Written communication from Sounding Board member in response to 1st Sounding Board draft agenda circulated on 13 March 2020

Communication from the EU Association of Specialty Feed Ingredients and their Mixtures (FEFANA) on behalf of the Business and Food Industry stakeholder category sent to TransparencyRegulationImplementation@efsa.europa.eu on 18/03/2020

Time	Agenda item	Preliminary industry inputs / remarks
14H30	1. Opening and welcome	
14H40	2. Adoption of agenda	
14H50	0. - Engagement framework during Transparency Regulation (TR): • Approach to engagement with Stakeholders and Member States • Sounding Board and Technical groups • Engagement plans 2020 - Adoption of Terms of Reference Q&A / discussion round	The stakeholder's group "Business and food industry" is too large to be represented by one or two persons. The challenges experienced by industry representatives of "regulated" and "non-regulated" products are very diverse and would deserve the creation of different categories of stakeholders. Feedback is requested to the EFSA about the procedure set for election of stakeholder representatives for the Sounding Board: - EFSA placed the burden of setting such procedure on the members of the Stakeholder Bureau - the option of having an alternate for the second representative was rejected by EFSA Regarding the technical group on the notification of studies, it appears that EFSA had difficulties to get laboratory representatives on board because they do not have a dedicated association. Can EFSA engagement approach be more flexible for this specific topic and allow individual CROs to be involved? This could be a limited engagement over time. This is considered important considering the legal obligation these laboratories in Europe will have to comply with. Will there be further technical groups, and especially to address modalities of disclosure? We believe it is essential for EFSA to engage with owners of the documents to be made available publicly so as to discuss technical aspects. (E.g. some companies have experience in disclosure and IT modalities).

		Discussion Groups (DG): a) Database of Notification of Studies: Concerns about the way EFSA managed this procedure, more transparency is requested specially on the criteria used to select the candidates accepted. b) Standarised Data Formats: Is EFSA intending to create additional DGs on data formats, besides the EUCLID for pesticides? If so, EFSA should have a systematic call for experts and the DG should be made according to the regulatory flows c) Release mechanisms: Is EFSA intending to create DGs on the approach to release the information? Given the links with intellectual property, industry needs clarity.
15H10	4. EFSA's overall approach to and planning for the TR implementation and timeline **Q&A /discussion round**	• When will the data format first clear applicable elements be communicated to applicants? o For Plant Protection Products we need internal resources to be ready ASAP so as to be ready for March 2021. For information, it took more than 500 hours in the EFSA pilot for a dedicated consultant to do the transfer into the suggested new format (IUCLID). o We also see that a fully functional product will not be available by the envisaged date of 27 March 2021 due to missing building blocks (e.g. harmonised OECD templates for several part of PPP dossiers). Will there be a gradual implementation, and if yes, by when will it be communicated. Please note that official submissions will already take place only 3 days after GFL application date. • Similarly 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 ? o In addition, we see in the technical group that EFSA plan to ask more information than initial planned by the regulation (e.g. study scope being extended to include a narrative on the study). There's also a need to clearly define what is understood by "study" in this context (e.g. would more generic modelling approaches be covered as "studies")

		• For both topics we would ask for elements to be clearly communicated to applicants at the latest in October 2020 (reminder that for PPP dossier we are talking about 300-400 studies each time, and many more if we look at what's commissioned, usually 5 to 6 years in advance of submission). We understand that full transparency will be ensured throughout the process of implementation of the Transparency Regulation, we would urge the disclosure of a as much as possible inclusive calendar of planned activities and list of technical groups so that relevant associations will be able to cope with the needed gathering of intelligence from the industry. Readiness by March 2021 seems quite challenging in present times.
15H30	5. I. Transparency & confidentiality and Quality II. and reliability of studies - Update on Practical arrangements on o Aarhus o Articles 38/39 o PPP o Notification of studies o Pre-submissio n advice o Public consultation - Update on EFSA Guidances - Update on EC Implementing acts **Q&A /discussion round**	• We understand that these requirements are still under discussion but we are concerned about the alarming picture of the GFL Expert Group debate over the implementation of the confidentiality provisions, described in the Working Document. • Stating that under Articles 2 and 4 of the Aarhus Regulation information on environmental aspects shall always be made public is in contradiction with the actual provisions of the Aarhus framework. Only information on emissions may always be disclosed to specific requestors. Moreover, several potential conditions for confidentiality currently under discussion within the expert group are manifestly inapplicable and lack any legal basis or reference in the text of the Revised GFL. • This is an issue of direct concern for all sectors affected by the Revised GFL and we would very much appreciate clear and practical guidance from EFSA/Commission on the description and demonstration of: (i) the damage that would be caused by disclosure/advantages of competitors that have access to the information; and (ii) the causal link between disclosure and harmful effects. • We believe that without immediate and coordinated action by EFSA and the Commission to implement the new provisions, the GFL system will not be ready by 27 March 2021. Discussing the overall feasibility of additional requirements that

		are not provided by the adopted text would not help to speed up the implementation process and meet the ambitious deadline set out in the Revised GFL. • 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?
16H40	6. III. Governance and sustainability - Cooperation with Member States - Expert selection - Management Board **Q&A /discussion round**	
17H00	7. IV. Risk communication - General Plan on Risk communication - Social science and engagement **Q&A /discussion round**	
17H20	8. Wrap-up and outlook - Next Sounding Board meeting, upcoming engagement events	

ADDITIONAL QUESTION: *In the implementation of the transparency Regulation, how does EFSA intend to address data provided by industry to EFSA:*

- *not related to authorised products (i.e. data on contaminants provided in the annual EFSA call for data on contaminants);*
- *not related to a specific scientific output (EFSA general call for data on contaminants); and*
- *forming part of the information on which the scientific output are based?*

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?

FINAL REMARK: *Due to the current situation with Covid-19, we see several authorities, companies and laboratories having to install new processes to work remotely. It can also mean that field studies or laboratory studies cannot be performed at all and will suffers delays. For sectors with timed regulatory processes and legal deadlines this will have an impact, and this might affect EFSA's work as well – we do hope that some flexibility can be considered due to the special circumstances.*