14th Stakeholder Bureau – Follow up meeting with Business & Food Industry Representatives

Engagement and External Relations Unit

ANNEX 3

List of questions raised by the representative of the "Business and Food Industry" category during the 14th meeting of the Stakeholder Bureau held on-line on 9 April 2024.

Agenda item 6: "*Discussion on operational aspects of Transparency Regulation (OSOA, IUCLID use and Post-TR tactics)*"

Introduction:

During the 14th EFSA Stakeholder Bureau meeting (held on 9 April 2024), the representative from the Business and Food Industry category delivered an extensive presentation (this can be found at the following page: 14th meeting of the Stakeholder Bureau | EFSA (europa.eu)) on operational aspects related to applications. Given that the time allocated to this agenda item was not sufficient, it was agreed that a follow-up meeting with the industry category representatives would be organized (27 May 2024), so to allow a deeper exchange. Meeting report notes can be found below:

Follow-up from previous EFSA Stakeholder bureau meetings

- *Slide 4* – Suggestion to encourage the use of applicants' technical hearings (reasons in the slide) => *Was this matter further considered?*
- *Slide 5 – Request to maintain the Industry roundtable with Industry Associations (category support detailed in the slide). If not on a regular basis (as it was) – at least on request => Can we reach an agreement?*

EFSA has decided to discontinue roundtable discussions, as engaging with representatives from a single category does not fit with the current engagement strategy. EFSA however acknowledges the need to engage with stakeholders on processes and support initiatives related to applications and an internal discussion is ongoing to identify the best new format beyond the existing services. EFSA believes the current technical group on tools serves as an excellent model that could be replicated for other purposes. EFSA's goal is to develop a proposal that facilitates co-creation and collaboration between industry and the agency, which is what already occurs in the mentioned technical group.
The results of these discussions are expected to be communicated in the context of the next SH Forum (November 2024 TBC).

EFSA reiterates that there are other initiatives offered in the Catalogue of support initiatives, like ad-hoc meetings with industry representatives (see e.g., with GMO sector, feed industry[1]). This format is used in some sectors more than others but has proven to be an efficient format to exchange with industry associations.

Industry roundtable, as it was in the past, was structured around more horizontal engagement, with topics of interest to different stakeholders. The new approach wants to target more specific engagement on applications and avoiding topics that are, according to EFSA, better fit to be discussed in info-sessions (such as guidance etc…).

[1] Few examples: https://www.efsa.europa.eu/en/events/ad-hoc-meeting-industry-representatives-gmo-applicants; https://www.efsa.europa.eu/en/events/event/ad-hoc-meeting-industry-representatives

Expected OSOA (One Substance - One Assessment) and IUCLID use - what impacts?

The introduction of OSOA is perceived as additional burden hitting especially Small and Medium-sized Enterprises (SMEs).

- *Slide 7* - The current version of the EC proposal for a Regulation (Chemical Strategy for Sustainability- CSS) could create a disadvantage for companies dealing with chemicals having multiple uses. In the uses under GFL, some studies won't have to be notified (under Practical Arrangements) while for other uses NoS will be requested – could EFSA engage and promote harmonisation and consistency (chemical legislation is taking TR as a reference model)?

For Food contact materials plastic substances, EFSA is currently mapping the table of content against IUCLID provisions. EFSA recognises that this work requires new templates and new formats to be developed and delivered (e.g. for migration studies). A similar process will take place also if other areas transition to the IUCLID format.

EFSA recognises also that much of the feedback derives from experiences in the pesticides area, however, given the unique complexity of pesticide dossiers, practices pertaining to this category should not be used as reference point for other domains. In any case, EFSA is ready to support applicants and especially SMEs in transitioning when the time comes, in addition to the dedicated support on IT tools for preparing applications that is already available to them in the Catalogue of support initiatives. Trilateral discussions are ongoing between EFSA-ECHA-EC on the future dossier submission tools.

Laurent Oger, alternate of the Business and Food Industry category, suggested EFSA to consider a transition period where both formats (ESFC and IUCLID) could coexist, allowing applicants to decide to submit dossiers in one way or another. This could allow SMEs to gradually transfer dossiers into IUCLID, while also being provided with all trainings and methodological instructions.

Moreover, it was pointed out that it would be beneficial if a roadmap with a high level planning of expected transition to IUCLID format for the different food domains could be made available. EFSA took note of this comment and will explore when such planning could be shared.

Luca Capodieci, the Bureau and Food Industry member, acknowledged EFSA's work on the definition of studies and inquired whether this work could be aligned with the provisions in the Chemicals Strategy for Sustainability (CSS), so to provide applicants with a consistent working approach. EFSA has actively contributed to the CSS during its drafting phase and strives to align with other agencies wherever possible.

EFSA emphasised the importance of distinguishing between the roles of policy makers (the Commission) and EFSA, which is responsible solely for risk assessment and does not have decisional power in this area.

