founding

[211] Annual Activity Report 2006, p. 4.
[212] EFSA's website.
[213] Annual Activity Report 2007, p. 36.
[214] Regulation (EC) No 178/2002.
[215] EFSA's website.
[216] Reference to the Direct Observations of the 51st MB (15th December 2011, Warsaw) and of the 52nd MB (15th March 2012, Parma).
[217] Regulation (EC) No 178/2002; EFSA's website.
[218] Code of Conduct of the Management Board of the European Food Safety Authority (MB 16 06 11), Art. 8.
[219] MB members' CV on EFSA's website.
[220] Source: MB members' CV available on EFSA's website.

Regulation (Art. 25), they have been appointed in such a way to ensure **a broad geographic distribution** within the Union: each member comes from a different European country[221].

Chart 17: Management Board composition[222].



(Source: EY elaboration of EFSA's data available on the website)

MB'S COMPOSITION

- **EMA** and **ECHA**'s MBs are composed by representatives of each MS with in addition representatives of the EC and the EP. Some stakeholders are included as MB's members in **EMA**, while considered as observers in **ECHA**. A fix number of observers are admitted. With this model, while bringing the Member States closely into the overall management of the agencies' work, there could also be a possible degradation of independence, should national interests and pressure be brought to bear.
- **FSA** is led by a Board that has been appointed to act in the public interest and not to represent particular sectors. Board members have a wide range of relevant skills and experience. Although the FSA is a government agency it does not report to a specific Minister and is free to publish any advice it issues.

The Management Board: working methods

In compliance with its Rules of Procedures, from 2006 to 2011 **the MB met on average 5 times per year. Its meetings are both public and private**. MB public sessions are open to the public on-demand via webcast; a private meeting is usually organized the day before the public one, to address confidential administrative issues[223]. Supportive documents are published on EFSA's website prior to public meeting being held and minutes are uploaded some weeks after the session.

As noticed during Direct Observations[224], representatives of EFSA's management may take part to the MB public sessions to inform the Board on the progresses in strategies and work programme implementation and to present documents submitted to the Board for adoption.

[221] MB members' CV on EFSA's website.
[222] This chart has been prepared considering the current or last work experience of MB members. Diána Bánáti and Url Berhnard have been included in the analysis, even though the former recently resigned as member and Chair of the MB, while the latter on 1st June 2012 took up the post of Acting Director of the Risk Assessment and Scientific Assistance Directorate (RASA).
[223] Rules of procedure of the Management Board of the European Food Safety Authority, Art. 7.
[224] Reference to the Direct Observations of the 51st MB (15th December 2011, Warsaw) and of the 52nd MB (15th March 2012, Parma).

MB'S MEETINGS

- **ECHA** and **EMA**'s MB meets 4 times per year, whereas **FSA**'s MB meets monthly. The sessions of **ECHA**'s MB are private and not webcasted. Meetings of **FSA**'s MB are open and their videos are available on demand in the Agency's website.

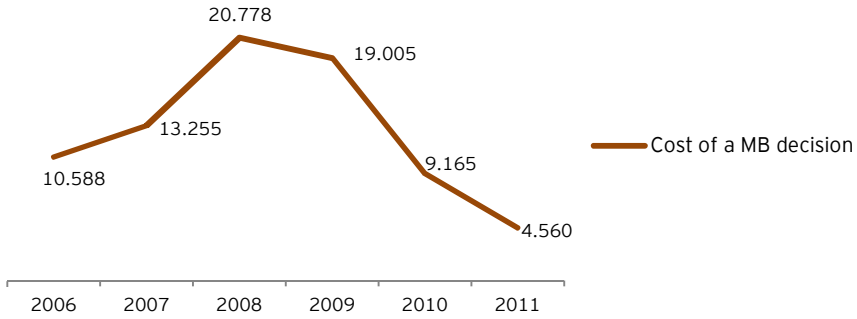
The Management Board: the costs

From 2009 the number of decisions issued by the Management Board increased (going from 27 in 2008 to 53 in 2011), while its budget has been significantly reduced starting from 2009 (56% reduction). Consequently, **the costs of a MB decision and meeting have gradually decreased** in recent years (Chart 18 and Chart 19). Nonetheless, in 2010 the costs of EFSA's MB remained high if compared with other EU Agencies[225] and the EP in the resolution on 2010 EU budget discharge[226] suggested their further reduction. In its answer to the Parliament EFSA has pointed out that the Board costs have been reduced in 2011 by switching from live video to live audio webcasting of public meetings. Moreover, in March 2012 the MB has further cut its meeting costs, by deciding:

- to no longer webcast live the audio recording of public sessions, while opting for a cheaper technology that allows to make the audio recording available on the website the day after the meetings;
- to meet only in Parma, at EFSA's seat, in order to avoid expenses related to the rent of premises.

Consequently, in 2012 MB costs are expected to fall below the average meeting costs incurred by other EU Agencies' MB[227] (around 40.950€/meeting in 2010[228]), as also confirmed by the cost of June 2012 EFSA's MB meeting (35.335€/meeting)[229].

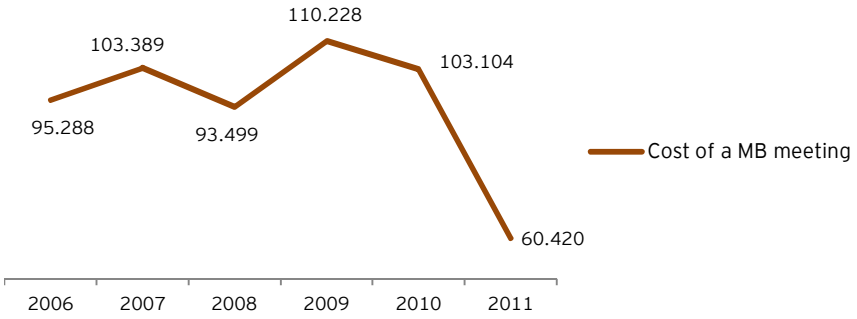
Chart 18: Cost of a Management Board's decision, 2006 – 2011



(Source: EY elaboration on EFSA's data, 2012)

[225] 2012 report on "EU Agencies' governance costs, financial management and operational efficiency: comparative data", p. 7.
[226] European Parliament resolution of 10 May 2012 on discharge in respect of the implementation of the budget of the European Union Agencies for the financial year 2010: performance, financial management and control of European Union Agencies (P7_TA-PROV(2012)0164).
[227] EFSA's website.
[228] 2012 report on "EU Agencies' governance costs, financial management and operational efficiency: comparative data", p. 7.
[229] Data provided by EFSA, 2012.

Chart 19: Cost of a Management Board's meeting, 2006 – 2011



(Source: EY elaboration on EFSA's data, 2012)

MB'S COSTS

- The costs per meeting of **EMA** and **ECHA**'s MBs are quite inferior to the ones of EFSA's Board and amounted respectively to 23.750 €/meeting and to 42.518 €/meeting in 2010.

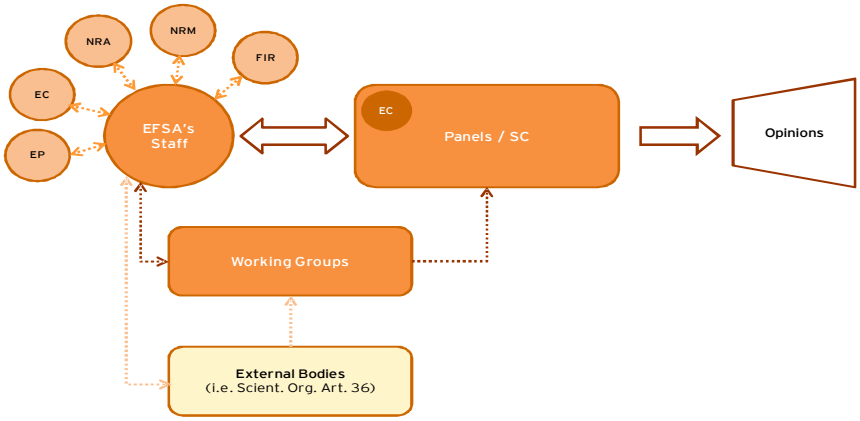
Organizational structure

EFSA's distribution of work

This section examines how EFSA distributes work among its staff, external experts and external bodies, and the quality of the human resources at its disposal.

As shown in *Figure 11*, EFSA's work is distributed among *i)* the Scientific Committee, Panels and Working Groups, *ii)* EFSA's staff and *iii)* external bodies (such as, for example, Art. 36 Scientific Organization).

Figure 11: Distribution of work in the provision of opinions

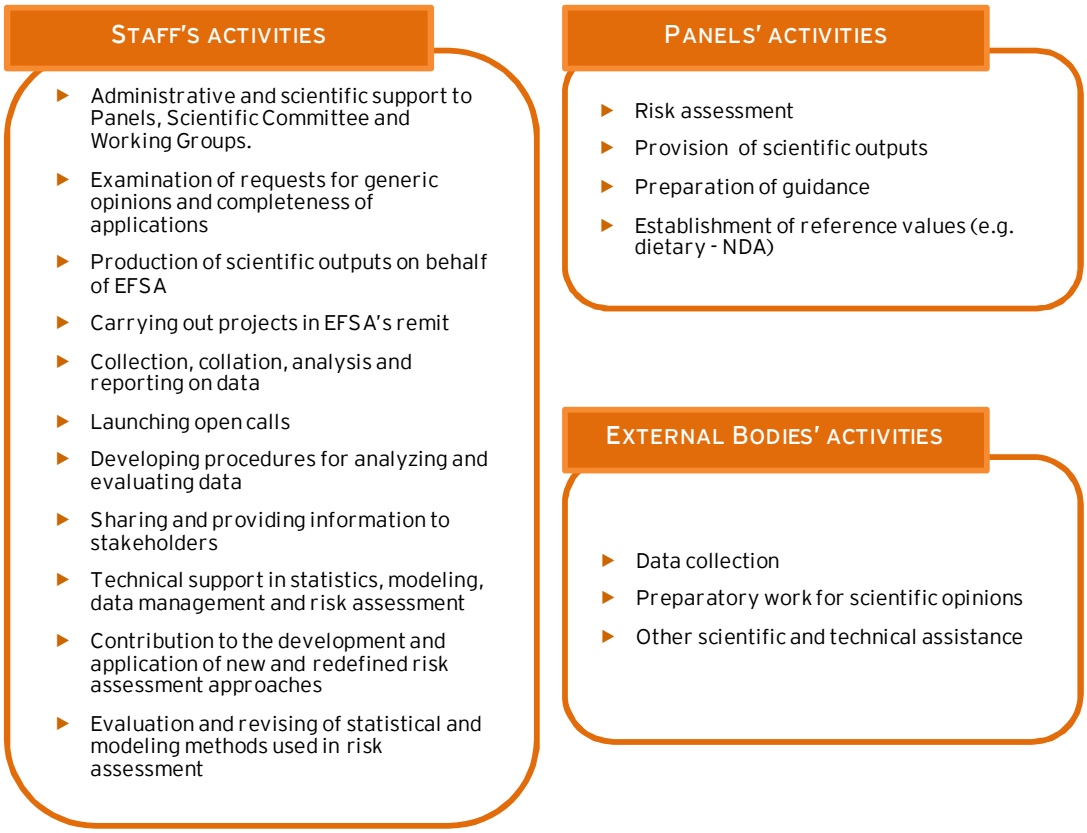


(Source: EY elaboration on EFSA's data available on the website)[230]

[230] According to the type of opinion requests may come from the EC, the EP and MS. They are firstly examined by the Authority's staff, that checks and validates their clarity and completeness, and may ask for information to the requestors. The Scientific Committee or the Scientific Panel competent for carrying out the assessment establishes a working group composed by experts, partially chosen among its members and partially coming from the expert database. The working group develops a draft scientific opinion. EFSA's staff assists the Panel and the Working Group by providing administrative and scientific support. External bodies may support the Authority in data collection or preparatory work for scientific opinions. Once the draft opinion is ready, it is submitted for adoption to the Scientific Committee or to the competent Panel at a plenary meeting. After the adoption, EFSA's staff formats the opinion and publishes it (Source: EFSA's website).

The Scientific Committee[231], Panels and Working Groups are responsible for risk assessment, including the approval of scientific opinions. EFSA's staff provides administrative and scientific support, and is more and more involved in the provision of scientific outputs. External bodies' contribution may be requested to support the Authority in data collection and preparatory work, helping EFSA respond more flexibly and effectively to the growing workload. Here below Figure 12 further details the activities in which EFSA's staff, Panels and external bodies are involved.

Figure 12: Comparison between EFSA's scientific Units, Panels and external bodies' activities



(Source: EY elaboration of EFSA's data available on the website)

In compliance with the Founding Regulation, the Scientific Committee, Panels and Working Groups are composed by **independent scientific experts** who are not employed by EFSA, but **volunteer part of their time** to it[232] and they yearly sign a declaration of interests (see par. 3.7 "Independence" for further details). External experts meet several times during the year and are supported by EFSA's staff, responsible, for example, of ensuring the compliance with the Authority's internal rules, assisting the Chairs, screening Declaration of Interests, drafting agenda and minutes of the meetings, etc.[233]

Some aspects of EFSA's distribution of work may receive particular attention:

- as noticed during Direct Observations[234], **not all the members** of the Panels **take an active role in the discussion**.

[231] In particular, the Scientific Committee supports the work of Panels on horizontal scientific matters and provides strategic advice to EFSA's Executive Director. It is also responsible for general co-ordination to ensure consistency in the scientific opinions prepared by the Scientific Panels. The Scientific Committee focuses on developing harmonised risk assessment methodologies (source: EFSA's website).
[232] Science Strategy 2012-2016, p.10.
[233] Rules of procedure of the Scientific Committee, the Scientific Panels and their Working Groups (MB 15 03 12).
[234] Reference to the Direct Observations of the 70th BIOHAZ plenary (25th January, Parma).

- While EFSA currently employs approximately 450 staff[235], the number of external experts participating to the Authority's activities amounted to 1789 in 2011[236]. **Efforts are thus required to EFSA's staff to manage and coordinate their participation** to the Scientific Committee, Panels and Working Groups meetings.
- The scientific expertise represented in the Scientific Committee and Panels is core to EFSA's activities, but it is finite and in some areas overburdened, according to 2012-2016 Science Strategy. **The high workload of external experts** has already emerged during the 2005 external evaluation[237].

Recently, in order to improve its staff capacity to manage and coordinate external experts' participation, EFSA is implementing **an integrated expert management system**: a cost centre is associated to every expert, where what relevant, such as DOI and ADOI signed, fees, transfers, is included. This integrated system will enable to monitor all the issues and costs connected to each expert, facilitating their management and coordination.

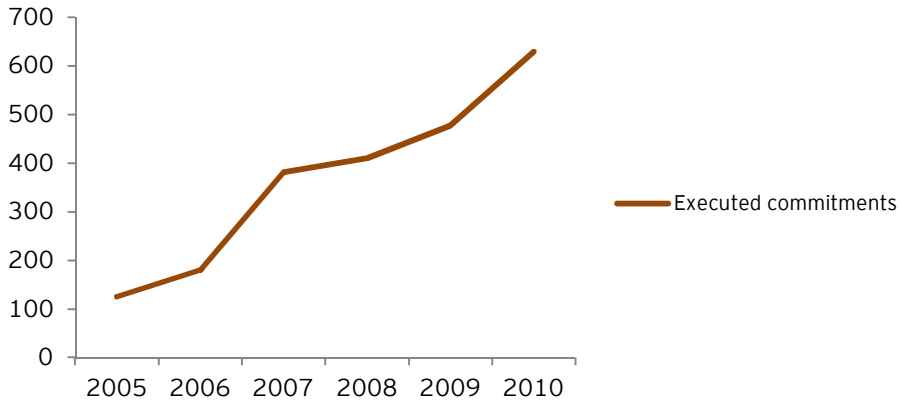
Moreover, over the years EFSA has striven to reduce external experts' workload, by building and better using internal scientific expertise, by increasing the staff's support to them and by outsourcing preparatory work.

EFSA has started building capacity among its own staff and established dedicated units to provide preparatory scientific support at the various stages of the scientific work (e.g., DCM, SAS, BIOMO): collection and analysis of data and information including literature review and exposure assessment and modelling. There is also substantial internal support in dossier evaluations and in the preparation of draft outputs[238]. In addition, through the previously illustrated right-sizing activity, EFSA's human resources will be reallocated to further reinforce the scientific capacity. More specifically, the percentage of the Authority's scientific staff is expected to pass from 60% to 70%[239] through the streamlining of EFSA's administrative and scientific processes.

To further develop its human resource (staff and external experts) skills and efficiently manage them, EFSA has developed the **Staff appraisal and career development program** in 2007 and has adopted a **Learning and training policy** in 2008, aiming at strengthening EFSA's staff skills and competencies through trainings initiatives[240]. Indeed, as shown in Chart 20, between 2005 and 2011 the budget portion allocated to training activities has steadily increased.

[235] EFSA's website.
[236] Number of external experts that signed the DOI in 2011 (source: data provided by EFSA, 2012).
[237] Evaluation of EFSA, final report, 2005, p. 19-20.
[238] Science Strategy 2012-2016, p. 11.
[239] Science Strategy 2012-2016, p. 11.
[240] Multiannual Staff Policy Plan 2011-2013, p. 23.

Chart 20: Executed commitments allocated to trainings (budget line 1420) in K€, 2005 – 2010



(Source: EY elaboration on EFSA's 2005-2010 financial reports)

The box below illustrates the training initiatives contained in the Multiannual Staff Policy Plan 2011-2013.

EFSA'S TRAININGS

- **Management training** at different levels (from team leaders to middle or senior managers and their deputies).
- Training **for scientific staff** to increase efficiency and quality outputs. The scope is both to provide scientific staff a common approach in their daily work (e.g.,, in assessing and analyzing risk) and through specific scientific training to maintain and enhance scientific knowledge and skills.
- Training to improve **writing and editing skills** for EFSA's scientific staff, to improve their redaction skills.
- Training **in the use of modern technologies and best practices** for chairing and conducting scientific meetings.
- Training **in communication skills and media relations**.
- **Language** training.
- Training to acquire proficiency in common **IT tools**.

(Source: EY elaboration on Multiannual Staff Policy Plan 2011-2013)

Furthermore, a **Human Capital & Knowledge Management Unit** has been established in May 2011 with the remit of developing EFSA's internal human capital (staff) as well as the external expertise at its disposal, reflecting the growing emphasis on increasing the expertise available to EFSA from both staff and experts[241]. Specifically, EFSA will implement a tri-annual programme for sharing the best risk assessment practices between scientific staff and external experts of EFSA (2013-2015)[242].

As stated in the Annual Management Plans, EFSA has put in place regular satisfaction surveys, to investigate external experts and staff satisfaction, in order to ensure that experts are fully supported[243].

[241] Annual Activity Report 2011, pp. 24-25.
[242] Science Strategy 2012-2016, p. 11.
[243] Annual Management Plan 2010, p. 4; 2011, p. 3-4.

DISTRIBUTION OF WORK BETWEEN PANELS, AGENCY AND EXTERNAL BODIES

According to benchmarked organizations, distribution of work between panels, external bodies and agency staff is not perceived as a difficulty:

- **ECHA**'s staff is engaged in both administrative (e.g.,, preparation of meetings) and scientific functions. Scientific preparatory work and analysis of dossiers is carried out solely by scientific staff, while Panels provide opinions. The reliance of ECHA on national expertise from MS is working very well, and they are working with the same objectives. ECHA organization is based on MS representativeness facilitating the **implementation of joint objectives**. Starting from 2012, they are now **aligning work programmes** to improve work sharing.
- In **EMA** there is not a fixed activities distribution between staff and external bodies.
- **FSA**'s staff is responsible for inspecting, (e.g.,, slaughtering houses or food business) and for developing policies to respond to incidents. Moreover, its representatives participate to scientific committees. Scientific opinions are provided by external experts.
- In the Netherlands, the **VWA** Office for Risk Assessment is supported by a staff composed of 13 permanent senior scientists. Given the volume of work, the Office does not carry out its own research but acts mainly as a knowledge broker with a supervisory and mediating role. It refers its own and others' requests for information to affiliated research institutes (RIVM, RIKILT and CIDC), universities and other institutions. It can also make use of any knowledge and laboratory capacity available within the VWA. Accordingly their advice is provided on the basis of the completed assessments and reports. The aim is to make the best use of national and international scientific networks
- In case of additional work, FSA and VWA **reallocate resources** to department or projects with limited capacity. The flexibility and sufficient internal capability of expertise is a major strength to face uncertainties. VWA encounters difficulty in the distribution of work with EFSA.

Resources allocation

This section aims at providing evidence on how EFSA allocates its resources in relation to its objectives and main activities.

EFSA's budget (76,96M€ in 2011) has gradually increased over time with a decreasing growth rate, as shown in Table 31 and Chart 21. The Authority's budgetary situation is expected to remain around the existing levels in the coming years[244].

EFSA's total revenues are mainly composed of European Union contributions, which represent 97,8% of total revenues in 2011, and of participation of third countries for a residual part, starting from 2011 (Table 31). As foreseen in the Founding Regulation and stated in the 2012-2016 Science Strategy, the possible introduction of fees for regulatory reviews carried out by EFSA is currently under consideration by the European Commission. Even though it is therefore possible that EFSA receives fees for work associated with the evaluation of regulated products, the timing and overall implications on EFSA's budget of this change are not known at present[245].

[244] Science Strategy 2012-2016, pp. 3, 6.
[245] Science Strategy 2012-2016, p. 6.

Table 31: EFSA's revenues by year (in mln€)246.

REVENUES	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Title 1 – European Community contribution	3,3	12,61	28,98	36,7	46,6	51,66	65,9	68,45	73,49	75,26
Title 2 – Participation of third countries	0	0	0	0	0	0	0	0	0	1,7
Other revenues	0	0	0	0	0	0	0	0	0	0
TOTAL REVENUES	3,3	12,61	28,98	36,7	46,6	51,66	65,9	68,45	73,49	76,96

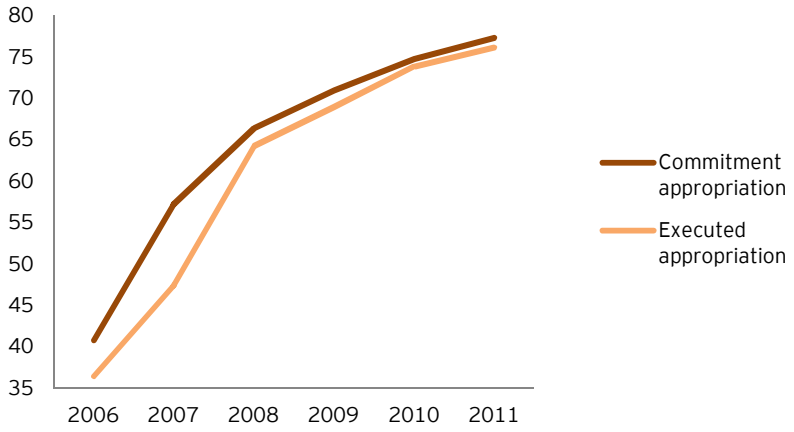
(Source: Statement of revenue and expenditure of the European Food Safety Authority 2002-2011)

SOURCE OF REVENUES

- **ECHA** and **EMA** are financed partly by the EU budget and partly by charging fees to the industry. **FSA** is funded by the UK Parliament, the Scottish Government, the Welsh Assembly Government, and the Northern Ireland Administration. **VWA** is funded by the Ministry of Agriculture, Nature and Food Quality.
- Over the past ten years, EU contributions to **EMA** remained quite stable, while the total budget increased, mainly due to the constant growth of industry's fees.

Considering the consistency between EFSA's resource allocation and its objectives, **the gap between commitment and executed appropriations has progressively reduced over time**, as shown in Chart 21. Indeed, the percentage of provisional budget executed by the Authority passed from 89% in 2006 to 98% in 2011[247].

Chart 21: Evolution of commitment and executed appropriations in mln€, 2006 – 2011.



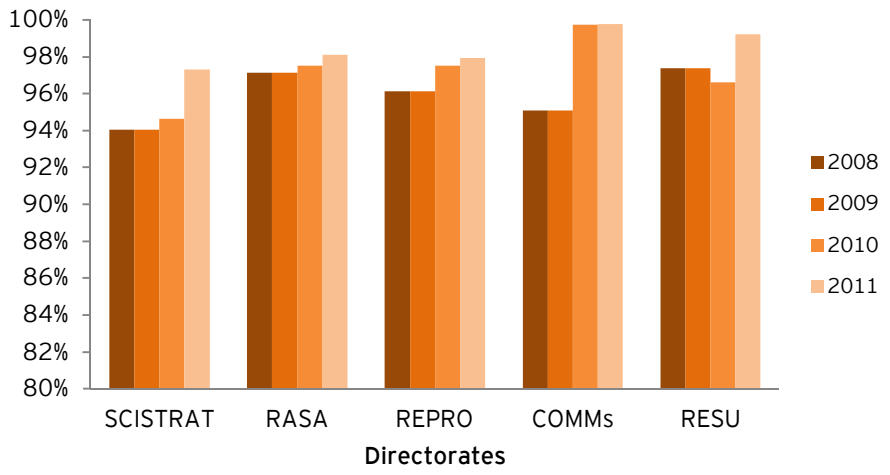
(Source: Annual Activity Reports 2006-2011).

Every Directorate has improved its capacity to use assigned appropriations (Chart 22) and EFSA's budget usage is slightly superior to the European Agencies average in the years 2008,

246 Other revenues are composed by: Title 3, revenue from services rendered; Title 4, revenue from administrative operations; Title 9, Miscellaneous revenue. Source: Statement of revenue and expenditure of the European Food Safety Authority 2002-2011.
247 Executed Appropriations/Commitment Appropriations. Source: EY elaboration on Annual Activity Reports 2006-2011.

2009, 2010[248].

Chart 22: Percentage of executed budget out of assigned, by Directorate, 2008 – 2011



(Source: EY elaboration on Annual Activity Reports 2008-2011)[249]

As relates **the allocation of EFSA's resources among its main areas of activities** (provision of scientific outputs, scientific cooperation and risk communication), the table below presents the distribution of financial and human resources across them[250]. The last column collects the Authority's future challenges as evaluated by stakeholders (Q12.1), in order to show the consistency of resource allocation with them.

Table 32: Distribution in the allocation of resources.

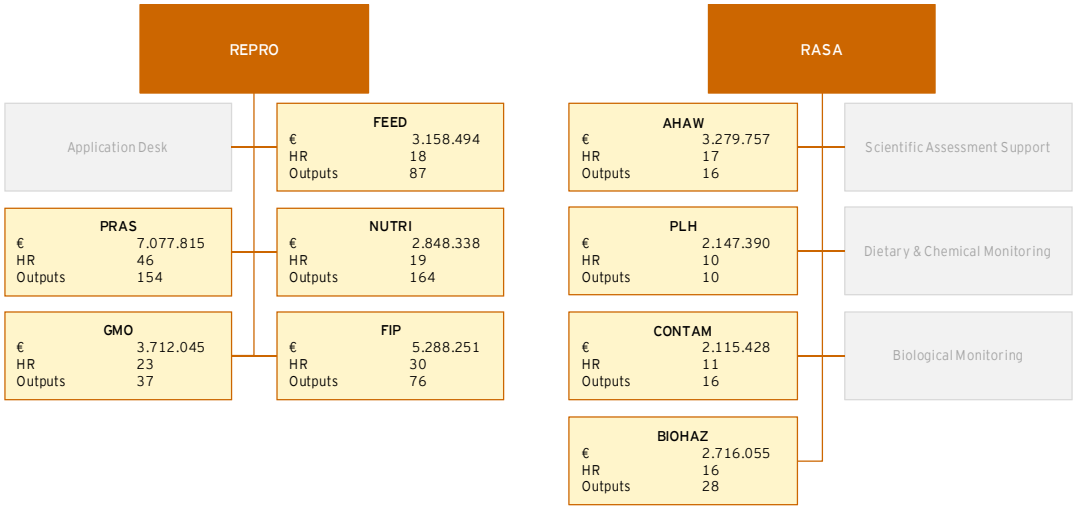
AREAS OF ACTIVITY	RESOURCES	2007	2008	2009	2010	2011	TREND	FUTURE CHALLENGES
PROVISION OF SCIENTIFIC OUTPUTS	Financial *% on Tot.*	47,2%	48,4%	43,2%	42,8%	39,9%	=	Workload Scientific quality Globalization/New food hazard Innovation in science Evolution of consumer Independence
	HR *% on Tot.*	42,9%	46,8%	42,0%	41,2%	45,5%		
SCIENTIFIC COOPERATION & DATA COLLECTION	Financial *% on Tot.*	17,8%	22,3%	27,6%	31,2%	31,1%	↑	Cooperation
	HR *% on Tot.*	14,1%	15,9%	24,3%	22,1%	24,6%		
RISK COMMUNICATION	Financial *% on Tot.*	16,1%	11,9%	14,4%	10,6%	9,2%	↓	Awareness and Communication EFSA's international role
	HR *% on Tot.*	13,2%	12,6%	11,6%	11,2%	9,3%		

[248] EU Agencies' governance costs, financial management and operational efficiency: comparative data, page 14. In this report Agencies' level of budgetary usage is compared for the years 2008, 2009, 2010.
[249] This chart has been prepared by aggregating 2008-2011 financial resources gathered from Annual Activity Reports (2008-2011) according to the new organization Directorates. It was not possible to aggregate in this way 2006 and 2007 data.
[250] Percentages have been calculated using data per activity 1, 2 and 3 (according to 2009 ABB nomenclature), gathered from 2007-2011 Annual Activity Reports. Concerning financial resources, executed appropriations have been considered.

(Source: EY elaboration on Annual Activity Reports 2007-2011[251])

The greatest part of EFSA's resources is assigned to the provision of scientific outputs, with 39,9% of financial and 45,5% of human resources in 2011 over the total (quite stable since 2007) (Table 32). More specifically, the figure below shows how these resources have been distributed in 2011 among Units mainly dealing with the provision of scientific outputs. By comparing human and financial resources assigned to different Units with the outputs released, it is possible to point out how an application (e.g., the majority of NUTRI outputs) requires fewer resources than a generic opinion (e.g., the majority of AHAW and PLH outputs). Nonetheless, a complete evaluation of the efficiency of each Panel should also take into consideration the high variety of types of outputs that EFSA has to deal with, as well as their increasing complexity (as better detailed in par. 3.6.3).

Figure 13: Resource distribution versus outputs produced by Units dealing with provision of scientific outputs in 2011.



(Source: EY elaboration on Annual Activity Report 2011)[252]

Scientific cooperation is the second area where most resources have been allocated and that has **gradually grown** in the considered period (Table 32). In particular, within scientific cooperation, financial resources allocated to data collection have increased over the years: in 2011 EFSA has allocated 7,23% of its budget (€ mil. 5,5) to data collection activities, a percentage 1,8 times higher than in 2007[253], as better described in par. 3.2 "Data Collection".

Moreover, the percentage of **budget and staff allocated to risk communication has progressively reduced** (Table 32) and is expected to remain stable in the coming years, as stated in EFSA's Communication Strategy[254].

[251] The listed future challenges correspond to *Q12.1* list. They are re-aggregated according to the activity areas in the first column.
[252] PRAS Units in 2011 produced 154 outputs, among which 55 relate to provision of scientific outputs, while 91 relate to data collection, scientific cooperation and networking.
[253] EY elaboration on EFSA's data, 2012.
[254] EFSA's Communications strategy 2010-2013 perspective (MB 16 12 10), p. 3.

RESOURCE ALLOCATION

- **ECHA** and **EMA**'s activities increased in the last five years, rising challenges around resource allocation.
- During the last ten years, **EMA**'s staff has increased from 200 people to 600 and due to restrictions on further growth of the establishment plan, the amount of non-established positions increased. Many Departments are understaffed.
- In **ECHA**, since the staff number is determined at EU level, the additional budget gathered through industry's fees cannot be used to enlarge the establishment plan, even though needed.

The internal processes

This part aims at evaluating the efficiency of EFSA's internal processes, analysing whether they are efficiently planned and managed. The following processes will be covered:

- EFSA's management systems and processes;
- Experts mobilization process;
- The Authority's planning and monitoring system;
- The flow of information between EFSA and the EC.

Since the Authority has grown and has diversified its tasks and outputs over the years, tools supporting the complex management and monitoring of its activities and resources have progressively changed.

EFSA's management systems and processes

The 2005 external evaluation pointed out the heterogeneity of EFSA's processes and the patchwork of different existing systems[255]. As a consequence, as illustrated in the Annual Management Plans, EFSA has tried to improve and develop its processes and methods. In particular, starting from 2011, in the context of the e^3 programme, a review of workflows and working processes across the organization has been carried out[256]. Thus, EFSA has started the Business Process Modelling (BPM) programme, consisting in the identification of activities, roles and responsibilities involved in the main processes and Units, in order to identify opportunities to improve efficiency. This programme has started in 2011 by mapping (AS IS situation) some of the processes related to the scientific activities of EFSA and to the CORSER Unit[257]. In the coming years, TO BE processes will be designed[258] and the same analysis will be extended to other business processes, aiming at their optimisation[259].

Among EFSA's management systems, IT systems represent a strategic area; significant initiatives have been implemented by the Authority to improve them. Indeed, the e^3 programme has pointed out the lack of standardization and integration in EFSA's IT systems and the lack of strategic guidance, clear priorities and objectives within the IT function[260]. In the context of the e^3 programme, EFSA will re-engineer IT processes and revise its IT governance. In addition, as recorded in the 52nd MB meeting minutes, a medium-term IT

[255] Such as Commission S12 for the budget, Infrastructure MS, document management system, hand-made applications for the scientific consultations, etc… (source: Evaluation of EFSA, final report, 2005, p. 14).
[256] Annual Management Plan 2011, p. 13.
[257] Corporate Services unit.
[258] With the exemption of the CORSER processes "Organization of events" already designed.
[259] Business Process Mapping, Draft Pilot Report for SCIENCE, 3/11/2011, p. 5-6. Business Process Mapping, Draft Pilot Report for CORSER, 3/11/2011, p. 5-6.
[260] EFSA efficiency programme initiation, SC4 Quick Scan Report, 2010.

operational strategy able to introduce a comprehensive and coherent approach on EFSA's investments and developments in IT systems is now ongoing, and an IT strategy document for adoption will be submitted to the Board in the coming months.

To standardize and harmonize the heterogeneous mix of processes previously detected, SOPs (Standard Operating Procedures) now exist for a significant part of the EFSA's scientific workflow, but according to the outcome of a recent internal survey,[261] these procedures are perceived by EFSA's staff as a burden and due to their complexity are frequently disregarded. (see also Provision of Scientific Outputs, Quality of scientific outputs). SOPs are described as numerous, unclear and subject to different interpretation, lacking plain implementing instructions. Moreover, a lack of enforcement or control is perceived on the application of procedures[262]. As consequence of this survey, SOPs are now under review.

Expert mobilization process

This paragraph relates to the specific process of selection of SC and Panels members as well as to the one followed by EFSA to mobilize experts.

Experts usually participate to EFSA's activities **voluntarily**. Indeed the Authority pays the experts by reimbursing travel and subsistence expenses and by paying an indemnity for their attendance to meetings or tele-meetings[263].

Regarding the process of selection, experts are selected through an **open and transparent procedure**. As the just finished (2012) process of renewal of the SC and of eight Panels demonstrates[264], the expert mobilization process has been implemented according to the following transparent phases as described in the related decision of the Executive Director[265]:

- launch of a call for expression of interest for membership of the Scientific Committee and Scientific Panels (Art. 2);
- appointment of the EFSA's Evaluation Team (Art. 3);
- screening of validity and eligibility of candidates (Art. 4);
- evaluation of all eligible candidates for scientific excellence (Art. 5);
- external review of the evaluation process (Art. 6);
- screening of Annual Declaration of Interests (Art. 7);
- sharing of the shortlist with the Advisory Forum for comments (Art. 7);
- candidates proposed for nomination (Art. 8);
- adoption of the list by the MB and appointment of the candidates (Art. 9).

More specifically, the above described expert mobilization process started in March 2011 with the launch of a call and ended in June 2012 with the adoption by the MB of the final lists of appointed experts. This means approximately 1 year and 3 months of duration.

The renewed SC and Panels are mainly composed by experts coming from universities (41%), but also from public research institutes (39%) and governmental bodies (15%), and a broad geographic distribution has been achieved[266].

[261] 2011 EFSA's Insight Survey – written feedback provided by EFSA's staff.
[262] 2011 EFSA's Insight Survey – written feedback provided by EFSA's staff.
[263] The indemnity amounts to 300€ per each full day of meeting attendance or 100€ per hour of tele-meeting attendance. Chairs may receive an additional indemnity to compensate costs incurred during the preparatory work for meetings. (Source: Rules of procedure of the Scientific Committee, the Scientific Panels and their Working Groups, Art. 31 MB 15 03 12).
[264] Renewal of Panels 2012 (MB 15 03 2012 and MB 14 06 2012).
[265] Decision of the Executive Director concerning the selection of members of Scientific Committee, Scientific Panels and external experts to assist EFSA with its scientific work.
[266] Appointment of the members of the Scientific Committee and eight Scientific Panels and placement of suitable candidates in the reserve list (MB 14 06 2012).

MOBILIZATION OF EXPERTS

The procedures to involve experts in panels (or committees) may vary in other EU agencies. The benchmarked organisations are spending less time in the recruitment of experts (in comparison with EFSA).

- Experts working for **EMA** and **ECHA** are mobilized from both National Authorities and professional Organizations, through a **nomination procedure performed by the Member States**. In the case of ECHA, each MS is entitled to nominate candidates for the Committee on Risk Assessment and the Committee for Socio-economic Analysis. The Executive Director prepares the list of nominees and then the Management Board appoints committee members from the list. As a general rule, members of EMA's scientific committees are nominated by the MS, after consultation with the Management Board. The expert mobilization is increasingly long, since it is growingly difficult to manage conflict of interests.
- Situations can arise where the need for additional expertise is not covered by nominations made by the Member States. At EMA, in such circumstances, the nomination of the identified expertise is undertaken by the Agency. All Scientific Committee members and experts must be included in the experts' database prior to the first appointment resulting in involvement in activities at the level of the Agency (meeting attendance, scientific evaluation, inspections, guidance development, etc.). At ECHA, they appoint specific expertise through grants contracts, **framework contracts** are set up to facilitate and speed up experts' involvement once the framework contract is signed.
- In the United Kingdom, the recruitment of experts is assigned to **professional recruitment societies**. The **FSA**'s Chief Scientist Advisor is involved in the process of selecting external experts **to supervise potential conflicts of interest**. In fact, selection procedures often check not just the scientific expertise of the candidates but also their independence. The declaration of interest document plays a key role in the process of nominating experts (*please refer to structure, governance and procedure for independence*).
- At VWA, the **expertise is hold internally**, for more reactivity.
- Across all the organizations, a key criterion for selection is scientific excellence in the specific field of work.
- Like the majority of EU Agencies, **ECHA** covers meeting costs and does not directly pay external scientists, whose salary is provided solely by MS. On the contrary, **EMA**, a part from covering travelling and hostel costs, pays a salary to experts.

The **selection criteria** used in the evaluation of eligible candidates show that high standards of quality are required to be selected (Figure 14). In addition, over the years, experts independence requirements have been progressively strengthened through, for example, the stricter controls of the new Policy on Independence 2011 (as further detailed in par. 3.7 "Independence").

Figure 14: Selection criteria applied in the evaluation of eligible candidates.

(Source: EY elaboration on "Decision of the Executive Director concerning the selection of members of the Scientific Committee, Scientific Panels and external experts to assist EFSA with its scientific work")

Besides the selection of experts for being members of the SC and Panels, external experts with specific and relevant scientific knowledge may also be invited to participate to the work of the Scientific Committee, Panels and Working Groups on an ad hoc basis, for a single meeting or for a longer term (i.e., for the duration of one or more specific mandates or projects)[267]. In order to easily identify adequate scientific profiles and mobilize them quickly once the need emerges, in 2008 the Authority has created an **expert database**[268], able to:

- assist in the selection of this type of external experts;
- enhance the transparency of the mobilization process;
- respond more effectively and flexibly to the growing workload (particularly in cases where very specialized, unexpected or urgent work may be required)[269].

As stated in the Expert Database 2009 and 2010 Annual Reports of Activities, the database has grown steadily, with information on 2579 experts in 2010, and EFSA continues actively promoting it[270]. Indeed, EFSA's purpose is to have an expert database as wide and variegated as possible, to ensure that experts with specific expertise can be quickly found when necessary, effectively answering to emerging situations and enhancing the Authority's capacity to conduct risk assessments[271].

The planning and monitoring system

EFSA has a set of **monitoring tools** at its disposal, such as, for example, a system of indicators (improved over time after the 2005 external evaluation), the Activity Based Budgeting, a Continuity Management Plan aimed at ensuring the continuous operation in case of practical difficulties (e.g., power failures, major computer failures etc)[272], a Register of Questions, a set

[267] Decision of the Executive Director concerning the selection of members of the Scientific Committee, Scientific Panels and external experts to assist EFSA with its scientific work, Art. 13.
[268] Expert Database 2009 and 2010 Annual Reports of Activities.
[269] Decision of the Executive Director concerning the selection of members of the Scientific Committee, Scientific Panels and external experts to assist EFSA with its scientific work, Art. 14.
[270] Expert Database 2010 Annual Report of Activities, p.13.
[271] Expert Database 2009 and 2010 Annual Reports of Activities.
[272] Annual Management Plan 2007, p. 7.

of Internal Control Standards, etc. Equally, EFSA disposes of work plans and public planning documents such as the Annual Management Plans.

Reporting documents are prepared annually[273], but have been frequently changed over time, making it difficult to compare EFSA's performance and to monitor the trend of resources allocated over time on its main activities. For instance, the nomenclature and composition of the ABB activities changed frequently as well as budget lines, indicators vary and changes are often not explained.

Moreover, the RAW (Risk Assessment Workflow)[274] is not configured to reconcile mandates with outputs provided. Thus, it is not possible to keep track of the amount of scientific outputs generated for each mandate and question.

Since 2011, within the e^3 programme, EFSA has started improving its planning and monitoring (P&M) capacity at the level of Executive Office and Directorates[275]. In particular, the Executive Office now embraces the centralized monitoring and reporting of organizational performance, supported by P&M teams, established at Directorate level[276].

In addition, in 2012 the Balanced Scorecard, established in 2011, should be fully implemented and will provide a better mechanism to monitor organisational performance and set priorities[277]. EFSA will also review its existing strategic initiatives to integrate them into an overall planning tool and it will develop a Multi-Annual Work plan covering all its activities[278].

Flow of information between EFSA and the EC

An essential element, to allow the Authority to appropriately plan and prioritise its work, is the constant and effective flow of information with NRM and the EC, the requestors of EFSA's opinions. Indeed, since the volume of requests for risk assessment continues to increase, open dialogue with risk managers on the quantity, nature and complexity of the workload is vital to enable EFSA to identify whether it has specific expertise available, to appropriately allocate resources and plan priorities[279]. In particular, since the majority of EFSA's work is in response to EC requests, a regular dialogue with the Commission is imperative, to jointly prioritise and plan the Authority's activities[280].

As a consequence of MB recommendations arisen from 2005 external evaluation (as shown in the box below)[281], EFSA has tried to strengthen its relationship with the EC, for example by participating in meetings of EC standing committees, Advisory Groups and Working Groups, having regular meetings with DG SANCO and other DGs Commissioners, and closely cooperating with DG RTD.

Medium and longer term planning with the Commission services has already been launched[282] and the information flow with the EC has gradually improved: in 2011 for the first time the EC provided EFSA with a roadmap, with a forecast on future requests[283].

[273] Such as, for example, Strategic documents, Budgets, Annual Activity Reports and Financial Reports.
[274] The RAW is an information system that keeps track of the progress of a question through the risk assessment process from the request receipt to the output delivery.
[275] Annual Management Plan 2012, p. 14.
[276] Annual Management Plan 2011, p. 14.
[277] Annual Management Plan 2012, p. 10.
[278] Annual Management Plan 2012, p. 14.
[279] Scientific Strategy 2012-2016, p. 10.
[280] Scientific Strategy 2012-2016, p. 10.
[281] Management Board conclusions on the external evaluation of EFSA and recommendations arising from the report, 2006, pp. 6-7.
[282] Science Strategy 2012-2016, p. 10.
[283] Annual Management Plan 2010, p. 9.

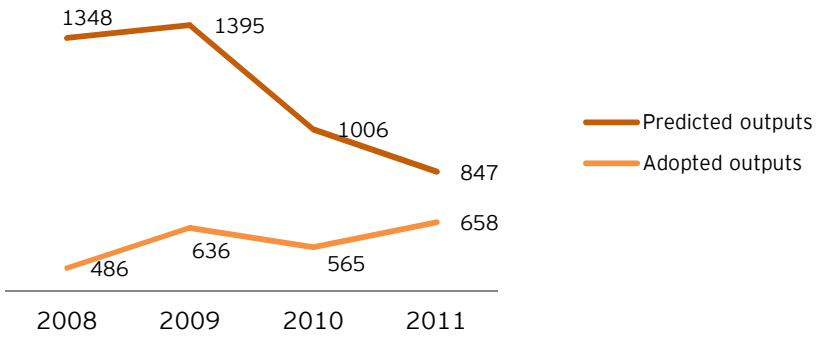
2006 MB RECOMMENDATIONS ON THE RELATIONSHIP WITH THE EC

- Encouraging the EU Institutions to involve EFSA more where there are issues that relate to its mandate under discussion.
- Fostering good working relations with the European Commission (in particular DG SANCO, RESEARCH, ENVIR, ENTR, AGRI, JRC) through regular dialogue at all levels.
- Establishing regular dialogue with the Commission and other EU Institutions to enable an appropriate allocation of resources and adaptation of the workload imposed by EU law.

(Source: Management Board conclusions on the external evaluation of EFSA and recommendations arising from the report, 2006)

The gap between EFSA's predicted and adopted outputs gradually decreased from 2008 to 2011 (Chart 23), witnessing the improved Authority's ability to define its work plan.

Chart 23: Comparison between EFSA's work plan and effective work, 2008 – 2011



(Source: EY elaboration on EFSA's data, 2012).

Nevertheless, according to the Science Strategy 2012-2016 it is essential that medium and longer term planning with the EC becomes even more comprehensive and efficient, in order to make EFSA better able to accommodate fluctuations in workload and anticipate the specific expertise it needs[284].

3.6.2.2 Stakeholders' point of view

The Management Board

Globally **the MB composition and decision-making processes are perceived as appropriate** (*Q15.3, Q15.1*) and the majority of respondents (60,38%[285] - *Q15.2*), suggest that no changes should occur to this body's composition and functioning. Nevertheless, even though EFSA's MB meetings are public and audio recordings and supportive documents are available online, survey and interviews reveal that **stakeholders know very little about this body** and, in particular, about its working methods. Indeed, this issue has encountered a significant level of NA for all the related questions both in the questionnaire and in the interviews. No specific reasons emerged to explain this result; only one NRA pointed out the difficulty for external parties to be aware about its functioning, because the MB it is not composed by Member

[284] Science Strategy 2012-2016, p.10.
[285] In this question (*Q15.2*) the percentage of NA is 37,65%.

States' representatives and rarely meets other EFSA's bodies[286].

The Management Board: role and composition

According to its interviewed members, the MB is playing its role effectively[287]. As a **strategic body**, it does not interfere with the daily functioning of the Authority, confirming what noticed in Direct Observations and through the desk analysis of the Annual Activity Reports.

80% of respondents (*Q15.3*[288]) judge the MB **composition** as **appropriate**, **in terms of mix of competencies and level of independence from national interests**. As previously illustrated, EFSA, differently from other European Agencies, has **the unique characteristic** that **its MB members are not Member States' representatives**: this, as pointed out by one MB member, should favour the decision-making process, reducing the occurrence of blocks and the risk that decisions are influenced by national interests. Nonetheless, some critics still persist on the independence of its members from the industry (as better detailed in par. 3.7 "Independence").

Despite the overall appreciated coverage of competencies, few stakeholders suggest that more experience in sociology and psychology (one EP), public health nutrition (one MB), provision of scientific outputs (one SC) and impacts on the environment (one NGO) may be a plus (*Q15.4*). Moreover, consumers (one Media and one MB) as well as small and medium enterprises (one FIR) should be more represented (*Q15.4*).

The Management Board: working methods

The MB decision-making process is perceived as adequate (82,8% of respondents rate it between 3 and 4 out of 4 – *Q15.1*[289]). Nonetheless, as pointed out by one MB member, webcasting of public session seems to influence the interaction among its members: discussion is more superficial and members do not say all they would like, due to the risk of being misunderstood by listeners. Discussion is assumed to be more open, deeper and less formal during private meetings. Regarding the frequency of MB meetings, 16,98%[290] of respondents would be pleased about a further increase in the number of Board meetings (*Q15.2* – MB, NRA, NRM, EP, SC[291]): in this way according to one of its members, the MB would be better able to discuss issues in deeper details.

The organizational structure

EFSA's distribution of work

It is **controversial whether the current distribution of work** among EFSA's staff, Panels and external bodies **is consistent with the Authority's objectives and activity evolution**. In particular, the reliance on external experts[292] is appreciated by some stakeholders, while questioned by others, and a dominant position on this point is not registered.

According to several stakeholders the reliance on external experts is **one of EFSA's main strengths**, since it guarantees **a wide portfolio of qualified and updated scientists** (NRM,

[286] Since EFSA's inception the Management Board met the Advisory Forum just once in 2011: this experience is judged very positively by some interviewed National Risk Assessors, because it was a very good opportunity to dialogue and exchange views.
[287] One MB member pointed out that the disposal of a higher perspective on political, financial and organizational dynamics would be positive to enhance MB capacity to effectively play its role (*Q15.5* – MB).
[288] In this question (*Q15.3*) the percentage of NA is 20,7%.
[289] The percentage of NA In *Q15.1* is 22%.
[290] In this question (*Q15.2*) the percentage of NA is 37,65%. If NA are considered, the portion of respondents suggesting an increase in the number of MB's meetings reduces to 10,59%.
[291] The majority (55,6%) of respondents wishing this change are Management Board's members (*Q15.2*).
[292] External experts are identified in Panel members, Scientific Committee and Working Groups' members.

NRA, FIR, EP[293]). Indeed, as suggested by one NRM, external experts' liaison with universities and research centres may enable them to enrich their knowledge and to be aware of the latest innovations. Further limiting experts' mandate renewals could ensure a more frequent expert/expertise turnover (one MB). This practice, should however be adequately balanced with the risk to limit expertise continuity as better explained in the following paragraphs. Coherently with the above presented opinion, it is inconceivable that EFSA develops internally all needed competences (NRM). As suggested by one IO, the **Authority's staff** should be engaged solely in **supportive or managerial functions** (e.g., data collection or management of emergencies), better cooperating with national Research Institutions, to better deal with scientific work (one EP).

On the contrary, other stakeholders would prefer a reduction of EFSA's dependence on external scientists, in favour of **inner expertise enlargement** (FIR, Scient.Org.[294]). Few reasons are suggested by stakeholders:

- the actual distribution of work does **not allow the efficient management and control of workload** (Scient. Org., FIR[295]). Indeed, external scientists, as employees of other Institutions, work for EFSA in their spare time, while an efficient and effective management of the increasing workload requires full time resources (Scient. Org., FIR). Alternatively, Panel members should be paid by the Authority to work more for it (one stakeholder per group: IOs, NGOs, EP, EC).
- As pointed out by one NRA, the Authority's **outputs**, since produced by external scientists, risk to be **perceived not as EFSA's opinions**. This reduces EFSA's recognition as an Authority in the field and limits its potential role.
- This reliance on external experts in the provision of scientific outputs **increases the Authority's exposure to attacks and critics**, because external scientists could be more influenced by interests (one NRA).

Thus, to overcome these limits, while taking advantage of the external expertise, scientific outputs could be produced by EFSA's scientific staff, whereas external experts should only intervene at the end of the process as peer-reviewers, evaluating and commenting the outputs internally provided (one stakeholders per group: NRA, Scient. Org., NGOs).

EFSA's staff, Scientific Committee and Panels' relative support is globally appreciated (*Q14.3* – EC, NRA, SC, Scient. Org.)[296]. Nonetheless, Panel members think that the dialogue with EFSA's staff is not always easy (*Q14.6* – one SC and one Scient. Org.). **An increased support to Panels and Scientific Committee** is demanded, in order to reduce Panel members workload and focus external experts' intervention only on value added tasks (*Q14.6* – one stakeholders per group: SC, NRM, Scient. Org., EC). Indeed, over the years EFSA has striven to improve its staff support to external experts as illustrated in the previous section.

When asked for other comparable organizations with a better distribution of work, EMA and ECHA are the first listed (*Q14.7* – Table 33[297]).

[293] This opinion is supported also by one Cons., one IO.
[294] This opinion is supported also by one NRM, one NRA.
[295] This opinion is supported also by one NRM.
[296] The evidences presented in this part do not include the opinions of the Authority's staff, Panels and Working Group's members, since they are not part of the cluster of stakeholders targeted in this evaluation.
[297] Acronyms of stakeholders in brackets mainly refer to one respondent.

Table 33: Organizations with a better distribution of work

Organizations with a better distribution of work	*Suggested more than once*	- ECHA (SC, Scient. Org., NRA) - EMA (FIR, NRA)	Scient. Org., NRA, FIR, SC
		- Dutch Health Council (SC) - IARC (Scient. Org.) - US EPA (NRA) - Netherland Health Council (NRA) - FSA (NRA) - FDA (NRA) - BFR (NRA) - ANSES (NRA)	

(Source: EY survey)

It is questioned whether EFSA's structure (Panel and Committee) is adequate to sustain the quality of work, both in terms of scientific outputs and needed expertise.

Beyond the debate on the Authority's reliance on external expertise illustrated before, increasing discussions on the sustainability of the Panels/Scientific Committee system are taking place:

- experts drafting and discussing opinions are few in comparison with the total number of Panel members (one NRA and one IOs), as also noticed in Direct Observations;
- managing and coordinating external experts' participation to EFSA's activities is time consuming and demanding for EFSA (NRA), as confirmed by the initiatives recently implemented by EFSA on this point (e.g., integrated expert management system);
- panel Chairs should be changed more frequently (one EC);
- the actual functioning of the Panels does not reflect the traditional scientific decision-making process (one NRA), because it is closed to external inputs both during the drafting of opinions and after their adoption.

Although questioned as still sustainable, the actual Panels and Committee structure seems adequate to support future challenges and increase in workload (63%[298] of respondents – *Q14.8*). **The Scientific Committee and Panels' interactions and expertise are adequate** to sustain the quality of scientific outputs (NRM, FIR, MB, NRA) (for further details see par. 3.1 "Provision of scientific outputs"). In the majority of domains, the Authority has a wide expertise variety at its disposal (NRM[299]), even though a more gradual Panels' renewals (*Q14.6* – one EC and one SC)[300]and longer experts' mandates (Scient.Org.) could better ensure expertise continuity. **The level of cooperation and networking among Panels is good,** although it may be further improved (e.g., between Animal Health and Bio Hazard) (NRA).

Globally, **EFSA's human resources are adequate** (3 or 4) **to support scientific outputs**, as stated by 78,9% of respondents (*Q14.5*). Moreover, in the majority of domains, the Authority provides all needed competences (NRM[301]) and EFSA's staff is perceived as professional and competent (one NRM and one IOs). Nonetheless, the Authority's staff is judged sometimes as **not enough experienced** (*Q14.6* – SC) and according to some stakeholders, **their scientific and managerial skills should be enhanced** (NRA, FIR). Indeed the Authority has put in place increasing trainings and professional development initiatives, as previously described.

[298] NA included.
[299] This opinion is supported by one MB and one FIR.
[300] In May/June 2012 one third of most experienced Panel members end their third mandate and are prevented to apply for the same Panel, *Q14.6* – one SC.
[301] This opinion is supported by one MB and one FIR.

Resources allocation

According to some stakeholders (FIR, NRM, NRA, MB), considering the context in which the Authority operates characterized by increasing workload and changing work areas, **the total amount of resources at EFSA's disposal is considered as not always adequate** to fulfil its objectives and challenges, suggesting an increase in the Authority's **size and financial resources**. According to few MB members, **more flexibility should be granted to EFSA's budget and establishment plan**, to deal with unexpected workload or new tasks, coming from newly adopted regulations or emerging situations.

Nevertheless, the position of some EP members is quite different: EFSA has followed the traditional EU Agencies' evolution in terms of resources and dimension, and now it has reached its maturity, therefore its budget and staff should not be further increased. At this point, according to one EC, the Authority should focus on improving the use of resources, by increasing its efficiency and better prioritizing its work. This is in line with the actions taken by the Authority over the years and with the plans illustrated in the Science Strategy 2012-2016.

According to some stakeholders (*Q13.3* – EC, MB) the way EFSA has allocated available resources among its activities **is consistent with its objectives, activity evolution and future challenges**, in terms of portions of budget assigned to each area and their relative growth over time. Indeed, resources allocated to provision of scientific outputs, cooperation and communication are rated positively (3 or 4 out of 4) respectively by 75%, 80% and 75% of respondents (EC, MB – *Q13.3*). This further confirms previous evidences coming from the analysis of the actual budget distribution. Nevertheless, when asked whether to maintain, decrease or increase the amount of resources allocated to these areas, stakeholders suggest some variations.

EFSA's should invest more in the **provision of scientific outputs**, as recommended by 71,4% of respondents (*Q13.4* – EC, MB), even though the highest percentage of EFSA's budget is already assigned to this area.

While the overwhelming majority of the EC respondents propose to maintain the current budget portion assigned to **cooperation** unchanged (*Q13.4*), this area represents an ongoing concern for NRA and MB members, as also noticed during the Direct Observation of Management Board's meetings[302]. According to these stakeholders, resources allocated to cooperation should be increased, to enhance sharing of data and work. In this context, more resources should be allocated to **data collection** (MB), where the level of standardization and the amount of data shared by Member States requires some improvements (NRM). Moreover, EFSA should invest in training activities, to harmonize and boost abilities in countries (*Q13.5* – MB).

Contrasting positions are registered among stakeholders about whether to decrease or maintain unchanged the current level of **communication resources**. In particular, according to 61,5% of Management Board respondents (*Q13.4*), EFSA should keep the budget portion devoted to communication steady, while the overwhelming majority of the EC respondents suggest to **further reducing** the amount spent in this area. Indeed, as suggested by one MB member, while at the beginning the Authority needed to significantly invest in communication to be known worldwide, now EFSA has reached an adequate communication level to Member States, media and general public and no further investments are needed.

The internal processes

EFSA's Management systems and processes

[302] Reference to the Direct Observations of the 51st MB (15th December 2011, Warsaw) and of the 52nd MB (15th March 2012, Parma).

A global stakeholder perspective on EFSA's internal processes is not available and interviewees do not know in detail EFSA's internal functioning. Nonetheless, some individual comments that should be considered in the analysis, although not exhaustive, are reported. Management systems and processes are perceived as **quite bureaucratic** (one stakeholder per group: NRM, FIR, Scient. Org., IOs) and some business processes and procedures should be simplified (one MB).

According to a MB member, **the IT still represents a big challenge** for EFSA, since there are many different IT systems not always communicating with each other and entailing high costs. Until now IT systems have been developed with limited coordination. As a consequence, reporting was not adequate, causing sometimes format incoherency and information incompleteness (MB). Nonetheless, **the new IT integrated strategy**, that should be adopted by the end of 2012, should support the implementation of an integrated IT system.

Moreover, some stakeholders pointed out that **EFSA's data collection software should be enhanced** (NRM, NRA), since it is considered heavy, expensive and incompatible with Member States' software (NRM, NRA). More specifically, it should become more flexible, to allow more effective interactions (NRM, NRA).

Expert mobilization process

The experts' mobilization process is **efficient in terms of expertise collected**, **objective evaluation** of the candidates (MB) and **independence**. Indeed, the main strengths of this process are identified in EFSA's capacity to select the best experts (*Q14.9*) and to guarantee their independence (*Q14.11* – SC, Scient. Org.). Also the transparency of the process and the information published on the website are appreciated (one NRM).

Nevertheless, few criticisms arise on **the application procedure** that is perceived by few stakeholders as quite **rigid** and **time consuming** (*Q14.11* – Scient. Org.)[303].

Few stakeholders identified the following issues as obstacles in EFSA's recruitment of experts:

- **national scientific organizations' budget constraints** that limit the participation of their experts to EFSA (one Scient. Org.);
- the geographically uncomfortable location of the Authority in Parma (NRM, NRA, IOs, EC), that sometimes discouraged applicants;
- the **low financial compensation** given to external experts (one EC).

Additional criticisms are directed to the usage of the expert database: it is extensive, but only a small percentage of experts eventually cooperate with EFSA (NRA, MB Direct Observations[304]). Nonetheless, as emerged from the desk analysis, the size of the expert database is justified by the need to ensure that whenever an expert with a specific expertise is needed he or she can be quickly found.

When asked to list other comparable organizations with more efficient mobilization processes, **EMA and ECHA** were proposed (*Q14.10* – Table 34[305]), but no specific reasons are given by stakeholders to explain their choice.

Table 34: Organizations with more efficient experts' mobilization processes

Organizations with more efficient mobilization	*Suggested more than once*	- ECHA (Scient. Org., FIR) - EMA (FIR, NRA)	Scient.Org., FIR, NRA, SC

[303] This opinion is supported also by one NRM.
[304] Reference to the Direct Observations of the 52nd MB (15th March 2012, Parma).
[305] Acronyms of stakeholders in brackets mainly refer to one respondent.

	Suggested once	- DG Research (SC) - IARC (Scient. Org.) - MedVetNet (NRA) - FDA (NRA) - WHO/FAO (NRA) - BFR (NRA) - ANSES (NRA)

(Source: EY survey)

The planning and monitoring system

Information provided by EFSA on its budget, resource allocation and HR seems to **meet the European Commission's requirements** according to EC respondents (*Q13.1, Q13.2* – EC)[306]. Nevertheless, **some improvements** in EFSA's information and justifications **are suggested** (*Q13.1, Q13.2* – EC). In particular, according to one EC, as regards EFSA's budget and resource allocation, the quality of the annual financial statement and the multiannual staff policy plan could be improved[307]. As regard HR, more clarity is requested on data concerning vacancy rate, the evolution of HR expenditure, changes in organizational categories and grades, and discrepancies between authorized and filled posts.

Flow of information between EFSA and the EC

According to MB members,[308] **the flow of information between the European Commission and EFSA improved over time**, supporting a better planning of the Authority's activities. This improvement is also confirmed, as seen before, by the introduction of the Roadmap in 2011 and by the reduced gap between foreseen and adopted outputs.

71,4% of EC respondents (*Q16.1* – EC) stated that **EFSA is able to use the information provided by the Commission** to plan appropriately its activity. Nonetheless, several EC respondents admit that it is difficult for the Authority to foresee the future amount of requests (*Q16.2* – EC)[309].

3.6.2.3 Analysis of evidences

The efficiency of the Authority has been evaluated in relation to:

- The Management Board (and more specifically: role and composition, working methods and costs);
- The organizational structure (and more specifically: roles and composition, distribution of work and resources);
- The internal processes (and more specifically: management system and processes, expert mobilization process and the flow of information between EC and EFSA).

The evaluation results starts with the analysis of the Management Board, due to its external role if compared with the rest of the EFSA's organizational structure and to its responsibility to set strategic directions for the Authority. The evaluation of EFSA's organizational structure is then presented taking into consideration its main bodies except the AF, better detailed in the Cooperation and networking paragraph. Internal processes and their contribution to EFSA's operations are detailed at the end due to their transversal nature.

[306] In questions *Q13.1* and *Q13.2* a high amount of NA is registered in EC answers, respectively 25% and 37%.
[307] For example, according to some EC respondents in the last financial statement information about the building was missing and information on outturn 2011 was succinct (*Q13.1*).
[308] This opinion is supported also by one EP.
[309] 83,3% of EC respondents rated 3 or 4 the gap between the EC foreseen opinions and the actual opinions requested. If NA are considered, this percentage reduce to 71,4% of respondents.

The Management Board

The EFSA's Management Board plays its strategic **role**, as described in the Founding Regulation, without influencing the Authority's scientific advices, as also observed during the direct observation of MB meetings. Its role has evolved since the Authority became operational in 2002, in order to adequately support the Authority's development steps. Thus it has shifted from an initial focus on the adoption of rules and procedures to its current emphasis on evolving EFSA's strategy and future direction.

Regarding its **composition**, despite some minor lack of competence has been pointed out, the members' broad range of expertise related to the food chain, their broad geographic distribution and the global compliance with the requirements set in the Founding Regulation, support the conclusion that there is no need to change. The current composition of the Management Board allows the Authority to assure all the tasks foreseen and to perform its role appropriately and independently. Indeed, differently from other EU agencies, like EMA and ECHA, the members are not MS representatives, they are appointed in a personal capacity and thus they do not represent any national interest during the discussion.

The increasing number of decisions adopted by the MB since 2009 in the decreasing number of meetings held shows the appropriateness of the MB working methods. Despite stakeholders seems to know very little about the MB functioning, EFSA's MB normally holds part of its meetings in public through a distinctive system of webcasting, differently from other EU agencies. This, together with the publication of agenda and supportive documents before each meeting, allows an adequate participation of all interested parties to the discussion. Therefore, a change in the working methods is not suggested.

There is evidence of progressive **gains of efficiency** of the EFSA's Management Board if we consider the decreasing trend of the unit cost per decision and the unit cost per meeting. Thanks to the switch from live video webcast to on demand audio webcast and to the decision to stop to organize meetings around Europe but to meet only in Parma seat, the EFSA MB costs in 2012 are expected to fall below the average meeting costs of other EU Agencies' MB. These gains of efficiency should thus continue while maintaining a high quality in the discussions, as also suggested by some stakeholders, and an appropriate level of transparency on decision making process.

The organizational structure

The Authority significantly relies on external experts in performing its main activities, as confirmed by the number of experts, three times higher than EFSA's staff. This structure seems appropriate and allows the Authority to fulfil its mandate as confirmed by the increasing trend in the number of outputs released, the global suitability of these outputs to clients' needs (see par. 3.1 "Provision of scientific outputs") and the high number of experts/expertise willing to participate to EFSA's work.

The broad range of expertise and the broad geographic distribution of **experts** involved in EFSA's activities show that experts are globally adequate to perform the different steps of EFSA's scientific decision-making processes in Panels/Scientific Committee/Working groups. Further supporting evidences come from stakeholders, whose majority consider external experts as one of EFSA's main strengths and as an active link with universities and research centres that enable the Authority to benefit from the latest innovations and findings.

