TECHNICAL REPORT

APPROVED: 11 February 2021

IMPLEMENTATION DATE: **27 March 2021**

doi:10.2903/sp.efsa.2021.EN-6464

Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure

European Food Safety Authority (EFSA)

Abstract

This document provides guidance to applicants submitting dossiers related to the approval of pesticide active substances and for setting of maximum residue levels, and to Member States preparing assessment reports on active substances within the scope of Regulation (EC) No 1107/2009 and Commission Implementing Regulation (EU) 2020/1740, or evaluation reports on maximum residue levels applications, within the scope of Regulation (EC) No 396/2005.

It describes the administrative requirements for the preparation and submission of the dossier to support an application for the approval, the amendment of approval or the renewal of an existing approval of a pesticide active substance, and for maximum residue levels, for applications submitted as of 27 March 2021. It also describes the support initiatives available from the preparation of the application (pre-submission phase) to the adoption and publication of EFSA's output.

The Transparency Regulation amended the General Food Law by introducing new provisions in the pre-submission phase and in the application procedure: general pre-submission advice, specific aspects for intended applications for renewal (notification of intended studies, including their design, public consultation on the intended studies, renewal pre-submission advice by EFSA), notification of information related to studies commissioned or carried out to support an application, public disclosure of non-confidential version of all information submitted in support of the application and related confidentiality decision-making process, public consultation on submitted applications. These new requirements, as implemented by the Practical Arrangements laid down by EFSA, are reflected in this guidance.

The guidance describes the procedures and the associated timelines for handling applications related to pesticide active substances. It provides additional instructions and guidance to applicants and rapporteur Member States, and co-rapporteur Member States where relevant, with the aim to enhance the quality of application dossiers and assessment reports.

The document also provides guidance to applicants and Evaluating Member States on applications for the setting of maximum residue levels, in particular concerning the provisions introduced by the Transparency Regulation amending the General Food Law and their implementation in the procedure for such applications, according to the Practical Arrangements laid down by EFSA.

Key words: Application, e-submission, pesticides, peer review, maximum residue level, Regulation (EC) No 1107/2009, Regulation (EC) No 396/2005.

Requestor: European Food Safety Authority

Question number: EFSA-Q-2020-00368

Correspondence: apdesk.applications@efsa.europa.eu, pesticides.peerreview@efsa.europa.eu, pesticides.mrl@efsa.europa.eu

Acknowledgements: EFSA wishes to thank the following for the support provided to this scientific output: Sara De Berardis, Simone Gabbi, Ilaria Mangerini, Daniela Maurici, Francesca Volpi, the staff of the Pesticide Peer Review and Pesticide Residues Units.

Suggested citation: European Food Safety Authority, 2021. Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure, EFSA supporting publication 2021: EN-6464. 77 pp. doi:10.2903/sp.efsa.2021. EN-6464

ISSN: 2397-8325

Summary

This document provides guidance on the preparation and submission of dossiers and assessment reports for the peer-review of applications related to pesticide active substances. It is therefore addressed to both applicants preparing an application, and Member States preparing an assessment report on such an application.

It takes into account the new provisions introduced in Regulation (EC) No 178/2002 (i.e. the General Food Law) and in Regulation (EC) No 1107/2009 by Regulation (EU) 2019/1381 (i.e. the Transparency Regulation).

This guidance applies to all applications submitted to the competent authority of a Member State as of **27 March 2021** and should be used for the preparation of applications intended to be submitted from that date onwards. Consequently, this guidance applies to all assessment reports concerning applications submitted as of 27 March 2021.

The guidance contains a separate chapter for applications related to maximum residue levels (MRL) applications and confirmatory data within the scope of Regulation (EC) No 396/2005, submitted as of 27 March 2021. It provides guidance to applicants and Evaluating Member States on the provisions set out by the Transparency Regulation and their implementation according to the Practical Arrangements[1] laid down by EFSA, related to applications for maximum residues levels.

It consists of five chapters and two appendices:

- Chapter 1. *Background and Terms of Reference* provides the context for the publication of this guidance document;
- Chapter 2. *Guidance on the peer-review of pesticide active substances* describes the procedure, the associated timelines and the documentation to be provided for an application related to a pesticide active substance;
- Chapter 3. *Practical guidance for Applicants and Member States for preparing Dossiers and Assessment Reports under Regulation (EC) No 1107/2009* provides information on how data should be presented in the dossier and in the assessment report;
- Chapter 4. *Guidance on the provisions of the Transparency Regulation for MRL applications* exclusively related to the implementation of the measures set out by the Transparency Regulation for MRL applications[2];
- Chapter 5. *Interaction with EFSA staff* presents different tools to interact with EFSA staff during the life-cycle of the application, from the preparation of the application (pre-submission phase) to the adoption and publication of EFSA's output;
- Appendix A – includes the completeness checklist that should be used by rapporteur Member States to verify that all the elements needed in the assessment reports are provided. It should be filled in and submitted by the rapporteur Member State together with the assessment report;
- Appendix B – provides a form to be used for submitting requests for sanitising confidential information from assessment reports, EFSA's conclusions and background documents.

[1] EFSA's Practical arrangements are available online at: https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements
[2] The MRL setting procedure is described in the EC Technical Guidelines (SANTE 2015/10595). Chapter 4 of this administrative guidance only addresses the provisions introduced by the Transparency Regulation.

Table of contents

1. Background and Terms of Reference as provided by EFSA

Since 2014, EFSA implemented dedicated services and initiatives to support applicants and other stakeholders during the whole life-cycle of applications for regulated products.

In this context, EFSA prepared this administrative guidance on the submission of dossiers and assessment reports for the peer-review of pesticide active substances and on MRL applications procedure.

As regards the peer-review of pesticide active substances, it provides applicants and Member States with updated and detailed information on the procedure for the preparation of dossiers and assessment reports, the format of the dossier and its online submission, and the handling of the application by EFSA.

It aims at improving the understanding of the administrative requirements for dossiers and assessment reports and in turn to improve their quality. The services in place during the life-cycle of the applications, from preparation of the application (pre-submission phase) to adoption and publication of EFSA's scientific output, are also presented.

The scope of Chapters 2 and 3 of this guidance document relates to Regulation (EC) No 1107/2009[3] regarding applications for approval of an active substance or for amendment to the conditions of an approval (Article 7), and renewal of approval (Article 14 and Commission Implementing Regulation (EU) 2020/1740[4]).

