Written communication from Sounding Board member in response to 2nd Sounding Board draft agenda circulated on 13 July 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 15/07/2020

List of questions forwarded on 15 July 2020 by the second Sounding Board representative in the group "business and food industry"

Replies would be appreciated during the forthcoming EFSA Sounding Board exchange on 20 July.

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Practical Arrangements (PAs)

General questions (to EC & EFSA)

- Will stakeholders have an opportunity to consult the text of practical arrangements before their adoption?
    - If the answer is no, how will EFSA ensure that the practical arrangements are fit for purposes for all sectors in EFSA's remit without a proper consultation?
- When will business operators be able to test the new IT platforms? (*Note*: We consider January–March 2021 as written in the MB internal report is a way too late to prepare for new submissions in March).
- What is the scope of the study notification obligation (which studies & when)?

- Have the minimum criteria for confidentiality claims found in EFSA's working document been revised since March?
- During the first Sounding Board meeting in March 2020, DG SANTE indicated there will be "transitional periods" for the notification of studies (which will indeed be desirable), will they apply to all sectorial regulations? How?
- What would be the approach taken by EFSA when considering multiple applications on the same molecule (*e.g.* renewal applications of use for food additives, feed additives, PPP…), both for the public consultation preceding the submission of the renewal dossier as well as for the consecutive evaluation? Regarding the latter, the spirit of the transparency regulation is to use all available information to make the risk evaluations; would EFSA then use all the available information provided by multiple applicants plus the information provided by all third parties to come to one joint conclusion for all? And will there be one opinion or multiple opinions in that case?

    - If indeed some form of joint evaluation is to take place, how would this relate to data protection rules? Would applicants be forced to organize data sharing arrangements with other applicants who own relevant data?

Specific questions (mostly to EFSA)

Art. 32b (notification of studies)

What will be the exact criteria that EFSA will consider in order to conclude on an irregularity worth a 6 months suspension penalty according to art. 32b(6)?

Art. 32c (Public consultation)

- To what extent is the applicant bound to follow the non-committal advice referred to in paragraph 1 of Art. 32c as given by EFSA after the consultation of third parties? Would possible arguments in a dossier to deviate from the EFSA advice be evaluated after the completeness check during the evaluation of the dossier?

- Should the potential additional requirements resulting from possibly updated EFSA technical guidance documents, published after a general pre-submission advice / renewal advice has been received but before submission of the associated dossier, already be incorporated in the dossier prior to submission? This is especially relevant for renewal dossiers which often have a tight deadline in order not to lose its authorization.

- Will an applicant be able to add a formal comment to the dossier on the (quality of) additional information gathered from third parties during a public consultation?

Art. 38 (Transparency)

- On publicly accessible dossier content (art. 38(1)(c)), a concern is that intellectual property rights will not be respected by other parties, and information will be used for applications outside (and perhaps even inside) the EU, despite efforts by EFSA to make information accessors declare the contrary (art. 38(1a) last paragraph). Is it therefore possible to restrict public access to the relevant information only of each submitted study? This could be organized by letting the applicant enter the relevant information in pre-set templates, *e.g.* like the ones in the public

IUCLID database. EFSA alone would then have access to the full reports. By this, illegal use of original studies could be prevented.
An alternative suggestion could be that EFSA considers ways to mark the documentation such that it becomes clear from each page of the documentation that the version made available on EFSA's website is only to be used in the frame of the specific application ABC by applicant XYZ it is submitted for, *e.g.* by printing such text in the form of digital watermarks?

- Will the recently adopted approach of EFSA to publish the first page of a Sin letter (and not the annex) be continued after 27 March 2021? And will further arrangements with applicants (*e.g.* communication on revised deadlines for submission of supplementary information, or possible post-adoption arrangements to submit additional information on defects observed in the opinion) be published as well?

- How will the information provided by third parties during a consultation, and which we believe is included in the items lists in art. 38(1)(d), be made accessible to the public in the EFSA website? Will this be linked to the application or stored in a different place? How will the identity of the third parties having submitted information be made public, in order to promote transparency? Will it be visible on the website when EFSA have disregarded certain information from third parties because of its insufficient scientific quality or will the quality of information obtained from third parties be discussed in the Scientific opinion?

- When scientific literature is part of an application dossier, the publication on the EFSA website would concern a violation of possibly existing copy rights of the publisher of these articles. How can an applicant fulfil his obligation to provide a complete overview of (published or in-house) safety data and respect such copy rights at the same time? Is it sufficient to provide summaries of those articles in the dossier (which are normally publicly available)?

Regarding costs of open source literature, in this article the cost structure of 'classical' scientific articles is estimated.
These costs per article would be around 3500 – 4000 $, so up to 3500 €.
The above article gives a clue on what type of cost could be involved for an applicant when they have to compensate publishers for the costs made per article now the article is freely available for everyone interested. A typical number of 30-50 articles is not excessive for a dossier, and even a cost per article of 'only' 2000€ would then mean a cost per dossier of 60,000 – 100,000€.
Even though a growing proportion of (especially recent) literature is so-called 'open source', the aforementioned cost impact is expected to remain substantial for the years to come.

Art. 39 (Confidentiality)

- Further clarification on the criteria for decision by EFSA on requests for confidential treatment of specific parts of the dossier is needed to explore before submission the chances of success of a possible request.
- Will the particulars of a request for confidential treatment be made public? Applicants may share even more sensitive information in their request than the dossier items at stake and therefore plead for confidential treatment of the confidentiality request itself (also considering that this is not specifically mentioned in art. 38(1))

- Question on how art. 39b(1)(e) (on partial publication of items for which the confidentiality request was not granted) is to be understood in the light of the fact that the justification that an applicant provides for its harmed interests will usually consider multiple items of art. 39(2) together: it is difficult for example to link commercial losses to only the publication of the manufacturing method or only to the publication of the quantitative composition, as the latter may also shed light on the manufacturing method (*e.g.* raw material choice leading to a certain composition) – so these items themselves are often be intertwined. If the verifiable justification for confidential treatment would need to be specified per item of art. 39(2) of the GFL or of applicable secondary legislation, it would add to the complexity of the set of criteria for decision by EFSA on confidentiality requests.