On the other hand, despite globally appreciated. **EFSA's staff** is not always experienced enough to adequately perform its roles under both a scientific and a managerial point of view. The increasing workload has entailed a progressive involvement of EFSA's staff in the provision of outputs through scientific and administrative support to experts in Panels and Committee. Despite the constant increase in the number of knowledge workers over the last

six years, the changing context has pointed out some lacks of skills in EFSA's staff that the Authority has already started to face through the reorganization of the HR Unit to improve HR management and to ensure to EFSA's staff learning and development processes adapted to individual and organizational needs. The recent adoption of a Learning and training policy to strengthen EFSA's staff skills and competences in line with EFSA's strategy is an additional evidence confirming the Authority's engagement on this issue. It is therefore recommended to continue in the same direction.

Despite all needed expertise is available and the structure is appropriate, the actual **distribution of work among experts and EFSA's staff** does not seem to be completely effective and efficient in a future perspective. Indeed, there are some evidences, coming from the desk analysis and the direct observation, confirming few stakeholders' comments, that the Panel/Committee system could be improved: experts are overloaded, not all members of a Panel take an active role in the discussion and significant efforts are required to EFSA to manage and coordinate experts' involvement. This suggests that the distribution of work between experts and EFSA's staff should be rebalanced in order to better manage the increasing workload and adequately exploit staff and experts competences. Experts should then be focused on value added tasks together with an increased role to EFSA's internal scientific capacity in supporting them. This rebalancing would contribute to a more sustainable situation in terms of independence, timeliness and attractiveness for external experts in particular for regulated products. A rebalancing of the roles given by the legislation to Panels/external experts could further support the Authority in the efficient allocation of resources to deal with its workload.

As regards **EFSA's overall resources** and their allocation, EFSA has now reached its maturity as confirmed by the decreasing growth rate of its budget trend. Despite many stakeholders have suggested an increase of the Authority's resources, no significant changes in EFSA's budget and staff are expected for the next years, in line with the development path of other EU agencies. Thus, coherently with the e^3 programme aiming at reviewing and enhancing the Authority's efficiency, EFSA should continue to improve its efficiency. Differently from EMA and ECHA, EFSA does not charge fees for its services. This option, already foreseen in the Founding Regulation and positively evaluated by FIR, is still under evaluation and it will be the occasion to see whether EFSA could further increase its budget in the future. EFSA's resources are globally consistent with the Authority's objectives as demonstrated by the decreasing gap between assigned and executed appropriations over the years.

The **current EFSA's resource allocation** is also coherent with the activities evolution. Indeed, as the trend in the number of requests has progressively increased, the greatest part of EFSA's human and financial resources has been assigned to the provision of scientific outputs. More specifically, coherently with the relevance of applications in this increasing workload (up to approximately 60% of EFSA's outputs in 2011), most resources assigned to the provision of outputs have been dedicated to applications. Also resources allocated to cooperation have increased over time confirming the importance of cooperation for the effectiveness of EFSA's performance. Lastly, resources assigned to risk communication have also followed the activities evolution. Indeed, after a first period of investment during which the Authority needed to be known worldwide, resources have started to decrease.

Considering both the **future** challenges (e.g., increasing demand for scientific opinions, increasing complexity and innovation of risk assessment), that the Authority will have to face, and the past trend of resource allocation, there is the need to continue in the same direction as previously illustrated. More specifically, and coherently with stakeholders' point of view, resources allocated to the provision of outputs should continue to increase together with those assigned to cooperation. In this area (as better illustrated in par. 3.2 "Data Collection") cooperation to gather high quality data is particularly crucial to allow EFSA to provide high

quality outputs. The budget portion dedicated to risk communication could instead gradually decrease.

The internal processes

Provided that, to better face future challenges, EFSA's structure and resources allocation should slightly change to be aligned with the evolution of the workload and the work areas, the internal processes should improve as well, being transversal to the main organizational Units. The heterogeneity of EFSA's **management systems and processes** in use has limited their contribution to the effectiveness of the Authority's operations, as shown by the differences among outputs produced (see par. 3.1 "Provision of scientific outputs"). There are evidences from the desk analysis that show that efforts are now ongoing in relation to this issue even if it is too early to evaluate their impact in terms of effectiveness and efficiency. Indeed, EFSA, within the e^3 programme, is implementing a Business Process Modelling to identify opportunities to improve the efficiency of its main processes.

Besides processes, implementing procedures are still complicated and thus frequently disregarded by EFSA's staff, as clearly emerges from a recent internal survey. SOPs are now under review and this will be the opportunity to evaluate their effectiveness as well as the Authority's enforcement capacity.

Within the management systems, the **IT systems** have represented a critical area due to the limited coordination in their previous development that has led, as suggested by interviewees of EFSA's bodies, high costs and compatibility criticalities. Relevant improvements are expected to come with the forthcoming adoption of a comprehensive operational IT strategy.

Despite EFSA disposes of a set of **monitoring systems** (e.g., performance indicators, Activity Based Budgeting, a Register of Questions/Risk Assessment Workflow) there are evidences about their limited effectiveness. Indeed, the analysis of reporting documents pointed out changes, not always enough explained (e.g., in the indicators, in the definition of budget lines and ABB activities) that make it difficult to compare EFSA's performances and to monitor the trend of resources allocated over time on its main activities. The Risk Assessment Workflow is not configured to reconcile mandates and questions with outputs thus limiting the monitoring of the relation between inputs (mandates) and scientific outputs produced. The implementation in 2012 of the Balanced Scorecard will provide a more structured mechanism to monitor organizational performance. Related impacts still need to be evaluated.

The **planning system** has improved as well through the e^3 programme and more specifically through the centralization of the planning capacity at the Executive Office and the creation of Planning and Monitoring Teams at the Directorate level to define a consistent strategy and to better implement it.

To further improve its planning capacity, EFSA has significantly enhanced **the flow of information with the EC**. Indeed, after ten years of "informal" relations (e.g., participation to meetings) between EFSA and the EC, the main requestor of EFSA's outputs, in 2011 the EC has provided EFSA for the first time with a roadmap on future requests in order to support the planning of the Authority's activities. This represents an important shift towards a more integrated and effective flow of information. Indeed, in 2011 the gap between foreseen and adopted opinions has significantly reduced if compared with previous years, thus confirming the improved planning capacity. The mutual (EFSA and EC) involvement to dialogue and exchange of information should continue to further enhance the Authority's planning capacity.

Coherently with the Founding Regulation, EFSA has defined a specific **process for the mobilization of experts**. In EFSA, differently from other EU agencies like EMA and ECHA where experts are nominated by MS, experts have to be selected through an open and independent procedure and they get, differently from EMA, just an indemnity and work voluntarily. In this context, EFSA expert mobilization process is efficient in terms of the wide

expertise collected as demonstrated by the profiles of experts recently selected for the SC and Panels renewals, by the recognized quality of EFSA's experts and also in terms of independence guaranteed by stricter controls. Nonetheless, as the recently closed renewal process demonstrates, the timeline of this process is quite long (more than 1 year) confirming the few comments received by stakeholders in relation to this issue. To speed up the activation of experts when a specific need emerges, the Authority has created in 2008 an Expert Database where needed experts' profiles could be searched and quickly activated. This database includes a high number of profiles and covers a broad range of expertise, nonetheless its use seems to be not completely efficient as further detailed in par. 3.4 "Cooperation and networking".

3.6.2.4 Evaluation results

EFSA's MB and the organizational structure allows the Authority to fulfil its mandate but the distribution of work among staff and experts seems to be unbalanced to adequately face future challenges. Resources are allocated consistently with the Authority's objectives and activities evolution, but processes could better contribute to the effectiveness and efficiency of EFSA's operations.

The **Management Board** plays its strategic role effectively and does not influence EFSA's scientific advices. Its composition guarantees a good mix of competences, independence from national interests and contributes to the effectiveness of the decision-making process, thanks to the distinctive characteristic that MB members are not MS representatives and thus do not represent any national interest during the discussions. The MB is also efficient. Indeed, EFSA has recently undertaken some actions (e.g., no more itinerant meetings, no more live video/audio webcast) to reduce the costs of its meetings that for 2012 are expected to fall below the average of other EU Agencies.

EFSA's **structure and the distribution of work** are globally appropriate to the type of work entrusted to the Authority, its experts are able to perform the different steps of the decision making process and they allow to cover all the fields of the Authority's activity. Despite all needed expertise is available and the quality of outputs is recognized, the actual Panel/Committee system seems not completely adequate to face future challenges. Experts, even though they are many, are overloaded and efforts are required to EFSA to manage and coordinate their participation to the Authority's work. This suggest that their involvement should be rebalanced in a way the Authority could better benefit from their competences, focusing the experts' involvement on value added tasks which require high scientific expertise and leaving to EFSA's staff supporting and standardized activities. Nonetheless, EFSA's staff is not always enough experienced under a scientific and managerial point of view and thus EFSA should continue to perform the planned trainings to fill its competences gaps in order to further strengthen EFSA's internal capacity (in particular in regulated products). A rebalancing of the roles given by the legislation to Panels/external experts could support the Authority in the efficient allocation of resources to deal with its workload.

EFSA's **resources are consistent with its objectives** as confirmed by the decreasing gap between assigned and executed appropriations. Coherently with the **activity evolution**, the greatest part of EFSA's resources is assigned to the provision of scientific outputs where the percentage dedicated to the applications has progressively increased over the years. Also resources allocated to cooperation increased while resources for risk communication have decreased after a first period of investment during which the Authority needed to be known internationally.

Despite EFSA's internal processes have significantly improved their effectiveness and

efficiency over the years, further improvements are still needed and EFSA is already undertaking significant changes through a variety of strategic initiatives. As regards the experts' mobilization process, it is efficient in terms of expertise collected, evaluation of the candidates and independence. The management system and processes are the object of an optimization through the Business Process Modelling within the e^3 programme. The differentiated framework of IT systems is the object of another ambitious program of integration that will start with an IT integrated strategy in 2012. The Planning and Monitoring capacity will be improved as well within e^3 programme. The monitoring system is the one that requires some further improvements to be better structured and integrated. At the moment it is difficult to compare EFSA's performance indicators and to monitor the trend of resources allocated over time on its main activities, also because changes are not always explained enough. In addition, the RAW limits the monitoring of the relation between inputs (mandates), the questions produced and scientific outputs provided.

The flow of information between EFSA and the EC has improved over the years: thanks to the Roadmap, the Authority is able to better map out its future work. Nonetheless, further commitment is required from both sides in order to make the exchanges more frequent and useful.

3.6.3 The Authority's structure sustainability

The following part relates to the evaluation criteria of sustainability, which is analysed considering the following issues:

- Impact of the evolution of workload and work areas;
- The adequacy of the structure and its adaptability to the changes;
- The impact of the legislative framework.

3.6.3.1 Facts & Figures

Impact of the evolution of workload and work areas

Since its inception in 2002, EFSA's operating context has changed, consequently determining an evolution of its workload and work areas. This section focuses on the impact of the changing workload and work areas on EFSA's organization and work, and on the actions taken by the Authority to face them.

The changing workload

In the period of analysis, EFSA's workload has significantly increased. Indeed, between 2006 and 2011, the **number of requests** (in terms of questions) received by the Authority **has increased** (as shown in Chart 24) passing from 253 to 993. This corresponds to an increase of 74,5%. Coherently with this trend, the **amount of scientific outputs released has increased** as well, passing from 174 to 658[310].

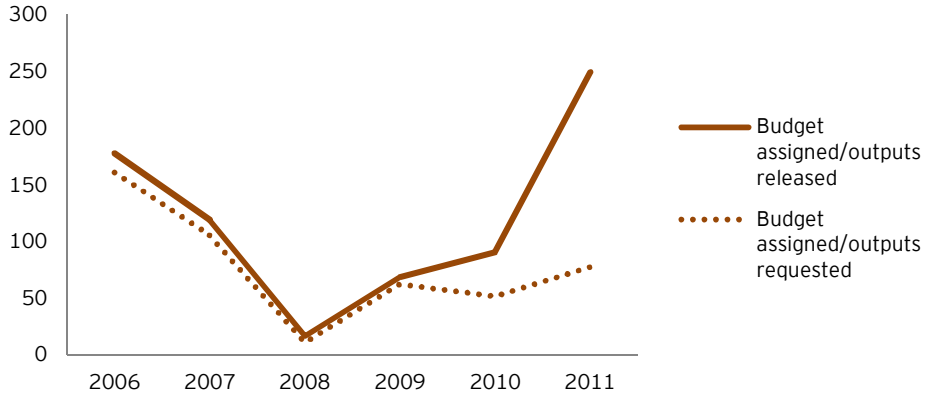
[310] Data provided by EFSA, 2012.

Chart 24: Evolution of requests (in terms of questions) in number and types, 2006 -2011

(Source: EY elaboration on EFSA's data, 2012)[311]

Nonetheless, volume is only one aspect of EFSA's workload, since the workload associated to a question may vary significantly: for example, different questions may require a different amount of new information to be gathered[312]. Indeed, as stated in the Authority's strategic documents, in the last years the adoption of new EU regulations, the spread of new technologies and innovation in food and feed production, the changes in consumption habits and the evolution of the EU landscape made **risk assessments more complex**, requiring new methodologies, multidisciplinary approaches and a higher stakeholders' involvement, and, thus, demanding higher time and efforts to process the requests[313], as witnessed by the increase in the unit cost per output and in the number of people involved per output since 2008, as shown in Chart 25 and Chart 26.

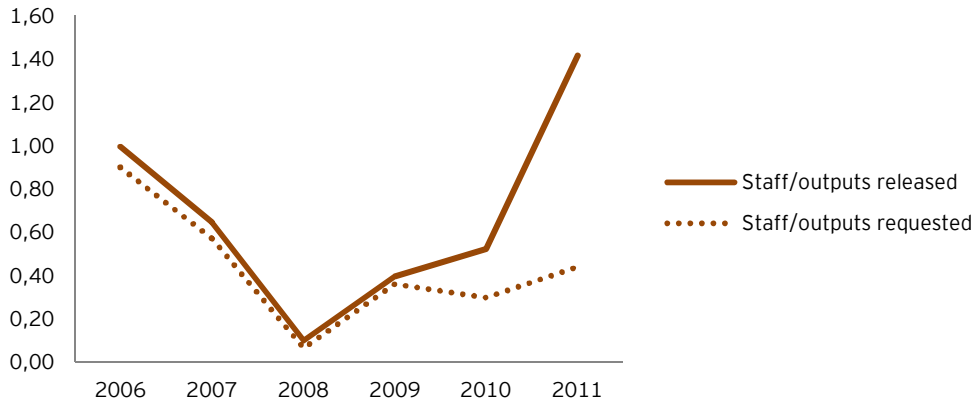
Chart 25: Budget/outputs requested and budget/outputs released (in terms of questions), in K€, 2006 – 2011



(Source: EY elaboration on EFSA's data 2012 and Annual Activity Reports 2006-2011)

[311] The peak of requests for applications occurred in 2008 is due to the implementation of the EU Regulation on Nutrition and Health Claims (Regulation EC No 1924/2006) that has required to EFSA the evaluation of high number of claims submitted by Member States to the European Commission.
[312] Science Strategy 2012-2016, p. 6.
[313] Strategic Plan for the European Food Safety Authority for 2009-2013.

Chart 26: Staff/outputs requested and staff/outputs released (in terms of questions), 2006 - 2011

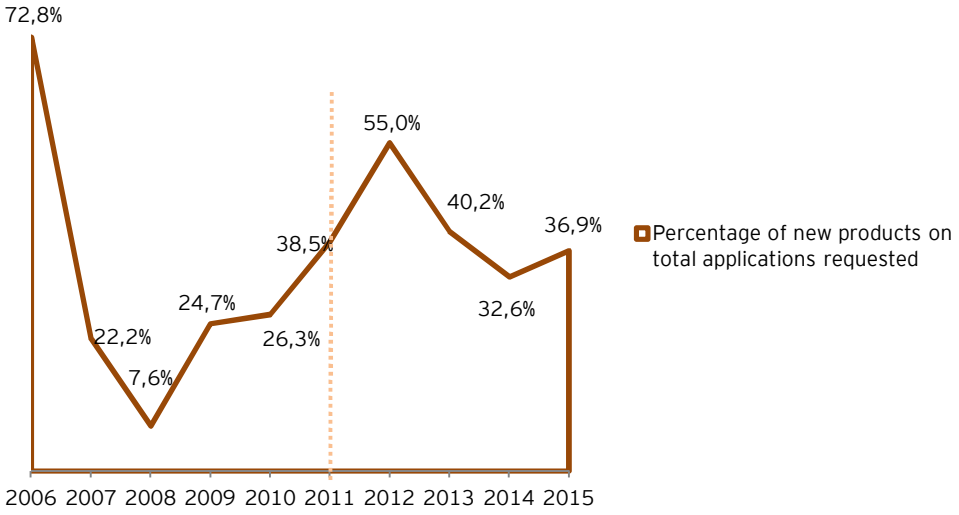


(Source: EY elaboration of EFSA's data 2012 and Annual Activity Reports 2006-2011)

The changing work areas

As stated in the Science Strategy, the above described changes have also modified EFSA's work areas[314]. While in 2006 the amount of requests for generic opinions and applications was similar, in the following years, the latter grew much more (Chart 24) and now applications account for more than 60% of EFSA's outputs[315]. Moreover, even though a significant part of the Authority's work for applications can be standardized, requests submitted by firms are highly heterogeneous and often unique. Indeed, a considerable percentage (on average 32%[316] from 2006 to 2011) of requests for applications regards new products (Chart 27).

Chart 27: Percentage of new products on total requests for applications (in terms of questions) 2006 – 2011 and estimates 2012-2015



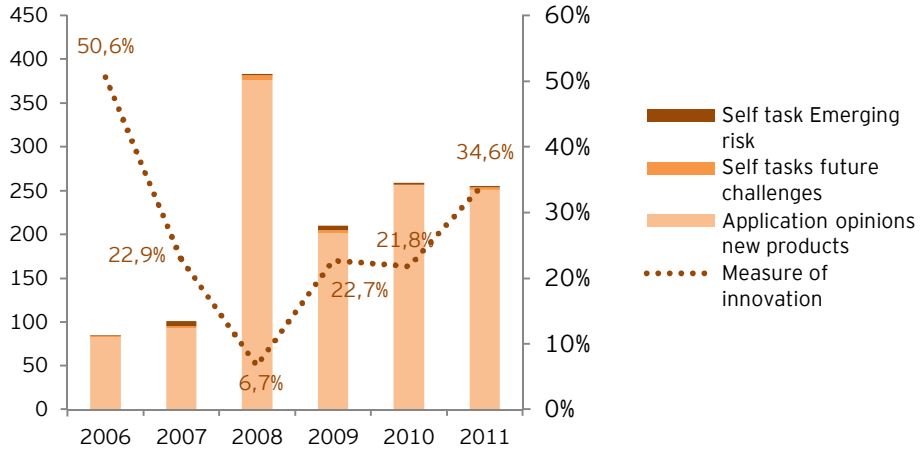
(Source: EY elaboration on EFSA's data, 2012)[317]

In addition to applications on new products, there are other outputs for which EFSA should use new competences and new methodologies: self-tasking outputs on emerging risks and on future challenges. A measure of innovation within the Authority could be thus calculated as

[314] Science Strategy 2012-2016.
[315] Data provided by EFSA, 2012.
[316] EY on elaboration of EFSA's 2012 data.
[317] Withdrawn questions have been subtracted to total amount of applications requested (in term of questions).

the ratio of requests related to applications on new products and self-tasking on emerging risks and future challenges to the total amount of requests. Chart 28 shows that since 2008 this ratio has progressively increased and that applications on new products have represented the major driver for innovation as the related requests are significantly higher than self-tasking ones.

Chart 28: Measure of innovation in EFSA from 2006 to 2011 (Requests on emerging risk, future challenges self-tasks318 and new products applications /tot. Requests - in terms of questions)

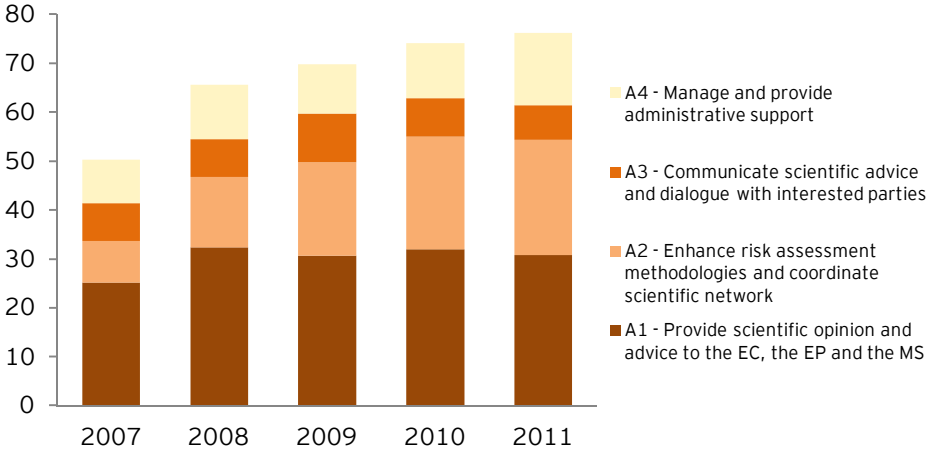


(Source: EY elaboration on EFSA's data, 2012)

Impacts of the changing workload and work areas on financial and human resources

These activity evolutions have strongly impacted the Authority and have demanded for more resources and more scientifically competent staff. Indeed, financial resources assigned to the provision of scientific opinions and advice have always represented the major portion of EFSA's budget, and those allocated to the enhancement of risk assessment methodologies and the coordination of scientific network have constantly increased over time (Chart 29).

Chart 29: Budget executed per activity in mln€, 2007 – 2011.



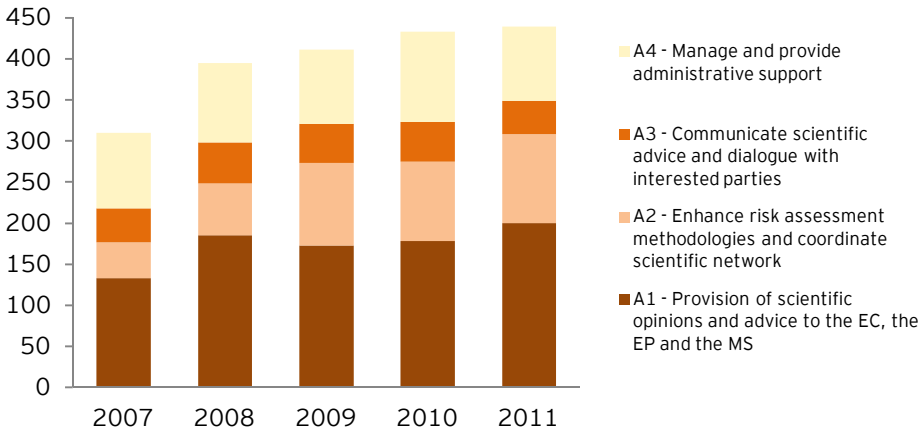
(Source: EY elaboration on Annual Activity Reports 2007-2011 [319])

[318] See par. 3.1 "Provision of scientific outputs" for further details on EFSA's self-tasking activities related to emerging risks and future challenges.

[319] Chart 29 and Chart 30 have been made by aggregating respectively 2007-2011 executed appropriation and staff, according to the ABB nomenclature adopted by EFSA in 2009. It has been assumed equal to ABB 2007 nomenclature (a part from a variation in A2 label). Equally, A1 has been

Equally, staff working in scientific Directorates has increased, while workforce employed in communication and administrative Directorates has remained pretty stable (Chart 30).

Chart 30: Staff per activity, 2007 – 2011



(Source: EY elaboration on Annual Activity Reports 2007-2011[320])

Coherently, according to the Authority's Multiannual Staff Policy Plan[321] in the near future managerial and organizational positions are expected to remain stable, while **scientific and technical positions will** mostly **absorb the limited staff growth** allowed to EFSA[322]. The constant increase in the number of knowledge workers (Administrators) confirms the increased professionalization of EFSA's staff (Chart 31: Evolution of Administrator (AD) and Assistant (AST) posts, 2006 – 2011). In addition, trainings have been implemented to enhance human resources' knowledge, expertise, skills and competences (as further detailed in the next paragraphs). Finally, **mobility and flexibility** in post allocation have been **put into motion** for general scientific competencies, in order to face high unexpected workload in specific scientific Units[323].

considered as corresponding to the sum of Activity 1 (Provision of scientific opinions and advice and risk assessment approaches) and 2 (Evaluation of products, substances and claims subject to authorization) in 2010 nomenclature, while A2, A3 and A4 has been treated as equal to respectively A3 (Data collection, scientific cooperation and networking), A4 (Communication and dialogue) and A5 (Governance and administration functions) in 2010 nomenclature.

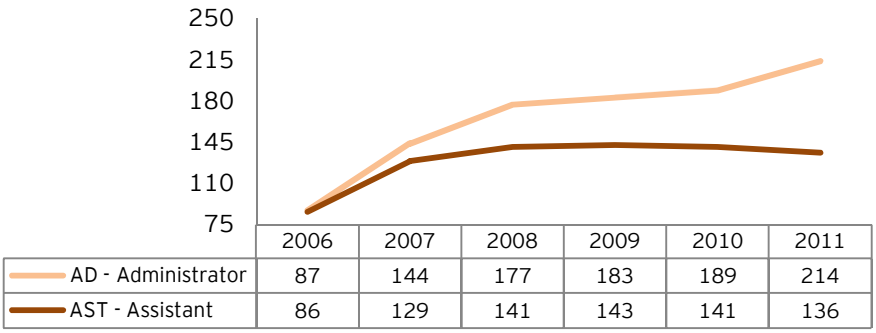
[320] See note 319.

[321] EFSA's Multiannual Staff Policy Plan 2011-2013.

[322] Multiannual Staff Policy Plan 2011-2013, pp. 11-12.

[323] Multiannual Staff Policy Plan 2011-2013, p. 21.

Chart 31: Evolution of Administrator (AD) and Assistant (AST) posts, 2006 – 2011



	2006	2007	2008	2009	2010	2011
AD - Administrator	87	144	177	183	189	214
AST - Assistant	86	129	141	143	141	136

(Source: EY elaboration on Annual Activity Reports 2006-2011).

In the considered period, **the number of Panels increased from 8 to 10**, in order to cope with the changing work areas or to better manage the workload in specific domains[324].

To better deal with the changing workload and work areas, in the context of the e^3 programme, EFSA has implemented a right-sizing[325]. This activity aims at identifying and reallocating resources to reinforce EFSA's scientific capacity. A number of administrative tasks (i.e., procurements, staff missions, meeting organization and application handling) have been centralized. This should allow savings and efficiency gains as well as the optimization of support process[326].

OPTIMIZATION OF SUPPORT PROCESSES

- Centralization of administrative and logistical aspects concerning meetings and events organization and handling of experts and staff mission in CORSER.
- Centralization of administrative and logistical aspects concerning procurement and contract management in P&M teams.
- Optimization of application handling process by pooling administrative aspects in the Application Desk.

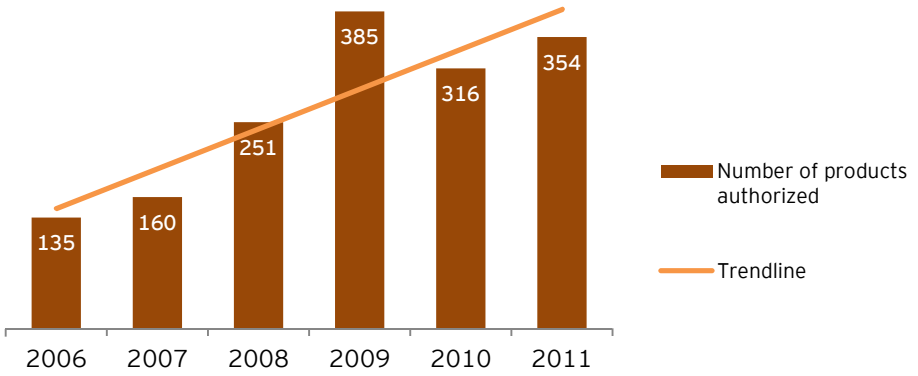
(Source: e^3 Programme, Final Right-sizing, Report Phase1, 1/12/2011)

Applications

As pointed out in the 2012 Annual Management Plan, the workload associated with applications is the highest one and is expected to remain considerable in 2012[327]. Since 2006 the amount of products authorized has gradually increased (Chart 32) as well as the number of applications requested and released (Chart 33)[328].

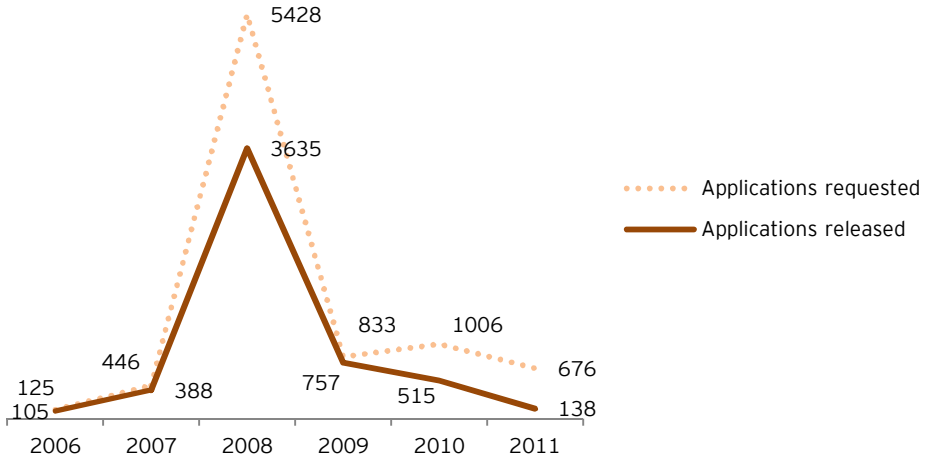
[324] More specifically, in 2006 the Panel on Plant Health was established and in 2008 AFC Panel was replaced by ANS and CEF. Source: Annual Activity Report 2006 and 2008, and Science Strategy 2012-2016.
[325] e^3 Programme, Final Right-sizing, Report Phase1, 1/12/2011.
[326] e^3 Programme, Final Right-sizing, Report Phase1, 1/12/2011.
[327] Annual Management Plan 2012, p. 6.
[328] As highlighted in the introduction, the impossibility to find a one to one correspondence between requests of authorization and outputs released limits the evaluation of the backlog.

Chart 32: Evolution of products authorized, 2006 – 2011



(Source: EY elaboration on EFSA's data, 2012)

Chart 33: Applications requested and released (in terms of questions), 2006 – 2011

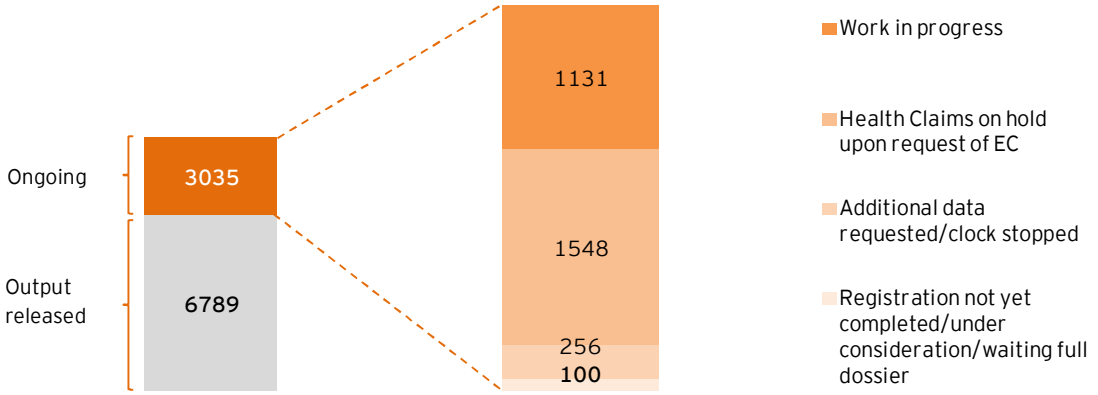


(Source: EY elaboration of EFSA's data[329])

As a matter of fact, **the increasing workload has determined a backlog**[330], corresponding to 1131 in progress outputs in term of questions (i.e., 11,5% of requests received from 2006 to 2011), as shown in Chart 34.

[329]Requests of applications have been calculated by subtracting the amount of total application requests (in terms of questions) and the number of questions withdrawn.
[330] In calculating the backlog withdrawn requests have been excluded.

Chart 34: EFSA's requests, ongoing and released in terms of questions, 2006 – 2011



(Source: EY elaboration on EFSA's data, 2012)

Applications represent the highest percentage of ongoing outputs (79%) both in terms of work in progress (45%) and in terms of on hold (99,6%)[331]. Nonetheless, with respect to the total amount of requests per type of output, the highest percentage of work in progress is counted in internal requests (53% of total internal requests), while the lowest in application (6% on total application requests).

The backlog may also depend on the increasing risk assessment complexity (previously detailed) as well as on the flow of information between EFSA and the EC, the EP and the MS. As stated in the 2012-2016 Science Strategy, in order to efficiently predict, prioritise and plan all its scientific activities, it is fundamental that EFSA entails an open dialogue with Risk Managers on the nature and the complexity of the workload[332].

EFSA has tried to face the growing requests for applications, searching for and implementing **new business solutions** (as further detailed in the box below). In particular, one of the aims of the new organizational model (May 2011) is to reflect the increasing workload on applications and to improve service to applicants[333].

In particular, the creation of **an ad hoc Directorate on scientific evaluation of regulated products** (REPRO) aims at bundling similar activities (by harmonizing working methods, increasing the flexibility in the distribution of workload in order to better handle peak periods, and sharing good practices). The focus on clients is further enhanced by the creation of **the Application Desk Unit**, strengthening the focus on science by centralizing certain administrative tasks, and preparing EFSA for future evolution[334]. The Application Desk acts as a front office and support desk for applicants and, in the future, it will also be responsible for centralising and processing the initial administrative steps of all applications (including reception, registration and controls on the administrative completeness of the information in the submitted application)[335]. Moreover, the unit has established a new helpdesk service on EFSA's website where users can access information on applications and submit specific questions related to the legal and technical requirements[336]. In parallel, as declared in the 2011 and 2012 Annual Management Plans, workshops, technical meetings and other forms of

[331] On hold requests correspond to questions whose registration is not yet completed or under discussion or waiting for full dossier, questions for which additional data have been requested and the clock has been stopped, and questions on hold upon request of the EC.
[332] Science Strategy 2012-2016, p.10.
[333] Annual Management Plan 2012, p. 6.
[334] E^3 programme and changes in the organization (MB 17 03 2011).
[335] Description on the scope of Directorates and Units within EFSA's new organizational model, p.11; EFSA's website.
[336] Annual Management Plan 2012, p. 6.

consultation and similar events will be prioritized, since dialogue with applicants is considered by the Authority a crucial aspect of EFSA's work[337].

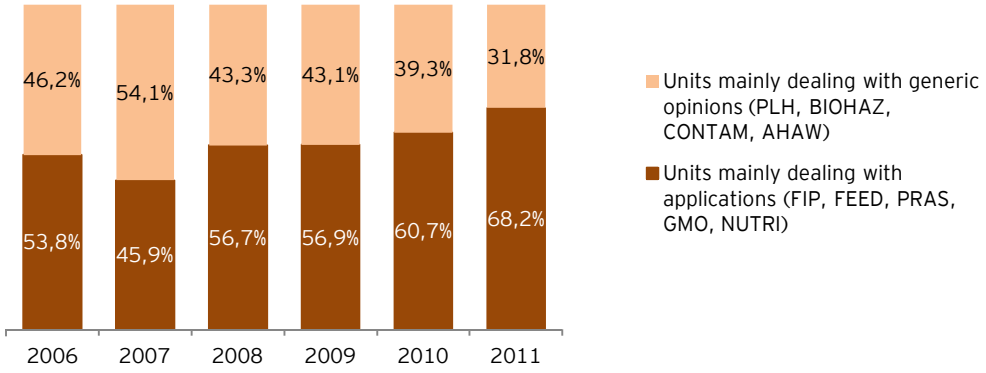
MAIN ACTIONS TO FACE THE APPLICATION WORKLOAD

- Creation of an **ad hoc Directorate**: Scientific Evaluation of Regulated Products, REPRO (2011).
- **Application desk** (2011):
  - Front office - support desk for applicants, MS and other stakeholders.
  - Back office - centralization and processing of initial administrative steps of applications.
- Guidance for applicants on how to design an application.
- Training sessions to increase EFSA's staff support to the drafting process of opinions on application dossiers.

(Source: 2006-2010 Annual Activity Reports and 2012 Annual Management Plan)

By comparing **resources allocated to Units mainly dealing with applications** and to Units mainly dealing with generic opinions, it emerges that budget and HR assigned to the first ones are **higher and have constantly increased** between 2006 and 2011 (Chart 35 and Chart 36).

Chart 35: Percentage of budget executed by Units mainly dealing with applications and generic opinions, 2006 – 2011

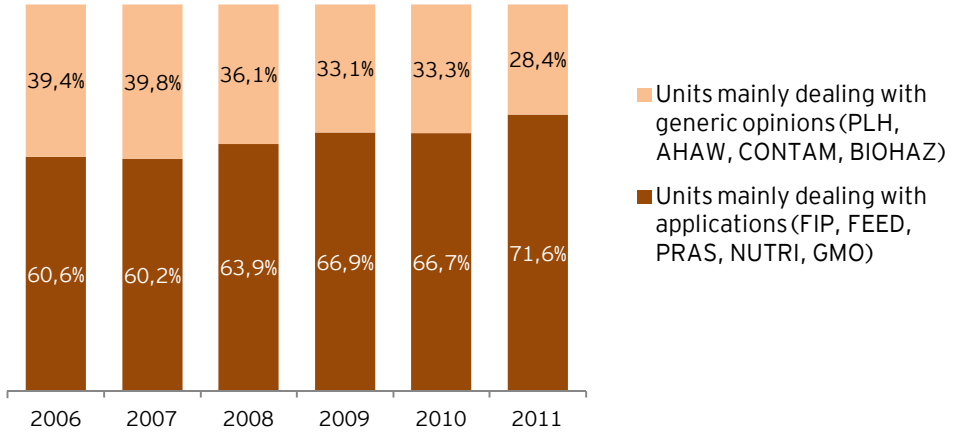


(Source: EY elaboration on 2006-2011 Annual Activity Reports[338])

[337] Annual Management Plan 2011, p. 3. Annual Management Plan 2012, p. 6.

[338] 2006-2007 financial resources have been aggregated according to Units of May 2011 Organization chart. Scientific Units have been grouped according to their main activity focus, i.e. generic opinions or applications. This exercise has required some approximations, due to the organizational changes occurred over time. For example, since absorbed by AHAW and BIOHAZ Units in 2011, Zonooses resources have been included among the ones related to Units mainly dealing with generic opinions. FIP resources correspond in 2006 and 2007 to AFC ones and from 2008 to 2010 are equal to the sum of budget assigned to ANS and CEF Units. Resources assigned to PRAS represent the sum of PPR and PRAPeR ones between 2006 and 2010.

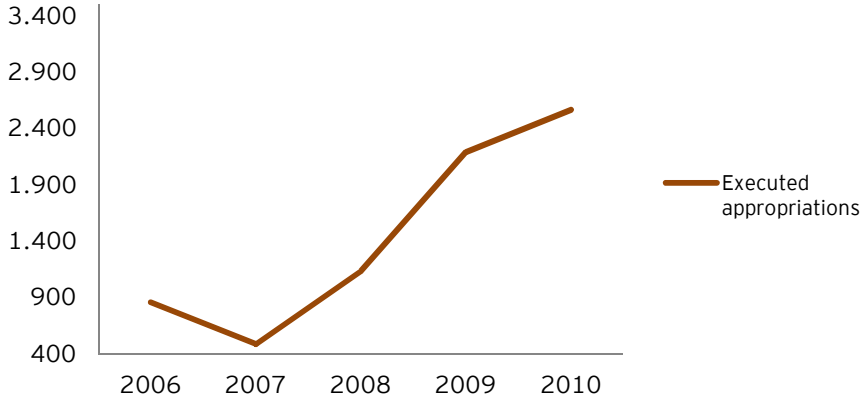
Chart 36: Staff by Units mainly dealing with applications and generic opinions, 2006 – 2011



(Source: EY elaboration on 2006-2011 Annual Activity Reports [339])

Equally, to better manage the workload of Units mainly involved in applications, **appropriations allocated to outsourcing** of reports, evaluations or studies to external experts or to MS' Research Organizations have increased in the considered period (Chart 37). EFSA aims at further developing outsourcing for various preparatory tasks, including in the area of review of regulated products by bringing investment in scientific cooperation with Member States. This activity will need to rely heavily on medium- and longer-term planning to support the needs of EFSA's risk assessment work[340].

Chart 37: Executed appropriations in K€ allocated to Units mainly dealing with applications, aiming at covering costs of scientific cooperation with external experts and to outsource studies and evaluations to MS's Research Organizations



(Source: EY elaboration on EFSA's statement of revenue and expenditure 2006-2010)[341]

[339] This chart has been prepared following the same logic applied in Chart 36: Staff by Units mainly dealing with applications and generic opinions, 2006 – 2011. For further details see footnote number 338.

[340] Science strategy 2012-2016, p. 11. Technical report of EFSA - Scientific Cooperation between EFSA and Member States: Taking Stock and Looking Ahead, 2011.

[341] The chart lines represent commitment and executed appropriations devoted to scientific cooperation with external experts and subvention for studies and evaluation, allocated to Units mainly dealing with applications (FIP, FEED, PRAS, GMO, NUTRI).

OUTSOURCING

- In **ECHA**, **EMA** and **FSA** the budget portion allocated to outsourcing activities (such as researches and surveys) has increased in the last 5 years.
- In order to increase its effectiveness and efficiency, some of **VWA** duties are outsourced and have been transferred to an independent non-profit organization.

EFSA's organizational structure adequacy and adaptability

EFSA's operating context has progressively evolved over the years, driven by, among others, scientific and technological advancement and by the changing legislative context[342]. Consequently, the Authority **has frequently tried to monitor and evaluate the adequacy of its structure and working methods** to the evolving context and the stakeholders needs. It is indeed true that EFSA has commissioned the 2005 external evaluation, public consultations on its strategic documents, insight surveys on experts' and internal staff satisfaction, the Eurobarometer survey, the current review of its efficiency (e^3 programme), etc. Coherently with the emerging results, there is evidence that the Authority adapted to continuous changes revising its priorities, management systems and practices, and modifying its organizational structure through **two important reorganizations occurred**, respectively, in October 2006 and May 2011.

The first reorganization in 2006 was the main outcome of the 2005 external evaluation[343] and of the related recommendations of the MB[344] as better detailed in the box below.

2005 EXTERNAL EVALUATION - MB RECOMMENDATIONS ON ORGANIZATION

- Revising the organization, in order to enhance the sense of common purpose, improve clarity of roles and streamline decision taking and reporting lines.
- Enhancing clarity of roles and responsibilities of departments and individuals.
- Developing management tools and processes, so as to facilitate day-to-day management.
- Further developing the MB's role to reflect the changing needs of the growing Authority.
- Better balancing in the distribution of work over the Scientific Panels, the Scientific Committee and EFSA's scientific staff.
- Increasing the maximum size of the Scientific Expert Panels and the number of independent experts on the Scientific Committee.
- Increasing recourses to outsourcing and co-operation with national authorities, notably through the implementation of the network provided for in Article 36 of EFSA's Founding Regulation.

(Source: Management Board conclusions on the external evaluation of EFSA and recommendations arising from the report, 2006)

As a consequence, in order to better cope with the Authority's main priorities, mission, tasks

[342] Science Strategy 2012-2016, p. 3.
[343] Required by Art. 61 of the Founding Regulation.
[344] The ensuing recommendations from the MB provided the framework for several changes in 2006 and in the following years, impacting a number of EFSA's aspects such as cooperation with Member States, relationships with institutional partners and stakeholders, the organizational efficiency, the effectiveness of communications, EFSA's role in nutrition, and its medium- and long-term vision (Source: Annual Management Plan 2008, p. 6).

and increasing size, the organisational chart was restructured, procedures, internal policies and monitoring system have been developed and improved[345], and various initiatives were implemented to improve the recruitment process, staff policies and appraisal systems, training policy and internal communications, and the quality management[346].

More specifically, the 2006 organizational chart envisaged some innovations that contributed to the improvement of the organization effectiveness:

- **the creation of new responsibilities in relation to the Scientific Cooperation and Assistance Directorate (SCA),** including more focus on Scientific Cooperation, Data Collection, Emerging Risks and Assessment Methodology[347] through the establishment of four specific units (Scientific Cooperation, Data Collection, Emerging Risks, Assessment Methodology). This has contributed to streamline the scientific experts' services and better manage projects aiming at improving risk assessment methodologies[348].
- **The creation of an Administration Directorate** centralizing all the support activities (Human Resources, Information Technology, Legal Affairs, Finance, Accounting and Facilities). This Directorate contributes to coordinate transversal organizational projects, such as, for instance, the Business Continuity Plan[349] and manage, centrally the administrative support to the organization.

Again, **in 2011 EFSA went through a reorganization in order** to review and enhance its efficiency and effectiveness, optimise the organisational performance and prepare the Authority to new challenges[350]. This occurred[351] as a consequence of the e^3 programme[352], launched by the Authority in 2010.

The box below shows the main organizational changes implemented in the 2011 reorganization.

MAY 2011 REORGANIZATION *(main changes)*

- Creation of a Science Strategy & Coordination Directorate (SCISTRAT).
- Split of the Risk Assessment Directorate into Scientific Evaluation of Regulated Products Directorate (REPRO) and Risk Assessment & Scientific Assistance Directorate (RASA).
- Merger of Units with similar remits (e.g.,, FIP = ANS+CEF; PRAS = PPR+PRAPeR).
- New Communication Units (Editorial and Media relations, and Communication Channels).
- Refocusing of human capital with an emphasis on skills development for both staff and experts (Knowledge Management).
- Establishment of new Units in business critical areas (e.g.,, Dietary and Chemical Monitoring, Biological Monitoring).
- Establishment of the Application Desk.
- Establishment of the Corporate Services Unit (CORSER).
- Strengthening of the Planning & Monitoring and Quality functions at the Executive Office (EXO) level. Creation of Planning and monitoring teams (P&M) at Directorates level.

[345] Annual Management Plan 2006, p. 4.
[346] Annual Management Plan 2007, p. 7, 56-57.
[347] Annual Management Plan 2007, p. 10.
[348] Annual Management Plan 2007, p. 20.
[349] Annual Management Plan 2007, p. 43.
[350] Annual Management Plan 2011, p. 3.
[351] Annual Management Plan 2012, p. 5.
[352] EFSA Efficient and Effective.

(Source: Annual Activity Reports 2011 and 2012, and additional secondary sources) [353]

This reorganization was due to the need to respond to a changing context, as already indicated in other parts of the report:

- The increasing demand for scientific opinions and more specifically for applications, representing now more than 60% of EFSA's outputs (see par. 3.6.3 for further evidences describing the increased and changing workload);
- The increasing need for cooperation with European and international stakeholders to enlarge the data collection pool and upgrade the debate on food hazards taking into account the enlargement of the food market entailed by the globalization (see par. 3.4 "Cooperation and Networking" and par. 3.5 "International role and recognition" for further details);
- The increasing differentiation of stakeholders interested in the Authority's activities and the variety of information needs to be satisfied (see par. 3.3 "Risk Communication" for further details);
- The limited increase in the future budget allocations and the subsequent need for the Authority to optimize the use of resources.

More specifically, **to manage the increasing demand for scientific opinions**, EFSA has decided to separate in two Directorates the activities related to applications from those related to generic opinions, to better deal with the specificities of the two different outputs. To reflect the increasing workload on applications, the new organization has envisaged **a Scientific Evaluation of Regulated Products Directorate** (REPRO), focused specifically on regulated products, and an Applications Desk Unit, to facilitate the interaction with stakeholders, and particularly applicants, and to enhance the internal efficiency of the application process[354]. To better manage generic opinions and more specifically to optimize resources for public health priorities, **the Directorate of Risk Assessment & Scientific Assistance** (RASA) is focused on generic public health issues and aims at facilitating efficient delivery of the work programme related to the core public health risk assessments. In addition, three new units have been created, i.e., Scientific Assessment Support (SAS), Biological Monitoring (BIOMO) and Dietary & Chemical Monitoring (DCM)[355], in order to better support risk assessments carried out by EFSA's staff and experts and to collect useful data and inputs for all scientific opinions.

To reinforce strategic coordination and support of scientific activities, the new organization has identified a specific Directorate specifically dedicated to the coordination of EFSA's scientific and cooperation activities (**the Science Strategy & Coordination Directorate**, SCISTRAT). Its key objectives include the implementation of EFSA's *Science Strategy 2012-2016* and the coordination of EFSA's activities in the area of emerging risks in the food and feed chain[356].

To reinforce the strategic approach to communications activities, **the Communications Directorate** has been **reorganized** into two functional units, Editorial & Media Relations, and Communication Channels respectively designed to streamline content development and editorial services, and information dissemination[357].

To optimize the use of resources, EFSA has **centralized previously de-centralised support services** in the Corporate Services Unit (CORSER) (i.e., maintenance of the premises, logistics and general services, logistic aspects for the organisation of events and linguistic

[353] Acronyms: ANS, food additives and nutrient sources; CEF, food contact materials, enzymes, flavourings; PPR, plant protection product; PRAPeR, pesticides.
[354] Annual Management Plan 2012, p. 3.
[355] Annual Management Plan 2012, p. 3, 5.
[356] Annual Management Plan 2012, p. 5.
[357] Annual Management Plan 2012, p. 10.

proofreading)[358].

An additional evidence of EFSA's adaptability and willingness to change could be found in the other foreseen axis of intervention of the ongoing **e³ programme,** as shown in the box below. Besides the new organizational chart, this programme identifies other key areas of intervention mainly related to: human capital management, organisational functioning, and IT governance[359]. Some of them will be detailed in the following paragraphs (e.g., paragraph Internal processes and paragraph Distribution of work).

E ³ PROGRAM KEY OBJECTIVES

- New organizational chart and right-sizing.
- Professionalization of Human capital & implementation of knowledge management.
- Optimization of Finance and IT governance.
- Optimization of processes.
- Optimization of strategic planning and budgeting.
- Implementation of an integrated performance management.

(Source: Annual Management Plans 2011-2012)

Impact of the legislative framework

The objective of this section is to evaluate the impact of the legislative framework on the Authority's functioning and performance.

EFSA's has been established in 2002 by the **EC Regulation No 178/2002**. This Regulation **defines several aspects of EFSA's organization and activities**, such as:

- its mission and tasks, Art. 22-23;
- the bodies it shall comprise (i.e., MB, ED, AF, Scientific Committee and Panels) and their main characteristics (e.g., the status of MB, Scientific Committee and Panels members), Art. 24-28;
- how it operates (e.g., provision of scientific opinions, data collection, identification of emerging risks), Art. 29-36;
- requirements concerning independence (e.g., experts' declaration of commitment and declaration of interests), transparency, confidentiality and communication, Art. 37-42;
- financial and general provisions, Art. 43-49.

Any change to the Authority's organization or functioning should be in compliance with what established in the Founding Regulation. Until now, even though EFSA's operating context evolved since its birth (as described in previous sections of the paragraph and transversally in the report), the Founding Regulation **remained unchanged**. The 2005 external evaluation pointed out the fuzzy character this Regulation has on some issues (such as EFSA's roles in communication and its degree of autonomy – self-tasking)[360].

Moreover, as stated in the Science Strategy 2012-2016, compared to other European Agencies undertaking safety assessments, the Authority's **Founding Regulation does not provide an overall regulatory framework for the evaluation of regulated products**. Rather, the regulatory processes, on which EFSA's evaluation activities of regulated products are

[358] Annual Management Plan 2012, p. 15.
[359] Annual Management Plan 2011, p. 3.
[360] Evaluation of EFSA, final report, 2005, p. 5.

based, are defined by **a large number of sector-specific regulations,** as listed in Table 35, **with different requirements**. Regulatory workflows in force in the various areas are numerous and diverse and have been established over time as a result of a succession of legislative initiative developed by the EU in the domain of food and feed safety. Currently EFSA operates on the basis of 34 different EU directives and regulations, which define some 39 different workflows for carrying out evaluations in the application area. This is an important source of complexity, which in EFSA tends to be higher than in other agencies such as EMA and ECHA, whose evaluation work is based on one or two workflows, applicable universally[361].

In 2012 a process of revision of this Regulation is envisaged at the European Commission level and it will be the occasion to evaluate whether the EFSA's main legislative framework will change.

Since 2002, as stated in the Science Strategy 2012-2016, EFSA's legislative framework has changed and European level policies have evolved[362], due to the progress in the harmonization of the EU food and feed safety system or to the onset of emerging issues. As a result, the volumes and content of application dossiers to be processed in a specific area have been subject to such changes, challenging both EFSA and MS organisations in appropriately planning and allocating resources[363]. An example of a strong increase of workload resulting from a change in the legislative framework is the implementation of the EC regulation No 1924/2006 concerning health claims, that caused in 2008 a substantial increase of applications submitted to the Authority[364] (as shown in Chart 24).

In order to enable an appropriate resource allocation, prioritization of work and adaptation to the workload imposed by the EU law, it is important that EFSA and EU Institutions are engaged in a regular dialogue, as recommended by the MB in 2006 following the first external evaluation[365]. As written in the Annual Management Plans, over the years the Authority has tried to reinforce its relation with EU Institutions, for example by ensuring its presence in the relevant committees of the EP and the EC or by fostering medium and longer-term planning with the EC. Nevertheless, as stated in the Science Strategy 2012-2016, it is essential to make further efforts on this point[366].

[361] Draft Technical report. Mapping and assessment of regulatory workflows concerning scientific evaluation of regulated products, EFSA.
[362] Science Strategy 2012-2016, p. 3, 5.
[363] Science Strategy 2012-2016, p. 6.
[364] Annual Activity Report 2008, p. 9.
[365] Management Board conclusions of the external evaluation of EFSA and recommendations arising from the report, 2006, p. 18.
[366] Science Strategy 2012-2016, p. 10.

Table 35: Legislation relevant to EFSA[367]

TOPIC	REGULATION
HORIZONTAL LEGISLATION	
EFSA Founding Regulation ("The General Food Law")	Regulation (EC) No 178/2002
Implementing measures of Regulation (EC) No 178/2002	Commission Regulation (EC) No 1304/2003 Commission Regulation (EC) No 2230/2004 Commission Regulation (EU) No 16/2011
Other relevant horizontal legislation	Regulation (EC) No 1049/2001 Regulation (EC) No 1367/2006 Regulation (EC) No 45/2001 Regulation (EC) No 1907/2006 Regulation (EC) No 851/2004 Regulation (EC) No 726/2004 Council Decision 1999/468/EC Regulation (EU) No 182/2011 Regulation (EC) No 596/2009 *COM(2008) 229 final* *COM(2011)137 final*
SECTORAL LEGISLATION	
GMO	Regulation (EC) No 1829/2003 Regulation (EC) No 1830/2003 Directive 2001/18/EC Commission Regulation (EC) 641/2004 Commission Regulation (EC) No 1852/2001 *COM(2010) 375 final*
Flavourings	Regulation (EC) No 2065/2003 Regulation (EC) No 1334/2008
Food additives	Council Directive 88/388/EEC Council Directive 89/107/EEC Directive 94/36/EC Directive 94/35/EC Directive 95/2/EC Directive 2006/52/EC Regulation (EC) No 1331/2008 Regulation (EC) No 1332/2008 Regulation (EC) No 1333/2008
Food supplements	Directive 2002/46/EC
Food hygiene package	Regulation (EC) 852/2004 Regulation (EC) 853/2004 Regulation (EC) 854/2004 Directive 2004/41/EC
Food contact materials	Commission Directive 2002/72/EC Regulation (EC) No 1935/2004 Commission Regulation (EU) No 10/2011
Contaminants	Council Regulation (EEC) No 315/93 Commission Regulation (EC) No 1881/2006 Directive 2002/32/EC
Food labelling	Regulation (EU) No 1169/2011 Directive 2000/13/EC Commission Directive 96/8/EC Council Directive 90/496/EEC Directive 2009/39/EC *COM(2011) 353 final*

[367] The list may not be exhaustive. A more detailed list is available in Annex 4. In the column "regulation" it is written in italic legislation in preparation with expected relevance for EFSA, according to the 2012 Annual Management Plan.

Biohazards	Regulation (EC) No 1069/2009 Commission Regulation (EU) No 142/2011 Regulation (EC) No 999/2001 Regulation (EC) No 2073/2005 Directive 2003/99/EC
Human nutrition	Regulation (EC) No 1924/2006 Regulation (EC) No 1925/2006 Commission Directive 2006/141/EC Commission Regulation (EC) No 953/2009 Commission Regulation (EC) No 41/2009 Commission Directive 2006/125/EC Commission Directive 1999/39/EC Commission Directive 96/8/EC
Animal nutrition	Regulation (EC) No 1831/2003 Regulation (EC) No 429/2008 Regulation (EC) No 1774/2002 Regulation (EC) No 767/2009
Animal health and animal welfare	Regulation (EC) No 183/2005 Directive 2003/65/EC Council Directive 2003/85/EC Council Directive 2008/119/EC Directive 2008/97/EC
Plant health	Council Directive 2000/29/EC
Plant protection products	Council Directive 91/414/EEC Commission Regulation (EC) No 451/2000 Commission Regulation (EC) No 1490/2002 Commission Regulation (EC) No 2229/2004 Regulation (EC) No 396/2005 Commission Regulation (EC) No 647/2007 Commission Regulation (EC) No 1095/2007 Commission Regulation (EC) No 33/2008 Regulation (EC) No 1107/2009
Residues of pharmacologically active substances in foodstuffs of animal origin	Regulation (EC) No 470/2009
Zoonoses	Directive 2003/99/EC Regulation (EC) No 2160/2003
Novel Foods	Regulation (EC) No 258/97 *COM(2007) 872 final*

(Source: Annual Management Plan 2012)

LEGISLATIVE FRAMEWORK

- **ECHA** and **EMA** are narrowly involved in the European legislative process. Every year new public health regulations are adopted, increasing **EMA**'s tasks, without usually raising its resources. This makes it difficult for the Agency to map out its future work and consequently to adapt its organization to its activity evolution. **ECHA** is unable to prevent the yearly amount of registrations and authorizations, depending on the Industry, the EC and MS. This reduces its capacity to plan its workload and reallocate its resources.
- **FSA** regularly meets Government representatives to report on progress in the strategic plan implementation and to review this strategy as a consequence of future regulations or emerging situations. Thanks to this "strategy management", reallocation or rise of resources is possible, whenever it is needed.
- Contrary to FSA, **VWA** is a ministerial agency; increasing difficulties of resources can be directly discussed with the Ministry of Agriculture, Nature and Food Quality.

3.6.3.2 Stakeholders' point of view

Impact of the evolution in workload and work areas

Impacts of the changing workload and work areas on financial and human resources

As confirmed by the actions taken by EFSA over the years to face the increasing workload, stakeholders unanimously recognise that the changing workload and work areas have an impact on the Authority's activities in the provision of scientific outputs. Workload is identified as one of EFSA's main challenges (*Q12.1*).

Applications

Despite the numerous actions taken by the Authority to manage the applications, the rate given to them by many respondents is not very high (62,5% of respondents rated them 1 or 2 out of 4, Q12.6 – EC, NRM, FIR). While recognizing that some improvements have been made, some FIR state that EFSA should go on working on this area. In particular, **concerning the Application Helpdesk, controversial opinions** and a high percentage (45,8%) of NA answers (*Q12.7*) are registered. On the one side, 46,1% of respondents rate negatively (1 or 2 out of 4) the support that this tool could provide to manage the increasing application workload (*Q12.7*) and are **cautious and distrustful** about it (FIR). On the other side, 53,8% of respondents judge it positively (3 or 4 out of 4, *Q12.7*), nourishing **high expectations** (NRA, FIR[368]) and considering it a good idea, able to improve the Authority's ability to process applications. In particular, one NRA has even registered a reduction in the amount of requests of support in dossier submission coming from industries to its National Agency.

Some further improvements are suggested by some FIR to boost EFSA's ability to face the application workload and effectively process the dossiers:

- a **more accurate and straightforward communication** with experts for clarification on application details and to have their support and advice, for instance, concerning testing methods and results interpretation. More specifically, the **Application Desk should work as a platform for discussion** between EFSA and applicants, and **hearings and pre-submission meetings** should be introduced, streamlining the application process and allowing EFSA and firms to gain efficiency.
- **An increased involvement of EFSA's scientific staff in processing applications**, even though the number of HR dealing with applications has grown in the considered period. According to some FIR an enlargement of the Authority's inner expertise is required.
- **The increase of resources allocated to this business**, despite the growth of budget assigned to the evaluation of regulated products registered in the last years. In particular, since FIR perceive budget constraints as the reason why EFSA is unable to implement further and deeper changes, some firm representatives are **in favour of fees introduction**, currently under discussion at EU level that may be paid by firms to get extra-services during the application process.

EFSA's organizational structure adequacy and adaptability

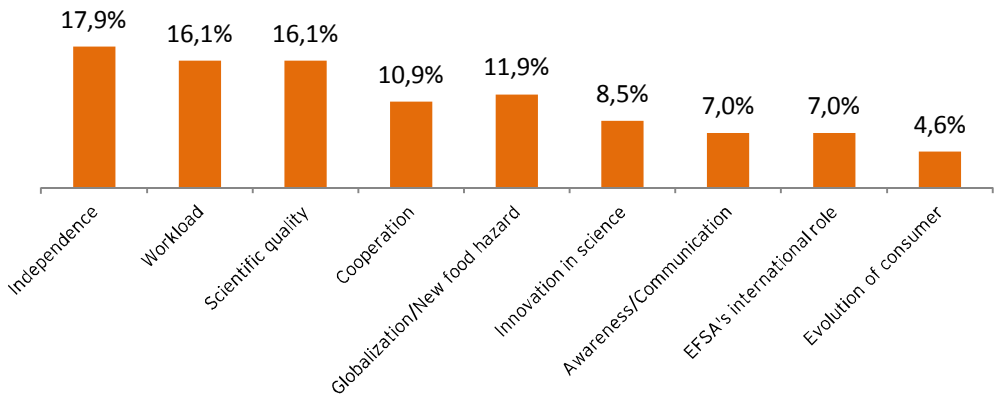
Overall, **EFSA's structure and organization are perceived as adequate to the work** entrusted to the Authority and to the current workload (NRM, MB, NRA)[369]. Indeed, most stakeholders think that EFSA's structure is adequate to meet stakeholders' needs (*Q12.3* – 60,9% 3 or 4 out of 4) and has been able to **evolve positively** over time, becoming more efficient and effective

[368] This opinion is supported also by one NRM.
[369] Opinion shared by one NGO.

(MB, NRA, NGOs[370]).

Regarding the organization adaptability to changes, 76,7% of respondents positively evaluate (3 or 4 out of 4 - *Q12.2.*) the Authority's **capacity to cope with new challenges** as listed in Chart 38 (*Q12.1*). Globally, EFSA is judged as **able to adapt to the changes** in the tasks entrusted to it and as flexible (NRM and one representative of Cons., NGOs, MB). This is demonstrated for example by the quick creation of new expert groups (e.g., nanotechnologies) when necessary (one Cons.) and by the timely response provided by the Authority during emergencies.

Chart 38: EFSA's main challenges



(Source: EY survey)

In particular, the **2006 and 2011 reorganizations are positively evaluated** by many stakeholders (MB, NRA[371]). Specific aspects of the 2006 reorganization have raised stakeholders' attention, like the centralization of administrative support in a unique Directorate that, according to one NRA, has produced cost-savings and benchmarking among Units. The new organization is also appreciated and globally considered as an improvement if compared with the previous one, according to 81,8% of respondents (*Q12.4* – EC, MB, NRA, SCP), because it is more flexible, effective, well-structured, efficient and smart (NRM, MB, NRA). Coherently with the aims underpinning the 2011 reorganization illustrated before, one of the MB members already perceives that the creation of the Science Strategy and Coordination Directorate (SCISTRAT) helps scientific Directorates to follow a common scientific strategy, and enhances scientific cooperation and knowledge sharing for transversal issues among Panels, assuring the maximum level of expertise deployment. Furthermore, the establishment of two Directorates (REPRO and RASA), specialized respectively in applications and generic opinions, is assumed to make EFSA better capable to face the specific dynamics of these two business areas and better manage the increase in the number of regulated product requests that have characterized EFSA's activity evolution in the last 10 years.

Nevertheless, this positive evaluation is not unanimous. 18,39% of respondents suggest further organizational changes, to better cope with new challenges (Q12.5). Among them, FIR consider the changes made to the Authority's organization until now as not completely satisfying, with specific reference to applications and related processes (as further detailed in par.3.6.3).

Impact of the legislative framework

[370] This opinion is supported also by one NRM and one FIR
[371] This opinion is supported also by one NRM and one FIR.

The European legislative acts relevant for EFSA are perceived as quite rigid and limiting EFSA's room for action, activities and opportunities to evolve (one stakeholder per group: NRA, Cons., EP): more specifically as suggested by one NRA the numerous **vertical regulations** listed before seem to limit the flexibility and the initiative of the Authority (e.g., the GMO sector regulations) as also described in the Science Strategy, and they **should be harmonized and updated** (one stakeholder per group EC, NRA, MB), since they impose different processes and limit standardization. Thus, the legislative framework should become more flexible and **simple** (MB, one stakeholder per group: NRA, Cons., *Q17.3* – EP).

The frequent adoption of new European scientific regulations and the limited consultation[372] of the Authority during the EU legislative process **reduce EFSA's capacity to adequately plan its workload** and, consequently, reallocate its resources (MB, one stakeholder per group: NRM, FIR, EC)[373]. This further confirms the evidences emerging from the Science Strategy and the 2005 EFSA external evaluation presented before. As stated by one NRM and one MB, while approving new regulations, the European Parliament and the Council seem to hardly consider their impact on EFSA's work, without modifying the resources at its disposal. As a result, as stated by one NRM, EFSA has to deal with an increasing number of issues without having an adequate amount of resources (e.g., health claims).

