European Crop Protection

POSITION PAPER
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ECPA position on Commission initiative on transparency and sustainability of the EU risk assessment model in the foodchain

Summary

We support the overall objectives of the Commission's proposal: increasing transparency in the EU risk assessment process can contribute to strengthening public trust in the system. This is why we committed globally to publish all information related to the safety of pesticide active substances: click here to access our global commitment. The Commission's proposal also looks to establish pre-submission meetings, places greater emphasis on risk communication, and increases the involvement of Member States in the governance of EFSA: we support these proposals and look forward to seeing them strengthened and refined by the co-legislators.

We believe however that the provisions related to when non-confidential information will be made public (art. 38), how it should be disclosed (art. 38), and the definition and protection of confidential information (art. 39), can be improved. Amendments to these provisions are essential to strike the correct balance between ensuring greater and appropriate transparency in the risk assessment process and protecting legitimate confidential business information, which are essential to guaranteeing continued innovation and investment by our sector in Europe.

- **On the timing of disclosure**, disclosing scientific information before EFSA reaches the conclusions of its risk assessment could cause delays to the assessment, or even lead to undue political pressure, thereby threatening EFSA's independence; for this reason we believe that the information should be made public after the first approval at Member State level of the PPP containing the active substance.
- **On the procedure for disclosure**, the current level of protection of the information to be made public is currently insufficient: the disclosure of information should be done in a controlled manner, to ensure the data provider is protected against loss of data compensation, and to protect against its commercial or regulatory use by competitors in other parts of the world. Proper sanctions for misuse should also be enforceable, which are currently not adequately foreseen in the proposal.
- **On the protection of confidential information,** the Commission's proposal reverses the burden of proof on the presumption of protection of confidential information: where information is deemed to be confidential, it should not be disclosed. The new threshold set for defining such confidential information (*"verifiable justification"*) sets a high threshold. Finally the fact that EFSA would act as sole decision-maker on what should be disclosed, particularly in cases of urgency, without any mechanism for appeal with suspensory effect, creates a clear risk for the protection of existing legal rights.

Improving the above elements is essential to ensuring a workable proposal which strengthens public trust in the process while still protecting the industry's capacity to invest and innovate. Our industry invests over €5 billion each year in research and development, and it now takes on average 11 years and €250 million to successfully bring a new active substance to market. Only a small number of new substances have been successfully commercialised since Regulation 1107/2009 entered in to force which makes it clear that the current evaluation process does not make it simple to bring a new product to market.

Finally, ECPA believes that the responsibility for commissioning studies should remain with applicants, while the responsibility for independently evaluating their robustness and quality should remain with Member States and EFSA. Further steps could be taken to improve the governance for conducting studies, which could include greater EFSA involvement.

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Our global commitment to transparency

On 26 March 2018, ECPA, CropLife International and their member companies launched their transparency commitment[1] to make more safety-related data of their products publicly available. Through this commitment, companies will accommodate access to safety data for non-commercial purposes, and will proactively engage in conversations with all stakeholders to explain the existing regulatory process and the safety, efficacy and benefits of crop protection products.

This comes on top of the relevant health and environmental safety information already made public through various channels, such as the product label, product brochures or company websites, peer reviewed scientific literature and regulatory summaries by competent authorities. In the EU, for example, the regulatory risk assessment and study summaries for all active ingredients, and sometimes also for the crop protection products, is online with links to review reports and decisions. Further, the active substance assessment reports (prepared by a rapporteur member state and containing the study summaries and risk assessment, as well as summaries on scientific literature) are published on the EFSA website. EFSA also peer-reviews the assessment reports and publishes their peer review. Note that each assessment report contains a confidential section, containing information such as on composition and manufacturing that is not public. With this initiative, the industry takes its responsibility and goes one step further in making safety data more easily accessible, and providing additional context and background information.

