Extract from EUROPABIO OBSERVATIONS AND POSITIONS ON PROCEDURAL AND SCIENTIFIC TOPICS RELATED TO THE RISK ASSESSMENT OF GM PRODUCTS, sent to EFSA on 29 June 2020

EU transparency regulation

EuropaBio welcomed efforts of the European Commission and EFSA to increase trust and confidence in the EU's procedure for risk assessment by making it more transparent and sustainable. In our view, the process for risk assessment should also become more efficient and consistent to help ensure consumer confidence and the system's viability in the long term.

EuropaBio welcomes the establishment of pre-submission meetings which should enable a more predictable and streamlined risk assessment process. Adopting good practices from the European Medicines Agency and its model for pre-submission would be a step in the right direction.

We hope that the reform of the EFSA Management Board will motivate Member States to take more responsibility and defend a streamlined EFSA and its scientific outputs and the extended term for the Panel members will contribute to greater consistency of scientific opinions.

We support the disclosure to the public of information supporting applications for product authorisations, provided that legitimate confidential business information remains protected and appropriate modalities of disclosure are put in place not to jeopardise innovation in the EU and the competitiveness of companies. We emphasise that disclosure of technical information, on its own, is unlikely to improve public understanding of science and trust in the risk assessment process. Also, comprehensive transparency should not be limited to regulatory studies, but include more transparency in EFSA's internal processes.

We would like to express concerns about the provisional minimum requirements for confidentiality requests described in the EFSA working document.[1] One of the criteria for granting confidential treatment is demonstrating that the harm corresponds to at least to 5% of the total yearly turnover. In our view it would be extremely difficult if not impossible to quantify the damage prior to disclosure of the information claimed confidential. Furthermore, EFSA foresees a confirmation that the information or data for which confidentiality status is requested is not older than five years. As with the requirement on turnover threshold, the Transparency Regulation does not provide a predefined threshold for data becoming obsolete and thus not harming applicants' interests. Disclosure of most items of information included in the categories indicated in Article 39(2) and in sectorial legislation, regardless of their age, will harm applicants' interests to a significant degree. We call on EFSA to re-evaluate their provisional position to ensure the establishment of workable and proportionate practical arrangements which do not jeopardise the legitimate interests of applicants.

The new provisions reinforcing risk communication will play a key role in providing the necessary context to the published technical information. EuropaBio is supportive of the general plan for risk communication that is to be developed by EFSA, the Commission and Member States, and with the proposed involvement of stakeholders.

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 new Regulation, leading to the unfeasibility of certain practical arrangements. This could

[1] EFSA staff Working Document on the practical arrangements implementing Articles 38 and 39 of the Regulation (EU) 2019/1381 of 26/02/2020; accessible here.

compromise the proper implementation process and the ambitious deadline set out in the Transparency Regulation.

We remain committed to sharing our expertise and experience to ensure a workable implementation of the provisions through stakeholder engagement platforms. However, we regret that only limited progress of the implementation has been achieved in the past months and clarifications on some key questions and points are needed to allow applicants to adapt to the new provisions in a timely manner. We also regret that there are no possibilities to have specific discussions within specific areas e.g. through an *ad-hoc* meeting.

EuropaBio calls upon EFSA to ensure appropriate stakeholder engagement and implement the new provisions in a way that would allow a workable, predictable and practical system for all the parties involved and would not result in more complexity of the risk assessment process.