EuropaBio questions to EFSA on the implementation of Regulation (EU) 2019/1381[1] on the *transparency and sustainability of EU risk assessment in the food chain.*

20 February 2020

Background and objective

On 6 September 2019, Regulation (EU) 2019/1381, amending Regulation (EC) No 178/20022 and 8 other pieces of sectorial legislation including Regulation (EC) No 1829/2003 and Directive 2001/18/EC was published. EuropaBio is supportive of the objective to increase transparency and consumer confidence in the risk assessment process but notes that implementation of the resulting new legal provisions will require key changes to the procedures for evaluating the safety of genetically modified organisms (GMOs) under Regulation (EC) No 1829/2003 and Directive 2001/18/EC. This document lists concerns and questions from an industry perspective on how the provisions detailed in the regulation will be applied in practice. This document provides input and several proposals relating to the implementation process.

Pre-submission advice, Article 32a

EuropaBio welcomes the introduction of pre-submission meetings and proposes to steer towards a pre-submission process based on the EMA model for pre-submission, which would allow flexibility regarding timing, allow applicants to receive meaningful advice and avoid disclosure of business sensitive information before submission of the application.

Key points:

- Scope of pre-submission advice: EFSA staff and applicants would cover the following (non-exhaustive) set of aspects in their meeting: (1) the scope of the application, (2) the scientific and regulatory requirements relevant to the application and (3) the EFSA view on the applicability of derogations for specific requirements (if applicable).
- Process structure of pre-submission advice: Pre-submission advice on the rules applicable to, and the content required for the application, should provide the applicant with insights on the necessary data to allow EFSA to complete the risk assessment within the time limit of six months[3].

[1] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.
[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.
[3] Article 6 (1) (for food) and Art 18 (1) (for feed) of Regulation (EC) No 1829/2003.

EuropaBio *aisbl*
Avenue des Arts 53, 1000 Brussels
+32 2 735 03 13
www.europabio.org
VAT: BE0477520310

In case of unexpected results, we hope there will be enough willingness for a second touch point in advance of application submission, allowing EFSA and applicants to discuss any initial study results and potential follow up testing.

Key question:

- How will EFSA ensure meaningful case-specific advice to applicants given the required separation of staff involved in pre-submission advice and the scientific evaluation?

Notification of studies, Article 32b

EuropaBio would appreciate clarification on several aspects of this requirement, such as the studies to be notified, the timing of the notification, the procedure of notification, and the compliance with the notification obligation.

Key points:

- Studies to be notified: It is essential to have clear criteria for identification of which studies to notify. EuropaBio understands that only studies commissioned/carried out to support regulatory applications in the EU which fulfil the OECD definition[4] of a study, are to be notified.
- Timing of notification: EuropaBio's understanding is that notification of commissioned/ carried out studies is required ahead of the submission of the application, *i.e.* that there will be no fixed deadline for notifications.
- Procedure of notification:
  - *Practical system*: notification requirements should not add complexity to the application process. To prevent undue delays for all involved parties, the input system for notification should be as pragmatic as possible, *i.e.* an electronic system accessible by applicants and laboratories/testing facilities where elements required under Art. 32b (2) and (3) can easily be entered. Such a system should allow coordinated notification between applicant and laboratory/testing facility in order to ensure consistency and efficiency.
  - *Collaboration and shared responsibility*: In case of collaboration between different applicants (*i.e.* stack applications[5]), one applicant might depend on studies notified by another. It is important to clarify responsibility in this case.
  - *Transitional phase / grace period*: A transitional process will be required to notify the studies which already exist, or which have already been commissioned in the period leading up to- and at the date of entry into force of the legislation.
- Compliance with the notification obligation: Article 61a of Regulation (EU) 2019/1381 states that Commission experts shall perform fact-finding missions in Member States to assess compliance by laboratories and by other testing facilities with the notification obligation. EuropaBio understands that compliance with the notification obligation should be assessed only for those laboratories and other testing facilities acting as study director for the specific study.

Key question:

- How will EFSA set up a general overview of notifications linked to applications, whilst addressing the above concerns and ensuring enforceability?

[4] Study "means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities" (OECD, 1998; European Union, 2004).

[5] These are applications for assessment of plants in which there is a combination of two or more modifications, a so-called stack.

EuropaBio *aisbl*
Avenue des Arts 53, 1000 Brussels
+32 2 735 03 13
www.europabio.org
VAT: BE0477520310

Consultation of third parties, Article 32c

EuropaBio trusts that the involvement of stakeholders and the public will not delay the risk assessment process.

Article 32c(1) states that the Authority shall launch a consultation of stakeholders and the public on the intended studies for renewal. For GMOs, renewal applications must comply with the requirements for "renewal of authorisations" as set in Articles 11 and 23 of Regulation (EC) No 1829/2003.