The **Founding Regulation** appears **fairly general**, as emerged in the 2005 external evaluation, and does not detail enough for the level of maturity and sophistication obtained by the Authority in its ten years of life (MB): for example, the types of outputs provided by EFSA should be further detailed (one FIR) as well as the composition and tasks of the Management Board (one MB, one NGO).

To improve the current EFSA's legislative framework, few stakeholders suggest the following issues (Table 36[374]).

Table 36: Main areas of improvement of the actual legislative framework

LEGISLATIVE FRAMEWORK	*Suggested more than once*	- More flexibility (MB, EP) - Harmonization of vertical legislation (EC, NRA)
	Suggested once	- Simplification (MB)
FOUNDING REGULATION	*Suggested more than once*	- Introduction of fees (EC, MB, FIR, NRA)
	Suggested once	- More flexibility in the management of resources (MB) - Better definition of power repartition among EFSA's organs (MB) - Reconsideration of task allocation among Panels, EFSA's staff and national bodies (EC) - Obligation to engage with industry (FIR) - Obligation to work with other international institutions (NRA)

(Source: EY survey)

3.6.3.3 Analysis of evidences

The changing workload and work areas has **influenced EFSA's activities and organization** over the years, as stated by stakeholders and confirmed by the actions taken by the Authority over the years to face these changes. The increased number of requests (workload), the growing relevance of applications on the total amount of outputs and the higher complexity

[372] Despite the opposite evidences coming from the EP.
[373] Food contact materials and Health claims regulations are mentioned as examples to demonstrate EFSA's difficulty to adapt to the changes of the regulations.
[374] Acronyms of stakeholders in brackets mainly refer to one respondent.

and degree of innovation of requests (work areas) have impacted the Authority on various dimensions. Indeed, financial and human resources allocated to the provision of scientific opinions have increased as well as the number of knowledge workers, and specific business solutions have been implemented to face increasing workload/backlog in the process of applications.

The global stakeholders satisfaction with EFSA's structure together with the progressive improvements undertaken and all the Authority's efforts to monitor and improve the adequacy of its structure through insight surveys, public consultations and external evaluations, let us conclude that EFSA's structure is **adequate** to the type of work entrusted to it and to the workload.

The structure is also flexible and **able to adapt to the changes**, as shown by the analysis of the allocation of resources and further confirmed by the analysis of the two main reorganizations of 2006 and 2011. Indeed, coherently with the changes in the workload (the significant increase in the number of requests for scientific outputs) and the changes in the work areas (the increased relevance of applications on the total amount of requests and the increased level of complexity and innovation of risk assessments), EFSA has implemented related measures and subsequently allocated resources. Among the most relevant initiatives that have contributed the most to make EFSA a flexible organization: the separation of the activities linked to applications from those related to generic opinions in two different Directorates, the creation of a specific Directorate responsible for cooperation to reinforce strategic coordination with interested parties and better face the most complex risk assessments, the increase in the number of Panels to adequately reflect the increasing number of fields of activities and the progressive centralization of support services to optimise the limited resources.

The business area related to **applications** is particularly important, as it is the area where the most relevant changes have occurred. In addition to the increased resources assigned and to the creation of the above mentioned Directorate, EFSA has undertaken additional initiatives demonstrating once again the structure's flexibility. Thus, an Application Helpdesk (2011) has been launched to improve the service to the applicants and the outsourcing of reports, evaluations or studies to external experts has increased to efficiently manage the workload related to applications. Nonetheless, this is also the area that has contributed the most to the backlog of scientific outputs and the area where the most controversial evidences from stakeholders emerge. While not fully aware of recent developments, the majority of them have rated negatively EFSA's efforts in this business area. Waiting to see whether the most recent business solutions will have a positive impact, EFSA should take into consideration the following critical area:

- *communication between FIR and EFSA's experts:* according to FIR the limited scientific exchanges often entail a lengthening of EFSA's scientific decision-making process and thus limit the workload processed. The need for pre-submission meetings as emerged from FIR is a useful tool of communication for which they would be available to pay a fee.

Changes are not only raised by the workload or the work areas, the legislative framework could also have an impact on EFSA's activity. This has happened in two different ways. Firstly, it has influenced the Authority's flexibility, limiting sometimes rooms for action and imposing different processes and reducing standardization, mainly in relation to the evaluation of regulated products. Indeed, in addition to the Founding Regulation, a large number of sector specific regulations define different requirements and workflows that the Authority has to respect. This diversity partly explains the differences of the processes adopted by Panels observed during the direct observations and the limited harmonization of outputs previously pointed out in the Provision of scientific outputs paragraph. An increased level of

harmonization of the sectoral regulations would allow the Authority to improve its global efficiency. These processes are not just highly diversified but also complex and entail burdens for economic operators, as already seen in the Provision of scientific outputs paragraph. The simplification of these workflows could have a potential double positive effect contributing on one side at improving the efficiency of the structure and on the other side at improving the relation with FIR that could easily understand processes without asking EFSA for further information. In a context of limited resources where EFSA does not have further resources for the communication with FIR (see previous paragraph), this option could allow the Authority to save money and make FIR more satisfied developing processes easily understandable that do not need further explanations.

Secondly, the legislative framework had an impact on EFSA's capacity to adequately plan and allocate its resources because of the poor exchanges with the EU Institutions during the legislative process and the limited notice of official communications. Despite the efforts done by the Authority to strengthen its relation with EU Institutions, it is still difficult for EFSA to map out its future workload and consequently to plan and allocate resources. Similarly to EMA and ECHA, EFSA's involvement in the European legislative process is still limited and does not allow the Authority to anticipate the future changes as demonstrated by the implementation of the EC Regulation No 1924/2006 concerning health claim and the substantial increase in the number of requests that the Authority had to face with limited notice in 2008. The backlog in the scientific outputs and the weak sharing of work plans between the Authority and risk managers, further support the Authority's difficulty to plan the future work. Indeed, a roadmap with the EC has been introduced only in 2011, as said before, and a similar document with MS does not yet exist. Thus, as also stated in the Science Strategy 2012-2016, despite the progress already done, it is essential that the dialogue between EFSA the EU Institutions and NRM on future workloads continues to be improved. In this way the Authority can adequately plan its own workload and, consequently, reallocate its resources.

3.6.3.4 Evaluation results

EFSA's organizational structure is adequate to the work entrusted to it and flexible enough to adapt to the progressive changes in its tasks. Nonetheless, the strict limits imposed by vertical regulations and the difficulty to foresee future workloads might undermine the Authority's capacity to plan and prioritize activities.

EFSA's structure is adequate to the current work and workload. As also shared by stakeholders, the new organization is flexible, effective and well structured.

The adequacy of the structure is mainly due to EFSA's efforts to progressively adapt the organization to changes and emerging challenges. More specifically:

- The implementation of two important reorganizations that have entailed, among others, *i)* the creation of a Science Strategy and Coordination Directorate to define and spread a common scientific strategy across the scientific units, and *ii)* the creation of two different Directorates, to deal respectively with applications and generic opinions, that enables EFSA to better face the specific dynamics of these two business areas;
- The implementation of a specific programme (e^3 programme) aimed at enhancing the efficiency and the effectiveness of the structure through the implementation of strategic horizontal actions.

Nonetheless, the structure can still be improved specifically in the application area that, despite major changes occurred to face the increasing workload, still contributes to 79% of the backlog of the scientific outputs accumulated over years. Waiting to see whether the most

recent business solutions (e.g., Application Helpdesk) have an impact, EFSA could evaluate to improve the communication between FIR and EFSA's experts while guaranteeing the opinions independence in order to speed up the evaluation process. Pre-submission meetings are suggested as a particularly useful tool of dialogue and exchange for FIR for which they would be available to pay a fee.

In addition to the changing workload and work areas, also the **European legislative acts** relevant for EFSA have influenced the Authority's flexibility, limiting sometimes rooms for action, imposing different processes and reducing standardization, mainly in relation to the evaluation of regulated products. Indeed, the large number of vertical and sector specific regulations define different requirements and workflows that EFSA has to respect. These processes are not just highly diversified but also complex and entail burden for economic operators. A simplification of these regulatory workflows could thus contribute to improve the efficiency of the EFSA's structure, working processes and at the same time the relation with FIR that could easily understand processes without asking EFSA for further information and favour safe innovation. This would free some resources and also support the flexibility needed for the evolution of EFSA's scientific outputs elaboration and validation process rebalancing the role given by the legislation to Panels/external experts towards an increased role of EFSA's internal scientific capacity.

In order to improve EFSA's capacity to meet the requirements of its mandate in the long term, it seems important that the Authority develops its **planning capacity**. The backlog and the differences between foreseen and adopted outputs, reveal it is difficult for the Authority to plan the future work. This depends also on the limited sharing of work plans between the Authority and risk managers. Indeed, a roadmap with the EC has been introduced only in 2011 and a similar document with MS does not exist. Thus, as stated in the Science Strategy 2012-2016, despite the progress already done, it is essential that the dialogue between EFSA and EU Institutions and NRM on future workloads continues to be improved.

3.7 Independence

3.7.1 Introduction to the results for the thematic area of evaluation

This part relates to the evaluation criteria of **Independence**, the main question being whether EFSA has fulfilled its obligations to operate in an independent manner.

To evaluate EFSA's level of independence, this paragraph addresses the following issues starting with an analysis of EFSA's procedures and activities, followed by the stakeholders' point of view:

- EFSA's overall structures and governance;
- EFSA's policies and procedures.

Independence in EFSA assumes specific connotations and importance. The evaluation of this issue should indeed consider the following elements:

- EFSA was established in 2002 as **the European Union's independent risk assessment body for food and feed safety** in a context of damaging food crises. The Authority's most critical commitment is to provide independent scientific advice of the highest quality to Europe's risk managers[375]. The Authority's Founding Regulation further emphasizes the functional separation of science (risk assessment) from policy (risk management) to guarantee the independence from political influences[376], and imposes specific obligations on the members of EFSA's bodies as well as on experts, who must make annually a declaration of commitment and a declaration of interest (DoI) indicating the absence of any interest prejudicing their independence.
- Unlike many of its international counterparts, EFSA **relies heavily on external expertise** from academia, research organizations and National Food Safety Agencies to generate its scientific advice[377]. This entails a higher responsibility for EFSA to ensure, through an adequate and rigorous system to deal with interests, that its scientific outputs are objective and unbiased.
- **EU public concern in relation to independence of scientific advice on food-related risks has been and is still high**. EU citizens have a high level of trust[378] in both scientists (73%) and national and European Food Safety Agencies (64%) as sources of information on food risks, but less than half of EU citizens (47%) think that scientific advice on food-related risks is independent of commercial or political interests. The agro-food sector is increasingly becoming a subject of matter for a great part of stakeholders that will pay more and more attention to the quality and the independence of scientific outputs of Risk Assessors' agencies.

Due to the recent adoption (2011) of the new Policy on Independence and the related implementing rules, the timeframe of the evaluation of EFSA's independence has been further extended, to consider important achievements that partially provide an answer to some criticisms on independence.

[375] See art. 22(7) of the Founding Regulation "The Authority has to be a point of reference of risk assessment in the food chain by virtue of the scientific and technical quality of the outputs it issues and its independence […].

[376] "The Authority shall provide independent information on all matters within the fields which have a direct or indirect impact on food and feed safety" and "shall carry out its tasks in condition which enable it to serve as a point of reference by virtue of its independence". Regulation (EC) 178/2002

[377] More than half of its Scientific Panel members come from the National Food Safety Agencies (Review of EFSA's Policy on Declarations of Interest: a reflection paper MB 10 03 11).

[378] Eurobarometer Survey Report on Science and Technology (2010).

3.7.2 EFSA's independence

3.7.2.1 Facts & Figures

EFSA's overall structures and governance

EFSA's structures laid down in the Founding Regulation (see Table 37) provide a **strong basis for the independence of the Authority's decision-making process**, guaranteeing the separation between EFSA's scientific work and the strategic management of the Authority.

Table 37: EFSA's structure and governance

EFSA BODIES	ROLE AND FUNCTIONING
Management Board	- Role: provides strategic direction, appoints the ED, SC and Panel members and adopts strategic documents including internal rules, budget, annual work programme, statements of estimates of revenues and expenditures, and establishment plan. The Management Board has no power to review EFSA's scientific outputs or to influence their adoption procedure. - Selection: 14 members (+ 1 EC representative) appointed by the Council of the European Union in consultation with the European Parliament on the basis of a list of the European Commission created following an open call for expression of interest. A representative of the EC sits on the MB. Members are appointed in a personal capacity and they are supposed to act independently in the public interest on the basis of their experience and expertise. They do not represent any Government, organization or sector, facilitating, in this way, the decision-making process. Members are to provide a portfolio of expertise, with four members "having their background in organizations representing consumers and other interests in the food chain"[379]. - Functioning[380]: The Board acts according to a Code of Conduct that upholds core principles and values, such as integrity, objectivity and serving in the public interest while providing guidance on standards expected by Union institutions and the general public.
Executive Director	- Role: implements the strategic documents adopted by the Board and manages the daily operations of the Authority. - Selection: Nominated by the Board on the basis of a list of candidates proposed by the EC.
Advisory Forum	- Role: advises the Executive Director regarding cooperation and networking with Member State Food Safety Authorities. - Selection: one representative identified by each MS, coming from competent bodies, which undertake similar tasks to EFSA's in MS (+ Iceland and Norway). The AF is chaired by the ED. - Functioning: MS use the Forum to advice EFSA on scientific matters, its work programmes and priorities and to address emerging risks as early as possible, but it has no direct influence on the strategic documents and budget. Through the AF, MS are involved in EFSA's activities without voting rights on scientific outputs or EFSA's policies documents.
Scientific Panels and Scientific Committee	- Role: adopt scientific opinions. - Selection: members/experts are selected following a call for expression of interest, on the basis of their scientific expertise and experience in risk assessment and according to objective and transparent criteria predetermined in the call. Panels are renewed every three years and there is a limit of three terms

[379] Founding Regulation 178/2002, art 25.
[380] Rules of procedure of the Management Board.

EFSA BODIES	ROLE AND FUNCTIONING
	in a row on the same Panel. - Functioning: Rules of Procedure[381] provide a procedural framework for the establishment and operation of these groups (e.g., number of members, renewal of membership, quorum for the adoption of decision, etc.), to grant impartiality and objectivity. Decisions are normally adopted by consensus or by majority so as to reduce the risk of one viewpoint exerting an undue influence over the other. Experts are not paid and they only get their costs reimbursed and a fee.
Units and Directorates *(EFSA's staff)*	- Role: provide scientific and technical advice and secretarial support to the Scientific Committee and Panels for their work. - Selection: hired on fix-term contracts following a transparent selection procedure. - Functioning: the Authority's staff is bound by the staff Regulations adopted by the Council and by the related implementing measures.

(Source: EY elaboration on secondary sources[382])

As far as the **Management Board** is concerned, EFSA's capacity to screen and manage interests of the Board members' profiles is limited. Indeed, as seen in the box above, MB members are subject to an external nomination procedure and although they have to submit the ADoI and ODoI (Oral Declaration of Interest), if a conflicting interest is detected, the final resignation from specific activities is on voluntary basis or appeal to Council[383] and EFSA has limited possibilities of action.

Despite this legal framework, EFSA monitors the independence of EFSA MB Members and, as the recent resignation of the Chair of the MB demonstrates[384], it suggests changes as soon as it disposes of relevant information.

EFSA's policies and procedures

EFSA's policies and procedures have evolved over time showing EFSA's flexibility and adaptability to change. Initially designed to guarantee the independence of an Authority that provided mainly generic opinions, the procedures have then been adapted to the needs emerging from the increased percentage of opinions on applications that the Authority has to deal with (60% of the current workload[385]) and that require a different approach to the screening of interests in order not to be biased by the industry perspective. Thus, EFSA's policies and procedures for independence have been characterized **by the progressive introduction of stricter controls for experts** working for the Authority and **a higher level of transparency** on how interests are screened for the external stakeholders' scrutiny.

Declarations of interests form the heart of EFSA's approach to independence. All professionals working in or for EFSA, in a position to influence EFSA's output, particularly in the core business areas of science and communications, must individually declare the interests (current and related to the past-5 years) they may have in the Authority's task both during the

[381] Rules of procedure of the Scientific Committee, Scientific Panel and their Working Group.
[382] See footnotes related to specific points in the table and EFSA website.
[383] EFSA's Policy on Independence and Scientific Decision-making Process: New rules in practice. Setting the Scene. 5 March 20102, Brussels.
[384] EFSA was informed on 8 May 2012 by the Chair of the MB of her decision to take up a professional position at the International Life Sciences Institute (ILSI). This position is not compatible with her role as member and Chair of the EFSA Management Board. Upon request of EFSA, the Chair has resigned from the EFSA Management Board and the Authority made this decision known as soon as possible on 9 May 2012. (Source: EFSA website).
[385] Workshop on Independence, Brussels 2012.

selection procedure[386] and then through a three-step screening scheme[387]. Depending on the roles, functions and activities concerned, they are required to complete and submit:

1. the **Annual Declaration of Interests** (ADoI[388]) which aims at highlighting all the possible interests that might be considered relevant to assess the independence of the expert and/or;
2. the **Specific Declaration of Interests** (SDoI[389]) which aims at pointing out interests linked to specific subject matters (e.g., substance/product) and/or;
3. an **Oral Declaration of Interests** (ODoI) frequently requested at the beginning of each meeting to declare interests, which might be considered prejudicial to the independence in relation to the items on the agenda.

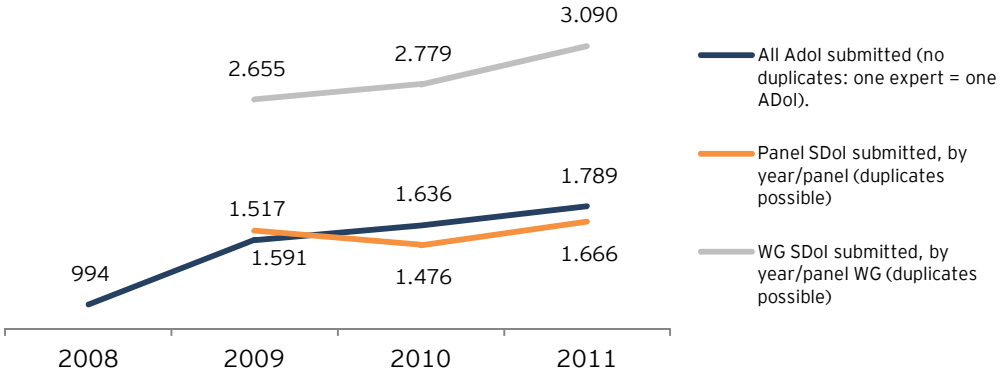
EFSA's first independence policy (**Policy on Declaration of Interest – 2007[390]**) has been considered in general efficient and effective by the Office of the Executive Director and the Management Board[391] on the basis of the outcomes of the audits performed in 2008 and 2009, and seems now to have reached the maturity phase. Evidences coming from the encouraging audit results[392], from the high number of Conflict of Interests prevented (365 in 2011) and the limited cases of breach of trust detected (5 cases in all EFSA life)[393] further confirm the policy effectiveness.

All experts working for the Authority have submitted the Annual Declaration of Interest, as shown by the 100% annual DoI coverage rate[394]. Compliance issues in the process of screening DoI are noted in a small minority of circumstances(1 or 2%) in the external review of the screening performed by EFSA's staff on ADoI or SDoI.

Over the years, the Policy of Declaration of Interest has been strengthened through the use of supporting IT tools and periodic audits and reviews. Following the increasing number of experts involved in EFSA's activities, the number of Declarations submitted and screened (Chart 39) increased as well thus entailing the higher costs related to the policy of Declaration of Interests (Chart 40).

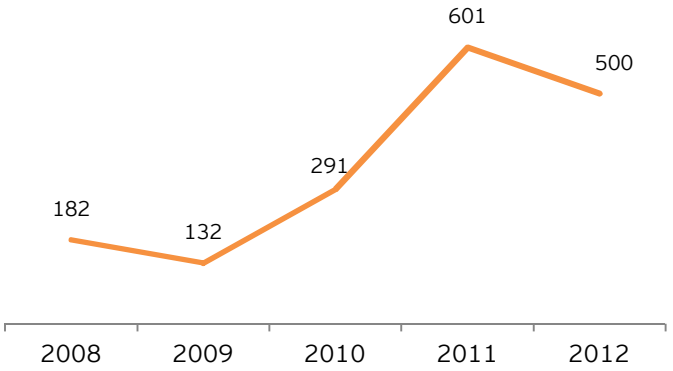
[386] Comparison between the tools ensuring EFSA's independent scientific advice and the instruments in use by organizations similar to EFSA, Milieu, January 2011
[387] Guidance documents on Declaration of Interests (mb 11-09-2007, 5.2)
[388] ADoI are published on the website in the Declaration of Interest Database
[389] SDoI as well as ODoI resulting in a potential conflict of interest are recorded in the minutes of the relevant meeting.
[390] EFSA Policy on declaration of interest (mb 11-09-2007).
[391] Review of EFSA's policy on Declarations of Interests: a reflection paper. (mb 17-3-11).
[392] As shown in the Internal Audit Report of 2009, except 3 cases (out of 61) of SDoI formally approved late, the tests did not disclose any major findings and revealed that the ADoI has reached 100% of implementation level and SDoI reached 95%. To measure the improvements that have been done it should be highlighted that one year before, in 2008, ADoI level of implementation was 78% and the SDoI one at 14% with 46% of SDoI missing for the meetings analyzed.
[393] Source: EFSA Workshop on Independence, Bruxelles 2012
[394] Source: data provided by EFSA, 2012.

Chart 39: Trend in the number of a DoI submitted



(Source: EY elaboration on EFSA's data, 2012)

Chart 40: Cost of independence policy of Declaration of Interests in K€



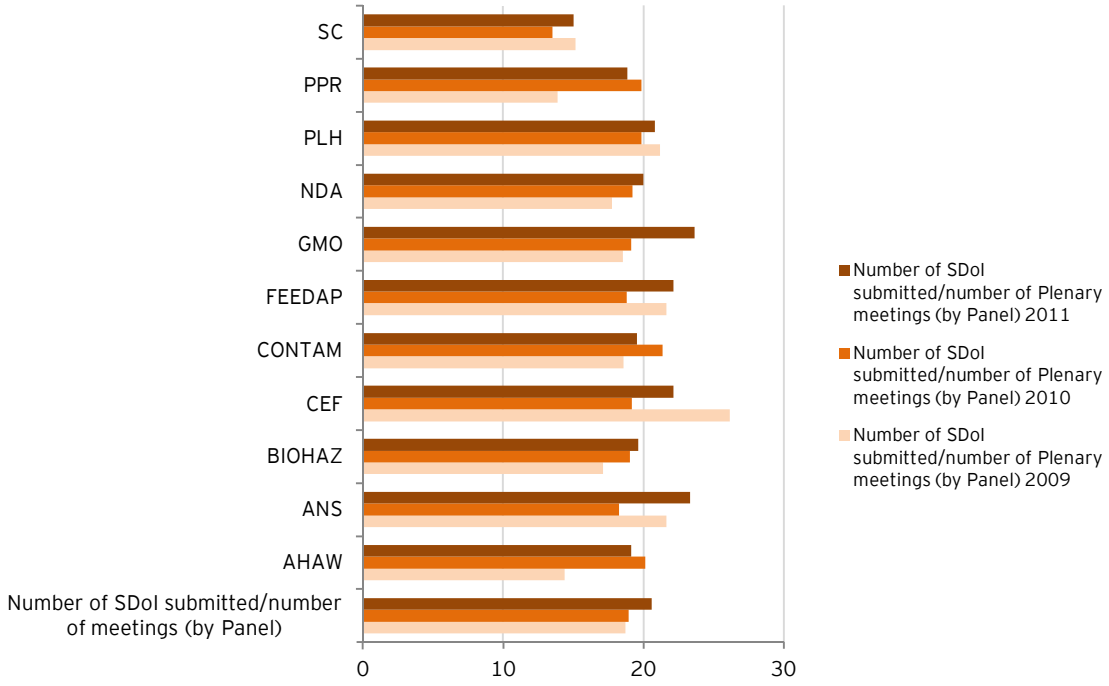
(Source: EY elaboration on EFSA's data, 2012)

More specifically, the number of SDoI has increased nearly in all Panels (as shown in Chart 41) with small differences according to the thematic areas and mainly for GMO, ANS and FEEDAP that normally deal with controversial scientific issues.

The DOI system has become much more selective as confirmed by the increasing percentage of rejected ADoIs per year that passed from 2,8% in 2008 to 4,1% in 2011[395].

[395] Source: data provided by EFSA, 2012

Chart 41: Number of SDoI submitted/number of Plenary meeting (by Panel)



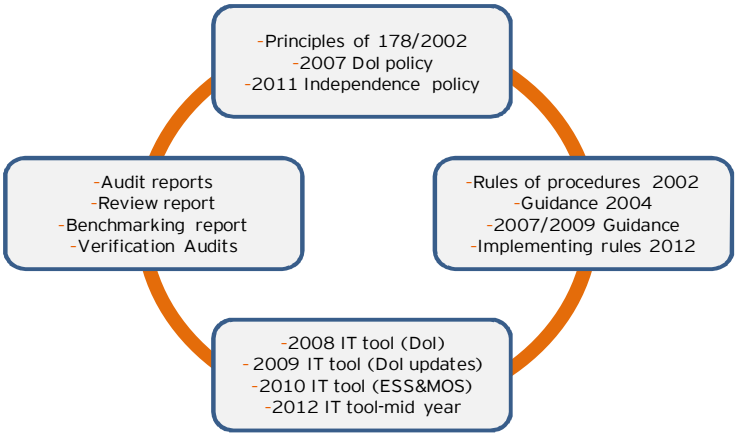
(Source: EY elaboration on EFSA's data, 2012)

EFSA is in charge of reviewing the declarations submitted in order to assess if there is any interest that could present a conflict and, if it is the case, to decide on the degree of participation of the person. The responsibility to correctly declare all the relevant interests relies on the single expert. There are some evidences showing that experts do not always fill the Declaration of interest in a proper way thus exposing the Authority to criticisms and attacks on its independence.

Recognizing that independence does not rely solely on the DoI assessment, **EFSA has launched in 2011 a new Policy on Independence** ("Integrated Policy on Independence and Scientific Decision-making process") to adapt the system to new challenges and work areas. This policy draws together, with a more comprehensive and clear approach, all the relevant existing elements related to EFSA's policies, procedures and systems affecting independence at different levels, like: organisational governance, transparent selection of experts, scientific quality, rules of procedures for the Panels and Scientific Committee, collegial decision-making, validation of data, broad consultation, transparency of scientific workflows and publication of all relevant documents regarding the policy and its implementing measures.

The current EFSA's policy on independence is conceived as a **continuous improvement cycle** that, combining policy documents, implementing rules, dedicated IT tools and external reviews on regular basis, guarantees that the Authority operates without excessive influence (Figure 15).

Figure 15: Independence Policy cycle



(Source: EFSA[396])

This Policy is the result of a process of extensive consultation[397]and takes into account more than three years of experience in the implementation of the 2007 Policy of Declaration of Interests as well as the recommendations of independent contractors and auditors[398].It introduces[399]:

- greater scrutiny and more safeguards;
- greater clarity and transparency;
- greater impartiality while accessing the best expertise.

The new policy system (as further described in the following table) continues to be based on the Declaration of Interests signed by people working for the Authority and then screened according to the specific role each one has to perform, but, in order to better clarify and reinforce EFSA's approach to independence, clearer implementing rules and horizontal exclusion criteria[400] have been introduced:

- no expert working with industry on which EFSA's outputs impact will be allowed to Scientific Committee, Panel and Working Group[401];
- no expert will be ever allowed to review or assess his or her own work.

EFSA has **progressively increased the compliance of its procedures to international standards** and more specifically to the OECD[402]. As an example, in the new Policy on Independence, EFSA has changed its definition of "conflict of interest" adopting the one used

[396] EFSA's Policy on Independence and Scientific Decision-making Process: New rules in practice. Setting the Scene. 5 March 20102, Brussels
[397] A consultation has been undertaken internally with EFSA staff and externally with interested parties and the Authority's Scientific Committee and Advisory Forum
[398] Independent contractors and auditors delivered respectively a benchmarking report, an external review of the implementation and audit reports.
[399] EFSA website.
[400] EFSA's Policy on Independence and Scientific Decision-making Process: New rules in practice. Setting the Scene. 5 March 20102, Brussels.
[401] The participation of organizations others than Food Safety Organizations (e.g.,,ILSI) is now explicitly limited as illustrated also through an example during the Information session on Implementing Rules of Independence Policy in Brussels on the 5th March 2012.
[402] OECD Guidelines for Managing Conflict of Interest in the Public Service, 2005. The OECD standards are made for public officials and leave uncovered 75% of the population of the EFSA that do not enter in this contractual category, namely the Management Board members, the scientific experts members of panels and working groups, the Advisory Forum members and the stakeholders consultative platform members.

in the OECD guidelines[403]. The following table identifies all the areas in which EFSA has increased the correlation of its procedures with the OECD guidelines progressively adopting its standards (arrows) and areas where further improvements are needed (= or NA).

[403] Conflict of interest is any "situation when an individual is in a position to exploit his or her own professional or official capacity in some way for personal or corporate benefit with regard to that person's function in the context of his or her cooperation with EFSA".

Table 38: Correlation of EFSA's measure to guarantee independence with OECD standards

Key recommendations for managing conflict of interest (OECD)	Correlation grade of EFSA's procedures	Main measures introduced through the new Policy on Independence
1. Identify relevant conflict of interest situations		
Provide a clear and realistic description of what circumstances and relationships can lead to a conflict-of-interest situation	↑	- Adoption of a new definition of conflict of interest. - A clearer set of definition of relevant activities which have to be declared by all persons. - Formulation of example on how interests are assessed and how decisions on participation to EFSA's work are practically taken by EFSA's staff.
Ensure that the conflict-of-interest policy is supported by organizational strategies and practices to help identify concrete conflict-of-interest situations at the workplace.	↑	- Creation of the Committee on Conflicts of Interest that will review decisions on interests subject to possible complaints or questioning. - Improvement of the IT tool to support the declaration of interests of all persons working for EFSA.
2. Establish procedures to identify, manage and resolve conflict-of-interest situations		
Ensure that public officials know what is required of them in identifying and declaring conflict-of-interest situations	↑	- A simplified table clarifying which declared interests would lead a scientific expert being allowed or disallowed to take part in EFSA's scientific groups and in what role. - An explicit reference to the requirements of external contractors and grant beneficiaries. - Identification of clear horizontal exclusion criteria applied to all the situations: no experts will be allowed to review or assess his or her own work and no experts working for industry are allowed to work for EFSA.
Set clear rules on what is expected of public officials in dealing with conflict-of-interest situations, so that both managers and employees can achieve appropriate resolution and management.	↑	- Training materials or advice/counselling for EFSA's staff to manage conflict of interest and for external stakeholders to declare correctly the interest required.
3. Demonstrate leadership commitment		
Managers and leaders in the public service should take responsibility for the effective application of conflict-of-interest policy, by establishing a consistent decision-making process, taking decisions based on this model in individual cases, monitoring and evaluating the effectiveness of the policy and, where necessary, enhancing or modifying the policy to make it more effective.	↑	- New and increased monitoring activities and reporting to interested parties over all the steps of the process (declaration of interests, screening interests and deciding on participation). - Stricter rules for EFSA's staff.
4. Create a partnership with employees.		
Ensure wide publication, awareness and understanding of the conflict-of-interest policy through training and counselling	↑	- Training sessions to EFSA's staff to learn the new implementing rules of EFSA's Policy on Independence

Review "at-risk" areas for potential conflict-of-interest situations. Identify preventive measures that deal with emergent conflict-of-interest situations.	=	- No identification of "at-risk" areas to be constantly monitored
Develop and sustain an open organizational culture where measures dealing with conflict-of-interest matters can be freely raised and discussed.	NA	
5. Enforce the conflict-of-interest policy		
Provide procedures for establishing a conflict-of-interest offence, and consequences for non-compliance, including disciplinary sanctions	↑	- A simpler and stricter scheme of preventing measures (in or out). - A consolidated procedure to manage breaches of trust. - More transparency on preventive and remedial measures through the publication in meeting minutes of all decisions including how they were addressed.
Develop monitoring mechanisms to detect breaches of policy and take into account any gain or benefit that resulted	↑	- Introduction of random sampling of DoIs to monitor for completeness and coherence with EFSA's rules.
Co-ordinate prevention and enforcement measures and integrate them into a coherent institutional framework	↑	- Inclusion in the same document (Policy on Independence and related implementing rules) of the wide range of initiatives EFSA has put in place to uphold its core values. It not only covers issues related to interests and independence but also sets out the various internal mechanisms and processes that EFSA follows to ensure good governance within the organization and throughout the scientific decision-making process.
Provide a mechanism for recognizing and rewarding exemplary behaviour related to consistent demonstrated compliance with the conflict-of-interest policy	=	- No mechanism for recognizing and awarding exemplary behaviours.
6. Initiate a new partnership with the business and non-profit sectors		
Involve the business and non-profit sectors in elaborating and implementing the conflict-of-interest policy for public officials.	↑	- Inclusion of comments raised by stakeholders during a public consultation as well as a stakeholder meeting before the formal adoption of the new Policy. - A more inclusive scheme for experts with interests in Food Safety Organizations is established.
Anticipate potential conflict-of-interest situations when public organizations involve persons representing businesses and the non-profit sector through boards or advisory bodies. Include safeguards against potential conflict-of-interest situations by making other organizations aware of the potential consequences of non-compliance and reviewing together high-risk areas.	↑	- Stronger measures concerning industry-related interests. (e.g., Scientific experts previously employed by industry must wait 2 years before being allowed to be a member of one of EFSA's scientific groups. - Stronger measures concerning funding related interests.

(Source: EY elaboration on secondary sources[404])

[404] Integrated Policy on Independence and Scientific Decision-making Process, 2011, Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-making process regarding Declarations of interests, 2012 and EFSA website.

As emerged from the comparative report commissioned by EFSA in 2010[405] to review its independence systems and procedures, the Authority has **one of the most advanced and robust systems in place for ensuring the independence** of its scientific advices. It has to be noticed, though, that when considering National Agencies responsible for risk assessment, the panorama of structures, governance and procedures for independence is very complex and articulated[406]. Each Member State has a peculiar institutional structure and regulatory infrastructure that influences the risk management/risk assessment system. In some countries, these two responsibilities are strictly separated (as in the EU model), in others they are mixed up in the same Institution, in others there is not even a national expertise in risk assessment. Those differences have a direct impact on the high variety of perceptions on these issues among European stakeholders and limit the comparability of the systems.

Independence is still an issue of interest, at a different level, for all similar organizations, and each one provides a peculiar example of structure, governance and procedures to guarantee the independence of its scientific advices, as synthesized in the following benchmark box.

[405] Comparison between the tools ensuring EFSA's independent scientific advice and the instruments in use by organizations similar to EFSA, Milieu, January 2011.
[406] As observed during 43rd Advisory Forum Meeting.

STRUCTURES, GOVERNANCE AND PROCEDURES FOR INDEPENDENCE

- In order to ensure that scientific committee members act independently of any external influence, **ECHA** (as well as EFSA) requires scientific committee members not only to sign declarations of interest but also **declarations of commitment** stating that they act in the public interest, that they will not delegate their duty, directly or indirectly, to other persons and will not allow themselves to be influenced in any way in the execution of their duties. This is a requirement of the REACH regulation.
- At **EMA**, four sets of declaration of interests can be considered: (1) upon nomination all European experts need to be registered in the EMA's database (initial declaration of interests), (2) potential conflict of interests should be declared before each meeting (specific declaration of interests), (3) conflicts of interest which appear during the meetings shall also be declared (**spontaneous declaration of interests**), (4) financial and other interests, including relations with pharmaceutical companies, shall be indicated in the annual declaration of interests. The spontaneous declaration of interests procedure requires that experts declare any potential conflict when it becomes apparent. This practice relies on the relationship of trust between the organization and the expert and can be seen as a flexibility mechanism, as experts are not limited to declaring only certain interests and are required to declare potential conflicts of interests at any time they occur.
- ECHA and EMA requests also that the experts declare as any other interests matters related to their household members (spouse, partner or child living at the same address).The term "household member" appears to be a wider category than the one in place within EFSA ("close family members").
- At EMA, risk levels have been defined:

  Risk level 1: No interests in the pharmaceutical industry declared;
  Risk level 2: Indirect interests in the pharmaceutical industry;
  Risk level 3: Direct interests in the pharmaceutical industry.

  The risk level is based on the expert's interests within the past five years.
- The annual declaration of interests procedure is used by most of benchmarked risk assessment agencies to follow the rapid change in activities of external experts.
- To ensure the independence of scientific advice, in addition to the declaration of independence, **FSA** put in place internal procedures including an internal check-list for experts to ensure their independence and the supervision role of the Chief Scientist Advisor (he must review all the scientific advices before any publication or communication). A similar procedure of supervision by the General Inspector of the **VWA**, supported by an Advisory Council, has been put in place in the Netherlands.
- At **EMA,** main committees have to judge new products whose development entails high costs for the industry. There are a number of rules and policies to avoid conflicts of interest and to control the procedures of provision of scientific outputs. A diagnosis is always done by a rapporteur and a co-rapporteur who operates independent analysis in different places in Europe: their conclusions can converge or diverge. **The committee acts as a peer-review committee to make the position unique.**
- EMA has also established an internal group (called DIAG) that aims at assessing, in case of ethical issues or conflicts of interest, whether the involvement of experts found to have conflicts of interest has a significant enough extent to warrant action.

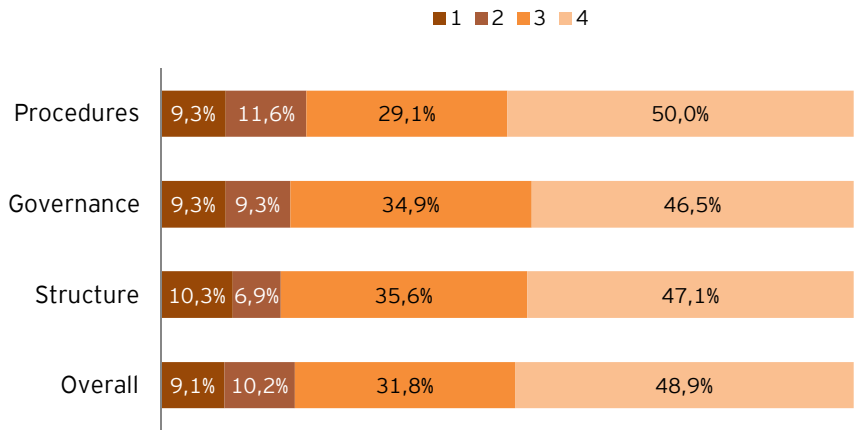
3.7.2.2 Stakeholders' point of view

EFSA's overall structures and governance

EFSA is **globally an independent Institution** according to the majority (81%) of the stakeholders, that gave a rate of 3 or 4 out of 4 (Q18.1 – Chart 42). More specifically, EFSA's **governance and structures are independent** (on average 82% 3 or 4 out of 4 - Q18.1) and stakeholders recognize the efforts that EFSA has done over the years to guarantee and safeguard its independence vis-à-vis its external stakeholders through the implementation of stricter rules and of improved communication initiatives.

No major changes in EFSA's structure and procedures for independence are needed and the current system is considered as a satisfying infrastructure by the majority of stakeholders (NRM, NRA, FIR, MB[407]).

Chart 42: Level of satisfaction on EFSA's independence



(Source: EY survey)

As relates governance and structures, EFSA's Management Board independence is an issue of discussion among stakeholders: The Board's independence has remained stable over time (Q15.6) and the selection process of its members assures its independence (65% 3 or 4 out of 4 – Q15.5). Its peculiar composition (i.e., members appointed in a personal capacity and not representing any MS interest) guarantees that decisions are taken uniquely in the interest of the Authority (MB). Nonetheless, some **criticisms** are still present and have been raised by few stakeholders as relates:

- the presumed presence of conflicting interests (i.e., more members than foreseen by the Founding Regulation having "a background in organizations representing consumers and other interests in the food chain"[408], and presence of members having relationships with ILSI[409]) (NGOs, Media[410]). This perception should be however counterbalanced by the recent case of resignation of the Chair of the Management Board that resigned to take up a position in ILSI thus demonstrating the links with this Institute are not compatible with EFSA's activities.
- the lack of clarity of the rules illustrating how interests of the Board's members should be dealt (MB);

[407] This opinion is also supported by one Cons., one IO and one EC.
[408] See the Organization Chapter for factual evidences on the composition of the Management Board.
[409] The International Life Sciences Institute (ILSI) is a member organization whose members are primarily food and beverage, agricultural, chemical and pharmaceutical companies.
[410] This opinion is supported also by one Cons.

- the proximity of Board's members to EFSA's management (one Media).

EFSA's policies and procedures

The majority of respondents are **satisfied with policies and procedures** that have been implemented (79% 3 or 4 out of 4 – Q18.1 see Chart 42) and recognize achieved improvements.

Nonetheless, according to the majority of stakeholders (EC, NRM, NRA, MB, FIR, IOs), the current level of detail and attention paid by EFSA to independence related issues is critical (if not already too high[411] and sometimes disproportionate if compared with the activities requested by the Authority).

Despite the recent publication, **the new Policy on Independence and the related implementing measures have already raised some reactions.** The increased level of transparency achieved and all EFSA's efforts to clearly communicate the new rules to stakeholders[412] have been appreciated by many stakeholders (Cons. NGOs, NRM, NRA). On the other side, a few doubts have been raised:

- no significant changes have been added (one Cons.) if compared with the previous policy framework of independence. Indeed, as illustrated before, the new policy on independence brings together all existing elements relating to EFSA's policies and procedures affecting independence at different level.
- the new rules of independence seem to limit the availability of experts because of the increasing number of requirements (NRM, NRA, FIR, Cons.) and the related higher perceived level of bureaucracy (NRA[413]).

Despite the new policy on independence already provides some concrete responses to stakeholders' most frequent criticisms, some of them still challenge this area of evaluation as relates:

- **EFSA's links with industry and industry-affiliated bodies** (NRM, NRA, EP, Media, NGOs, Cons.). Despite the strict measures introduced by EFSA's Policies on Independence illustrated before, this issue deserves more transparency according to many stakeholders that still perceive the existence of links between EFSA's experts and industry (and more specifically with ILSI[414]) and the level of conflict of interests that the Authority accepts is considered too high, due to the fact that the responsibility for completing and updating declarations of interest lies only with the holder. The use of data and studies coming from industry in EFSA risk assessments is questioned as well from few NGOs that cannot have an access to them because of the use of confidentiality clauses (see also par. Provision of scientific outputs, Data Collection and Openness and Transparency).
- **Loss of professional expertise and quality in the provision of scientific outputs due to** the introduction of **stricter rules of participation** to Panels and Committee for experts coming from industry (EP, NRA, FIR[415]). More specifically, and apparently in

[411] For some respondents (NRA, NRM, one Scient.Org.) the requirements that an expert should respect to work for EFSA are already not proportionate to the task and the responsibility that the expert will have within the Authority.
[412] EFSA has organized various meetings to present the new policy and implementing rules for independence to all the key stakeholders (e.g.,, MB, AF, experts working for Panels and Scientific Committee, FP, external stakeholders, etc) as well as training session for the internal staff responsible for the implementation. Agricultural, chemical and pharmaceutical companies.
[413] This opinion is supported also by one Scient.Org.
[414] NGOs and EP critic EFSA's past links with this Institute and the involvement of EFSA's experts in ILSI activities.
[415] This opinion is supported also by one Cons.

contrast with the previous point, Food Industry Representatives complain that EFSA has progressively weakened exchanges with industry and that the new implementing rules of the Policy on Independence, as described before, limit their contribution to EFSA's activities. According to their perspective, these elements have considerably limited the use EFSA could do of the pool of expertise and added value represented by all experts having worked for industry and consequently have had a negative impact on the quality of the scientific outputs,

- **Lack of transparency on procedures of screening and deciding on conflicts of interests** (NRA, Cons., MB, FIR, Media). It seems difficult for any external stakeholders to know the steps of the screening process and to have a follow-up from the Authority on the related decisions taken. Despite previously described EFSA's efforts to clearly communicate new rules providing concrete examples on how interests are normally assessed, some stakeholders still perceive the need for an increased level of transparency.
- **Unclear definition of "conflict of interest"** (Media, Cons, FIR). EFSA should define conflict of interest more clearly. It should act more swiftly and in a more open way when there are breaches. The recent adoption of the OECD definition of conflict of interest and the ongoing EFSA's efforts to better clarify which interests would lead a scientific expert being allowed or disallowed to take part in EFSA's work, may probably impact on this perception on the long term.
- **The unclear separation of risk management from risk assessment activities** (FIR, Cons., IOs, MB). EFSA's role is not defined enough and the boundaries between risk assessment and risk management are sometimes not respected. Various examples are presented by stakeholder to support this perception. Firstly, the E.Coli case witnesses how EFSA's communication went beyond what should normally be expected from a risk assessor, informing, together with the EC, how to deal with the risks (one NRM). Secondly, concerning feed additives, EFSA does not restrict itself to detail the effects of the use or the non-use of a product, but has provided a decision on the use of the products where those decisions should be left to the EC (one FIR). At the end, another example is a Slovenian member elected as Risk Manager in the Ministry of Agriculture in Slovenia and having a position in the MB until the end of his mandate (one Cons.). Even though the Consumer Association strongly complained against this initiative, asking for his resignation as a member of EFSA's MB in order to avoid conflict of interests, nothing has changed and he remained in the MB until the end of his mandate.
- Despite EFSA's actions to mitigate criticisms are adequate according to 46%[416] of respondents (rate 3 or 4 out of 4 - Q18.5), **EFSA seems to be ineffective in mitigating specific criticisms towards its experts' independence** (EC, NRA, FIR, MB, IOs and experts during the direct observation[417]). The Authority does not take enough care of its experts and should be more proactive in responding to attacks better explaining the procedural aspects of its policy on independence as well as correcting the misleading image that external stakeholders may have on experts (e.g., Mantovani and Barlow cases). Nonetheless, as pointed out by one EC, a greater role of EFSA in the debate concerning the independence of its experts could expose EFSA to accuses of lobbying and dependence, furthermore compromising its credibility.

[416] NA included

[417] During the 63rd Plenary Meeting of the Animal Health and welfare Panel, when explaining recent EFSA's independence policy measures, and decisions taken by EFSA's staff regarding the resignation of the Chair of the working group on meat inspection, experts have raised their dissatisfaction concerning EFSA's ways to deal with criticisms.

- **The limited awareness of EFSA of the political roots of the majority of criticisms on independence** (NRA, NRM, FIR. MB, Cons.[418]). Many of the independence related criticisms have political roots and damage the image of the Authority, reducing the effectiveness of the efforts accomplished over the years. The Authority should pay attention to distinguish those criticisms from those scientifically based.

Some suggestions to further improve the system are proposed by few stakeholders and mainly relate to the Panel structure, the recruitment procedures, the assessment of interests' procedure and, more globally, the Founding Regulation requirements. Table 39 provides a synthesis of the most significant inputs coming from stakeholders **to improve EFSA's governance and procedures.**

Table 39: Suggested changes in EFSA's governance and procedures to assure independence[419]

PANELS AND WORKING GROUPS	*Suggested more than once*	- Reduce the number of external experts and consider them as peer reviewers. Rely and invest more on internal staff expertise. (Media, NRA) - Increase the participation of young experts. (Media, NRA) - Panel members/experts should be paid. (NGOs, NRA) - Rely more on MS to improve the provision of outputs. (EC, NRA) - Open meetings. (NRA, MB, NGO, FIR)	EP, EC, MB, Media, NRA, FIR, NGOs
	Suggested once	- More rotation of experts (EC) - and limited re-appointment of experts (NRA) - Increase the use of public consultation on scientific outputs. (NRA) - Find new and transparent ways to involve experts coming from industry to preserve the quality of the final work. (EP)	
RECRUITMENT PROCEDURES	*Suggested more than once*	- Longer contracts for Staff in order to limit the potential approaches of industry ("revolving doors") (Media, NRA, NGO) - Orient the selection procedures to increase the number of scientists. (Media, NRA) - Create career paths for staff so that they are not influenced by the prospect of future jobs in the industry. (NRA, Cons.) - Avoid that people working for EFSA can afterwards have a job in an industry involved in the field of decision (ex: period of 5 years with no possibility to work in that field). (Media, NRA, NGOs, Cons.)	Media, NRA, Cons., NGOs

[418] This opinion is supported also by one IO.

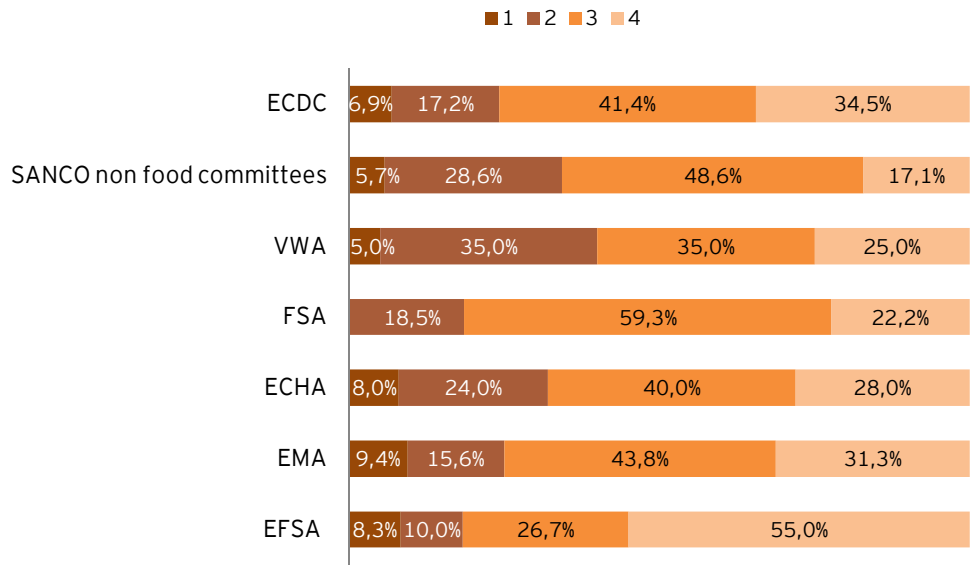
[419] Acronyms of stakeholders in brackets mainly refer to one respondent. Please consider that some of the listed suggestions may also be linked to EFSA's structure as described in the previous paragraph.

ASSESSMENT OF INTEREST	*Suggested more than once*	- Publication as a matter of course, EFSA's internal investigations on the screening of expert's interests. (NGOs, MB, Cons) - More detailed evaluation of Panel members independence based on previous and current projects. (EP, MB, Cons)	EP, Cons., NGOs, MB
	Suggested once	- Disqualification of past works undertaken by EFSA with industry (e.g., creation of a blacklist of biased undertakings). (EP) - Declaration of interest should be checked by EFSA once submitted. (NGOs)	
FOUNDING REGULATION	*Suggested more than once*	- No more food industry interests to be represented in the Management Board. (NGOs, Media) - Possibility for EFSA to commission studies for risk assessments to independent laboratories. (NGOs, Media, NRM)	Media, NGOs, NRM
	Suggested once	- Inclusion of representatives from the EP in the Management Board. (Media) - More influence to environmentalist and consumer associations. (Media)	

(Source: EY survey)

Following the attacks by NGOs, Consumers, trade unions and organizations representing professionals from the food chain (one EC) (e.g., GMO, Round-up), EFSA has progressively reinforced its rules and increased rigor in the use of selection criteria for experts (EC), and is indeed now perceived by the vast majority of respondents as having one of the most solid independence policy and process of decision-making about the conflicts (82% giving 3 or 4 out of 4 – Q18.3 – Chart 43). According to respondents that have given a rate, FSA gets a good overall rate as well with 82% of 3-4 out of 4 rates, followed by ECDC with 76%, EMA 75%, ECHA with 68%, DG SANCO non-food committees with 66% and VWA with 60%.

Chart 43: Stakeholders' evaluation of other organizations on independence policy and process of decision-making about the conflicts



(Source: EY survey)

INDEPENDENCE AT FSA

FSA independence is recognized among stakeholders. This recognition is mainly based on a very clear separation of risk assessor and risk manager: independent committees and working groups are external to the agency and they advise FSA in order to ensure that advice to consumers is always based on the best and most recent scientific evidence.

3.7.2.3 Analysis of evidences

The analysis of EFSA's independence has been performed on two levels. The first one relates to the compliance of its structures, governance and procedures with the Founding Regulation requirements and the second one to their effectiveness, also in comparison with similar organizations and relevant standards.

EFSA has developed its structures and governance in compliance with the Founding Regulation, in such a way to provide a strong basis for the independence of its decision-making process. Indeed EFSA's structure and governance have been able to guarantee the separation between the scientific work and the strategic management. As observed during EFSA's key meetings and further detailed in the "Organization" paragraph, the body responsible for strategic decisions (MB) does not influence the provision of scientific outputs, exclusive responsibility of Panels, Scientific Committee, WG and EFSA's staff. These evidences, together with the great satisfaction of stakeholders, show that EFSA's overall structures and governance have been effective in ensuring that the Authority can operate without undue influence.

As far as the Management Board is concerned, despite few criticisms on its independence from industry interests, recent cases (e.g., EFSA's management of the resignation of the MB Chair) have confirmed the attention paid by the Authority to the MB's independence through a monitoring of its members' profiles. In addition, the fact the MB members are not MS representatives, as already detailed in the "Organization" paragraph, is a guarantee of the MB independence from national political interests.

EFSA has implemented in 2007 a Policy on Declaration of Interests, which translates into detailed procedures the Founding Regulation principles. The encouraging audit results, the high number of conflicts of interests prevented and the limited cases of breach of trust detected demonstrate the effectiveness of this policy that seems now to have reached the maturity phase.

EFSA's actions for independence went beyond the compliance with the Founding Regulation and, in order to adapt the system to new challenges and work areas (i.e., increasing relevance of applications on the total amount of requests of opinions), EFSA has launched in 2011 a new Policy on Independence, to further improve and clarify the Authority's approach to independence. This Policy represents a significant effort of comprehensiveness as it has drawn together all the relevant existing elements related to EFSA's policies, procedures and systems affecting independence at different levels and in addition it has represented a shift towards stricter controls and higher level of transparency on how interests are screened.

Even though it is not yet possible to evaluate the effectiveness of this new policy due to its recent adoption (2011 and June 2012 for the relating implementing rules), the analysis of the correspondence between its content and the main stakeholders' criticisms on EFSA's independence let us say that through the new Policy EFSA has addressed the majority of criticisms (as shown in Table 40).

Table 40: Matrix of coverage of criticisms/new Independence Policy measures.

Main criticisms	Main responses provided by the new EFSA Independence policy
Link with industry	Stronger measures concerning industry-related issues and funding-related interests (e.g., allowed below 25% private funding, experts having worked for industry must wait 2 years to be a member of EFSA's scientific groups).
Loss of quality in the provision of final outputs and expertise	Selection criteria of experts firstly oriented to award scientific excellence and option of waivers.
Lack of transparency on the procedures of screening and deciding on conflicts of interests	Clarification of which declared interests would lead to a scientific expert being allowed or disallowed to take part in EFSA's work. Practical examples of screening and assessing procedures published on EFSA website. Recording of all the decisions in the meeting minutes.
Unclear definition of conflict of interests and complexity of the procedures	Adoption of a new definition of "conflict of interest" and of a clearer set of definitions of relevant activities which have to be declared by all persons.
Unclear separation of risk management/risk assessment activities	
Limited effectiveness in mitigate criticisms towards experts' independence	

(Source: EY elaboration on secondary sources)

Despite the identification of some areas where further improvement is still needed (as better described below), EFSA's policies and procedures have been effective, as also confirmed by stakeholders, in ensuring that the Authority operates independently and mitigates external criticisms. As relates these, the Authority should distinguish political criticisms from scientific-based ones and implement the most adequate action to deal with them. Indeed, as pointed out by many stakeholders, criticisms on EFSA's independence are not always scientifically sound.

In the analysis of EFSA's evolution in policies and procedures for independence, there are evidences that EFSA's has progressively increased the compliance of its procedures with *OECD Guidelines for managing conflict of interests*.

If compared with similar organizations, EFSA's overall structure, governance and procedures for independence define one of the most advanced and robust systems in place, as confirmed by the 2011 comparative report[420]. Despite similarities, like the use of declaration of interests, that get ECHA and EMA close to EFSA, the Authority's system of conflict management, the sound procedures for the declaration of interests and the transparency of the system guarantee to EFSA a high level of independence. This is further confirmed by the majority of stakeholders, recognizing EFSA as having one of the most solid independence policy and processes.

The above illustrated evidences show that no major changes are needed in EFSA's structure and procedures. Nonetheless, further detailing the correspondence between stakeholders' criticisms and EFSA's actions to deal with them (see Table 40) some minor areas of improvement have been identified.

[420] Comparison between the tools ensuring EFSA's independent scientific advice and the instruments in use by organizations similar to EFSA, Milieu, January 2011.

The first one is linked to the mismatch between the stakeholders' criticisms and the actions implemented by EFSA to face them, corresponding to areas where stakeholders' criticisms have revealed a lack of awareness or understanding of EFSA's most recent policy measures. This situation requires the Authority to implement actions to improve the external perception due to the fact that concrete measures have been already taken. The second area of improvement is linked to criticisms that EFSA has not faced adequately through its various initiatives yet. These areas, therefore, require a more substantial intervention of the Authority.

Regarding the first group, we have identified the following critical issues:

- *Links between EFSA and industry/industry-affiliated bodies*.
  Despite the strict measures progressively introduced by EFSA over the years, some stakeholders still perceive the existence of links between EFSA and Industry. The limited control by EFSA on the content of experts' Declarations of Interest is perceived as exposing the Authority to a high risk of unexpected conflicts of interests. Moreover, as already detailed in the Provision of outputs paragraph and in the Data collection paragraph, EFSA's use of data and studies coming from the industry is questioned because confidentiality clauses often limit their publication. NGOs represent the most critical stakeholder group on this issue considering that 5 out of 13 targeted NGOs and out of 6 NGOs responding have provided negative comments on EFSA's independence from industry.
- *Transparency of procedures of screening and detecting conflict of interests*.
  Most of the documents related to the screening procedures and decisions on conflicts of interest are not published, and despite EFSA's efforts to clarify the screening and assessing procedures through concrete examples, it is difficult for any external stakeholder to understand how decisions on conflicts of interest are taken and feedbacks from the Authority on the final decision are rare.
- *Definition of conflict of interests*.
  What is a conflict of interest for EFSA and how EFSA identifies the conflicting situation is still unclear for some stakeholders.
- *Actions to mitigate criticisms on EFSA experts' independence*.
  EFSA's actions to address attacks towards experts' independence are still ineffective. Indeed, despite the increased commitment of the Communications Directorate to answer to external criticisms through for example the creation of the new website section "EFSA answers back", experts feel unconfident; more adequate and timely answers to external criticisms are expected. This situation, as also stated by some stakeholders, may limit experts' future willingness to work for the Authority and should be adequately managed maintaining EFSA's independence without exposing it to critics of lobbying and dependence.

All the above listed criticisms are counterbalanced by recent measures adopted by EFSA through the new Policy on Independence, as shown in Table 40, and by additional initiatives undertaken by the Authority. Waiting for the full implementation of the Policy to evaluate its impact in mitigating these criticisms, EFSA should progressively increase the level of transparency of its procedures and further communicate on new rules and ongoing changes in order to improve the external perception on the previously described issues.

Regarding the second area of improvement, EFSA should address through specific initiatives the following issues:

- *Separation of risk assessment from risk management*.
  The separation of risk assessment from risk management is not always clear:

boundaries between the role of RA and RM are sometimes not respected when observing for example EFSA's scientific outputs that, as stated by some stakeholders, contain recommendations for risk managers.

- *Effectiveness of independence related rules*.
  EFSA's approach in dealing with independence mainly consists of policies and implementing rules to be respected. After having implemented the requirements set in the Founding Regulation through its 2007 Policy on Declaration of Interest, EFSA has decided to develop additional rules to further enhance its independence (e.g., the new Policy on Independence and new implementing rules). The current level of regulation of this issue is critical and not well perceived by the majority of stakeholders. The analysis of the actions undertaken by EFSA over the years to demonstrate its independence to external stakeholders show that additional efforts to introduce further rules on this issue should be adequately counterbalanced by an appropriate cost/risk/benefit assessment and with different complementary initiatives in order to be effective (e.g., experts could be made more responsible for the declaration of their interests to limit situations where they do not declare all their relevant interests). Indeed, further strengthening controls on experts may reduce the number of experts compliant with EFSA's requirements and may gradually undermine the scientific quality of EFSA's outputs. Coherently, the greater scrutiny and safeguards introduced by the new Policy on Independence for the involvement of experts coming from industry may bring, if not adequately managed, to the loss of the industry professional expertise.

3.7.2.4 Evaluation results

EFSA is generally independent and it has one of the most advanced and robust systems in place for ensuring the independence.

EFSA has **fulfilled its obligations** to operate in an independent manner and, despite criticisms, no major changes in EFSA's structure and procedures for independence are needed; the current situation is considered as a satisfying infrastructure also if compared with other European Agencies and relevant international standards, like OECD ones.

The current good level of independence is mainly due to:

- Governance and structure laid down by the Founding Regulation that provide EFSA with a strong basis for the independence of the decision-making process, and guarantees a clear separation between EFSA's scientific work and strategic management.
- The effective implementation of the Policy on Declaration of interests as further confirmed by the encouraging audit results.
- The progressive evolution of procedures towards both stricter controls and a high level of transparency on how experts' interests are screened. More specifically, the recently adopted Policy on Independence (2011) and the related implementing measures represent a shift towards a more comprehensive approach to independence, including complementary issues like: organizational governance, transparent selection of experts, collegial decision-making, validation of data, broad consultation transparency of scientific workflow, etc.

Nonetheless, as independence remains one of the main issues called into question by some stakeholders and by the public at large, the following areas of improvement have been identified. The first ones relate to areas where EFSA has already taken concrete measures mainly through the new Policy of Independence but where these measures are not known

enough. An increased level of transparency on procedures and a better communication is required to improve the external perception on these issues.

- *EFSA's links with industry and industry-affiliated bodies*: stakeholders still perceive the existence of links between EFSA and Industry. Waiting for effects of the implementing rules of the new Policy on Independence that include stronger measures concerning industry-related issues, there is a need for more transparency and for a proper communication of the existing rules to prevent such a perception. Regarding this aspect, the most critical target the Authority has to deal with is NGOs.
- *Transparency on screening procedures*: most of the documents related to the screening procedures and decisions on conflict of interests are still not published and, despite EFSA's efforts to clarify the screening and assessing procedure through concrete examples, it is difficult for any external stakeholder to understand how decisions on conflicts of interest are taken; feedbacks from the Authority on the final decision should be available.
- *Actions to mitigate criticisms*: EFSA is still ineffective in mitigating criticisms towards its experts' independence. This situation, if not adequately managed, risks to limit experts' future willingness to work for the Authority. EFSA should thus continue to improve the experts' confidence in the structure and better communicate all the activities implemented in this regard. Moreover, as criticisms on EFSA's independence are not always science based, the Authority should also be able to identify the nature of the attack and to subsequently define the most adequate strategy to deal with it.

Parallel to the improvement of the external perception, EFSA should also address the effectiveness of independence related rules. EFSA's approach in dealing with independence mainly consists of policies and implementing rules to be respected. The current level of regulation of this issue is critical and not well perceived by the majority of stakeholders. Indeed, further strengthen controls on experts may reduce the number of experts compliant with EFSA's requirements and can gradually risk to undermine the scientific quality of EFSA's outputs. Any additional effort to introduce further rules on this issue should be adequately counterbalanced by an appropriate cost/risk/benefit assessment and with different complementary initiatives in order to be effective (e.g., experts could be made more responsible for the declaration of their interests to limit situations where they do not declare all their relevant interests).

3.8 Openness and Transparency

3.8.1 Introduction to the results for the thematic area of evaluation

This area of evaluation relates to the evaluation criteria of **Openness and transparency** and refers to the extent to which these principles have been implemented in EFSA's work.

The principles of openness and transparency are transversal to all EFSA's activities and thus they have been already treated, at different levels, in previous paragraphs. More specifically, in par. 3.1 " Provision of scientific outputs" as relates the transparency of the decision-making process underpinning scientific opinions, in par. 3.2 "Data Collection" as relates the transparency on data collection activities performed by EFSA, in par. 3.3 "Risk Communication" as relates the use of specific tools and in par. 3.7 "Independence" as relates the transparency in the screening of interests process.

This section addresses the evaluation of the current level of EFSA's openness and transparency, analyzing the following issues:

- EFSA's level of transparency;
- EFSA's level of openness[421];
- The relevance and cost-effectiveness of openness and transparency.

Whereas the principle of transparency is clearly defined in Reg. 178/02 in its implications (art.38), the principle of openness remains a bit more ambiguous and is left to EFSA's implementation rules. The evaluation of transparency relates to the compliance of EFSA's procedures and activities with the requirements of its Founding Regulation, whereas the evaluation of openness relates more to EFSA's capacity to be open to relevant input, scrutiny and dialogue in its work as well as to the effectiveness of the actions undertaken.

The evaluation of EFSA's transparency and openness is strictly linked to the level of complexity of the activities performed by the Authority that is why sometimes non-transparency might be more connected to difficulties in communication rather than to lack of transparency.

EFSA's current procedures for openness and transparency should be evaluated as the changeable result of the balance between the need of external stakeholders to be more informed about the Authority's way of functioning and the need of the Authority to preserve confidentiality of sensitive information in order to stimulate open, active and high quality discussions.

3.8.2 EFSA's level of openness and transparency

3.8.2.1 Facts & Figures

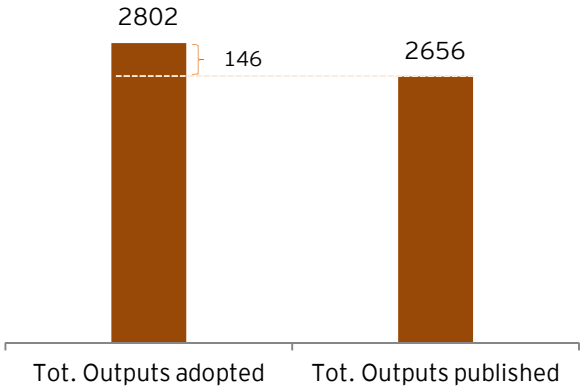
EFSA's level of transparency

During the evaluation period, **EFSA has progressively implemented the requirements set in the art. 38 of the Founding Regulation**[422]**.** More specifically, as seen from the website, the Authority has made public an increasing number of documents:

[421] Stakeholders' do not always make the distinction between EFSA's openness and related tools and activities from EFSA's transparency and related tools and activities. Despite the structure of this paragraph separates stakeholders' evaluations linked to openness from those related to transparency, this distinction should be considered flexible.