Transparency also means protecting legitimate confidential information

The correct balance needs to be struck between ensuring greater transparency and the need to protect legitimate confidential business information (CBI) and intellectual property (IP). Transparency can be ensured through an appropriate mechanism for disclosure while still protecting commercial information which is essential to fostering innovation and competitiveness. Appropriate access to relevant safety data should contribute to improving public confidence in the regulatory evaluations (risk assessments) supporting the decisions on approval or non-approval of substances.

Timing of disclosure (Article 38)

The Commission's proposal will require EFSA to "*make public without delay*" scientific data, studies and other information supporting applications for authorisation and the information on which its scientific outputs are based. We understand it is intended that this information would be disclosed before the Rapporteur Member State (RMS) evaluation has effectively started, in advance of the delivery of their assessment report (DAR/RAR) to EFSA and in advance of EFSA performing its peer-review and developing its conclusions.

ECPA is highly concerned that this early release of information will undermine the risk assessment process, either by causing unnecessary delays or as a result of undue political or public pressure on the RMS and/or EFSA. The proposed timing of disclosure is also in contrast with the approach taken under Regulation 1049/2001 on access to EU interinstitutional documents[2], which generally lays out that information should not be released during ongoing evaluations. ECPA believes that **disclosure should occur after the first approval** at Member State level of the Plant Protection Product containing the active substance which is the subject of the EU authorisation. This timing would ensure the EU evaluation process is not undermined and would be consistent with the processes applied in other sectors and under Regulation 1049/2001.

[1] https://croplife.org/data-transparency/ http://www.ecpa.eu/industry-data-transparency

[2] Article 4(3), Reg 1049/2001 on access to interinstitutional documents which has an exception from disclosure for ongoing decisions:
"Access to a document, drawn up by an institution for internal use or received by an institution, which relates to a matter where the decision has not been taken by the institution, shall be refused if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure."
"Access to a document containing opinions for internal use as part of deliberations and preliminary consultations within the institution concerned shall be refused even after the decision has been taken if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure."

Procedures for disclosure of information (Article 38)

The Commission proposal states that EFSA shall make this information public "*on a dedicated section of the Authority's website. That section shall be publicly available and easily accessible. The relevant items shall be available to download, print and search through in an electronic format"*. Beyond these general provisions, the detailed procedures for how information will be made available are expected to be defined by EFSA in their internal rules.

In order to avoid loss of data compensation[3] in regions beyond the EU and to comply with EU international obligations (e.g. Article 39 of the TRIPS agreement[4]), it is important to highlight the distinction between the "publication" and "disclosure" of studies. Studies should be released via a mechanism of **controlled disclosure**, rather than "published". Procedures should also be put in place to ensure that information made available in the EU (which represents a significant investment for applicants) cannot be used for regulatory or commercial purposes in other parts of the world by a competitor and that the EU ensures that sanctions for misuse of such information are enforceable. The level of protection in the Commission proposal against such misuse is currently insufficient.

Confidential business information (Article 39)

The Commission proposal establishes a list of information in Article 39 for which confidential treatment may be requested by an applicant based upon *"verifiable justification"* that disclosure would *"significantly harm the interests concerned"*. Article 39(a) sets out the process for applicants to submit such a request to EFSA, and Article 39(b) describes the process and timelines for EFSA to review the request, to inform applicants of their (intended) decision and to adopt a *"reasoned decision"*. These decisions are challengeable before the General Court of the Court of Justice of the European Union (CJEU).

ECPA has several critical concerns regarding these provisions:

- the presumption of protection of confidential information appears to have been removed and the burden of proof reversed, and now lies upon applicants. The approach under the current wording in Article 63 of Regulation 1107/2009 establishes a legal presumption that disclosure of such information would cause harm. The presumption of protection for confidential information should be adjusted to reflect the current situation, where the presumption is that confidential information is protected.
- the standard of proof for justifying confidentiality has increased. The requirement of *"verifiable justification"* that disclosure would *"significantly harm the interests concerned"* sets a high threshold. All other information in the EU under Regulation 1049/2001 (access to interinstitutional documents) applies the standard that disclosure *"would undermine the protection of commercial interests*". Currently under Article 63 of Regulation 1107/2009 it is only necessary for applicants to *"provide verifiable evidence to show that the disclosure of the information might undermine his commercial interests*".
- EFSA will act as the sole decision-making body on what is and what is not considered confidential information without any appeal mechanism with suspensory effect. Under the proposal decisions are only challengeable before the CJEU (with uncertainty about whether a suspensive injunction will be granted). An appeals procedure similar to the one available for ECHA would be a more appropriate mechanism for applicants to request a review the EFSA decisions. A workable process must be put in place by EFSA when assessing *"verifiable justification"* and an appeals procedure should be established to review the EFSA decisions on confidentiality.

