





# **Final Minutes**

# 83rd MEETING OF THE EFSA ADVISORY FORUM

# **Meeting details**

Venue: ANSES Headquarters, Maisons-Alfort, France (Hybrid meeting)

Meeting dates and hours: 06.04.2022, 9:00 - 17:30 07.04.2022, 9:00 - 12:40

	Attendance		
Members	In person	Virtual	
Austria (AT)	Klemens Fuchs		
Belgium (BE)		Fabien Bolle (2 <sup>nd</sup> day)	
Bulgaria (BG)	Iliyan Kostov		
Croatia (HR)	Darja Sokolić		
Cyprus (CY)	Stelios Yiannopoulos	Charitini Frenaritou	
Czech Republic (CZ)		Jitka Götzová	
Denmark (DK)	Christine Nellemann		
Estonia (EE)	Mari Reinik		
Finland (FI)		Pia Mäkelä Tuominen Pirkko	
France (FR)	Matthieu Schuler Salma Elreedy		
Germany (DE)	Andreas Hensel		
Greece (EL)	Stavros Zannopoulos		
Hungary (HU)	Akos Jóźwiak		
Iceland (IS)	Hrönn Ólína Jörundsdóttir		
Ireland (IE)		Pamela Byrne	
Italy (IT)		Alessandra Perella	
Latvia (LV)	Olga Valcina		
Lithuania (LT)	Deimante Bikneryte		
Luxembourg (LU)	Marc Fischer		
Malta (MT)	Ingrid Busuttil		
Netherlands (NL)	Antoon Opperhuizen		
Norway (NO)	Harald Gjein	Danica Grahek-Ogden	
Poland (PL)	Jacek Postupolski		
Portugal (PT)	Pedro Portugal Gaspar	Filipa Melo de Vasconcelos	





Romania (RO)		Simona Radulescu	
Slovak Republic (SK)		Milo Bystricky	
Slovenia (SI)		Urška Blaznik	
Spain (ES)	Isabel Peña Rey	Icíar Fierros Sánchez-Cuenca	
Sweden (SE)	Per Bergman		
Observors & Other Participants	Attendance		
Observers & Other Participants	In person	Virtual	
Bosnia and Herzegovina (BA)	Dzemil Hajric		
Montenegro (ME)	Ana Velimirovic		
Republic of North Macedonia (MK)		Nikolche Babovski	
Serbia (RS)	Tamara Bošković		
Switzerland (CH)	Michael Beer		
Turkey (TR)		Serap Hanci	
European Commission – DG SANTE (Observer)		Athanasios Raikos	
European Commission – DG SANTE (Observer)		Luis Vivas-Alegre	
European Commission – DG ENV (Guest speaker, 1 <sup>st</sup> day)		Vujaldin Kovacevic	
European Commission – DG SANTE (Observer, 1 <sup>st</sup> day)		Sofie Hofkens	
European Commission – JRC (Observer, 1 <sup>st</sup> day)		Ana Montero Castaño	
Representative of European Commission DG SANTE's unit on "Pesticides and Biocides" (Observer, 2 <sup>nd</sup> day)			
European Chemical Agency (ECHA) (Guest speaker, 1 <sup>st</sup> day)		Simón Gutiérrez Alonso	
European Environment Agency (EEA) (Guest speaker, 1 <sup>st</sup> day)		Markus Erhard	
French Agency for Food, Environmental and Occupational Health & Safety (ANSES) (Guest speakers, 1st day or 2nd day)	Roger Genet Gilles Salvat Marie-Pierre Chauzat Arnaud Callegari		
Belgium Institute of Health SCIENSANO, Belgium (Guest speaker, 2 <sup>nd</sup> day)		Hein Imberechts	

EFSA Representatives		
Bernhard Url (Chair) – In person	Agnes Rortais – Virtual	
Barbara Gallani (Co-Chair) – In person	Andrea Gervelmeyer – Virtual	





Nik Kriz (Co-Chair) – In person	Stef Bronzwaer – Virtual	
Guilhem de Seze (Co-Chair) – In person	Sérgio Potier Rodeia (Advisory Forum Secretariat) – In person	
Victoria Villamar – In person	Maria Azevedo Mendes (Advisory Forum Secretariat) – Virtual	
Eileen O'Dea – In person	Cristina Alonso Andicoberry (Advisory Forum Secretariat) – Virtual	
Claudia Heppner – Virtual	Sofia Altesini (Advisory Forum Secretariat) – Virtual	
Julia Fabrega – Virtual		

# 1. Opening and welcome address

The Chair, Bernhard Url, welcomed the Advisory Forum (AF) members and observers to the 83<sup>rd</sup> AF meeting, first in-person meeting after two years, and the first ever organised as hybrid event.

He thanked ANSES for hosting the event and gave the floor to Roger Genet, ANSES Director General, for some welcoming words.

Mr. Genet started by welcoming all participants to ANSES and to Paris, and then stressed ANSES' strong commitment with EFSA and all the other AF organisations. He indicated that ANSES scientists are encouraged to engage with EFSA activities. He congratulated the new opportunities and strengthened collaboration facilitated by the Transparency Regulation. He highlighted the key role played by the AF in enabling the links among institutions and in maximising the sharing of information for a better protection of consumers.

He concluded reminding the audience that pandemics like COVID have proven the need for science and expertise to help deal with new threats and the need to work together, and that Europe offers several opportunities for collaboration, like Horizon Europe partnerships; in several of which, ANSES is actively taking part. Some of these opportunities have already been discussed at the AF level, and ANSES is pleased to support and encourage their moving forward.

The Chair thanked Mr. Genet for his welcoming words and for highlighting how important collaboration is. He stressed that EFSA has collaborated with ANSES for many years in different fields, and that EFSA would like to intensify this in the years to come by long-term cooperation, the development of partnerships, based on shared objectives, shared values and on mutual creation of new values.

#### 2. Welcome address from the French Presidency of the Council of the EU

Roger Genet gave the floor to Bruno Ferreira, Director General of the Directorate General for Food, at the Ministry of Agriculture and Food (connected remotely), for the Welcome Address on behalf of the French Presidency of the Council of the EU.

In his speech, Mr. Ferreira stressed the importance of the promotion of scientific excellence and networking to achieve transparent, independent and high-level expertise, by strengthening the relationships between EFSA and food safety institutions in the Member States (MS). He emphasised the need to face together the numerous challenges in the food chain, some of which are linked to emerging and re-emerging risks. He commented specially on the need to develop surveillance activities and increase the efforts in collecting harmonised and standardised data, as well as in reporting these data in a harmonised way, although the constraints from Member States should also be considered.





He continued by acknowledging EFSA's role in the promotion of multidisciplinary and multisectoral collaborations, essential to explore potential developments in the risk assessment science and to examine the food and feed safety from a broader perspective.

Mr. Ferreira concluded by congratulating EFSA on the organisation of the ONE Conference in June, which he considered to be an important message from the European Union of Europe's engagement in the One Health concept.

The Chair thanked Mr. Ferreira for his reassuring words and praised the effort that France has put on the One Health concept, that allows to go from food safety to sustainable food systems. He reminded that this needs to be a joint effort.

# 3. Adoption of the agenda and action points from last meetings

The Chair thanked again Mr. Ferreira and Mr. Genet for their words and bade them farewell.

Afterwards, he informed about the rules for a smooth running of the meeting, to avoid difficulties arising from the hybrid format.

Bernhard welcomed the participants again and particularly:

 Ms. Rossana Valentini – new AF Alternate for Italy - Ministry of Health, replacing Simonetta Bonati, although she was not connected at that moment.

He also welcomed the **EC representatives:** 

- o Athanasios Raikos and Luis Vivas-Alegre, observers in the meeting on behalf of the EC.
- He informed that other representatives of DG SANTE, representatives of DG-ENV, DG-AGRI and JRC would join for the thematic discussion on bees and pollinators initiatives in the afternoon.

Apologies were received from Belgium.

After providing an overview of the agenda for the meeting, the Chair:

- o Asked the Plenary if there were additional items to be raised under AOB. Sweden, The Netherlands and Denmark raised additional items.
- Noted that the final minutes of the 82<sup>nd</sup> Advisory Forum meeting had been published on the EFSA website on the 15<sup>th</sup> of February.
- o Informed the Plenary that all action items from last AF meeting have been implemented.
- o Informed the Plenary that the meeting would be recorded for minute-taking purposes.

The agenda was adopted without any further comments and no objections were raised for the recording of the meeting.

# 4. Update from the AF Discussion Groups

# ■ 4.1 - Update from the Advisory Group on Data

The Chair gave the floor to Akos Jozwiak (HU) as Chair of the Advisory Group on data, to provide an overview on the outcome of the  $5^{th}$  and  $6^{th}$  meetings of the Group, held virtually, and on the  $7^{th}$ , organised as a physical workshop back-to-back to the AF Plenary.





During the 5th and 6th meetings the members discussed 1) the strategic context of the activities of the group, for instance the EFSA Strategy 2027 and EFSA Multi-Annual Programmes, 2) the workplan 2022 and beyond, and 3) the governance model.

Akos stressed the challenge of the rapid evolution of the new world of data science and the complexity of the data remit, being the coexistence of different actors and strategies (e.g., EC, sister agencies, MS) an important part. He also highlighted the need for the Group to address such complexity by discussing both strategic and technical issues, and he proposed the creation of sub-groups which will allow to focus the discussion around specific aspects on a more detailed level. Proposed topics for the working groups are the following ones:

- Developing and Sharing Tools and Technology;
- Digital Platforms and Ecosystems, including communication and engagement;
- Innovative Data Analytics and New Data Stream;

Moreover, among possible topics for additional identified sub-groups and that could be kicked off at a later stage: data literacy and data capacity, data quality, data modelling and terminology, data analysis and visualisation.

On the organisation of the sub-working groups, Akos informed the Plenary about the participation of the AGoD members but also the willingness to involve other experts coming from the already existing networks related to EFSA. He also explained that meetings would take place online between AGoD meetings, and that each sub-group will develop its own work programme and roadmap and report back to AGoD meetings.

Akos then provided an update on the outcome of the 7<sup>th</sup> meeting, held on the day before the Plenary. During the workshop, AGoD members presented the common characteristics of data flows in each represented country, and, in break-out session, they identified the applicability of three tools - Business Rules Engine, Mapping tools, Data sampling at the point of collection - at country level and willingness of their adoption to overcome some of the identified challenges. The exercise gathered much insight on the proposed three tools particularly regarding: 1) pain points where these tools could help in; 2) benefits; 3) challenges that in the developments of the tools we might encounter and solve; and 4) engagement aspect, both at co-design level and adoption level. What the group identified is that there are common problems and challenges in the data streams and flows around all the MS but also some already solutions, which in some cases have been developed in parallel leading to duplications or divergences. The group identified several foreseen benefits in the introduction of the proposed tools and there was a willingness to co-create and adopt at this small group level. Akos mentioned the positive feeling of the group after the exercise and the enthusiasm in adopting a collaborative approach to solve common issues.

Akos clarified that the tools identified were stemming from the Data task force recommendations, delivered in 2020, and that they were identified as priority tools during 2021. He also reiterated the need of more systematic and complete knowledge on data processes, the bottlenecks and the solutions at MS level, and the possibility for 2022 and 2023 to benefit from the support of a consultancy to perform this activity, by making a deep scanning of the system on systematic basis.

Akos concluded his presentation by outlining the next steps, in particular 1) the continuation of the work of the group during 2022 as per the calendar of meetings scheduled May, June, September, October (back-to-back with AF), and November/December; 2) the introduction of sub-working groups, subject to discussion during the Plenary; and 3) the decision on the project of mapping national data flows, challenges and bottlenecks at systematic level for 2023-2024.

The Chair praised the valuable work of the AGoD and stressed the importance of identifying challenges and divergences in order to foster interoperable solutions in the data remit which is key to support the reporting and processing of data both for risk assessment and risk management purposes. He then opened the floor for discussion and gave the floor first to Eileen O'Dea, as coordinator of the AGoD on EFSA's behalf.





Eileen thanked Akos and the members of the group for the commitment and cooperation in this initiative and reiterated the positive outcome of the last meeting. She stressed that the AGoD aims at delivering concrete solutions to overcome existing challenges, making the data processes as much automated as possible. She also outlined that some MS have already created tools which can be made available to other countries, and this already represents an important step forward. Eileen concluded by expressing support to Akos' proposal to look systematically at the data flow in each MS as this is a way through which identifying those cases where funding and support in automation could be beneficial.

The Chair thanked Eileen by noting that the example of the AGoD could represents a blueprint on how to work in the future with MS also on other remits, fostering partnerships but also reflecting on how to bring in this picture the Focal Point Network, whose framework is currently under revision.

Iceland intervened by emphasizing the relevance of the work carried out by the group and how being part of this initiative could benefit also those countries with limited resources to be invested in the design of tools for improving data flows and processes.

The Netherlands raised a comment on the added value brought by the activities of the group, by referring to the improvements introduced in the data infrastructure and data flows at MS level, since the kick-off of the data task force activities in 2017. He also emphasized the improved collaboration in the data remit not only between EFSA-MS but also among MS and reiterated the importance of adopting collaborative approaches and joint solutions, making existing tools and infrastructures available also to other countries. He noted that data collection and information streams are fundamental issues in the RA remit, and he then remarked the support to the initiative and proposed way forward.

The Chair reinforced the Netherlands comment on the adoption of collaborative solutions and noted how duplication of works should be avoided through making those solutions developed by one MS available to all. Only through distribution of work between MS and EFSA can the work progress. The Chair also put the focus on the need of doing more in this field and with an increase speed and raised a question on what EFSA and MS can do as a community to meet this goal.

Sweden congratulated the group for the achievements and agreed with The Netherlands regarding the complexity of the data remit and the need of adopting joint approaches and solutions. He supported AGoD initiative and offered additional assistance and expertise to progress with the work.

Denmark intervened by noting the existence of different governance structures in the various data remits in the MS and the need of adopting different tools to be able to use the available data. Supporting the work of the AGoD is a way to move ahead in this context and make progress. She also suggested to look at the RAKIP initiative aimed at creating a platform to access different RA models and to integrate knowledge.

Spain praised the work of the group and mentioned the importance of ensuring good synergies between the activities of the AGoD and the ones of the Focal Point, avoiding duplication of work at MS level.

Germany supported the comment raised by Spain, and noted the importance of adopting also top-down solutions to ensure harmonisation at EU level to what concern interfaces, programming and how data are structured in the MS. The identification of feasible solutions to tackle existing problems is important but there are areas which cannot be influenced by MS and that should be described and solved at a different level. In order to agree on a possible way forward those distinctions should be made.

Ireland showed support to the initiative and raised a comment on the successful outcome achieved thanks to join forces and work together. She also emphasized the complexity of some of the issues related to the data remit and the amount of resources invested by EFSA and MS to overcome those issues. EFSA plays an important role in this context, by helping and supporting MS in navigating such complexity, optimizing the value brough by data and enhancing a better cooperation and alignment. The contribution and central role of the EC and MS and the need of alignment between all the actors





involved is crucial. Along the lines of the comment raised by Germany, Ireland also referred to the need of identifying those gaps where EFSA could concretely intervene hence contributing to shaping a better system.

