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NON-PAPER

Renewal of approval under Commission Implementing Regulation (EU) 2020/1740: possible options for obtaining studies submitted in previous dossiers for the approval or renewal of approval of active substances (“old studies”) for use as required under points (e) and (f) of Article 6, paragraph 2, of Commission Implementing Regulation (EU) 2020/1740

This non-paper was discussed between the Commission, Member States and EFSA and a consultation of the three applicant associations (CLE, ECCA and IBMA) was carried out in July-August 2023. The options outlined in the non-paper are possible best practices but do not preclude other options from being suggested or utilised by Member States.

This non-binding document was endorsed by the Standing Committee on Plants, Animals, Food and Feed (section phytopharmaceuticals) on 31 January 2024 and may be amended, as needed, based on practical experience.

Background

Regulation (EC) No 178/2002 (‘General Food Law’ or ‘GFL’), as amended by Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain, requires that scientific data, studies and other information that is part of, or supporting, an application shall be made public by the Authority, without delay, once a valid or admissible application has been received by EFSA (Article 38 of Regulation (EC) No 178/2002).

Such studies or information may have already been submitted in previous applications to support the first approval or renewal of the approval of an active substance under Directive 91/414/EEC or Regulation (EC) No 1107/2009 (“old studies”) or submitted for the first time in the context of an application under Regulation (EC) No 1107/2009 (“new studies”).

Therefore, any study submitted as part of an application for renewal of approval (including both old and new studies) will be published in the context of renewal of approval under Implementing Regulation (EU) 2020/1740¹, such studies will be subject to public consultation, ensuring maximum transparency and scrutiny.

Such publication, however, shall not provide permission or licence for their dissemination, re-use, reproduction, or exploitation in breach of rules concerning existing rights, including intellectual property rights, or data exclusivity rules under Union law².

¹ Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012 (OJ L 392, 23.11.2020, p. 20).

² See Article 7 of EFSA’s Practical Arrangements concerning transparency and confidentiality: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-transparency-and-confidentiality.pdf

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It is worth to recall that, as provided by Article 3(21) of Regulation (EC) No 1107/2009, “data protection” means the temporary right of the owner of a test or study report to prevent it being used for the benefit of another applicant.

Such protection, as specified in Article 59 of Regulation (EC) No 1107/2009, only temporarily applies either at first authorisation of PPPs or at renewal of authorisation and, unless explicitly recognised in the regulatory framework of a third country, it is limited to the EU. Nevertheless, as any decision taken at EU level should always be in line with the obligation of “professional secrecy” (Article 339 of the Treaty on the Functioning of the European Union), the Institutions and its officials should always adhere to the general obligation of not disclosing information received, in particular about undertakings, their business relations and their cost components.

As a general remark and for completeness purposes, it is worth mentioning that the TRIPS agreement (The Agreement on Trade-Related Aspects of Intellectual Property Rights, a treaty under the World Trade Organization) takes a different approach to protected works, focusing on the investment made. This approach allows for the protection of utilitarian works such as software, designs, and more. However, it should be emphasized that TRIPS is an international convention that is implemented differently by each signatory state.

Additionally, TRIPS includes a special provision regarding undisclosed test data submitted as a requirement for approving the marketing of pharmaceutical or agricultural chemical products.

The provisions related to data protection in the context of plant protection products (PPP) reflect the obligations outlined in Article 39 of TRIPS (as stated in recital 39 of Regulation (EC) No 1107/2009). However, it is important to note that this protection does not originate from intellectual property (IP) law but rather from competition law. Its primary purpose is to safeguard applicants against unfair commercial practices. As a result, there are two distinct forms of protection: data protection in the strict sense and copyright protection. Data protection in the strict sense is ensured through the relevant provisions of sector-specific regulations governing plant protection products. Copyright protection, on the other hand, falls outside the scope of sector-specific legislation and is subject to national law.

Renewal of approval under Commission Implementing Regulation (EU) 2020/1740 (“Regulation 2020/1740”)

In order to ensure a comprehensive and robust risk assessment of active substances at renewal of approval, all available data must be taken into account by regulatory authorities; this includes not only new studies but also the relevant studies and information submitted as part of previous approval/renewal procedures (as well as the available scientific literature)³. New studies that are repetitions of old studies cannot substitute the need to submit old studies all data has potential relevance, in particular in the context of a weight of evidence approach.

Article 6(3) of Regulation 2020/1740 states:

³ Article 6(2) of Implementing Regulation (EU) 2020/1740, in particular points (e), (f), (l) and (m)

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“Applicants shall make their best efforts to obtain access to and provide the studies which were part of the approval dossier or subsequent renewal dossiers as required under points (e) and (f) of paragraph 2.

The Member State that acted as rapporteur for the previous approval and/or subsequent renewal dossiers or the Authority shall endeavour to make available such studies where the applicant provides evidence that its attempts to obtain access from the study owner have failed.”