Additional comments on the Commission's proposal

Verification studies (Article 32e)

[3] TRIPS: agreement on Trade-Related Aspects of Intellectual Property Rights

ECPA does not support the option of EFSA commissioning verification studies as part of the risk assessment process. We believe the responsibility for commissioning studies should remain with applicants. The responsibility for independently evaluating the robustness and quality of those studies resides with Member State authorities and EFSA. ECPA would have significant concerns regarding any recommendations to repeat or conduct additional vertebrate testing which would be contrary to the requirements to avoid and reduce use of laboratory animal studies as laid down in Directive 2010/63[5] and Regulation 1107/2009.

Instead ECPA supports further steps to improve the governance for conducting studies, including greater involvement of EFSA in the process of agreeing which studies should be performed (pre-submission advice), independent auditing of the adherence to the principles of Good Laboratory Practice (GLP) or Good Experimental Practice (as described in Article 38d) or other measures to ensure studies are undertaken according to required regulatory requirements. In the event the Commission does request EFSA to commission any verification studies, these should be conducted according to the data requirements and Commission communication (test methods and guidelines) supporting Regulation 1107/2009, and should not lead to unnecessary delays in the evaluation process.

Pre-submission advice (Article 32a)

ECPA is supportive of pre-submission advice involving Member State authorities and EFSA. The establishment of this advice as part of the risk assessment process would ensure that prior to dossier submission applicants have clarity on the requirements of risk assessors. This concept should ensure an efficient use of scarce public resources by helping to avoid unnecessary disruption later in the evaluation process. However, it is essential that commercially sensitive information disclosed by the applicants during the course of such meetings, be treated as confidential.

Union register of studies/notification of studies and consultation of third parties (renewals) (Article 32b, 32c)

ECPA is not opposed to the concept of a Union register of studies and also the concept of applicants notifying EFSA prior to dossier submission on which studies they intend to perform in the case of substance renewals. Such a procedure should assist in having a clearer agreement on the nature and design of studies applicants must submit to satisfy the requirements of risk assessors.

In publicly consulting on the intention of studies (renewals), applicants should have the ability to remove or redact any CBI in line with Article 63 of Regulation 1107/2009. Also the obligation to notify studies to the register should sit with applicants alone and not with (EU) laboratories. Our member companies develop data packages intended for global use and therefore studies are routinely performed in laboratories in regions outside the EU. However, studies are usually always performed according to relevant OECD test guidelines and to GLP. The OECD's mutual acceptance of data (MAD) provisions then provide that data generated in another (OECD) member country should be accepted by another member[6].

Risk communication (Article 8)

ECPA supports the proposals aimed at strengthening risk communication including the development of a risk communication plan by the Commission. More effective risk communication will require improved cooperation between risk assessors and risk managers at both EU and national level.

EFSA organisation (Article 25, Article 28)

[5] Directive 2010/63 on the protection of animals used for scientific purposes

[6] To ensure the same chemicals are not being tested and assessed in several countries, the OECD Council adopted a Council Decision in 1981 – on Mutual Acceptance of Data (MAD) - stating that test data generated in any member country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP) shall be accepted in other member countries for assessment purposes and other uses relating to the protection of human health and the environment.

ECPA supports the proposals around the governance of EFSA to increase the involvement of Member States both within the Management Board and the scientific panels. We support exploring means of ensuring greater involvement of Member State authority experts (risk assessors) in conducting EU evaluations as part of the EFSA processes (e.g. similar to the system coordination established for EMA).