France congratulated Akos and the group and noted how we are currently facing two challenges in the data remit. On the one hand, there is need of streamlining the data collection process making it as efficient as possible while on the other, it is important to make the structure of available data fit for purpose and useful to perform risk assessment.

Eileen intervened by providing some examples of shared effort and best practises between MS. In particular she referred to the Portugal-Croatia initiative, funded by EFSA aimed at developing a tool for data capture to support high quality data reducing routine tasks. She also touched upon a project led by Sweden focused on building an automated data pipeline through the national data processing system to transmission of data to EFSA which helped identifying key areas where additional effort was needed.

The Chair, referring to the comment raised by Germany, reiterated the importance of data standardization and data governance and emphasized the importance of looking further on how we can make use of the development of the European Chemical Data Space for our risk assessments, mentioning the envisaged use of e.g. IUCLID for managing all chemical data or even to be used outside the 'chemical world'. He also noted the importance of mapping data flows and streams in the MS and to take into considerations ongoing initiatives in this matter.

Akos thanked EFSA, the AF and members of the Group for showing support to this initiative. He stressed the relevance of issues raised by the MS particularly in the context of a fast-moving world becoming more and more data driven, requiring a continuous update and development of the tools and an increasing investment to ensure change management and adaptation. Akos agreed with Germany that there are issues which cannot be influenced by MS but stressed that using analytical tools or AI possibly workarounds, beyond data standardization, can be found. He also reiterated that making distinction between what can be achieved with the MS and what should be tackled in higher for a of discussion is very important. He then concluded the need to act in a timely manner and the relevance of having everybody on board in this endeavour also for those countries with limited capacity.

The Netherlands agreed with Akos with regards to the food safety environment, moving towards data driven and risk based, and raised a comment related to how the future will be data steered and risk driven.

Denmark suggested to take into consideration the multiple research projects under Horizon Europe, falling in the data remit as means to advance in this context.

Germany noted the importance of the huge amount of data resulting from self-controls by food companies (e.g. retailers, producers) which is not used, and it could enormously enlarge the basis for the risk assessments. He stressed the need to adopt a standardized approach among all MS to obtain and use these food business operators' results, which are quantitatively far superior to the official controls' ones, have already been paid for, and are not used except in crisis situations. Although the EC does not foresee this possibility since the data is owned by industry, most companies would have no problem. Germany pointed out that the harmonization of the analytical system towards a European standard would be essential, and this could perhaps be achieved using the national system or the European Reference Laboratory system.

The Chair acknowledged the validity of the comments from Germany, however stressed its complexity linked to aspects such as the confidentiality and reliability of data. He also noted how EFSA's role in embracing this change is quite limited but noted that some progress could be attempted in this matter.

The Chair thanked the MS for the intervention and closed the agenda item.





## 4.2 - Update from the AF Discussion Group on the Future of Partnerships (AFDGFoP)

Salma reminded the meeting participants of the Terms of Reference of the Group and provided a brief update of the work that this DG had been conducting since the last AF meeting. She informed on the Group's indication of the value in identifying (among Focal Points) good practices in stimulating the interest of Art. 36 in engaging in EFSA-related work; in providing training to the Focal Points, in areas where it might be helpful; and in sharing information on envisaged calls or other cooperation opportunities with the community, as early as possible. On the first two points, Salma suggested that a discussion among the Focal Points would be useful and could lead to concrete proposals. On the third point, Salma conveyed that the group noted that it would be worth reviewing and improving on the possibility and mechanisms for EFSA to provide early information to the MS on envisaged calls or cooperation opportunities, as this provides time for interested parties to prepare.

Salma informed the Plenary that they will look further into the way that the EU reference centres for animal welfare operate, as a source of inspiration for potential Partnership modalities by EFSA, as well as into the tools that EFSA currently uses to identify cooperation opportunities with the MS.

Salma took the opportunity to thank EFSA for preparing updated versions of the infographics on Grants and Procurement, which are a useful tool in promoting engagement between the MS organisations and EFSA.

She informed the AF that the Group would have a meeting coming up in a few days and it would look at the expected deliverable the Group would like to bring to the AF.

Salma concluded by highlighting that the interaction and the bringing together of the ambitions and ideas identified in the different AF DG, are a mechanism to further enhance the work, and invited the AF to also propose any other topics they would deem relevant to be addressed by the DG.

Victoria pointed out that they had all benefited from this DG as a sounding board, verifying ideas and learning from the experiences of its members. The group has been collecting and collating all these inputs and will now also discuss how best to present them to the AF. She informed that there would be an upcoming meeting with the Co-Chairs of the other discussion groups, to develop synergies and see how they could use their deliberations and reflections. When talking about partnerships, while some overlap among the different discussion groups may exist, one can also identify the potential to possibly bring together a framework or different model features that would help us move partnerships with Member States, and beyond. Recognizing that no one size fits all, she pointed out that we embrace diversity, so we try to dive deep into specifics of Member States. However, she highlighted that we also want to find a common denominator that can serve all MS. She pointed out that all this is at the core of the work within the Focal Point operational framework.

The Chair thanked Salma and Victoria and acknowledged the need to broaden the expertise base that EFSA has access to, and improve on long-term planning, also exploring innovative options. Long term collaboration would imply not only in the use of data and methodology, but partnering on what regards expertise, so to use it both on a European and national levels. He stressed that this lack of expertise is not an EFSA problem, but a European one, and as such Partnerships could be a way to overcome this issue, e.g. by hiring staff together where possible, or by having working groups sitting in any MS, jointly funded, working towards the same goal. Trust and mutual value creation, which would enable co-investment and sharing of benefits and risk, would be important.

The Netherlands stressed that Partnerships are something urgent which has been under discussion for too long, hence the need to speed up. He questioned about what other colleagues were doing in this field and found it strange that nobody provided any contributions when previously asked, reaffirming that the changes are moving to slow.

Hungary pointed out that the partnership concept is rather burdened. He highlighted that actors beyond the Art. 36 may – at some point – need to be considered, for example, for Data or Environmental science or other areas that are borderline on the remit of EFSA. This concern was also





shared by Spain. Further to that, Hungary noted that there may be a need to re-think the rules, which implies legal and financial questions, also involving the EC. This challenge may not be possible to be tackled within the AFDGFoP, so we may need to narrow the problem.

France supported the concept and the aim of the Partnership concept but highlighted that the details should not be underestimated. He outlined the example of the enzymes assessment pilot, stressing the current interest to open the discussion from bilateral to multilateral. There are plenty of details to be sorted out, including financial and legal ones. France is one of the few countries with national activities on enzymes, due to a national regulation. However, it would be beneficial to do the work of the assessment only once, to meet both national and European regulatory expectations.

Spain agreed that there may be organisations worth working with beyond those in the Art. 36. For AESAN, she mentioned that the challenge is that their budget is annual, so long-term planning, with regards to resources, is not easy.

Denmark proposed to move ahead and launch a partnership. She suggested putting together a group with complementary competences to work, for example on mixtures. Examples will show us how to proceed.

Germany pointed out that the important factor for partnerships is connecting people, not systems. Also, things are driven by the MS – not necessarily by the European idea of having a single, harmonised approach. In the case of BfR, speed can be important as they may have to complete a quick risk assessment in hours or days. The ecosystem requirements would also be different for the BfR. Hence, space needs to be made for the needs of EFSA. It is important to stress that the win-win situation is different for the various countries. We are all captured by the needs of the regulatory system. Thus, it would make sense to focus on what can be solved.

Ireland outlined that Partnerships in the research area have started more than 16 years ago and are just beginning to deliver, via public-public or public-private partnerships, meaning that things need effort and time to mature. Since there is the need for more actors outside our close ecosystem, she suggested that we could articulate our vision at MS level and use it to lobby for support. Irelands also pointed out that we should identify the outcomes from effort so far, share them with the AF members for them to use it at national level to ask for additional support where feasible and needed. While we cannot continue doing things the same way, having clarity in our vision would be important in moving forward

Sweden noted that in the discussion on how to move ahead, different MS have different level of freedom of manoeuvre. An info-pack with the vision for partnerships could help get buy-in in the MS. Sweden asked whether the new MB of EFSA could help towards that direction.

The Chair concluded by outlining that EFSA looks forward to having the Member States on board and having this discussion also at Management Board level.

The Chair thanked all and closed the item.

### ■ 4.3 - Update from the AF Steering Group on the New FP Operational Framework

The Chair gave the floor to Antoon Opperuizen (NL) and Barbara Gallani, co-chairing the Advisory Forum Steering Group on the new FP operational framework (AFSG), for presenting the Terms of Reference, the progress made and the next steps of the group.

Antoon introduced the presentation by stressing the need of evolving the FP network and its way of working to make it fit for purpose to address existing and future needs but also taking into consideration its limited capacity.

He provided an overview on the main steps leading to the establishment of the steering group, with special mention to the 82<sup>nd</sup> AF meeting where EFSA, following MS input, agreed to set-up a steering group composed by EFSA and AF/FP representatives mandated to shape the new FP operational





framework during 2022. The call for expression of interests was launched in the second part of December with a mid-January 2022 deadline.

Antoon outlined the main elements of the Terms of Reference of the Group, particularly:

- The mandate: discuss and shape the new operational framework of the FP Network;
- The composition: Austria, Cyprus, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Spain, Kosovo¹ (observer)
- chairing: The Netherlands and EFSA;
- duration: the AFSG will carry-out its activities from February until July 2022; ambition to conclude the main part of the work by the 84<sup>th</sup> AF meeting (June);
- reporting: AF and FP plenaries in 2022 and by written procedure as needed;
- working methodology: the AFSG is meeting at least twice per month with provision of input and work carried-out by the members in between meetings;
- deliverables:
  - a) ToR which is tabled for approval of the AF during the meeting;
  - b) Framework and outline of the new agreements;
  - c) Final adoption of the new framework and an outline of the future FP agreements (to be endorsed by the AF by end of July 2022).

Antoon also presented the table of content and the progress made by the AFSG. He noted that the AFSG had already agreed on the vision and mission of the FP network of the future. He reiterated the importance of a fit-for-purpose and sustainable FP function and introduced the concept of FP as connecting hubs, meaning that the capacity to perform all required activities does not necessary fall within the FP organisation itself, but FP have the role and skills to connect and find this capacity in other organisations at national level.

On goals, still under discussion within the group, Antoon stressed the link between FP and partnerships and the support to risk assessment and risk communication.

Antoon then provided an overview on some of the proposals of the AFSG regarding possible models and areas of work for the future FP network. On the model, the AFSG raised the need to make it 1) multiannual, so to ensure a predictable approach at least until 2027, 2) flexible, with mandatory tasks and selectable tasks with a cluster approach.

He concluded by presenting the next steps until end of May, mentioning which topics the AFSG would tackle during the months ahead. He also noted the possible discussion on overlaps and synergies between FP and the Communication Experts Network (CEN) during the joint CEN-FP workshop scheduled for May 2022, and the discussion on the future FP network during the FP meeting as well. He finally noted that by end of May the AFSG would finalise a proposal to be presented at the 84<sup>th</sup> Meeting of the AF.

The Chair thanked Antoon and the AFGS for the work carried out and praised the clarity of the proposed direction. He also stressed the importance of envisaging the FP as connecting hubs, and the flexible nature of the model, which better fits MS needs and priorities. The Chair remarked the links between the proposal made by the AFSG and broader strategies as the partnerships strategy and ecosystem thinking.

Sweden took the floor by showing appreciation on the ToR and the presented proposals on the future FP network, particularly on the concept of FP as connecting hubs with a well-established sustainable function fostering partnerships and supporting risk assessment and risk communication. The element

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<sup>&</sup>lt;sup>1</sup> This designation is without prejudice to positions on status and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.





of flexibility was also defined as a good asset of the new framework. He also asked for clarifications on the cluster approach idea.

Antoon, in reply to Sweden, explained that the clusters can be laid down as regional or topic-based groups of countries working in different areas or on any item which is not shared by all as an immediate priority. Antoon brought the example of communication as an area where the strengthening of the current capacity would benefit more coordinated communications across the EU. He concluded by stressing that flexibility can also be intended in terms of time, with grant agreements which can vary in the duration between countries and over the years.

France thanked Antoon for volunteering to chair the working group and praised the engagement of the MS to shape the next FP framework. He also showed appreciation to the change of direction agreed between EFSA and MS at the end of 2021, and the importance of addressing together the how, the what and the implications of adopting different solutions.

Barbara thanked Antoon and the AFSG members for their commitment to meet biweekly. She also highlighted the need to have an alignment between the expectations from the AF and the FP to ensure appropriate support of the FP function in the future. Barbara stressed the opportunities brought by the Transparency Regulation and the associated financial boost which allows further work in different areas, for example data, communications and collation of research needs. It is not always possible to bring all MS working together on a specific topic all the time, but the possibility of adopting a cluster approach can allow some countries to start work in certain areas and others to follow when interested and/or ready.

The Chair stressed the feedback received from the MS during 2021 was key to take the right direction with the establishment of a steering group on the new FP framework.

Spain intervened by stressing the need to align the FP activities with the ones carried-out by the scientific networks in fields such as data. The definition of the role of the FP in specific remit is fundamental so to avoid overlaps and foster synergies. Antoon replied by mentioning that these issues can be also tabled for discussion at the level of specific discussion groups set under the AF as the one of data for example. He also invited MS to raise any comment on the process, possible open questions to be further discussed during the AF meeting.

# 5. State of play on implementation of the Transparency Regulation (TR) in the food chain

#### ■ 5.1 - What has changed and next steps

The Chair gave the floor to Guilhem de Seze to debrief the Plenary on where we are after one year of TR implementation regarding 1) EFSA's scientific process, 2) the new MB and panel renewal, and 3) the general plan on risk communication.

Guilhem informed that the new processes and dossiers are flooding into the new systems EFSA has created and all the systems are holding up. He provided an overview on the number of received dossiers and validated applications submitted through the new IT submission system in electronic format and on the consultations. He expanded on other ongoing actions as the confidentiality assessment which, he mentioned, has been generating quite a volume of work, noting that on sanitization we are still in the learning curve. Guilhem also referred that EFSA is getting many more requests for public access to documents, which could be due to the easier access provided by the new tools. He proceeded by explaining other current actions, as the support provided by EFSA to MS in the phases preceding the declaration of admissibility of IUCLID pesticide dossiers, which encompasses the clarifications on the errors identified in the validation report, the guidance on the interpretation of the General Data Protection Regulation (GDPR), and the clarifications on the discrepancy of information





among IUCLID and the Database. He outlined EFSA's support not only to MS, but also to applicants on the implementation of the big change for structured data.

Guilhem proceeded by providing an update on the state of play of the implementation of EFSA's new organisational design, highlighting the functions of the departments and the new units.