These chapters are to be read in conjunction with the above-mentioned Regulations, as well as with Regulation (EU) 2019/1381[5] (hereinafter 'Transparency Regulation') amending *inter alia* Regulation (EC) No 178/2002[6] (i.e. the General Food Law, hereinafter 'GFL Regulation') and Regulation (EC) No 1107/2009 and with EFSA's Practical Arrangements implementing the Transparency Regulation.[7] In case of discrepancy between the content of this document and applicable legal acts, or EFSA's Practical Arrangements, the legal acts and the latter prevail.

This administrative guidance does not replace the relevant guidance documents issued by the European Commission, which remain to be consulted for the preparation of dossiers and assessment reports as appropriate[8]. While preparing the dossier, the applicant should also refer to EFSA's guidance documents and opinions available on EFSA's website.[9]

Basic substances are outside the scope of this document. A dedicated EC guidance is available on EC's website.[10]

This guidance applies to all applications submitted to the competent authority of a Member State as of 27 March 2021 and should be used for the preparation of applications intended to be submitted from

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

[4] 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. C/2020/7982 OJ L 392, 23.11.2020, p. 20–31.

[5] 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, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

[6] 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, as amended by 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, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

[7] EFSA's Practical arrangements are available online at: https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements

[8] List of EC guidance documents: https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en

[9] http://www.efsa.europa.eu/en/applications/pesticides/regulationsandguidance

[10] https://ec.europa.eu/food/plant/pesticides/approval_active_substances_en

that date onwards. Consequently, this guidance applies to all assessment reports concerning applications submitted as of 27 March 2021.

For applications submitted before 27 March 2021, the previous version of the guidance applies (EFSA, 2019a). Accordingly, the previous version of the guidance applies also to assessment reports concerning applications submitted before that date (regardless of the submission date of those assessment reports).[11]

The guidance contains a separate chapter for applications for maximum residue levels (MRLs) within the scope of Regulation (EC) No 396/2005[12]. It provides guidance to applicants and Evaluating Member States on the provisions set out by the Transparency Regulation and their implementation according to EFSA's Practical Arrangements towards the procedure for maximum residues level applications. The chapter should be read in conjunction with Regulation (EC) No 396/2005, EFSA's Practical arrangements implementing the provisions of the Transparency Regulation and with EC's guidance document on the MRL setting procedure (European Commission, 2018). In case of discrepancy between the content of this document and applicable legal acts, or EFSA's Practical Arrangements, the legal acts and the latter prevail. Chapter 4 of this guidance applies to all MRL applications submitted as of 27 March 2021.

For the purpose of this guidance document, an 'applicant' means any legal or natural person (e.g. individuals, business operators, industry associations, consultancy companies), who has submitted an application under Regulation (EC) No 1107/2009 or under Regulation (EC) No 396/2005.

EFSA will update this document, if needed, in line with relevant changes of the legislation and/or guidance documents and according to the experience gained in the peer-review of the assessment of pesticide active substances and in the assessment of MRLs. Therefore, applicants and Member States are advised to always consult the latest published version of this document available on EFSA's website.[13]

[11] Commission Implementing Regulation (EU) 2020/1740 applies with respect to the renewal of the approval of active substances for which the approval period ends on or after 27 March 2024. Implementing Regulation (EU) No 844/2012, and the previous version of the administrative guidance, continue to apply to active substances whose approval period on 27 March 2021 expires before 27 March 2024 or for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

[12] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

[13] https://www.efsa.europa.eu/en/applications/pesticides/regulationsandguidance

2. Guidance on the peer-review of pesticide active substances

This guidance applies to all applications submitted to the competent authority of a Member State as of 27 March 2021 and should be used for the preparation of applications intended to be submitted from that date onwards. Consequently, this guidance applies to all assessment reports concerning applications submitted as of 27 March 2021.

For applications submitted before 27 March 2021, the previous version of the guidance applies (EFSA, 2019a). Accordingly, the previous version of the guidance applies also to assessment reports concerning applications submitted before that date (regardless the submission date of those assessment reports).[14]

Note: The Member State appointed as "rapporteur" to carry out an initial risk assessment and to prepare a draft assessment report (DAR) or a renewal assessment report (RAR) is referred to as 'RMS'. In the case of renewals (and sometimes in the case of first approval), the initial risk assessment is carried-out with the contribution of a Member State which is appointed as Co-rapporteur (Co-RMS). When the guidance refers to 'assessment report', this should be understood as general terminology referring to either the DAR or RAR, as appropriate. The 'draft DAR/RAR' corresponds to the initial assessment report received by EFSA once the RMS risk assessment is completed. 'Revised DAR/RAR' is used to refer to the updated version of the assessment report, which includes the revised assessments carried out by the RMS throughout the peer-review process and in the case of the evaluation of confirmatory information, thereafter.

In the course of the evaluation process, application documents are made available to the public. Before publication, the applicant may request that certain information is treated as confidential in accordance with the combined reading of Article 63 of Regulation (EC) No 1107/2009 and EFSA's Practical Arrangements concerning transparency and confidentiality[15] (EFSA, 2021a) and EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009[16] (EFSA, 2021b). In this regard, specifically, 'sanitisation' means the process of masking or unmasking information and data in accordance with a confidentiality request by an applicant or with a confidentiality decision.

The applicant must ensure that terms and conditions asserted by any rightsholder of studies, information or data submitted to EFSA are fully satisfied. The applicant may consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing the appropriate licenses to provide studies, information or data to EFSA, taking into account the proactive disclosure requirements as detailed in Section 2.7. For publications already available to the public upon payment of fees (e.g. studies published in scientific journals) for which the applicant does not have or cannot obtain intellectual property rights for the purposes of the proactive public disclosure requirements, the applicant must provide (a) a copy of the relevant publications along with the relevant bibliographic references/ citations for scientific assessment purposes only, in the confidential version of its application and (b) these relevant bibliographic references/citations where these publications are available to the public in the non-confidential version of its application for public dissemination on the OpenEFSA portal.

The tools that applicants are expected to use in the preparation of the application and subsequent phases (e.g. EFSA's portal supporting pre-submission activities, database of study notifications, IUCLID software, IT tool for submitting comments on the assessment reports, as detailed below) are available on EFSA's website[17], together with a brief description of each tool, how to access it and dedicated user manual/guide where available. IUCLID is also accessible to Member States.