- Agendas and minutes of the Scientific Committee and Panels.
- Most of the opinions of the Scientific Committee and Panels after adoption (Chart 44), with the inclusion of minority opinions. Opinions are generally integrated by all supporting information and documents without prejudice to the rules on document accessibility and confidentiality.

Chart 44: Total outputs adopted and published, 2006-2011

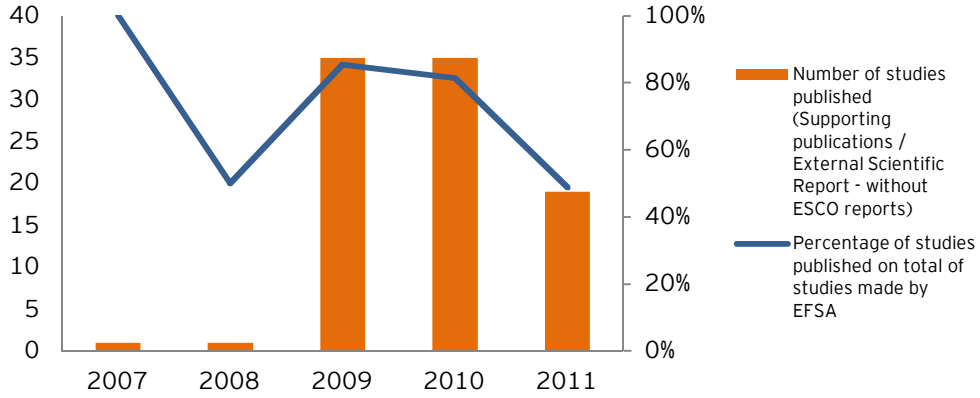


(Source: EY elaboration on EFSA's data, 2012)

- The annual Declarations of Interest made by the Executive Director and by members of the Management Board, of the Advisory Forum, of the Scientific Committee and Panels, as well as Declarations of Interest made in relation to specific agenda items during meetings (included into meetings minutes).
- Most of the results of its scientific studies (Chart 45).

[422] In order to efficiently implement the requirements set in the Art. 38 ("the Authority shall ensure that it carries out its activities with a high level of transparency. It shall in particular make public without delay: (a) agendas and minutes of the Scientific Committee and the Scientific Panels; (b) the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included; (c) without prejudice to Articles 39 and 41, the information on which its opinions are based; (d) the annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels, as well as the declarations of interest made in relation to items on the agendas of meetings; (e) the results of its scientific studies; (f) the annual report of its activities; (g) requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification. The Management Board shall hold its meeting in public unless, acting on a proposal from the Executive Director, it decides otherwise for specific administrative points of its agenda, and may authorize consumer representatives or other interested parties to observe the proceedings of some of the Authority's activities.". EFSA has laid down in 2006 and 2009 its internal rules and practical arrangements.

Chart 45: Percentage of studies published on total of studies made by EFSA



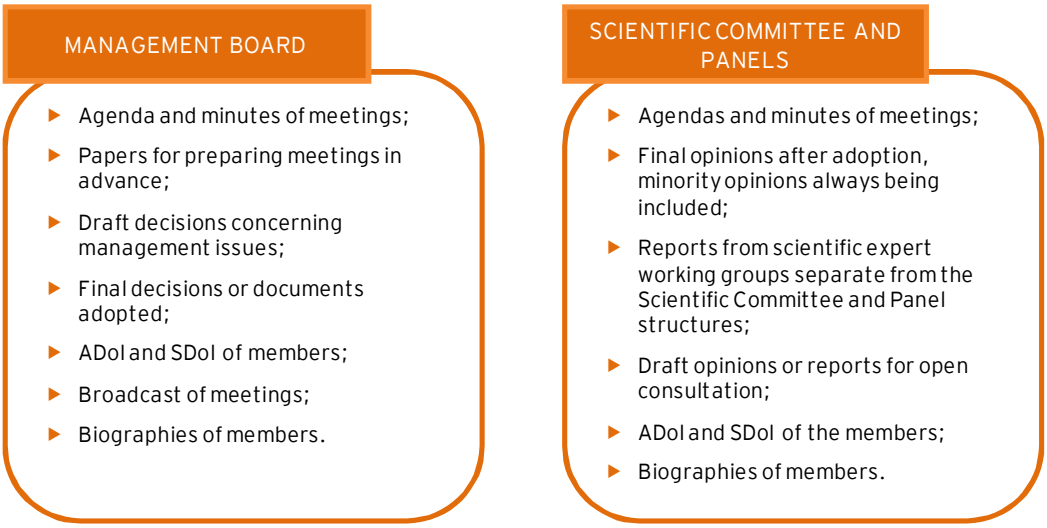
(Source: EY elaboration on EFSA's data, 2012)

- The annual reports of its activities since 2003.
- Requests from the European Parliament, the European Commission, or the Member States for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

  Concerning this last point, in addition to the publication of opinions, EFSA has created a Register of Questions (RoQ) (see also par. 3.6.2.1) which gathers all the requests for scientific outputs and describes the status of progress of EFSA's scientific work, from the mandate received to the output produced. The RoQ is a free access IT tool through which everyone can check the status of a specific request and the responsible Panel. This tool has been recently (2009) integrated with new functions, allowing the external user to monitor the whole Risk Assessment Workflow (e.g., receipt of request, new deadline agreements, "stop the clock mechanism", assessment, communication of the opinion, etc.) and to access the supporting documentation.

The evolution of tools and procedures developed by the Authority over time shows that the **level of transparency has progressively increased**. EFSA has given priority to building transparency into all aspects of its work since its inception in all its strategic documents and has renewed this engagement in the recent Science Strategy 2012-2016.

In addition to the requirements explicitly indicated in the Founding Regulation, the Authority has **progressively widened the portfolio of documents to be made public by** the Management Board and the Scientific Committee/Panels that now make public the following documents.



(Source: EY elaboration of EFSA's public information).

Some transparency **requirements have been also extended to the Advisory Forum** and its working groups, even though its role is mainly consultative. In order to clearly describe how MS interests are integrated and considered in EFSA's decision-making process, the AF regularly publishes agendas and minutes on the website as well as the Forum's supporting documents produced by EFSA[423].

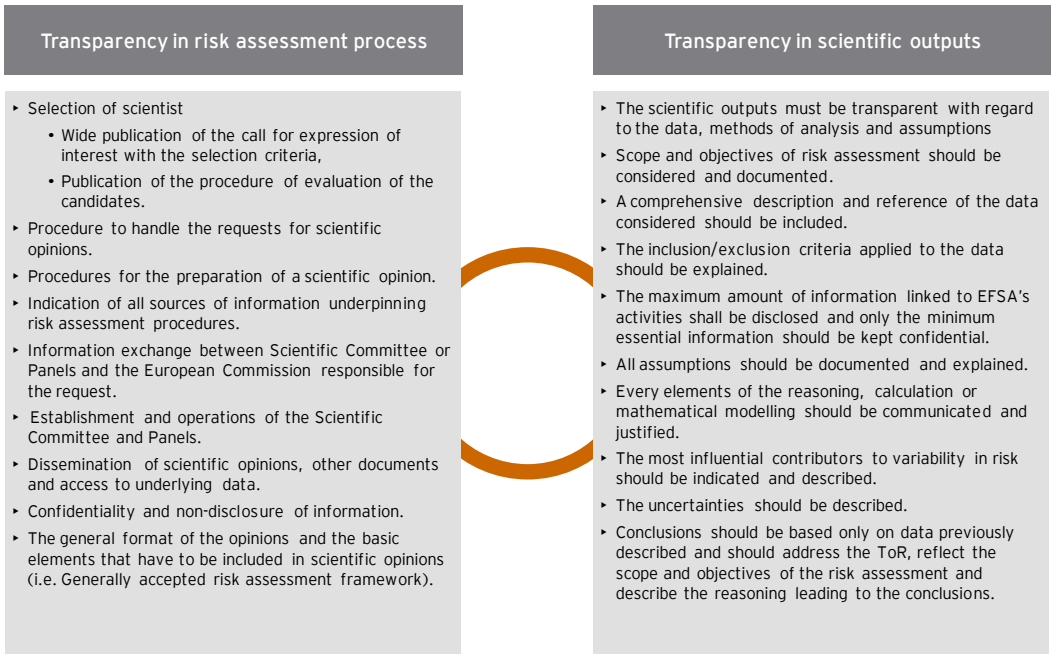
In addition, to better face the increasing stakeholders' requests to improve the level of transparency on EFSA's internal functioning, the Authority has implemented the following actions:

- **A comprehensive body of risk assessment best practices and methodologies** accessible via website to guide the work of EFSA's Scientific Committee, Panels and the scientific staff to ensure their opinions respect the highest scientific standards[424].
- **Standard Operating Procedures**[425] that describe in details the different steps of EFSA's workflow for scientific opinions. (see also par. 3.6.2.1)
- The distinctive **system of webcasting**[426] (2006) that allows the general public to "participate" to the public session of the MB (on demand since 2012). (see also par. 3.3.2.1)
- A **Pilot project**[427] (2012) **allowing observers to attend** three **Panels** and one **Steering Committee** meeting to promote a better understanding of how scientific risk assessment works, and provide a new possibility of interaction with EFSA's scientific experts.
- **Two guidance documents**[428] (in 2006 and 2009), detailing, as synthesized in Figure 16: respectively **transparency in risk assessment procedural aspects** and **scientific**

[423] Openness, Transparency and Confidentiality (MB 16.09.2003 -13- Agreed).
[424] EFSA website
[425] Overview and status of SOPs, QM/AVI/11 March 2011.
[426] However the evolution of this instrument over the years followed an interesting path. Starting from 2006 with a live and on demand video webcasting, EFSA has then limited it in 2011 to a live and on-demand audio webcasting and it is now under discussion the decision to further limit this instrument (MB on the 7 March 2012) to an on demand audio webcast.
[427] Guidelines for observers, EFSA website, 2012
[428] Transparency in risk assessment carried out by EFSA: Guidance document on procedural aspects (EFSA Journal 2006 353, 1-16) and Transparency in risk assessment – Scientific aspects. Guidance of the Scientific Committee on transparency in the Scientific aspects of risk assessment carried out by EFSA. Part 2: General principles. (EFSA Journal 2009 1051, 1-22).

aspects and general principles to be applied to the identification of data sources, criteria for inclusion/exclusion of data, handling of confidential data, documentation and explanation of assumptions and uncertainties. (see also par. 3.1 "Provision of scientific outputs"). These documents describe how things should be done and lay the foundations for harmonized scientific outputs. Nonetheless there are still some doubts on how these rules, best practices or standard procedures are implemented in reality, considering the differences that could be found in outputs produced by Panels (e.g., differences in the use of terminology as pointed out directly by the Chairpersons of Panels during the 53rd Scientific Committee and other incoherencies previously discussed in the paragraph of Provision of scientific outputs). In addition EFSA seems to have some difficulties in enforcing the application of those Guidance documents across its bodies as observed in the 53rd Scientific Committee. During the meeting, the discussion on a draft opinion[429] has pointed out the necessity to include in all risk assessments an uncertainty analysis despite the same request has been already made some years before in a previous guidance that the Scientific Committee has produced.

Figure 16: Content of the two guidance documents on transparency



(Source: EY elaboration on secondary sources)

As a further element of EFSA's transparency, **members of EFSA's Scientific Committee and Scientific Panels are selected according to objective and transparent criteria** predetermined in an open call for expression of interest published on the Official Journal of the European Union, EFSA's website and selected scientific publications. EFSA follows a detailed selection procedure including an external evaluation as set out in the Decision of the EFSA Executive Director on the selection of the Scientific Committee, Scientific Panels and external experts[430] (see par. 3.6 "Organization" for further details on the procedures).

Nonetheless, EFSA's risk assessment process is not completely transparent (e.g., not all Panels are open to external observers). More specifically, the evaluation process

[429] Draft opinion on risk assessment terminology.
[430] Decision of the Executive Director concerning the selection of members of the scientific committee, scientific panels and external experts to assist EFSA with its scientific work. 2011

underpinning the dossiers for application submitted by the industry is the vaguest one[431], considering that EFSA has to keep a certain level of confidentiality and protect sensitive commercial information provided by applicants.

The changing legislative context is asking for a new approach to transparency and for an increased relevance of this principle in the rules of procedures for EFSA's main decision-making bodies. **The recent evolution of the case law[432]** and the increasing number of requests for access to documents sent to the European public Institutions and then taken to the Court[433] are **progressively increasing the level of required transparency**. All documents become now potentially accessible to the general public[434] and applicants do not have to motivate the access request and leave to the public body the responsibility to give the reasons of any denial. The current interpretation of the legislation is also pushing towards a higher degree of detail in the justification of disclosure refusals. In the future, there will not be formal or informal, public or restricted documents, but only documents that can be accessed.

EFSA's level of openness

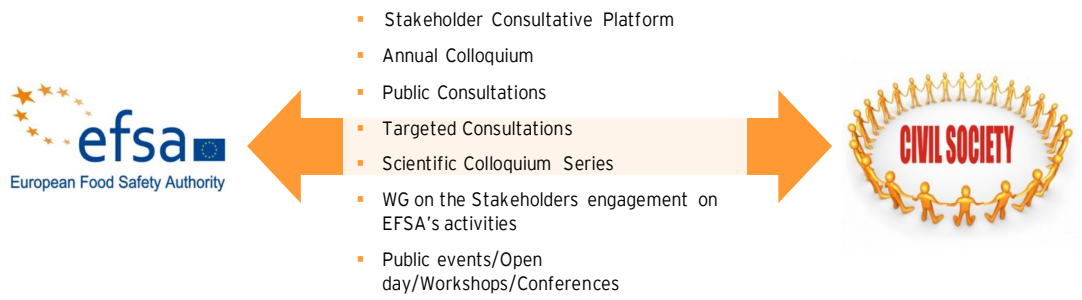
In this part, according to the specific evaluation framework, the focus is primarily on tools/procedures that the Authority has developed to make the participation of civil society stakeholders[435] easier and more significant. More specifically, civil society stakeholders include: consumer groups, NGOs, media, market operators (such as farmers, food manufacturers, distributors or processors and science professionals) and general public more extensively.

Coherently with the Founding Regulation[436] and with the most recent activities of the European Commission concerning "Europe for citizens"[437], EFSA **has progressively developed different tools and procedures to seek stakeholders' inputs and enhance their**

[431] Draft policy on Independence and scientific decision-making processes of EFSA, EFSA consultative work on Independence, October 2011.
[432] As illustrated during the Scientific Committee Plenary (7-02-2012) by the Head of Unit Legal and Regulatory Affairs reporting on the increasing number of requests for access to documents sent to EFSA and Memo on the handling of requests of public access to documents in line with the case law of the Court of Justice of the EU (EFSA/SC/1400, 2012).
[433] Greenpeace appealed to Court in Germany to obtain one specific document from EFSA.
[434] Due to its public nature, EFSA should disclose the maximum amount of information linked to its activities (publications, newsletters, EFSA journal, Register of Questions). Nonetheless it has always maintained an essential minimum confidential in order to safeguard the freedom of the scientific debate and guarantee independence vis-à-vis external influence (art. 39 of the Founding Regulation, "*the Authority shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified*" unless in case of overriding public interest in disclosure). For the access to documents which are not directly available, EFSA disposes of a formalized working practice for managing applications and requests coming from external stakeholders and refuse the disclosure of certain documents. More specifically, the application should be made in written form to the ED and should be handled promptly: within one month from the registration of the application, the Authority shall either grant access to the document requested or write the reasons for a total or partial refusal of access. Where access is refused, the decision shall specify which of the exemptions has been used (art.4 Reg. 1049/2001).
[435] Cooperation and exchanges with institutional stakeholders (European Commission, the European Parliament and Member States) is treated in detail in the Cooperation and Networking Chapter.
[436] (Art. 42) The Authority is supposed to have, "effective contacts with consumer representatives, producer representatives, processors and any other interested parties" and in addition (Art.9) "There shall be open and transparent public consultation directly or through the representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it".
[437] EFSA Strategic Plan 2009-2013.

respective contribution[438]. Starting from 2005 when the Authority first set up the Stakeholder Consultative Platform, a various portfolio of activities and tools for inclusion and public scrutiny has been developed (Figure 17). In addition, EFSA has significantly insisted, as confirmed in the Science Strategy 2012-2016, on the importance to bring the Authority closer to all the interested parties (the direct clients as well as the general public) in order to enable them to contribute to the decision-making process and to foster a sense of belonging to a common European Food safety system.

Figure 17: Tools and procedures of exchange with civil society stakeholders

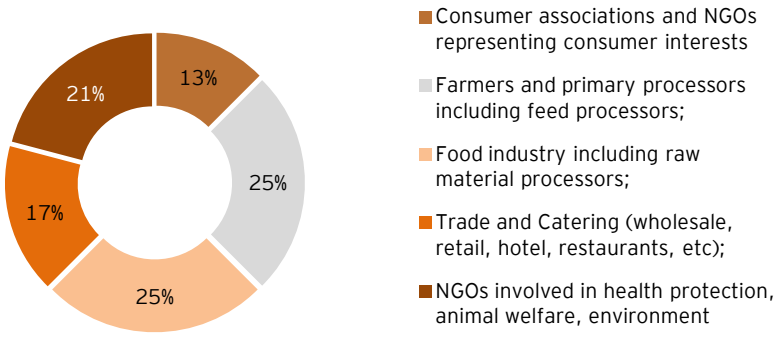


(Source: EY elaboration on secondary sources[439]*).*

The Stakeholder Consultative Platform[440] is the main tool that EFSA has implemented to permanently consult its stakeholders. Since its creation, its activity has been steadily growing and has become more and more relevant for EFSA[441]. This emerges from the increased number of plenary meetings (1 in 2005 to 3 in 2010[442]), from the implementation of complementary technical meetings (focused on the provision and collection of information, exchange of views and data) and from the increasing involvement of the Platform's members in reviewing and providing opinions on EFSA's strategic documents and policies (e.g., Approach to public consultation on scientific opinions, EFSA Communication Strategy, etc.). New Terms of Reference have been adopted in 2010 by the MB to guarantee the effectiveness and efficiency of the Platform's functioning. Now the SCP is composed of 24 EU-wide stakeholder organizations[443] operating in the food chain and active within the mandate of EFSA, covering in particular food and feed safety, nutrition, animal health and welfare, plant health. Platform members represent the main areas of EFSA's activity[444] (see par. 2.1 for more details on EFSA's mission and activities) with an underrepresentation of Consumer associations and NGOs representing consumer interests (13% of the Platform's members).

[438] Guidance document on procedural aspects on transparency in risk assessment carried out by EFSA, 2006.
[439] EFSA website.
[440] The Stakeholder Consultative Platform is a forum for regular dialogue and exchanges with organizations significantly represented at European level offering advices with regard to general issues concerning EFSA and, in particular, the impact of its work on stakeholders.
[441] In 2010 a Rolling Work Plan was established to promote better resource constantly updated to enhance the interaction with EFSA's stakeholders.
[442] Only in 2005 the Stakeholder Consultative Platform met once (EFSA website).
[443] List of Members, EFSA website.
[444] Stakeholder Consultative Platform: Terms of Reference, 2010

Figure 18: The composition of the Stakeholder Consultative Platform 2011



(Source: EY Elaboration on EFSA website)

EFSA continues to assure that interested parties could take part at meetings of the Platform and, therefore, announcements are made via EFSA's website some time before each meeting. Interested parties can attend the meeting upon registration on the EFSA website as observers. Observers that register to attend the meeting can be invited to participate to the discussion[445]. Agendas, documents, minutes and any other relevant information about the Platform are then placed on EFSA's website.

Minutes and papers resulting from the Platform are normally brought to the attention of the EFSA Management Board[446] in order to allow this decision-making body to take into consideration the stakeholder's inputs. In addition, members of EFSA's staff are involved in meetings of the Platform to ensure a proper exchange of information and dialogue, to consolidate the link with the Authority and to give support to the Platform with the Secretariat.

In order to meet the increasing requests of stakeholders to be involved in EFSA's decision-making processes and to manage efficiently the Platform's workload, EFSA has progressively broaden the Platform's activities setting up complementary bodies as detailed in the box below.

[445] Stakeholder Consultative Platform: Terms of Reference, 2010.
[446] Stakeholder Consultative Platform: Terms of Reference, 2010.

SCP COMPLEMETARY BODIES

- **Platform' Working Groups**[1], formed by Platform member organizations working together on horizontal issues of common interest in order to act as a specialized advisory group reporting back to the Platform. Members could be nominated by EFSA on its own initiative or in response to a proposal of the Platform members.
- **The Working Group on the Stakeholders engagement on EFSA's activities**[2], formed in 2010 by those Platform Members expressing their interest to be part of it in order to explore new and better forms of stakeholders' inclusion.
- **Stakeholder Consultative Groups**, set up in 2010[3], and formed by Platform Members willing to provide early information and data on issues where the knowledge of different approaches and perspectives are relevant for the EFSA's preliminary work[4]. Members are selected by EFSA through an open call of candidatures.

[1] Stakeholder Consultative Platform: new Terms of Reference, 2010.
[2] EFSA Rolling Work Plan on the activities with its stakeholders, EFSA stakeholder Consultative Platform Meeting, April 2010.
[3] Until now it exists only a Stakeholder Consultative Group on Emerging Risks.
[4] See footnote 2 above.

(Source: EY Elaboration on secondary sources)

In addition to formalized activities that require membership (e.g., SCP), EFSA also promotes relations with the general public and those who feel they can contribute to the Authority's work[447], with different instruments to foster inclusion, as described in the following box.

[447] EFSA website.

MAIN INSTRUMENTS TO FOSTER INCLUSION

- **The Annual Colloquium,** launched in 2003, is a participative event for industry, farmer groups, consumer groups and other non-governmental organizations to informally share knowledge and exchange views on food and feed safety with EFSA staff. Participants at the Annual Colloquium are invited directly by EFSA. Others who wish to attend without a direct invitation from EFSA can express their interest to the Authority which will subsequently assess the availability of places.
- **The Scientific Colloquium,** set up in 2004, is an opportunity for EFSA to engage in scientific discussions and debates with leading scientists from Europe and beyond. At least once a year, EFSA organizes this kind of meeting to deepen the understanding of the fundamental scientific issues related to risk assessment of food and feed safety. The participation is open to the public. The interaction with participants is supported through the preparation of briefing notes and discussion points distributed before the meeting date.
- **Public consultations** is the more often used tool[1] that has been clearly regulated through internal regulations[2] and through the implementation of a Standard Operating Procedure in 2011[3]. It is a form of exchange on a draft scientific output aiming at receiving comments from the public (namely the non-institutional stakeholders). EFSA has developed and published common criteria that allows public involvement in a transparent, coherent and timely manner. More specifically EFSA has defined: the criteria for the identification of the need underpinning the decision to use this tools, the nature of scientific outputs on which public consultation could be used and the means to report on the outcome of the consultation process. To guarantee the widest access, public consultations are addressed to the stakeholders via the EFSA website with essential background information.

In addition to these tools of involvement institutionally defined through formal regulations or internal definitions, EFSA has developed a high number of complementary activities hardly classifiable and traceable and not always known even by the Authority's main stakeholders[4].

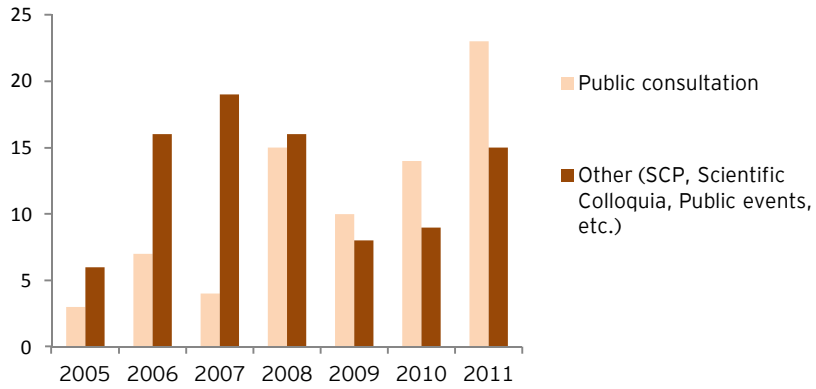
- **Targeted consultations, technical meetings or hearings/brainstorming** are focused on specific outputs allowing to target specific groups that could be particularly affected by the output discussed, members of the Platform and other stakeholders' organizations. EFSA organized 11 targeted consultation in 2010 (until April)[5].
- **Public events, Open days, Workshops and Conferences,** to inform the general public on issues on issues relevant for many stakeholders, like the independence policy and its implementing rules. The access to these events is open and free.

[1] The ability of EFSA to publicly consult must be viewed in the context of the applicable legal framework. Public consultation will be carried out by EFSA when and in a manner which is compatible with the procedures and deadlines laid down in the relevant EU legislation or required by the risk managers.
[2] EFSA's approach on Public Consultations on scientific outputs
[3] Public Consultation on EFSA scientific output, 2011 (Overview and Status SOPs, March 2011)
[4] Image Survey 2010
[5] EFSA Rolling Work Plan on the activities with its stakeholders, EFSA stakeholder Consultative Platform Meeting, April 2010

(Source: EY elaboration on secondary sources reported in the box).

This approach has brought to an **increasing number of public consultations** on specific scientific subjects and data collection activities where any interested member of the public can submit relevant data and information, **and of other public events** such as Colloquia, workshops, technical meetings (see Chart 46).

Chart 46: Trend in the number of meetings (and public consultations) for exchange information with stakeholders



(Source: EY elaboration on EFSA's website[448])

In case specific knowledge is required, EFSA can use its capacity to invite **hearing experts**[449] coming from the scientific community to participate in discussions, further broadening the scientific expertise at its disposal without directly influencing the scientific decision-making process as stated in the new Policy on Independence and decision-making process. Indeed EFSA has created a firewall that prevents hearing experts from exerting any undue influence over the discussions of the independent experts by excluding them from the drafting of outputs and from the final exchanges and voting on those outputs. This allows the Authority to take stock of the data or expertise developed by industry, non-governmental organizations and other interested parties on newly developed practices, processes, substances and products.

Despite the growing number of dialogue opportunities that EFSA has created with its stakeholders, there is a limited traceability of stakeholders' contribution. Currently, EFSA does not dispose, except in the case of public consultations, of a formal procedure for external complaints and suggestions and this limits the capacity of external stakeholders to monitor if and how their inputs are considered in the Authority's decision-making process. With regard to public consultations EFSA prepares a written report collecting all the comments received and integrates them in a final report, addressing them one by one.

Parallel to these activities, in order to enhance its relation with Food Industry Representative, EFSA has created (2011) and is gradually improving an Application Helpdesk (as better illustrated in par. 3.6 "Organization") where applicants, Member States and other stakeholders can ask questions regarding applications. Given the recent implementation of this tool, it is still too early to evaluate the effectiveness of this tool.

[448] Methodology note: data regarding EFSA's events for stakeholders are quite confusing because of a lack of consistency in the use of terminology that has been developed over the years. Data that could be deduced in the EFSA website are not always comparable with those contained in the Activity Reports. (e.g.,, 91 public consultation in 2010 and 14 published on the website).

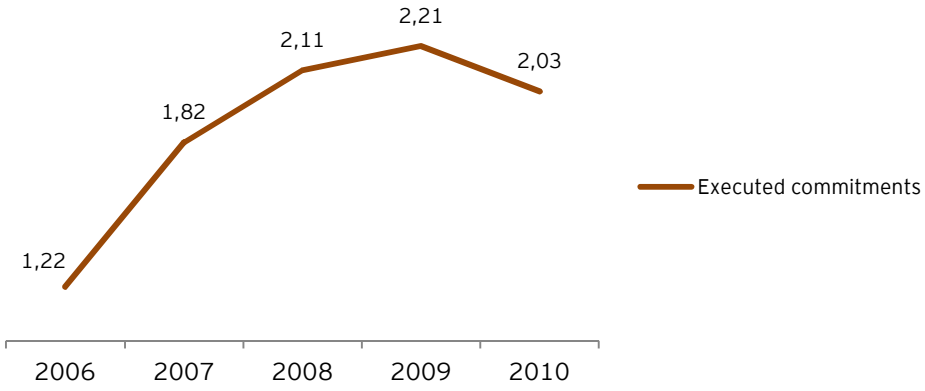
[449] Policy on Independence and Scientific Decision-Making Process of the European Food Safety Authority (mb 15-12-11)

The relevance and cost-effectiveness of openness and transparency

Openness and transparency have always been among EFSA's key principles, as stated in the Founding Regulation. These principles assumed a different importance over the years. Indeed, their importance in the 2005 EFSA's evaluation as well as in the evaluation of decentralized Agencies (2009) was limited. Since then, stakeholders' needs have increasingly evolved and EFSA has adapted consequently, increasing the relevance of openness and transparency in its work.

To progressively adapt EFSA's ways of working to the changing principles of openness and transparency, EFSA has allocated an **increasing amount of resources** to their implementation as shown in Chart 47.

Chart 47: EFSA's total costs (mln€) for Openness and Transparency



(Source: EY elaboration on EFSA Annual Financial Reports[450]).

COST EFFECTIVENESS OF TRANSPARENCY AND OPENNESS

All benchmarked organizations are looking for more openness and transparency in the process, but the costs dedicated to it are not monitored so far. However, in a context of decreasing resources, efforts are made to limit the costs of new initiatives

- **VWA** estimates that budget dedicated to transparency has increased whereas the team dedicated to openness has reduced.
- Transparency and openness is a constant issue at **ECHA**, but the costs are limited: stakeholders (civil society association, industries) are invited to attend committee meetings, at their expense. There is no webcasting.

If compared with EMA and FSA, according to the benchmark study 2011[451], **EFSA is characterized by a lower level of inclusion of external stakeholders in its decision-making** processes. Indeed, these organizations have provided[452] for increased involvement of stakeholders and other interested parties in certain processes, such as the possibility to participate in meetings as observers or to provide comments to draft reports. EFSA, as

[450] Costs for Openness and Transparency have been calculated considering the following budget lines: External Relations, Web Activities, Conferences and Events, Publication, Translation & Interpretations in the Annual Financial Reports.
[451] Comparison between the tools ensuring EFSA's independent scientific advice and the instruments in use by organizations similar to EFSA, Milieu, January 2011.
[452] Comparison between the tools ensuring EFSA's independent scientific advice and the instruments in use by organizations similar to EFSA, Milieu, January 2011.

illustrated before, has recently launched the Pilot Project to open-up its Panels to external observers that represents an important step towards an increased level of transparency. Nonetheless, observers will still not be allowed to participate to the scientific discussion of experts.

In the following box, specific tools and procedures for openness and transparency in other comparable organizations are presented more in details.

OPENNESS AND TRANSPARENCY

- To ensure a very high transparency, **FSA** and **EMA** work in open sessions. This is considered as really important to establish the trust of consumers. For EMA, there is one restriction that concerns the discussions about new products to be authorized: the opinion becomes public once the committee agrees in order not to infringe the liberty of individuals within the panel facing a lobbying pressure.
- **EMA** and **FSA** have also established a stakeholders' forum to enable main stakeholders to raise matters of concern with the Agency through regular consultations. Procedures to ensure that stakeholders' opinions are taken into account exist in both agencies.
- **EMA** and **FSA** do not publish everything online but EMA is moving from a reactive approach to a proactive one and an increasing number of information is published on the website to avoid individual questions that require a lot of resources. EMA suggests that more resources should be devoted to respond to consumers' questions: today there are only 10 people at EMA whereas FDA in the US has around 100 people to react to consumers' messages.
- In the Netherlands, **VWA** is also committed to publish every opinion on its website, in any case within four weeks after making decision.
- **ECHA**, **FSA** and more recently **EMA** publish all the experts' Declaration of Interests and the FSA has organized a listing of committee members outside interests into a publicly available register to enable the public to easily look up the declared interests of all committee members.

Openness and transparency still remain among the priorities of the Authority's future development as demonstrated by the EFSA's Strategic Plan 2009-2013 and by the Science Strategy 2012-2016. In the latter, as relates transparency, EFSA highlights its engagement in ensuring that its processes and the basis for its opinions are documented and understood[453]. EFSA has already identified ambitious objectives such as transparently demonstrating how data provided to EFSA are used and managed, as well as mechanisms by which an opinion is developed and scientific consensus is reached.

Regarding openness and dialogue, in the Science Strategy 2012-2016 EFSA renews its engagement to build meaningful dialogue[454] with consumers and stakeholders, in order to understand and address their risk perceptions and information needs and preferences, particularly related to new or complex scientific issues. EFSA will continue to perform public consultations on scientific opinions, particularly when preparing guidance documents, and by doing so collect views from various stakeholders, risk managers and risk assessors, including the global scientific community.

[453] Science Strategy 2012-2016 (mb 15-12-11)
[454] Science Strategy 2012-2016 (mb 15-12-11)

3.8.2.2 Stakeholders' point of view

EFSA's level of transparency

EFSA is a transparent organization according to the majority of stakeholders (NRM, NRA, EP, Cons., Scient.Org., IOs in interviews and 77,6% of the respondents of the survey having expressed a rate equal to or higher than 3 out of 4 – *Q19.1*).

Most of the information is freely available via the website through differentiated tools according to the target group, as already discussed in par. Risk Communication (e.g., newsletter, EFSA journal, Register of Questions, etc.) (NRA, NRM, FIR, Cons., IOs). Despite the large amount of documents and information uploaded, the RoQ represents, according to some FIR, a limit to the global transparency of the Authority due to its complex IT interface that limits stakeholders' capacity to keep track of submitted requests.

In addition, provided that agendas of all meetings are published, everyone can be aware in advance of the issues that will be discussed by the Authority's decision-making bodies. EFSA has globally achieved a satisfying level of transparency and stakeholders have recognized improvements over the years. Significant improvements have been noticed by members of the European Parliament since 2006[455], and EFSA's activities and decision-making processes seem now to be much more clear and transparent to external observers.

Despite the implemented tools, procedures and actions illustrated in the previous paragraph, **EFSA's level of transparency remains questioned, although only by a limited number of stakeholders**, that have raised criticism (about meetings, internal procedures, risk assessment process) and have suggested some priority areas of intervention, as reported in Table 41[456] (*Q19.2* and interviews).

Table 41: Main issues on transparency

MEETINGS	- Too much time spent to publish minutes of Panels, WG or stakeholder meetings. (FIR, NRA, Cons.) - Closed sessions of Management Board. (Media) - Reduced informative content in the minutes. (FIR) - Unavailability of all supporting documents related to the Advisory Forum. (Media) - Limited notice of the time schedule of stakeholders' meetings reducing an adequate preparation and fruitful involvement of participants. (Cons.) - Lack of media briefing on key topics/difficult issues (e.g., TTC). (Media)
INTERNAL PROCEDURES	- Unclear screening and assessing of interests. (NRA, Cons., MB, FIR, Media, NGOs) - Unclear selection procedure of external experts. (Scient. Org.) - Unclear recruitment procedure of EFSA's staff. (NRA) - Unavailability of Panel's member CVs. (NRA) - Lack of contact with experts. (FIR)
RISK ASSESSMENT PROCESS	- Closed scientific panels. (NRA, Scient. Org., Media, FIR, Cons., NGOs) - Unclear acceptance criteria for opinions. (Scient. Org.) - Unclear drafting and adoption of a scientific opinion. (NRA, FIR, IOs) - Limited knowledge and use of data provided by external stakeholders.(FIR) - Unclear process of evaluation of application dossier submitted by industry. (EC) - Expression of scientific uncertainty. (EC) - Use of a non harmonized terminology. (EC) - Weak description of exposure scenarios. (FIR) - Lack of clarity on the underpinning reasons of a self task mandate

[455] Starting date of the first mandate of the current Executive Director.
[456] Acronyms of stakeholders in brackets mainly refer to one respondent/interviewee.

	and the way the results will be used. (FIR)
THEMATIC ISSUES	- OGM (Media) - Isoflavones, bse, semicarbacide (NRA)

(Source: EY survey and Interviews).

In addition to the above mentioned criticisms, **EFSA's use of the confidentiality exemptions** described in footnote 432 is questioned as a tool to totally or partially refuse access to documents (e.g., industry dossiers – NGOs). Nonetheless, the definition of the adequate level of transparency for scientific discussions is still controversial among stakeholders. On the one side, NGOs, FIR and Cons. state that EFSA should be more transparent in the way it works and takes decisions, on the other side, IOs[457]stress that too much transparency may affect the process and the scientific discussion, the quality of the work of experts, and consequently the scientific outputs.

EFSA's level of openness

EFSA is an open organization according to the majority of stakeholders, in interviews NRM, NRA, EP, Cons., Scient.Org., IOs and 78,6% of the respondents of the survey having expressed a rate equal to or higher than 3 out of 4 – *Q19.4*).

EFSA has progressively improved the level of inclusion of external stakeholders in its decision-making process through a variety of instruments (e.g., SCP, workshop, etc.), as appreciated by most stakeholders (NRM, NRA, EP, Cons., Scient.Org.[458] in interviews). According to a few stakeholders[459], EFSA's attitude towards the comments from stakeholders has also changed and EFSA appears to be more willing to take into consideration stakeholders' opinions and advice.

The Stakeholder Consultative Platform is effective and effectively used (NRA, FIR, Cons.), stakeholders are increasingly consulted by EFSA (NRA, Cons.) and they consider it is not just because the Authority wants to be compliant with its internal regulations, but also because it wants to benefit from the stakeholders' points of view, considered as increasingly valuable according to some of the participants involved in the survey. SCP Members are quite satisfied with the quality of the discussions, even though sometimes they find them too technical, limiting a wide participation (one FIR). Few Stakeholder Platform Members (27% Q19.5) highlight some areas of improvement and more specifically more opportunities for discussion and an improved consideration of SCP meeting outcomes by EFSA.

Some additional criticisms concern **the functioning of the Panel system that does not seem to reflect the traditional scientific decision-making process** due to the fact that, as already seen in the previous par. 3.8.2.1. , it is not open to public scrutiny and comments during the decision-making process (NRA[460]). FIR complain that, once the opinion is published[461] external inputs are rarely considered and if new information comes out, a very bureaucratic and long process has to be undertaken (NRA[462]). In this process, according to some NRA, scientific contribution provided by national experts not belonging to Panels or working groups

[457] This opinion is supported also by one MB and one Scient.Org.
[458] This opinion is supported also by one IO.
[459] 1 Cons., 1 NRA.
[460] This opinion is supported also by one representative of the following targets: Scient. Org., Media, FIR, Cons., NGOs.
[461] According to a NRA a proposition to keep the Panel opened for 3 weeks after the publication of the opinion has been done but refused by EFSA because of a limited capacity to manage the comments coming from external stakeholders.
[462] In 2005 EFSA launched a call for data on poppy seeds. One of the main producers of poppy seeds in Europe was not able respond to the call. Thus, EFSA came out with an opinion without trying to ask again for data coming from that country. Once the opinion was published, this country tried frequently to ask EFSA to reconsider the output without any result. Finally, the opinion was not completely relevant for the national market and this country will wait for the next official updating of the opinion to send its contribution (NRA).

is underestimated, even though supported by a sound expertise. Some stakeholders question also the **way EFSA takes into consideration suggestions and comments raised during stakeholders' meetings and consultations** (FIR[463],Cons. and also one NGOs, one Media and one NRA).

Specific criticisms come from Food Industry Representatives whose majority complain about **EFSA's recent closure in dealing with industry** (FIR) (see also par. 3.1.2.2). While in some areas EFSA has always been closed to industry inputs in the development of guidance documents and in the exchange of scientific views (e.g., Health claims), in others this closure has been perceived to increase progressively (e.g., Flavourings). This has entailed increasing difficulties for industries that have to proceed on dossiers with the risk to invest money on an expensive testing phase not in line with EFSA's requirements, especially for new substances. Indeed, communication with EFSA's experts is always mediated by the Secretariat and, according to FIR, it takes too much time compared to industry's needs and timelines.

The recent (2011) implementation of the Application Helpdesk, mentioned before, is perceived as a useful step forward in the dialogue between the FIR and the Authority; nonetheless, transparent and scientific bilateral meetings are suggested by FIR[464] as an additional instrument to allow stakeholders to raise a specific issue to the attention of the Authority and to get experts' point of view.

The relevance and cost-effectiveness of openness and transparency

The principles of openness and transparency are extensively part of EFSA's work and culture (respectively 50% and 48% of respondents rated 4 out of 4 – *Q19.12*).

Among the tools that EFSA has implemented to foster openness and transparency in its functioning, **access to documents is more relevant to stakeholders' work and activity** (83,3% of respondents rate 3 or 4 out of 4, Q19.9) **than the participation to meetings** (68,8% of respondents rate 3 or 4 out of 4, Q19.9). Tools for openness and transparency are not just relevant for stakeholder's activity and work, but they are also useful to provide inputs to the Authority (72% of respondents average rate of 3 and 4 out of 4 – Q19.10-Q19.11).

Among **similar organizations**, those **operating in a more open and transparent way** according to the majority of respondents are **FDA and FSA** (with respectively 4 and 3 out of 4 preferences out of 18 respondents – *Q19.7*). Mentioned only by a few BfR (the German Food Safety Agency), ANSES (the French Food safety Agency), EMA and ECHA.

OPENNESS AT FSA

All decisions made by **FSA** board are public. All information is available from the website: description of the board, supporting evidences to reach each decision, publications with direct links to committees. It is possible to track and have access to complete information on the process through which FSA reached an opinion.

Since the advice provided by EFSA is a main basis for decision-making in the food and feed sector, NRA, NRM and consumers claim a deeper understanding of risk assessment procedures, of the validity and limitations of the outcomes and of all the associated implications. Thus, coherently with EFSA's engagements illustrated before in the Science Strategy 2012-2016, **the relevance of openness and transparency to EFSA's work should**

[463] E.g., comments made for data collection on additives were not taken into consideration for exposure assessment .
[464] Also by one Media and one Cons.

further increase to adequately face future challenges, as also confirmed by 66% of respondents (*Q19.13*).

3.8.2.3 Analysis of evidences

The analysis of EFSA's level of openness and transparency has been performed on two levels. The first level relates to the compliance of EFSA's activities with the Founding Regulation requirements and the second to their cost-effectiveness and relevance for EFSA's work today and in the future.

The principles of openness and transparency are transversal to all EFSA's activities, and thus they have also been treated in other parts at different levels and from different perspectives (e.g., Provision of scientific outputs, Data collection, Independence and Risk Communication). The objective of this part is to provide an overall evaluation of EFSA's level of openness and transparency, making also reference to related paragraphs for a deeper analysis of specific issues.

As regards compliance, EFSA has published all the documents that according to art. 38 of the Founding Regulation should be made public and it has progressively implemented various tools and procedures to seek stakeholders' inputs and enhance their respective contribution thus developing effective contacts with civil society stakeholders, as foreseen in art. 42 of the Founding Regulation. These evidences let us conclude that globally **EFSA has fulfilled its obligations to operate in an open and transparent manner**.

Focusing on **transparency**, EFSA went far beyond the strict compliance with the Founding Regulation requirements, and much has been done to make clear to external stakeholders the Authority's internal functioning. Indeed, EFSA has progressively widened the portfolio of public documents for the MB, Panels/Scientific Committee and the Advisory Forum. But the increase in the number of public documents is only one of the aspects that have characterized EFSA's evolution over the last years. Indeed, as better detailed in the Risk Communication paragraph, documents and information have been channelled through differentiated tools of communication, coherently with the different information needs of stakeholders (e.g., Newsletter, EFSA journal, Register of Questions). These two aspects together with the high level of satisfaction of stakeholders that now can easily find most of the information they need, demonstrates the effectiveness of EFSA's tools and procedures to assure transparency. While stakeholders confirm that the website is the main source of information (see par. 3.3 "Risk Communication") justifying all the investments that EFSA has done over the years to improve this tool, the need to improve the Register of Questions has emerged, integrating the need to enhance its navigation. As the evaluation team has directly experienced and further confirmed by some users involved in the evaluation, this tool is not user friendly and do not allow externals to adequately follow the scientific-decision making process.

Information collected from the desk analysis shows that EFSA is a transparent organization also thanks to additional actions that the Authority has undertaken over the years to further increase the understanding on its internal processes, like:

- the creation of a comprehensive body of risk assessment and best practices to guide the work of its scientific staff and bodies and to make the Authority's way of working clear;
- the definition of Standard Operating Procedures describing EFSA's workflow for scientific opinions;
- the use, differently from EMA and ECHA, of a webcasting system (2006) allowing the "participation" of the general public to the MB public sessions;
- the implementation of a transparent selection procedure for members of EFSA's Scientific Committee and Scientific Panels that could be followed by external stakeholders through public documents (as better described in par. 3.6

"Organization");

- the launch of a Pilot project (2012) allowing observers to attend three Panels and one Steering Committee meetings and to understand how decisions are taken;
- the adoption of two guidance documents (in 2006 and 2009), detailing transparency in risk assessment in relation to procedural and scientific aspects and aiming at harmonizing procedures and requirements among Panels. Despite the good level of detail of these guidance documents, there are evidences collected through the direct observation of Panels meetings that these documents are not correctly implemented. Indeed differences in the use of terminology still persist as directly stated by the Chairpersons of the Panels, and the content seems to be unknown when, during discussions, new propositions cover the same points included in those guidances.

Similarly to other EU agencies, like EMA and ECHA, the level of transparency is a constant challenge for EFSA and, even though much has been done to increase transparency over the years, criticisms are still present and mainly relate to the use of **confidentiality exemptions**. Indeed, EFSA deals with many commercial sensitive data (e.g., industry dossiers) that, coherently with the legislative framework, cannot be published (see the par. Provision of scientific outputs) and receives many data from MS whose use is limited by confidentiality agreements signed with data providers (see par. 3.2 "Data collection"). EFSA deals also with personal confidential data when, for example, screening interests of people that want to work for the Authority (see also par. 3.7 "Independence"). EFSA has always maintained a certain level of confidentiality on data and information it manages, and in a legislative context that allowed room for interpretation, EFSA had privileged a restrictive interpretation of specific rules (e.g., access to documents) to safeguard the freedom of the scientific debate. This approach seems to be the origin of related criticisms emerging transversally from different thematic areas taken in consideration, of the increased number of requests for access to documents taken to the Court (see footnote 432) and of the increasing number of access to documents that the Authority has subsequently granted. All these evidences show that the context is changing and EFSA should progressively adequate its way of working to the new expected levels of transparency. The case law will likely pushing up the accountability requirements for public Institutions that will be asked to act in an open way guaranteeing transparency on the use of public money, and stakeholders will become more and more demanding in relation to public decisions. The relevance of transparency to EFSA's work should then further increase in the future in a way to protect and guarantee the quality of work.

Provided that EFSA has a good level of transparency and adequately explains its internal functioning, **the capacity of the Authority to involve different stakeholders in its activities is adequate**. There are evidences from the desk analysis and from stakeholders that EFSA has progressively and effectively enhanced the stakeholders' contribution to its decision making process developing a variety of tools and procedures coherently with the type of stakeholder and with its potential contribution. Thus EFSA has developed:

- The Stakeholder Consultative Platform to permanently consult EU-wide stakeholders organizations working in areas related to the food chain and assisting the Authority in the development of its overall relations and policy with stakeholders. The increasing number of SCP meetings per year, the establishment of complementary technical bodies to provide stakeholders with additional opportunities to participate, the increased involvement of the Platform in reviewing and providing opinions on EFSA's strategic documents and policies show, in accordance with the majority of SCP members, that the SCP is effective and effectively used.
- On-line public consultation to quickly reach and consult a high number of non institutional stakeholders to get comments on draft scientific outputs.

- Different types of public events (e.g., Colloquia, Workshops, Technical meetings, Open Days, etc.) to promote the relations with the general public and those who feel they can contribute to the Authority's work without specific membership requested.
- Procedures to involve hearing experts to bring specialized scientific expertise in the Authority's scientific discussions when dealing with new or complex risk assessments.
- The Application Helpdesk to enhance the dialogue between EFSA and FIR, and more specifically to get from FIR useful inputs on market trends and to support them in case they have specific questions on EFSA's procedures. Considering also evidences emerging from the "Provision of scientific outputs" and the "Data collection" paragraphs, Food Industry Representatives are the only target, among those involved in the evaluation, clearly asking for a higher involvement in EFSA's decision-making process. EFSA has already recognized the importance to have a valuable relation with FIR and it has indeed progressively implemented actions to foster the dialogue while maintaining the independence of the decisions taken through an improved system of Declaration of Interests (see par. 3.7 "Independence").

The development and the customization of the above listed tools together with the global appreciation of stakeholders that do think that the Authority is now more willing to listen to their opinions and advices, let us evaluate EFSA as an open organization.

Although much has been done to make the principles of openness and transparency part of EFSA's work and activities, as previously illustrated, there are some evidences from the desk analysis and from stakeholders, that the results are not completely satisfying in so far the **Authority risk assessment process is still too closed** if compared with other EU agencies like EMA. Indeed, the Panel system functioning and decision-making is not open to public scrutiny and comments. Although the recent Pilot Project Observers represents an important shift towards a higher level of transparency, it seems not enough as observers are still not allowed to take part to the scientific discussions. A detailed analysis of the above mentioned project and its impacts, once it will be concluded, will allow to better plan future actions on transparency. As already detailed in par. 3.1 "Provision of scientific outputs" and 3.2 "Data collection", despite the presence of guidance documents and standard procedures explaining the theoretical steps of EFSA's decision-making processes, it is not clear how data are processed, how the scientific consensus is reached and how decisions are taken. The previous evidences, the lack of a standard procedure to take into consideration external inputs, complaints and suggestions (except for public consultations) together with negative stakeholders' feedbacks on the way EFSA takes into consideration comments, let us identify the level of openness and transparency in the risk assessment process as an area of improvement.

After a first period of increasing resources invested in the implementation of the principles of openness and transparency through the development of various initiatives, EFSA should now capitalize the expertise gained. Coherently with other similar organizations and in line with a context of decreasing resources, the Authority should continue to make these principles as a part of EFSA's work and culture (as stated in the Science Strategy 2012-2016) while choosing the most effective and efficient tools, documents or meetings, to explain its internal functioning and adequately involve stakeholders.

3.8.2.4 Evaluation results

EFSA has fulfilled its obligations to operate in an open and transparent manner and these principles are relevant to EFSA's work today and in the future.

Documents that according to article 38 of EFSA's Founding Regulation should be made public[465] **are indeed all available** on EFSA's website through differentiated tools in order to satisfy different clients' needs (e.g., newsletter, EFSA journal, Register of Questions – RoQ, etc.). Among these tools the RoQ is not user friendly enough and does not allow stakeholders to adequately follow the Authority's scientific-decision making process. In addition to the obligations explicitly indicated in the Founding Regulation, the Authority has widened over the years the portfolio of public documents regarding its decision-making bodies.

The current level of **transparency** is satisfying according to the majority of stakeholders and this is due to the following actions:

- comprehensive body of risk assessment best practices and methodologies;
- Standard Operating Procedures that describe EFSA's workflow for scientific opinions;
- the distinctive system of webcasting (2006) for the "participation" of the general public to the MB public session;
- two guidance documents (in 2006 and 2009), detailing transparency in risk assessment in relation to procedural and scientific aspects;
- the implementation of a transparent selection procedure for members of EFSA's Scientific Committee and Scientific Panels as described in the decision of the EFSA Executive Director;
- a Pilot project (2012) allowing observers to attend three Panels and one Steering Committee meeting.

EFSA's use of **confidentiality clauses** limits the transparency on certain issues (e.g., industry dossiers). The increasing requests for access to documents coming from stakeholders together with the recent evolution of the case-law will ask EFSA a higher level of transparency in its way of working and a progressive awareness that an increasing number of documents will potentially become accessible in the upcoming future.

As relates openness, coherently with the Founding Regulation[466], **EFSA has progressively increased the level of inclusion of external stakeholders** in its decision-making process **through a variety of instruments** that globally satisfy stakeholders. More specifically:

- The creation and use of the Stakeholder Consultative Platform, the main tool that EFSA has implemented to permanently consult its stakeholders. Its activity has been growing steadily and has become more and more relevant for EFSA's activities and for stakeholders, whose point of view is increasingly requested.
- The promotion of relations with the general public and those who feel they can contribute to the Authority's work through an increasing number of public consultations and other public events like: Colloquia, Workshop, Technical meetings, Open Days, etc.

[465] (a) agendas and minutes of the Scientific Committee and the Scientific Panels; (b) the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included; (c) without prejudice to Articles 39 and 41, the information on which its opinions are based; (d) the annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels, as well as the declarations of interest made in relation to items on the agendas of meetings; (e) the results of its scientific studies; (f) the annual report of its activities; (g) requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

[466] (Art. 42) The Authority is supposed to have, "effective contacts with consumer representatives, producer representatives, processors and any other interested parties" and in addition (Art.9) "There shall be open and transparent public consultation directly or through the representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it".

- The invitation of hearing experts in scientific decision-making processes in case a specialized scientific knowledge is required.

Even though much has already been done, the actual level of openness and transparency could be further improved as relates **the risk assessment process**. Most of Panels are still not accessible to external stakeholders and, even in those selected for the above mentioned Pilot project, observers cannot take part to the scientific decision-making process. As also emerges from the evidences related to the "Provision of scientific outputs" and "Data collection" paragraphs, it is not clear how data are processed, how the scientific consensus is reached and how decisions are made. The recent Pilot Project will need an accurate analysis to evaluate whether it satisfies the stakeholders' need for transparency. EFSA's efforts to increase the openness and transparency of its decision-making processes are unanimously appreciated, but more transparency should be achieved on the way the Authority takes into consideration suggestions, comments and inputs raised by stakeholders, during or outside meetings, considering that a standard procedure is not yet formalized.

Food Industry Representatives are the only target, among those involved in the evaluation, clearly asking for a higher involvement in EFSA's decision-making process. The creation in 2011 of the Application Helpdesk is the main initiative that EFSA has undertaken at this regard, and an evaluation of its impact, once it will be completely implemented, will allow to better understand and, in case, improve the relations with Food Industry Representatives.

The principles of openness and transparency are extensively part of EFSA's work and culture as demonstrated by the increasing number of activities developed and confirmed by strategic documents (e.g., Science Strategy 2012-2016). Nonetheless, the relevance of these principles should further increase to adequately face future challenges linked to the changing legal context pushing EFSA towards a higher degree of transparency.

In ten years EFSA has implemented a high number of tools of inclusions and others are still ongoing. The Authority should now capitalize the expertise gained and chose the most effective and efficient tools, documents or meetings to communicate its internal functioning.

4. Conclusions and recommendations[467]

According to the analysis conducted, EFSA has globally accomplished its mission and its performance is good and appreciated across the different areas of responsibility. A summary of the conclusions presented at the end of previous paragraphs (evaluation results and conclusions) and some subsequent recommendations are reported below for each thematic area of evaluation. Some transversal recommendations are reported in the last paragraph. References to the appropriate evaluation criteria are reported in brackets along the text.

Recommendations are presented with addresses and the associated level of priority (L= Low, M= Medium, H= High), that has been defined according to three criteria: *i)* the impact of the recommendation on the general performance of EFSA; *ii)* the relevance of the recommendation for EFSA's mission; *iii)* the intensity of the problem according to stakeholders.

4.1 Conclusions and recommendations for thematic areas of evaluation

Provision of scientific outputs and technical support

Effectiveness and scientific quality

The provision of outputs originated from external requests is effective and of good quality.

The **process meets EFSA clients' needs**: despite the evolution in workload and work areas, crisis situations and the difficulty to foresee changes in the legislative framework, EFSA has maintained its capacity to fulfil its overall remit, providing its main stakeholders the support they needed. As discussed in par. 3.1.2.3, the global stakeholders' satisfaction should be added to the implementation by EFSA of specific procedures to identify clients' needs and deliver outputs according to the specific target and content of the communication.

The effectiveness in the provision of outputs is especially appreciated in **emergency situations**, when EFSA is able to provide clear and timely risk assessment, used by risk managers as a basis for their political decisions.

Nonetheless, EFSA does not anticipate crisis/emergencies and normally reacts to EC requests for urgent advice, as demonstrated by the past crisis/emergency situations. Despite EFSA has created in 2008 a dedicated Unit (EMRISK), activities aiming at identifying emerging risks before they become a crisis/emergency need to be further improved, and a more proactive behaviour is also expected by some stakeholders. (see par. 3.1.2.2 and 3.1.2.3)

EFSA's clients appreciate the high **quality, accessibility and reliability of outputs**. Quality has progressively improved, with the result that negative comments reported in external experts' reviews have reduced more and more (reaching 1,4% in 2011), and EFSA's outputs are definitely considered as reliable, even more than those of other organizations according to some stakeholders. (see par. 3.1.2.2 and 3.1.2.3)

[467] The recommendations were not assessed in terms of impact on the actual resources or the potential necessity of additional resources for EFSA.

EFSA is at the forefront of scientific knowledge and risk assessment methods as shown by the increasing trend of EFSA's outputs citations in key relevant scientific journals. Food science and technology represent the main area of recognition followed by Toxicology and Veterinary science.

The stakeholders' global positive assessment of EFSA's scientific outputs is quite homogeneous. Nonetheless, Food Industry Representatives question the limited exchange of scientific information with EFSA as they assume it is at the origin of some misunderstandings with specific issues applicants have to deal with. Coherently with the Founding Regulation[468], EFSA should continue to dialogue with applicants, ensuring that all parties share a common understanding. Nonetheless, risk managers remain the Authority's main clients and, despite the increasing weight of the applications on the total amount of requests received annually, all further efforts (if considered necessary) towards a greater inclusion of FIR in the decision-making process, should be adequately balanced with EFSA's duty to act independently (see also par. 3.1.2.2, 3.6.3.2, 3.8.2.2).

In this global positive context, there are though some **areas of improvement** that EFSA might take into account to better align its outputs to clients' needs and increase their quality:

- *usability*: opinions are considered by some risk managers to be too long and not immediately usable from a legislative perspective or from a MS's point of view in so far they do not take into account national contexts. As far as guidance documents are concerned, while considered of high scientific quality, they are too theoretical and difficult to be implemented (par. 3.1.2.3);
- *update/integration*: according to some stakeholders, opinions are not quickly updated once new evidences becomes available or following critics, and a need to increase the effectiveness of the existing process has emerged (par. 3.1.2.2);
- *timeliness*: although there is a substantial compliance with formal deadlines and a general satisfaction on timeliness, the process is considered long if looking at applications and the need to take into account Industry needs of commercialization. Urgent advices instead globally satisfy stakeholders as EFSA has always provided a response within 30 calendar days (par. 3.1.2.3);
- *transparency*: the scientific soundness of opinions does not appear to be clear enough, as far as it concerns the use of data, the integration of different schools of thought (including industry dossiers), methodologies, rationales, uncertainties and last but not least independence of experts (par. 3.1.2.3);
- *harmonization*: outputs are heterogeneous as regard formats, terminology, level of detail, methodology, etc. and do not adhere to predefined templates. In addition, SOPs, as confirmed by internal staff, are too complicated to be followed (par. 3.1.2.3).

The **provision of outputs originated from internal mandates and self-tasking function,** to investigate on emerging issues and/or future challenges, is less effective: although looking at the type of works undertaken, it is possible to say that EFSA is definitely active in its internal mandates and self-tasking function, the food system is not aware of the added value coming from this function and does not recognise a dominant role of EFSA in tackling emerging issues or future challenges. It emerges quite clearly that there is need to better focus the aim of Internal mandates and self tasking mandates to enhance their future utility and to better report on them.

[468] Art. 42 " The Authority shall develop effective contacts with consumer representatives, producer representatives, processors and any other interested parties".

Added value

EFSA's provision of outputs provides added value, in terms both of use of an integrated approach covering the entire food chain and of development of tools and procedures to support risk managers.

The **integrated approach** of EFSA's opinions is globally recognized by stakeholders and is further sustained through the availability of a wide range of expertise in EFSA's Panels and through improved rules allowing greater flexibility in the multidisciplinary composition of Working Groups.

The support coming from downstream stakeholders (retailers, consumers, etc.) through, for example, the Stakeholder Consultative Platform, further contributes to strengthen the integrated approach.

An issue remains on whether the system put in place is sustainable.

EFSA provides a **continuous support to risk managers** and a recently approved business continuity strategy guarantees the continuity of business in the event of unforeseeable business disruption. The exchange of information with Member States has continuously improved (e.g., with consultations on annual and multiannual working plans with the Advisory Forum Members and inviting risk mangers to share their future priorities). Nonetheless, more cooperation with national risk assessors and other national scientific institutions to dispose of a wider portfolio of expertise should be taken into account.

Various tools and activities are developed by EFSA to support risk managers **in times of crisis situations** (e.g., crisis room, specific task force, meetings and teleconferences, etc.) and globally EFSA's support is appreciated by risk managers.

#	RECOMMENDATIONS SPECIFIC TO PROVISION OF SCIENTIFIC OUTPUTS AND TECHNICAL SUPPORT	ADDRESSEES	PRIORITY	Impact on performance	Relevance for EFSA mission	Relevance for stakeholder
1	Address the concern of timeliness *i)* *(as relates Openness and Transparency)* improving the user friendliness of the RoQ in order to allow requestors and other interested stakeholders to follow the process and *ii)* improving the dialogue with partners to limit bottlenecks.	EFSA, EC, NRM, NRA	Medium	L	H	H
2	Improve the usability of guidance documents, enriching them with practical examples of implementation and identify specific point of contact.	EFSA	Medium	L	M	H
3	Promote the harmonization of outputs, *i)* controlling the compliance of Panels and Committee to the guidance documents detailing scientific and procedural aspects of the risk assessment workflow and *ii)* simplifying SOPs related to the scientific decision-making process and encourage their use.	EFSA	Medium	H	M	M
4	Increase the external awareness of internal mandates and self-tasking activities on emerging issues, better communicating outputs and activities.	EFSA	High	H	H	H

Data Collection

Effectiveness

EFSA's data collection activity is compliant with the requirements set in the Founding Regulation and is effective and adequate to support the Authority in responding to requests for advice even in crisis situations.

EFSA's system of cooperation for data collection is positively evaluated by most stakeholders, recognizing the efforts made by EFSA in this field and thinking that data collected are adequate for country specific studies and to support decision-making processes. A widespread awareness of the strategic importance of this activity clearly emerges from the several activities implemented by the Authority over the years (e.g., increased number of reports with methodology recommendations, use of new mechanisms of cooperation – grants and procurements, calls for data – harmonization activities).

Nonetheless, the complex implementation and the limited availability of resources at national and EFSA level make the cooperation with MS and the harmonization in data collection methodologies one of the biggest challenges.

In this regard, the main areas of improvement are linked to:

- *IT interface:* despite the efforts made by EFSA in this field (e.g., publication of guidance on Data Exchange and Standard Sample Description, use of ontology system to harmonize different data collection domains), EFSA IT Data Collection Framework is not easily compatible with national IT systems for data collection and national format requirements are different from EFSA's ones; according to some stakeholders it is difficult and requires a high amount of resources for data providers to follow the expected requirements.
- *Transparency of the process*: no feedback is given to data providers once data are submitted to EFSA and the final outputs do not always contain enough information on how data have been used. In addition, a lack of clarity on the ownership and on the final level of accessibility of data limits MS willingness to share data. Stakeholders' perception is confirmed also by the Authority, who has considered this aspect as one of most critical ones on which work on in the future.

Beyond the European borders, EFSA's data collection activity is limited by the lack of an international harmonized approach, confirming the need, already pointed out in EFSA's Science Strategy, to strengthen data sharing and data access agreements with other key national, European agencies (e.g., EMA, ECDC) and IOs (e.g., WHO, FAO, OECD).

Data collection is properly carried out by EFSA. Data are globally perceived by the majority of stakeholders as accessible and available in the four thematic areas identified by the Founding Regulation, and mainly in Food Consumption, where indeed a significant number of actions have been undertaken by the Authority over the years (see below). Due to the increasing number of emerging issues that can potentially have an impact on the food/feed safety chain (see par. 2.2) EFSA has de facto widened data collection activities including additional thematic areas. This situation should however be adequately regulated to be sustainable.

The general effectiveness of accessibility and availability of data is mainly due to:

- The increasing trend of resources allocated by EFSA (in 2011 more than 4,5 times compared to 2006);
- The implementation of a portfolio of initiatives to rationalize EFSA's expertise (e.g., creation of specific databases, development of an integrated IT system, establishment of three specific units – DCM, BIOMO, SAS – to collect useful data and inputs for all

scientific opinions, creation of an IT Working Group on Data Warehousing and Web Reporting, etc.);

Nonetheless, the survey reveals the presence of some uncertainties among stakeholders, pointing out that the level of accessibility to databases could be further improved. Too many filters, indeed, limit the consultation of all data, this together with the weak query function and the limited user friendliness of databases distort the stakeholders' perception on data availability.

EFSA issues a variety of report on data collection activities (e.g., Annual Report on veterinary medicinal residues in food from animals, Annual Report on Pesticide Residues, others specific technical reports, etc.). **The quality of these reports** on data collection **is very high**. Reports contain a good level of aggregation of all data collected, allow Member States to have a useful overview on the trends in EU related to the main thematic areas foreseen by the Founding Regulation and provide clear recommendations for appropriate data collection methodologies.

In crisis situations, despite the limited amount of time and data at disposal, EFSA's data collection activities support the capacity of the Authority to respond to urgent requests for advice, as EFSA has shown to be able to collect data in a short time and to use them effectively in providing specific outputs (e.g., supporting activities for data sharing with MS during E-coli crisis).

Scientific quality

EFSA usually provides data of good quality.

EFSA provides a complete overview of the leading topics/issues that the data are collected for, mainly in relation to the thematic areas foreseen by the Founding Regulation but also to emerging specific topics identified over the years. Stakeholders have confidence in the quality and reliability of EFSA's data.

Nonetheless the quality of EFSA's data still strongly depends on the initial data quality, that seems to be limited for many data providers and namely for smaller countries. A higher commitment of some national data providers to improve the quality of data seems to be necessary.