On communication and engagement actions, Guilhem briefly outlined the continuous targeted communication and engagement initiatives foreseen, namely on the Pesticide Steering network meeting, and the new subgroup on IUCLID replacing the technical group, and on other events as the webinar on IUCLID in May, and the one on GMO workflow and new confidentiality, in June. There will be a meeting of the technical group on notifications of studies database both for applicant and MS and update will be given on this in June, in the next AF meeting.

He then informed the plenary about the next steps of the TR implementation, namely on the new Management Board (MB), effective as of 1 July 2022, and on the Expert Panel Renewal. On the latter, he explained that it is currently being revised in order to implement the TR requirements, with the relevant documentation being updated for adoption by the new MB in October 2022. The call for expressions of interest for panel renewal is planned to be published early 2023 and members will start their new mandates in 2024.

Guilhem summed up his presentation by stressing that there is still some work to do to fine-tune the whole system, namely further improving the computer systems, continuing to adjust EFSA's processes.

Barbara Gallani took the floor to debrief the Plenary on the general plan on risk communication, as the fourth pillar of the transparency and sustainability Regulation deals with risk communications. The context includes increased responsibilities for EFSA, the EC and MS for coordinated communications and engagement with citizens, and its communication across risk assessment and risk management. The vision has been discussed in the past months with a community of communication practitioners that can work on localized content and dissemination, but with a focus on European priorities. She outlined that some of the options have been tested to see what might work and what not.

Nik concluded by outlining the efforts made by EFSA on the TR implementation, namely the challenges faced with the huge reorganisation in virtual mode during Covid times. He stressed the need to further improve and the will from EFSA to keep working to achieve the best outcome. He pointed out that, on the panel renewal process, panel members will be appointed now for 5 years, different to the three-year mandates in place at the moment. In this context, he referred the importance, from a strategic point of view, where we want to be in 2024, because this will take us through to 2029. He informed that work has already started and that EFSA would engage to have input to make sure the results will be the best.

The Chair thanked Guilhem and Barbara for the comprehensive overview and opened the floor for questions.

On the new panels framework, Denmark asked if EFSA was envisaging to have different panels or if the existing ones would remain; also, what the foreseen process was to engage the best competence, and if EFSA was expecting the MS input. In response, Guilhem explained that the remit will remain the same, since the legislation had not changed in that respect. Therefore, the existing 10 panels dealing with the same issues would remain. In terms of the composition of the panels, EFSA is now starting the process that will lead to the new panels to be in place in 2024. From experience, EFSA knows that it is a lengthy process, and time is needed from thinking about the profiles to advertising the calls. The new panels mandates will last for five years, until 2029, going beyond the EFSA Strategy. In this sense, panels then accompany the big development EFSA wants to do on data, on digitalization, but also under partnerships. EFSA wants to take all these reflections on board in terms of what kind of panel, what kind of expert individual profiles and what kind of expertise are needed compared to today. On the input proposed from the AF, he outlined that it could be something that would be certainly very useful. He explained that the objective is to organize the panels so that we will be able





to bring answers to the new types of questions that are coming both from the natural science but also from the social science.

The Netherlands asked whether the number of experts in panels would change. Bernhard gave an overview of the framework explaining that currently panels have distinct domain and methodology needs and that legislation only allows for a maximum of 21 members. The number of members is legally fixed for 5 years and cannot be changed easily within that period.

Nik highlighted some of the questions to be tackled on the new panels, namely on how to get the flexibility to substitute people dropping out of panels, how to add experts or to bring younger scientists, how to deal with gender imbalance, and what can be done to attract more active researchers. The Netherlands agreed with EFSA's perspective on the need to equate the panels to EFSA's ambition, strategy, and future challenges, and emphasized that the establishment of the composition and criteria for selection of panel members should also be an AF task, thus proposed to discuss this later in one of the next AF meetings. He also challenged the 5 years duration with the fixed number of 21 members and suggested a more flexible approach. Although praising the work of the panels over the years, he outlined that they are sensitive systems which need a serious refreshment of its structure or even maybe on the mandate and the participation of the countries. Therefore, he stressed the need to have a very fundamental discussion about the system and its organisation. He then suggested to expand the engagement and the role of focal points to create something which may be added to the present system. To this end, he reinforced the need to talk about the risk assessment process and the system, as well as the false incentives which can be overcome, either by adding something now or in the future by rearranging the system.

In his intervention, Germany also challenged the 5 years duration, incompatible with the careers of young researchers, but also the criteria for selecting people considering the needs of the future. He stressed the high amount of time to deliver some opinions by some panels. The issue of duplication of mandates (EFSA and MS) was also pointed out and outlined the need to have a better interaction among all actors (sister agencies/MS) to avoid duplication. On the selection criteria, the knowledge of the type of competences needed (e.g., selecting people with vast experience and a lot of papers vs young scientist with less experience but more active/motivated) should trigger the need to change the system. He further supported the proposal, raised by NL, to evaluate the system and to give input to rearrange the system (now and in the future), highlighting its crucial importance for the AF, and therefore the need for input from this forum, apart from the one given by the people inside the panels. He finally suggested to set up a working group (WG) for that purpose with a very short Term of Reference and a timeline.

The Chair welcomed the proposal from Germany and suggested to look further into the possible creation of a working group, which would work on a SWOT analysis of the current system and, from the results, to proceed with the proposals for the relevant changes accordingly. Bernhard outlined that the new EC in 2024, and the new College, might come up with proposals to change the system. In addition, he suggested that input from AF/all could be used so that the EC could trigger a proposal to change the related legislation. He referred that Sustainability is on the table and therefore there will be changes anyway in the legal framework. Still, on the possibility of a change in the legislation, the Chair expanded by mentioning that we have seen this happening with the Transparency Regulation. Finally, Bernhard invited MS to join the working group. Germany, The Netherlands, Denmark, and France volunteered to be part of it during the meeting. EFSA will approach AF in due time to enable for the possibility of AF members to provide input on criteria for composition and competencies of Scientific Panels.

Action Point 1: EFSA to seek input on criteria for composition and competencies of Scientific Panels

#### ■ 5.2 - Update on SPIDO

Claudia Heppner provided an overview of the high-level recommendation of the two finalised roadmaps for action on Artificial Intelligent (AI) for evidence management and on New Approach Methodologies





(NAM), where she focused on the implementation part. The first one was developed by PWC and Interella consulting, and its main objective was to increase the accessibility and the body of evidence to apply human centric AI in close co-existence with the human expertise, and to develop harmonised approaches on the implementation of AI methods in the evidence management, by 2027.

Claudia clarified the meaning of evidence management in EFSA's risk assessment process, which is a structural process of the collation and analysis of the different streams of evidence generated through multiple methods and reported by multiple sources. EFSA has developed a methodological framework to select appraise and integrate evidence in the scientific assessments to decide basically which evidence to be used and which evidence not to be used. The framework has four steps: plan, do, verify, and report. The steps 'do' and 'verify' comprise evidence collection, evidence appraisal, evidence synthesis and integration, and evidence visualisation and dissemination. These activities are very important for the risk assessment process, but they are resource intensive and time-consuming. Here, AI technology can provide benefits not only to resist time, effort, and cost, but it also can lead to an increased quality and can reduce the human bias.

In a nutshell, the recommendations of the AI roadmap refer to a set of horizontal recommendations which should be implemented within EFSA, to equip the data infrastructure system, to accommodate the benefits for AI technology, but also a set of vertical actions. These are actual use cases where EFSA wants to apply AI technologies in certain areas of the risk assessment process. Now, this comprises 10 use cases, prioritised through feedback gathered in interviews and workshops and from desk research. For 2022, EFSA proposes to start with three horizontal recommendations. The first project is to develop (or adopt existing) ontologies for the domains of relevance for EFSA in the area of text mining, which require knowledge bases in form of structured ontology, for the purpose to understand, extract and retrieve information from unstructured text. The second project is related to the implementation of a data governance framework which addresses and governs AI related processes, and the third project is related to develop data science competencies in natural language processing, to allow the user to better understand AI applications and to build trust in AI technology and its application. This year, she said, EFSA will also embark on one use case related to data collection terminology assessment, text summarization and activities related to systematic literature. All these projects will be implemented through existing framework contracts. There will be no open call, but the activities planned for 2023 and 2024 will be implemented through grants or open procurements.

She continued explaining that there are also complimentary projects not stemming from the roadmaps, like the European Foodome, aimed at using AI technologies for food chemical profiling and the application of network science by linking such data with specific data on proteins, genes, and metabolism to disease outcomes.

Claudia proceeded by sharing with the Plenary the outcome on the New Approach Methodologies (NAMs) roadmap, which was developed by Faunhofer Institute together with DTU-FOOD, RIVM, VU<sup>2</sup> and EurA AG. The key objective was to define priorities to incorporate NAMs in hazard and exposure assessment of chemicals in food and feed and to recommend a multi annual strategy. Five different areas of interest were analysed as well as their impact on the reduction refinement and replacing of animal testing. EFSA has received good proposals on the way forward. A very prominent outcome was that everything misses an overarching concept for data integration the NAM area, and therefore, the proposal to start with for 2022, is to have a specific project on data integration using a case study on nanomaterials.

Claudia further expanded on the project calls for 2022, for which feedback will be asked from the MS, specifically on:

i) NAMs data integration via proof-of-concept case studies with nanomaterials (slide 10).

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<sup>&</sup>lt;sup>2</sup> DTU-FOOD = The National Food Institute, Denmark; RIVM = National Institute for Public Health and the Environment, Netherlands; VU = Vrije Universiteit Amsterdam;





ii) Case studies to support the development of advanced in vitro ADME models and the development of an open access reference database with in vitro and in vivo ADME data for model development including information on variability, and uncertainty (slide 10).

In addition, EFSA will launch a call for project proposals (slide 11) where MS/Art. 36 organisation can provide project proposals in a specific area of NAMs (e.g., adverse pathway outcome) in a 2 step-procedure: 1) high-level project outline (scope); 2) fine-tuning of scope and detailed objectives with EFSA and the beneficiary. This is a new financial grant tool to be launched as a pilot and has elements of a thematic grant combined with the novelty of a fine-tuning step with EFSA. This process shall ensure that the project and its results suit both MS and EFSA's needs. For all three projects EFSA would be interested in learning if MS are interested to apply, and in case of lack of interest what is the reason behind.

In relation with the virtual collaboration platform (slide 12), EFSA would be interested to learn if MS think that such a platform i) would be useful for the specific case studies to discuss practical issues related to the application of NAMs tools and approaches in regulatory science, and ii) if so, if EFSA should take the lead in setting up and managing this platform or maybe there would be an article 36 organisation interested in doing so.

The Co-chair thanked Claudia and opened the floor for questions.

Denmark asked how the data mining or text binding was linked to the AF discussion Group (AF DG) on Data, as there could be obvious synergies between them.

The Netherlands supported the question from Denmark and expanded by asking for clarity on how the whole data integration project or concept was linked with the AF DG on Data. There was the suggestion to take more time discussing the whole SPIDO process and how it is linked and can be integrated with all the other activities, namely on what concerns the engagement work as well as with the Focal Points work.

Claudia acknowledged the diverse ongoing projects, and on the specific calls brought to this meeting, she outlined the opportunity to engage with MS and Article 36 organisations, and to build closer connections with the work from the AF DG on Data. She referred that, once these project calls are launched, they will work with the AF DG on Data to understand how they can support, strengthening and bridging activities.

The Chair took the floor to recall the way AI is seen – an all-encompassing technology in the future, which will be used everywhere, like electricity or like computing. He explained that EFSA's first proposal, how to use artificial intelligence in the selection, collation, integration, and evaluation of evidence, is just a use case that was selected because there is too much evidence and not enough brains to analyse it. Therefore, the way this can be linked to data and the future of the data ecosystem is an important question since there's no AI without data.

On the proposal from the Netherlands, Bernhard supported the idea of a Thematic session on the way forward, though he outlined that the same question comes up on the NAMs, as both are data driven. He remarked how positive it was to have outside views like the AF ones, who question the integration of all the ongoing activities.

Spain thanked for the presentation outlining the interest also for the future 2023 and 2024 work on nutrition: the sustainable systems, nutrition, and Health and the One health. For these topics, data gathered from other sources managed in EFSA or AF organisations are needed. It was pointed out that it is a very important but complex matter.

Hungary thanked The Netherlands for raising the question on integration, which is important and highly complex. It would be very important to connect the SPIDO planning processes with the AF DG on Data and its different subgroups. Hungary also supported the idea of a Thematic Discussion on data and the use of AI. Referring to what Spain outlined on the data from other sources, it was stressed that these topics are borderline to EFSA's scope and most of AF institutions activities. Thus, he





reinforced that to have that expertise and knowledge on board, it is needed to reach organisations outside the Article 36 List and current networks.

Spain agreed and added that it may be needed to look at the issues from a different angle.

Claudia expanded by saying that indeed there is need of data outside EFSA's domains, thus this discussion on where the right data can be found is very important. On the other mentioned topics, she explained that these project proposals will be implemented through grants, partnership approach and within the Article 36 list, but there are no AI companies on this list.

Eileen intervened by referring to a presentation that Bernhard Url gave about 18 months before to the AF, in which he talked about a vision of a future digital ecosystem, not only a data ecosystem, but also a risk assessment ecosystem. She just wanted to remind about this topic of digital ecosystem and to point out that these things could be brought together, as EFSA is trying to do. There is a close cooperation with the technology group in SPIDO, with the AI project, with all of the colleagues in the partnership and the communications team, trying to bring together all of these strands, which will create the future digital ecosystem. She finalised by saying that this could also be a useful discussion in a future AF meeting.

#### **Action Point 2:**

- -MS to support the dissemination of the open calls for developing roadmaps for action on communication science and animal welfare in April, as well as Omics (<u>prior information notice now</u>) and relaunched call in May
- -MS to support the dissemination of an open call on multi-omics (value €3.25M)
- -MS to share their views on the direction taken on NAM by launching 3 projects calls in May 2022 (total overall value 18.3M)
- -MS to share their views to establish a virtual collaboration forum on NAMs dedicated to knowledge development and knowledge implementation
- -MS to take note of the recently updated EFSA Scientific Cooperation plan (G&P) which contains several high value calls.

# 6. Engagement & Communications update – Moved to day 2

## 7. ONE Conference 2022

The Chair, Bernhard Url, provided an update on the ONE Conference taking place on 21-24 June 2022 in Brussels and online. The conference programme intends to cover different perspectives of health, environment and society. The objective is to put food safety in a wider context of sustainable food systems. In his presentation, Bernhard provided information on the narrative of the event, the structure of the event, the side events to be organised by the MS, and some details on the registration process and attendance, including deadlines. AF members and observers were encouraged to register and attend in person. Finally, the Chair thanked the members of the MS Advisory Board for their feedback and suggestions in the development of the conference programme.

The Netherlands congratulated EFSA for the Conference and asked if the thematic session on "One Planet" would be world-oriented or only Europe-oriented, since EU is highly dependent on imports from third countries, which in some cases are non-compliant with EU rules and therefore end-up in other non-EU countries for consumption. Moreover, it is also a global issue that raising food safety standards in Europe would narrow down the number of countries having access to safe food. The Chair





indicated that when it comes to sustainability, these issues can only be discussed from a "One Planet" perspective.