[14] Commission Implementing Regulation (EU) 2020/1740 applies with respect to the renewal of the approval of active substances for which the approval period ends on or after 27 March 2024. Implementing Regulation (EU) No 844/2012, and the previous version of the administrative guidance, continue to apply to active substances whose approval period on 27 March 2021 expires before 27 March 2024 or for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

[15] See Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality

[16] See Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009

[17] https://www.efsa.europa.eu/en/applications/toolkit

Pre-submission phase

Before submitting an application for approval, amendment of approval or renewal of approval of a pesticide active substance, a potential applicant should first register in EFSA's portal supporting pre-submission activities available on EFSA's website.[18] The registration is needed only if at least one of the pre-submission activities is carried out.

Upon request addressed to EFSA, potential applicants are given a reference i.e. pre-application identification 'ID' (EFSA-ID-YYYY-NNNNNN[19]), valid for a specific regulated product and a given regulated product area, to be used for any activity related to the pre-submission phase (see Sections 2.1, 2.4, 2.5), as introduced by the GFL Regulation:

- possibility to request general pre-submission advice from EFSA (optional, applicable to all types of applications);
- in case of intended applications for renewal: notification of intended studies (mandatory if new studies are planned), including information on how the various studies are to be carried out (proposed study design), consultation of third parties and renewal pre-submission advice from EFSA;
- notification of information related to studies commissioned or carried out (mandatory, applicable to all types of applications).

The pre-application ID may be also requested by a potential applicant on behalf of a group of potential applicants in relation to all the pre-submission activities, which are envisioned to support a future joint application.

The pre-application ID(s), if any, must be provided when submitting the application (see Section 2.6).[20]

The sections below provide an overview to applicants of the procedure governing the pre-submission phase. They are to be read in conjunction with binding Union legal acts, in particular with the GFL Regulation and with EFSA's Practical Arrangements on pre-submission phase and public consultations[21] (EFSA, 2021c), which provide comprehensive information and instructions on that matter.

2.1. General pre-submission advice in accordance with Article 32a(1) of the GFL Regulation

Potential applicants may request general pre-submission advice (GPSA) from EFSA at any time before submitting the corresponding envisaged application with respect to intended applications for approval or amendment of approval conditions, or for renewal of existing approvals.[22] The GPSA is optional for the potential applicant. Within the framework of GPSA, EFSA provides advice on the rules applicable to, and the content required for, an application prior to its submission.

In particular, the following items are considered outside of the scope of the GPSA:

- design of the studies to be submitted and questions related to hypotheses to be tested, unless the advice concerns guidance documents developed by EFSA in which study design is addressed;
- risk management questions;
- any aspects going beyond the information available in the legislation, rules, guidance documents or guidelines applicable to applications.

[18] https://www.efsa.europa.eu/en/applications/toolkit
[19] YYYY corresponds to the year and NNNNNN is a progressive number.
[20] In accordance with Article 5 of Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021c).
[21] See Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations
[22] This is without prejudice to the possibility for the potential applicant to request pre-submission advice from the RMS outside of the framework of Articles 32a(1) of the GFL Regulation (see Section 2.2).

EFSA recommends submitting the request for GPSA at least six months before the envisaged submission date of the application.

Requests for general pre-submission advice must be submitted to EFSA by filling in the dedicated general pre-submission advice online form ('GPSA form') available on EFSA's website.[23]

The GPSA is given by EFSA in close collaboration with the intended or designated RMS, and where applicable, the Co-RMS.[24] To this end:

- in case of intended applications for approval of new substances, the requester must provide the indication of the intended RMS in the GPSA form. If the intended RMS is not indicated, the GPSA will be provided by EFSA alone. The potential applicant is informed accordingly;
- in case of intended renewal applications, the requester must provide the indication of the designated RMS/co-RMS in the GPSA form. If the potential applicant fails to indicate the designated RMS/co-RMS, the request is rejected. The requester can submit a new request.

Upon receipt, the request for GPSA is transmitted to the intended/designated RMS (and co-RMS where applicable). All the exchanges will take place electronically in the tool supporting pre-submission activities available through EFSA's website.

Following an administrative check, EFSA informs the intended/designated RMS (and co-RMS) whether the request for GPSA is accepted and whether a reply will be provided in writing or in the context of a meeting. The intended/designated RMS (and co-RMS) is requested to confirm within 5 working days if they are willing to prepare the draft written advice or draft assessment in case of a meeting.

GPSA requests for which the reply is provided in writing

- In the event that the intended or designated RMS is willing to prepare the draft written advice: the intended/designated RMS (and co-RMS), prepares the draft written advice and sends it to EFSA for consultation within 15 working days from the confirmation that the request is accepted by EFSA (i.e. up to 5 working days at the latest for confirming willingness to prepare the draft advice + up to 10 working days for preparing the draft). Within 5 working days as of the date of receipt of the draft written advice, EFSA provides the intended/designated RMS (and co-RMS) with its comments on such draft and with a draft summary of the advice (to be later published);
- in the event that the intended/designated RMS is not willing to prepare the draft written advice: within 10 working days from receipt of a reply from the intended/designated RMS, EFSA prepares the draft written advice and related summary and shares them with the intended/designated RMS (and co-RMS) for possible comments. In case no comments are received within 5 working days, EFSA will provide the advice to the potential applicant, as previously communicated to the intended/designated RMS;
- within 20 working days as of the date of the acceptance of the request, EFSA provides the written advice and the related summary agreed by EFSA and the intended/designated RMS (and co-RMS) to the requester.[25] In case the intended/designated RMS (or co-RMS) disagrees with EFSA about one or more replies, the written advice and the summary will reflect both opinions;
- EFSA shares the written advice and the summary with the competent authorities of all Member States for information purposes.

GPSA requests for which the advice is provided in a meeting

- In the event that the intended/designated RMS is willing to prepare the preliminary assessment: the intended/designated RMS (and co-RMS) prepares its preliminary assessment of the questions to be addressed during the meeting, and sends it to EFSA within 15 working days

[23] https://www.efsa.europa.eu/en/applications/toolkit

[24] EFSA is committed to providing the most helpful support possible by way of general pre-submission advice in close cooperation with the relevant national competent authorities. However, in situations whereby the relevant national competent authorities do not consent to such collaboration, EFSA may not be held liable for any divergences between the general pre-submission advice provided by EFSA and that possibly provided separately by the relevant national competent authority.

