

Dr Bernhard Url
Executive Director of EFSA
European Food Safety Authority
Parma, Italy

By email only

Brussels, 28 April 2020

Subject: “Business and food industry” EFSA stakeholder group call for a higher level of engagement in the implementation process of the Transparency Regulation

Dear Dr Url,

This letter is sent on behalf of ["Business and Food industry" EFSA stakeholders](#)¹ representing thousands of companies whose businesses are directly and indirectly impacted by EFSA processes and scientific outputs.

First of all, we would like to thank EFSA and the Commission for their continuous work regarding implementation measures of the Regulation (EU) 1381/2019 (“Transparency Regulation”) despite the current COVID-19 circumstances. However, we would appreciate a higher level of interaction and exchange on crucial elements and practical measures with the sectors directly impacted. The new transparency rules, which will become applicable in less than one year, in some cases are already changing the way EU business and food industry stakeholders operate. A practical, workable and proportionate implementation of the Regulation with clear rules is of high importance. We are concerned that many specific considerations will not be timely addressed, ending up in rushed implementation as we get closer to the deadline of March 2021.

We understand that some of our questions, shared at the first EFSA Sounding Board meeting, or conveyed by individual stakeholders, cannot be answered for the time being and might be addressed at future stakeholder engagement opportunities. Unfortunately, the current uncertainties are affecting business operators who need to conduct internal planning regarding future submissions. This is especially the case on topics like data formats, mechanisms for the notification and disclosure of studies and submission of confidentiality claims. The implementation of the general legal requirements should be considered in the light of the different regulatory procedures and sector-specific input and engagement is of the utmost importance to ensure consistency with the applicable procedures.

Due to the complexity of the tasks to be accomplished, a lack of sectorial consultation and input could imply the risk of introducing additional requirements not foreseen by the Regulation, this leading to the unfeasibility of certain practical arrangements (as outlined in Annex 2). This could affect the proper implementation process and the ambitious deadline set out in the Transparency Regulation. It is also not clear how and if business operators’ concerns are being considered as individual written replies to questions from any interested parties are not foreseen and no real dialogue is currently possible outside of the 2 existing EFSA technical groups or very general fora like the EFSA sounding board or the DG SANTE Advisory Group on the Food Chain and Animal and Plant Health. The foreseen written consultations would also be of limited value as core elements would require discussion now.

¹ A draft of this letter was circulated by the alternate member of the Stakeholder Bureau to the mailing list of the ‘Business and Food industry’ EFSA stakeholders. The draft was subject to a 1-week consultation for comments and approval, offering an opt-out of signing.

We believe the current interaction level with stakeholders is not sufficient to ensure a valuable exchange of views and proper information for EFSA and Commission. We call on EFSA and Commission to ensure a higher level of stakeholders' involvement in an evidence-based implementation plan of the new provisions. We call for the establishment of additional technical groups or consultation groups maximising the involvement of technical expertise, being at EFSA or Commission level.

We would propose to launch as many Groups as the number of announced Practical Arrangements (listed in Annex 2). This would be done in accordance with the principles for stakeholder interaction of the EFSA engagement framework. The lack of consultation may put at risk the development of a **workable implementation** of the transparency rules, the published working document on key concepts of the practical arrangements for Articles 38 and 39 being an example². Business and Food Industry operators are ready to contribute to the challenging EFSA tasks with our expertise and experience as applicants and data providers to EFSA.

Thank you for considering our suggestions to optimise exchanges and interaction with the stakeholder community which we believe are in line with EFSA's implementation principles of openness, engagement and inclusiveness.

We look forward to your reply.

Best wishes,

On behalf of the ["Business and Food industry" EFSA stakeholders](#)¹

CC: Matthew Hudson (Director for Food chain: Stakeholder and international relations, DG SANTE)
Sabine Jülicher (Director for food and feed safety, innovation, DG SANTE)
Barbara Gallani (Head Communication, Engagement and Cooperation Department, EFSA).

² https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_expg_20200303_efsafsa.pdf

Annex 1

Non-exhaustive list of pending questions, which had been gathered and submitted by the industry representatives in advance of the first meeting of the Sounding Board held on 23 March:

- Standardised Data Formats: Is EFSA intending to create additional discussion groups on data formats, besides the IUCLID for pesticides?
- Release mechanisms: Is EFSA intending to create discussion groups on the approach to release the information?
- When will the data format first clear applicable elements be communicated to applicants?
- For the database of notified studies, when will a test version be available so applicants can train and prepare their staff to incorporate it in their normal workflow?
- Business strategy relies in the possibility to act promptly and propose products in the market as soon as market signals (driven by entrepreneurs' business study and choices) start becoming promising. How to convert this activity in percentage of turn-over terms?
- The valuation of intellectual property involves assigning a monetary value to the non-tangible assets of a company, this process is extremely complex and has a cost, was this cost considered in discussions? Will stakeholders be given the opportunity to provide inputs in these debates? When?
- In the implementation of the transparency Regulation, how does EFSA intend to address data provided by industry to EFSA:
 - o not related to authorised products (i.e. data on contaminants provided in the annual EFSA call for data on contaminants);
 - o not related to a specific scientific output (EFSA general call for data on contaminants); and
 - o forming part of the information on which the scientific output are based?
 - o Does EFSA intend to address them under the current DCF (data collection framework) system? Under which format is EFSA intending to release them? Is EFSA planning a specific stakeholder discussion group to address this?

Annex 2

List of announced Practical Arrangements (PAs):

- (1) Confidentiality
- (2) Transparency
- (3) Public Access to Documents (PAD) & Aarhus Regulation
- (4) Consistency of confidentiality assessments for new active substances (NAS) and renewals under the Plant Protection Products Regulation, and presenting a timeline for all PAs, including also the PAs on
- (5) Notification of studies
- (6) Public consultation of third parties
- (7) Pre-submission advice.