Bulgaria commented that, in the last decade, there has been a strong association between climate change and the raise of diseases, both animal and human, and wanted to know if this will be discussed at the Conference. The chair replied that it will be a topic in the Conference, under the thematic session on 'Infectious diseases, from emergence to pandemics: improving understanding and getting prepared'.

### 8. Thematic discussion on Bees and Insects Pollinators initiatives

The Chair introduced the Thematic Discussion for the afternoon, on bees and insect pollinators initiatives, and welcomed the guest speakers, experts who look into biodiversity, bee health, insect pollinators from different perspectives. These experts were from organisations such as the EC (DG-ENV, DG-SANTE, DG-AGRI or JRC), EEA, ECHA and ANSES. The objective of the session was not only to provide these different perspectives, but to reflect on how they can be integrated into the bigger picture of biodiversity and saving the pollinators. The vital role of pollinators is highlighted in the European Commission's Green Deal, which also stresses the need to reverse their decline, widely documented in several studies. Bernhard also indicated that there are several factors affecting this, such as land use, habitat destruction and the use of pesticides. The session, therefore, focused on informing the Plenary on activities carried out at EFSA, projects from EFSA's sister agencies, the EC's EU pollinators initiative, and ANSES' work on bee health. Bernhard stressed that this issue can only be tackled through collaboration, maybe with the ambition of having a pollinators partnership forum.

# ■ 8.1 - Moving towards a high level of protection for insect pollinators from chemicals

The Chair gave the floor to Julia Fabrega, from EFSA's Chief Scientist Office, to inform the Plenary about the IPOL-ERA project, one of the SPIDO roadmap projects on advancing the environmental risk assessment (ERA) of pollinators, and that will kick-off in June.

The project foresees some areas for potential collaboration/discussion with MS and sister agencies, including the objective of building a partnership with experts on the field, to discuss relevant aspects of environmental risk assessment for pollinators, to work towards enhancing the protection of these species. A second area of interest for MS is the future project calls that will result from the IPOL-ERA roadmap that EFSA would like to launch (period 2023-2027) once the roadmap for action (first step of any SPIDO project) is finalised. MS will be informed and encouraged to apply in due time.

Regarding the IPOL-ERA project, Julia explained that it is one of the scientific themes selected in the period 2020-2022, given the gaps identified in the science behind the reasons for decline of pollinators. This project is also thought to be a good case study to consider the feasibility of developing a more holistic approach for environmental risk assessments, an approach from the current environmental risk assessments paradigm that is already being considered under the project PERA (Developing a partnership for moving towards a systems based environmental risk assessment) .

Julia also explained that the main drivers identified so far at global level in the decline of pollinators are land use, invasive pathogens and species, pollution, intensive agriculture, and the use of pesticides. The IPOL ERA has the ambition that by 2030 the ERA of chemicals will be advanced to better protect insect pollinators, their diversity, and their ecological functions, as well as the ecosystem services they provide. The project also supports several Commission's initiatives: e.g., Farm to Fork, the Biodiversity Strategy, and the EU pollinators initiative.

IPOL ERA project has four main objectives: (i) consolidate the current methodology; (ii) refine the methodology developing landscape scale population level tools for environmental stressors; (iii) improve the methodology by creating systems-based approaches; and (iv) connect, by creating an





IPOL partnership, where MS can contribute with national expertise. Julia further explained the goals of this fourth objective, where the project intends, first, to broaden the scope of the EU Bee partnership to insect pollinators and include new partners, and additionally, to address risk assessment difficulties, support the setting of research priorities, connect with relevant and complementary partnerships, and strengthen cooperation opportunities at EU level.

Finally, Julia concluded her presentation indicating that this project has identified the need of a partnership in pollinators to advance the ERA of chemicals (objective iv), to recognise the complexities associated to the protection of pollinators, as well as the challenges related to policy and societal demands. Therefore, EFSA has the ambition to work with partner and sister agencies towards the creation of this partnership.

As a final note, Julia reminded the audience that in the ONE Conference there will be a session on ERA of pesticides, on moving towards a system-based approach.

The Chair thanked Julia for the presentation and opened the floor for comments, while stressing the need of partners in succeeding in this multiannual type of projects.

Germany asked whether this project would have implications in the process of marketing pesticides, for example, by identifying the current regulatory gaps in existing guidelines. He also wanted to know what the size of the overall project was. On the first question, Julia replied that the outcome of the project will be incorporated in the regulatory processes, having an impact on how ERAs are performed. Regarding the size of the project, the roadmap for action will be developed by a consortium of several organisations. Once the roadmap is developed, EFSA will have an idea of the areas to be prioritised and the calls to be launched. The size of the consortia will depend on the capacity of the organisations and the scope of each individual project. In financial terms, the projects will have a support of  $\{0\}$ 1-4M per year. The Chair also indicated that this type of calls and support could also fit in the idea of capacity building by taking organisations into a consortium with focus also on knowledge transfer, stressing that this would be the best possible outcome.

Spain congratulated the speaker and asked how different organisations at MS level could be involved, and gave the example of AESAN, that could influence consumers towards a more sustainable food consumption. However, in some other areas, other institutions at national level are better positioned to get involved and wanted to know if other MS saw themselves reflected in this situation. Julia explained that the shift of paradigm reflects on the drivers that call for a change in how ERAs are performed, but obviously any project of this type needs to take into consideration the perception from the society. When the roadmap was developed, all types of stakeholders were reached out, including consumers associations, with the intention to capture the starting points of the societal and regulatory interests. To the question on how to involve other institutions at national level, the Chair reassured Spain that this is indeed a joint effort of agriculture, environment, and health ministries (or equivalent) in all countries and acknowledged the difficulties to bring together all these actors.

Greece thanked Julia for the presentation and asked if there had been reports on actual extinction of any species. Julia asked EFSA colleague Domenica Auteri to take the question at a later stage in the meeting.

France commented that there are several drivers for decline of pollinators but not so many processes are regulated, as plant protection products (PPP) are. Therefore, when asking society about their concerns, PPP tend to come first, thus putting pressure on the authorisation scheme of pesticides. He indicated that there might be some other high contributors and asked whether the project will provide tools that could be used also for considering other drivers. Julia explained that this concrete project will not focus on other drivers but reminded that habitat loss and pesticides have been identified in all studies as the main contributors to pollinators decline. However, through the partnership, it is expected that, at different stages of the project, other elements are also addressed. The Chair indicated that the comparative impact assessment of different factors affecting the decline is indeed an important aspect.





**Action Point 3:** MS to express interest to be partners in projects aimed at advancing the RA of pollinators including IPOL projects and short-term collaboration for the revision of the guidance document for pesticides risk assessment

#### ■ 8.2 - The EU Pollinator Initiative

The Chair gave the floor to Vujadin Kovacevic (DG-ENV) to inform the AF members about the EU Pollinator Initiative, which was adopted by the Commission in June 2018, as the first-ever EU initiative on exclusively wild pollinators. It is a very strategic Communication that aims at enhancing all the existing sector policies, many of which include legislative acts. The initiative is comprehensive, with more than 30 actions, to be taken by the EU and its Member States, to address the decline of pollinators in the EU and contribute to global conservation efforts. It sets the framework for an integrated approach to the problem and a more effective use of existing tools and policies.

Vujadin explained that the actions are envisaged under 3 main pillars: (i) Improving knowledge of pollinator decline, its causes, and consequences; (ii) tackling the causes of pollinator decline by influencing the existing policies; and (iii) raising awareness, engaging society-at-large and promoting collaboration. The consultation carried out indicated that the pressure from society is high. Regarding the major causes, there is no full scientific consensus, but both loss of habitat and pesticides are among the major drivers. However, there is little knowledge about the interactions among drivers.

On pesticides, the Initiative focuses on the revision of guidance documents for authorisation of pesticides, the sustainable use of pesticides, and, within the existing legislative framework, the Initiative reviews national plans and provides guidance.

Vujadin indicated that there are already some areas identified for improvement, such as knowledge, data and tools (which is a critical gap); engagement with environmental authorities and collaboration with agricultural authorities, ensuring coherence in the policies; and engagement with stakeholders, improving access to data and decision-making process.

Vujadin then focused on the area of knowledge and informed the Plenary about the scope and timelines of several projects, such as the EU Pollinator Monitoring Scheme (EUPOMS), INSIGNA Pilot on pesticide monitoring, using honeybee as bio-indicator, and the EMBAL project on pollinator habitat monitoring. The two latter projects are important to understand the context and the contribution of other decline factors. He also provided figures on decline (1 out of 3 species is losing population) and extinction (1 out of 10 species of bees and butterflies is on the verge of extinction) though he underlined that there are still several data gaps, meaning that the situation could even be worse. The projects also intend to monitor the society's response, including the impact of the actions, and to cover the area of research, to ensure those knowledge gaps are overcome.

He stressed the importance of communicating and engaging with society. And in this regard, the EC has created the EU Pollinator Information Hive, which contains guidelines; possibilities of networking; educational material for younger generations, etc., all with the objective of educating and raising awareness.

Vujadin ended his presentation with a brief update of the state of the art of the EU Pollinator Initiative, which was reviewed in 2021. The revision concluded that the Initiative is still valid, but it needs to step up in terms of actions, including potentially a legally binding target to reverse pollinator decline by 2030, maybe in the Nature Restoration Law, whose adoption has been delayed.

The Chair thanked Vujadin Kovacevic for his presentation and gave the floor to Markus Erhard (EEA) for an oral intervention focusing on EEA georeferenced data that can be used and shared for working together to implement a landscape risk assessment and move towards system-based approaches.

Markus' contribution focused mostly on the spatial dimension. He explained that there is a growing polarization between the land use and the food production provoking a severe loss of biodiversity especially linked to the agricultural sector. The intensive land use and the loss of other ecosystems





beneficial to the pollinators imply several other factors correlated with the decline of the latter, even if the actual contribution cannot be determined.

Increasing amount of geo-referenced data is available (e.g., Mapping and Assessment of Ecosystems and their Services (MAES) final report), and EEA and its EIONET partners are acting as a key provider of this information. The Copernicus land service portfolio is now increasing substantially with a series of recently established or upcoming new services (e.g., High Resolution Vegetation Phenology and Productivity, HR-VPP). Further environmental accounting coordinated by Eurostat will increasingly contribute to standardize European wide data sets (e.g., ecosystem extent accounts). There are other initiatives that also involve EFSA, not explicitly addressed at pollinators but of indirect benefit. Markus stressed that from the climate change perspective, much pressure is being put on the pollinators, especially in the current setting, since in terms of eutrophication and land use intensity, the humanity has exceeded the planetary boundaries. He explained that some work needs to be performed in the attribution exercise, and the outcomes of the EU Pollinator Initiative will be essential for this. Overall, it can be expected that data availability will improve significantly over the next years in terms of timeliness, spatial resolution, and thematic accuracy. But there are still significant gaps especially for land management. Another important aspect calling for knowledge is the functional relationship between the pressures and the impacts on pollinators both individually and even more in their combination (cumulative impacts).

The Chair thanked the speakers and opened the floor for questions and comments.

Bernhard asked the presenters what contribution could be made from the MS perspective. The speakers replied that data, knowledge, expertise, sharing good practices in risk assessment. In fact, the agencies and the EC cooperate with the MS in their own networks. However, this is a situation where there is need to learn from each other, thus there is a need for enhanced cooperation, cocreation, and integration. Vujadin, from the EC, stressed the need for data in a standardised way, reason why they have developed the EUPOMS project. Harmonised data are essential for attributing the contribution to each factor in a significant way. For this, all MS must be on board. There is also a role for MS in the developing of robust testing protocols, and in the involvement of the local and regional levels, as well as the society.

The Chair concluded saying that there seems to be a common aspect in the need of integration, harmonised data, engagement of society to provide clear basis for policies.

Spain asked for the floor to reiterate that the role of institutions like AESAN could be to inform the society about the scientific knowledge behind sustainable food, and about the benefits associated to consumption of food of proximity, for example. The Chair said that indeed informing the society about what consumers can do is important, and part of the transformation needed.

The Netherlands thanked the presenters for the information and acknowledged that there is a severe issue with pollinators but also strong political ambition. He indicated that there seemed to be many organisations and experts involved but maybe also a lack of a "conductor" to orchestrate the scientific challenge and the ambitious goals. He asked for some guidance on who should be this coordinating body. The Chair replied that it was a difficult political question, considering subsidiarity of the MS and the power of the EC or the Council. The speakers agreed on this. The experts are calling in the legislative bodies, especially the Parliament and the EC, to state the ambition and to follow it. The EC is also developing platforms and mechanisms under the biodiversity strategy for 2030, like the Knowledge Centre for Biodiversity under JRC. From the knowledge side, there is a mechanism, also involving other EU bodies and MS, but from the political side, it is not stated who should be setting and leading the ambitions.

The Chair thanked both speakers and closed the agenda item.

■ 8.3 - Strengthen RA in insect pollinators: data sharing among stakeholders, research, and tool development





The Chair gave the floor to Agnes Rortais (EFSA) to inform AF members the work carried by EFSA to strengthen risk assessment (RA) in insect pollinators with harmonised data collection and sharing among stakeholders, and with research and tool development.

Agnes started her presentation echoing all that had been said by previous speakers regarding the need of data and testing methods. Her presentation focused on honey bees. EFSA strengthens environmental risk assessment (ERA) in insect pollinators by linking current regulatory approaches (EFSA 2013 bee Guidance Document) with future (MUST-B scientific opinion published in 2021) systems-based approach along with the most updated science and knowledge available in this area.

She explained that the systems-based approach for ERA consists of two systems: (i) the monitoring system, using digitally equipped sentinel hives placed across representative EU landscapes, and (ii) the modelling system (ApisRAM model) which simulates the population dynamics of a honey bee colony in its environment. The systems-based approach allows both predictive (prospective) and post-authorisation (retrospective) risk assessments of pesticides.

EFSA supports the EU Bee Partnership (EUBP, established in 2017) and its platform to promote harmonised data collection and sharing among stakeholders on insect pollinators in Europe. The partnership brings together European professional beekeepers, farmers and Cooperatives, Crop protection associations, NGOs and EFSA. Besides there are also scientists, experts from the JRC and other European projects, and observers from the EC and EU Reference laboratory on honey bee health from ANSES. The prototype platform is under implementation, and the final version will be delivered in 2024. The project is led by BeeLife, a member of the Partnership. Agnes explained that the platform intends to be a one-stop-shop, offering unique information to industry and associations, as well as a collaborative central knowledge base. The data will come from several sources.

In addition, EFSA supports the implementation of a honey bee colony model, ApisRAM that is led by Aarhus University. A first version of the model was published in early 2022 and implemented versions will be produced in the next years for its use as a tool for the RA of pesticides (i.e. for single and multiple substances/uses assessments by 2025).

Agnes also informed the Plenary about some new work started in 2022 to advance the environmental risk assessment on non-target arthropods (NTA) for pesticides by accounting for the impact on ecosystem services and on ecological functions (AENEAS). It is a four-years project.