[25] In this context, EFSA remains bound by the scope outlined in Article 7(1) and (2) of Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021c).

from the confirmation that the request is accepted by EFSA (i.e. up to 5 working days at the latest for confirming willingness to prepare the preliminary assessment + up to 10 working days for preparing the preliminary assessment); EFSA and the intended/designated RMS (and co-RMS) have 5 working days to exchange views before the meeting takes place;

- in the event that the intended/designated RMS is not willing to prepare the preliminary assessment: within 10 working days from receipt of a reply from the intended/designated RMS, EFSA prepares its preliminary assessment of the questions to be addressed during the meeting and shares it with the intended/designated RMS (and co-RMS). EFSA and the intended/designated RMS (and co-RMS) have 5 working days to exchange views before the meeting takes place;
- the meeting is organised within 20 working days as of the date of the acceptance of the request; both EFSA and the intended/designated RMS (and co-RMS) must attend;
- the advice is provided by EFSA, in collaboration with the intended/designated RMS (and co-RMS) during the meeting[26];
- after the meeting, EFSA provides the intended/designated RMS (and co-RMS) with a summary of the advice. In case the intended/designated RMS (or co-RMS) disagrees with EFSA about one or more replies provided to the potential applicant during the meeting, the summary will reflect both opinions. The summary is sent for information to the requester;
- EFSA shares the summary with the competent authorities of all Member States for information purposes.

The summary of the GPSA is kept by EFSA and made public together with the non-confidential version of the application dossier once the application is declared admissible. To this end, it is important that the RMS notifies EFSA as soon as the application is declared admissible.

For a comprehensive description of applicable procedures and provisions, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c, see in particular the section 'Special and exceptional provisions applicable to the area of plant protection products and maximum residue levels of pesticides').

2.2. Requests for pre-submission advice submitted to the RMS that are outside of the framework of Article 32a(1) of the GFL Regulation

Potential applicants may request pre-submission advice from the RMS/co-RMS at any time before submitting the corresponding application. RMS/co-RMS may provide advice in written form or via pre-submission meetings. The RMS may decide to consult EFSA where considered appropriate.

Pre-submission meetings can be organised by the RMS/co-RMS at any time before the submission of an application if required. The objective of these meetings is to establish a common understanding between the applicant, RMS and co-RMS regarding the dossier to be submitted. The discussion should be based on the document containing the new information to be submitted as prepared by the applicant. A full in-depth evaluation of new data by the RMS – or co-RMS - is not foreseen at this early stage. It should therefore be noted that the Member States' authorities cannot be definitive on what information may be required since this is ultimately dependent on the full evaluation and peer review of all available information.

In particular the following elements can be considered during the advice:

- clearly identify the reference specification in case of renewals, however it must be ensured that confidential information such as business and trade secrets will not be disclosed (in the case of multiple applicants and/or joint applications);

[26] In this context, EFSA remains bound by the scope outlined in Article 7(1) and (2) of Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021c).

- clearly identify the representative formulation/plant protection product(s) and the use(s) to be supported;
- clearly identify the specifications and test materials used in the new studies; If the new (proposed) representative formulation for the renewal is different to the former (reference) formulation, it should be demonstrated by the applicant that differences are minor for the different sections (ecotox, tox…) in case that data from the former (reference) formulation should also be used for the assessment of the new (proposed) formulation;
- identify the current classification of the active substance and any factors that may have an influence on classification;
- reach an understanding of the guidance and scientific and technical knowledge that will apply to the submission;
- draw attention to EFSA's guidance documents and/or pertinent scientific opinions, where relevant, and make them available;
- systematically consider the potential issues that may arise in the evaluation with respect to the criteria in Article 4 of Regulation (EC) No 1107/2009 (nevertheless discussion may only be preliminary based on the information given by the applicant at that time, as the decision on the applicability of the cut-off criteria may result from the complete evaluation of the dossier) and Annex II to Regulation (EC) No 1107/2009 including point 4 of Annex II (candidates for substitution);
- consider potential critical issues that may arise in the re-evaluation of the active substance for renewals in consequence of the new data provided and/or changes in the scientific and technical knowledge e.g. leading to changes in the previous evaluation of studies and the risk assessment based on those studies;
- take account of the availability of the full documentation supporting the approval.

It is highlighted that EFSA may be able to look into the scientific aspects that could be considered for the given case but cannot provide full consultancy to applicants – it should be recalled that the applicant bears full responsibility for demonstrating safety. In addition, in some cases, acceptability of certain approaches involves risk management decisions, so EFSA advice may not be possible.

The following standard disclaimer should be used by Member States in all pre-submission meetings or during written advice: '*This meeting/written advice is to assist the applicants in preparing their dossier. The advice given does not bind the Member States, EFSA in the subsequent peer review or the European Commission, and should not be seen to create any expectations on the part of the applicants concerned'*.

The following standard disclaimer should be used by Member States in all records and minutes of pre-submission meetings:

'*This is a record of pre-submission meeting held to assist the applicant in preparing their dossier. The advice given does not bind the Member States, EFSA in the subsequent peer review or the European Commission, and should not be seen to create any expectations on the part of the applicant concerned'*.

There are no legal restrictions to the number of pre-submission meetings or written advice. It is up to the applicant and RMS and Co-RMS to decide what is considered necessary for the respective active substance.

2.3. Requests for advice during the assessment phase originating from the RMS

The RMS may wish to discuss specific issues relevant for the active substance with EFSA and/or other Member States during the assessment phase. In particular, the RMS has the possibility and can request support and scientific advice from EFSA during the assessment phase in case complex or novel issues are encountered.

In fact, according to Article 7(5) of Regulation (EC) No 1107/2009, '*when assessing the application the rapporteur Member State may at any time consult the Authority'*.

EFSA is committed to provide support to the RMS at any time when assessing the application and before the peer review starts. EFSA may provide support to the RMS:

- via a written process (via email);
- via ad-hoc bilateral teleconference.

Issues that might be requested by the RMS for EFSA's support when assessing the application can include e.g. overall risk assessment approach, interpretation of the test guidelines, etc. Other requests might be considered on a case-by-case basis. EFSA may provide advice on requests to deviate from test guidelines in certain cases (e.g. in relation to ECHA/EFSA, 2018) Guidance document to add parameters in a study design with regards to the test guidelines).