It is expected that in most cases applicants will obtain old studies through negotiations with data owners. However, in cases where access cannot be obtained despite best efforts, and in view of the above, it is considered that:

- ✓ Article 6 can be used as a basis for Member States that acted as rapporteur for the previous approval and/or subsequent renewal dossiers (RMS)⁴ to make available old studies to applicants, **in the event the applicant(s) could not obtain these studies from the data owner despite best efforts** (typically this would consist of negotiations with the data owner(s)). It must be underlined that applicants should make best efforts, in good time and in good faith, to obtain old studies and therefore that the need for Member States to make available old studies to applicants is expected to be rarely required.

In case no agreement is reached between the applicant and data owner, the applicant shall provide the RMS with evidence of its attempts to reach an agreement with the data owner. The RMS shall then decide whether the applicant has complied with its duty to try to obtain the studies with best efforts, in good time and in good faith. In case the applicant has not complied with its duty, the RMS may decide to deny making the studies available. In case the applicant has fulfilled its duties, the RMS shall notify the applicant and data owner and support further negotiations to make the studies available. If after 60 days no agreement has been reached, the RMS will inform the data owner that the studies will be made available, subject to personal information being redacted/sanitised.

- ✓ Letters of access: Since Regulation 2020/1740 requires that the full text of each test or study report are submitted in the application for renewal of approval (available for subsequent public consultation), physical access to the studies (at least in redacted form) is required in order for the applicant to upload them into IUCLID. Therefore, letters of access alone are not considered a viable option for the first renewal under Regulation 2020/1740.
- ✓ Data protection status of studies does not impact the possibility to give access:
 - Article 59 of Regulation (EC) No 1107/2009 refers to data protection in the context of applications for **authorisation of plant protection products** at which level data on the active substance of a plant protection product may be protected.
 - More specifically, Article 59(1), second subparagraph, states that *“Where a report is protected, it may not be used by the Member State which received it for the benefit of other applicants for authorisation of plant protection products, safeners or synergists and*

⁴ Reference to ‘rapporteur Member State (‘RMS’)’ throughout the document shall be interpreted as the ‘Member State that acted as rapporteur for the previous approval and/or subsequent renewal dossiers’, unless specified otherwise.

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adjuvants, except as provided in paragraph 2 of this Article, in Article 62 or in Article 80". It does not refer to the **approval/renewal of approval** of active substances.

- Making studies available does not overrule or alter the data protection status of the study (nor the need to provide data to support applications of PPPs, as the study cannot be used for the benefit of applicants for product authorisations).
 - If relevant and known, Member States can inform applicants, when making studies available, that the study is protected in their Member State (or has not yet been submitted at MS level and hence cannot be referred to at MS level without a Letter of Access) this will help to pre-warn applicants about possible implications for renewal of PPPs in event of renewal of approval.
 - At the end of the renewal process the rapporteur Member State for renewal will prepare a list of studies necessary for renewal (Article 60 of Regulation (EC) No 1107/2009).
 - In case the substance is renewed, at the time of renewal of authorisation (Article 43 of Regulation (EC) No 1107/2009) or in the event that new applications for PPPs are submitted, the applicant would need to provide a letter of access or an alternative study to any data that was necessary for renewal of approval of the active substance and remains protected in a given Member State. Article 62 of Regulation (EC) No 1107/2009 also applies.
- ✓ Therefore, overall, making studies available under Article 6 of Regulation 2020/1740 does not interfere with the data protection status of the given study data protection is still relevant in the context of authorisation of PPPs.
 - ✓ Two possible options to make available old studies are foreseen. It must be underlined that in order to fulfil the requirements of the legislation, the provision of both full (non-redacted) and (where relevant) redacted copies of studies should be submitted, where possible.

1. RMS manages the process directly (including redaction/sanitisation⁵)

The RMS (as clarified in footnote 4, ideally the rapporteur Member State for the previous approval and/or subsequent renewal dossiers⁶) would inform the original applicant/data owner that it intends to make the study(ies) available under Article 6(3) of Regulation 2020/1740 and provide a short period (e.g. 30 working days) for the data owner to reach an agreement with the applicant. In case no agreement is reached, the RMS will inform the data owner that the studies will be made available, subject to personal information being sanitised and inviting the data owner to identify within a reasonable deadline (e.g. 30 working days) confidential information, if any, accompanied by verifiable justifications in line with the applicable requirements. The RMS releasing the studies will assess any

⁵ It is noted that the confidentiality check performed under this option is carried out before the submission of the renewal application, in the context of making old studies available, in accordance with Article 6(3) of Regulation 2020/1740. Therefore, this option does not interfere with the confidentiality duties EFSA is called upon, pursuant to Article 39 of Regulation (EC) No 178/2002, after the submission of the renewal application.

⁶ In case the RMS does not have the original studies in its records, it can obtain the studies from other Member States or EFSA as in any case the RMS (plus other MS and EFSA) must have access to the original studies for its assessment. Sharing studies amongst Member States and/or EFSA can be arranged on an *ad hoc* basis.