She finalised her presentation asking the MS for support in some activities/projects: (i) express interest in sharing harmonised data on bee/insect pollinators, including participation in the next EUBP workshop (Dec. 2022); (ii) provide input to the ApisRAM testing phase (2023/24) and express interest in receiving training on the use of the model (beyond 2025); (iii) promote harmonised data collection in MS (e.g., by using MUST-B data models); and (iv) express interest in receiving reports on the progress of the activities.

The Chair thanked Agnes and opened the floor for questions and comments.

Sweden asked if there were data providers on this topic in his country and told EFSA to contact him in case there were not, so actions can be taken. The Chair thanked Sweden for the offer and indicated that even if the AF representatives are not responsible for this topic at national level, they could support in making the link and help EFSA get more contributors. Agnes confirmed that both the platform and the models would benefit from specific data (e.g. on colony weight/development in relation with landscape data).

Markus Erhard (EEA) offered their support and the data they have already collected.

Greece asked for the floor to remind the audience that the Green Deal includes "eco-schemes", implementing environment-friendly policies in agriculture, and wanted to know if the project presented by EFSA plans to take measurements and data to check the impact of those eco-schemes in the pollinator's population. Agnes confirmed that if EFSA has access to the data, they will be incorporated.

The Chair asked whether some cost-relationship effects between the eco-schemes and the improvement of the health of pollinators could also be proven. Markus Erhard explained that EEA is





not directly linked to the eco-schemes. Vujadin Kovacevic indicated that indeed eco-schemes are important in the EU Pollinator Initiative and are working towards more targeted monitoring to check the impact of the compliance of the eco-schemes and the Green Deal in general. Markus ended up by explaining that the use of land in Europe is a big gap in knowledge and there are negotiations with DG-AGRI to get access to data that is already available at MS level, since ownership of the data is a barrier.

France asked a question about the systems-based approach and wanted to know if it was already in place. Agnes replied that the modelling part is being developed and the monitoring part is not yet in place, although there are some initiatives scattered in Europe. The Chair thanked Agnes for the presentation and the speakers from EEA and the EC and closed the agenda item.

**Action Point 4**: MS to express interest to EFSA to share data from national programs or monitoring on pollinators that could populate the EUBP data platform and also support the development of ApisRAM.

## ■ 8.4 - Update on the revision of the EFSA bee guidance

The Chair gave the floor to Domenica Auteri (EFSA) to inform the AF members about the update on the revision of the EFSA bee guidance, following a mandate from the EC in 2019. The mandate had several Terms of Reference, including (i) support to risk managers in defining the Specific Protection Goals (SPGs), focusing on the magnitude dimension; (ii) revise the crop attractiveness for pollen and nectar; (iii) collect data on bee mortality; (iv) revise risk assessment methodologies; and (v) revise the requirements for field studies, all together with a specific mandate to consult all potential stakeholders and MS in the revision.

Domenica then moved to the technical aspects of the revision of the guidance, providing the audience with some background to appreciate the complexity of the revision. Exposure to pesticides is a complex issue, since bees can be exposure directly (oversprayed) or indirectly through their relevant matrices, like contaminated nectar or pollen. In turn, pollen and nectar, can be contaminated directly or via intake of residues from the soil or by translocation, from the plant tissue. The bee exposure could occur through the treated crop, from the flowering weeds that are present in the treated area or through the crops or plants at the edge or surrounding the treated areas. Regarding the exposure routes, these can be by contact or dietary, and the effect is mortality of adults but also of larvae, including sub-lethal effects. All these aspects are covered by the guidance document.

She continued explaining that the crop attractiveness is very relevant to understand the exposure in the treated areas and specifically the exposure from the treated crop. Already in EFSA guidance in 2013, it was clear that there was no literature available and that there were several crops for which attractiveness was considered controversial. Therefore, the revision was performed running an expert knowledge elicitation (EKE) to revise the list of crops already available in the 2013' guidance.

In the guidance document, EFSA intends to review the risk assessment methodology and, in general, to increase the accuracy. For this, one of the requests in the mandate is to collect data on bee mortality. This has been performed via a systematic literature review that was published in July 2020. EFSA has also focused on other aspects like the revision of the dietary exposure estimation, which has also been carried out via a systematic review, to get a better estimation of the food consumption of honey bees and other bees. In addition, there is a better estimation of the sugar content in nectar and of the residues in pollen and nectar through data from different residues trials and dissipation studies.

Domenica further explained that another important aspect of the guidance is the revision of the relevance of weed scenario, where different efficacy trials have been analysed. In addition, a better use of the dose-response relationship has been achieved by using the ecotoxicity studies that are currently available. Because the guidance document is meant to address the risk for not only honey bees but also for bumble bees and solitary bees, EFSA has tried to consider the diversity by taking





into account biological traits, so to get a better estimation of specie-specific dietary exposure, contact exposure and also the intraspecies sensitivity.

Regarding the involvement of stakeholders and MSs, Domenica explained that an *ad hoc* consultation group where different stakeholders are represented was set up at the beginning of the revision. Moreover, EFSA is also engaging with MSs through the Pesticide Steering Network. In addition, several consultations among the *ad hoc* group and the Pesticide Steering Network, and different workshops with risk managers on the definition of the specific protection goals have been run. When needed, other experts have been engaged, like modellers or agronomists.

Domenica concluded her presentation by indicating what the next steps are. EFSA is waiting input from the risk managers on the specific protection goals for bumble bees and solitary bees. Once this is received, the guidance document will be finalised, and the public consultation will be launched. She stressed the relevance of the participation of MS in the public consultation to early identify of concerns and facilitate the subsequent endorsement of the guidance. This latter aspect was reiterated by the Chair, reminding the audience that the previous guidance document was never endorsed.

The Chair thanked the speaker and opened the floor for comments, but no question was raised.

**Action Point 5**: MS to support dissemination at national level and provide input on the revision of the EFSA bee guidance once the consultation is launched

# ■ 8.5- ECHA guidance on biocides

The Chair gave the floor to Simón Gutierrez Alonso (ECHA) to inform the AF members about ECHA's guidance on biocides, including the status of ECHA's work on bees and pollinators and the preliminary findings on non-bee pollinators.

Simón started his presentation reminding that some of the authorisations for some neonicotinoids that are also used as biocides were done several years ago, and it was already recognised that further work was needed in relation to protection to bees. In 2019, the EC issued a mandate for ECHA to work on the on developing a methodology to protect bees, but also, they included assessment of other arthropod pollinators.

In 2021, ECHA brought to the attention of risk managers that it was essential to avoid a repetition on the discussion on the protection goals, and that alignments had to be sought, for both the protection goals and the risk assessment methodology. Moreover, the latter should also be harmonized, following the principles of the one substance, one assessment under the chemical strategy for sustainability. Simón also explained that, although it is important that pesticides and biocides risk assessment methodologies are brought together, biocides have their own reality. This may mean that in the future, while the same methodology is being applied, some substances may be approved for a pesticide use and not as biocides, and vice versa, mostly due to the different exposure routes.

Simón further explained that there are 22 different product types used as biocides, that are used in different ways, and reach the environment following different exposure patterns. This difference in mostly the exposure assessment of this substances in comparison to plant protection products is an essential part of the problem formulation.

The discussion on the protection goals has delayed the original deadline of the EC mandate to ECHA, which was the end of 2021. ECHA requested an extension of it which is now linked to the publication of the EFSA guidance on bees. In the meantime, ECHA has been developing methodologies related to biocides and doing some work on other arthropod pollinators. This work is being performed with a group of volunteers from different Member States, which represent the geographical distribution in Europe. Moreover, ECHA is collaborating closely with EFSA, ensuring communication, participation in each other's working group's meetings and ensuring that methodologies remain aligned.

Regarding non-bee pollinators, Simón explained that, over the last two years, ECHA has been collecting literature and reviewing the databases that are available to collect information, trying first





to define the families and orders which play a role in pollination and are representative in Europe. The information includes data on characteristics of relevant species, habitat types, ecological role and feeding behaviour. The information is scarce and mostly related to just some families of arthropods. Therefore, this part of the of the guidance development is also being used to identify some data gaps that can also then be used afterwards by other projects that are run by other organisations, like EFSA. One of the largest data gaps relates to the most vulnerable and relevant species, which rarely are tested species. To overcome this, bees are frequently used as a surrogate to protect other pollinators, despite the big differences in species sensitivity, feeding behaviour and role in pollination, among others. He indicated that more laboratory studies are needed, and those laboratory studies need to be performed in a similar way and following the similar parameters, to allow a meaningful comparison overall. For this, ECHA's initial hypothesis of trying to protect non-bee pollinators using honeybees as a surrogate does not seem a reasonable route now. Among other approaches being explored, ECHA considers extending their terrestrial risk assessment using some of the already existing methodology and some of the scientific developments that EFSA gathered for its opinion on non-target arthropods.

Simón concluded his presentation summarising the list of activities in which ECHA is involved in this regard, together with EFSA and the EC, always considering the resource constraints. He stressed that much collaboration and partnership creation can be observed, and that hopefully this will ensure some fruitful results soon.

The Chair thanked the speaker and asked whether all the data gaps identified will impede the publication of the guidance. Simón explained that the agreement with the EC is that ECHA will publish the biocides guidance within six months after the publication of the updated EFSA guidance, to allow using the methodologies developed by EFSA. Those six months will be used to adapt them to their purposes. However, he continued, this will relate to honeybees, bumblebees, and solitary bees;

The Chair further asked about the use of a concept like that of toxicity equivalent factors applied to different congeners of chemicals, that could be used to say that there are sensitivity equivalence factors applicable to different species of arthropods because the honeybees do not seem to be the most appropriate surrogate species. Simón explained that there have been some developments with regards to body size and body weight of different organisms that allow correcting the sensitivity depending on the size but making extrapolation to the vast world of different insects is extremely difficult. Moreover, just gathering information on weight and size is challenging because of the high number of families and orders.

Domenica Auteri, from EFSA, added that there are standard protocols available using standard species. In an evidence-based approach, extrapolation factors for toxicity and other aspects are used. In EFSA's guidance, a tier 1 risk assessment will be delivered, and this will allow, in a conservative way, to consider the three bee groups.

France asked about the group of biocides that have insects specifically as their target group and whether there is a guideline for this group of biocides. Simón replied that this is exactly the type of products ECHA aims to cover in the guidance. He explained that some neonicotinoids are used as biocides, for example in the stables and around stables; this way they reach the manure which is subsequently spread on the field. Currently there are clear and defined exposure models, and ECHA has been performing risk assessment for water or for soil. However, there is some knowledge gap on what the attractiveness of these insecticides and whether some protective species are being put at risk when using these products.

Guilhem de Seze (EFSA) asked about the possibility of using the data to be collected by the project presented earlier in the afternoon, where digitally equipped sentinel beehives would be used, to extrapolate to other variety of insect pollinators. Simón replied that indeed that project and others will provide useful information on hot spots and pollutants fate, although some information on other aspects will still be needed to understand the actual effect of those hotspots on organisms other than honeybees.

The Chair thanked the speakers and closed the agenda item.





# ■ 8.6 - Bee health: Surveillance systems in France and Research for assessment of risks to bees from chemicals

The Chair gave the floor to Marie-Pierre Chauzat and Gilles Salvat from ANSES to inform the AF members about the surveillance systems in France and Research activities for the assessment of risks to bees arising from chemicals.

Marie-Pierre started this section by presenting the work performed at ANSES on the implementation of EU H2020 "PoshBee" and MOPGA (Make Our Planet Great Again) "Save the bee" research projects. Regarding the first one, there are two objectives related to risk assessment: (i) to develop new model species and innovative protocol for testing chemicals in bees, with a full work package dedicated to the development of novel wild bee species for risk assessment; and (ii) to develop dynamic landscape environmental risk assessment models for bees, again with a full work package dedicated to this objective.

Marie-Pierre continued explaining the second project, a collaborative project with the University of Maryland (US): "Save the bees", under the French Visiting Fellowship Program for Young Researchers. As a result of this collaboration, at least two scientific papers will be produced: (i) a systematic literature review and meta-analysis that summarizes and re-interprets the available qualitative and quantitative information on lethal, sublethal, and combined toxicity of a comprehensive range of pesticides on bees (paper submitted); and (ii) a document collecting the development of novel methodologies for ERA that allow the assessment of the cumulative risk of chemical mixtures, estimating the cumulative Risk Quotient of all pesticides co-occurring in a sample, with data from the US (paper in preparation).

Marie-Pierre gave the floor to Gilles Salvat to provide information on the surveillance systems that have been implemented in France: (i) surveillance of winter honeybee colony losses in France (a declaration system in which all beekeepers in France have been involved and contacted); and (ii) the honeybee losses and weakening observatory (OMAA - Observatoire des Mortalités et des Affaiblissements de l'Abeille mellifère).

Gilles explained that in the survey to beekeepers, winter mortality was defined including dead colonies, accidents, weak colonies, and colonies with queen problems. In the past four years, it has been observed a fluctuation in mortality, being very high in 2018 (attributed to climatology and difficulties in nutrition). The mortality decreased in 2019 and 2020, and an increase has been observed again in 2021, with no explanation so far.

Gilles continued presenting the OMAA, an innovative surveillance system based on declaration by phone of health events in beehives, with the objective of creating an inventory and analysing the spatio-temporal dynamics of losses and weakening of bee colonies in France. This supports the detection of the deterioration of the health status and the origin, thus allowing early warning to risk managers. It has been experimentally deployed in three regions since 2017, and its operationality and compliance with the objectives are being assessed before implementing at national level. Besides notifications of notifiable diseases and acute mass mortalities, most of the notifications belong to "other disorders", still to be determined. He concluded by indicating that an evaluation of this network will be done in 2022, and the extension to the totality of the territory will be considered.

The Chair thanked both speakers and opened the floor for questions and comments.

Greece commented on the temporary permit given by France for the use of imidacloprid insecticide on the sugar beet plantations, which is a major crop in France, and asked if France has assessed any possible impact on the immortality of the bee population. Gilles replied that no concrete correlation has been found because exposure to neonicotinoids is a chronic disorder and it could be under "other disorders", but the system is not as precise as to allow the detection of effects within just one year. Moreover, the regions where OMAA has been implemented are not sugar beet producers. Marie-Pierre also stressed that demonstrating those correlations on the field is not easy nor straightforward, and that the surveillance systems that would allow that are extremely costly and unavailable for the moment.





Germany asked several questions to the speakers. First, whether the data have been corrected considering potential infection status, including low-level viral infections. Second, whether there were data available on this infection status that could be correlated with the use of pesticides. And third, whether the data from the surveillance system differentiated information coming from professional and non-professional beekeepers, since there are several studies showing correlation between the quality of the keeper and the health of animals, including bees.

Gilles replied to Germany that the question about professional beekeepers is addressed in the survey under the consideration of the number of beehives in the farm. According to the available data, only 20% of the total honey production in France is attributed to non-professional beekeepers. Regarding the potential infectious causes, the projects do not intend to measure exposure to just one potential cause for winter losses, but the first surveillance system presented does not allow differentiation. This could probably be achieved with the OMAA system. Marie-Pierre stressed that there is a big percentage of the mortality that cannot be explained with certainty. She also confirmed that in previous studies, a strong correlation had been found between mortality of the colonies and the quality of the beekeeper.