#	RECOMMENDATIONS SPECIFIC TO DATA COLLECTION	ADDRESSEES	PRIORITY	Impact on performance	Relevance for EFSA mission	Relevance for stakeholder
5	Improve the compatibility of the Data Collection Framework with national IT systems for data collection, revising the Data Collection Framework in order to make the formats for data submission more flexible and usable for all MS.	EFSA	Medium	H	M	M
6	Improve the accessibility to data and information *i)* making the databases more user-friendly and intelligible and improving the query function; *ii)* identifying strategies to harmonize EFSA's data collection requirements with non European ones.	EFSA	Medium	M	M	M
7	Strengthen the role given to EFSA in assisting risk managers on continuous pro-active risk monitoring in areas not specifically identified by the Founding	EP, Council, EC	Medium	L	M	H

	Regulation (e.g., GMOs).					

Risk Communication

Effectiveness

EFSA's communication is effective and of high quality.

EFSA's stakeholders mainly appreciate the **content** of the Authority's communication. **Quality**, **relevance** and **timing** of the messages are also satisfying and communication outputs are useful to improve knowledge and awareness of existing food-chain risks.

Notwithstanding, the following areas of improvements are identified to improve EFSA's communication effectiveness:

- *clarity*: despite the Authority's efforts to make its communication more understandable (e.g., executive summaries of opinions, newsletters, press releases, etc), messages are still conceived as adequate for a well educated public. Language barriers related to the use of English further undermine this objective, indeed EFSA's opinions are still mainly written in English.
- *outreach*: navigation on the website is still too complicated – even if visible improvements have occurred over the years (e.g., redesign of the website, implementation of new software, new content sections, new search functions, etc.) – and the search engine is not effective, as also stated by some stakeholders.
- *target*: despite the efforts accomplished by EFSA to communicate to the general public (e.g., videos, summaries, etc.), and despite its engagement in the Communication Strategy to expand its public outreach, EFSA's communication to the general public remains questioned by some stakeholders in terms of both effectiveness and efficiency. A clear position of the Authority is therefore necessary to optimize the effectiveness of its future communication activities, taking into account a better dialogue and cooperation with NRA and NRM.

Value Added

EFSA has succeeded in building awareness, trust and reputation for itself and the overall food safety system and has contributed to the harmonization of different scientific positions.

The Authority is relatively well known and understood and perceived as **a reliable system** in the European system of risk assessment. This positive evaluation is also the result of several efforts made by the Authority over the years like:

- EFSA's high commitment to dialogue with partners and stakeholder to reinforce trust and confidence, as confirmed in the Science Strategy 2010-2016;
- EFSA's efforts to improve public trust, for example in terms of reduction of the time needed to produce opinions, increased level of openness and transparency, improvement of the communication process, adoption of a longer and wider perspective including extra EU MS.

Nonetheless, to further improve public trust, the Authority should address the following challenges:

- *the highly differentiated recognition of MS*: according to the specific institutional system and the risk assessment expertise, each MS differently perceives EFSA's role and reliability and holds different expectations. This trend is highlighted by some stakeholders and has also emerged from the direct observation of interactions

between the MS representatives during the 43rd AF meeting[469]. Countries with a limited risk assessment capacity usually rely more on the work of the Authority than more experienced ones.

- *The communication to the general public*: EFSA has usually an indirect impact on public awareness, being mainly mediated by other institutions.

EFSA is recognized by most stakeholders as a contributor to the coordination, harmonization and decrease of the divergent scientific opinions, as further confirmed by the limited number of cases of implementation of the "reconciliation" procedure ex art.30 of the Founding Regulation. Nevertheless, divergent opinions still exist, at both EU and international level.

To further contribute to the coherence of risk communication, the following areas of improvement have been identified:

- *AFCWG*: this WG does not satisfy the different expectations of MS representatives as it answers in the same way to different needs and expectations. Its support could be further improved especially in crisis situations.
- *communication in crisis situations:* communication activities lack of harmonization in the European system, as emerged for example during the E-coli crisis, where no clear responsibilities were defined as for the communication and different MS started to communicate separately, as interviews have revealed. Further cooperation among MS is needed to effectively face the communication during crisis situations.
- *cooperation with NRM-NRA*: it seems impossible to prevent NRM to rely on their national agencies, but the increasing credibility of EFSA should ensure that MS, in the future, before beginning a risk assessment activity, will address the Authority to verify the existence of similar studies, thus avoiding the risk of duplication and overlapping opinions.
- *international cooperation*: procedures to deal with divergent scientific opinions with IOs are perceived as difficult by some stakeholders due to EFSA's limited provision of data and details of risk assessments, notwithstanding EFSA has implemented an international strategy for cooperation in risk communication.

#	RECOMMENDATIONS SPECIFIC TO RISK COMMUNICATION	ADDRESSEES	PRIORITY	Impact on performance	Relevance for EFSA mission	Relevance for stakeholder
8	Bring more clarity in EFSA's communication, *i)* adapting the communication language taking into account the targets and *ii)* further increasing the use of other languages (other than English) for publications and communication on the website.	EFSA	Medium	M	H	L
9	Make the website more effective, reducing the complexity of the navigation on the website and strengthening the search engine.	EFSA	Medium	M	M	H
10	Strengthen the role given to EFSA in supporting the EC and risk managers in MS in ensuring coordinated and coherent communications when urgent scientific advice is required to address risks	EFSA, EC, NRM	High	H	H	M

[469] 43th Advisory Forum, 7-8 March 2012, Parma.

	associated with the food chain *i)* defining clear responsibilities in risk communication as soon as a crisis arises and *ii)* making more effective the support of AFCWG in crisis situations.					

Cooperation and networking

Effectiveness

Globally EFSA's scientific cooperation system is effective.

The quality of the **cooperation of EFSA with the EC** is good, and even if the EC involvement in EFSA's activities may be perceived negatively by some external stakeholders, the presence of EC's representatives to EFSA meetings, as per the Founding Regulation, is essential to help EFSA better fulfil its mandate and to help the EC better anticipate on future legislative work. They participate to bilateral meetings and are involved in EFSA's activities (presence in the MB, participation in AF meetings and frequent participation in panels and scientific committees' meetings).

Cooperation with MS relies on a wide portfolio of instruments but still represents an ongoing concern and a clear sharing of responsibilities with EFSA is not yet achieved, partly due to weak work programme sharing and communication. The stable level of requests sent by MS reflects their difficulty to entrust EFSA instead of their national agencies (if any). The sharing of responsibilities between national agencies and EFSA is often listed as a main challenge for EFSA by interviewed stakeholders.

The cooperation with MS is based on the use of networks contributing to EFSA's activities:

- The Advisory Forum is a facilitator to share work programmes outputs, risk assessment practices and methodologies for the NRA. The previous evaluation pointed out the limit of the AF meetings and underlined the need to develop additional tools to foster cooperation between EFSA and MS.
- The appointment of a network of Focal points in all MS in 2006 effectively contributed to developing communication between EFSA and National Food Safety Authorities and to the sharing of information. Focal points have been actively involved in the promotion of EFSA activities that require active MS participation (grants, procurements and experts' contribution). The activity of focal points almost doubled since 2008 (sent requests and participation to events – see Chart 9: Evolution of Focal Points activities) reflecting the utility of these networks. They appropriately complement the existing tools according to stakeholders.
- The outsourcing of activities to Article 36 organisations or individual experts in MS has significantly increased in the recent years (e.g., EFSA's expenditures dedicated to grants and procurements have almost tripled between 2007 and 2010, see Chart 10). They are actively involved in data collection activities and preparatory activities (preparatory work and scientific tasks – see Chart 3).

There are though some areas of improvement to ensure better effectiveness and efficiency in the coordination of work:

- *The situations of misalignment*: situations of misalignments are still pointed out by stakeholders, including duplication of work on specific national sensitive issues (the strong links between NRA and NRM still limit the number of requests directly sent to EFSA by NRM) (see par. 3.4.2.1).
- *The procedures to involve external expertise*: they must be adjusted in order to improve the effectiveness of external experts' contribution, notably through the

increase of application rates to procurements, the diversification of participants and the renewing of the pool of expertise. 14% of the procurements remain unsuccessful between 2007 and 2009 and less than 25% of the registered organisations in the list of competent bodies (Art. 36) have been involved at least once in the process (see par. 3.4.2.1).

Efficiency

The use of AF advice and assistance can be improved to be more efficient.

Stakeholders underlined the need to further improve the use of AF advice. Four main areas have been identified to improve EFSA use of AF:

- the definition of common priorities and sharing of work programme among AF members to improve coordination of work and avoid situations of misalignments;
- a stronger use of the possibility to set up AF working groups to focus on a specific issue;
- a harmonization of AF members expertise to facilitate the resolution of contentious issues associated to targeted trainings;
- efforts to promote the best quality and availability of scientific data.

Sustainability

The actual system for cooperation and networking is adequate also considering the high quality of the support (in terms of expertise) provided by MS agencies to EFSA's work.

The quality of scientific outputs relies on the contribution of experts sent by the MS. MS with stronger risk assessment capacity are perceived to participate more significantly to the decision-making process. This is confirmed by the over representativeness of a few Member States in the expert database (see Table 25): Italy, United Kingdom, Germany, France, Netherlands and Spain are the countries presenting the highest number of experts, corresponding to 56% of all included experts. A more balanced contribution between MS is required to adequately involve national expertise.

Considering the reliance of EFSA on external expertise, the professional attractiveness of EFSA is a key aspect to ensure sustainable quality of work. The careful monitoring of EFSA's professional attractiveness will contribute to maintaining a high level of expertise within EFSA.

Value added

National food safety authorities benefit from EFSA's activities in terms of streamline of expenditures.

MS declare that their expenditures related to finding best methodologies, communication support or trainings have been reduced in national food safety authorities (see par. 3.4.3.1).

However, the benefits vary from one MS to another. The impact of EFSA on National Agencies' expenditures highly depends on MS risk assessment capacities:

- for MS with limited own risk assessment capacities, EFSA provides an activity that they would not provide by themselves;
- for MS with strong internal risk assessment capacities, EFSA's activities are perceived to bring additional costs through the involvement of internal staff on EFSA's activities as well as entailing translation of EFSA's opinions to a national level.

#	RECOMMENDATIONS SPECIFIC OR RELATED TO COOPERATION AND NETWORKING	ADDRESSEES	PRIORITY	Impact on performance	Relevance for EFSA mission	Relevance for stakeholder
11	Further strengthen the cooperation with Member States: *i)* improving the integrated system of exchange of information (IEP) giving the opportunity to signal to EFSA new risk assessments, divergent opinions, etc.; *ii)* increasing the diffusion and communication of EFSA's risk assessment in MS; *iii)* sharing agenda and work plans (including priorities) to make the most of existing and on-going works and develop joint activities; *iv)* stimulating exchanges and the participation of each MS at AF meetings and a better matching between meetings' agenda items and participants.	EFSA, NRM, NRA	High	H	H	H
12	*(As relates Data collection)* Promote a higher quality of data evaluating to allocate funds to the implementation of a project aimed at establishing/improving data quality provision by MS and promoting assurance systems according to a harmonized approach for data collection. Difficulties faced by MS in providing data (both in terms of available resources and IT interface) should be taken into account.	EFSA, NRM, NRA	Medium	H	L	M

International role and recognition

Scientific quality and sustainability

EFSA plays a role in the international scientific community to promote risk assessment.

This role relies on three types of activities targeting the scientific community:

- Organization and participation to international scientific events. EFSA's events receive a good feedback from stakeholders and the participation of EFSA Scientific Committee members to international scientific congress has slightly increased in the recent years. A stronger commitment in international scientific events would increase EFSA international recognition as well as keep it abreast of scientific research outputs on the area of its remits. Colloquia organized by EFSA with international scientific experts contribute to bringing the best expertise to support EFSA's activities. The increasing participation of EFSA's Scientific Committee members to congresses attests its commitment to maintain the quality of the scientific expertise among EFSA's staff (although its participation remains at a low level).
- Production of scientific outputs and use of these outputs by the international scientific community. With a growing number of scientific outputs, the number of quotations of EFSA papers has considerably risen in the scientific literature (from 13 in 2006 to 487 in 2011). This statement strongly supports the contribution of EFSA to the international scientific community.

- Scientific cooperation with third countries agencies and international organizations. EFSA is developing partnerships with national agencies in third countries in order to facilitate the sharing of data and the harmonisation of methodologies.

Since the drafting of "EFSA strategic approach to international activities" in 2006, the sustainable positioning of EFSA in the international community is steadily increasing but additional efforts (participation to events, formal cooperation with third country agencies and international organisations) are required to enhance the international role of EFSA.

Added value

There is a large consensus by European Member States on the fact that EFSA is reliable.

EFSA gathers the best experts across Europe and its opinions are respected by all Member States. 91% of respondents indicate that EFSA is at the forefront of risk assessment methodologies in Europe. In terms of European positioning, considering that its expertise relies on MS contribution, the leadership of EFSA competes with largest agencies that provide experts to EFSA.

Its added value can be found in the capacity to provide pan-European opinions, to attract the best experts to address new challenges, to increase the visibility of European position vis-à-vis third countries.

Further improvements are still needed regarding EFSA's recognition outside Europe.

The strategic approach to international activities of EFSA set up in 2009 is the first step to improve the international recognition of EFSA outside Europe, but is still not visible.

Two partnerships with third countries national agencies (USA in 2007 and Japan in 2009) to share scientific data and perform risk assessment contribute to increasing the recognition of EFSA outside Europe. Several other countries are interested in scientific opinions produced by EFSA and have approached EFSA to foster cooperation, considering the number of invitations they received from third countries in 2011 (Korea, China, Australia, Colombia, etc.).

Divergent opinions among NRA, EFSA and IOs (ex: conflict on GMO potato with WHO) and obstacles in data sharing still limit the Authority's fruitful involvement in the international scientific community. EFSA is considered as one (not the only one) source of information taken into account by IOs when dealing with specific issues. In addition, the strict European food safety standards on which EFSA's scientific outputs are based, are often criticized by IOs because they are not always relevant neither consistent with those used in other areas of the globe. This makes EFSA's opinions sometimes inapplicable at a larger scale. More efforts should be put into the identification at an early stage of any potential source of divergence and a more coordinated approach, in order to fully achieve its mission defined in article 30 of the Founding Regulation. Moreover, EFSA's international role could be further strengthened through the broadening of the Authority's mandate in international cooperation on risk assessment that is actually limitative, thus reducing the influence that the EU can achieve in the definition of international standards.

EFSA's contribution to the EU legislation and policies is still perceived as too weak.

Despite the fact that Members of the European Parliament underline the strong support provided by the Authority in informing the legislative process, several external stakeholders have the feeling that EFSA's scientific point of view is not enough considered in comparison with other factors taken into consideration in the decision-making process (economic, social, political) (see par. 3.5.3. on EFSA added value from a European and international perspective).

From an international perspective, EFSA's scientific opinions form part of the references that are used by policy-makers to set standards (Codex Alimentarius, FAO, WHO, OIE and national agencies). Recent examples show that EFSA took the leadership over JECFA on specific issues like flavourings.

Scientific quality

EFSA is globally considered as an attractive place to work for external leading experts.

Among the main strengths of working for EFSA the high quality of the scientific work undertaken, the international and multi-cultural environment and the public recognition of the good reputation of the EFSA are considered very valuable for external experts working for EFSA (see par. 3.5.4 on the EFSA scientific quality: professional attractiveness for best experts).

Among the main limits that are often listed:

- the location in Parma : if compared with Brussels the location of EFSA in the Italian city is more expensive, entailing higher travel expenses and time. This aspect, alongside with the pressure in external experts' full-time jobs, was pointed out as reducing their willingness to work for the Authority in the 2005 evaluation;
- the heavy burden of internal bureaucracy: independent scientific experts can be reluctant to the process that leads to the production of scientific opinions;
- the frequent external attacks to the independence of experts working for the Authority;
- the limited financial compensation considered not sufficient if compared with the increasing workload of experts;
- the lack of EFSA's internal scientific research capacities that limits EFSA's possibility to develop its own researches/testing.

These limits must be seriously considered and monitored in order to avoid a possible lack of scientific expertise. As an example, the high level of turnover in panels should be carefully watched to differentiate voluntary leaves from internal turnover.

#	RECOMMENDATIONS SPECIFIC TO INTERNATIONAL ROLE AND RECOGNITION	ADDRESSEES	PRIORITY	Impact on performance	Relevance for EFSA mission	Relevance for stakeholder
13	Strengthen agreements/scientific partnerships with other agencies and IOs for the exchange of information and the use of data fostering the convergence of international risk assessment standards with EU approach in a globalizing economy.	EFSA, Council	Medium	H	M	M
14	More actively participate in international discussions on risk assessment methodologies.	EFSA	Medium	M	H	H
15	Monitor the professional attractiveness of EFSA for external experts to maintain a high quality of scientific outputs, limiting the travelling time for experts by promoting the use of IT tools (interactive video-conference, webinars, etc.).	EFSA	Medium	H	L	M

The organizational structure, its operational efficiency and its adaptability to change

Efficiency

EFSA's MB and the organizational structure allows the Authority to fulfil its mandate but the distribution of work among staff and experts seems to be unbalanced to adequately face future challenges. Resources are allocated consistently with the Authority's objectives and activities evolution, but processes could better contribute to the effectiveness and efficiency of EFSA's operations.

The **Management Board** plays its strategic role effectively and does not influence EFSA's scientific advices. Its composition guarantees a good mix of competences, independence from national interests and contributes to the effectiveness of the decision-making process, thanks to the distinctive characteristic that MB members are not MS representatives and thus do not represent any national interest during the discussions. The MB is also efficient. Indeed, EFSA has recently undertaken some actions (e.g., no more itinerant meetings, no more live video/audio webcast) to reduce the costs of its meetings that for 2012 are expected to fall below the average of other EU Agencies.

EFSA's **structure and the distribution of work** are globally appropriate to the type of work entrusted to the Authority, its experts are able to perform the different steps of the decision making process and they allow to cover all the fields of the Authority's activity. Despite all needed expertise is available and the quality of outputs is recognized, the actual Panel/Committee system seems not completely adequate to face future challenges. Experts, even though they are many, are overloaded and efforts are required to EFSA to manage and coordinate their participation to the Authority's work. This suggest that their involvement should be rebalanced in a way the Authority could better benefit from their competences, focusing the experts' involvement on value added tasks which require high scientific expertise and leaving to EFSA's staff supporting and standardized activities. Nonetheless, EFSA's staff is not always enough experienced under a scientific and managerial point of view and thus EFSA should continue to perform the planned trainings to fill its competences gaps in order to further strengthen EFSA's internal capacity (in particular in regulated products). A rebalancing of the roles given by the legislation to Panels/external experts could support the Authority in the efficient allocation of resources to deal with its workload.

EFSA's **resources are consistent with its objectives** as confirmed by the decreasing gap between assigned and executed appropriations. Coherently with the **activity evolution**, the greatest part of EFSA's resources is assigned to the provision of scientific outputs where the percentage dedicated to the applications has progressively increased over the years. Also resources allocated to cooperation increased while resources for risk communication have decreased after a first period of investment during which the Authority needed to be known internationally.

Despite EFSA's internal processes have significantly improved their effectiveness and efficiency over the years, further improvements are still needed and EFSA is already undertaking significant changes through a variety of strategic initiatives. As regards the experts' mobilization process, it is efficient in terms of expertise collected, evaluation of the candidates and independence. The management system and processes are the object of an optimization through the Business Process Modelling within the e^3 programme. The differentiated framework of IT systems is the object of another ambitious program of integration that will start with an IT integrated strategy in 2012. The Planning and Monitoring capacity will be improved as well within e^3 programme. The monitoring system is the one that requires some further improvements to be better structured and integrated. At the moment,

it is difficult to compare EFSA's performance indicators and to monitor the trend of resources allocated over time on its main activities, also because changes are not always explained enough. In addition, the RAW limits the monitoring of the relation between inputs (mandates), the questions produced and scientific outputs provided.

The flow of information between EFSA and the EC has improved over the years: thanks to the Roadmap, the Authority is able to better map out its future work. Nonetheless, further commitment is required from both sides in order to make the exchanges more frequent and useful.

Sustainability

EFSA's organizational structure is adequate to the work entrusted to it and flexible enough to adapt to the progressive changes in its tasks. Nonetheless, the strict limits imposed by vertical regulations and the difficulty to foresee future workloads might undermine the Authority's capacity to plan and prioritize activities.

EFSA's structure is adequate to the current work and workload. As also shared by stakeholders, the new organization is flexible, effective and well structured.

The adequacy of the structure is mainly due to EFSA's efforts to progressively adapt the organization to changes and emerging challenges. More specifically:

- The implementation of two important reorganizations that have entailed, among others, *i)* the creation of a Science Strategy and Coordination Directorate to define and spread a common scientific strategy across the scientific units, and *ii)* the creation of two different Directorates, to deal respectively with applications and generic opinions, that enables EFSA to better face the specific dynamics of these two business areas;
- The implementation of a specific programme (e^3 programme) aimed at enhancing the efficiency and the effectiveness of the structure through the implementation of strategic horizontal actions.

Nonetheless, the structure can still be improved specifically in the application area that, despite major changes occurred to face the increasing workload, still contributes to 79% of the backlog of the scientific outputs accumulated over years. Waiting to see whether the most recent business solutions (e.g., Application Helpdesk) have an impact, EFSA could evaluate to improve the communication between FIR and EFSA's experts while guaranteeing the opinions independence in order to speed up the evaluation process. Pre-submission meetings are suggested as a particularly useful tool of dialogue and exchange for FIR for which they would be available to pay a fee.

In addition to the changing workload and work areas, also the **European legislative acts** relevant for EFSA have influenced the Authority's flexibility, limiting sometimes rooms for action, imposing different processes and reducing standardization, mainly in relation to the evaluation of regulated products. Indeed, the large number of vertical and sector specific regulations define different requirements and workflows that EFSA has to respect. These processes are not just highly diversified but also complex and entail burden for economic operators. A simplification of these regulatory workflows could thus contribute to improve the efficiency of the EFSA structure, working process and at the same time the relation with FIR that could easily understand processes without asking EFSA for further information and favour safe innovation. This would free some resources and also support the flexibility needed for the evolution of EFSA scientific outputs elaboration and validation process, rebalancing the role given by the legislation to Panels/external experts towards an increased role of EFSA's internal scientific capacity.

In order to improve EFSA's capacity to meet the requirements of its mandate in the long term, it seems important that the Authority develops its **planning capacity**. The backlog and the

differences between foreseen and adopted outputs, reveal it is difficult for the Authority to plan the future work. This depends also on the limited sharing of work plans between the Authority and risk managers. Indeed, a roadmap with the EC has been introduced only in 2011 and a similar document with MS does not exist. Thus, as stated in the Science Strategy 2012-2016, despite the progress already done, it is essential that the dialogue between EFSA and EU Institutions and NRM on future workloads continues to be improved.

#	RECOMMENDATIONS SPECIFIC TO THE ORGANIZATIONAL STRUCTURE ITS OPERATIONAL EFFICIENCY AND ITS ADAPTABILITY TO CHANGE	ADDRESSEES	PRIORITY	Impact on performance	Relevance for EFSA mission	Relevance for stakeholder
16	Improve the monitoring system, *i)* improving the readability of reporting documents by using a uniform nomenclature; *ii)* using the same indicators in strategic and reporting documents over the years; *iii)* inserting a column in the budget reconciling budget lines with activities; *iv)* limiting changes in budget, reporting documents, indicators, activity repartition and explain them whenever they occur, enabling comparison across years; v) establishing a system to reconcile mandates received, questions produced and the outputs provided.vi) increase the level of reliability and integrity of data used,	EFSA	High	H	H	L

Independence

EFSA is generally independent and it has one of the most advanced and robust systems in place for ensuring the independence.

EFSA has **fulfilled its obligations** to operate in an independent manner and, despite criticisms, no major changes in EFSA's structure and procedures for independence are needed; the current situation is considered as a satisfying infrastructure also if compared with other European Agencies and relevant international standards, like OECD ones[470].

The current good level of independence is mainly due to:

- Governance and structure laid down by the Founding Regulation that provide EFSA with a strong basis for the independence of the decision-making process, and guarantees a clear separation between EFSA's scientific work and strategic management.
- The effective implementation of the Policy on Declaration of interests as further confirmed by the encouraging audit results.
- The progressive evolution of procedures towards both stricter controls and a high level of transparency on how experts' interests are screened. More specifically, the recently adopted Policy on Independence (2011) and the related implementing measures, represent a shift towards a more comprehensive approach to independence, including complementary issues like: organizational governance, transparent selection of experts, collegial decision-making, validation of data, broad

[470] The OECD standards are made for public officials and leave uncovered 75% of the population of the EFSA that do not enter in this contractual category, namely the Management Board members, the scientific experts members of panels and working groups, the Advisory Forum members and the stakeholders consultative platform members.

consultation transparency of scientific workflow, etc.

Nonetheless, as independence remains one of the main issues called into question by some stakeholders and by the public at large, the following areas of improvement have been identified. The first ones relate to areas where EFSA has already taken concrete measures mainly through the new Policy of Independence but where these measures are not known enough. An increased level of transparency on procedures and a better communication is required to improve the external perception on these issues.

- *EFSA's links with industry and industry-affiliated bodies*: stakeholders still perceive the existence of links between EFSA and Industry. Waiting for effects of the implementing rules of the new Policy on Independence that include stronger measures concerning industry-related issues, there is a need for more transparency and for a proper communication of the existing rules to prevent such a perception. Regarding this aspect, the most critical target the Authority has to deal with is NGOs.
- *Transparency on screening procedures*: most of the documents related to the screening procedures and decisions on conflict of interests are still not published and, despite EFSA's efforts to clarify the screening and assessing procedure through concrete examples, it is difficult for any external stakeholder to understand how decisions on conflicts of interest are taken; feedbacks from the Authority on the final decision should be available.
- *Actions to mitigate criticisms*: EFSA is still ineffective in mitigating criticisms towards its experts' independence. This situation, if not adequately managed, risks to limit experts' future willingness to work for the Authority. EFSA should thus continue to improve the experts' confidence in the structure and better communicate all the activities implemented in this regard. Moreover, as criticisms on EFSA's independence are not always science based, the Authority should also be able to identify the nature of the attack and to subsequently the most adequate strategy to deal with it.

Parallel to the improvement of the external perception, EFSA should also address the effectiveness of independence related rules. EFSA's approach in dealing with independence mainly consists of policies and implementing rules to be respected. The current level of regulation of this issue is critical and not well perceived by the majority of stakeholders. Indeed, further strengthen controls on experts may reduce the number of experts compliant with EFSA's requirements and can gradually risk to undermine the scientific quality of EFSA's outputs. Any additional effort to introduce further rules on this issue should be adequately counterbalanced by an appropriate cost/risk/benefit assessment and with different complementary initiatives in order to be effective (e.g., experts could be made more responsible for the declaration of their interests to limit situations where they do not declare all their relevant interests).

#	RECOMMENDATIONS SPECIFIC TO INDEPENDENCE	ADDRESSEES	PRIORITY	Impact on performance	Relevance for EFSA mission	Relevance for stakeholder
17	Focus the communication on independence, specific aspects of implemented rules, procedures and results that address still existing criticisms. Analyse criticisms, keeping track of "scientific" and "political" ones and defining strategies to deal with both.	EFSA	High	H	H	H

18	Conduct a survey focused on NGOs to better understand the obstacles to a fruitful cooperation, identifying expectations and areas of potential cooperation.	EFSA	Medium	L	L	M

Openness and transparency

EFSA has fulfilled its obligations to operate in an open and transparent manner and these principles are relevant to EFSA's work today and in the future.

Documents that according to article 38 of EFSA's Founding Regulation should be made public[471] **are indeed all available** on EFSA's website through differentiated tools in order to satisfy different clients' needs (e.g., newsletter, EFSA journal, Register of Questions – RoQ, etc.). Among these tools the RoQ is not user friendly enough and does not allow stakeholders to adequately follow the Authority's scientific-decision making process. In addition to the obligations explicitly indicated in the Founding Regulation, the Authority has widened over the years the portfolio of public documents regarding its decision-making bodies.

The current level of **transparency** is satisfying according to the majority of stakeholders and this is due to the following actions:

- comprehensive body of risk assessment best practices and methodologies;
- Standard Operating Procedures that describe EFSA's workflow for scientific opinions;
- the distinctive system of webcasting (2006) for the "participation" of the general public to the MB public session;
- two guidance documents (in 2006 and 2009), detailing transparency in risk assessment in relation to procedural and scientific aspects;
- the implementation of a transparent selection procedure for members of EFSA's Scientific Committee and Scientific Panels as described in the decision of the EFSA Executive Director;
- a Pilot Project (2012) allowing observers to attend three Panels and one Steering Committee meeting.

EFSA's use of **confidentiality clauses** limits the transparency on certain issues (e.g., industry dossiers). The increasing requests for access to documents coming from stakeholders together with the recent evolution of the case-law will ask EFSA a higher level of transparency in its way of working and a progressive awareness that an increasing number of documents will potentially become accessible in the upcoming future.

As relates openness, coherently with the Founding Regulation[472], **EFSA has progressively increased the level of inclusion of external stakeholders** in its decision-making process **through a variety of instruments** that globally satisfy stakeholders. More specifically:

[471] (a) agendas and minutes of the Scientific Committee and the Scientific Panels; (b) the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included; (c) without prejudice to Articles 39 and 41, the information on which its opinions are based; (d) the annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels, as well as the declarations of interest made in relation to items on the agendas of meetings; (e) the results of its scientific studies; (f) the annual report of its activities; (g) requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

[472] (Art. 42) The Authority is supposed to have, "effective contacts with consumer representatives, producer representatives, processors and any other interested parties" and in addition (Art.9) "There shall be open and transparent public consultation directly or through the representative bodies, during

- The creation and use of the Stakeholder Consultative Platform, the main tool that EFSA has implemented to permanently consult its stakeholders. Its activity has been growing steadily and has become more and more relevant for EFSA's activities and for stakeholders, whose point of view is increasingly requested.
- The promotion of relations with the general public and those who feel they can contribute to the Authority's work through an increasing number of public consultations and other public events like: Colloquia, Workshop, Technical meetings, Open Days, etc.
- The invitation of hearing experts in scientific decision-making processes in case a specialized scientific knowledge is required.

Even though much has already been done, the actual level of openness and transparency could be further improved as relates **the risk assessment process**. Most of Panels are still not accessible to external stakeholders and, even in those selected for the above mentioned Pilot Project, observers cannot take part to the scientific decision-making process. As also emerges from the evidences related to the "Provision of scientific outputs" and "Data collection" paragraphs, it is not clear how data are processed, how the scientific consensus is reached and how decisions are made. The recent Pilot Project will need an accurate analysis to evaluate whether it satisfies the stakeholders' need for transparency. EFSA's efforts to increase the openness and transparency of its decision-making processes are unanimously appreciated, but more transparency should be achieved on the way the Authority takes into consideration suggestions, comments and inputs raised by stakeholders, during or outside meetings, considering that a standard procedure is not yet formalized.

Food Industry Representatives are the only target, among those involved in the evaluation, clearly asking for a higher involvement in EFSA's decision-making process. The creation in 2011 of the Application Helpdesk is the main initiative that EFSA has undertaken at this regard, and an evaluation of its impact, once it will be completely implemented, will allow to better understand and, in case, improve the relations with Food Industry Representatives.

The principles of openness and transparency are extensively part of EFSA's work and culture as demonstrated by the increasing number of activities developed and confirmed by strategic documents (e.g., Science Strategy 2012-2016). Nonetheless, the relevance of these principles should further increase to adequately face future challenges linked to the changing legal context pushing EFSA towards a higher degree of transparency.

In ten years EFSA has implemented a high number of tools of inclusions and others are still ongoing. The Authority should now capitalize the expertise gained and chose the most effective and efficient tools, documents or meetings to communicate its internal functioning.

#	RECOMMENDATIONS SPECIFIC TO OPENESS AND TRANSPARENCY	ADDRESSEES	PRIORITY	Impact on performance	Relevance for EFSA mission	Relevance for stakeholder
19	Increase the level of transparency on how external scientific studies, as well as suggestions and comments coming from stakeholders are taken into account (especially the diverging ones).	EFSA	High	M	M	H

the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it".

20	Enforce IT platforms/points of contacts to exchange information and updates in meetings on how comments/studies have been taken into account can help for specific scientific decision-making processes.	EFSA	Medium	M	M	M
21	Evaluate the impact on the external perception of transparency of the Pilot Project to open up Panels to external observers.	EFSA	Medium	M	M	M
22	Assess the cost-benefit of the tools of involvement of stakeholders, in order to prioritize them and focus efforts on the most efficient and effective tools.	EFSA	High	H	H	M
23	*(As relates Data Collection)* Provide feedbacks to data providers on the quality, quantity, relevance and use of collected data.	EFSA	Medium	M	L	M
24	*(As relates Data Collection)* Address the issues of the ownership and of the final level of accessibility of data.	EFSA	Medium	M	M	M
25	*(As relates Provision of scientific outputs)* Improve the procedure to update opinions once new evidence is available in terms of timeliness.	EFSA	Medium	M	M	L
26	*(As relates Provision of scientific outputs)* Make clearer reference in the scientific outputs to the sources of data, conflicting data, assumptions and uncertainties.	EFSA	Medium	L	L	H
27	*(As relates Independence)* Evaluate the opportunity to give stakeholders the possibility to get access to documents related to the screening procedures and decisions on conflict of interests.	EFSA	Medium	L	L	H

4.2 Transversal recommendations

We report hereafter recommendations that come from findings transversal to different thematic areas of evaluation.

#	RECOMMENDATIONS	ADDRESSEES	PRIORITY	Impact on performance	Relevance for EFSA mission	Relevance for stakeholder
Take into account different stakeholders' needs and better customize its services.						
28	Organize bilateral meetings and evaluate the opportunity to insert specific national context details when dealing with opinions, and to provide an additional service consultancy for NRM to interpret/adapt the opinion to a specific national context.	EFSA, NRM, NRA	Medium	M	L	H

29	Evaluate the opportunity to integrate meetings with complementary projects developed in cooperation with specific MS in order to take benefit of MS expertise and increase the value of their contribution.	EFSA	High	H	L	H
30	The application desk should work as a platform for discussion between EFSA and applicants, and EFSA should evaluate the cost opportunity of introducing hearings and pre-submission meetings (even with fees), to streamline the application process and allow EFSA and firms to gain efficiency.	EFSA	High	H	L	H
31	Evaluate whether the general public represents a priority target for communication and thus, in case, design adequate tools of information.	EFSA	Low	M	L	L
Increase planning and prioritization capacity.						
32	Improve the effectiveness of the consultation of EFSA during the EU legislative process, to anticipate impacts of new legislations on EFSA's work and allow EFSA to organize at best.	EFSA, EP,EC, Council	Medium	H	L	M
33	Establish regular meetings to report on progress in the work plan implementation and review the work plan, in case of new regulations or emerging issues.	EFSA, EC	High	H	L	M
34	Increase the number of EC's feedbacks on the usefulness of the outputs, to allow EFSA to identify priority work areas and focus available resources (including an efficient use of outsourcing).	EC	Medium	H	L	M
35	Continue strengthening its "Intelligence capacity" to study the global context, be aware of the international trends and regularly monitor evolutions and changes.	EFSA	High	H	M	H
36	Increase of exchanges/partnerships with public research institutions and MS to have inputs in terms of knowledge and innovation is recommended, as well as a better use of stakeholders meetings to identify emerging issues and future work areas.	EFSA	High	H	M	H
37	Formally recognize that EFSA's mandate has been de facto extended over the years in order to address the changing needs and expectations of risk managers (i.e., environmental risk assessment).	EP, Council, EC	High	H	H	H

Annexes

1. Questionnaire and supporting documents

a. Table of questionnaires completed

TARGET GROUPS	STAKEHOLDER	QUESTIONNAIRES COMPLETED
Institutional Stakeholders	European Commission[473]	8
	EP	3
	National Risk Managers	11
	National Risk Assessors	23
External Stakeholders	Scientific Org. (Art 36)	12
	Food Industry/Applicants	13
	NGOs	3
	Consumer Organizations	5
	Media	3
EFSA bodies	MB	13
	SC	10
Total		104

b. List of respondents

STATUS	ORGANIZATIONS
European Commission	DG SANCO
European Commission	DG SANCO
European Commission	DG SANCO
European Commission	DG SANCO
European Commission	DG SANCO
European Commission	DG SANCO
European Commission	DG SANCO
European Commission	DG BUDG
European Parliament	ENVI Committee
European Parliament	AGRI Committee
European Parliament	AGRI Committee
Risk Manager	FASFC Federal Agency for the Safety of the Food Chain (Belgium)
Risk Manager	MOA Ministry of Agriculture and Natural Resources and Environment (Cyprus)
Risk Manager	BLV Federal office of Food and Consumer Protection and Food Safety (Germany)
Risk Manager	Ministry of Health, Direzione (Italy)
Risk Manager	Ministry of Agriculture, Rural Development and Fisheries (Portugal)

[473] In the report European Commission stands usually for DG SANCO and DG BUDG when included in the questionnaire.

Risk Manager	National Sanitary Veterinary and Food Safety Authority (Romania)
Risk Manager	Ministry of Agriculture, Forestry and Food (Slovenia)
Risk Manager	Department for Environment, Food and Rural Affairs (United Kingdom)
Risk Manager	Norwegian Food Safety Authority (Norway)
Risk Assessor	Head of Risk Assessment - Austrian Agency for Health and Food Safety - Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH (Austria)
Risk Assessor	Director of Risk Assessment Centre, Bulgarian Food Safety Agency (Bulgaria)
Risk Assessor	Director - State General Laboratory - Ministry of Health (Cyprus)
Risk Assessor	Director - Food Safety Department - Ministry of Agriculture (Czech Republic)
Risk Assessor	Director - National Food Institute (Denmark)
Risk Assessor	Head of Food and Veterinary Department - Ministry of Agriculture (Estonia)
Risk Assessor	Director General - Finnish Food Safety Authority EVIRA (Finland)
Risk Assessor	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (Anses) - General Director (France)
Risk Assessor	President - BfR Bundestintitut für Risikobewertung - Federal Institute for Risk Assessment (Germany)
Risk Assessor	President Hellenic Food Authority (E.F.E.T.) Management Board (Greece)
Risk Assessor	General Director - Hungarian Food Safety Office, MEBiH (Hungary)
Risk Assessor	Chief Executive - Food Safety Authority (Ireland)
Risk Assessor	Director of the Food Centre of the Food & Veterinary Service (Latvia)
Risk Assessor	Deputy Director - Lithuanian State Food and Veterinary Service (Lithuania)
Risk Assessor	Foodstuffs Chemicals Cosmetics Directorate (FCCD) - Competition and Consumer Affairs Authority (Malta)
Risk Assessor	Director Office for Risk Assessment - Voedsel en Waren Autoriteit, VWA (Netherlands)
Risk Assessor	Director of the Norwegian Scientific Committee for Food Safety (Norway)
Risk Assessor	Deputy Director - National Institute of Hygiene (Poland)
Risk Assessor	Head of the division of communications matters and risk assessment – ASAE, Autoridade de Segurança Alimentar e Económica (Portugal)
Risk Assessor	General Director - National Sanitary Veterinary and Food Safety Authority (Romania)
Risk Assessor	Director Dept of Food Safety of Ministry of Agriculture (Slovak Republic)

Risk Assessor	President - Spanish Food Safety and Nutrition Authority - Agencia Española de Seguridad Alimentaria y Nutricion -AESAN, Ministerio de Sanidad, Política Social e Igualdad (Spain)
Risk Assessor	National Food Agency – Livsmedelsverket (Sweden)
Scientific organizations (Art. 36)	Bundesinstitut für Risikobewertung (BfR)
Scientific organizations (Art. 36)	Austrian Agency for Health and Food Safety (AGES)
Scientific organizations (Art. 36)	Chemicals Regulation Directorate (CRD)
Scientific organizations (Art. 36)	Finnish Food Safety Authority (EVIRA)
Scientific organizations (Art. 36)	Central Institute for animal disease control
Scientific organizations (Art. 36)	National Food and Nutrition Institute
Scientific organizations (Art. 36)	Food and Veterinary Service
Scientific organizations (Art. 36)	Institut de Recerca i Tecnologia Agroalimentàries – IRTA
Scientific organizations (Art. 36)	Aarhus University, Faculty of Agricultural Science
Scientific organizations (Art. 36)	Norwegian Veterinary Institute
Scientific organizations (Art. 36)	National Centre of Public Health Protection (NCPHP)
Scientific organizations (Art. 36)	University Dunarea de Jos Galati
Food industry/applicants	CEFIC - The European Chemical Industry Council) (SCP)
Food industry/applicants	FoodDrinkEurope (SCP)
Food industry/applicants	ECPA - European Crop Protection Association (SCP)
Food industry/applicants	EFFAT - European Federation of the Food, Agriculture and Tourism Trade Unions (SCP)
Food industry/applicants	FEFAC - European Feed Manufacturers Federation (SCP)
Food industry/applicants	ILSI Europe (SCP)
Food industry/applicants	UEAPME – European Association of Craft, Small and Medium-sized Enterprises (SCP)
Food industry/applicants	BASF
Food industry/applicants	Ajinomoto Eurolysine
Food industry/applicants	Nestlé Nutrition
Food industry/applicants	DSM Nutritional Products Ltd
Food industry/applicants	EFFA
Food industry/applicants	Red Bull GmbH
NGO	EEB - European Environmental Bureau (SCP)
NGO	EPHA - European Public Health Alliance (SCP)
NGO	CEO

Consumer organizations	BEUC-European Consumers' Organization (SCP)
Consumer organizations	EuroCoop - European Community of Consumer Co-operatives (SCP)
Consumer organizations	EKPIZO (Greece)
Consumer organizations	Forbrugerrådet - FR (Denmark)
Consumer organizations	Consumentenbond (Netherlands)
Media	EU Food Policy
Media	ANSA
Media	Die Tageszeitung
Management Board	Management Board
Management Board	Management Board
Management Board	Management Board
Management Board	Management Board
Management Board	Management Board
Management Board	Management Board
Management Board	Management Board
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Scientific Committee	Scientific Committee

NB. 2 Risk Managers appear as anonymous, their answers have been taken in consideration

c. Template for questionnaires

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
PROVISION OF SCIENTIFIC OUTPUTS AND TECHNICAL SUPPORT						
			1	**Provision of scientific outputs**		
Q1.a	EFSA's outputs are suitable to the needs of its clients and in particular the European Commission, Parliament and Member States	Identification of the expectations and of the perceived gaps between actual and expected outputs	1.1	To what extent are EFSA's scientific outputs relevant to your needs? Please specify your rating for: Clarity Completeness	1-4	DG RTD; DG SANCO; EP; NRM; FIR; NRA; SCP; External NGOs; National Consumer Organizations;
			1.2	What are the main areas of improvement in the provision of scientific outputs you suggest? (Enter no more than 3 responses)	list	DG RTD; DG SANCO; EP; NRM; FIR; NRA; SCP; External NGOs; National Consumer Organizations;
Q1.b	EFSA is issuing timely outputs (opinions and technical advice) as requested by the Commission, the European Parliament and Member States (adequacy of systems/procedures to ensure the respect of deadlines)	Analysis of the gaps between perceived and actual level of timeliness and by type of output	1.3	How often does EFSA meet the deadlines to issue outputs (authorizations, scientific opinions; technical advice, etc.)? always, usually, rarely, never	select	DG RTD; DG SANCO; EP; NRM; FIR/A; NRA;
			1.4	Please rate your level of satisfaction as for timeliness as relates the following outputs (when appropriate): - authorizations - scientific opinions - technical advice	1-4	DG RTD; DG SANCO; EP; NRM; FIR; NRA
Q6.g	The perception of the quality of EFSA scientific output is comparable to that of other similar organization. The quality of EFSA scientific output is in line with that of organizations carrying out similar tasks	Analysis of perception about the validity/reliability of EFSA scientific output compared to EMA, ECHA FSA, VWA	1.5	Please rate the reliability of the scientific outputs for each of the following organizations: EFSA EMA ECHA FSA VWA	1-4	DG RTD; DG SANCO; EP; NRM; NRA; SCP; External NGOs; National Consumer Organizations;
			1.6	Can you please explain your best and worst choice?	text	DG RTD; DG SANCO; EP; NRM; NRA; SCP; External NGOs; National Consumer Organizations;
Q7.a Q7.d	The delivery of scientific advice regarding food chain is made through an integrated approach	Analysis of the level of integration of EFSA's approach to delivering scientific advices regarding	1.7	To what extent has EFSA implemented an integrated approach to deliver scientific advice? *(i.e., The Authority should provide a comprehensive independent scientific view of the safety and other aspects of the whole food and feed supply chain,*	1-4	DG SANCO; EP; NRM; NRA; SC; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR;

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
		the food chain		*including issues having a direct or indirect impact on the safety of the food and feed supply chains, animal health and welfare and plant health).* Please rate		
			1.8	To what extent does EFSA involve the relevant upstream stakeholders (producers, manufacturers, etc.) when delivering scientific advice associated with the food chain? Please rate.	1-4	NRM; NRA; SC; SCP; External NGOs; Scientific Org. (Art 36); FIR/A;
			1.9	To what extent does EFSA involve the relevant downstream stakeholders (retailers, consumers, etc.) when delivering scientific advice associated with the food chain? Please rate.	1-4	NRM; NRA; SC; SCP; External NGOs; National Consumer Organizations;
			2	**Self tasking function**		
Q1.d	EFSA is using its self-tasking function effectively to keep abreast of emerging issues	Analysis of the level of satisfaction on EFSA's self-tasking function by type of stakeholder	2.1	To what extent is EFSA using its self-tasking function properly to keep abreast of emerging issues? Please specify your rating for: Usefulness Clarity of studies Timeliness	1-4	DG RTD; DG SANCO; EP; NRA; SC; SCP; External NGOs; Scientific Org. (Art 36); NRM; National Consumer Organizations;
Q6.e	EFSA is using self-tasking function effectively to keep abreast of emerging issues, undertaking scientific work on its own initiative, particularly in fields such as emerging risks where scientific knowledge and approaches are continually evolving.	Analysis of stakeholders' recognition of scientific works undertaken under EFSA self-tasking function	2.2	Please rate the relevance, within the scientific community, of scientific works undertaken under EFSA self-tasking function?	1-4	DG RTD; DG SANCO; NRA; SCP; External NGOs; Scientific Org. (Art 36); NRM; National Consumer Organizations;
			3	**Support to risk managers**		
Q7.g	EFSA has developed tools and procedures to support National Risk Managers in the EU	Analysis of the relevance of EFSA input to risk managers	3.1	To what extent do EFSA's tools and activities support you in risk mitigation activities in your country? Please rate:	1-4	NRM;
				What kind of support/specific tool, do you appreciate most? Please describe it briefly	text	NRM;
			3.2	Do you receive support from other organizations?	Y/N	NRM;
				In case, please list the names of the organizations	List	NRM
Q3.c; Q3.h	EFSA has ensured business continuity and has been able to	Analysis of stakeholders	3.3	To what extent has EFSA ensured business continuity? Please rate	1-4	DG RTD; DG SANCO; EP; NRM; NRA; SCP;

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
	sustain its support to risk managers within assigned resources	satisfaction	3.4	To what extent has EFSA been able to support risk managers within assigned resources? Please rate	1-4	DG RTD; DG BUDG; DG SANCO; EP; NRM;
			3.5	Please list 3 actions EFSA should do to improve its contribution to risk managers	list	DG RTD; NRM; SCP;
Q1.h	EFSA has been able to support the EU in emergency food/feed safety situations	Analysis of EFSA crisis response capacity	3.6	If you have requested EFSA's support to face food/feed situations emergency situations, please rate the quality of EFSA's scientific outputs in terms of - Clarity - Relevance - Timeliness	1-4	DG RTD; DG SANCO; EP; NRM; NRA;
DATA COLLECTION						
			4	**Data collection and analysis**		
Q1.c	EFSA fulfils its mandate to collect and analyze data relevant for the safety of the food chain	Analysis on access and availability of data, quality of reports on data, actions of EFSA for data harmonization (Art. 33 Reg. 178)	4.1	Please rate the level of accessibility to databases *(i.e., To what extent are EFSA's databases open to stakeholders?)* related to: - food consumption per different groups of the population and in particular children (up to 9 years of age) - incidence and prevalence of biological risk - occurrence of chemical contaminants in food and feed - residues of veterinary drugs and pesticides	1-4	DG RTD; DG SANCO; EP; NRM; NRA; SC; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A;
			4.2	Please rate the level of availability of data *(i.e., To what extent are data included in databases comprehensive?)* related to: - food consumption per different groups of the population and in particular children - incidence and prevalence of biological risk - occurrence of chemical contaminants in food and feed - residues of veterinary drugs and pesticides	1-4	DG RTD; DG SANCO; EP; NRM; NRA; SC; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A;
			4.3	In your view are there are any data gaps?	Y/N	DG RTD; DG SANCO; EP; NRM; NRA; SC; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A;
				Please specify in which areas	text	DG RTD; DG SANCO; EP; NRM; NRA; SC; SCP; External NGOs; National Consumer

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
						Organizations; Scientific Org. (Art 36); FIR/A;
			4.4	Are you satisfied with the quality of reports on data collection provided by EFSA? Please rate	1-4	DG RTD; DG SANCO; EP; NRM; NRA; SC; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A;
			4.5	Please rate the clarity of EFSA's recommendations for appropriate data collection methodologies	1-4	DG RTD; DG SANCO; NRM; NRA;
			5	**Cooperation for data collection**		
Q1.f; Q3.g	EFSA cooperates with the Commission and Member States to promote coherence between risk assessment, risk management and risk communication functions The existing system for cooperation and networking with national bodies provides an appropriate basis to support EFSA's work The existing system for cooperation and networking with national bodies can be maintained to ensure a critical mass of expertise throughout the EU in the medium and long term	Analysis of the satisfaction on the actions done by EFSA with respect to: ▸ Collection and exchange of scientific data and information	5.1	Please rate the adequacy of EFSA's system of cooperation as relates to: - collection of scientific data and information - exchange of scientific data and information	1-4	DG SANCO; NRM; NRA; SCP; External NGOs; National Consumer Organizations; FIR/A;
			5.2	Do you think you could provide more valuable support?	Y/N	NRM; NRA; SCP;
				Please specify in which ways	text	NRM; NRA;
			6	**Quality of data**		
Q6.b	Data collected support high quality scientific outputs	Analysis of the reliability of data used by EFSA to support scientific output and of the appropriateness of EFSA Data Quality Management system	6.1	Are you satisfied with the quality of EFSA's data in order to produce your work? Please rate	1-4	DG RTD; DG SANCO; EP; NRM; NRA; SC; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A
				Please explain	text	NRA; SC; Scientific Org. (Art 36);
			6.2	Please rate the reliability of data underpinning EFSA's opinions	1-4	DG RTD; DG SANCO; EP; NRM; NRA; SC; SCP; External NGOs;

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
						National Consumer Organizations; Scientific Org. (Art 36); FIR/A;
			6.3	Do you have in place any quality system that supports the appropriateness of scientific outputs and data?	Y/N	DG RTD; DG SANCO; EP; NRM; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A;
RISK COMMUNICATION						
			7	**Risk communication quality**		
Q1.g	EFSA communicates effectively and openly on risks in the food chain in a timely manner	Analysis of the level of satisfaction of stakeholders as relates content, clarity, quality, timing, relevance and outreach of the communication	7.1	Please rate EFSA's communication as relates to: Content Clarity Quality Timing Relevance Outreach	1-4	DG RTD; DG SANCO; EP; NRM; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;
			7.2	To what extent has EFSA communication activity increased awareness of the risks in the food chain? Please rate	1-4	DG RTD; DG SANCO; EP; NRM; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;
			7.3	Please list issues not adequately communicated, if any. Enter no more than 3 responses	list	DG RTD; DG SANCO; EP; NRM; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;
Q7.a Q7.d	Risk communication across the EU is coherent and relevant	Analysis of the contribution of EFSA to the coherence and relevance of risk communication across the EU	7.4	Please rate the coherence of the communication on risks in the food chain?	1-4	DG SANCO; EP; NRM; NRA; External NGOs; National Consumer Organizations; Scientific Org. (Art 36);
			7.5	Are there other opinions (besides EFSA's ones) you take into account in your activities?	Y/N	DG SANCO; EP; NRM; NRA; National Consumer Organizations; Scientific Org. (Art 36);
				Please specify which ones	list	DG SANCO; EP; NRM; NRA; National Consumer Organizations; Scientific Org. (Art 36);
			8	**Risk communication effectiveness**		

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
Q5.e	EFSA activities have been effective in enhancing trust in EFSA within the overall food safety system	Analysis of the effectiveness of communication activities in enhancing trust in EFSA	8.1	Please rate your trust in EFSA's activities and in the overall food safety system	1-4	NRM; SC; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;
Q7.d	EFSA risk assessment system is reliable and trusted by EU members	Analysis of risk assessment coordination by EFSA	8.2	To what extent is EFSA risk assessment system reliable? Please rate	1-4	DG SANCO; EP; NRM; NRA;
Q7.b	The level of EFSA commitment to dialogue with partners and stakeholders is high. EU citizen's confidence in the EU Agro-food sector has improved. Efsa is perceived as a reliable body in which stakeholders have confidence	Analysis of the level of satisfaction on EFSA's commitment to dialogue with partners and stakeholders	8.3	Are you satisfied with EFSA's capacity to dialogue? Please rate	1-4	DG SANCO; EP; NRM; NRA; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A;
Q7.c	Divergent scientific opinions are reducing. (In terms of numbers and contents). EFSA is perceived as a reference scientific body in its field of activity. EFSA has contributed to scientific homogeneity in the field of food safety.	Analysis of scientific homogeneity in the field of food safety	8.4	To what extent have divergent scientific opinions decreased since EFSA creation? Please rate	1-4	DG SANCO; NRM; NRA; FIR/A;
Q2.d	The processes related to the AF are efficient (the AF is able to assist and advise EFSA and EFSA is able to make the most efficient use of this advice and assistance)	Analysis of the level of satisfaction of the AF members and stakeholders in terms of appropriateness of the composition of the AF and the efficiency of its working methods	8.5	To what extent is the Advisory Forum Working Group on Communications promoting coherence? Please rate	1-4	DG SANCO; NRM; NRA;
COOPERATION AND NETWORKING						
			9	**Cooperation and networking**		
Q1.f; Q3.g	EFSA cooperates with the Commission and Member States	Analysis of the level of satisfaction on the	9.1	To what extent is EFSA cooperating to promote coherence between risk assessment, risk	1-4	NRM; NRA; DG SANCO

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
	to promote coherence between risk assessment, risk management and risk communication functions The existing system for cooperation and networking with national bodies provides an appropriate basis to support EFSA's work The existing system for cooperation and networking with national bodies can be maintained to ensure a critical mass of expertise throughout the EU in the medium and long term	actions done by EFSA with respect to: ‣ Convergence and harmonization in risk assessment among MS ‣ EFSA contribution, through the AF, to the harmonization of methodologies for risk assessment		management and risk communication? Please rate		
			9.2	To what extent are risk assessment methodologies you use, coherent with EFSA guidelines? Please rate	1-4	NRA;
			9.3	Have you ever had situations of misalignment with EFSA's advices?	Y/N	NRA;
		Assessment of the effectiveness of the interface between risk assessors and risk managers on key topics	9.4	Do you benefit from taking part to the EFSA AF meetings when you deal with specific requests of your NRM?	Y/N	NRA;
Q2.d	The processes related to the AF are efficient (the AF is able to assist and advise EFSA and EFSA is able to make the most efficient use of this advice and assistance)	Analysis of the level of satisfaction of the AF members and stakeholders in terms of appropriateness of the composition of the AF and the efficiency of its working methods	9.5	To what extent do you share work programmes, risk assessment practices or methodologies in AF meetings? Please rate	1-4	NRA;
Q1.f; Q3.g	EFSA cooperates with the Commission and Member States to promote coherence between risk assessment, risk management and risk communication functions The existing system for cooperation and networking with national bodies provides an appropriate basis to support EFSA's work The existing system for cooperation and networking	Assessment of the effectiveness of the interface between risk assessors and risk managers on key topics	9.6	Do you benefit from having a national risk assessor representative attending EFSA AF meetings when adopting a policy?	Y/N	NRM;
			9.7	Please rate the role of EFSA as an interface between RA and NRM	1-4	SCP; Scientific Org. (Art 36);

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
	with national bodies can be maintained to ensure a critical mass of expertise throughout the EU in the medium and long term					
Q2.d	The processes related to the AF are efficient (the AF is able to assist and advise EFSA and EFSA is able to make the most efficient use of this advice and assistance)	Analysis of the level of satisfaction of the AF members and stakeholders in terms of appropriateness of the composition of the AF and the efficiency of its working methods	9.8	To what extent is EFSA taking benefits from the presence of the AF? Please rate	1-4	DG SANCO; NRM; NRA;
			9.9	To what extent are the processes related to the AF effective? Please specify your rating for: - exchanging scientific data; - addressing contentious issues and diverging opinions; - setting up working groups to focus collectively on specific issues; - coordinating work and avoid duplication	1-4	DG SANCO; NRM; NRA;
Q2.h	The distribution of work between the panels, EFSA's staff and external bodies is consistent with EFSA's objectives and activity evolution	Analysis of the involvement of competent organizations in EFSA's activities as per Art. 36(2) Reg. 178/2002, by type of activity	9.10	What is the activity where there is the highest involvement of external organizations (e.g., through art.36 grants, procurements, etc.)? - Preparatory work for scientific opinions and assessment of application - Scientific and technical assistance - Collection of data	select	DG SANCO; SC; Scientific Org. (Art 36); SCP
Q3.f	EFSA's structure (Panels and Committee) and the actual system for cooperation and networking are adequate to sustain the quality of work, both in terms of scientific outputs and needed expertise	Analysis of the appropriateness of the expertise available in MS agencies to support EFSA's work.	9.11	Please rate the quality of the support (in terms of expertise) provided by the MS agencies (or other types of national bodies in charge of RA) to sustain EFSA's work	1-4	DG SANCO; MB; Scientific Org. (Art 36);
Q7.d	The reduction of the risk assessment led to a decrease in national bodies' budget	Analysis of risk assessment coordination by EFSA	9.12	Have you registered a reduction of risk assessment activities in your organization after EFSA creation?	Y/N	DG SANCO; EP; NRM; NRA;
Q7.a Q7.d	Cost for National Food Safety Authorities has reduced thanks to EFSA's activities	Analysis of the economies for National Food Safety Authorities	9.13	Does your National Food Safety Authority benefit from EFSA's activities in terms of cost savings?	Y/N	NRM; NRA;
				Please specify your which costs have been mainly influenced?	list	NRM; NRA;
EFSA'S INTERNATIONAL ROLE AND RECOGNITION						
			10	**EFSA's international role and recognition**		

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
Q7.d	EFSA risk assessment system is reliable and trusted by EU members	Analysis of risk assessment coordination by EFSA	10.1	To what extent do you recognize EFSA at the forefront of risk assessment methodologies in Europe? Please rate	1-4	DG SANCO; EP; NRM; NRA;
Q6.f	EFSA has been involved in the international scientific community to maintain its overview of best practices and evolving scientific issues	Analysis of EFSA involvement in the international scientific community	10.2	To what extent is EFSA involved in the international scientific community? Please rate	1-4	DG RTD; DG SANCO; EP; NRM; NRA; SC; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); media;
			10.3	To what extent does EFSA involvement in the international scientific community provide added value? Please rate	1-4	DG RTD; EP; SC; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); media;
			10.4	Please rate the level of recognition of EFSA as a player of the international scientific community?	1-4	DG RTD; DG SANCO; EP; NRM; NRA; SC; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); media;
Q7.a Q7.d	The scientific community agrees to consider EFSA as a contributor to improvements in the provision of scientific advice	Analysis of the relevance of scientific advice	10.5	To what extent does EFSA contribute to the detection of risks in the food chain? Please rate	1-4	DG RTD; DG SANCO; NRM; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A;
			10.6	Do you have more information on the risks of the food chain since the creation of EFSA?	Y/N	DG RTD; DG SANCO; NRM; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A;
			10.7	Please specify in which areas EFSA contribution has been more significant. Enter no more than 3 responses	list	DG RTD; DG SANCO; NRM; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A;
Q7.c	EFSA is internationally recognized.	Analysis of EFSA position at EU and international levels	10.8	Please rate the following organizations according to their importance at EU and international level - EMA - ECHA - EFSA	1-4	DG RTD; DG SANCO; EP; NRM; NRA; SC; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;
			10.9	What should EFSA do to improve its recognition at international level?	text	DG RTD; EP; SC; FIR/A; media;
Q1.f; Q3.g	EFSA cooperates with the Commission and Member States to promote coherence between	Analysis of the satisfaction on the actions done by	10.10	How useful do you consider events organized by EFSA (e.g., scientific colloquia on scientific topics)? Please rate	1-4	DG SANCO; NRM; NRA; SC; SCP; Scientific Org. (Art 36);

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
	risk assessment, risk management and risk communication functions The existing system for cooperation and networking with national bodies provides an appropriate basis to support EFSA's work The existing system for cooperation and networking with national bodies can be maintained to ensure a critical mass of expertise throughout the EU in the medium and long term	EFSA with respect to: ‣ EFSA participation in European projects		Please explain, (e.g., high level network, exclusive information, etc.)	text	SC; SCP; Scientific Org. (Art 36);
Q3.f	EFSA's structure (Panels and Committee) and the actual system for cooperation and networking are adequate to sustain the quality of work, both in terms of scientific outputs and needed expertise	Analysis of EFSA's activities with regard to its participation to international programmes	10.11	Do you have visibility on EFSA's participation to international programmes?	Y/N	SCP; Scientific Org. (Art 36); media;
			11	**EFSA professional attractiveness**		
Q6.a	Human resources are adequate to ensure high quality scientific outputs	Analysis of the level of attractiveness of EFSA	11.1	Please rate EFSA's level of attractiveness in terms of professional development?	1-4	DG SANCO; NRA; SC; SCP; External NGOs; Scientific Org. (Art 36); FIR/A;
				Please list the main reasons of attractiveness and its limits	list	DG SANCO; NRA; SC; SCP; Scientific Org. (Art 36); FIR/A;
THE ORGANIZATIONAL STRUCTURE, ITS OPERATIONAL EFFICIENCY AND ITS ADAPTABILITY TO CHANGE						
			12	**EFSA structure**		
Q2.e	The organization of EFSA is able to adapt to the changes in the tasks entrusted to it	Level of satisfaction of stakeholders, MS, EC relates to EFSA's adaptability to change	12.1	What are the main challenges EFSA has to face? Please select: - independence - scientific quality - workload - globalization/new food hazards - evolution of consumer - awareness/communication - cooperation - innovation in science	select	DG RTD; DG BUDG; DG HR; DG SANCO; EP; NRM; MB; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A;

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
				- EFSA's international role - other (list)		
			12.2	To what extent is EFSA able to cope with the new challenges it has to face? Please rate	1-4	DG RTD; DG BUDG; DG HR; DG SANCO; EP; NRM; MB; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A;
Q2.a	The structure and organization of the agency is adequate to the work entrusted to it and to the actual workload	Perception analysis of the organization and structure (as relates size, staff composition and recruitment procedures) adequacy to the work entrusted to EFSA and the actual workload.	12.3	To what extent do EFSA structure and organization meet your needs? *(i.e., To what extent could EFSA structure and organization be considered as a "customer friendly" structure able to answer to your requests in an effective way?)* Please rate	1-4	DG RTD; DG SANCO; NRM; FIR/A;
			12.4	Please rate the structure of the new organization (May 2011) in comparison with the previous one?	1-4	DG RTD; DG HR; DG SANCO; MB; NRA; SCP;
Q2.e	The organization of EFSA is able to adapt to the changes in the tasks entrusted to it	Level of satisfaction of stakeholders, MS, EC relates to EFSA's adaptability to change	12.5	Please indicate if there are areas where you think there is a need for a change in order for EFSA to be able to cope with the new challenges - change in size - change in the organization - change in staff composition/skills - change in the recruitment process - change in training activities - financial resources - change in staff turnover - other	select	DG RTD; DG BUDG; DG HR; DG SANCO; EP; NRM; MB; NRA; SCP; Scientific Org. (Art 36); FIR/A;
Q3.d	EFSA has taken actions to face increasing workload and/or backlogs in the process of applications for authorizations	Analysis on how EFSA has managed increasing workload in application for authorisations, looking at trends, processes and procedures	12.6	Please rate EFSA's actions to manage its workload in application for authorizations	1-4	DG RTD; DG SANCO; NRM; FIR/A;
			12.7	To what extent could the application desk provide a support to manage increasing workload? Please rate	1-4	DG RTD; DG SANCO; NRM; FIR/A;
				Please specify your suggestions to improve this process?	text	DG RTD; FIR/A;
			13	**Resources allocation**		
Q2.f	EFSA resources allocation is consistent with its objectives	Analysis of the level of satisfaction on	13.1	To what extent does the information provided by EFSA on its budget and resource allocation meet	1-4	DG BUDG; DG SANCO;

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
	and activity evolution	resource allocation appropriateness		your requirements? Please rate		
				Please specify areas of improvement?	text	DG BUDG; DG SANCO;
			13.2	To what extent does the information provided by EFSA on its human resources (actual and foreseen) meet your requirements? Please rate	1-4	DG BUDG; DG HR; DG SANCO;
				Please specify areas of improvement?	text	DG BUDG; DG HR; DG SANCO;
			13.3	Please rate the adequacy of the allocation of resources to: - provision of scientific outputs - cooperation - communication	1-4	DG BUDG; DG HR; DG SANCO; MB;
			13.4	Please indicate whether you would increase, decrease or maintain: - provision of scientific outputs - cooperation - communication	select	DG BUDG; DG HR; DG SANCO; MB;
			13.5	What are, in your opinion, the main disproportions in the allocation of resources that could affect the Authority's future sustainability? Would you suggest any specific improvement?	text	DG BUDG; DG HR; DG SANCO; MB;
			13.6	Can you indicate other similar organizations where you find a better allocation of resources, if any? Enter no more than 3 responses	list	DG BUDG; DG HR; DG SANCO; MB;
Q2.h	The distribution of work between the panels, EFSA's staff and external bodies is consistent with EFSA's objectives and activity evolution	Analysis of the perception on the distribution of work between panels, EFSA's staff and external bodies.	**14**	**Distribution of work between Scientific Committee/Panels, EFSA's staff and external bodies**		
			14.1	Do you benefit from the support of: - EFSA's staff - Scientific Committee/Scientific Panels - external bodies (other than members of Panels and Scientific Committee)	Y/N	DG RTD; DG SANCO; NRA; SC; Scientific Org. (Art 36);
			14.2	Please rate the quality of the support to your work of external bodies (other than members of Panels and Scientific Committee)	1-4	SC
			14.3	Please rate (when appropriate) the quality of the support to your work of: - EFSA's staff - Scientific Committee/Scientific Panels	1-4	DG RTD; DG SANCO; NRA; SC; Scientific Org. (Art 36);
			14.4	Please indicate whether you would increase,	select	DG RTD; DG SANCO; NRA; SC;