Key point:

- EuropaBio understands that only studies in line with the OECD definition[5] of a study should be subject to this provision.

Article 31c(2) states that the Authority shall consult stakeholders and the public on the basis of the non-confidential version of the application or notification made public by the Authority in accordance with Articles 38 to 39e, and immediately after such disclosure to the public, in order to identify whether other relevant scientific data or studies are available on the subject matter concerned by the application or notification. Some clarifications on the consultation process would be appreciated.

Key points and questions:

- Scope of consultation: The stated objective of the consultation, launched immediately after disclosure of the non-confidential version of the application, is solely "*to identify whether other relevant scientific data or studies are available on the subject matter concerned by the Application*". Therefore, EuropaBio understands that EFSA will only consider in the risk assessment process any inputs or contributions that are in the scope of this consultation.
- Process of publication of comments: Considering the objective of enhanced transparency, EuropaBio understands that EFSA will apply principles for transparency reciprocally and to all involved parties. It would also be useful to understand when, how and to whom inputs received during the public consultation will be made available. In line with the public consultation prior to a GMO authorization[6], a duration of 30 days from the launch of the consultation should be adequate.
    - Could EFSA confirm our understanding and address the questions on the process?

Transparency, Article 38 and confidentiality, Article 39 and 39(a)

EuropaBio shares the views on the value of providing information to the public. However, this does require safeguards against misuse of information for commercial and regulatory purposes and safeguards for protecting intellectual property (IP). EuropaBio asks for a clarification on how to submit requests for confidentiality and how these will be handled by EFSA.

Key points and questions:

- Lack of clarity around modalities of disclosure of non-confidential information: The provision states that EFSA shall make public the information listed under Article 38(1)(c) (dossier) "*…in a dedicated section of the Authority's website. That dedicated section shall be publicly available and easily accessible. That information shall be available to be downloaded, printed and searched*

[6] Public consultations on GM food & feed authorization applications: https://ec.europa.eu/food/plant/gmo/public_consultations_en. Accessed on Jan. 08, 2020.

through in an electronic format". EFSA will define the procedure for making public the information, though Article 38(1a) further clarifies: "*The disclosure to the public of the information referred to in point (c) of the first subparagraph of paragraph 1 shall not be considered to be explicit or implicit permission or licence for the relevant data and information and their content to be used, reproduced, or otherwise exploited in breach of any intellectual property right or data exclusivity rules, and the Union shall not be responsible for its use by third parties. The Authority shall ensure that clear undertakings or signed statements are given to that effect by those who access the relevant information prior to its disclosure*.';

  - While Article 38(1a) provides some guidance on how applications (*"scientific data, studies and other information supporting applications…")* will be made public under Article 38(1)(c), what will be the system and procedures established by EFSA to disclose this information?

- Potential for misuse of disclosed information: These procedures must facilitate legitimate public access but also prevent misuse of the information (*e.g.* by third parties in the EU and/or other regions[7]). In order to ensure Applicant's rights to be enforced in case of misuse of the information, EFSA should maintain a register of persons seeking access to the studies in order to identify the person(s) accessing. The access system should contain a legal note and the person accessing the studies must affirmatively acknowledge and agree, as a condition of receipt, that receipt of information under this new process conveys no right to cite, reference, or otherwise use data that is disclosed in the EU and other regions. Releasing studies individually rather than allowing the whole dossier to be downloaded is crucial in reducing the risk of misuse.
  - What safeguards will EFSA put in place to prevent misuse of the information in the EU and/or other regions?
- Requests for confidentiality: Having considered implications for disclosure of information, EuropaBio feels there is a lack of clarity on the process of requesting confidentiality EuropaBio understands that all personal data will be redacted in line with GDPR[8].

Standard data formats, Article 39f

EuropaBio would welcome further clarity on the standard data formats expected to support applications.

Key points and questions:

- Required resources for implementation: In view of continuous applications and renewals, EuropaBio is concerned that applicants and EFSA will need significant time and resources to adapt to any changes in the standard data formats to support applications. Timely clarity and guidance are needed.
  - How is EFSA planning to engage with applicants to define suitable standard data formats?
  - What will be the timing and overall scoping of implementation of a standard data format?
  - Which standard data formats is EFSA considering?

[7] Under WTO rules, the EU has agreed to protect legitimate commercial interests, including CBI, and to protect undisclosed data submitted to regulatory authorities from unfair commercial use. Article 39(2) of the TRIPS agreement states that *"Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use"*

[8] General Data Protection Regulation - Regulation (EU) 2016/679

- Which efficiency gains in the completeness check and risk assessment process does EFSA envisage by using standard data formats? Comments on efficiency gains provided by EuropaBio during the Matrix project should be considered.

EuropaBio *aisbl*
Avenue des Arts 53, 1000 Brussels

+32 2 735 03 13
www.europabio.org

VAT: BE0477520310