EFSA inconclusive opinions - impact on innovation

- *Slide 9* - Can EFSA provide updated and detailed statistics on inconclusive opinions and its viewpoint on how to prevent them? => link to slide 4

EFSA recognises there are some inconclusive opinions mainly in the area of feed additives and food enzymes applications.

  - Feed additives area: number of inconclusive opinions has decreased from 57% in 2020 to 47% in 2023 (10% decrease). Discussions on the efficacy for zootechnical additives, as they more frequently lead to inconclusive opinions, are still on going. The EFSA FEEDCO Unit will get back to SHs in the next months with the intention of opening to more data requests under the 'stop the clock' procedure.
  - Food enzymes area: decreased from 5% in 2022 to 1.5% in 2023. EFSA explained that the applicant is always given the opportunity to provide additional information under the 'stop the clock' provision.

Moreover, EFSA is updating several sectoral guidance documents that should also help in providing clearer structure and requirements from the beginning of the application process, which hopefully will result in even less inconclusive opinions.

Regarding technical hearings: EFSA is currently discussing with respective scientific units how to increase the use of this tool, to avoid multiple clock stops. These discussions will feed the annual revision of the Catalogue of support initiatives, planned to be published at the beginning of 2025.

Post-TR statistics and some feedback from applicants

- *Slide 12* - Graphics are based on EFSA parameter "Evaluation of regulated products (SO1)" taken in EFSA annual reports 2017-2022 (or 2021). EFSA data on "*timeliness for regulated products*" has been extracted for each year and in most of the cases shows "adoption delays" (this is especially true for certain products):
    - *Slide 13* – line 1 - What is the meaning of **this**: *Overall, the timeliness for regulated products stands at 87%, **excluding backlog***. => does it mean that the percentage reported does not consider "**backlog"? =>** if so, aren't results distorted? (the information on backlog data should be clarified in each annual report).
    - *Slide 13* – line 5 and 6: line 6 refers to *82,6 %* as the *timeliness of adoption* for 2021. Line 5 however refers to *75% as timeliness of adoption* for 2021. What criteria was used?

EFSA has seen a general drop in applications received since the implementation of the Transparency Regulation in March 2021 as applicants needed time to adapt to the new requirements.

EFSA further clarified some of the numbers in its Annual Activity Report (AAR), e.g. due to internal reorganisations comparison of numbers across different years and units might easily lead to misinterpretation, the number on timeliness (see slide 13) in 2022 is an overall number

(including timeliness of generic mandates), whereas the 2021 number was only referring to regulated products. EFSA took note of the request to provide more clarity on the backlog in its AAR.

It is important to remind that transparency, independently of the number of resources EFSA will put behind, comes with additional tasks and efforts for all actors, e.g. the fact that dossiers are published upon validity requires them to be of sufficient quality, cleared of personal data etc…

This required time from EFSA and applicants to adapt. However, the average time from dossier receipt until validation shows a clear positive trend (average of 140 days in 2021 to 70 days in 2023), demonstrating an important improvement in the dossier validation process.

- *Slide 15*: pre-submission advice limited to what is the guidance and not giving comments on the study design

The limited scope of the General pre-submission advice (GPSA) as defined in the Transparency Regulation is acknowledged. However, EFSA is convinced that the intake phase of some applications (especially first-time applicants) could have been significantly reduced if there would have been early interaction and request for support.

Bureau members reiterated the need for more targeted advice, in order to provide specific support to applicants, also to those who are already experienced with the application procedure.

EFSA management of confidential information and IT tools

- *Slide 17*:
  - Can EFSA detail the quality control steps taken to avoid such mishandlings leading to unwanted disclosure?
  - Can EFSA provide reassurance on its databases security policies and any plans to keep them to the highest standard possible to prevent any breaches?

EFSA has agreed with the European Commission an architecture that is meeting the highest security standards and has carefully chosen key suppliers that comply with the same standards.

- Security assessments are made regularly, and our systems are updated to ensure protection against the latest threats. EFSA conducts regular checks on the security of its IT systems using specialized 3rd parties and relies on the European Computer Emergency Response institution for continuous monitoring of new threats.
- EFSA uses encryption at rest and in transit for all data transmissions between European Commission and EFSA and Member State IT systems.
- EFSA does not contract Microsoft technology directly, but instead leverages a specific European contract meeting Information Technology and European Data Protection requirements.

All data are analysed and stored in a safe and confidential environment, and access to the tool is protected by various security measures (including Multi-Factor Authentication). EFSA is ISO/IEC 27001:2013 certified, which shows EFSA's commitment to the highest security standards.

ANNEX 4

PARTICIPANTS LIST

EFSA

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Christophe Wolff	Policy Officer, Engagement and External Relations Unit
Martina Liccardo	Junior Officer, Engagement and External Relations Unit

STAKEHOLDERS

Name	Category
Luca Capodieci	Business and Food Industry – Member
Laurent Ogier	Business and Food Industry – Alternate