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
				decrease or maintain the resources allocated to: - EFSA's staff - Scientific Committee/Scientific Panels - external bodies (other than members of Panels and Scientific Committee)		Scientific Org. (Art 36);
Q6.a	Human resources are adequate to ensure high quality scientific outputs	Mapping of the distribution of skills	14.5	To what extent are EFSA human resources (staff and external experts) adequate to support scientific outputs? Please rate	1-4	DG HR; DG SANCO; NRM; NRA; SC; SCP; Scientific Org. (Art 36); FIR/A;
			14.6	In your opinion what are the main lacks of skills of EFSA's HR (staff and external experts), if any?	text	DG HR; DG SANCO; NRM; NRA; SC; SCP; Scientific Org. (Art 36); FIR/A;
Q2.h	The distribution of work between the panels, EFSA's staff and external bodies is consistent with EFSA's objectives and activity evolution	Analysis of the perception on the distribution of work between panels, EFSA's staff and external bodies.	14.7	Can you indicate other similar organizations where you find a better distribution of work, if any? Enter no more than 3 responses	list	DG RTD; DG SANCO; NRA; SC; SCP; External NGOs; Scientific Org. (Art 36);
Q3.f	EFSA's structure (Panels and Committee) and the actual system for cooperation and networking are adequate to sustain the quality of work, both in terms of scientific outputs and needed expertise	Analysis of the composition of Committees and Panels.	14.8	To what extent will the actual Panel and Committee structure be adequate to support future challenges and the increase in workload? Please rate	1-4	DG RTD; DG SANCO; MB; SC; SCP; External NGOs; Scientific Org. (Art 36);
				Please specify in which way the support provided by Panels and Committee could be improved	text	DG RTD; DG SANCO; MB; SC; SCP; External NGOs; Scientific Org. (Art 36);
Q2.g	The process to mobilise the network of experts is efficient	Analysis of the level of satisfaction on the mobilization process efficiency.	14.9	Please rate the process of mobilization of experts (members of the Scientific Committee/Panels and their Working Groups) in terms of - timeliness - expertise collected - average duration of mandates - administrative and scientific support given for the experts	1-4	DG SANCO; NRA; SC; SCP; External NGOs; Scientific Org. (Art 36);
			14.10	Please indicate whether you think there are other organizations with more efficient processes of mobilization? Enter no more than 3 responses	list	DG SANCO; NRA; SC; SCP; Scientific Org. (Art 36);
			14.11	What is, in your opinion, the main strength of EFSA's mobilization process?	text	SC; Scientific Org. (Art 36);
			15	**Management Board**		
Q2.c	The composition and the working methods of the	Analysis of the level of satisfaction on the	15.1	Please rate the appropriateness of EFSA's MB process of decision-making	1-4	DG SANCO; EP; NRM; MB; NRA; SC; SCP; External NGOs;

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
	Management Board is appropriate and efficient	appropriateness of the composition of the MB and the efficiency of its working methods				National Consumers Organizations;
Q2.c			15.2	Do you suggest any change in the MB composition and working methods? - increase in the number of members - decrease in the number of members - increase in the number of meetings - decrease in the number of meetings - no changes	select	DG SANCO; EP; NRM; MB; NRA; SC; SCP; External NGOs; National Consumers Organizations;
Q2.c			15.3	Please rate the appropriateness of EFSA's MB composition	1-4	DG SANCO; EP; NRM; MB; NRA; SC; SCP; External NGOs; National Consumers Organizations;
Q2.c			15.4	Is there any lack of skills in the MB composition?	Y/N	DG SANCO; EP; NRM; MB; NRA; SC; SCP; External NGOs; National Consumers Organizations;
Q2.c				In case, please list. Enter no more than 3 responses	list	EP; MB; SC; SCP; External NGOs; National Consumers Organizations;
Q2.c			15.5	To what extent does the process of selection of the MB members guarantee its independence?	1-4	DG SANCO; EP; NRM; MB; NRA; SC; SCP; External NGOs; National Consumers Organizations;
Q2.c			15.6	Can you indicate how the independence of the MB has changed over time? - stable - increased - decreased	select	DG SANCO; EP; NRM; MB; NRA; SC; SCP; External NGOs; National Consumers Organizations;
			16	**Flow of information between EFSA and EC**		
Q2.j	The flow of information between EFSA and the EC supports the planning activities	Analysis of the flow of information between the EC and EFSA and their contribution to EFSA's capacity planning on short and medium term	16.1	To what extent is EFSA able to use the information you provide to plan appropriately its activities?	1-4	DG SANCO;
Q2.j			16.2	Please rate the gap between the foreseen opinions and the actual opinion requested	1-4	DG SANCO;
Q2.j			16.3	Would you recommend any modification/improvement of processes to make the flow of information with EFSA more efficient?	text	DG SANCO;
			17	**Legislative framework**		

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
				We refer to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, its implementing measures as well as to sector-specific vertical regulations. For more detail:http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R0178:EN:NOT		
Q3.b	EFSA overall legislative framework is able to support the evolving expectations (in terms of workload and work areas) placed upon the Authority in short, medium, long term	Analysis of the level of satisfaction on the adequacy of EFSA's overall legislative framework to support the evolving expectations of its clients.	17.1	Please rate EFSA's legislative framework support to evolving expectations in terms of: Workload Work area	1-4	DG SANCO; EP; NRM; MB;
			17.2	What are the main obstacles? Enter no more than 3 responses	list	DG SANCO; EP; NRM; MB;
			17.3	Which are in your opinion the main areas of improvement of the actual legislative framework? Enter no more than 3 responses	list	DG SANCO; EP; NRM; MB; NRA; SCP; External NGOs; National Consumer Organizations;
INDEPENDENCE						
			18	**Independence**		
Q4.a; Q4.d	EFSA's overall structures, governance and procedures have been effective in ensuring that the Authority can operate without undue influence	Analysis of EFSA's effectiveness in ensuring independence Analysis of the structures, governance and procedures established to guarantee independence.	18.1	Please rate EFSA's independence detailing your evaluation for: - overall - structure - governance - procedures	1-4	DG SANCO; EP; NRM; MB; NRA; SCP; External NGOs; National Consumer Organizations; FIR/A; media;
			18.2	Please briefly describe what should change in: - structure - governance - procedures in order to assure independence	text	DG SANCO; EP; NRM; MB; NRA; External NGOs; National Consumer Organizations; FIR/A; media;
Q4.b; Q4.c	EFSA's overall structures, governance and procedures to assure independence are in line with relevant standards and other similar organizations	Comparison between EFSA's tools to ensure independence of scientific advice and those in use in EMA and ECHA, DG SANCO non food committees , FSA,	18.3	Please rate the following organizations, as relates independence policy and process of decision-making about the conflicts: EFSA, EMA, ECHA, FSA, VWA, SANCO non food committees, ECDC	1-4	DG SANCO; EP; MB; NRA; SCP; External NGOs; National Consumer Organizations; FIR/A; media;

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
		VWA				
4.e	The procedures and policy EFSA has developed and is developing are able to mitigate the criticism on the independence	Analysis of the level of satisfaction of EFSA's capacity to mitigate the criticisms	18.4	Can you please list the 3 main criticisms to EFSA's independence? Enter no more than 3 responses	list	NRM; NRA; SCP; External NGOs; National Consumer Organizations; FIR/A; media;
			18.5	Please rate your level of satisfaction on actions done by EFSA to mitigate your criticism, if any	1-4	DG SANCO; EP; NRM; NRA; SCP; External NGOs; National Consumer Organizations; FIR/A; media;
			18.6	What do you expect from EFSA to improve its independence, if anything?	text	NRM; FIR/A; media;
OPENNESS AND TRANSPARENCY **Openness** is crucial to EFSA's organizational reputation; if advice and action in relation to food safety risks are to be trusted, it is important that risk assessments are published in a timely way and that information on which decisions are made can be scrutinised. Open dialogue with stakeholders and interested parties is also critical to building trust in the risk assessment process. **Transparency** is closely linked to openness and is equally important in building trust and confidence. Transparent decision-making and a transparent approach to explaining how an organization works, its governance and how it makes its decisions, are also crucial. For example, the Authority strives to convey clearly any areas of uncertainty in the risk assessment, whether and how these can be addressed by the risk assessor and/or risk manager, and the implications of these remaining uncertainties for public health.						
			19	**Openness and transparency**		
Q5.a	EFSA has fulfilled its obligation to operate in an open and transparent manner	Analysis of the level of satisfaction on EFSA's transparency procedures	19.1	Please rate the level of transparency of EFSA procedures	1-4	DG SANCO; NRM; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;
			19.2	Please list evidences about non transparency, if any. Enter no more than 3 responses	list	DG SANCO; NRM; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;
			19.3	What are the areas of improvement? Please list. Enter no more than 3 responses	list	media;
Q5.a; Q5. b	EFSA and its networks (as per art. 2 2230/2004) have - developed and implemented joint projects with stakeholders platform members - have organized forum and meetings for sharing information and best practices (art.36 178/2002) - have created a methodology	Analysis of the level of satisfaction on EFSA's openness procedures	19.4	Please rate the level of openness of EFSA procedures	1-4	DG SANCO; NRM; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;
			19.5	Please list evidences about non openness, if any. Enter no more than 3 responses	list	DG SANCO; NRM; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;

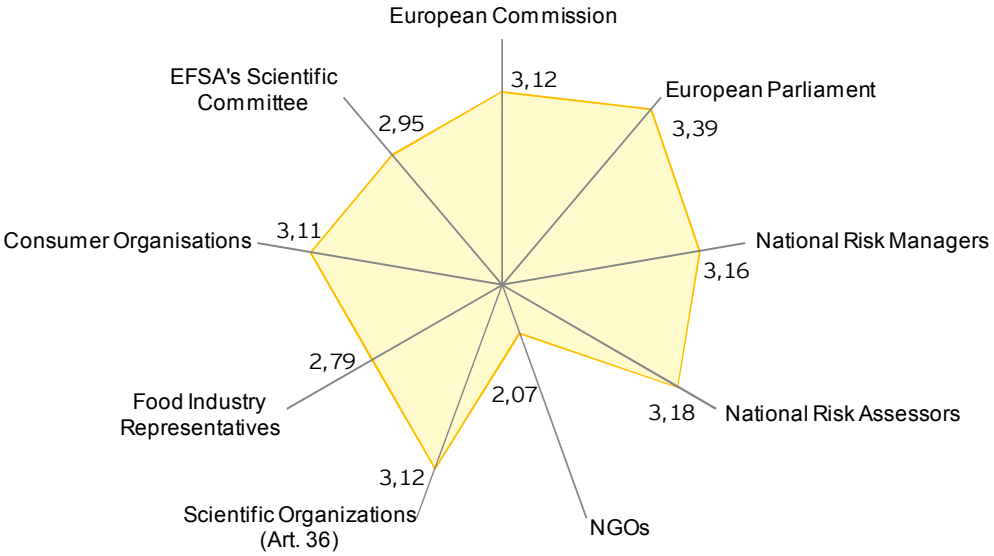
Ref JC	JC	Type of analysis	n°	Questions	Type	Target
	to collect suggestions from stakeholders platform members. - have created a methodology to collect complaints from stakeholders platform members - been open about EFSA's decision-making processes		19.6	What are the areas of improvement? Please list. Enter no more than 3 responses	list	media;
			19.7	Can you indicate where there are similar organizations that operate in a more transparent and open manner? Enter no more than 3 responses	list	DG SANCO; NRM; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;
		Analysis of exchanges between EFSA and interested parties	19.8	Are you satisfied with the procedures to communicate (suggestions and complaints) to EFSA? Please rate	1-4	SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;
				Please specify how EFSA takes into account your communication	text	SCP; FIR/A; media;
Q5.c	The principles of openness and transparency are relevant to EFSA's work today and in the future	Analysis of the perception on the principles of openness and transparency in present and future challenges	19.9	Please rate the relevance of EFSA openness and transparency for your activities as relates to: - access to documents - participation to meetings	1-4	NRM; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;
			19.10	To what extent do the procedures of openness allow you to provide inputs to EFSA's work?	1-4	NRM; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;
			19.11	To what extent do the procedures of transparency allow you to provide inputs to EFSA's work?	1-4	NRM; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;
			19.12	To what extent principles of openness and transparency are part of EFSA's work and culture? Please specify your rating for - openness - transparency	1-4	NRM; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;
			19.13	Please indicate whether, in your opinion, the relevance of openness and transparency to EFSA's work will increase decrease or be maintained to adequately face future challenges. Specify for: - openness - transparency	select	NRM; NRA; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media;
Q5.d	The cost-effectiveness of the implementation of the principles of openness and transparency is adequate	Comparison of tools of openness and transparency used by EFSA with those used by EMA, ECHA	19.14	Please rate the following organizations, as relates openness: EFSA, EMA, ECHA, FSA	1-4	DG RTD; DG SANCO; EP;
			19.15	Please rate the following organizations, as relates transparency: EFSA, EMA, ECHA, FSA	1-4	DG RTD; DG SANCO; EP;

Ref JC	JC	Type of analysis	n°	Questions	Type	Target
		and FSA				
ADDITIONAL COMMENTS						
				Do you wish to add any further comments on EFSA's role and performance?	text	DG RTD; DG BUDG; DG HR; DG SANCO; EP; NRM; MB; NRA; SC; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; media.

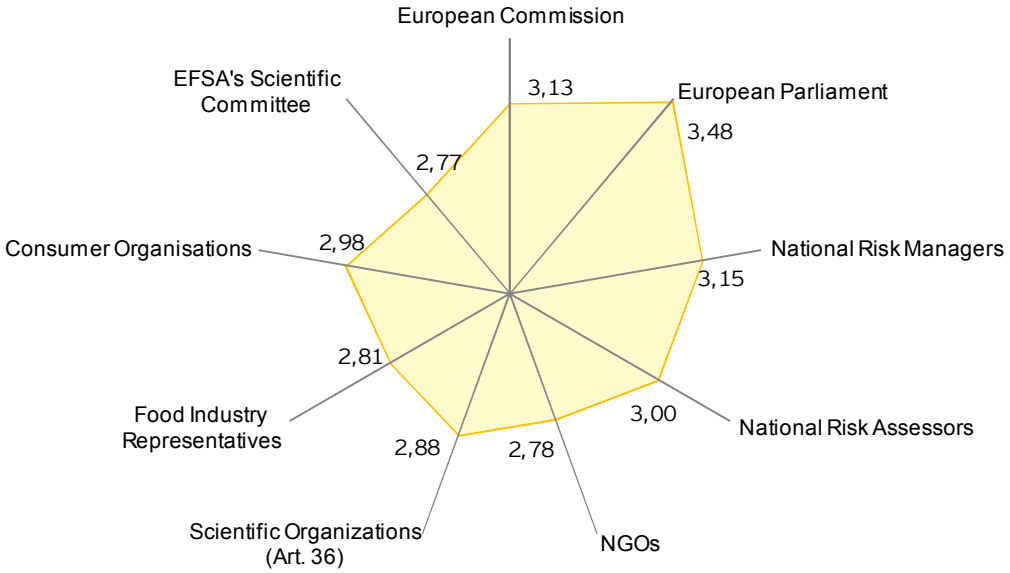
d. Questionnaires results

Stakeholders' overall perception on thematic areas

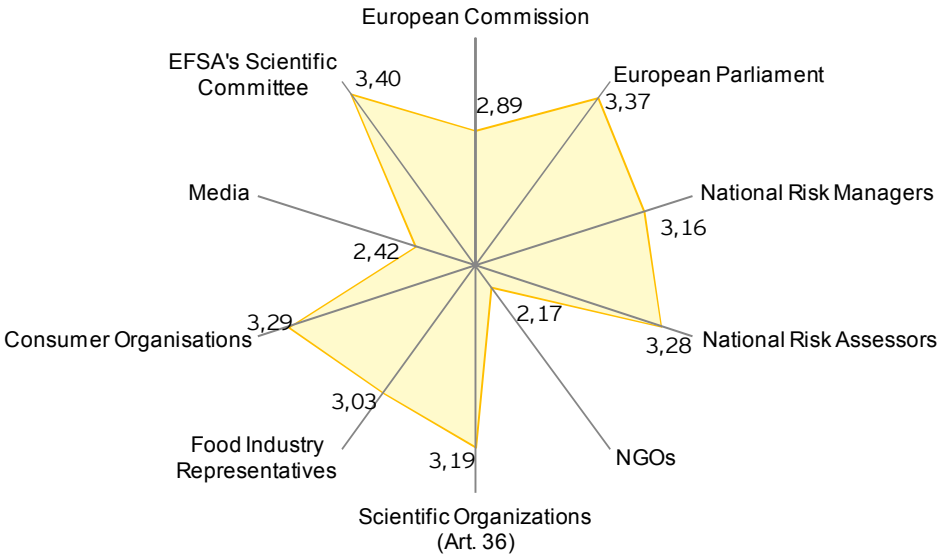
Provision of scientific outputs and technical support



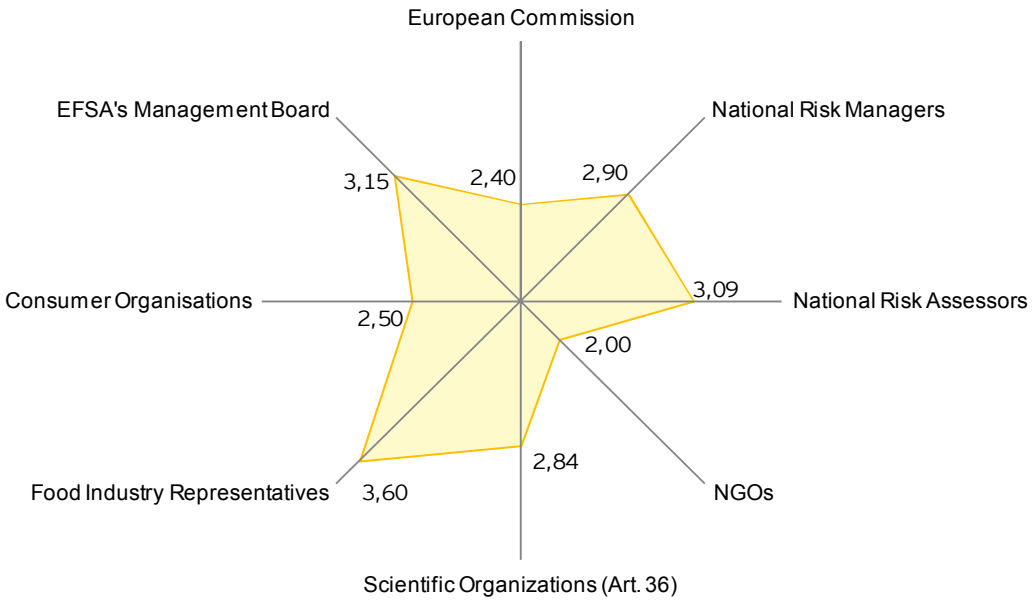
Data collection



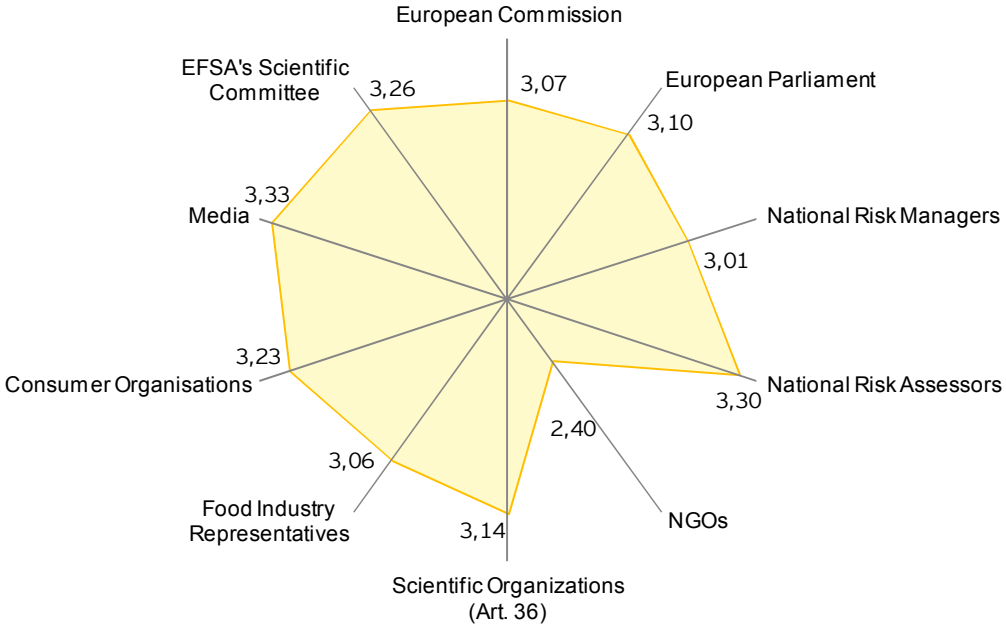
Risk communication



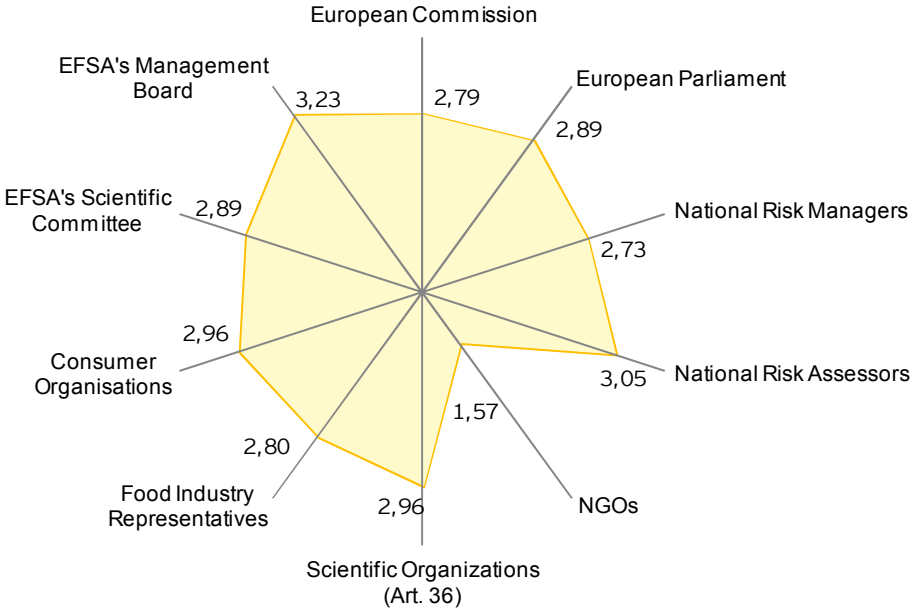
Cooperation and Networking



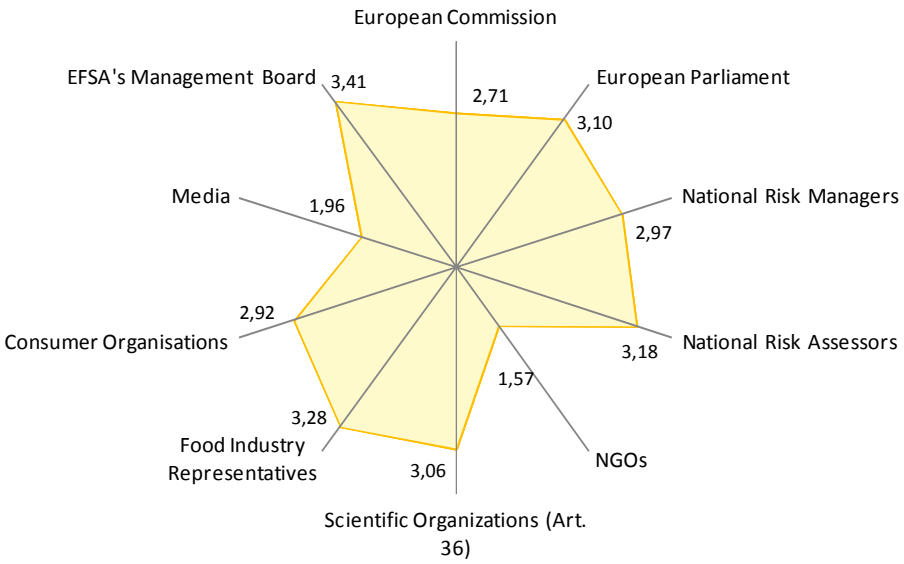
International role and recognition



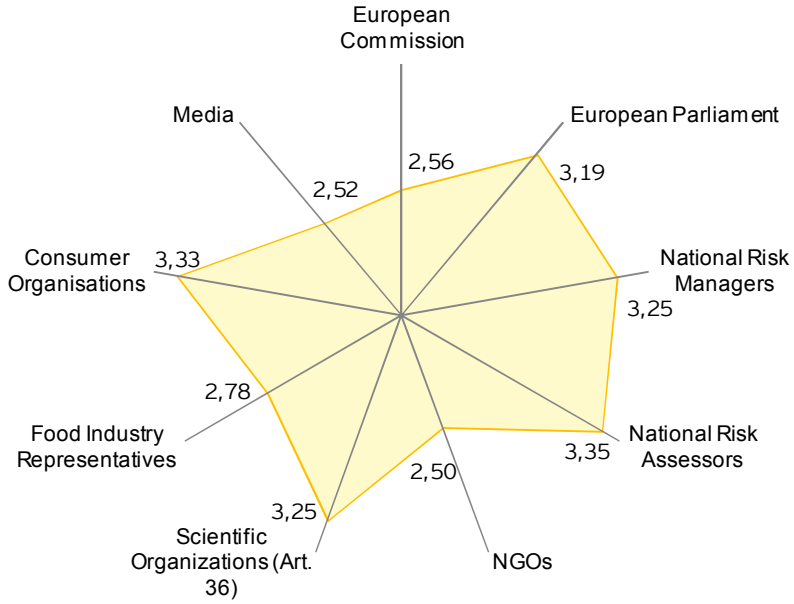
Organizational structure, operational efficiency and adaptability to change



Independence

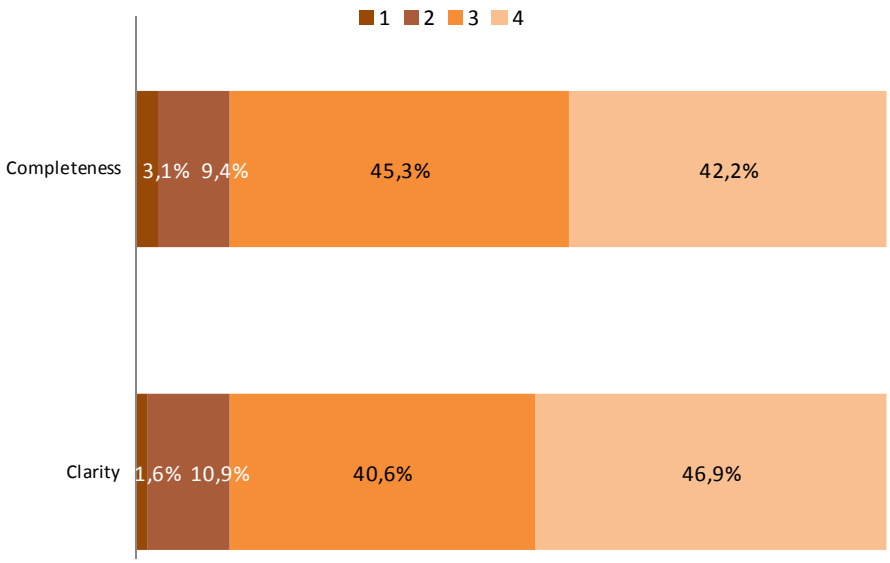


Openness and transparency



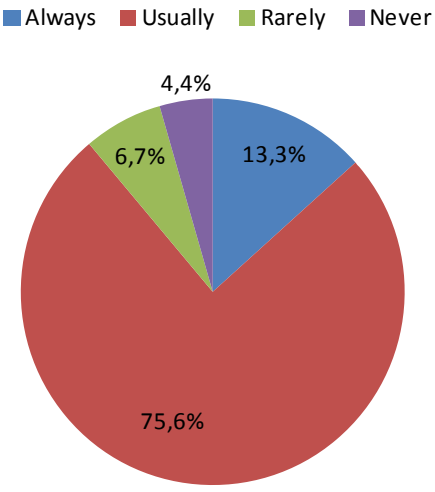
1) Provision of scientific outputs and technical support

1.1 To what extent are EFSA's scientific outputs relevant to your needs? Please specify your rating for:



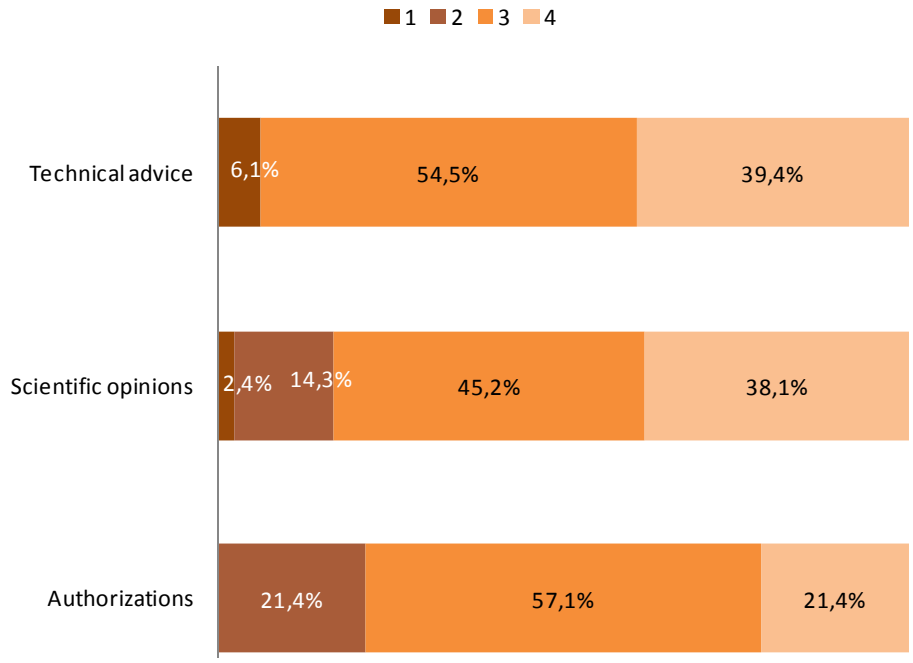
Sample composed by: 7 EC, 23 AF, 3 EP, 3 NGOs, 13 FIR/A, 5 Cons., 10 NRM

1.3 How often does EFSA meet the deadlines to issue outputs (authorizations, scientific opinions; technical advice, etc.)?



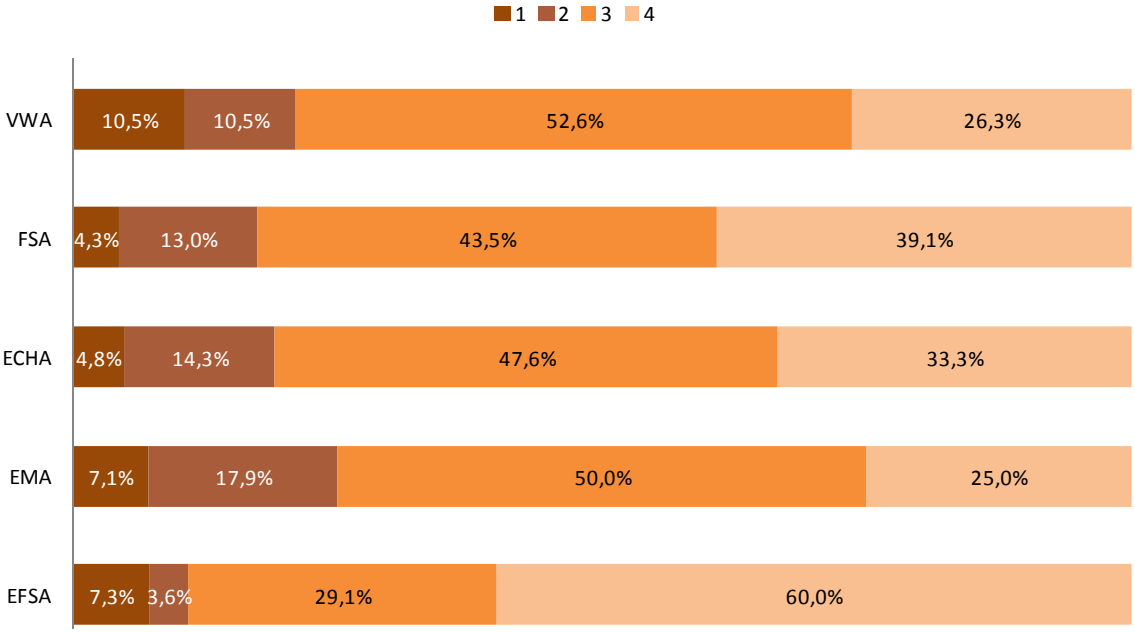
Sample composed by: 7 EC, 21 AF, 2 EP, 6 FIR/A, 9 NMR,

1.4 Please rate your level of satisfaction as for timeliness as relates the following outputs (when appropriate):



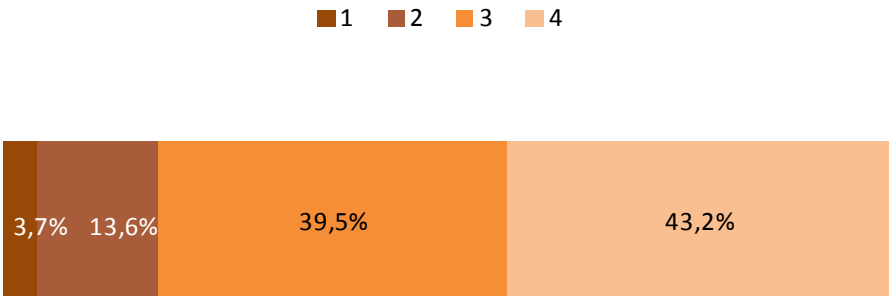
"Authorizations" and "Scientific opinions" samples composed by: 7 EC, 23 AF, 3 EP, 3 NGOs, 13 FIR/A, 5 Cons., 10 NRM
"Technical advice" sample composed by: 2 EC, 16 AF, 2 EP, 3 FIR/A, 5 NRM

1.5 Please rate the reliability of the scientific outputs for each of the following organizations:



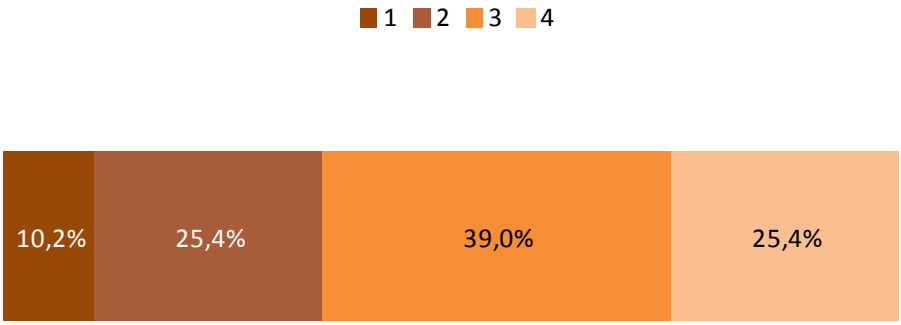
"VWA" sample composed by: 2 EC, 10 AF, 2 EP, 1 FIR/A, 5 NRM
"FSA" sample composed by: 2 EC, 10 AF, 2 EP, 1 FIR/A, 3 Cons., 5 NRM
"ECHA" sample composed by: 2 EC, 11 AF, 2 EP, 1 NGOs, 2 FIR/A, 3 NRM
"EMA" sample composed by: 2 EC, 13 AF, 2 EP, 1 NGOs, 3 FIR/A, 1 Cons., 6 NRM
"EFSA" sample composed by: 7 EC, 22 AF, 3 EP, 3 NGOs, 7 FIR/A, 4 Cons., 9 NRM

1.7 To what extent has EFSA implemented an integrated approach to deliver scientific advice?



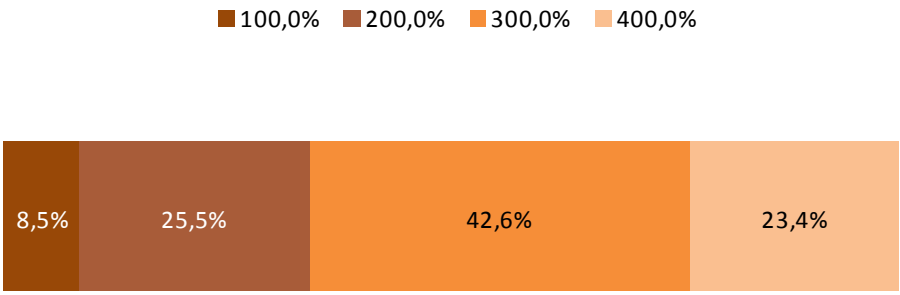
Sample composed by: 6 EC, 22 AF, 9 SC, 3 EP, 2 NGOs, 13 FIR/A, 5 Cons., 9 NRM, 12 Scient. Org.

1.8 To what extent does EFSA involve the relevant upstream stakeholders (producers, manufacturers, etc.) when delivering scientific advice associated with the food chain? Please rate:



Sample composed by: 21 AF, 9 SC, 12 FIR/A, 1 Cons., 7 NRM, 9 Scient. Org.

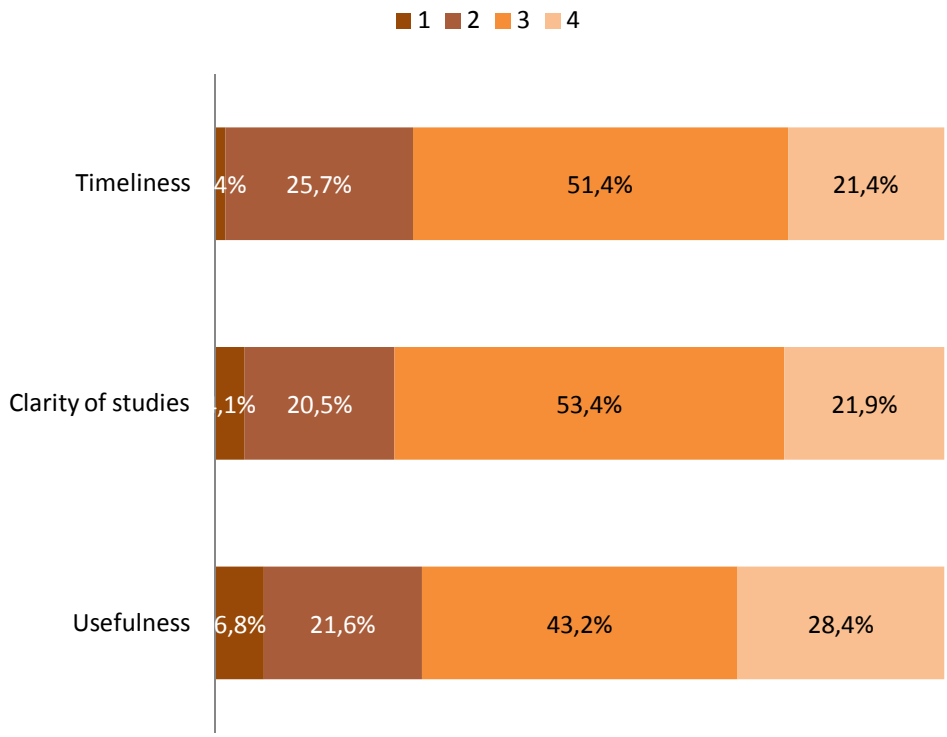
1.9 To what extent does EFSA involve the relevant downstream stakeholders (retailers, consumers, etc.) when delivering scientific advice associated with the food chain? Please rate:



Sample composed by: 21 F, 9 SC, 1 NGOs, 4 FIR/A, 5 Cons., 7 NRM

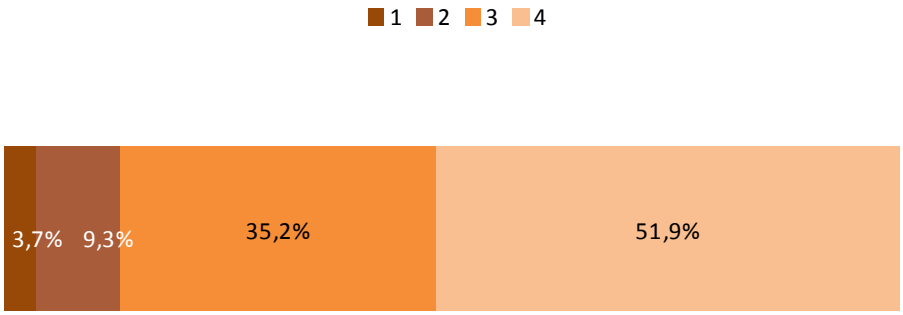
2) Self tasking function

2.1 To what extent is EFSA using its self-tasking function properly to keep abreast of emerging issues? Please specify your rating for:



"Timeliness" sample composed by: 6 EC, 23 AF, 10 SC, 3 EP, 4 FIR/A, 3 Cons., 10 NRM, 11 Scient. Org.
"Clarity of studies" sample composed by: 7 EC, 23 AF, 10 SC, 3 EP, 10 NRM, 6 FIR/A, 3 Cons., 11 Scient. Org.
"Usefulness" sample composed by: 7 EC, 23 AF, 10 SC, 3 EP, 10 NRM, 1 NGOs, 5 FIR/A, 4 Cons., 11 Scient. Org.

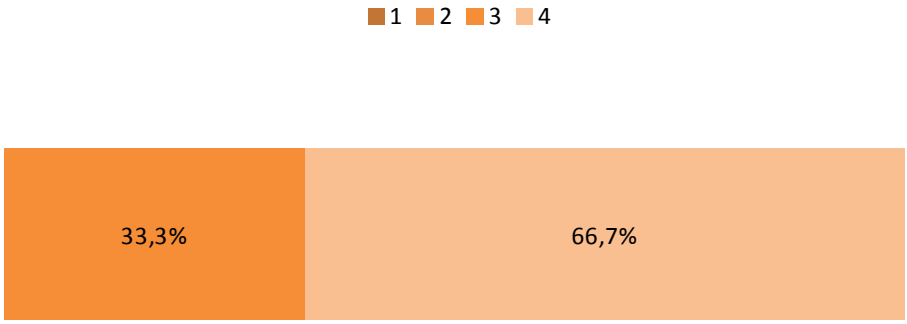
2.2 Please rate the relevance, within the scientific community, of scientific works undertaken under EFSA self-tasking function



Sample composed by: 4 EC, 22 AF, 1 NGOs, 6 FIR/A, 2 Cons., 8 NRM, 11 Scient. Org.

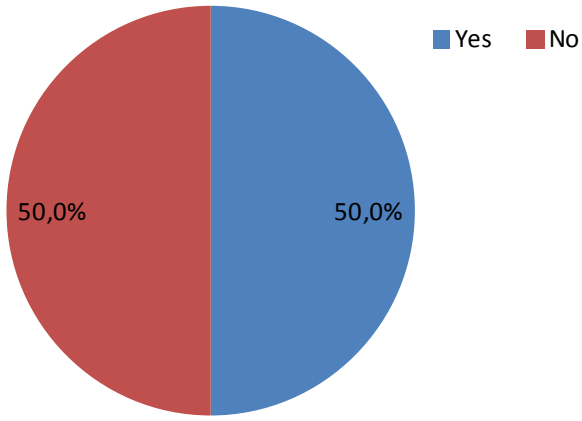
3) Support to risk managers

3.1 To what extent do EFSA's tools and activities support you in risk mitigation activities in your country? Please rate:



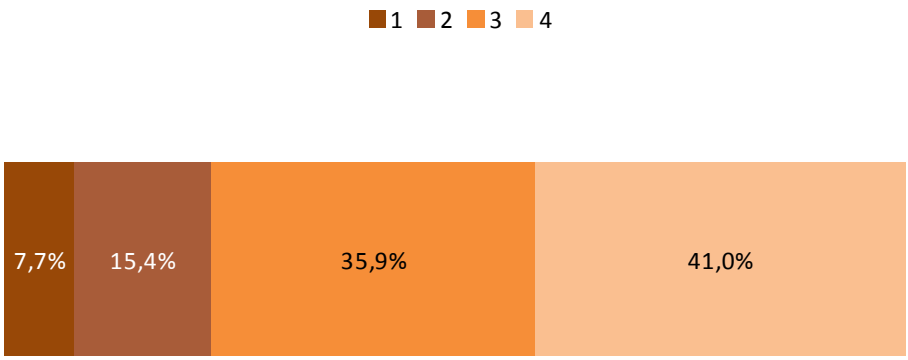
Sample composed by: 9 NMR

3.2 Do you receive support from other organizations?



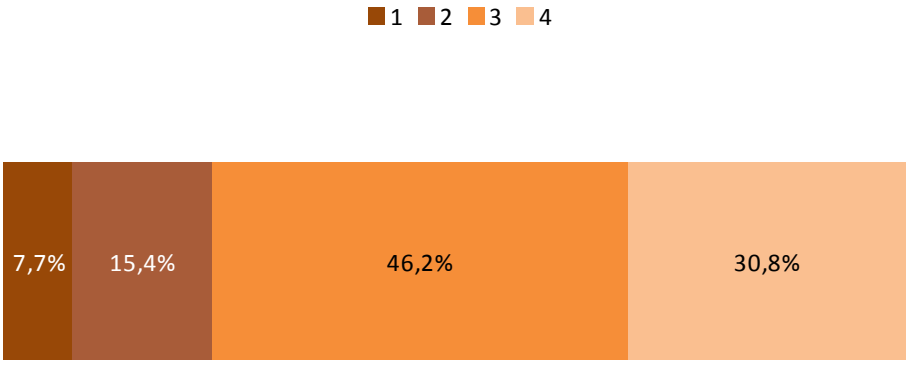
Sample composed by: 8NRM

3.3 To what extent has EFSA ensured business continuity? Please rate:



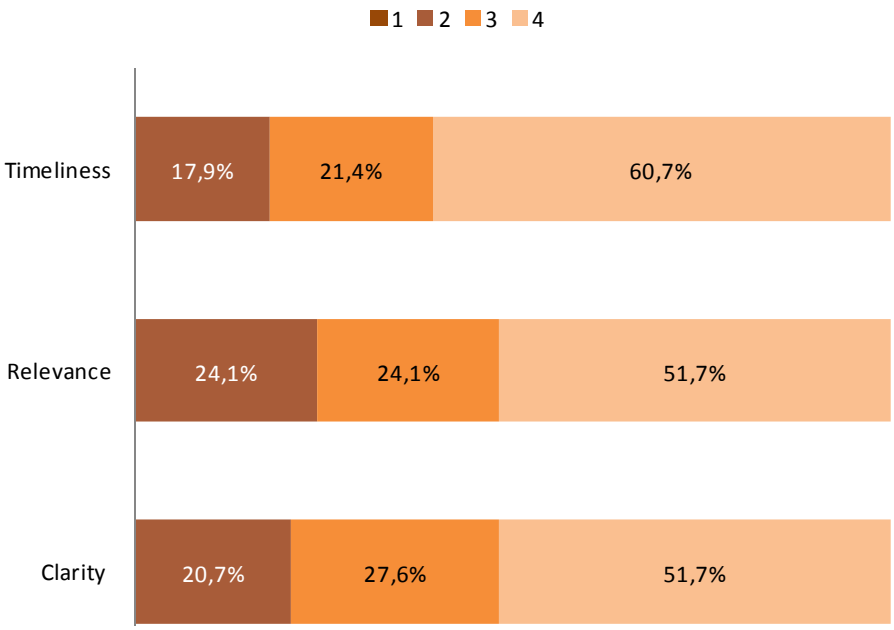
Sample composed by: 4 EC, 18 AF, 1 EP, 1 NGOs, 6 FIR/A, 9 NRM

3.4 To what extent has EFSA been able to support Risk Managers within assigned resources? Please rate:



Sample composed by: 5 EC, 1 EP, 7 NRM

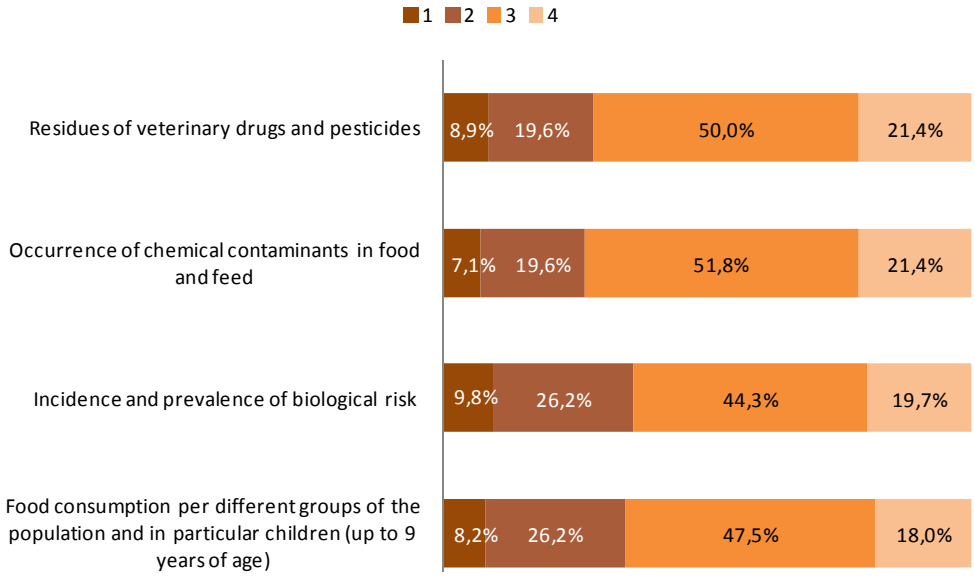
3.6 If you have requested EFSA's support to face food/feed situations emergency situations, please rate the quality of EFSA's scientific outputs in terms of:



"Timeliness" sample referred to: 6 EC, 15 AF, 1 EP, 6 NRM
"Relevance" sample referred to: 6 EC, 15 AF, 1 EP, 7 NRM
"Clarity" sample referred to: 6 EC, 15 AF, 1 EP, 6 NRM

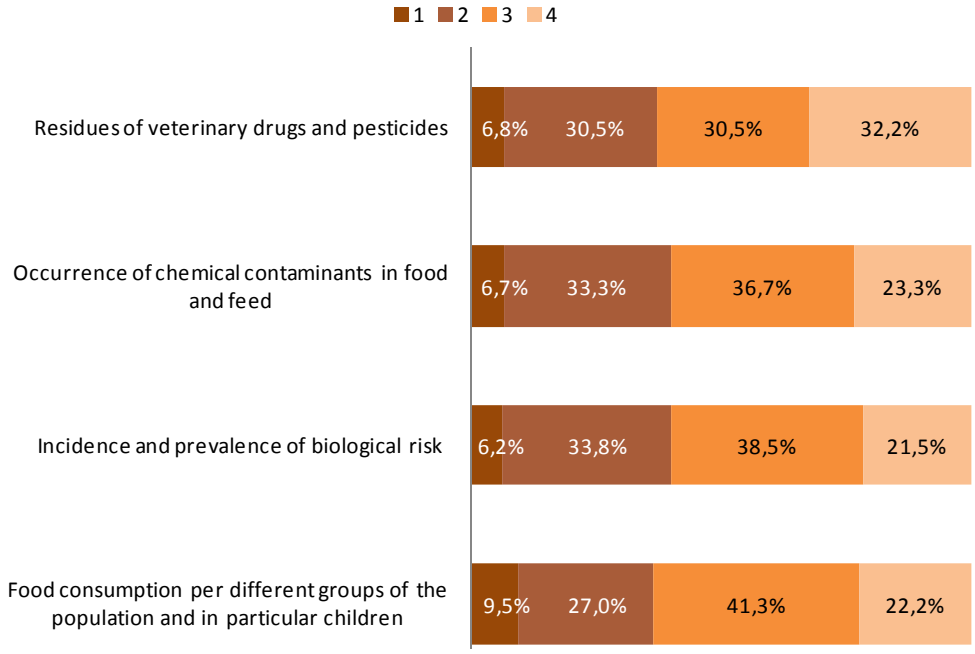
4) Data collection and analysis

4.1 Please rate the level of accessibility to databases (i.e. To what extent are EFSA's databases open to stakeholders?) related to:



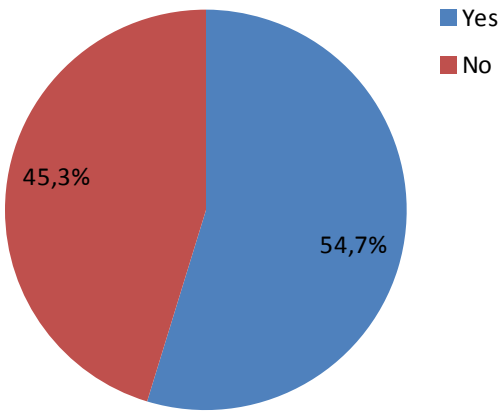
"Residues of drugs" sample composed by: 3 EC, 20 AF, 6 SC, 3 EP, 6 FIR/A, 1 Cons., 1 NGOs, 7 NRM, 9 Scient. Org.
"Occurrence" sample composed by: 3 EC, 19 AF, 6 SC, 3 EP, 8 FIR/A, 1 Cons., 1 NGOs, 6 NRM, 9 Scient. Org.
"Incidence" sample composed by: 3 EC, 19 AF, 8 SC, 3 EP, 8 FIR/A, 1 Cons., 1 NGOs, 9 NRM, 9 Scient. Org.
"Food consumpt." sample composed by: 4 EC, 20 AF, 6 SC, 3 EP, 11 FIR/A, 1 Cons., 1 NGOs, 5 NRM, 10 Scient. Org.

4.2 Please rate the level of availability of data (i.e. To what extent are data included in databases comprehensive?) related to:



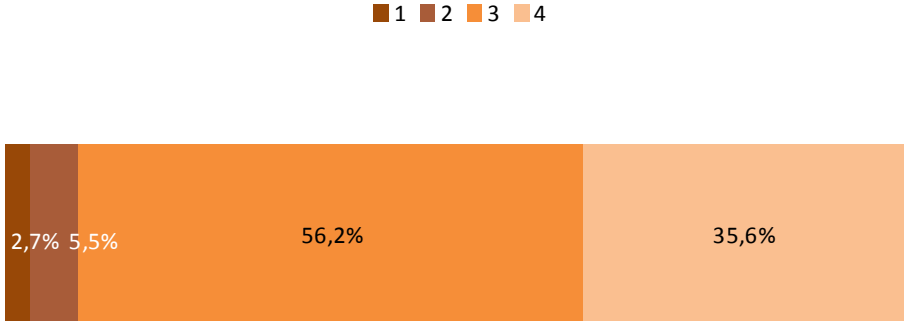
"Residues of drugs" sample composed by: 4 EC, 22 AF, 6 SC, 3 EP, 6 FIR/A, 1 Cons., 9 NRM, 9 Scient. Org.
"Occurrence" sample composed by: 3 EC, 22 AF, 6 SC, 3 EP, 8 FIR/A, 1 Cons., 8 NRM, 9 Scient. Org.
"Incidence" sample composed by: 4 EC, 21 AF, 8 SC, 3 EP, 8 FIR/A, 1 Cons., 1 NGOs, 11 NRM, 8 Scient. Org.
"Food consumpt." sample composed by: 4 EC, 22 AF, 6 SC, 3 EP, 9 FIR/A, 1 Cons., 1 NGOs, 7 NRM, 10 Scient. Org.

4.3 In your view are there are any data gaps?



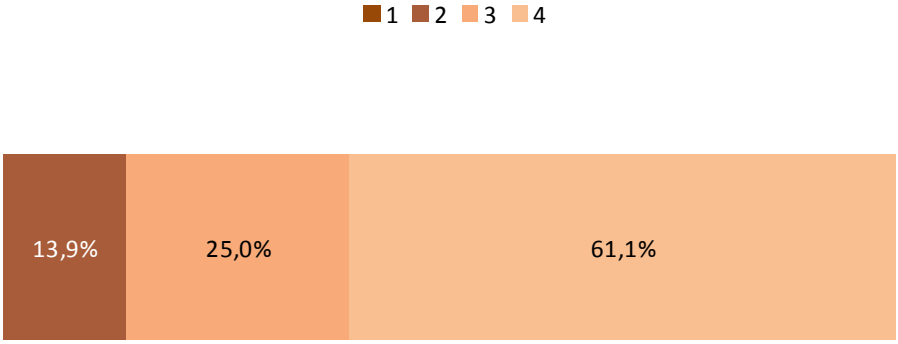
Sample composed by: 5 EC, 17 AF, 5 SC, 2 EP, 1 NGOs, 7 FIR/A, 1 Cons., 9 NMR, 6 Scient. Org.

4.4 Are you satisfied with the quality of reports on data collection provided by EFSA? Please rate:



Sample composed by: 5 EC, 22 AF, 9 SC, 3 EP, 1 NGOs, 10 FIR/A, 5 Cons., 10 NMR, 8 Scient. Org.

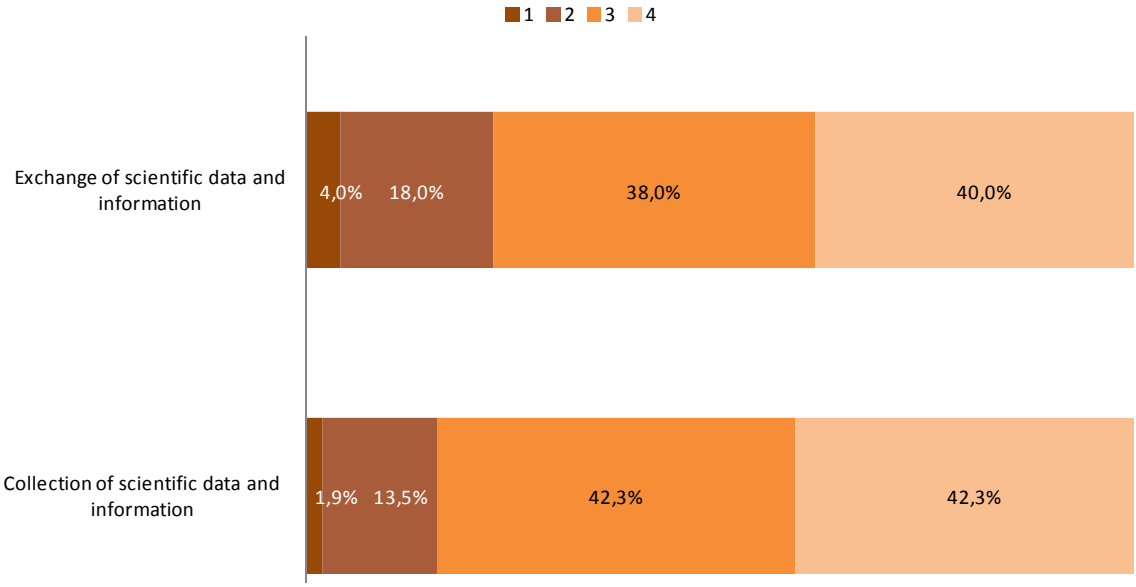
4.5 Please rate the clarity of EFSA's recommendations for appropriate data collection methodologies



Sample composed by: 4 EC, 21 AF, 11 NRM

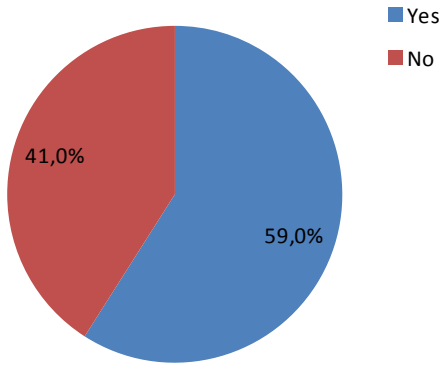
5) Cooperation for Data collection

5.1 Please rate the adequacy of EFSA's system of cooperation as relates:



"Exchange of scientific data" sample composed by: 5 EC, 23 AF, 9 FIR/A, 2 Cons., 11 NRM
"Collection of scientific data" sample composed by: 5 EC, 23 AF, 10 FIR/A, 3 Cons., 11 NRM

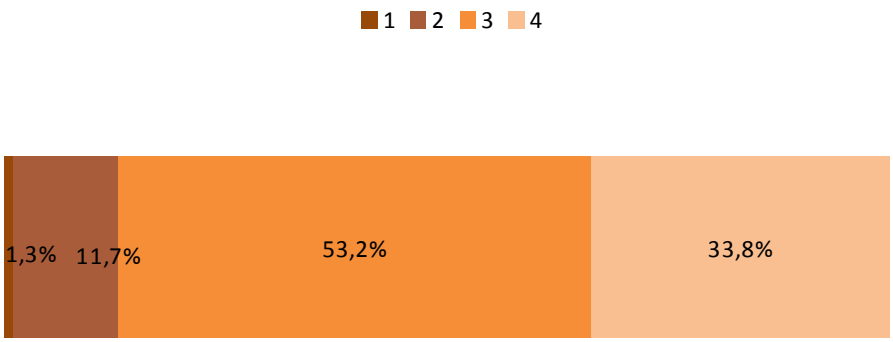
5.2 Do you think you could provide more valuable support?



Sample composed by: 23 AF, 7 FIR/A, 9 NMR

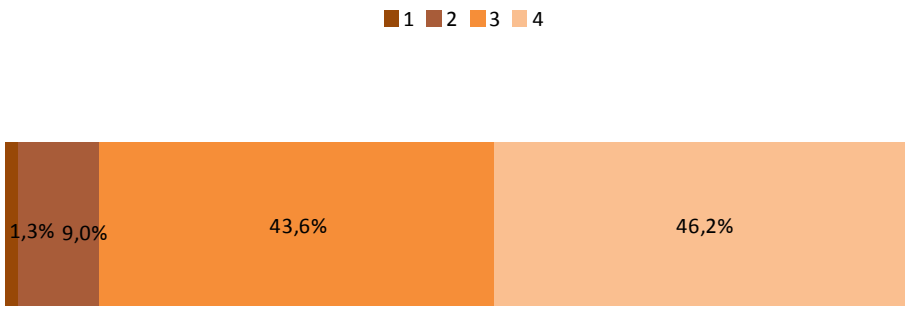
6) Quality of Data

6.1 Are you satisfied with the quality of EFSA's data in order to produce your work? Please rate:



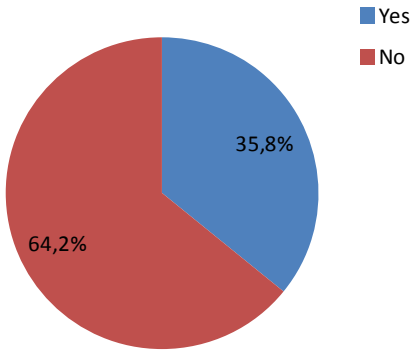
Sample composed by: 7 EC, 22 AF, 10 SC, 3 EP, 2 NGOs, 10 FIR/A, 5 Cons., 10 NRM, 8 Scient. Org.

6.2 Please rate the reliability of data underpinning EFSA's opinions



Sample composed by: 7 EC, 22 AF, 10 SC, 3 EP, 2 NGOs, 9 FIR/A, 5 Cons., 10 NRM, 10 Scient. Org.

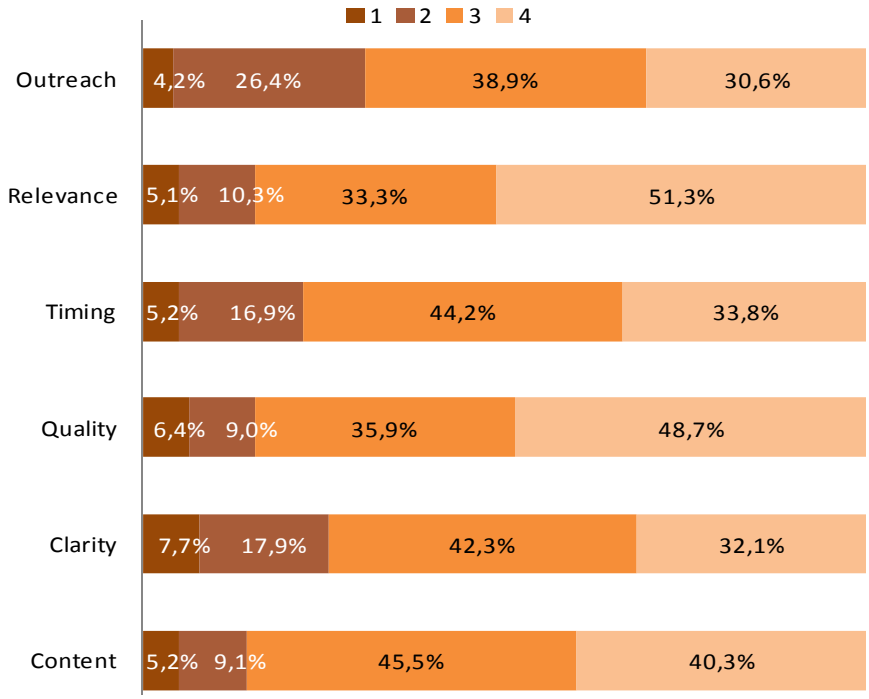
6.3 Do you have in place any quality system that supports the appropriateness of scientific outputs and data?



Sample composed by: 4 EC, 19 AF, 1 EP, 1 NGOs, 8 FIR/A, 2 Cons., 9 NRM, 9 Scient. Org.