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confidentiality requests made before making them available to the applicant for the renewal in the (less frequently expected) cases where redactions should be carried out only the redacted version of the study will be made available to the applicant (provided that it can be made clear that the release is for the purpose of the renewal of approval of the active substance only and not for permission or licence for their dissemination, re-use, reproduction, or exploitation in breach of rules concerning existing rights, including intellectual property rights, or data exclusivity rules under Union law see Article 7 of EFSA's Practical Arrangements concerning transparency and confidentiality which can also be used as a disclaimer).

Applicants will upload the (sanitised) studies under the relevant IUCLID dossier so that a full data package is available for public consultation (Article 10 of Regulation 2020/1740), thus ensuring that the core objective of transparency is fulfilled.

Although not expected for most studies, in case redactions were requested by the data owner related to confidential information as set out in Article 63(2) of Regulation (EC) No 1107/2009, the applicant should provide an explanation/guidance on the way the original study can be retrieved (e.g. by an identifier such as an EFSA Question number), to allow Member States and EFSA to easily locate the full study if/when needed⁷.

As confidentiality requests, if any, have already been assessed by the RMS under this scenario, no new confidentiality requests should be submitted by the applicant when including the (sanitised) study under the relevant IUCLID dossier. In other words, upon conclusion of the confidentiality check by the RMS, the applicant uploads the (sanitised) study without using the confidentiality flagging functionality in IUCLID for the (sanitised) study concerned. That way the (sanitised) studies will not be reflected in the IUCLID confidentiality report that is automatically generated based on the confidentiality flags set in the relevant IUCLID dossier and will be removed from the scope of EFSA's confidentiality assessment.

2. A consultant manages the process (via a non-disclosure agreement)

The RMS⁸ would inform the original applicant/data owner that it intends to make the study(ies) available under Article 6(3) of Regulation 2020/1740 and provide a short period (e.g. 30 working days) for the data owner to reach an agreement with the applicant. In case no agreement is reached, the RMS will inform the data owner that the studies will be made available, to a consultancy hired by the RMS. Within a reasonable deadline set by the RMS, the data owner may submit a request to treat certain parts of the study confidential because it constitutes personal information and/or commercially sensitive information

⁷ If needed, the applicant may consult the data owner directly or indirectly via the RMS to obtain this information for inclusion in the relevant IUCLID dossier

⁸ In case the RMS does not have the original studies in its records, it can obtain the studies from other Member States or EFSA as in any case the RMS (plus other MS and EFSA) must have access to the original studies for its assessment. Sharing studies amongst Member States and/or EFSA can be arranged on an ad hoc basis.

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within the meaning of Article 63(2) of Regulation (EC) No 1107/2009, accompanied by a verifiable justification. Alongside the confidentiality requests, if any, also a non-confidential version with all information deemed confidential duly redacted and a confidential version with all information considered confidential boxed or earmarked should be provided. If the data owner has no confidentiality requests, only the full, unredacted study needs to be provided.

The RMS will inform the applicant for renewal that it will hire a consultancy to submit the studies in IUCLID for which no agreement could be reached with the data owner and that the costs would need to be covered by the applicant for the renewal. A non-disclosure agreement between the RMS and the consultancy will be made to ensure confidentiality of the information transmitted to the consultancy by the RMS. The RMS will transfer the data owner's confidentiality requests, if any, alongside the confidential (boxed/earmarked) and non-confidential (sanitised) version of the study to the consultancy. The consultancy will then create a dataset in IUCLID uploading the confidential and non-confidential versions of the studies thereunder and filling in the relevant study records and study summaries accordingly (as well as provide any confidentiality requests concerning the studies, if relevant⁹). If the data owner had no confidentiality requests, only the full, unredacted study needs to be provided¹⁰. The data set thus created will be merged as an inherited template with the IUCLID data set provided by the applicant. In this way a full data package of the dossier is available for public consultation (Article 10 of Regulation 2020/1740), thus ensuring that the core objective of transparency is fulfilled. At the same time, the inherited template cannot be accessed by the applicant for renewal thus preserving the confidential nature of studies vis-à-vis the applicant and data owner.

- ✓ In case certain studies cannot be submitted despite best attempts to locate and obtain them, this should not preclude admissibility of the renewal application. In such cases, the rapporteur Member State for renewal should take the study (or if the study cannot be obtained despite all efforts by the applicant and the RMS - the study summaries available from previous evaluations) into account in its evaluation (Article 11(3) of Regulation 2020/1740). A clear explanation of the steps taken to locate/obtain the study should be provided by the applicant.

Timing: The renewal process has clearly defined steps which are subject to certain time limits or deadlines. In order to ensure a smooth renewal process and prevent delays to submission of complete applications and subsequent decisions on admissibility, obtainment of old studies must be sought by applicants as early as possible and ideally before notification of studies pursuant to Article 3 of Regulation 2020/1740, so that applicants can make fully informed decisions on whether new studies need to be performed. and in view of the time needed to negotiate with data

⁹ Using the confidentiality flagging functionality in IUCLID in the IUCLID records/summaries concerned

¹⁰ In the field "Attached (sanitised) documents for publication" of the relevant IUCLID records/summaries

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owners. Starting negotiations with data owners early will also ensure that sufficient time is available to reach an agreement.