Spain commented that some recent studies have correlated the mortality in bees with heat waves, also in wintertime. Gilles explained that winter mortality is chosen as an indicator because it refers to the past year health status of the beehive. It does not replace surveillance systems focused on health during summertime. In fact, OMAA provides data from the totality of the year.

France asked why bee wax was not considered in the presentations as a potential source of exposure and wanted to know if this was because it was out of scope or because it was not described in detail Domenica Auteri (EFSA) replied that indeed there are several other matrices relevant for exposure, but they will not be covered in the guidance because of lack of information.

The Chair thanked all contributions and closed the agenda item and closed the meeting for the first day.

#### 9. Risk assessment activities

### 9.1-EFSA's risk assessment activities: mandates, MS's plans and public consultations

The Co-Chair, Barbara Gallani, welcomed the participants and the EC representatives for the 2<sup>nd</sup> day of the meeting, presented an overview of the sessions and topics, highlighting the relation of this session with the discussions held on the first day of the meeting on alignment of risk assessment cooperation and partnerships.

The Co-chair gave the floor to Guilhem to highlight the key RA activities, the MS RA Plans covering the last quarter, and upcoming public consultations.

Guilhem welcomed the ongoing sharing of MS RA activities through the Database, which is beneficial for identifying areas of common interest and potential collaboration. He outlined that where interest has been noted on MS activities, MS were invited to provide additional information to EFSA Units and EFSA Units representatives would contact the concerned MS. Guilhem proceeded by highlighting the MS RA plans of EFSA interest, namely from Spain, Sweden, France, Germany and Belgium where there is potential collaboration/information exchange. He presented some of EFSA's mandates which could be of MS interest.

Barbara thanked Guilhem an opened the floor for questions. Hungary intervened on the 4th Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA), that will soon be published by ECDC/EMA/EFSA, highlighting that the use and consumption of antimicrobials is something which has a large connection with data and that hundreds of different data from diverse sources could be utilized and not only the one which is transmitted and reported to EFSA, i.e. open data sources which might come into play and could enhance risk assessment.





The Chair outlined the interest in the possible use of external data sources that are not regularly used and that could be useful and suggested the possibility of the EFSA unit working in this area looking at how these other data sources could be used.

Austria referred that last year's numbers on the use of antimicrobials had gone down more than 10%, with a 95% coverage of the antimicrobials sold in Austria, but he said not to be aware about Austria's experience on the data sources used.

Denmark added on their experience on the WHO/FAO global surveillance of AMR infections in which they were involved, and where sewage water surveillance from 100 cities around the world was performed. It was outlined that a lot of other data was used, among others, demographic data and sanitary data. She pointed out that usage data is more dependent on the sanitary status, number of clinicians, child deaths, etc and that a lot of these data was incorporated in this global surveillance, which she offered to make available to be used in the AMR analysis.

Germany informed the Plenary on a study they conducted regarding the cannabidiol transfer to milk and on their availability to provide further information.

Barbara thanked MS for the use of the RA database and stressed the importance of its update in between meetings, to check the relevant activities that could benefit from close collaboration. She highlighted that this was one of the systems that EFSA had put in place for better alignment and asked for MS input, namely if there were any suggestion for improvement. She reminded the Plenary that all running EFSA mandates were available through the OpenEFSA portal and could be accessed at any time by MS representatives and any interested parties. On this regard, she also outlined the need for input from MS from a user perspective since this tool was also a new one, created following the Transparency Regulation.

# Update on EFSA's work to support DG SANTE, in the context of addressing the disruption of food/feed supplies coming from Ukraine

Barbara Gallani thanked all and gave the floor to Guilhem to give an update on the work EFSA has done to support colleagues in DG SANTE, in the context of addressing the disruption of food/feed supplies coming from Ukraine and on the alternative sources that need to be investigated, i.e., the possibility of moving to alternative supply sources for some major cereals/oilseeds.

EFSA was asked to work specifically on the comparison of the currently established EU maximum residue limits (MRLs) versus Codex Alimentarius MRLs, taking into account the possible transfer of pesticide residues in feed. This work has been done on a rapid basis to support EC colleagues and EFSA is now considering how to report the conclusions.

To expand on this item, Guilhem asked the EC representative to introduce herself and give an overview on the subject. She explained that due to the Russian invasion in the Ukraine, the Commission was contacted by stakeholders and MS, alerting them that there would be a very high risk of feed shortage, as the raw materials for feed were coming to a very large extent from the Ukraine.

At the beginning of March, an extraordinary meeting of the Standing Committee for Plants, Animals, Food and Feed (PAFF) had been organised to discuss this issue with the Member States in order to find a solution to the expected problems.

In that meeting, the EC pointed to the possibility of the use of the Article 18 (4) of the MRL Regulation (Regulation (EC) No 396/2005), which allows Member States to take national measures in exceptional circumstances, permitting them the placing on the market and/or the feeding to animals of treated food or feed not complying with maximum residue levels established in the MRL Regulation. When doing so the food/feed must remain on their national territory. Furthermore, Member States are also obliged to carry out a risk assessment and notify the national measures taken. EFSA's role was to do preliminary assessments to evaluate whether Member States could temporarily use some Codex maximum residue limits that had so far not been taken over in EU legislation. EC informed that after that meeting, two Member States (Portugal and Spain) have set national temporary MRLs for some cereals, used for feed purpose only. Both MS have provided detailed information on their national risk





assessments to the EC, which will now be shared with the MS in the next regular meeting of the Standing Committee taking place on 11/12 April 2022<sup>3</sup>, alongside detailed information on controls of feed and food of animal origin.

The EC representative thanked EFSA for the work done at a very short notice and under time pressure, which provided important guidance to MS. This work has not yet been formalized by means of a mandate, but the EC is planning to prepare such a mandate and will further discuss the details with EFSA.

Barbara thanked the EC representative for this overview and informed the Plenary that EFSA would keep them updated on any mandate to be received from the EC.

#### 9.2 - Member States Risk assessment activities

# a) Contribution of a national phyto pharmacovigilance scheme to risk governance

The Co-Chair gave the floor to France, for a presentation on their national phyto pharmacovigilance scheme to risk governance, a system that collects and analyses monitoring data on plant protection products, to identify, as early as possible, any adverse effects related to the use of these products.

Matthieu Schuler started by pointing out that one aim of his presentation was to present the role of a vigilance scheme within a risk governance that is set up at the regulatory level. He expanded by providing an overview of possible governance schemes for the risk generating products and installations: 1) authorizations; 2) registration of products like tobacco products; and 3) the general marketing under responsibility of the producer, provided that the legislation is followed.

He further informed on the specificity for plant protection products which are under an authorisation regime, explaining that usually, a vigilance scheme refers to the signals that must be mandatorily addressed by the companies' holders of the products and by professionals (both the ones who apply the PPP in the field but also the health professionals). So, all these categories of individuals must signal what seems to be an adverse effect on human health that has not been foreseen, and that happens when using the products.

This normal vigilance practice is usually effective mainly for acute problems, for example in the domains of veterinary medicinal products and of medicines for human use. What is not as usual in the case of plant protection products, is that the adverse effects might arise in many domains - water, air, soil, plants, animal health, both domestic and wild health wild animal and, of course, as mentioned already on human health, for both workers and the general population. In France, there were already numerous monitoring actors and partners, so the scheme was not created from zero. To build up the phytopharmacovigilance scheme in France, a network of 19 partners has been gathered to be able to cover the whole scheme for all the domains.

Another specificity on the PPP vigilance is that the main concern for society is not on acute effects, but mainly on the long-term effects. For these, such as diseases like cancer or neurodegenerative diseases, France has added one specific mechanism in the scheme, which is including literature surveys.

The French PPV scheme collects the signals, both mandatory and those coming from the partners, analyses them and generate information reports; the signals which are not characterized are kept on a database.

He proceeded by given three examples of the assessment performed in France, stemming from: 1) the presence of residues from Prosulfocarb in non-target products (fruits); 2) a scientific claim and publicly raised «alert» for succinate dehydrogenase inhibitors; and 3) the frequent detection of Metolachlor ESA in ground water.

<sup>&</sup>lt;sup>3</sup> Minutes of the meeting are available at this link https://ec.europa.eu/food/system/files/2022-05/sc phyto 20220411 ppl sum.pdf





Matthieu concluded by providing the needs and purposes for the PPP vigilance schemes: 1) a necessary «Awareness» posture; 2) a useful source for international exchange; 3) an effective source for checking and questioning the robustness of the safety framework and guidelines; and 4) a necessary resource for introducing evolutions in the decision granted, should risk evidence arise.

For the next steps, France envisages to identify who are the entities and the partners that could have some vigilance-type mission for PPPs within other MS organisations, to start exchanges with the national institutions in charge, and also with EFSA, on: how to collect data, how to analys the signals and what kind of information may be of mutual interest.

Barbara Gallani thanked Matthieu for the impressive systematic approach system presented and opened the floor for questions, asking whether there were similar schemes in other countries that go beyond human health and look at the effects on biodiversity.

Guilhem intervened relating this presentation with the SPIDO session of 1st day, as one of the themes EFSA developed concerns environmental risk assessment, which is moving toward a more systematic platform-based approach. He stated that one of the of the reasons behind this work is the realization that EFSA does a lot of premarketing assessment for pesticides, but has limited access to post marketing data, which would be very much needed for RA. EFSA is very interested to approach France on how this scheme could be fed into the thinking about putting in place a platform for a more holistic environmental risk assessment, to start with in the field of pesticide.

The Chair questioned if this was a passive surveillance system. He outlined that when talking about dietary exposure and learning whether the MRLs are the right ones, they go actively on the market. MS take samples providing a feedback loop that is actively driven by the sampling scheme. In this regard, he mentioned that with dietary feedback information into the predictions on human health, Europe is quite well equipped. From EFSA's perspective, what is missing is a more systematic countrywide approach on effects of pesticides on biodiversity aggregated at a European level.

Matthieu explained that the passive part is collecting signals, while the active one is for example literature survey, performed by ANSES, or the surveillance in the soil or in the air, which is done by the partners. Although France does not count any partners that would be able to claim they are an active watcher of biodiversity, they have elements that are proxies for biodiversity. Also, the information is not an aggregated appreciation of biodiversity. This is probably also why there is currently no possibility of including in a pre-assessment scheme a potential impact on that. It will need to be discussed also with the institutions that are worried about the decline of biodiversity, to know how it is possible to evaluate the contribution of different type of products or anthropic activities to that decline.

Matthieu suggested participants to consider whether a group should be created for exchanges on these types of issues, pointing out, however, that perhaps there were already existing groups to which such input should be added before considering creating a new group.

Guilhem emphasised the importance of a tool like this to move towards a more comprehensive risk assessment, needed for pesticides and other chemicals. He also supported Mathieu's idea, proposing to start with the discussion in the Pesticide Steering Network with colleagues in the field, and then see where to go further. He also mentioned that once a year there is a meeting with the Directors of the pesticide risk assessment organizations in the MS, with whom this could also be discussed.

Questioned about the resources invested, Matthieu explained that the activity is financed by the additional taxes paid by the PPP applicants for marketing authorisations, which enables ANSES to hire staff and gives it the possibility to launch studies to improve the detection system and to investigate on some post-signal studies. He pointed out that they also count on the mobilization of partners.

Italy informed the Plenary that Italy has created a platform for the monitoring of the beehives able to evaluate namely pesticide impacts on the beehives in the country. On other types of monitoring, they do not have any kind of schemes.

## b) Risk assessment of dioxins and dioxin-like PCBs in food in Norway





The Co-Chair gave the floor to Harald Gjein, from Norway, for a presentation on the ongoing RA of dioxins and dioxin-like PCBs in food in Norway

Harald explained this work was triggered by the published risk assessment from EFSA, in which the tolerable weekly intake (TWI) was reduced from 14 to 2 pg/kg bodyweight/week. According to the EFSA report, the European population is exposed to dioxins and dl-PCBs above the new TWI, and the main food contributors of dioxins and dl-PCBs are fish, seafood, meat, eggs, and dairy products.

Following EFSA's opinion, the Norwegian Food Safety Authority decided for the need to perform exposure assessments of dioxins and dioxin-like PCBs (DL-PCBs) for the total Norwegian diet and assess if the Norwegian population or sub-groups of the population have different eating patterns leading to different dietary dioxin and DL-PCB exposures compared to what EFSA reported for the European population. The work is undergoing as well as the assessment of the risk from dioxins and DL-PCBs exposures from marine oils taken as food supplements and from reindeer consumption. Apart from these, the health consequences of exceeding the tolerable weekly intake (TWI) are also being evaluated. Finally, Norway will also identify risk-reducing factors, which could reduce dioxin and DLPCB exposure in the population and if possible present them quantitatively.

Harald informed that a detailed protocol was available at their Internet site and that the risk assessment would be published on May  $11^{th}$ .

The Co-Chair thanked Harald and opened the floor for questions.

Denmark applauded the presentation and informed that they have also been performing risk benefit assessment related with fish and fish oil.

France asked if Norway had performed any kind of assessment on eggs, as the evaluation of dioxinlike substances contamination in eggs, especially from hens growing outside, could be relevant.

Iceland praised the work undergoing in Norway outlining that this assessment is something they were waiting for and that they will follow it up. Iceland also questioned if there has been cooperation between Denmark and Norway regarding the Nutrition Recommendations and this assessment, and if these results would be included in next year's recommendations.

The Netherlands questioned if any report on other kind of chemicals, apart from dioxins and DL-PCB, could be expected in Norway. He proceeded by informing that the Netherlands would be publishing in June a report which covers most of microbial and chemical contaminants, as well as animal welfare in the production of fish products. The Netherlands stressed that the main problems regarding animal welfare were on fish and that this should be an item to be tackled. Considering that are many fishing countries, he suggested a Thematic Discussion on fish in the near future.

On the question from France, Harald explained that they are also considering eggs as a source, but data are scarce. He mentioned that they are also considering occurrence in fruit and vegetables, using EFSA data.

As for the Nordic recommendations, he confirmed these would be discussed. He mentioned that in Norway, they will come up in June with a bigger risk benefit assessment of fish in Norwegian diet, on which they have been working in parallel. He outlined the importance of cooperation among others, because it is a too big project just for one country, and the sustainability of meat fish production is an important matter. Harold stressed that 95% of the feed fed to the fish produced in Norway is imported and questions on sustainability need to be tackled. He supported the idea of coming back to this subject on a Thematic Discussion.

He finally explained that the reports will cover more than dioxins, but for the sake of time he would not expand further.

Barbara thanked the suggestion, outlining that there is much to learn from each other from these approaches and also by looking at the fish as an overall aspect.

The Chair highlighted that EFSA is also interested on the methodology to have a better comparison between risk and benefits, which EFSA found to be quite tricky and time consuming. He mentioned





that the Scientific Committee will take some time to develop this sort of an overarching methodological framework and showed interest to know how Norway has approached this question.