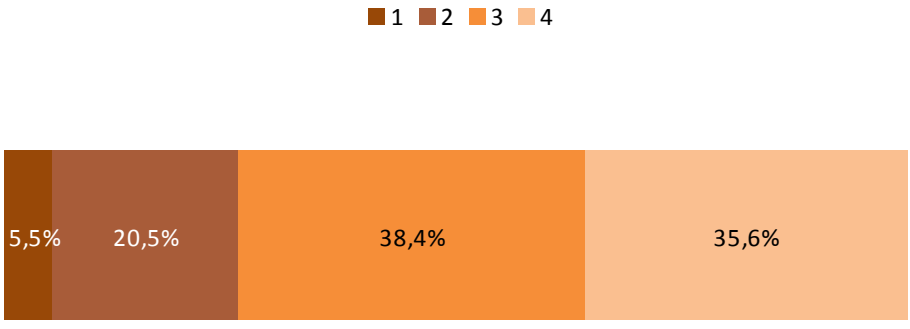
7) Risk Communication

7.1 Please rate EFSA's communication as relates to:



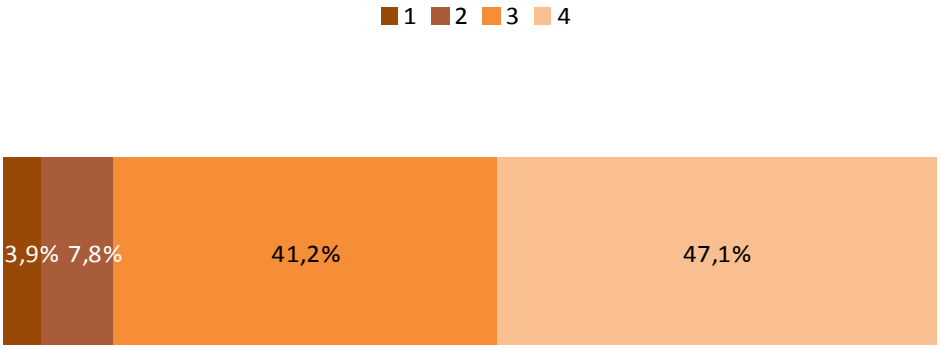
"Outreach" sample composed by: 7 EC, 21 AF, 11 FIR/A, 2 Media, 3 EP, 5 Cons., 2 NGOs, 10 NRM, 11 Scient. Org.
"Relevance" sample composed by: 7 EC, 23 AF, 13 FIR/A, 3 Media, 3 EP, 2 NGOs, 5 Cons., 11 NRM, 11 Scient. Org.
"Timing" sample composed by: 6 EC, 23 AF, 13 FIR/A, 3 Media, 3 EP, 2 NGOs, 5 Cons., 11 NRM, 11 Scient. Org.
"Quality" sample composed by: 7 EC, 23 AF, 13 FIR/A, 3 Media, 3 EP, 2 NGOs, 5 Cons., 11 NRM, 11 Scient. Org.
"Clarity" sample composed by: 7 EC, 23 AF, 13 FIR/A, 3 Media, 3 EP, 2 NGOs, 5 Cons., 11 NRM, 11 Scient. Org.
"Content" sample composed by: 7 EC, 23 AF, 12 FIR/A, 3 Media, 3 EP, 2 NGOs, 5 Cons., 11 NRM, 11 Scient. Org.

7.2 To what extent has EFSA communication activity increased awareness of the risks in the food chain? Please rate:



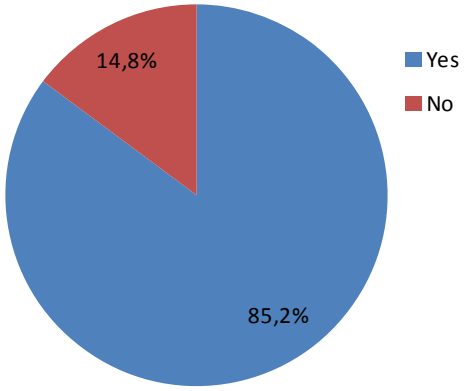
Sample composed by: 5 EC, 23 AF, 3 EP, 1 NGOs, 12 FIR/A, 3 Media, 5 Cons., 10 NRM, Scient. Org.

7.4 Please rate the coherence of the communication on risks in the food chain



Sample composed by: 5 EC, 20 AF, 3 EP, 3 Cons., 10 NRM, 10 Scient. Org.

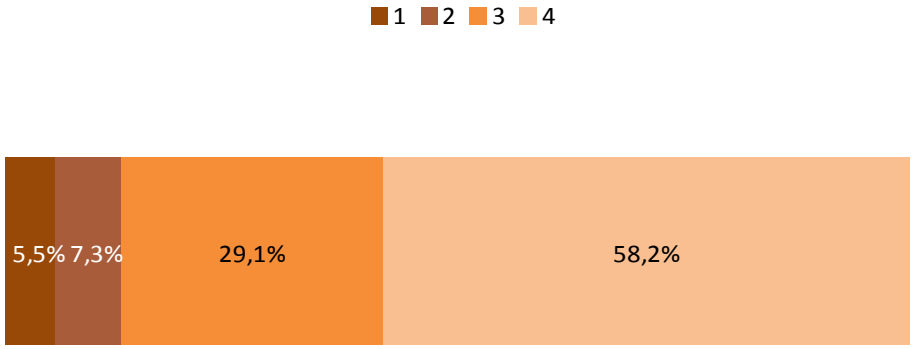
7.5 Are there other opinions (besides EFSA's ones) you take into account in your activities?



Sample composed by: 7 EC, 22 AF, 3 EP, 2 Cons., 10 NRM, 10 Scient. Org.

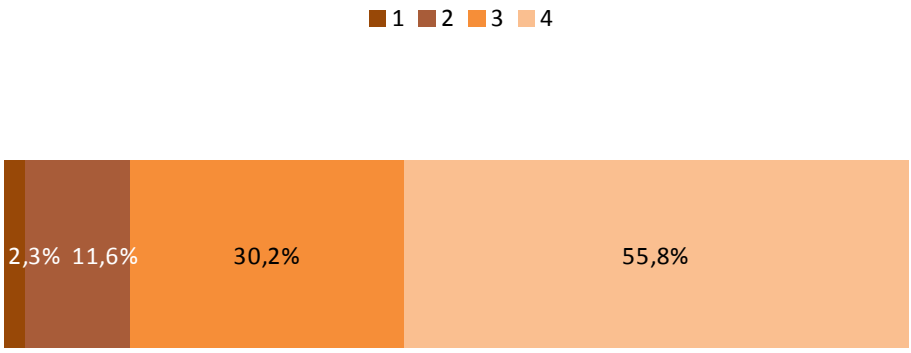
8) Risk Communication effectiveness

8.1 Please rate your trust in EFSA's activities and in the overall food safety system



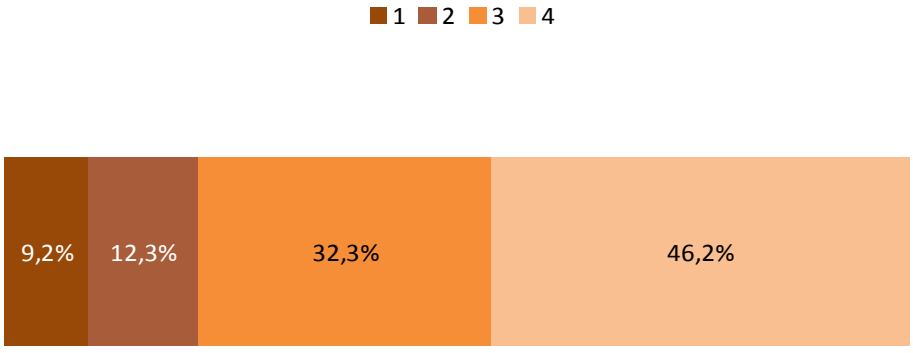
Sample composed by: 10 SC, 2 NGOs, 13 FIR/A, 3 Media, 5 Cons., 10 NRM, 12 Scient. Org.12

8.2 To what extent is EFSA risk assessment system reliable? Please rate:



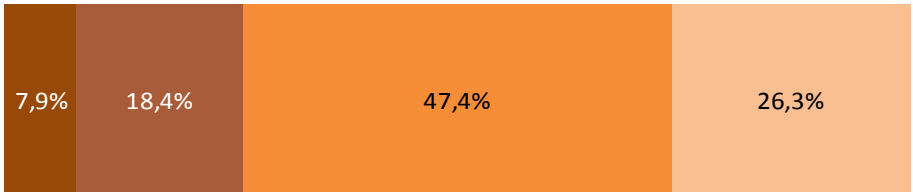
Sample composed by: 7 EC, 23 AF, 3 EP, 10 NRM

8.3 Are you satisfied with EFSA's capacity to dialogue? Please rate:



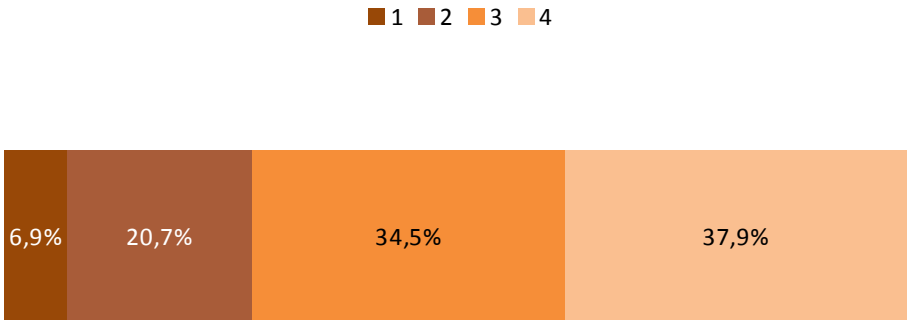
Sample composed by: 7 EC, 23 AF, 3 EP, 1 NGOs, 6 FIR/A, 3 Cons., 10 NRM, 12 Scient. Org.

8.4 To what extent have divergent scientific opinions decreased since EFSA creation? Please rate:



Sample composed by: 7 EC, 18 AF, 5 FIR/A, 8 NRM

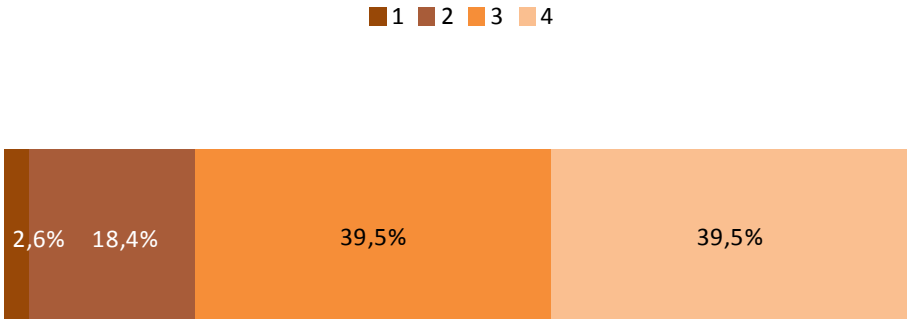
8.5 To what extent is the Advisory Forum Working Group on Communications promoting coherence? Please rate:



Sample composed by: 2 EC, 21 AF, 6 NRM

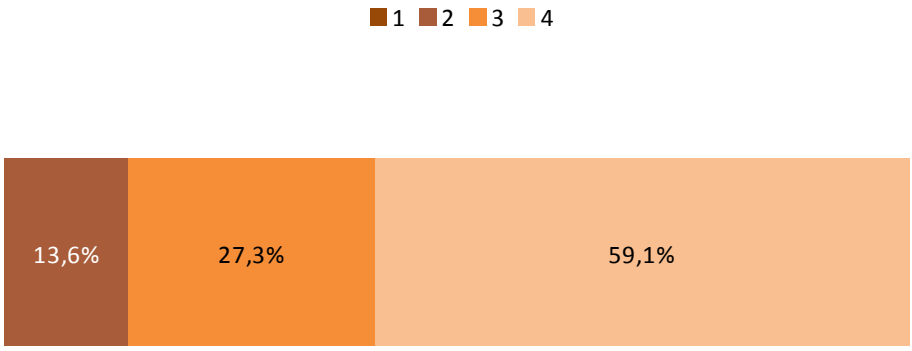
9) Cooperation and networking

9.1 To what extent is EFSA cooperating to promote coherence between risk assessment, risk management and risk communication? Please rate:



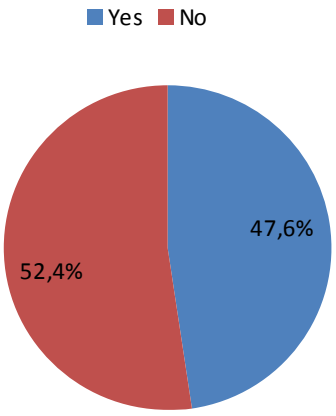
Sample composed by: 5 EC, 23 AF, 10 NRM

9.2 To what extent are risk assessment methodologies you use, coherent with EFSA guidelines? Please rate:



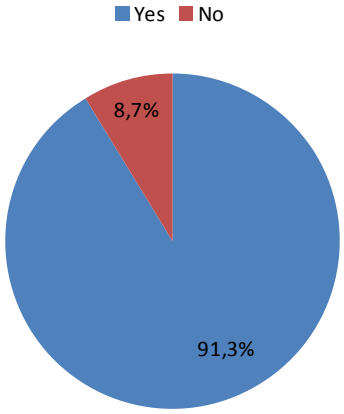
Sample composed by: 22 AF

9.3 Have you ever had situations of misalignment with EFSA's advices?



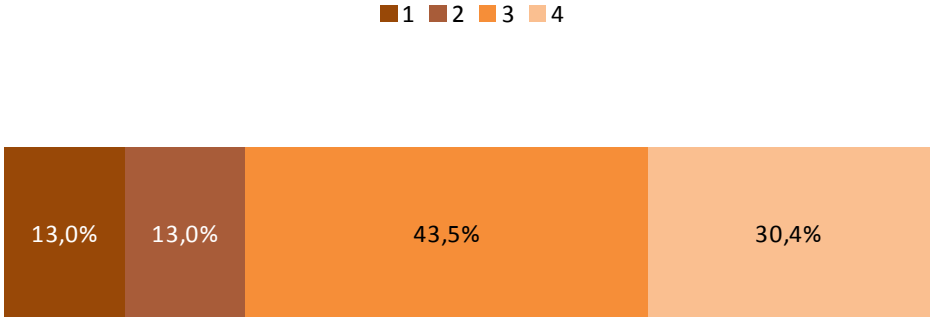
Sample composed by: 21AF

9.4 Do you benefit from taking part to the EFSA Advisory Forum meetings when you deal with specific requests of your Risk Manager?



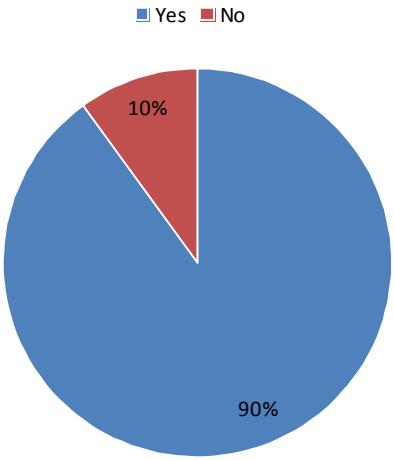
Sample composed by: 23 AF

9.5 To what extent do you share work programmes, risk assessment practices or methodologies in Advisory Forum meetings? Please rate:



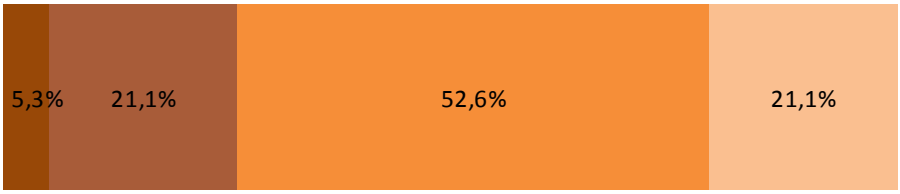
Sample composed by: 23 AF

9.6 Do you benefit from having a national risk assessor representative attending EFSA Advisory Forum meetings when adopting a policy?



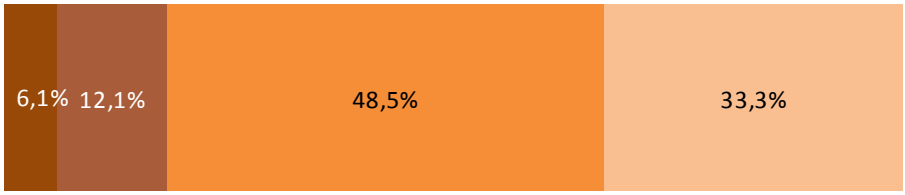
Sample composed by: 10 NRM

9.7 Please rate the role of EFSA as an interface between Risk Assessors and Risk Managers



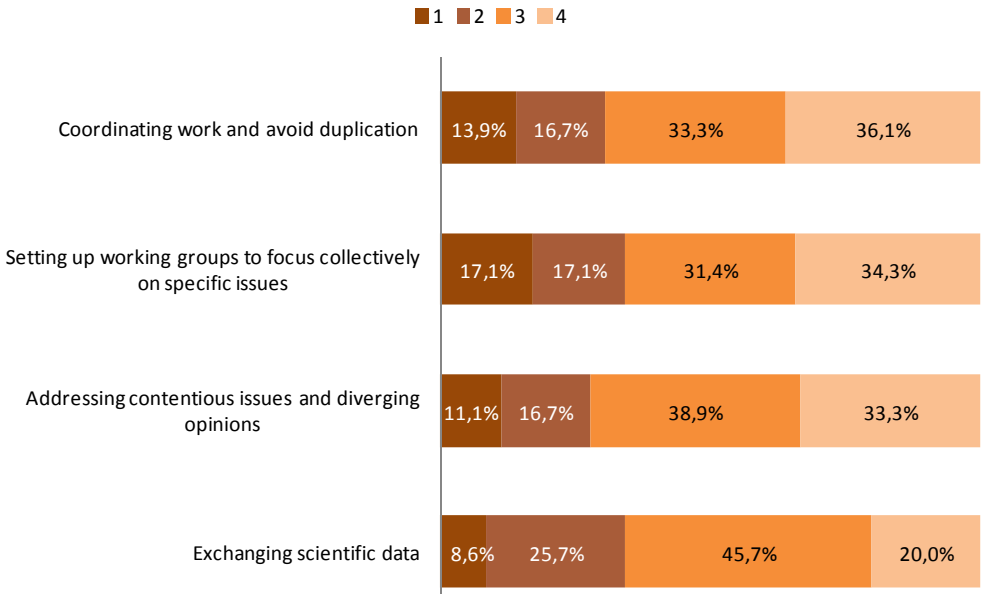
Sample: 2 NGOs, 5 FIR/A, 2 Cons., 10 Scient. Org.

9.8 To what extent is EFSA taking benefits from the presence of the Advisory Forum? Please rate:



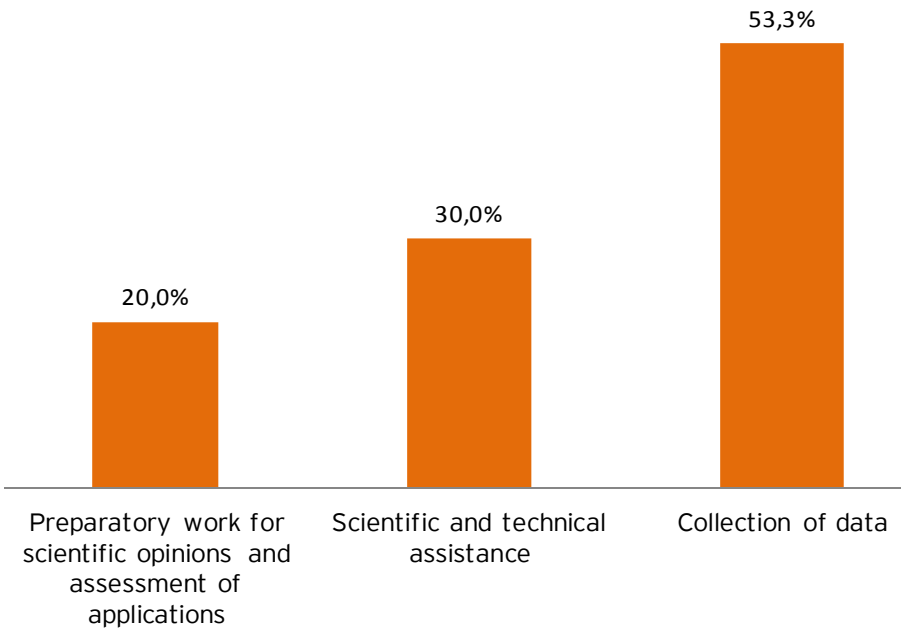
Sample composed by: 2 EC, 23 AF, 8 NRM

9.9 To what extent are the processes related to the Advisory Forum effective?



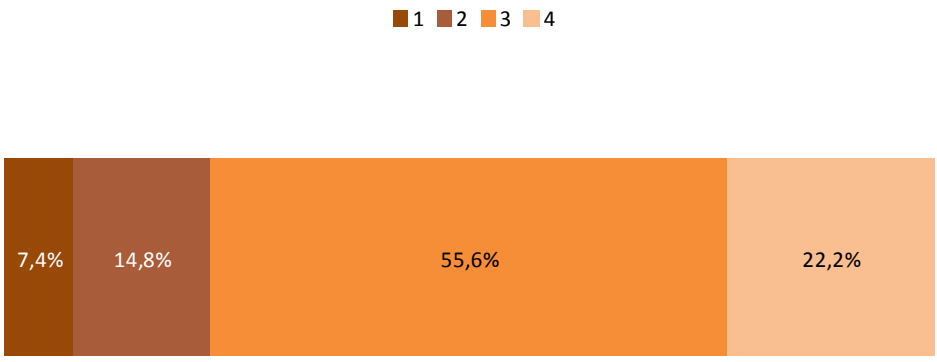
"Coordinating work" sample composed by: 23 AF, 4 EC, 9 NRM
"Setting up working group" sample composed by: 23 AF, 3 EC, 9 NRM
"Addressing contentious issues" sample composed by: 23 AF, 4 EC, 9 NRM
"Coordinating work and avoid duplication" sample composed by: 23 AF, 4 EC, 8 NRM

9.10 What is the activity where there is the highest involvement of external organizations (e.g. as per through art.36 grants, procurements, etc.)?



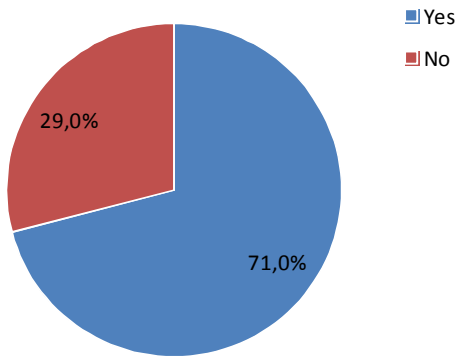
Sample composed by: 2 EC, 10 SC, 1 NGOs, 6 FIR/A, 12 Scient.Org.

9.11 Please rate the quality of the support (in terms of expertise) provided by the Member State agencies (or other types of national bodies in charge of risk assessment) to sustain EFSA's work



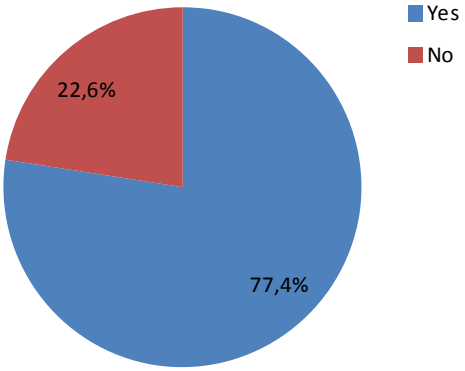
Sample composed by: 5 EC, 13 MB, 9 Scient. Org.

9.12 Have you registered a reduction of risk assessment activities in your organization after EFSA creation?



Sample composed by: 3 EC, 19 AF, 9 NRM

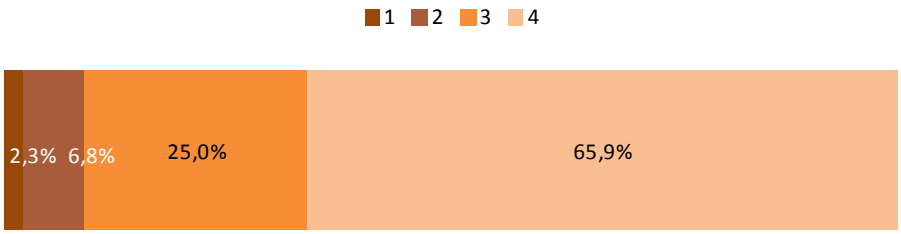
9.13 Does your national food safety authority benefit from EFSA's activities in terms of cost savings?



Sample composed by: 22 AF, 9 NRM

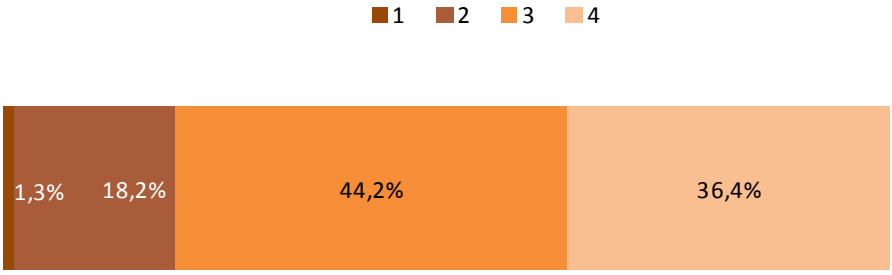
10) EFSA's international role and recognition

10.1 To what extent do you recognize EFSA at the forefront of risk assessment methodologies in Europe? Please rate:



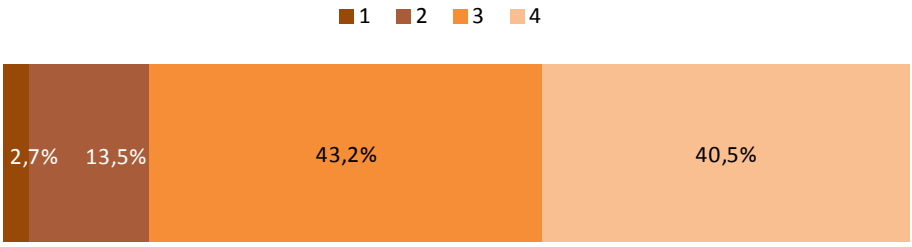
Sample composed by: 7 EC, 23 AF, 3 EP, 11 NRM

10.2 To what extent is EFSA involved in the international scientific community? Please rate:



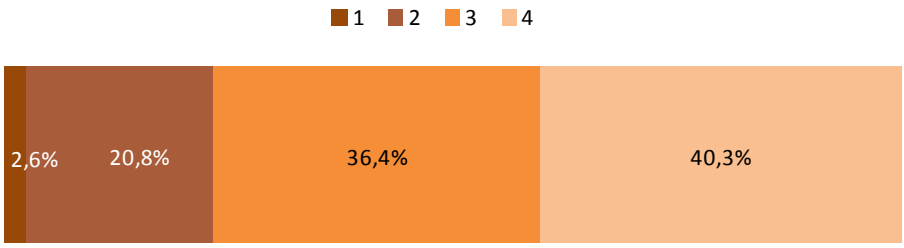
Sample composed by: 6 EC, 23 AF, 10 SC, 3 EP, 6 FIR/A, 3 Media, 3 Cons., 11 NRM, 12 Scient. Org.

10.3 To what extent does EFSA involvement in the international scientific community provide added value? Please rate:



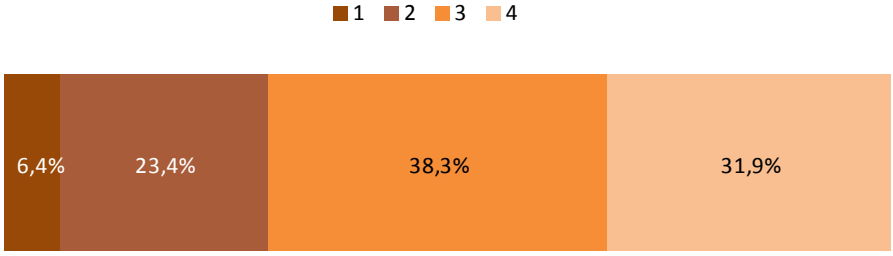
Sample composed by: 10 SC, 3 EP, 7 FIR/A, 3 Media, 2 Cons., 12 Scient. Org.

10.4 Please rate the level of recognition of EFSA as a player of the international scientific community



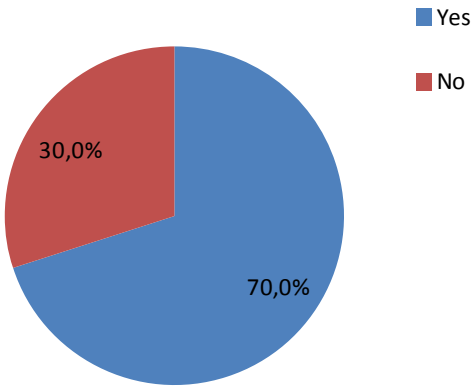
Sample composed by: 7 EC, 23 AF, 10 SC, 3 EP, 6 FIR/A, 3 Media, 2 Cons., 11 NRM, 12 Scient. Org.

10.5 To what extent does EFSA contribute to the detection of risks in the food chain? Please rate:



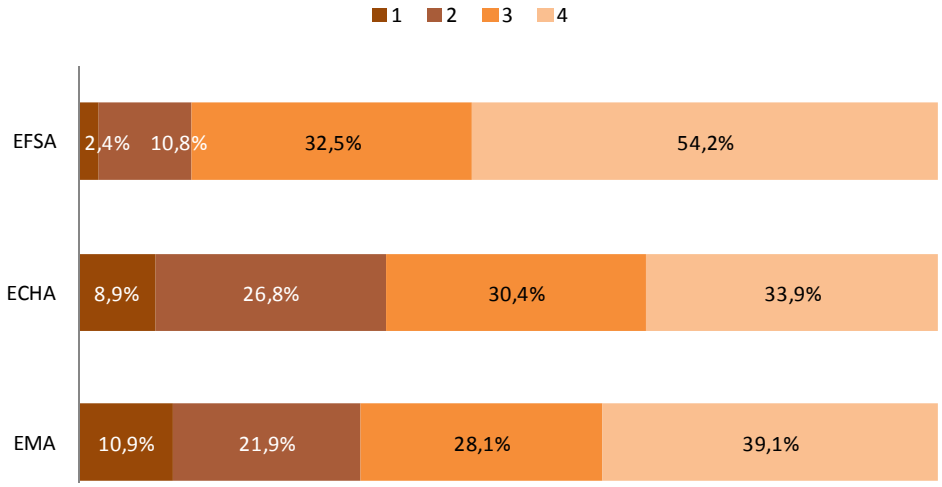
Sample composed by: 7 EC, 13 FIR/A, 4 Cons., 11 NRM, 12 Scient. Org.

10.6 Do you have more information on the risks of the food chain since the creation of EFSA?



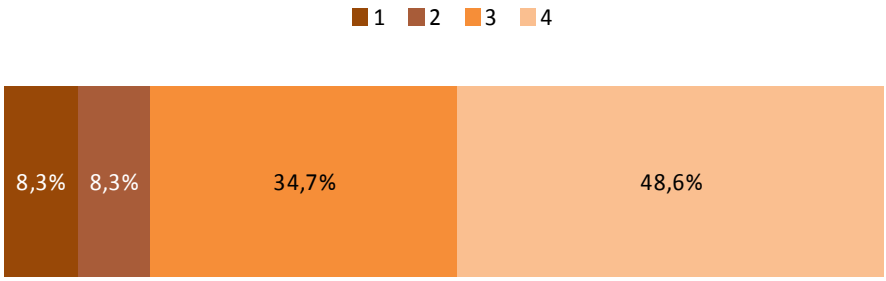
Sample composed by: 7 EC, 4 FIR/A, 1 Cons., 9 NRM, 9 Scient. Org.

10.8 Please rate the following organizations according to their importance at EU and international level?



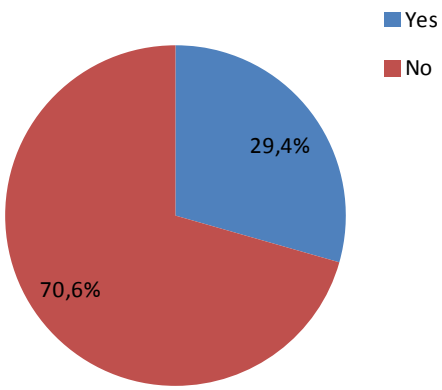
"EMA" sample composed by: 4 EC, 18 AF, 7 SC, 2 EP, 2 NGOs, 10 FIR/A, 2 Media, 1 Cons., 9 NRM, 9 Scient. Org.
"ECHA" sample composed by: 2 EC, 15 AF, 7 SC, 2 EP, 1 NGOs, 10 FIR/A, 3 Media, 9 NRM, 9 Scient. Org.
"EFSA" sample composed by: 7 EC, 21 AF, 10 SC, 3 EP, 2 NGOs, 13 FIR/A, 3 Media, 2 Cons., 11 NRM, 11 Scient. Org.

10.10 How useful do you consider events organized by EFSA (e.g. scientific colloquia on scientific topics)? Please rate:



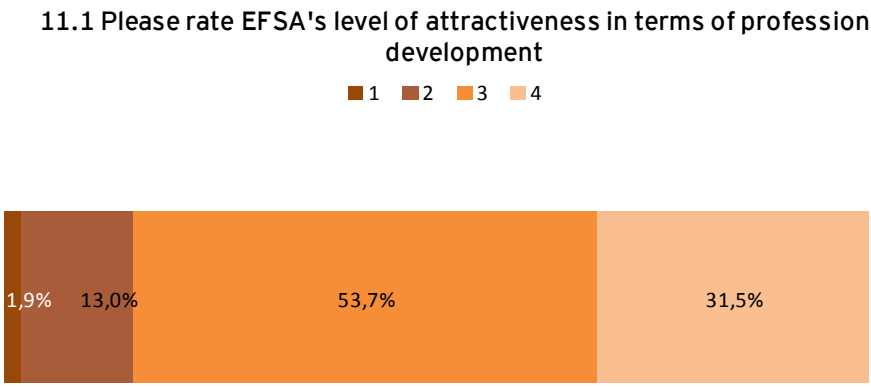
Sample composed by: 7 EC, 23 AF, 10 SC, 2 NGOs, 7 FIR/A, 2 Cons., 10 NRM, 11 Scient. Org.

10.11 Do you have visibility on EFSA's participation to international programmes?



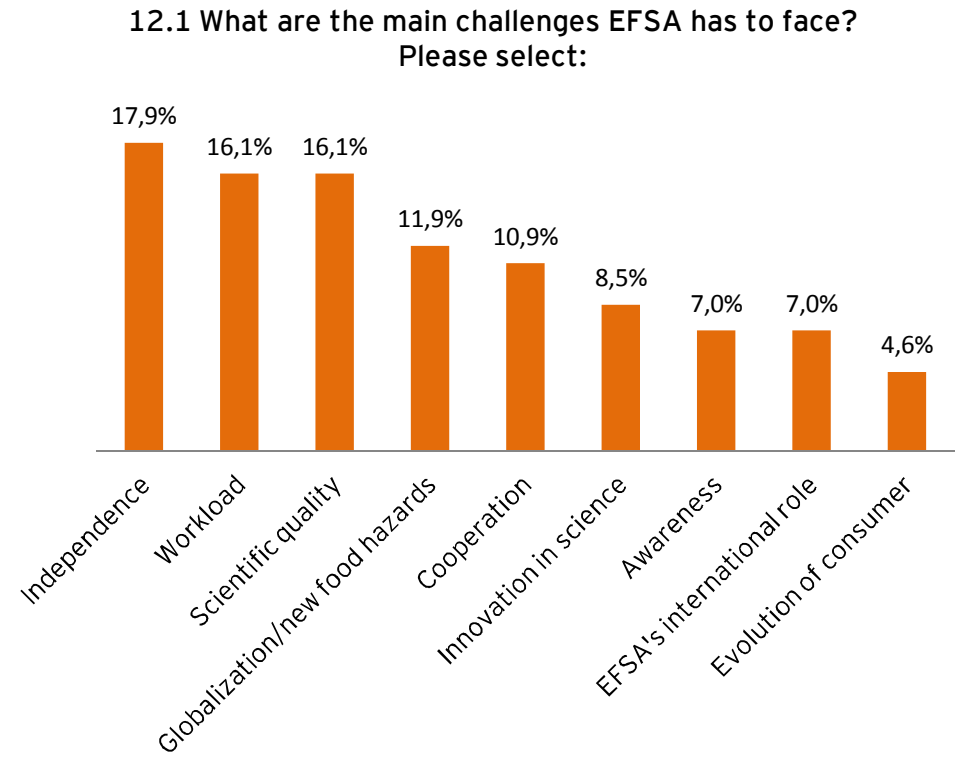
Sample composed by: 1 NGOs, 5 FIR/A, 2 Cons., 9 Scient. Org.

11) EFSA professional attractiveness



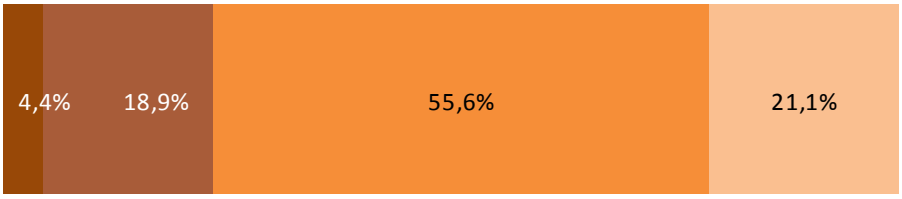
Sample composed by: 4 EC, 23 AF, 9 SC, 2 NGOs, 6 FIR/A, 10 Scient. Org.

12) EFSA structure



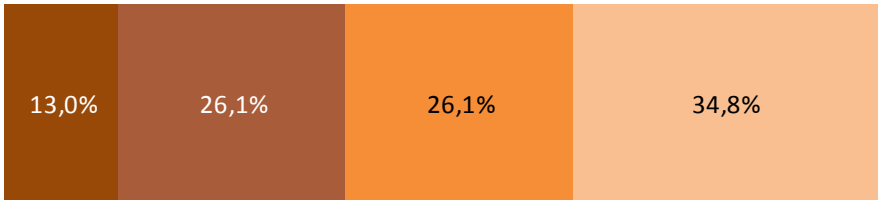
Sample composed by: 8 EC, 23 AF, 13 MB, 3 EP, 3 NGOs, 13 FIR/A, 5 Cons., 11 NRM, 12 Scient. Org.

12.2 To what extent is EFSA able to cope with the new challenges it has to face? Please rate:



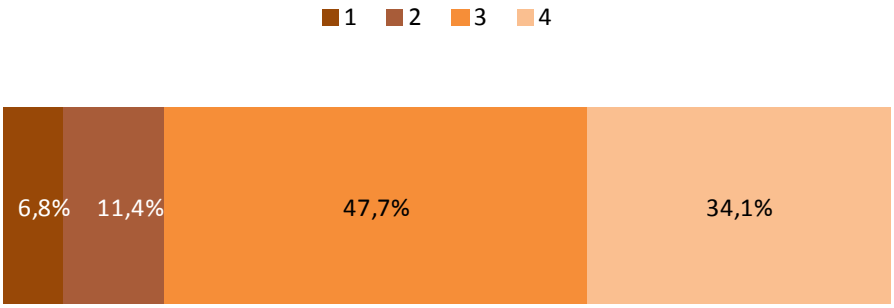
Sample composed by: 8 EC, 23 AF, 13 MB, 3 EP, 3 NGOs, 12 FIR/A, 5 Cons., 11 NRM, 12 Scient. Org.

12.3 To what extent do EFSA structure and organization meet your needs?

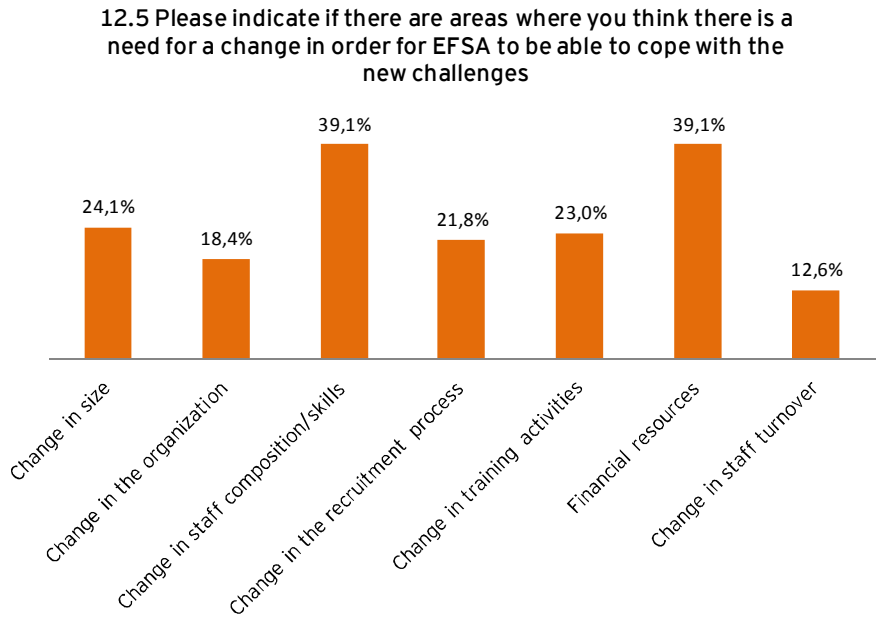


Sample composed by: 7 EC, 6 FIR/A, 10 NRM

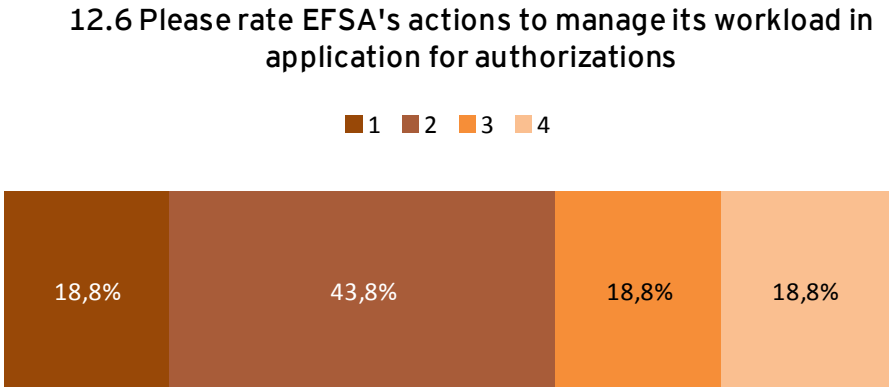
12.4 Please rate the structure of the new organization (May 2011) in comparison with the previous one



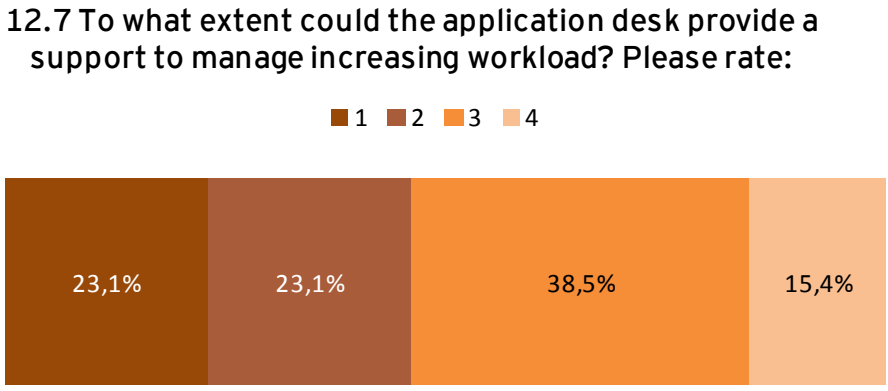
Sample composed by: 4 EC, 20 AF, 13 MB, 1 NGOs, 5 FIR/A, 1 Cons.



Sample composed by: 8 EC, 23 AF, 13 MB, 3 EP, 2 NGOs, 13 FIR/A, 2 Cons., 11 NRM, 12 Scient. Org.



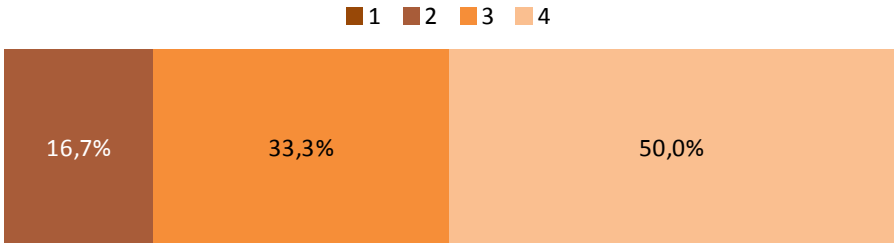
Sample composed by: 5 EC, 4 FIR/A, 7 NRM



Sample composed by: 2 EC, 4 FIR/A, 7 NRM

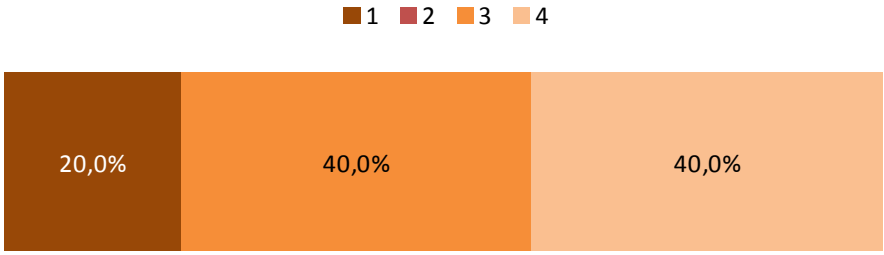
13) Resource allocation

13.1 To what extent does the information provided by EFSA on its budget and resource allocation meet your requirements?



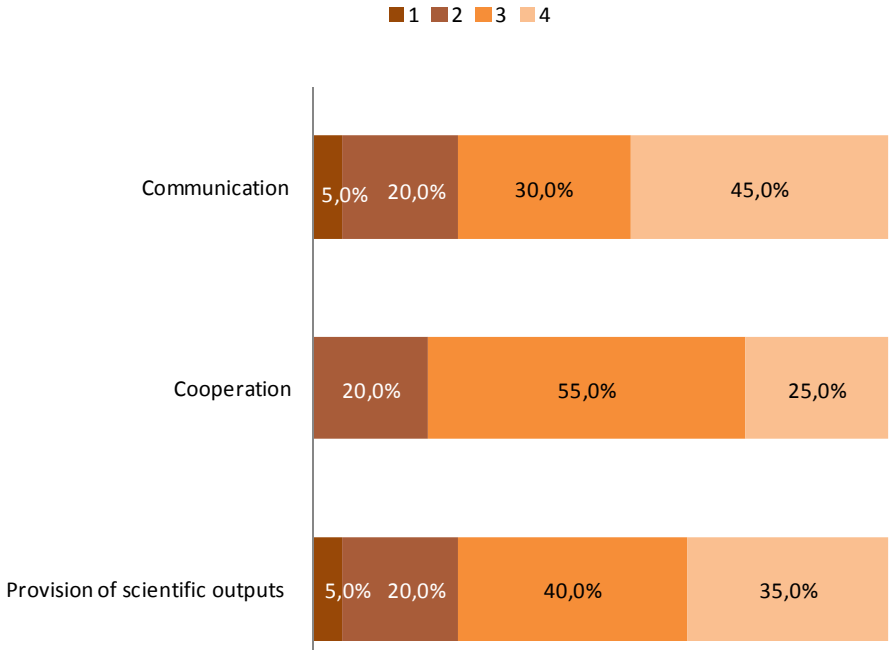
Sample composed by: 6 EC

13.2 To what extent does the information provided by EFSA on its human resources (actual and foreseen) meet your requirements? Please rate:



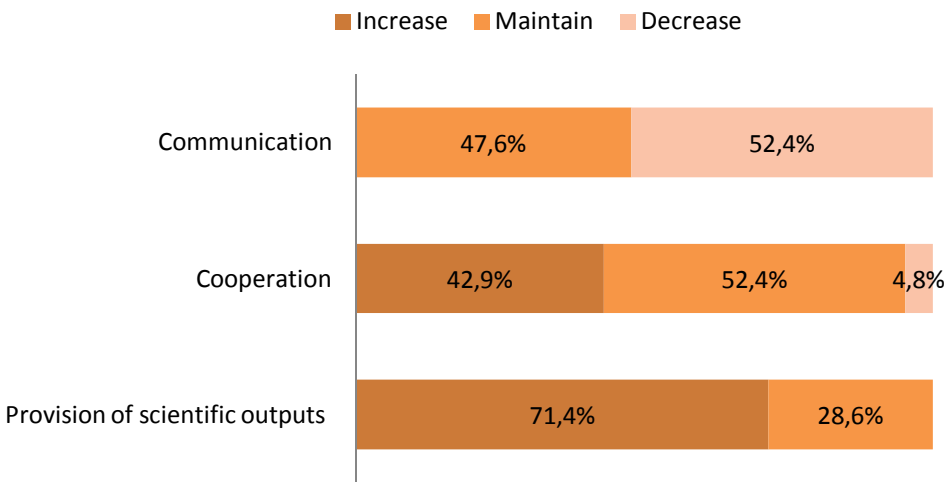
Sample composed by: 5 EC

13.3 Please rate the adequacy of the allocation of resources to:



Sample composed by: 7 EC and 13 MB

13.4 Please indicate whether you would increase, decrease or maintain to allocation of resources to:

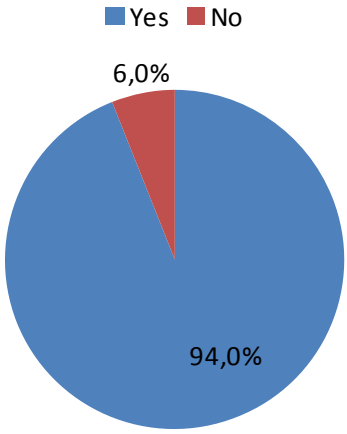


Sample composed by: 8 EC, 13 MB

14) Distribution of work between Scientific Committee/Panels, EFSA's staff and external bodies

14.1 Do you benefit from the support of:

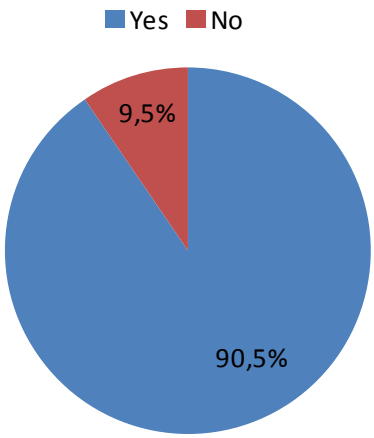
EFSA staff



Sample composed by: 6 EC, 23 AF, 10 SC, 11 Scient. Org.

14.1 Do you benefit from the support of:

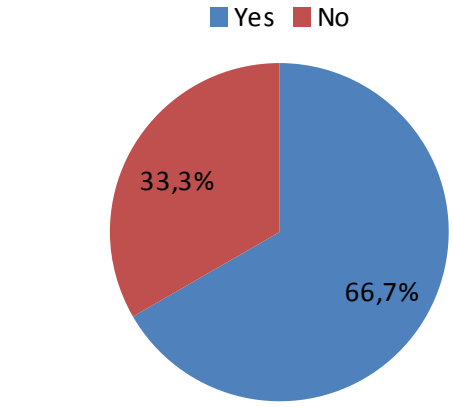
Scientific Committee/ Scientific Panels



Sample composed by: 5 EC, 20 AF, 9 SC, 8 Scient. Org.

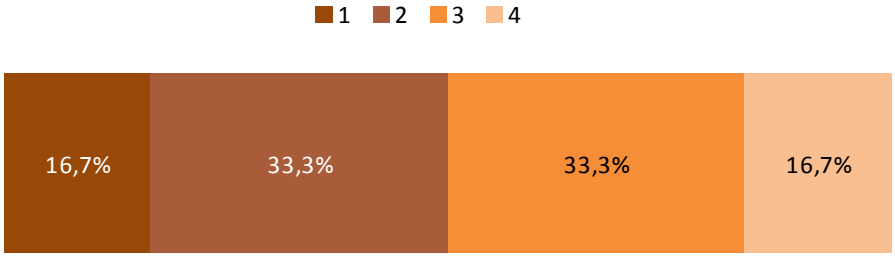
14.1 Do you benefit from the support of:

External bodies (other than members of Panels and Scientific Committee)



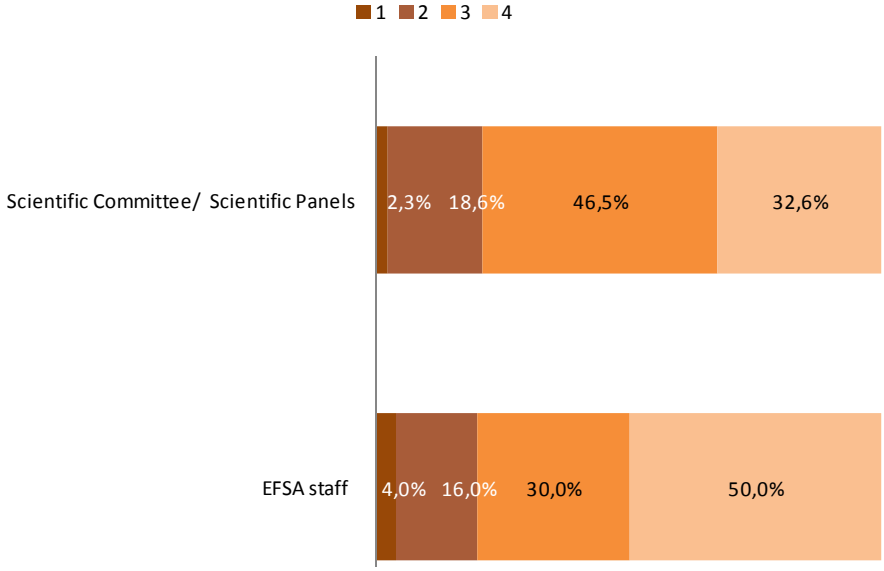
Sample composed by: 2 EC, 17 AF, 9 SC, 8 Scient. Org.

14.2 Please rate the quality of the support to your work of external bodies (other than members of Panels and Scientific Committee)



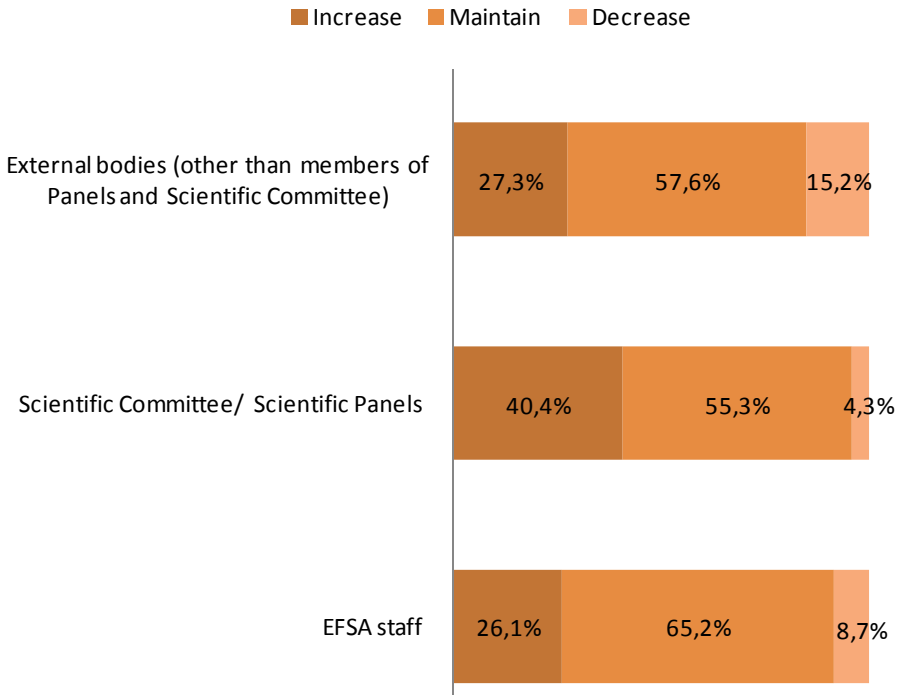
Sample composed by: 6 SC

14.3 Please rate (when appropriate) the quality of the support to your work of:



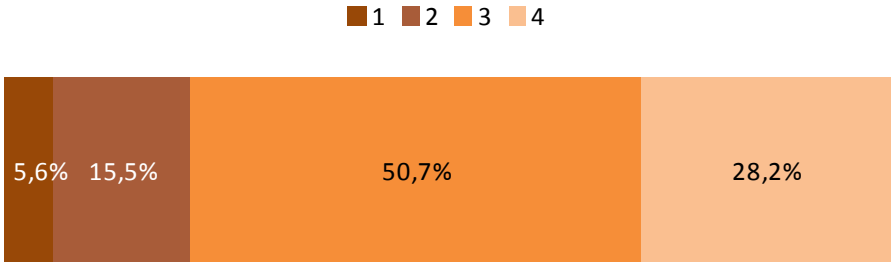
"Scientific Committee" sample composed by: 6 EC, 19 AF, 9 SC, 9 Scient. Org.
"EFSA's staff" sample composed by: 7 EC, 22 AF, 10 SC, 11 Scient. Org.

14.4 Please indicate whether you would increase, decrease or maintain the resources allocated to:



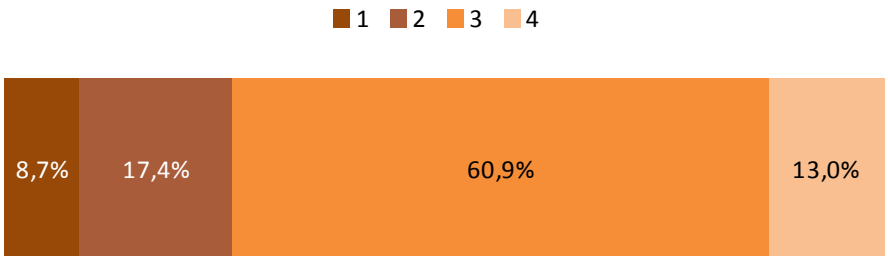
"External bodies" sample composed by: 4 EC, 17 AF, 6 SC, 6 Scient. Org.
"Scientific Committee" sample composed by: 7 EC, 20 AF, 10 SC, 10 Scient. Org.
"EFSA's staff" sample composed by: 7 EC, 19 AF, 10 SC, 10 Scient. Org.

14.5 To what extent are EFSA human resources (staff and external experts) adequate to support scientific outputs? Please rate:



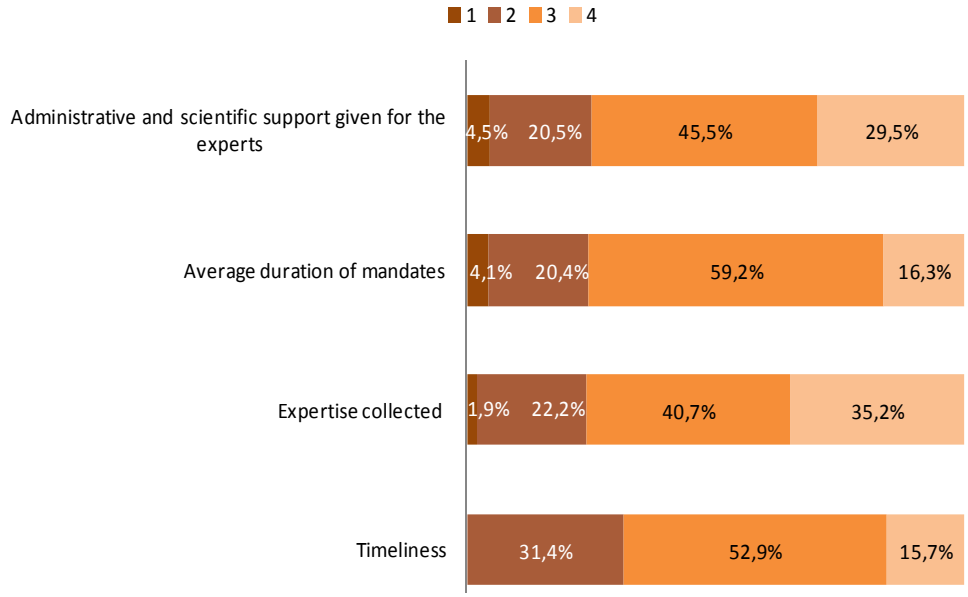
Sample composed by: 5 EC, 22 AF, 10 SC, 1 NGOs, 13 FIR/A, 1 Cons., 10 NRM, 9 Scient. Org.

14.8 To what extent will the actual Panels and Committee structure be adequate to support future challenges and the increase in workload? Please rate:



Sample composed by: 5 EC, 13 MB, 10 SC, 1 NGOs, 7 FIR/A, 10 Scient. Org.

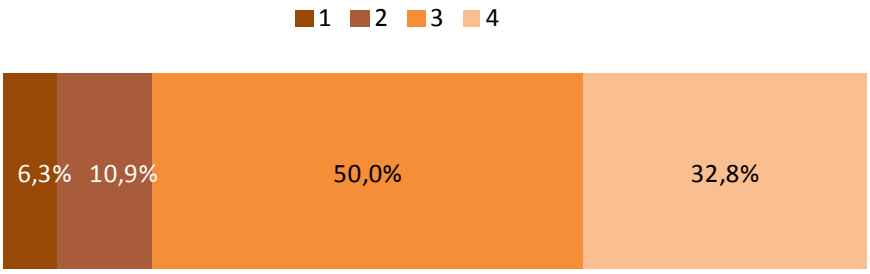
14.9 Please rate the process of mobilization of external experts (members of the Scientific Committee/Panels and their Working Groups) in terms of in terms of:



"Administrative and scientific support" sample composed by: 3 EC, 19 AF, 10 SC, 2 FIR/A, 10 Scient. Org.
"Average duration of mandates" sample composed by: 5 EC, 19 AF, 10 SC, 1 NGOs, 4 FIR/A, 10 Scient. Org.
"Expertise collected" sample composed by: 6 EC, 20 AF, 10 SC, 7 FIR/A, 11 Scient. Org.
"Timeliness" sample composed by: 5 EC, 19 AF, 10 SC, 1 NGOs, 5 FIR/A, 11 Scient. Org.

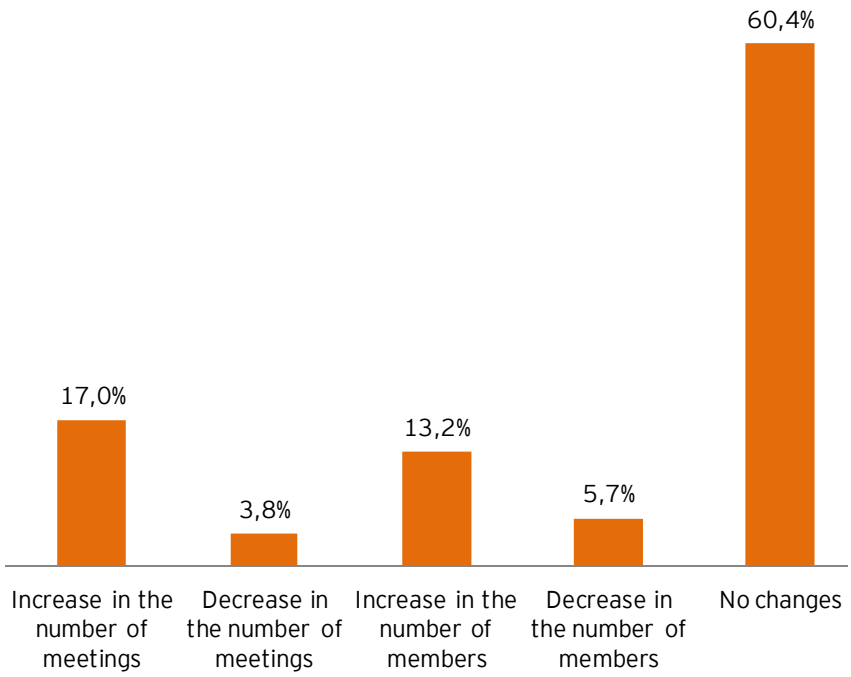
15) Management Board

15.1 Please rate the appropriateness of EFSA's Management Board process of decision making



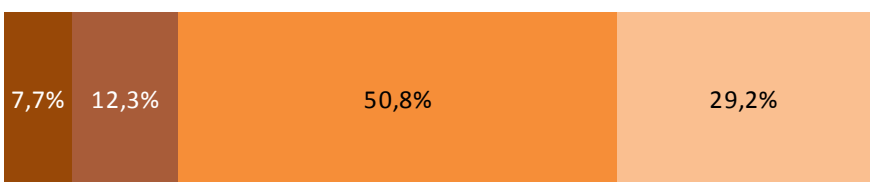
Sample composed by: 3 EC, 19 AF, 13 MB, 6 SC, 3 EP, 1 NGOs, 5 FIR/A, 5 Cons., 9 NRM

15.2 Do you suggest any change in the Management Board composition and working methods?



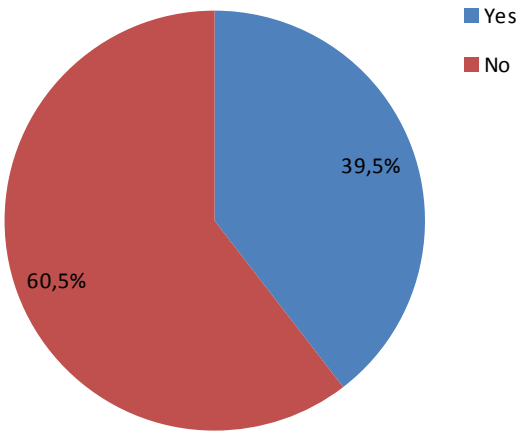
Sample composed by: 1 EC, 16 AF, 13 MB, 5 SC, 2 EP, 3 FIR/A, 4 Cons., 6 NRM

15.3 Please rate the appropriateness of EFSA's Management Board composition



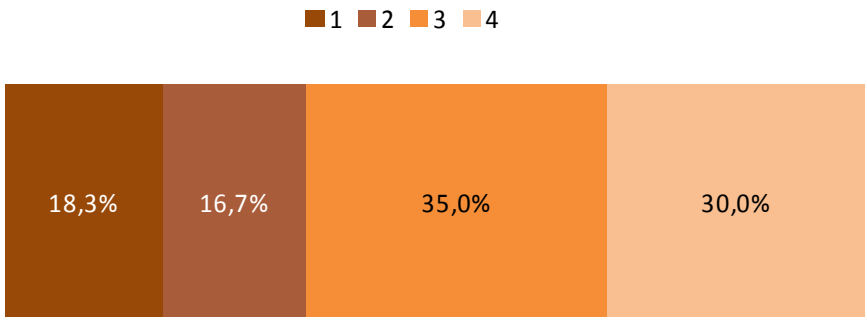
Sample composed by: 3 EC, 20 AF, 13 MB, 6 SC, 2 EP, 2 NGOs, 6 FIR/A, 5 Cons., 8 NRM

15.4 Is there any lack of skills in the Management Board composition?



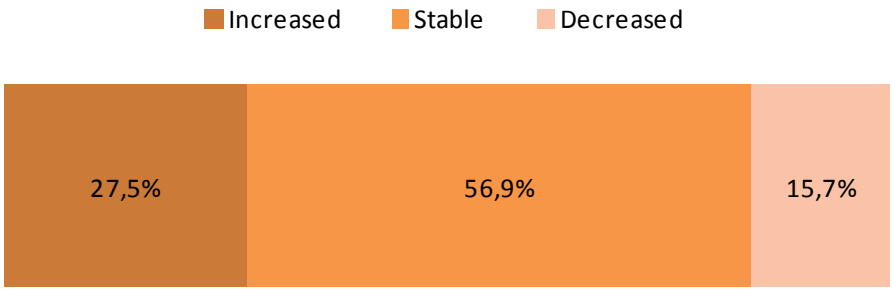
Sample composed by: 3 EC, 10 AF, 12 MB, 3 SC, 2 EP, 2 NGOs, 5 FIR/A, 1 Cons., 5 NRM

15.5 To what extent does the process of selection of the Management Board members guarantee its independence? Please rate:



Sample composed by: 3 EC, 20 AF, 13 MB, 4 SC, 2 EP, 2 NGOs, 5 FIR/A, 4 Cons., 7 NRM

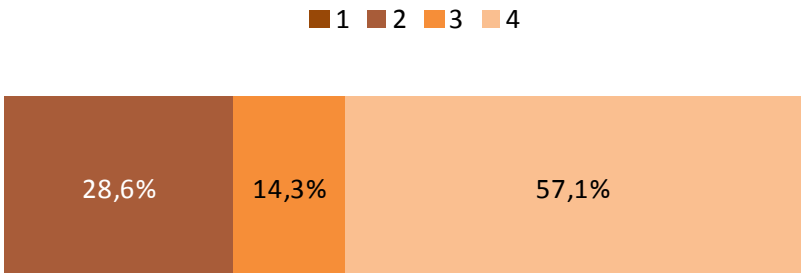
15.6 Can you indicate how the independence of the Management Board has changed over time?



