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SAFE response to Public Consultation on the Draft Implementing Regulation amending Regulation (EU) No 234/2011 on EU Transparency on risk assessment in the food chain.

SAFE welcomes the feedback session on the Draft Implementing Regulation regarding the rules on applications for food additives, enzymes, and flavourings. We strongly support the aim of the initiative to better implement the requirements of the Transparency Regulation 2019/1381 on risk assessment in the food chain to ensure higher level of transparency within the assessment process.

Nonetheless, we would like to present a few considerations on the proposed initiative.

First, one of the main concerns related to the assessment performed by EFSA stands on the lack of **independence**. During the assessment procedure, EFSA does its peer review based on scientific studies generated by the industry. As independent agency, EFSA should ensure the gathering of opinion provided also by independent experts, whose absence in the assessment procedure undermines the possibility of a fair comparative analysis. In its roadmap, the Commission pointed out that the distrust over the EU's food regulatory system was due to "*EFSA's evaluations of authorisation dossiers being essentially based on studies, data and information generated (and paid for) by the applicant for authorisation*". The current procedures says that "the applicant for an authorisation [must] provide the scientific evidence supporting it", which means such applicant will have to spend its own funds in (costly) studies, as those "will eventually help industry put a product on the market". In conclusion, the lack of independence generates problems on the impartiality of "industry-generated studies and data": without independent studies and data to assess the applicants' claim, there cannot be a fair peer review.

Second, as stated in the Commission Initiative's Roadmap, citizens perceive the risk assessment process (and the decision-making based on it) as **not very clear and transparent**. One of the most important factors to this perception is the plethora of transparency and confidentiality rules, which applies to the risk assessment process depending on the sub-area concerned. This multitude of rules (EU sectorial legislation, in the GFLR and in Regulation 1049/2001 on public access to EU documents), whose sector-based differences may not be fully understood by the EU citizens, contributes to the opacity of the risk assessment process. In addition, the capacity of EFSA to ensure transparency within the procedure clashes with its rules on confidentiality. While EFSA should be open about the

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scientific studies and data collections, it must avoid harming intellectual property rights and commercial and manufacturing secrets coming from the applicants. Therefore, as the applicant is in general the industry and has little interest in rendering any document available to the public, an increasing number of documents has not been made open for public review, up to the point that there are more confidential documents than publicly available documents in EFSA's dossiers. This makes EFSA's decisions less and less transparent in the eyes of EU citizens', strengthening the image of opaque procedures.

Finally, the negative perception of the lack of independence and transparency has clearly affected EFSA's **credibility**. It is controversial for EFSA to perform a transparent peer review of the applicants' requests for authorisation if there is no public access to documents, if the experts chosen to perform this peer review are not impartial, and if there is a lack of independent scientific studies to perform such peer reviews.

To conclude, it is fundamental for the authorisation process of additives to ensure higher level of transparency in the EU. The problems mentioned above risk weakening consumer welfare and the implementation of healthier EU food policies. On this regard, we welcome the amendment proposed on **Article 4(a)(m) of the Draft Implementing Regulation** stating that the applicant can present a lists of documents to be treated as confidential together with a "verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree". Although the term "significant degree" stays vague, it could lead to a more transparent and open procedure, benefitting EU consumers and the upcoming legislative packages foreseen in the Farm to Fork strategy.

We look forward to continuing the dialogue with the Commission and EFSA on these matters, thanking the Commission for the possibility of providing the above-mentioned comments.

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