Barbara closed the session outlining the importance of comparing methodologies because it is the starting point and there is much experience in different countries.

# c) The upgrade of the dietary exposure assessment model "ImproRisk": the role of EFSA and other stakeholders.

The Co-Chair gave the floor to Stelios Yiannopoulos, from Cyprus, to update the Plenary on the upgraded dietary exposure assessment model "ImproRisk.

Stelios provided some background information and a brief timeline of ImproRisk major developments and how the interaction with EFSA and other stakeholders facilitated the development of the model. The State General Laboratory (SGL) has developed its own risk assessment model called "ImproRisk" since 2014. This model has been upgraded in 2022 into an online model that accommodates FoodEx2, to meet EFSA's requirements and risk assessors' needs at national and European level. During the activities for the development and to ensure that enough risk assessment experts would use the model and provide feedback, several stakeholders were engaged. Stelios stressed that to ensure ImproRisk would reach its desired format, besides the diverse interactions with the different actors, Cyprus allocated a significant amount of their national budget for subcontracting. Moreover, it has been turned into an open access model, thanks to which a high number of risk assessors from diverse countries expressed their interest and were provided with access to the model. Stelios thanked EFSA for its support and collaboration through the signing of a Grant Agreement for the further development the model, also facilitated by the valuable feedback of the registered ImproRisk users and the organization of trainings/Workshops at EU level. He expanded on the basic functionalities of the model and on its benefits. As for the immediate and future plans regarding it, he informed that the final version of the model would go online in April and this information would be disseminated to FPs and other stakeholders in order to allow access to the model. The SGL is planning to organise a follow-up Workshop on "hands-on" training on ImproRisk, aimed at risk assessors from MS and Pre-Accession countries, in September 2022, for which EFSA's contribution is highly envisaged. Stelios highlighted they that are open to any collaboration with any MS, and he thanked EFSA for the good results achieved.

The Co-Chair thanked Stelios and reaffirmed the will from EFSA to continue supporting the development of this model.

The Netherlands complimented Stelios for the progress of the work in this model system and informed that they also have a model, which is compatible to this one, outlining their interest to see if they could compare the two systems since the objective is common. He further informed that they would sign up to test and use this model system for their purposes as well as well as for the September workshop in Cyprus.

France joined the congratulations and asked whether the proposed scheme is able to cope with both probabilistic- and deterministic- type of assessments.

The Chair thanked Stelios for presenting this model again and pointed out that ImproRisk, from its creation, was meant to be a simply usable model for MS who did not have the capacity for Monte Carlo simulations or probabilistic assessments, which turned out to be very successful. Referring to the question from France, he stressed that in fact the model was not a fully probabilistic model, although very useful for practical reasons in MS who do not have all the resources that others have.

The Chair concluded by reinforcing EFSA's support in its further development, as well as in its distribution to all who might profit from it and perhaps also improve it, also inviting MS to collaborate.

### ■ 9.3 – EFSA Scientific Committee work programme 2022-2024

The Co-Chair, Guilhem De Seze, gave the floor to Nik Kriz to inform the Plenary on the EFSA's Scientific Committee work programme 2022-2024





Nik provided an overview of the role and responsibilities of the Scientific Committee (SC) and on the steps in developing its work-programme 2022-2024. Some of the topics to be included in the work-programme have been already identified but more discussion is planned for the April SC plenary, after feedback gathered from Units and panels. A prioritisation exercise is also needed to decide which activities should be initiated in 2022 and which ones could be initiated later. He expanded on the working groups activities on the diverse cross-cutting topics. Nik proceeded by elaborating on network activities from the Scientific Committee, as well as on new activities identified by the SC.

On the cross-cutting guidance lifecycle, discussion is still ongoing on the need to update the existing guidance documents and/or develop new cross-cutting methodologies.

As for the next steps, after the SC plenary and the prioritisation exercise, the finalised work programme 2022-2024 will be communicated to the relevant stakeholders, including the AF, DG SANTE, and the sister agencies.

He proceeded by announcing the relaunch of a literature review framework contract in March with a closing date at the end of May. Nik explained that EFSA launched a call on systematically literature review last year which was unsuccessful. The tasks will be to conduct or support EFSA on: 1) conducting full or parts of Systematic Literature Reviews (SRs) (includes extensive literature searches - ELS); 2) narrative literature reviews; 3) scoping literature reviews; and on 4) reviewing, assessing and appraising the quality of already conducted reviews.

Nik asked MS for support in disseminating the call to ensure its success.

The Co-Chair thanked Nik and opened the floor for questions.

Germany congratulated EFSA for the ambitious SC program and outlined the importance of the systematic review of literature, referring that it should even be part of a quality management system. In the narrative it was referred that we would expect that within 5 to 10 years all risk assessment (RA) would include some bibliographic data on the systematic reviews performed. Therefore, Germany recommended AF to work on this as there are special needs - not the same 'customers', and sometimes for RA the need to make it 'rough and dirty and quickly', thus questioning its validity. In this context, he suggested to have this item discussed in one of the next meetings, so that exchanges on the way it is being performed could enable the development of a common approach.

The Co-chair supported the idea to further discuss it also at the methodological aspect, outlining that to be able to partner, we need to have common methodologies, and that the systematic literature review is a key one. Related to the presentation of the framework contract, he asked if this could be a service that other regulatory risk assessment actors would be interested to use. He suggested, for reflection, creating a pool of capability to do systematic literature review would be also a good partnership area, so that not every single interested party would have to maintain this capability or procure it.

Guilhem gave the floor to the Netherlands who, referring to some of the complicated issues dealt with by the SC, questioned: 1) if it is a standard procedure for the SC to consult other authorities, since several items are also tackled by other agencies; 2) since some of the issues are of social concern, if there is a parallel risk communication plan; and 3) on the issues which are not taken on board by the Scientific Committee, if they are resolved or not and which discussions were not included in the agenda.

Hungary intervened to add his views to what Germany commented regarding the systematic literature reviews. He stressed that much has changed in the last few years in terms of technological development, in terms of using AI data analytics, text mining in SLR's. There are new tools that will certainly influence how we think about systematic literature reviews, but also continuous reviews. He emphasised that, from a procedural perspective, the capabilities will certainly influence the thinking about the procedures. So, as a first answer, he supported the idea of having a common service since it is a very complicated task and practically impossible to develop in each country. He suggested that a shared competence or shared service also with partnerships would most probably be the best option.





Hungary concluded by saying that to develop a national good systematic literature review capability is beyond their possibilities currently.

Sweden concurred to the fact that many important cross cutting issues are addressed by the SC but questioned why the fluoride and copper fit into the mandate of the SC and was not dealt with by a scientific Panel.

Claudia Roncancio-Peña asked for the floor and answered some of the questions posed by the MS. Starting with the systematic review, she explained that the call was not only for systematic review, but also for narrative assessment or extensive literature search. In relation with the scientific literature reviews and AI, she mentioned that EFSA is aware that there are many different tools on the market. Some of them are free to be used regarding several steps or some of the steps of this systematically literature review, although not interconnected, meaning that there is the need to start with one and then it will be difficult to link among them. In EFSA there is currently a programme working on identifying and trying to connect the different tools that allow to work on the systematic literature review using AI. Systematic literature reviews are not new to EFSA as it is also in one of its operative procedures. For the generic mandates, EFSA is using it more and is now an established practice. Regarding other opinions from the SC, like fluoride or copper, these are mandates that EFSA received from the EC and have been identified as cross-cutting issues, reason why they are addressed by the SC instead of any specific panel. For copper, the SC is arriving to an end of the opinion (public consultation to be soon launched and finalisation by end of the year); as for fluoride, a public consultation of the protocol has already been launched. Regarding the point on the prioritization of activities for the work program, the SC is now identifying the way forward, i.e., how is going to rank the different input and the different contributions received. It will also be considered the way forward for those lower in the ranking.

On the question from the Netherlands regarding other authorities, she referred that besides bringing it to the AF, the working plan is not circulated for comments to all authorities.

As for the query on risk communication, Barbara explained that EFSA has strengthened its social science research capabilities and for every opinion and topic dealt with, there is an assessment which is data driven: the end-to-end approach to engagement that EFSA has taken – an overall view at the whole process of developing opinions or guidance documents detecting for what points engagement is required. This approach has been taken after the reorganization and EFSA is very keen to test how this is going to work in practice.

The Chair asked for the floor to go back to the systematic literature review issue and to the suggestions from Germany. In his perspective, before start working on an opinion, a protocol which guides the scientific the risk assessment is developed, and it also defines the extent of the literature search: extended search, a systematic review, or other ways, how to organize the evidence, how to search it, to find it, to final assess it and finally to integrate it. However, he mentioned, EFSA wants to go further into finding partners to which we can entrust parts of the processes and use one part of the process to organise evidence. Though, finding partners is difficult and this capability is not readily available, and consultancies do not always yield the expected results. He doubted that there could be something like a European competence centre for systematic literature reviews, but it could be worthwhile to explore together with MS. The chair expanded on his narrative saying that EFSA has been working for many years on the use of AI specifically for the appraisal of evidence with many partners - European agencies, MS agencies, EC, and that he believed that the methodological question is only one part of the equation. The other one is if this work could be centrally organised or more in a Cochrane-like approach. He agreed that this was an important topic because it defines also the quality and scientific value of the assessments. For him, it is essential for the outcome of the RA, how evidence is dealt with, found, appraised, and integrated. The Chair supported the suggestion to have a session on this topic in an AF meeting and outlined the need for a collaborative approach using the diverse capabilities in a partnership approach.

Germany intervened to support Hungary, namely acknowledging that in the last years, all the AI and the systematic research on AI basis has been significantly improved. Thus, it could be a good idea





also to invite people leading in this field and who can give us an idea how we can be integrated in artificial intelligence.

**Action Point 6:** MS to support dissemination of Call on Literature reviews Framework Contract (deadline 30/05/2022)

# (Item 6 FROM DAY 1) - Engagement & Communications update

The Chair gave the floor to Barbara Gallani, to debrief on engagement & communication activities. The topic was moved from day 1. Barbara provided a short overview and invited the Plenary to access the full presentation as uploaded before the meeting.

She indicated that EFSA is using the time before the EC drafts the general plan of risk communication as an opportunity to try and test the different ways of working in a collaborative and coordinated way to produce and disseminate communications across Europe. Communication campaigns are one of the explored instruments. The "Stop African Swine Fever" campaign (#StopASF) was implemented in many pre-accession countries as well as some EU countries. Thanks to the lessons learnt during this first campaign, EFSA was able to develop a broader campaign in 2021: #EUChooseSafeFood, intended to raise awareness of the food safety system, of the interactions between the European level and the national level; using cobranded materials and materials already available in Member States. In addition, EFSA was approached by the Slovenian Presidency regarding a possible plant health campaign from 2023. EFSA will work with FPs and CEN members, DG SANTE, and the EC representations in MS to develop it. AF will receive updates on this campaign at future AF meetings.

Barbara then noted that EFSA is also exploring the development of a digital platform: Food.eu, using a modular approach to improve accessibility to different materials produced by Member States with the aim of providing a space where citizens can access information from several reputable sources. For curation and governance, EFSA is working with a group of Member States to develop a possible model for use at a pan-European level in the future.

Regarding EFSA's 20th anniversary, EFSA is aware of several other countries also celebrating this year and will support joint celebrations and social media presence where possible.

On glyphosate, and as an action from the previous Advisory Forum meeting, Barbara informed that EFSA had created an info-sharing space for the CEN members and now extended to the FPs. The space is regularly updated, including the media coverage overview, EFSA's lines to take and any information MS consider worth sharing.

Barbara touched upon the EU-FORA Fellowship. She announced that the deadline of the Call had been extended, acknowledging the difficulties organisations may be experiencing in application due to the changes introduced. She reminded of the new deadline (16<sup>th</sup> May) and suggested that MS contact potential facilitators for consortia creation, including organisations that are already involved in as EFSA's partnering grants or other EU-funded projects (e.g. FS4EU, OHEJP, PARC).

The Chair thanked Barbara for her contribution and opened the floor for questions.

The Netherlands thanked EFSA for the activities on risk communication, including on the Food.eu portal, acknowledging that some of the approaches are very innovative for agencies and indicating their willingness to contribute.

DG SANTE asked for the floor to make an intervention on the General Plan on Risk Communication, first thanking EFSA for its commitment and support to the EC in the preparatory work. He informed that the EC is still analysing the input provided by EFSA, upon request of the EC, and it is not excluded that EFSA will be requested for additional preparatory work. Barbara replied that EFSA is very pleased to continue to work to set the foundations to develop a General Plan with the Member States that can be helpful for Europe.

The Chair closed the agenda item.





**Action Point 7**- MS to support dissemination of extended EU-FORA call (deadline 16/05/2022) and to reach out to EFSA for support in the identification of partners for consortia creation.

# 10. Research engagement initiatives (11H30)

## ■ 10.1 – One Health European Joint Programme (OHEJP)

## a) Dissemination efforts and Legacy of the One Health European Joint Programme

The Co-Chair gave the floor to Hein Imberechts, from Sciensano, and Arnaud Callegari, from ANSES, Scientific Coordinator and Coordinator, respectively, of One Health EJP, for a presentation on "Dissemination efforts and Legacy of the One Health EJP".

Hein Imberechts provided an overview of the One Health European Joint Programme (OHEJP), a project coordinated by ANSES under Horizon 2020, with 44 partners across Europe in the fields of animal health, food safety, public health, dealing with three domains: foodborne zoonoses, antimicrobial resistance and emerging threats. Through the OHEJP there are opportunities for harmonisation of approaches, methodologies, databases and procedures for the assessment and management of foodborne hazards, emerging threats, and antimicrobial resistance across Europe, thus improving the quality and compatibility of shared information for decision making processes. He presented the integrative strategy matrix that OHEJP has followed from the start of the project until now and further on. It represents the successive steps in setting up surveillance programmes, showing that setting up surveillance and being prepared is a multidisciplinary approach. So, there is need of people with different competences and with different functions. The challenge of one health in the context that they use it in OHEJP is that these activities across these different steps of the surveillance process of the preparedness process should be done in alignment among the sectors. He proceeded by informing about the next steps after these five years of the project.

The legacy of the OHEJP is a unique European network of public health, animal health and food safety organizations, with results and outcomes with significant cross-sector value, an alignment with national and international stakeholders and oriented towards impact. To reinforce this process, they will set up a working group that concentrates on this dissemination and on this legacy activity, to identify and analyse the results and outcomes that can be taken up, which will coordinate dissemination actions that will be implemented in 2022-2023. Hein gave some examples of OHEJP projects informing that many more projects and results will come available on their portal. Hein concluded informing the Plenary about their research community, with 24 research projects 17 PhD, and more than 850 people working in integrating activities and six joint integrative projects. Besides, training and education is provided via mainly a summer school. Apart from this, there are also workshops that are organized and Continuing Professional Development modules, with about 300 scientists over 46 countries involved.