It is essential that a preliminary assessment including explanation of the RMS position should be always provided by the RMS regarding all the available and relevant data in relation to the complex scientific issue presented, so that EFSA can provide an informed opinion/advice on the matter. Overall, EFSA's advice should be limited to specific questions on complex issues encountered during the assessment by the RMS and those questions should be clearly communicated to EFSA. In case of recurring complex questions, the issue might also be discussed in a peer review expert meeting.

In all cases, EFSA's advice to the RMS when assessing the application is provided without prejudice of the subsequent peer review process and is based on the information available at that moment.

2.4. Provisions applicable to intended renewal applications

2.4.1. Notification of intended studies for renewals

In accordance with Article 32c(1) of the GFL Regulation, if new studies are planned for the purpose of a renewal of approval, the potential applicant must submit a notification of the studies it intends to perform for that purpose, including information on how the various studies are to be carried out to ensure compliance with regulatory requirements (study design).[27] The notification of the intended studies for renewal must be carried out by the potential applicant in a dedicated section of EFSA's database of study notifications.[28] In particular, the potential applicant should submit a complete list of studies it intends to perform for the purpose of supporting an application for renewal, including information on how the various studies are to be carried out to ensure compliance with regulatory requirements. EFSA recommends that the design of the studies is accompanied by the detailed proposed study protocols.

The notification of intended studies for renewal is mandatory.[29]

EFSA recommends to notify the intended studies for renewal at least five months before the date of the intended commissioning of the studies in order to allow for the appropriate consultation to take place.

For a comprehensive description of applicable procedures and provisions, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c).

2.4.2. Public consultation on the intended studies for renewal

In accordance with Article 32c(1) of the GFL Regulation, upon notification to EFSA of the complete list of studies the applicant intends to perform for the purpose of the renewal, EFSA launches a public consultation on the intended studies for renewal, including on the proposed design of studies. The public

[27] The full list of information to be notified for each study is provided in Annex I to Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021c).
[28] https://www.efsa.europa.eu/en/applications/toolkit
[29] See also Article 3 of Commission Implementing Regulation (EU) 2020/1740.

consultation will be launched on a dedicated EFSA's webpage[30], after an administrative check of the information notified.

All comments received from third parties during the public consultation will be made public by EFSA without delay upon the closure of the public consultation.[31] The results of the consultation of third parties (i.e. how the comments have been taken into account) will be inserted in the summary of the renewal pre-submission advice (see Section 2.4.3).

For a comprehensive description of applicable procedures and provisions, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c).

2.4.3. Renewal pre-submission advice

In accordance with Article 32c(1) of the GFL Regulation, after the closure of the public consultation on the intended studies for renewal (see Section 2.4.2), EFSA reviews the comments received from third parties and provides renewal pre-submission advice (RPSA) to the potential applicant, taking into account those comments which are relevant for the risk assessment of the intended renewal. EFSA provides the potential applicant for renewal with its advice with the participation of the designated RMS and, where considered appropriate, the co-RMS.

To this end EFSA provides the information notified by the potential applicant and the comments received during the public consultation to the designated RMS (and co-RMS) and informs the latter whether it intends to reply in writing or in the context of a meeting. All the exchanges will take place in the tool supporting pre-submission activities available through EFSA's website.[32]

The designated RMS (and co-RMS) is requested to confirm within 5 working days if it is willing to prepare the draft written advice or draft assessment in case of a meeting.

RPSA for which the reply is provided in writing

- In the event that the RMS is willing to prepare the draft written advice: the RMS (and co-RMS) prepares the draft written advice on the basis of the information notified by the potential applicant and of the comments received during the public consultation, and sends it to EFSA for consultation within 20 working days (i.e. up to 5 working days at the latest to confirm willingness to prepare the draft advice + up to 15 working days for preparing the draft). Within 10 working days as of the date of receipt of the draft written advice, EFSA provides the RMS (and co-RMS) with its comments on such draft and with a draft summary of the advice (to be later published);
- in the event that the RMS is not willing to prepare the draft written advice: within 20 working days from receipt of a reply from the RMS, EFSA prepares the draft written advice and related summary and shares them with the RMS (and co-RMS) for possible comments. In case no comments are received within 10 working days, EFSA will provide the advice to the potential applicant, as previously communicated to the RMS (and co-RMS);
- Within 30 working days after the closure of the public consultation, the written advice and its summary, as agreed by EFSA and the RMS (and co-RMS), are provided to the potential applicant. In case the RMS (or co-RMS) disagrees with EFSA about one or more replies, the written advice will reflect both opinions;
- EFSA shares the written advice and the summary with the competent authorities of all Member States for information purposes.

RPSA for which the advice is provided in a meeting

- In the event that the RMS is willing to prepare the preliminary assessment: the RMS (and co-RMS) prepares its preliminary assessment of the issues to be addressed during the meeting on the basis of the information notified by the potential applicant and of the comments received

[30] https://www.efsa.europa.eu/en/applications/toolkit
[31] The public disclosure of the comments received, is done pursuant to Article 5(2), letter (g) of Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality (EFSA, 2021a).
[32] https://www.efsa.europa.eu/en/applications/toolkit

during the public consultation, and sends it to EFSA within 20 working days (i.e. up to 5 working days at the latest to confirm willingness to prepare the preliminary assessment + up to 15 working days for preparing the preliminary assessment); EFSA and the RMS (and co-RMS) have 9 working days to exchange views before the meeting takes place;

- in the event that the RMS is not willing to prepare the preliminary assessment: within 15 working days from receipt of a reply from the RMS, EFSA prepares its preliminary assessment of the questions to be addressed during the meeting and shares it with the RMS (and co-RMS); EFSA and the RMS (and co-RMS) have 9 working days to exchange views before the meeting takes place;
- the meeting is organised within 30 working days after the closure of the public consultation; both EFSA and the RMS (and co-RMS) must attend;
- the advice is provided by EFSA, in collaboration with the RMS (and co-RMS), during the meeting;
- after the meeting, EFSA provides the RMS (and co-RMS) with a summary of the advice. In case the RMS (or co-RMS) disagrees with EFSA about one or more replies provided to the potential applicant during the meeting, the summary will reflect both opinions. The summary is sent for information to the potential applicant;
- EFSA shares the summary with the competent authorities of all Member States for information purposes.