Sample composed by: 3 EC, 16 AF, 12 MB, 5 SC, 2 EP, 1 NGOs, 4 FIR/A, 2 Cons., 6 NRM

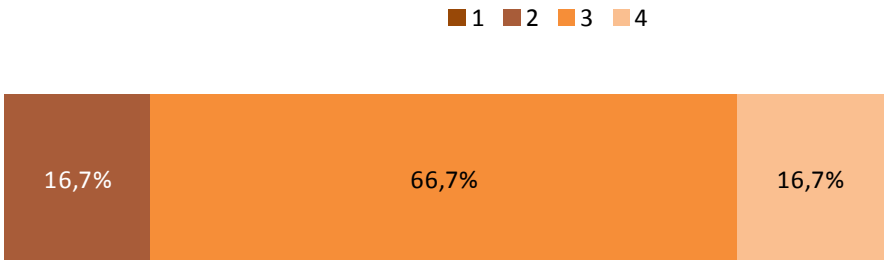
16) Flow of information between EFSA and EC

16.1 To what extent is EFSA able to use the information you provide to plan appropriately its activities?



Sample composed by: 6 EC

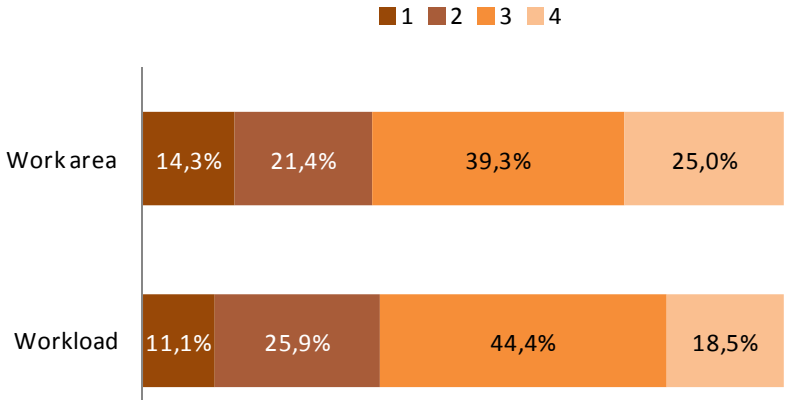
16.2 Please rate the gap between the foreseen opinions and the actual opinion requested



Sample composed by: 5 EC

17) Legislative framework

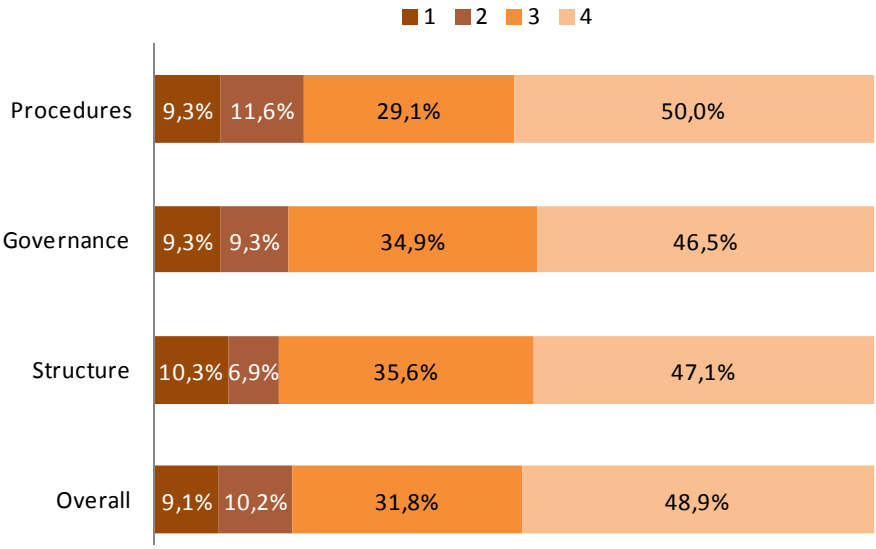
17.1 Please rate EFSA's legislative framework support to evolving expectations in terms of:



"Work area" sample composed by: 3 EC, 11 MB, 3 EP, 11 NRM
"Workload" sample composed by: 2 EC, 11 MB, 3 EP, 11 NRM

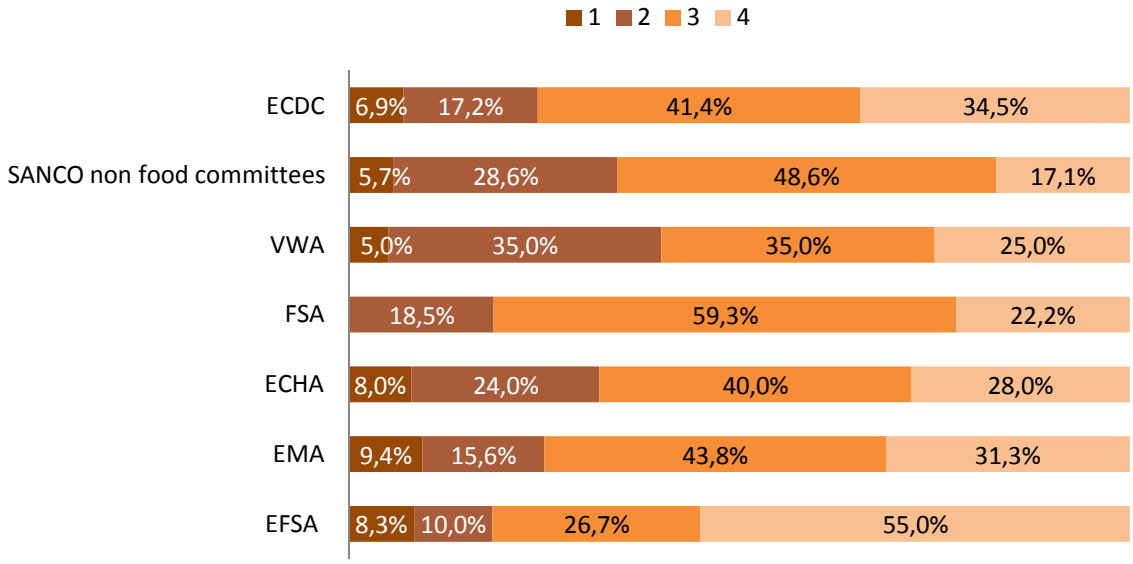
18) Independence

18.1 Please rate EFSA's independence detailing your evaluation for:



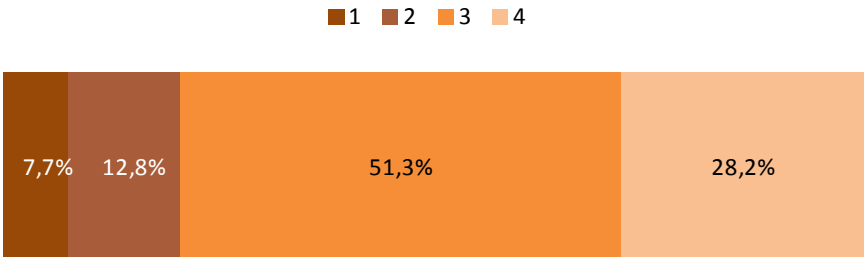
"Procedures" sample composed by: 6 EC, 13 MB, 3 EP, 2 NGOs, 11 NRM, 22 AF, 2 Media, 4 Cons., 11 Scient. Org.
"Governance" sample composed by: 6 EC, 13 MB, 3 EP, 2 NGOs, 11 NRM, 21 AF, 2 Media, 4 Cons., 12 Scient. Org.
"Structure" sample composed by: 6 EC, 13 MB, 3 EP, 2 NGOs, 11 NRM, 22 AF, 2 Media, 4 Cons., 11 Scient. Org.
"Overall" sample composed by: 6 EC, 13 MB, 3 EP, 2 NGOs, 11 NRM, 22 AF, 3 Media, 5 Cons., 11 Scient. Org.

18.3 Please rate the following organizations, as relates independence policy and process of decision making about the conflicts:



"ECDC" sample composed by: 2 EC, 10 AF, 8 MB, 3 EP, 3 FIR/A, 3 Media
"SANCO" sample composed by: 3 EC, 10 AF, 7 MB, 3 EP, 1 NGOs, 7 FIR/A, 3 Media, 1 Cons.
"VWA" sample composed by: 1 EC, 8 AF, 4 MB, 1 EP, 1 NGOs, 2 FIR/A, 3 Media
"FSA" sample composed by: 2 EC, 10 AF, 7 MB, 1 EP, 4 FIR/A, 2 Media
"ECHA" sample composed by: 2 EC, 9 AF, 6 MB, 2 EP, 4 FIR/A, 2 Media
"EMA" sample composed by: 2 EC, 12 AF, 7 MB, 2 EP, 2 NGOs, 4 FIR/A, 2 Media, 1 Cons.
"EFSA" sample composed by: 6 EC, 18 AF, 13 MB, 3 EP, 2 NGOs, 11 FIR/A, 3 Media, 4 Cons.

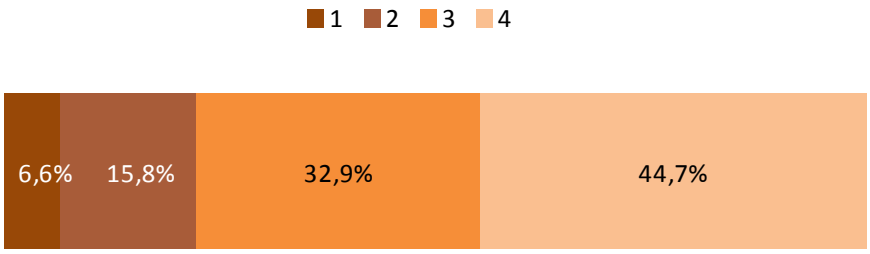
18.5 Please rate your level of satisfaction on actions done by EFSA to mitigate your criticism, if any:



Sample composed by: 4 EC, 14 AF, 1 EP, 3 NGOs, 6 FIR/A, 2 Media, 4 Cons., 5 NRM

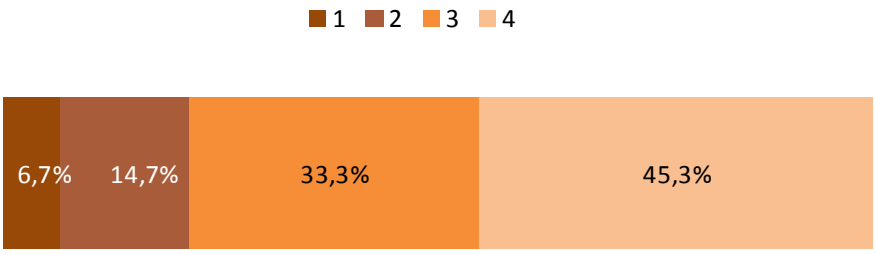
19) Openness and transparency

19.1 Please rate the level of transparency of EFSA procedures



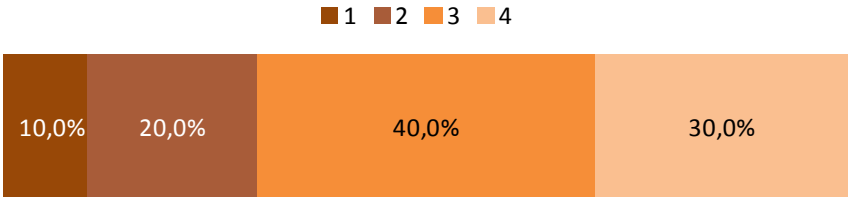
Sample composed by: 7 EC, 23 AF, 2 NGOs, 13 FIR/A, 3 Media, 5 Cons., 11 NRM, 12 Scient. Org.

19.4 Please rate from level of openness of EFSA procedures



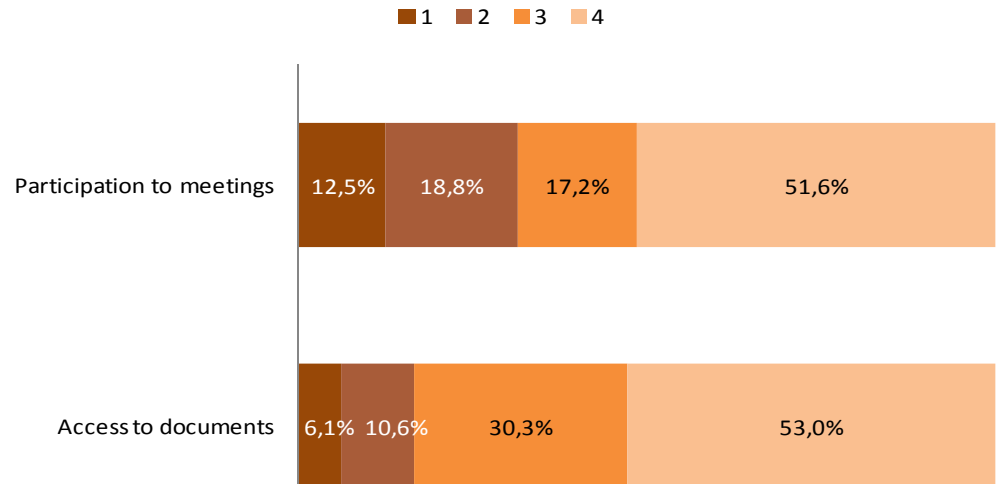
Sample composed by: 7 EC, 23 AF, 2 NGOs, 12 FIR/A, 3 Media, 5 Cons., 11 NRM, 12 Scient. Org.

19.8 Are you satisfied with the procedures to communicate (suggestions and complaints) to EFSA? Please rate:



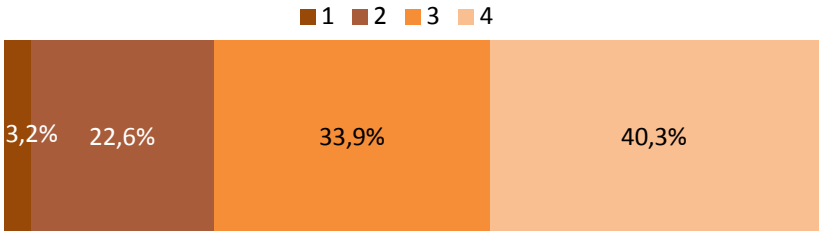
Sample composed by: 1 NGOs, 11 FIR/A, 2 Media, 4 Cons., 12 Scient. Org.

19.9 Please rate the relevance of EFSA openness and transparency for your activities as relates to:



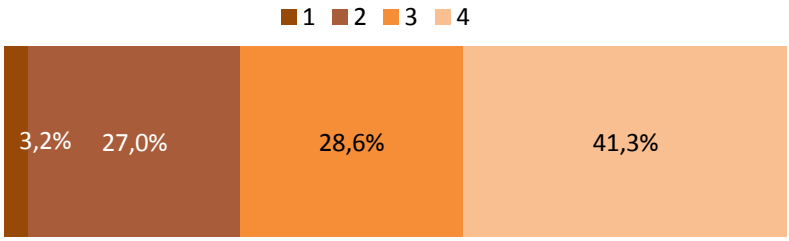
"Participation to meetings" sample composed by: 23 AF, 2 NGOs, 12 FIR/A, 5 Cons., 9 NRM, 3 Media, 11 Scient. Org.
"Access to documents" sample composed by: 23 AF, 2 NGOs, 12 FIR/A, 5 Cons., 9 NRM, 3 Media, 12 Scient. Org.

19.10 To what extent do the procedures of openness allow you to provide inputs to EFSA's work? Please rate:



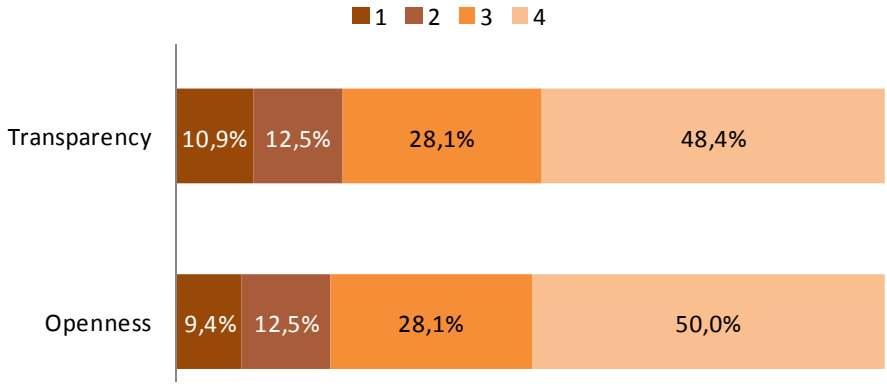
Sample composed by: 21 AF, 1 NGOs, 13 FIR/A, 2 Media, 5 Cons., 8 NRM, 12 Scient. Org.

19.11 To what extent do the procedures of transparency allow you to provide inputs to EFSA's work? Please rate:



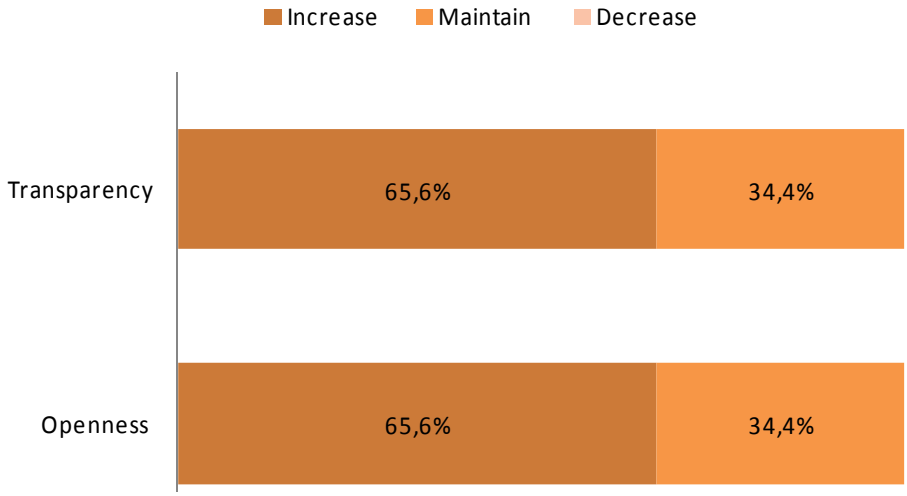
Sample composed by: 21 AF, 2 NGOs, 13 FIR/A, 2 Media, 5 Cons., 8 NRM, 12 Scient. Org.

19.12 To what extent principles of openness and transparency are part of EFSA's work and culture? Please specify your rating for:



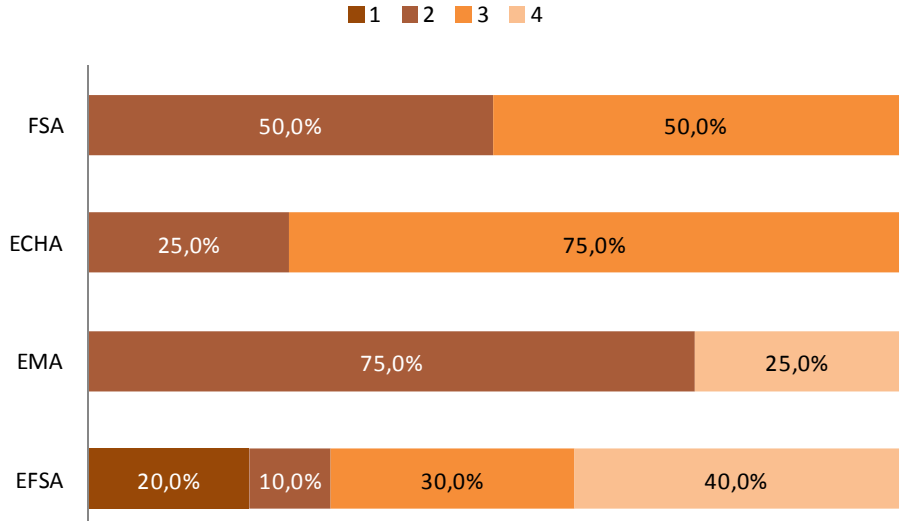
Sample composed by: 23 F, 1 NGOs, 13 FIR/A, 2 Media, 5 Cons., 9 NRM, 11 Scient. Org.

19.13 Please indicate whether, in your opinion, the relevance of openness and transparency to EFSA's work will increase decrease or be maintained to adequately face future challenges. Specify for

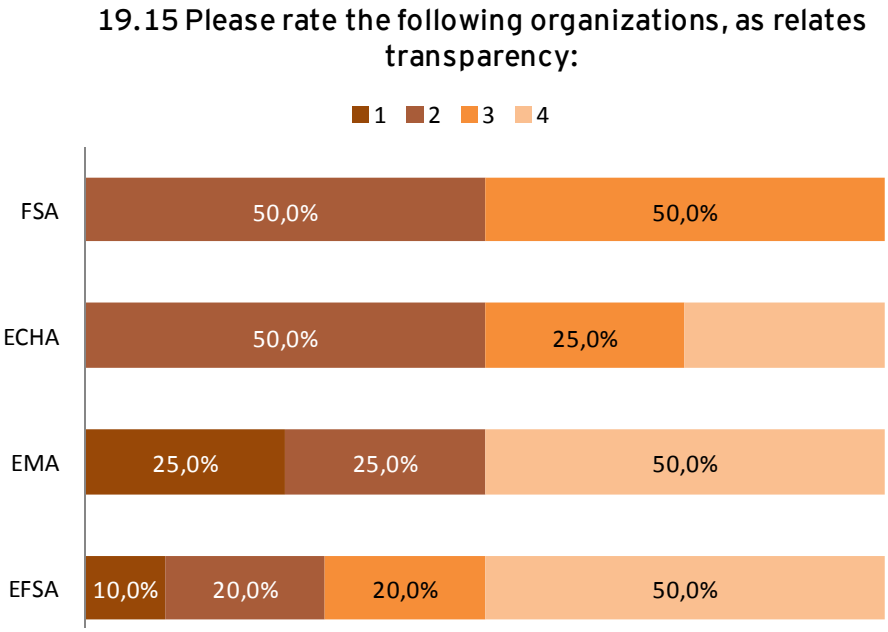


Samples composed by: 23 AF, 2 NGOs, 12 FIR/A, 3 Media, 4 Cons., 9 NRM, 11 Scient. Org.

19.14 Please rate the following organizations, as relates openness:



"FSA" sample composed by: 2 EC
"ECHA" sample composed by: 2 EC, 2 EP
"EMA" sample composed by: 2 EC, 2 EP
"EFSA" sample composed by: 7 EC, 3 EP



"FSA" sample composed by: 2 EC
"ECHA" sample composed by: 2 EC, 2 EP
"EMA" sample composed by: 2 EC, 2 EP
"EFSA" sample composed by: 7 EC, 3 EP

2. Interviews and supporting documents

a. Table of interviews done

TARGET GROUPS	STAKEHOLDER	INTERVIEWS DONE
Institutional Stakeholders	European Commission	2
	EP	4
	National Risk Managers	6
	National Risk Assessors	8
External Stakeholders	Scientific Org. (Art 36)	2
	Food Industry/Applicants	6
	NGOs	3
	Consumer Organizations	4
	International Institutions	4
EFSA bodies	MB	2
Total		41

b. List of Institutions

STATUS	ORGANIZATIONS
European Commission	DG SANCO
European Commission	DG SANCO
European Parliament	ENVI Committee
European Parliament	ENVI Committee
European Parliament	ENVI Committee
European Parliament	ENVI Committee
Risk Manager	MZE Czech Ministry of Agriculture
Risk Manager	Spanish Food Safety and Nutrition Authority (Spain)
Risk Manager	Danish Veterinary and Food Administration (Denmark)
Risk Manager	Federal Ministry for Food, Agriculture and Consumer Protection (Germany)
Risk Manager	Italian Ministry of Health
Risk Manager	Department for Environment, Food and Rural Affairs (DEFRA) - UK
Risk Assessor	Swedish National Food Administration
Risk Assessor	Italian Ministry of Health, UVAC - Veterinary offices for the fulfilment of European Union requirements
Risk Assessor	Food Standard Agency - UK
Risk Assessor	Poland, National Institute of Hygiene
Risk Assessor	Cyprus Ministry of Health, State General Laboratory
Risk Assessor	Hungarian Food Safety Office
Risk Assessor	Federal Institute for Risk Assessment (BfR)-Germany
Risk Assessor	Ministry of Agriculture of the Czech Republic, Food Safety Department
Food industry/applicants	EFFA

Food industry/applicants	Food&Drinks Europe (ex CIAA -Confederation of the Food and Drink Industries in the EU)
Food industry/applicants	COPA COGECA
Food industry/applicants	Rohm & Haas (food contact)
Food industry/applicants	EuropaBio (Biotech & Pesticides)
Food industry/applicants	Saqual GmbH (Feed)
NGO	Eurogroup for animals
NGO	EuroCoop - European Community of Consumer Co-operatives
NGO	BEUC-European Consumers' Organization
Consumer organizations	EuroCoop - European Community of Consumer Co-operatives
Consumer organizations	BEUC-European Consumers' Organization
Consumer organizations	Food and Environment Research Agency (FERA)
Consumer organizations	Technical University of Denmark (DTU)
Scientific organizations (Art. 36)	Food and Environment Research Agency (FERA)
Scientific organizations (Art. 36)	Technical University of Denmark (DTU)
International Institutions	WHO
International Institutions	FAO
International Institutions	OIE
International Institutions	FDA
Management Board	Management Board
Management Board	Management Board

c. Templates of Interviews for Stakeholders

A - Interviewee's profile

- **Name:**
- **Company:**
- **Areas of activities:**
- **Function:**
- **Contact:**

B – General objectives of the interview

- To gather detailed information concerning specific evaluation issues (through the exploration of areas of interest during the course of the interview).
- To collect relevant qualitative data.
- To deepen the comprehension of who are the stakeholders (beyond organizational structure) and how the Authority functions in its everyday process.
- To gather personal points of view on the main critical aspects of the Authority system and on the identification of improvement areas.
- To enrich and interpret the data collected through secondary sources or questionnaires.

C – Structure of the interview, targets and main issues to be treated

Questions	Main issues to be treated through the interviews	Target
PROVISION OF SCIENTIFIC OUTPUTS AND TECHNICAL SUPPORT		
Can you provide your view on EFSA's process of provision of scientific outputs as well as their scientific quality?	More specifically we would like to deepen the following issues: - quality of outputs (clarity and completeness) - delivery procedures - procedures to communicate needs and EFSA's ways of taking these into consideration (DG SANCO, EP, NRM, FIR/A) - timeliness of outputs with the indication of the main causes of delay if so. A specific focus will be done for the satisfaction as relates deadlines agreements - quality of support in emergency situations - validity/reliability of EFSA's scientific outputs compared to other similar bodies - level of integration of EFSA's approach in providing scientific advices with identification of possible areas of improvement - usefulness, timeliness , clarity and relevance of EFSA self- tasking function as relates emerging issues	DG SANCO; EP; NRM; AF; SCP; Scientific Org. (Art 36); FIR/A; (Int. Inst.) WHO, FAO, OIE, FDA;

	- relevance of EFSA's support to NRM to risk mitigation actions - capacity to guarantee business continuity within assigned resources - critical success stories - areas of improvement	
DATA COLLECTION		
Could you provide your view on data collection activity?	More specifically we would like to deepen the following issues: - access and availability of data with the indication of specific data gaps - quality of reports on data collection - effectiveness of EFSA's actions to for data harmonization - the capacity of the existing system of cooperation to support EFSA in the collection and exchange of scientific data with the indication of potential area of improvement of external stakeholder contribution - the reliability of data used to support scientific outputs with a specific focus on the Data Quality Management System and the data quality requirements agreed with data providers (FIR/A, Scientific Org., AF) - Risk Manager contribution to EFSA's scientific tasks - main areas of improvement	DG SANCO; EP; NRM; AF; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36);
RISK COMMUNICATION		
Could you provide your point of view on EFSA's communication activities?	More specifically we would like to deepen the following issues: - tools - quality (Clarity, Timing, Relevance) - reasons underlying EFSA communication towards your target (e.g., information, co decision, institutional publicity) - outreach of the communication - the capacity to dialogue - main issues that are not adequately communicated - the effectiveness in enhancing trust in the Authority and in the agro-food sector - coherence and relevance of EFSA risk communication with indication of cases of divergent opinions when appropriate and explanation of their management - the role of the AFCWG - main areas of improvement	DG SANCO; AF; SCP; External NGOs; National Consumer Organizations; Scientific Org. (Art 36); FIR/A; (Int. Inst.) WHO, FAO, OIE, FDA;
COOPERATION AND NETWORKING		
Can you provide your point of view how EFSA activities on cooperation and networking?	More specifically we would like to deepen the following issues: - Effectiveness and relevance of EFSA's cooperation activities - Convergence and harmonization in risk assessment among MS with an illustration of situations of misalignment when appropriate - Integration of EFSA scientific evaluations to National bodies' ones? (DG SANCO,NRM)	DG SANCO; NRM; AF; SCP; External NGOs; Scientific Org. (Art 36); (Int. Inst.) WHO, FAO, OIE, FDA;

	- effectiveness of the interface between risk assessors and risk managers with a particular focus on the role of the AF - involvement of competent organization in EFSA activities with the indication of strengths and weaknesses - relevance of support provided by MS agencies - economies for National Food Safety Authorities (NRM, AF) and evolution of budget - diminution of risk assessments throughout the EU - impact on scientific homogeneity - main critical issues/area of improvement	
EFSA'S INTERNATIONAL ROLE AND RECOGNITION		
Can you express your point of view on EFSA's international role and recognition?	More specifically we would like to deepen the following issues: - EFSA recognition in the international community - Contribution of EFSA to improvements in providing scientific advice - Positioning with respect to other similar bodies - usefulness of events and international projects organized by EFSA - EFSA participation to international projects and main areas of involvement - main areas of improvements -contribution to EU's objectives, legislation and policy - professional attractiveness - main areas of improvement (EC, EP, NRM)	DG SANCO; EP; NRM; AF; SCP; External NGOs; Scientific Org. (Art 36); (Int. Inst.) WHO, FAO, OIE, FDA;
THE ORGANIZATIONAL STRUCTURE, ITS OPERATIONAL EFFICIENCY AND ITS ADAPTABILITY TO CHANGE		
Can you express your point of view on the organization of EFSA, its operational efficiency and its adaptability to change?	More specifically we would like to deepen the following issues: - adequacy of the organizational structure with a focus on the changes occurred in May 2011 and the indication of strengths and weaknesses - satisfaction on the management systems and procedures in place - composition of the MB and efficiency of its working methods - how far the MB members act for public interest - how could the MB working methods improve - new future challenges - the organization's flexibility and adaptability to change - process of mobilization of experts (comparison with other organizations) and identification of EFSA's competitive advantages - relevance of the flow of information between EFSA and EC and analysis of planning practices with key partners - consistency of resources allocation with EFSA objectives and activity evolution and identification of disproportions if any - EFSA ability to support risk managers within assigned resources and identification of possible areas of improvement - balance of work among panels, experts and EFSA's staff and comparison with other similar organizations	DG SANCO; EP; NRM; MB; AF; SCP;

	- adequacy of human resources and competences available to manage the actual workload - effectiveness of EFSA mobilization process and comparison with other similar organization - adequacy of the overall legislative framework to support evolving expectations with a specific focus on the coherence between vertical/sectorial regulations and EFSA's Founding ones. - effectiveness of EFSA's actions to face increasing workload and/or backlogs in the process of applications for authorizations - areas of improvement	
INDEPENDENCE		
What is your point of view on the capacity of EFSA to operate in an independent manner?	More specifically we would like to deepen the following issues: - structures, governance and procedures to guarantee independence - comparability with other organizations - criticisms about independence and the reasons underpinning - effectiveness of EFSA actions to mitigate criticisms - main areas of improvement and change	DG SANCO; EP; NRM; AF; SCP; External NGOs; National Consumer Organizations; FIR/A;
OPENNESS AND TRANSPARENCY		
What is your point of view on EFSA transparency and openness in its scientific communications and others works?	More specifically we would like to deepen the following issues: - transparency of EFSA procedures and publication the relevant information, scientific and others - main evidences - main areas of improvements - openness of EFSA to inputs, scrutiny and dialogue with its networks - main evidences - main areas of improvements - relevance of the principles of openness and transparency for EFSA's mission today and in the future with a focus on the use that stakeholders do of the Authority's procedures for openness and transparency - comparison with similar organizations - main areas of improvement	DG SANCO; EP; NRM; AF; SCP; External NGOs; National Consumer Organizations; FIR/A; (Int. Inst.) WHO, FAO, OIE, FDA;

3. List of Judgment Criteria

PROVISION OF SCIENTIFIC OUTPUTS AND TECHNICAL SUPPORT	
Q1.a	EFSA's outputs are suitable to the needs of its clients and in particular the European Commission, Parliament and Member States
Q1.b	EFSA is issuing timely outputs (opinions and technical advice) as requested by the Commission, the European Parliament and Member States (adequacy of systems/procedures to ensure the respect of deadlines)
Q6.g	The perception of the quality of EFSA scientific output is comparable to that of other similar organization. The quality of EFSA scientific output is in line with that of organizations carrying out similar tasks
Q7.a Q7.d	The delivery of scientific advice regarding food chain is made through an integrated approach
Q6.c	The quality assurance procedures are adequate to ensure high quality scientific outputs
Q6.d	The quality assurance procedures are similar to those of other organizations.
Q1.d	EFSA is using its self-tasking function effectively to keep abreast of emerging issues
Q6.e	EFSA is using self-tasking function effectively to keep abreast of emerging issues, undertaking scientific work on its own initiative, particularly in fields such as emerging risks where scientific knowledge and approaches are continually evolving.
Q7.g	EFSA has developed tools and procedures to support national risk managers in the EU
Q3.c; Q3.h	EFSA has ensured business continuity and has been able to sustain its support to risk managers within assigned resources
Q1.h	EFSA has been able to support the EU in emergency food/feed safety situations
DATA COLLECTION	
Q1.c	EFSA fulfils its mandate to collect and analyze data relevant for the safety of the food chain
Q7.g	Data collection by EFSA ensures its ability to respond to request for advice
Q1.f; Q3.g	EFSA cooperates with the Commission and Member States to promote coherence between risk assessment, risk management and risk communication functions The existing system for cooperation and networking with national bodies provides an appropriate basis to support EFSA's work The existing system for cooperation and networking with national bodies can be maintained to ensure a critical mass of expertise throughout the EU in the medium and long term
Q6.b	Data collected support high quality scientific outputs
RISK COMMUNICATION	
Q1.g	EFSA communicates effectively and openly on risks in the food chain in a timely manner
Q6.f	EFSA actively publishes all its scientific outputs, including its scientific opinions and a range of supporting publications
Q7.a; Q7.d	Risk communication across the EU is coherent and relevant
Q5.e	EFSA activities have been effective in enhancing trust in EFSA within the overall food safety system
Q7.d	EFSA risk assessment system is reliable and trusted by EU members
Q7.b	The level of EFSA commitment to dialogue with partners and stakeholders is high. EU citizen's confidence in the EU Agro-food sector has improved. EFSA is perceived as a reliable body in which stakeholders have confidence
Q7.c	Divergent scientific opinions are reducing. (In terms of numbers and contents). EFSA is perceived as a reference scientific body in its field of activity. EFSA has contributed to scientific homogeneity in the field of food safety.

Q2.d	The processes related to the AF are efficient (the AF is able to assist and advise EFSA and EFSA is able to make the most efficient use of this advice and assistance)
COOPERATION AND NETWORKING	
Q1.f; Q3.g	EFSA cooperates with the Commission and Member States to promote coherence between risk assessment, risk management and risk communication functions The existing system for cooperation and networking with national bodies provides an appropriate basis to support EFSA's work The existing system for cooperation and networking with national bodies can be maintained to ensure a critical mass of expertise throughout the EU in the medium and long term
Q2.d	The processes related to the AF are efficient (the AF is able to assist and advise EFSA and EFSA is able to make the most efficient use of this advice and assistance)
Q1.e	EFSA acts in close cooperation with the competent bodies in the Member States carrying out similar tasks, especially those as per art. 4, 2230/2004
Q2.h	The distribution of work between the panels, EFSA's staff and external bodies is consistent with EFSA's objectives and activity evolution
Q3.f	EFSA's structure (Panels and Committee) and the actual system for cooperation and networking are adequate to sustain the quality of work, both in terms of scientific outputs and needed expertise
Q7.d	A system of risk assessment coordination between EU Member States and EFSA has been set up. The reduction of the risk assessment led to a decrease in national bodies' budget
Q7.a Q7.d	Cost for National Food Safety Authorities has reduced thanks to EFSA's activities
EFSA'S INTERNATIONAL ROLE AND RECOGNITION	
Q7.d	EFSA risk assessment system is reliable and trusted by EU members
Q6.f	EFSA has been involved in the international scientific community to maintain its overview of best practices and evolving scientific issues
Q7.a Q7.d	The scientific community agrees to consider EFSA as a contributor to improvements in the provision of scientific advice
Q7.c	EFSA is internationally recognized.
Q1.f; Q3.g	EFSA cooperates with the Commission and Member States to promote coherence between risk assessment, risk management and risk communication functions The existing system for cooperation and networking with national bodies provides an appropriate basis to support EFSA's work The existing system for cooperation and networking with national bodies can be maintained to ensure a critical mass of expertise throughout the EU in the medium and long term
Q3.f	EFSA's structure (Panels and Committee) and the actual system for cooperation and networking are adequate to sustain the quality of work, both in terms of scientific outputs and needed expertise
Q7.h	Did EFSA contributed to a more science based legislation. EFSA's inputs (works and actions) are considered and integrated within the EU institutions activity
Q6.a	Human resources are adequate to ensure high quality scientific outputs
THE ORGANIZATIONAL STRUCTURE, ITS OPERATIONAL EFFICIENCY AND ITS ADAPTABILITY TO CHANGE	
Q2.e	The organization of EFSA is able to adapt to the changes in the tasks entrusted to it
Q2.a	The structure and organization of the agency is adequate to the work entrusted to it and to the actual workload
Q3.a; Q3.e	The changing workload and work areas affect the ability of EFSA (in term of both financial resources and needed skills and recruitment practices) to deliver high quality outputs

Q3.d	EFSA has taken actions to face increasing workload and/or backlogs in the process of applications for authorizations
Q2.f	EFSA resources allocation is consistent with its objectives and activity evolution
Q1.c; Q1.e; Q1.f	The resource allocation to data collection, communication and cooperation are proportionate to activities
Q2.j	There is a system in place to monitor the relation between inputs and outputs (cost-effectiveness)
Q2.b	The management systems and processes contribute to the effectiveness and efficiency of its operations
Q2.h	The distribution of work between the panels, EFSA's staff and external bodies is consistent with EFSA's objectives and activity evolution
Q6.a	Human resources are adequate to ensure high quality scientific outputs
Q3.f	EFSA's structure (Panels and Committee) and the actual system for cooperation and networking are adequate to sustain the quality of work, both in terms of scientific outputs and needed expertise
Q2.g	The process to mobilise the network of experts is efficient
Q2.c	The composition and the working methods of the Management Board is appropriate and efficient
Q2.j	The flow of information between EFSA and the EC supports the planning activities
Q3.b	EFSA overall legislative framework is able to support the evolving expectations (in terms of workload and work areas) placed upon the Authority in short, medium, long term
INDEPENDENCE	
Q4.a; Q4.d	EFSA's overall structures, governance and procedures have been effective in ensuring that the Authority can operate without undue influence
Q4.b; Q4.c	EFSA's overall structures, governance and procedures to assure independence are in line with relevant standards and other similar organizations
Q 4.e	There are specific issues on independence emerging from stakeholders. The procedures and policy EFSA has developed and is developing are able to mitigate the criticism on the independence. There are actions that EFSA can do to improve the perception of stakeholders on independence.
OPENNESS AND TRANSPARENCY	
Q5.a	EFSA has fulfilled its obligation to operate in an open and transparent manner
Q5.a; Q5. b	EFSA and its networks (as per art. 2 2230/2004) have - developed and implemented joint projects with stakeholders platform members - have organized forum and meetings for sharing information and best practices (art.36 178/2002) - have created a methodology to collect suggestions from stakeholders platform members. - have created a methodology to collect complaints from stakeholders platform members - been open about EFSA's decision-making processes
Q5.c	The principles of openness and transparency are relevant to EFSA's work today and in the future

Q5.d	The cost-effectiveness of the implementation of the principles of openness and transparency is adequate

4. Legislation relevant to EFSA[474]

TOPIC	REGULATION
HORIZONTAL LEGISLATION	
EFSA Founding Regulation ("The General Food Law")	- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1) [last amended by Regulation (EC) No 596/2009]
Implementing measures of Regulation (EC) No 178/2002	- Commission Regulation (EC) No 1304/2003 of 11 July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it (OJ L 185, 24.7.2003, p. 6) - Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission (OJ L 379, 24.12.2004, p. 64) - Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed (OJ L 6, 11.1.2011, p. 7)
Other relevant horizontal legislation	- Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43) - Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p. 13) - Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1) - Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1; corrected version in OJ L 136, 29.5.2007, p. 3) [last amended by Commission Regulation (EU) No 143/2011] - Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1) - Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1) [last amended by Regulation (EU) No 1235/2010 of the European Parliament and of the Council] - Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23) [amended by Council Decision 2006/512/EC] - Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13) - Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June

[474] The list may not be exhaustive. In the column "regulation" it is written in italic legislation in preparation with expected relevance for EFSA, according to the 2012 Annual Management Plan.

TOPIC	REGULATION
	2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny – Adaptation to the regulatory procedure with scrutiny – Part Four (OJ L 188, 18.7.2009, p. 14) - *Proposal for a Regulation of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents, COM(2008) 229 final* - *Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents, COM(2011)137 final*
SECTORAL LEGISLATION	
GMO	- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1) [last amended by Regulation (EC) No 298/2008 of the European Parliament and of the Council] - Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24) [amended by Regulation (EC) No 1137/2008 of the European Parliament and of the Council] - Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1) [last amended by Directive 2008/27/EC of the European Parliament and of the Council] - Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation (OJ L 102, 7.4.2004, p. 14) - Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97 (OJ L 253, 21.9.2001, p. 17) - *Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, COM(2010) 375 final*
Flavourings	- Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1) [amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council] - Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)
Food Additives	- Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production (OJ L 184, 15.7.1988, p. 61–66) [last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council] - Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (OJ L 40, 11.2.1989, p. 27) [last amended by Regulation (EC) No 1333/2008 of the European Parliament and of the Council] - European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs (OJ L 237, 10.9.1994, p. 13) [last amended by Regulation (EC) No 1333/2008 of the European Parliament and of the Council]

TOPIC	REGULATION
	- European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs (OJ L 237, 10.9.1994, p. 3) [last amended by Commission Directive 2009/163/EU] - European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners (OJ L 61, 18.3.1995, p. 1) [last amended by Commission Directive 2010/69/EU] - Directive 2006/52/EC of the European Parliament and of the Council of 5 July 2006 amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs (OJ L 204, 26.7.2006, p. 10) - Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1) - Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7) - Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16) [amended by Commission Regulation (EC) No 238/2010]
Food supplements	- Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51) [last amended by Commission Regulation (EC) No 1170/2009]
Food hygiene package	- Regulation (EC) 852/2004 on the hygiene of foodstuffs, 29 April 2004 - Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin, 29 April 2004 - Regulation (EC) 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, 29 April 2004 - Directive 2004/41/EC repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC, 21 April 2004
Food contact materials	- Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (OJ L 220, 15.8.2002, p. 18) [last amended by Commission Directive 2011/08/EU] - Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4) [amended by Commission Regulation (EC) No 596/2009] - Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1)
Contaminants	- Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1) [last amended by Commission Regulation (EC) No 596/2009] - Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5) [last amended by Commission Regulation (EU) No 165/2010] - Directive 2002/32/EC of the European Parliament and of the Council on 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10) [last amended by Commission Regulation (EU) No 574/2011 of 16 June 2011]
Food labelling	- Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18-63)

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	- Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29) [last amended by Commission Regulation (EC) No 596/2009] - Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22) - Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs (OJ L 276, 6.10.1990, p. 40) [last amended by Regulation (EC) No 1137/2008 of the European Parliament and of the Council] - Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (OJ L 124, 20.5.2009, p. 21) - *Proposal for a Regulation of the European Parliament and of the Council on food intended for infants and young children and on food for special medical purposes COM(2011) 353 final (inter alia aiming at repealing Directives 92/52 and 96/8 and amending Directives 2009/39, 2006/141, 2006/125, 96/8, 1999/21 and Commission Regulation 41/2009)*
Biohazards	- Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation). - Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (as last amended by Commission Regulation (EU) No 749/2011 of 29 July 2011). - Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1) [last amended by Commission Regulation (EC) No 189/2011]. - Regulation (EC) No 2073/2005 on microbiological criteria in foodstuffs as amended by Regulation (EC) No 1441/2007. - Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC; Official Journal of the European Union L 325/31. (In order to obtain information on antimicrobial resistance that is comparable between Member States and in time, Commission Decision 2007/407/EC on a harmonised monitoring of antimicrobial resistance in Salmonella in poultry and pigs was adopted on 12 June 2007).
Human nutrition	- Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9; corrected version in OJ L 12, 18.1.2007, p. 3) [last amended by Commission Regulation (EU) No 116/2010] - Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26) [last amended by Commission Regulation (EC) No 1170/2009] - Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ L 401, 30.12.2006, p. 1) [amended by Commission Regulation (EC) No 1243/2008] - Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29–36) [as last amended by Commission Directive 2006/141/EC of 22 December 2006] - Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses (OJ L 269, 14.10.2009, p. 9–19) - Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten (OJ L 16,

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	21.1.2009, p. 3-5) - Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (OJ L 339, 6.12.2006, p. 16-35) - Commission Directive 1999/39/EC of 6 May 1999 amending Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children (OJ L 124, 18.5.1999, p. 8-10) - Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22-26)
Animal nutrition	- Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29) [last amended by Regulation (EC) No 767/2009 of the European Parliament and of the Council] - Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1) - Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption (OJ L 273, 10.10.2002, p. 1) [last amended by Commission Regulation (EU) No 790/2010] - Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1) [last amended by Commission Regulation (EU) No 939/2010]
Animal health and animal welfare	- Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1) [last amended by Regulation (EC) No 219/2009 of the European Parliament and of the Council] - Directive 2003/65/EC of the European Parliament and of the Council of 22 July 2003 amending Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (OJ L 230, 16.9.2003, p. 32) - Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (OJ L 306, 22.11.2003, p. 1) [last amended by Commission Decision 2011/7/EU] - Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves (OJ L 10, 15.1.2009, p. 7) - Directive 2008/97/EC of the European Parliament and of the Council of 19 November 2008 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists (OJ L 318, 28.11.2008, p. 9)
Plant Health	- Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000, p. 1) [last amended by Commission Regulation (EU) No 1/2010]
Plant protection products	- Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1) [last amended by Commission Directive 2011/9/EU] - Commission Regulation (EC) No 451/2000 of 28 February 2000 laying down the detailed rules for the implementation of the second and third stages of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC (OJ L 55, 29.2.2000, p. 25) [amended by Commission Regulation (EC) No 1044/2003] - Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work

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	referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000 (OJ L 224, 21.8.2002, p. 23) [last amended by Commission Regulation (EU) No 741/2010] - Commission Regulation (EC) No 2229/2004 of 3 December 2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC (OJ L 379, 24.12.2004, p. 13) [last amended by Commission Regulation (EU) No 741/2010] - Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1) [last amended by Commission Regulation (EU) No 893/2010] - Commission Regulation (EC) No 647/2007 of 12 June 2007 amending Regulation (EC) No 2229/2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC (OJ L 151, 13.6.2007, p. 26) - Commission Regulation (EC) No 1095/2007 of 20 September 2007 amending Regulation (EC) No 1490/2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and Regulation (EC) No 2229/2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC (OJ L 246, 21.9.2007, p. 19) - Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I (OJ L 15, 18.1.2008, p. 5) [amended by Commission Regulation (EU) No 78/2010] - Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)
Residues of pharmacologically active substances in foodstuffs of animal origin	- Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11)
Zoonoses	- Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31) [last amended by Commission Regulation (EC) No 219/2009] - Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents (OJ L 325, 12.12.2003, p. 1) [last amended by Regulation (EC) No 596/2009]
Novel Foods	- Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1) [last amended by Regulation (EC) No 596/2009] - *Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX, COM(2007) 872 final (inter alia aiming at repealing Regulation (EC) No 258/97)*

(Source: Annual Management Plan, 2012)

5. EFSA's Executive Director and Directorates

Executive Director

Appointed by the Management Board, the Executive Director is the legal representative of the Authority and is generally responsible for the daily administration and budget implementation of EFSA. Drawing up a proposal of the work programme for the Authority, implementing it (in consultation with the EC) and maintaining contact with the European Parliament are also among the responsibilities of the Director.

Directorates

As part of the restructuring action, the Authority is now composed of five Directorates supervised by EFSA's Executive Director:

- Risk Assessment and Scientific Assistance;
- Scientific Evaluation of Regulated Products;
- Science Strategy and Coordination;
- Communications;
- Resources & Support.

The scientific Directorates support the work of EFSA's Scientific Committee and Panels. They employ 450 staff.

Risk Assessment and Scientific Assistance

The Risk Assessment and Scientific Assistance Directorate (RASA) is responsible for risk assessment implementation on general health and safety priorities. Its areas of competence are:

- Animal health and welfare, including support to the AHAW Panel;
- Biological hazards, including support to the BIOHAZ Panel;
- Biological monitoring;
- Contaminants, including support to the CONTAM Panel;
- Dietary and chemical monitoring;
- Plant health, including support to the PLH Panel;
- Scientific assessment support.

Scientific Evaluation of Regulated Products

The Scientific Evaluation of Regulated Products Directorate (REPRO) carries out the evaluation of substances, products and claims intended to be used in the food chain. It normally deals with private sector requests. Its areas of competence are:

- Feed, including support to the FEEDAP Panel;
- Food additives & nutrient sources, including support to the ANS Panel;
- Food contact materials, enzymes & flavourings, including support to the CEF Panel;
- GMO, including support to the GMO Panel;
- Nutrition, including support to the NDA Panel;

- Pesticides, responsible for the EU peer review of active substances used in pesticides, scientific advice on setting Maximum Residue Levels and support to the PPR Panel;

Science Strategy and Coordination

The Science Strategy and Coordination Directorate (SSC) is responsible for the implementation of the Authority's science strategy. With REPRO and RASA, it coordinates EFSA's risk assessment activities and manages cross-cutting scientific issues. The Directorate organizes and relies on the work of the Scientific Committee and the Advisory Forum. It encourages partnership and collaboration with national and international stakeholders. SSC focuses on the following specific areas:

- Advisory Forum & scientific cooperation;
- Emerging risks;
- Scientific Committee.

Communications

The Communications Directorate (COMM) is responsible for risk communication. Based on the independent scientific advice of the scientific panels, it divulgates to the relevant stakeholders and beneficiaries the risks associated with the food chain. The Communications Directorate is divided into two units: the Editorial unit and the Communications Channels unit. The Editorial unit sets communications approaches, key messages and content for dissemination. The Channels Unit develops integrated communications activities across all communications channels and tools.

EFSA communicates with risk managers, national authorities, other agencies and the public at large through online and offline communications tools. Its areas of competence are:

- Editorial and Media Relations;
- communication channels.

Resources and Support

The Resources and Support Directorate (RESU) is responsible for administrative and support services to the organization. The main services include a strategic approach to human resource management, an IT system in support of the scientific work, and financial management and procurement services in support of, for instance, networking and partnership. Its areas of competence are:

- accounts;
- corporate services;
- finance;
- human capital & knowledge management;
- IT systems;
- legal & regulatory affairs.

6. List of documents

Regulations

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law; establishing a European Food Safety Authority and laying down procedures in matters of food safety, as amended by Regulation (EC) No 1642/2003 of the European Parliament and of the Council of 22 July 2003;
- PPT Regulation (EC) No 178/2002 of the European Parliament and of the Council (2002);
- Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, in so long it applies to documents held by the Authority;
- Regulation (EC) No 1304/2003 of 23 July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it;
- Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organizations operating in the fields within the European Food Safety Authority's mission;
- Financial regulation of the European Food Safety Authority (2009);
- Regulations related to EFSA by field of intervention (see Annex 4).

Documents for strategies, policies, procedures and reports

- Strategic plan of EFSA for 2009-2013 (2008);
- Science strategy 2012-2016 (2011);
- International activities – a strategic approach. Document describing EFSA's strategic approach to international activities (2009);
- Interim Review of the Strategy for Cooperation and Networking between EU Member States and EFSA (2008);
- Strategy for Cooperation and Networking between the EU Member States and EFSA (2006);
- Technical report of EFSA on Scientific Cooperation between EFSA and Member States: Taking Stock and Looking Ahead (2011);
- PPT Article 36 and application procedure, EFSA (2010);
- EFSA's Communications Strategy: 2010-2013 perspective (2010);
- PPT EFSA's Communications Strategy 2010-2013: implementing a thematic approach (2011);
- Review of EFSA's Communications Strategy: What have we achieved? What have we learned? (2010);
- Technical report – Report on Data Collection: Future Directions (2010);
- Multiannual Staff Policy Plan 2011-2013 of the European Food Safety Authority (2010);
- Progress Report on the implementation of the Management Board decision to further develop Impact Indicators within EFSA as appropriate tools for measuring the effectiveness of EFSA (2011);
- Impact indicators – using appropriate tools for measuring the effectiveness of EFSA

(2010);

- EFSA's approach on Public Consultations on scientific outputs;
- Management Board conclusions of the external evaluation of EFSA and recommendations arising from the report (2006);
- Roadmap: priorities for selected EFSA activities, EFSA - DG Sanco (2010);
- Roadmap European Parliament and Council Regulation on fees for EFSA (2011);
- Description of the scope of Directorates and Units within EFSA's new organization model;
- PPT EFSA IT governance structure and composition, EFSA (2010);
- Definition and description of "Emerging risks" within the EFSA's mandate (2007);
- Definitions of EFSA scientific outputs and supporting publications (2011);
- PPT From the reception of a mandate to the publication of a scientific output (2011);
- PPT How does EFSA produce its science? The workflow of scientific opinions, EFSA (2010);
- EFSA policy on declaration of interest (MB 11 09 2007);
- A policy on independence and scientific decision-making processes of the EFSA (2011);
- Draft policy on Independence and scientific decision-making processes of EFSA, EFSA consultative work on Independence (October 2011);
- Review of EFSA's policy on declarations of interest: a reflection paper (2011);
- Decision of the Executive Director implementing EFSA's policy on independence and Scientific Decision-making process regarding Declarations of interests (2012);
- Implementing act to the policy on declaration of Interests procedure for identifying and handing potential conflicts of interests (2009);
- Implementing act to the policy on declaration of interests - Guidance document on declaration of interests (2009);
- EFSA's policy on independence and scientific decision-making process: New rules in practice. Setting the scene. 5 March 2012, Brussels;
- Decision of the Management Board of the European Food Safety Authority concerning Implementing measures of transparency and confidentiality requirements (2005);
- Openness, transparency and confidentiality – general principles (2003);
- Decision concerning access to documents (2003);
- Implementing rules concerning the tasks, duties and powers of the Data protection officer (2006).
- Technical Report: activities, processes and quality assurance elements on data collection programmes with Member States (2011);
- Rules of procedure of the Management Board of the European Food Safety Authority (2011);
- Code of conduct of the Management Board of the European Food Safety Authority (2011);
- EFSA code of good administrative behaviour (2003);
- Decision concerning the operation of the Advisory Forum (2008);
- Advisory Forum Working Group on Communication – Terms of reference (2007);
- Decision concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups (2009);

- Decision of the Executive Director concerning the selection of members of Scientific Committee, Scientific Panels and external experts to assist EFSA with its scientific work (2011);
- Call for expressions of interest for scientific experts to be considered for membership of the Scientific Panels and the Scientific Committee of the European Food Safety Authority and Annex I (2011);
- PPT Renewal of panels 2012 (MB 15 03 2012);
- Appointment of the members of the Scientific Committee and eight Scientific Panels and placement of suitable candidates in the reserve list and PPT Renewal of Panels 2012 (MB 14 06 2012);
- Rules of procedure of the Scientific Committee, the Scientific Panels and their Working Groups (2012);
- Internal and external review – Scientific advice by the Scientific Committee (Question NºEFSA-Q-2007-060). Proposal for a review system for EFSA's scientific activities (EFSA Journal 2007 526, 1-15);
- Internal report – INEX exercise 2008;
- Technical report of EFSA – EFSA's INEX activities in 2009 (2011);
- Decision concerning the establishment and operation of European Networks of scientific organizations operating in the fields within the Authority's mission (2010);
- Stakeholder Consultative Platform: Terms of Reference (2010);
- PPT EFSA rolling work plan on the activities with its stakeholders (2010);
- Risk assessment workflow (website);
- Overview and status of SOPs, QM/AVI/11 (March 2011) and EFSA's specific Standard Operational Procedures;
- Technical report of EFSA - EFSA procedures for responding to urgent advice needs (2011);
- Technical report of EFSA - EFSA procedures for responding to urgent advice needs (2012);
- Support and Assistance in the development of the European Food Safety Authority's science strategy 2010-2016, Hardy (2010);
- Decision of the Executive Director of the European Food safety Authority regarding multisectoral issues (2012);
- Internal control standards (MB 23 01 2008);
- Communication to the Commission - Revision of the Internal Control Standards and Underlying Framework, SEC(2007)1341;
- Annual Management Plans from 2005 to 2011;
- Annual activity reports from 2005 to 2011;
- Annual financial reports from 2005 to 2010;
- Reports on the annual accounts of the European Food Safety Authority of the financial years from 2008 to2010 (with the Authority replies), European Court of Auditors;
- Annual Reports on EFSA's food and feed safety crisis preparedness and response from 2009 to 2011;
- Editorial: EFSA's food and feed crisis preparedness and response, Tobin Robinson and Hubert Deluyker, EFSA (2012);
- Scientific report of EFSA - Shiga toxin-producing E. coli (STEC) O104:H4 2011 outbreaks in Europe: Taking Stock (2011);

- Technical report - The advice from the EFSA Scientific Committee on a general format for scientific opinions of the EFSA (2009);
- Report on focal point activities from 2008 to 2011;
- Technical report of EFSA - Annual report on Article 36 activities. Follow-up to the 2009 evaluation report of EFSA's grant and science procurement schemes (2011);
- Review of the work carried out under Article 36 and proposed contract and grant activities for 2009;
- Project report of EFSA - Evaluation of EFSA's science grants and procurement schemes (2010);
- Reports of the Quality Manager from 2008 to 2011;
- Technical report of EFSA - Information exchange platform (IEP), evaluation report (2010).
- Technical reports of EFSA – Expert database annual reports of activities (2009 and 2010);
- EFSA Insight Survey – Written feedback provided by EFSA staff (2011);
- Summary report – EFSA scientific colloquium XVI. Emerging risks in plant health: from plant pest interactions to global change (2011);
- Draft Technical Report – Mapping and assessment of regulatory workflows concerning scientific evaluation of regulated products and related annexes;
- IAC – Audit report on the process of receipt of request for scientific advice (2011);
- IAS – Final audit report on recruitment in the European Food Safety Authority (2009);
- IAS – Final audit report on operational planning and budgeting in the European Food Safety Authority (2011);
- IAS – Final follow-up audit report on the in-depth audit of EFSA (2007);
- IAC - Carry forward report (2008);
- IAC - Follow up audit report of EFSA internal audit report on annual declaration of interest and specific declaration of interest (2008);
- IAC – Follow up audit report of IAS audit report on Declarations of Interest of Experts (2009);
- IAS – Final audit report on declarations of interests on experts and staff in the European Food Safety Authority (2009);
- IAS – Final follow-up report on the audit of declarations of interests of experts and Staff (2009);
- IAC – Review report on expert contribution to a scientific opinion (conflict of interest) – The population reference intakes for carbohydrates and dietary fibre scientific opinion (2010);
- IAC – Review report on expert contribution to a scientific opinion (conflict of interest) – Nutrient profile opinion (2010);
- IAC – Review report on expert contribution to a scientific opinion (post conflict of interest) – scientific opinion on risk assessment for a selected group of pesticides from the triazole group to test possible methodologies to assess cumulative effects from exposure through food from these pesticides on human health (EFSA-Q-2007-183) (2011);
- IAC – Review report on expert contribution to a scientific opinion (post conflict of interest) – the potential developmental neurotoxicity of deltamethrin opinion to EFSA-Q-2008-373 (2011);

- IAC – Review report on expert contribution to a scientific opinion (post conflict of interest) – updating the opinion related to the revision of Annexes II and III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market – Toxicological and metabolism studies (EFSA-Q-2009-00615) (2011);
- IAC – Review report on expert contribution to scientific opinions (post conflict of interest) – scientific opinions adopted by the PPR Panel in the reference period (2011);
- IAC – Review report on expert contribution to a scientific opinion (post conflict of interest) – scientific opinion on preparation of a guidance document on pesticide exposure assessment for workers, operators, bystanders and residents (EFSA-Q-2008-261) (2011).

Guidance documents and guidelines

- Transparency in risk assessment in risk assessment carried out by EFSA: guidance document on procedural aspects (EFSA Journal 2006 353, 1-16);
- Guidance of the Scientific Committee on transparency in the Scientific aspects of risk assessment carried out by EFSA. Part 2: General principles (EFSA Journal 2009 1051, 1-22);
- Guidance of EFSA - Standard sample description for food and feed (2010);
- Guidance of EFSA - Guidance on data exchange (2010).
- Guidance document on Declaration of Interests, EFSA (MB 11 09 2007);
- OECD Guidelines for managing conflict of Interest in the Public Service (2005);
- Recommendation of the Council on guidelines for managing conflict of interest in the public service, OECD (2003);
- Guidelines for observers, EFSA website (2012).

Budgets and indicators

- Statement of revenue and expenditure of the European Food Safety Authority from 2002 to 2011;
- Indicators provided by EFSA (2012);
- Progress indicators from 2008 to 2011;
- Internal statistics on DoI – BO reports (2012).

Previous evaluation reports/external studies

- Evaluation of EFSA Final Report, Bureau van Dijk Ingénieurs Conseils with Arcadia International EEIG (2005);
- Self assessment report to assess the European Food Safety Authority in terms of alignment with the requirements of ISO 9001:2008 Quality Management Standard, FERA (2011);
- Preparation for scientific quality assessment, Stewardship Solutions Ltd (2011);
- EC Report - Special Eurobarometer 354, Food related risks (2010);
- EC Report – Special Eurobarometer 340, Survey Report on Science and Technology (2010);
- Image of the European Food Safety Authority – Qualitative research report, FPA (2010);
- PPT The image of EFSA – Qualitative research, FPA (2010);
- EFSA efficiency programme initiation - Quick Scan Report (2010);

- EFSA efficiency programme initiation – Kick-off presentation, executive summary (2010);
- PPT e3 Programme, Final rightsizing, report phase1 (2011);
- PPT e3 programme and changes in the organization (MB 17 03 2011);
- Business Process Mapping, Draft Pilot Report for Science, Deloitte (2011);
- Business Process Mapping, Draft Pilot Report for CORSER, Deloitte (2011);
- PPT Report on the results of the IT Risk Assessment workshop, Deloitte (2009);
- PPT IT internal audit report following the IT Risk Assessment at EFSA, Deloitte (2009);
- Independent Report of factual findings in connection with the implementation of EFSA policy on Declarations of Interests in certain Scientific Panels, Acertis (2011).

Other

- EFSA's website;
- EFSA journal;
- EFSA Database;
- EC website.
- PPT presentation on EFSA provided by EFSA;
- Management board broadcast of the 51st Management Board Meeting (MB 15 12 2011);
- Minutes of the 52nd Management Board meeting (MB 15 03 2012);
- Minutes of the 43rd Advisory Forum Meeting (7 03 2012);
- AFWG on Communication meeting minutes;
- European Parliament resolution of 10 May 2012 on discharge in respect of the implementation of the budget of the European Union Agencies for the financial year 2010: performance, financial management and control of European Union Agencies (P7_TA-PROV(2012)0164).
- Commission Decision 2004/478/EC concerning the adoption of a general plan for food/feed crisis management.
- Case law of the Court of Justice of the EU, EFSA/SC/1400 (2012);
- Conflict on the menu, CEO (2012).

Benchmark documents

EMA

- EMA's website;
- Annual report from 2008 to 2010;
- European Medicines Agency policy on the handling of conflicts of interests of scientific committee members and experts (2012);
- Recruitment at the European Medicines Agency (2012).

ECHA

- ECHA's website;
- Annual reports from 2008 to 2010;
- Founding Regulation 2006/1907.

FSA

- FSA's website;

- Annual Report from 2008 to 2010;
- National perspective on independence (Presentation 2012 at EFSA advisory forum);
- The Food Standards Agency's approach to risk.

VWA

- VWA's website;

EU WIDE

- EU Agencies' governance costs, financial management and operational efficiency: comparative data (2012);
- Evaluation of EU decentralized agencies, Ramboll, Eureval, Matrix insights (2009);
- Comparison between the tool ensuring EFSA's independent scientific advice and the instruments in use by organizations similar to EFSA, Milieu (2011).