Hein Imberechts thanked the Plenary and gave the floor to Arnaud Callegari, coordinator of the OHEJP dealing with the engineering of the project, who informed the Plenary that the program is approaching its final year of operation (9-months extension to new end date: 30/09/2023). Moving now towards the end of the OHEJP, ample attention is being given to the impact of the deliverables and the follow-up after the project. Unfortunately for OHEJP there will not be a new opportunity under Horizon Europe to fund a similar One Health consortium. However, the Med-Vet-Net Association may be well suited to take up outcomes that are expected from the various planned European Partnerships that will include One Health activities (in particular OH AMR, Pandemic Preparedness, Animal Health & Welfare, and Safe and Sustainable Food Systems). The Commission services (DG AGRI, DG RTD and DG SANTE) are keen that this large co-funded programme (90 M Euros, 50% of EU funding) brings added value and they strongly welcome the take-up and use by EFSA and MS authorities of the many OH EJP's deliverables and tools.





He outlined that they have one year and a half now to achieve their goals and to disseminate and legate what has been produced. The Project Management are finalising deliverables, analysis of outcomes and updates of EJP outputs by stakeholders. Arnaud progressed by outlining the main outcomes which have the potential to be taken up and sustained by the stakeholders. The main stakeholders that were identified so far were ECDC, EFSA, DG-AGRI, DG-SANTE. He then provided concrete examples of ready to use outcomes from all the projects that have been run by the OHEJP. Main outcomes have been classified according to the strategy metrics earlier presented. He presented the dissemination plan: 1) EFSA Advisory Forum, 7 April 2022; 2) Program Managers Committee (PMC)- Program Owner Committee (POC) meeting, in October-November 2022, in presence of high-level scientific representatives of ECDC and EFSA; 3) One Health EJP Stakeholders Conference, in March-May 2023; 4) Bilateral discussions in the second half of 2022 or first half of 2023 with, respectively, DG-Agri, DG-Health, EFSA, ECDC, for concrete propositions of uptake; and 5) One Health EJP Policy Event with ECDC, EFSA, DG-AGRI, DG-SANTE (and DG-RTD) to discuss uptake of defined outcomes, planned for September 2023.

Hein took up the floor to conclude this session, highlighting that the OHEJP has many valuable outputs and possible outcomes. He invited the AF, regional and national programme owners, laboratory managers, risk assessors and risk managers to use the deliverables and instruments developed.

The Co-Chair thanked both speakers and informed that the floor would be opened for discussion after the next item.

# b) New EFSA activity on a coordinated surveillance system under the One Health approach for cross-border pathogens that threaten the Union (EJP)

The Co-Chair gave the floor to Andrea Gervelmeyer (EFSA) to briefly inform the MS about the upcoming EFSA activity on coordinated surveillance in animals and the environment for cross-border zoonotic pathogens.

Andrea provided an overview of the background for the request for scientific and technical assistance for a coordinated surveillance system under the One Health approach, for cross-border pathogens that threaten the Union. To support this grant program, EFSA has been tasked to design the EU coordinated surveillance system, to implement the surveillance system data reporting and analysis, and to carry out regular risk assessments based on the surveillance data to review surveillance priorities and methodologies. It will focus on emerging and re-emerging zoonotic pathogens (non-food- or waterborne zoonotic pathogens, including also the unknown) on animals and environment. She proceeded by providing the list of tasks assigned to EFSA and to the involved MS, providing the details of each phase, the foreseen timelines and the envisaged next steps. In preparation of the setting up the One Health surveillance system in animals and the environment, EFSA reviews the literature for relevant examples of coordinated One Health surveillance approaches, maps existing structured systematic EU surveillance initiatives for zoonoses in animals and the environment and prepares a workshop at which the priority pathogens for the One Health surveillance will be established.

MS who wish to apply for a grant need to nominate a competent authority to HaDEA by 01/09/2022. HaDEA will launch the call by 15/12/2022 and MS need to submit their proposals by 15/03/2023. While the workshop is planned for October 2022, MS can already engage with EFSA on this activity, specifically during the Animal Health Meeting of EFSA's Animal Health and Welfare Network on 27-28/06/2022. To facilitate the work EFSA is carrying out, Andrea outlined that EFSA invites MS interested in applying for a direct grant to liaise directly with EFSA, so that they can start collaborating on this initiative as of now.

The Co-chair thanked Andrea and opened the floor for questions.

Denmark thanked for the interesting presentations and asked Andrea if EFSA would be looking into the different EU research projects that have been going on, informing that they have been involved in some but there would be probably many more that have looked into tools, for example the upcoming Kobe Health Data Collection project.





Andrea explained that this is part of the mapping and that EFSA had already contacted the different DG to get informed about activities in animals and in the environment. EFSA will share the map with MS to avoid missing any foreseen or ongoing projects.

The Co-chair highlighted that, as referred during the presentations, EFSA will look into the very useful information and tools created by the EJP initiative.

On the presentation on the Dissemination efforts and Legacy of the One Health EJP, France commented that, as it was mentioned earlier in this AF meeting, Horizon Europe partnerships are new cooperation tools and that it would be important that all the cooperation undertaken in the One Health EJP would find a continuation within the new tools that the Horizon Europe partnerships are providing. As for Andrea's intervention, France outlined that the surveillance of known pathogens is interesting, but also pathogens that could be zoonotic or could evolve to zoonotic should also be included in the scheme.

On the latter, Andrea explained that the term 'emerging' is intended as the known diseases that are not yet in the EU, and also the unknown pathogens. For the yet unknown pathogens, there is the need to decide which test to use, here metagenomics, in a similar way the Schmallenberg virus was identified some years ago, might be the solution.

As for the first comment from France, Arnaud explained that the website of the OH EJP would be sustained and taken over by the Med-Vet-Net Association to keep all information available. Apart from this, OHEJP is projecting an open access, open science, so everything will also be made available. All results are also available on the website.

Hungary outlined the relation of the last presentations with data models. He referred that the DG on Data most probably will come in contact and liaise with the whole process so to see the outcomes and to be sure that these models are the same or similar to the already existing ones.

The Chair thanked the speakers for the presentations and stressed on the follow up and the take up measures made with the stakeholders by the OHEJP. He explained this was a very important question for the future from an agency perspective. In his narrative he explained that sometimes there is much academic focus on the research programs, which although fine for Academy, it is not enough. He believes this was taken on board by the OHEJP, as they invest in trying to exploit, disseminate, ensure that this has a longer life than just scientific publications. The Chair appealed to go even further in the future, so to have research projects that could have relevance for regulatory science, so to get the best value for the society. The question is how to bridge this gap between academic research and the use for regulatory scientific advice and risk assessment.

Hein Imberechts agreed with the Chair. He pointed out that they would now want to go further, reason why they have proposed this new additional work program dealing with dissemination and legacy, to be developed together with the whole project management team and, if possible, with their stakeholders (international, European, national and regional). Hein concluded by asking the AF to help them to achieve their aim.

**Action Point 8**: MS to indicate interest in collaborating on this initiative with EFSA (interest in application to open call CP-g-22-04.01)

#### ■ 10.2 - Update on RARA

The Co-Chair gave the floor to Pamela Byrne, from Ireland, for an update on RARA, following the recent programme committee meeting held on the 29<sup>th</sup> March.

After several postponements due to the COVID19 situation, the Risk Assessment Research Assembly (RARA) will take place in person on 7 December 2022 in Berlin, back-to-back with AF and FP meetings. The main reason for postponement was that travel restrictions and frozen travel budget would have hindered participants to come in person, which would undermine the objective 3 of the RARA





(networking). The new timeline will allow to advertise for the RARA at the ONE conference in June, but also to consider the relevant outcomes of the ONE conference at the RARA event.

Pamela provided a brief update on the preparations for the RARA event, following the recent Programme Committee meeting on 29 March 2022. As for the previous RARA conference, the aim will be to provide an AF statement.

The Programme Committee resumed their work at the end of March 2022, addressing both practical aspects as well as content of the conference. Overall, the RARA programme and main messages will remain similar. Speakers have been asked to confirm their attendance for the new date and the Programme Committee is currently working on few changes to finalise the programme. The AF statement should be drafted by the Programme Committee in autumn for finalisation and endorsement by the AF in October/November, but for sign off and confirmation at the Advisory Forum meeting in December, back-to-back with the event itself. She informed that they were currently finalising the arrangements and that more information would be provided to the AF.

The AF will be able to sign up for the RARA when the registrations open (foreseen in September 2002) and EFSA will provide further information in due course. Pamela encouraged the AF to make the FPs reach out to national funders out to let them know about the event, but also to pick up on previous conversations with respect to connecting the outputs of research to the policymakers, and for the policymakers to articulate very clearly to the research community and the research funders.

The Co-Chair thanked Pamela Byrne and opened the floor for questions.

# 11. Any Other Business

The Co-Chair gave the floor to Sweden, Denmark, and the Netherlands for the AoB:

# ■ 11.1 - Upper intake levels in dietary sugars (Sweden)

Sweden provided a brief update on the follow up from the recently published opinion on tolerable upper intake levels of dietary sugar. This scientific opinion comes following a request from the national food competent authorities of five European countries (Denmark, Finland, Iceland, Norway, and Sweden) to deliver a scientific opinion on the tolerable upper intake levels (UL) for dietary sugars based on available data for chronic metabolic disease, pregnancy-related endpoints and dental caries.

The opinion concluded that food groups that contributed to the intake of added and free sugars in the EU population were 'sugars and confectionary' such as table sugar, honey, syrups, confectionery, and water-based desserts, closely followed by sugar-sweetened beverages, fruit juice and fine bakery wares.

If upper tolerable limits are set for dietary sugar off the back of this, it will enable EU member states to set population goals and recommendations on how much sugar an individual should consume through diet.

Sweden thanked EFSA staff and all the experts for taking on the task of providing this scientific advice, and informed that the opinion will feed directly into the ongoing updating of the 2012 Nordic nutrition recommendations to be published mid-2023. The updating will impact the "sweets and confectionaries" chapters, as well as the chapter on drinks including artificially sweetened drinks.

### **■** 11.2 – PFAS (Denmark)

Per- and polyfluoroalkyl substances (PFASs) are key ingredients of firefighting foams designed to suppress fires involving flammable and combustible liquids. Such foams are used by firefighters during fire training at dedicated sites. Because PFASs are very persistent chemicals, substantial soil and groundwater contamination has been observed in the vicinity of firefighter training areas.





Denmark informed the Plenary that they have found PFASs in meat from cows and fish and in drinking water wells from areas close to where they had some fire workers training. Trainings happened several years ago, but the pollutants are still in the ground. So, in Denmark, they have stopped the consumption of fish and meat from these zones. They also found that some of the people who have been eating this meat for several years have developed immune-related effects. The aim of bringing this issue to the AF was to make participants aware of it as this is something that might be relevant to all and may have spread as well. The Netherlands intervened asking Denmark if there was any report on this contamination and if they could notify them in case there was.

## ■ 11.3 Contaminants in fish (The Netherlands)

The Netherlands took the floor and informed the Plenary that, as previously mentioned, two kinds of reports on fish will be published soon. The importance of this issue was stressed as in the Netherlands there is also problems with contamination of rivers and cow meat from cows living on the sides of the rivers, with the concern going much beyond dioxins.

Denmark expressed interest in the reports from the Netherlands and explained that all the answers on questions related to this issue are published in their website, but of course they would be happy to engage with the Netherlands on these findings.

A second question was on actions from Portugal and Spain related to the increase of MRLs tackled on agenda item 9, and if EFSA would issue any communication or ask Spain and Portugal to distribute their communication messages, as there will probably be media concern and they would want to have a coherent response. Guilhem answered that as mentioned, EFSA is looking with DG SANTE colleagues on the format of this communication to ensure that the technical and scientific basis is clear, and informed that the communication would be presented soon.

The Netherlands thanked France as the host country for this meeting, as well as EFSA, and expressed its appreciation for the thematic discussion. However, he stressed that he felt the session on OHEJP was not appropriate for this forum, as the outcome of this research project could not be discussed. Guilhem thanked The Netherlands for the feedback but referred that he believed that this session was an opportunity for everyone to become aware of the work undergoing and of all the available tools that can be valuable for all countries. He mentioned EFSA's presentation on the mandate received, relevant to this forum, and for which there is a link to OHEJP and to some of the outcomes they have created. The Co-Chair gave the floor to the Chair, Bernhard, for the closure of the meeting

The Chair thanked The Netherlands' feedback on the items in the agenda, important for EFSA to think about which topics are fit to be discussed at these meeting, and how to best use the time. Bernhard concluded by thanking France again for hosting the meeting, and for the support and organization of the social event. He acknowledged all that contributed putting the meeting together.

The Chair closed the meeting, reminding that the following AF meeting would be held virtually 8-9 June, and that the 85<sup>th</sup> and 86<sup>th</sup> AF meetings would be held physically, in Prague on 25-26 October, and in Berlin together with the RARA, in December, respectively.





# **LIST OF ACTION ITEMS**

Ref	Who	Agenda topic	What
Action 1	EFSA and MS	5.1 – Update on TR	EFSA to seek input on criteria for composition and competencies of Scientific Panels
	on 2 MS	5.2 – Update on SPIDO	<ul> <li>MS to support the dissemination of the open calls for developing roadmaps for action on communication science and animal welfare in April, as well as Omics (prior information notice now) and relaunched call in May</li> </ul>
			<ul> <li>MS to support the dissemination of an open call on multi-omics (value €3.25M)</li> </ul>
Action 2			<ul> <li>MS to share their views on the direction taken on NAM by launching 3 projects calls in May 2022 (total overall value 18.3M)</li> </ul>
			<ul> <li>MS to share their views to establish a virtual collaboration forum on NAMs dedicated to knowledge development and knowledge implementation</li> </ul>
			MS to take note of the recently updated EFSA Scientific Cooperation plan (G&P) which contains several high value calls.
Action 3	MS	Item 8.1 – Moving towards a high level of protection for insect pollinators from chemicals	MS to express interest to be partners in projects aimed at advancing the RA of pollinators, including IPOL projects and short-term collaboration for the revision of the guidance document for pesticides risk assessment MS to express interest to be partners in projects aimed at advancing the RA of pollinators
Action 4	MS	Item 8.3 – Strengthen RA in insect pollinators: data sharing among stakeholders, research, and tool development	MS to express interest to EFSA to share data from national programmes or monitoring on pollinators that could populate the EUBP data platform and also support the development of ApisRAM
Action 5	MS	Item 8.4 – Update on the revision of the EFSA bee guidance	MS to support dissemination at national level and provide input on the revision of the EFSA bee guidance once the consultation is launched
Action 6	MS	Item 9.3 – Scientific Committee Work Programme	MS to support dissemination of Call on Literature reviews Framework Contract (deadline 30/05/2022)





Action 7	MS	Item 6 – Engagement and Communication update	MS to support dissemination of extended EU-FORA call (deadline 16/05/2022) and to reach out to EFSA for support in the identification of partners for consortia creation
Action 8	MS	Item 10.1.b -New EFSA activity on a coordinated surveillance system under the One Health approach for crossborder pathogens that threaten the Union (EJP)	MS to indicate interest in collaborating on this initiative with EFSA (interest in application to open call CP-g-22-04.01)