A summary of the RPSA is kept by EFSA and made public together with the non-confidential version of the application dossier, as soon as the application is declared admissible. To this end, it is important that the RMS notifies EFSA as soon as the application is declared admissible.

The RPSA summary of the advice will also include how the comments received during the public consultation have been taken into account by EFSA.[33]

For a comprehensive description of applicable procedures and provisions, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c, see in particular the section 'Special and exceptional provisions applicable to the area of plant protection products').

2.5. Notification of studies

In accordance with Article 32b of the GFL Regulation, potential applicants commissioning or carrying out studies as of 27 March 2021 to support an application for a pesticide active substance (approval, amendment of approval conditions or renewal of the approval) have the obligation to notify EFSA without delay of the following information[34] related to those studies:

- title and scope of the study;
- laboratory or testing facility carrying out the study;
- starting and planned completion dates of the study.

The same obligation applies to the laboratories and other testing facilities located in the EU[35] for studies commissioned by potential applicants and carried out by such laboratories and other testing facilities. Therefore, both potential applicants and laboratories/testing facilities have the obligation to notify information about all studies commissioned or carried out to support an application. Study notifications

[33] The public disclosure of the results of the public consultation is done pursuant to Article 6(1), letter (d) of Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality (EFSA, 2021a).

[34] The full list of information to be notified for each study is provided in Annex II to Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021c).

[35] The same obligation applies to laboratories and testing facilities located in third countries insofar as set out in relevant agreements and arrangements with those third countries, including as referred to in Article 49 of the GFL Regulation.

must be submitted in EFSA's database of study notifications available on EFSA's website[36] without delay before the starting date of the study. The database will assign a unique study identification 'ID' to each study notification (i.e. study ID: EFSA-YYYY-NNNNNNNN[37]).

For any study notification submitted after the starting date of the study, the applicant must provide justifications for the delay in the application dossier when submitting the application.

The study notification obligations apply to any additional studies provided after the submission of the application, either during the admissibility check of the application by the RMS or during the RMS risk assessment or EFSA peer-review, if such studies are commissioned or carried out as of 27 March 2021. Furthermore, in case the (renewal of) approval of an active substance is subject to the condition of the submission of further confirmatory information to Member States, the Commission and EFSA, studies necessary to meet that condition are likewise subject to the study notification obligations if such studies are commissioned or carried out as of 27 March 2021.

Applicants should be aware that non-compliance with the study notification obligations may result in the non-admissibility of the application or in delays in the RMS risk assessment process and EFSA peer review (see Sections 2.6.1, 2.6.2, 2.13).

Studies submitted to support either the approval or the renewal of the approval of an active substance are not subject to the obligations of study notifications if they were commissioned or carried out before 27 March 2021.

For a comprehensive description of applicable procedures and provisions, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c).

The RMS is responsible for checking the compliance with obligations of notifications of studies during the admissibility check. The RMS will not have direct access to EFSA's database of study notifications. EFSA will extract the relevant information from the database and share it with the RMS strictly on a need-to-know basis and for the period necessary to complete the assessment.

[36] https://www.efsa.europa.eu/en/applications/toolkit
[37] YYYY corresponds to the year and NNNNNNNN is a progressive number.

From submission of the application to adoption of EFSA's conclusion

From the submission of the application (see Section 2.6) to the launching of the commenting period on the draft assessment report (see Section 2.12), applications are handled by the EFSA Applications Desk Unit (APDESK), while the EFSA Pesticide Peer-review Unit (PREV) is taking over the procedure from the opening of the commenting period on the draft assessment report to the publication of EFSA's conclusion (see Section 2.13).

2.6. Preparation and submission of an application

In order to support an application, the applicant has to submit an application dossier, containing scientific information and studies. The dossier must be prepared using the IUCLID (International Uniform ChemicaL Information Database) software, which is a software application to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances and the standard data format agreed for pesticides.[38] Please refer to the instructions of the IUCLID user manual[39] for information on how to prepare and submit an application dossier.

Once prepared, the applicant must submit the dossier through the EFSA central submission system[40], indicating the intended RMS, or the designated RMS/co-RMS in case of renewals. Via IUCLID, the valid dossier[41] is automatically made available to the European Commission, the Member States (including the one receiving the application), and to EFSA, which will be notified accordingly.

The obligation to submit scientific information and studies using the IUCLID software also applies to any additional information requested after the submission of the application, either during the admissibility check of the application by the RMS or during the RMS risk assessment or EFSA peer-review. Furthermore, in case the (renewal of) approval of an active substance is subject to the condition of the submission of further confirmatory information to Member States, the Commission and EFSA, studies necessary to meet that condition are likewise subject to the obligation to use the IUCLID software for their submission.

2.6.1. Application for approval of a new active substance, or for amendment of approval conditions

In order to obtain approval of an active substance (i.e. an active substance that is not currently approved in the EU often referred to as a 'new active substance'), the applicant must submit an application dossier. The RMS (and where relevant co-rapporteur Member State(s)) carries out the initial risk assessment and prepares a draft assessment report (DAR), which EFSA peer-reviews. EFSA coordinates the peer review process in collaboration with all Member States. The same procedure applies to application for amendment of the conditions of approval.

Documentation

When submitting an application, the applicant must upload through the EFSA central submission system a **dossier**, prepared using the **IUCLID software**[42], including amongst others, elements listed in Regulation (EC) No 1107/2009[43]:

- for each of the data requirements: the full text of each test/study report, and a sanitised version if the full text version contains information on which the applicant submits a confidentiality request and a completed endpoint study record;
- completed endpoint study records and results of scientific peer-reviewed open literature, as well as the full text of the relevant literature studies;

[38] IUCLID must be used for applications submitted as of 27 March 2021. For more details on applicability, cf. footnote 11.
[39] https://www.efsa.europa.eu/en/applications/toolkit
[40] The central submission system will be available from March 2021 on EFSA's website.
[41] A dossier is considered valid (i.e. successfully submitted) once it has gone through and passed the automatic submission checks.
[42] Available at: https://iuclid6.echa.europa.eu/it/download
[43] See Article 8 of Regulation (EC) No 1107/2009.

- summaries for each endpoint and analysis where multiple studies are used to inform the evaluation;
- requests for confidentiality, using the relevant IUCLID functionality;
- non-confidential version of each attached document in the dossier for which confidentiality is requested;
- a proposal for classification in accordance with Regulation (EC) No 1272/2008[44];
- where relevant, an application for maximum residue levels (MRLs). The data needed for supporting the application should also be prepared using IUCLID and submitted through the central submission system at the same time of the dossier[45];
- all information needed to comply with obligations of study notifications[46] (see Section 2.5 and information provided below).

IUCLID provides for the possibility to insert directly in the system the endpoint study records of the studies according to OECD Harmonised Templates (OHTs).[47] IUCLID also has functionalities to flag information that according to the applicant should be treated as confidential, insert requests for confidentiality and generate automatically the **non-confidential version of the dossier** (meaning the dossier where confidential information is filtered and confidential documents are replaced by their non-confidential version, as provided by the applicant).

In accordance with Regulation (EC) No 1107/2009[48], applicants must also provide a summary dossier (SD) and its sanitised version (sanitised summary dossier, SSD). SD and SSD should be uploaded in IUCLID as attachments under 'Summary and evaluation'.[49]

Regarding the study notification obligations of Article 32b(2) and (3) of the GFL Regulation, when submitting an application, the applicant must provide in IUCLID the following information:

- **pre-application ID(s)** related to the active substance which is the subject matter of the submitted application provided to the applicant at pre-submission phase, in case pre-submission advice was requested and/or or new studies have been notified;
- **study ID** generated by EFSA's database of study notifications for each study submitted in the application.
- if necessary, **justifications** explaining the divergences between the information notified in accordance with Section 2.5 and the studies included in the application, linked, where applicable, to the study ID.

For a comprehensive description of the information to be provided when submitting applications to allow verification of compliance with study notifications obligations, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c).

Compliance with the obligations of study notifications laid down in Article 32b(2) and (3) of the GFL Regulation is verified by the RMS in the context of the admissibility check of the application.

The RMS is expected to consider the application as not admissible if during the admissibility check it concludes that:

---

[44] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

[45] For technical reasons, the MRL submission will have to be done before the dossier submission to allow the system to link the two items.

[46] In accordance with Article 32b of GFL Regulation and in line with Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021c).

[47] Where the nature of the information, documents or data is technically not compatible with OHT, semi structured data may be submitted.

[48] cf. Article 8 of Regulation (EC) No 1107/2009.

[49] Specifically, under Section 11 for the active substance and Section 13 for the plant protection product. In case of dossiers on microorganisms, the corresponding sections in IUCLID are Section 10 for the microbial active and Section 12 for the plant protection product.

- a submitted study was not previously notified in EFSA's database of study notifications or was notified after the starting date of the study (i.e. non-notification regulated by Article 32b(4) of the GFL Regulation) and the applicant has provided no valid justification; and/or
- a study previously notified in EFSA's database was not included in the application and the applicant has provided no valid justification (i.e. non-inclusion of a study regulated by Article 32b(5) of the GFL Regulation);
- a notification of a study was withdrawn and the applicant has provided no valid justification (Article 21(b)(iii) of EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c)).

The application may be re-submitted, provided that:

- the applicant notifies in the database the studies that were not previously notified; and/or
- the applicant submits all the studies which were previously notified in the database or, in case of unjustified withdrawal of a notification of a study, the data delivered by the relevant laboratory or testing facility even without having the study completed.

The admissibility check will commence six months after the re-submission of the application.

The table below illustrates the standard data format for the dossiers, the timing and the submission route of the documentation.

Table 1: Standard data format, timing and submission route of the documentation applicants should present for new active substances or for amendment of approval conditions

Documentation	Standard data format	Timing	Submission route
Dossier	IUCLID	At submission of the application	e-submission through EFSA central submission system
Summary Dossier	IUCLID		
Justification for any piece of information requested to be treated as confidential	IUCLID		
Non-confidential version of documents for which confidentiality is requested	IUCLID		
SSD	IUCLID		

At the reception of the notification of admissibility from the RMS, the application is displayed in the OpenEFSA portal.[50]

Upon admissibility of the application, EFSA makes available on the OpenEFSA portal a link to the non-confidential version of the dossiers in 'public' IUCLID, which is the version accessible by the public.[51] To

[50] https://open.efsa.europa.eu
[51] In accordance with Article 10 of Regulation (EC) No 1107/2009, as amended by the GFL Regulation.

this end, it is important that the RMS notifies EFSA[52] as soon as the application is declared admissible. The RMS should include in the notification the following information, retrievable in IUCLID:

- Dossier UUID[53]
- Dossier URL[54]
- European Reference number[55]
- Dossier subject/Substance name
- Pre-application ID(s)
- Purpose of application

In addition, when sending the notification, the RMS is expected to make available to EFSA the following documents: validation assistant report, confidentiality assessment report, notification of studies report. These documents can be automatically generated by IUCLID following the instructions provided in the IUCLID user manual.

The validation report can be exported from IUCLID in standardised Excel format. The confidentiality report and notification of studies report can be generated from IUCLID in Word or PDF format. It is also possible to make a request to EFSA for an extraction from the notification studies database in order to make a comparison.

The non-confidential version of the dossier and the SSD proactively disclosed on the public IUCLID and through the OpenEFSA portal upon admissibility will be republished at a later stage, should the RMS reject any of the confidentiality requests presented by the applicant (see Section 2.7).

Following the implementation of the confidentiality decision, the non-confidential version of the dossier will be subject to public consultation (see Sections 2.7 and 2.8).

[52] By sending an email to: apdesk.applications@efsa.europa.eu, Cc: pesticides.peerreview@efsa.europa.eu
[53] Universal Unique Identifier generated by IUCLID for each dossier submitted.
[54] Link to a specific dossier in IUCLID.
[55] Unique identifier to link all dossiers in the regulatory action (e.g. original dossier and all subsequent updates).

2.6.2. Application for renewal of approval of an active substance

Upon application, approved active substances are re-evaluated before their approval period ends (the renewal procedure) to determine if approval can be renewed, or not. For the renewal review of each active substance, applicants have to submit an application dossier, containing scientific information and studies using the IUCLID software. The RMS appointed to carry out an initial risk assessment, prepares a renewal assessment report (RAR), with the contribution of a co-RMS where so agreed. EFSA coordinates the peer review process in collaboration with all Member States.

A group of Member States may jointly assume the role of RMS, and in this case no co-RMS is appointed.[56]

Documentation

The application for the renewal of approval of an active substance, consisting of a renewal dossier, must be submitted no later than 3 years before the expiry of the approval.[57]

When submitting an application for the renewal of the approval of an active substance, the applicant must upload through the submission portal a **renewal dossier**, prepared using the **IUCLID** software[58], including, amongst others elements listed in Commission Implementing Regulation (EU) 2020/1740[59]:

- for each of the data requirements: the full text of each test/study report, and a sanitised version if the full text version contains information, for which the applicant requests confidentiality and a completed endpoint study record. For studies which were part of the approval dossier or subsequent renewal, all efforts should be made by the applicant to obtain access to and provide the full text of each test and study report;
- completed endpoint study records and results of scientific peer-reviewed open literature, as well as the full text of the relevant literature studies;
- summaries for each endpoint and analysis where multiple studies are used to inform the evaluation;
- requests for confidentiality, using the relevant IUCLID functionality;
- non-confidential version of each attached document in the dossier for which confidentiality is requested;
- where relevant, a proposal for classification in accordance with Regulation (EC) No 1272/2008;
- where relevant, an application for maximum residue levels. In this case, the data needed for supporting the application should also be prepared using IUCLID and submitted through the central submission system at the same time of the renewal dossier[60];
- all information needed to comply with obligations of study notification[61] (see Section 2.5 and information provided below).

IUCLID provides for the possibility to insert directly in the system the endpoint study records of the studies according to OECD Harmonised Templates (OHTs).[62] IUCLID also has functionalities to flag information that according to the applicant should be treated as confidential, insert requests for confidentiality and generate automatically the **non-confidential version of the renewal dossier**

[56] In accordance with Article 5(1) of Commission Implementing Regulation (EU) 2020/1740.
[57] In accordance with Article 5(1) of Commission Implementing Regulation (EU) 2020/1740.
[58] Available at: https://iuclid6.echa.europa.eu/it/download
[59] Full list of requirements is given in Article 6 of Commission Implementing Regulation (EU) 2020/1740.
[60] For technical reasons, the MRL submission will have to be done before the dossier submission to allow the system to link the two items.
[61] In accordance with Article 32b of GFL Regulation and in line with Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021c).
[62] Where the nature of the information, documents or data is technically not compatible with OHT, semi structured data may be submitted.

(meaning a version of the dossier where confidential information is filtered and confidential documents are replaced by their non-confidential version, as provided by the applicant). For a comprehensive description of the information to be provided when confidentiality is requested please refer to EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a).

Regarding the study notification obligations of Article 32b(2) and (3) of the GFL Regulation, when submitting an application, the applicant must provide in IUCLID the following information:

- **pre-application ID(s)** related to the specific active substance which is the subject matter of the submitted application provided to the applicant at pre-submission phase; and
- **study ID** generated by the database for each study submitted in the application.
- if necessary, **justifications** explaining the divergences between the information notified in accordance with Section 2.5 and the studies included in the application, linked, where applicable, to the study ID.

For a comprehensive description of the information to be provided when submitting applications to allow verification of compliance with study notification obligations, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c).

Compliance with the obligations of study notifications laid down in Article 32b(2) and (3)s of the GFL Regulation is verified by the RMS in the context of the admissibility check of the application.

The RMS is expected to consider the application as not admissible if during the admissibility check it concludes that:

- a submitted study was not previously notified in EFSA's database of study notifications or was notified after the starting date of the study (i.e. non-notification regulated by Article 32b(4) of the GFL Regulation) and the applicant has provided no valid justification; and/or
- a study previously notified in EFSA's database was not included in the application and the applicant has provided no valid justification (i.e. non-inclusion of a study regulated by Article 32b(5) of the GFL Regulation);
- a notification of a study was withdrawn and the applicant has provided no valid justification (Article 21(b)(iii) of EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c)).

The application may be re-submitted, provided that:

- the applicant notifies in the database the studies that were not previously notified; and/or
- the applicant submits all the studies which were previously notified in the database or, in case of unjustified withdrawal of a notification of a study, the data delivered by the relevant laboratory or testing facility even without having the study completed.

The admissibility check will commence six months after the re-submission of the application.

If the six-month period following the notification of the relevant studies and/or submission of studies ends later than three years before the expiry of the approval of the active substance, the resubmitted application for renewal will be considered inadmissible.[63]

The table below illustrates the standard data format required for the renewal dossiers, the timing and the submission route of the documentation.

Table 2: Standard data format, timing and submission route of the documentation applicants should present for renewal of the approval

[63] In accordance with Article 8 of Commission Implementing Regulation (EU) 2020/1740.

Documentation	Standard data format	Timing	Submission route
Renewal dossier	IUCLID	At submission of the application	e-submission through EFSA central submission system
Justification for any piece of information requested to be treated as confidential	IUCLID		
Non-confidential version of documents for which confidentiality is requested	IUCLID		

At the reception of the notification of admissibility from the RMS, the application is displayed in the OpenEFSA portal.[64]

Upon admissibility, EFSA makes available on the OpenEFSA portal a link to the non-confidential version of the dossiers in 'public' IUCLID, which is the version accessible by the public.[65] To this end, it is important that the RMS notifies EFSA[66] as soon as the application is declared admissible. The RMS should include in the notification the following information, retrievable in IUCLID:

- Dossier UUID[67]
- Dossier URL[68]
- European Reference number[69]
- Dossier subject/Substance name
- Pre-application ID(s)
- Purpose of application

In addition, when sending the notification, the RMS is expected to make available to EFSA the following documents: validation assistant report, notification of studies report. These documents can be automatically generated by IUCLID following the instructions provided in the IUCLID user manual.

The validation report can be exported from IUCLID in standardised Excel format. The notification of studies report can be generated from IUCLID in Word or PDF format. It is also possible to make a request to EFSA for an extraction from the notification studies database in order to make a comparison.

The non-confidential version of the renewal dossier proactively disclosed on the public IUCLID and through OpenEFSA portal upon admissibility may be republished at a later stage, should EFSA reject any of the confidentiality requests presented by the applicant (see Section 2.7).

Following the implementation of the confidentiality decision, the non-confidential version of the renewal dossier will be subject to public consultation (see Sections 2.7 and 2.8).

[64] https://open.efsa.europa.eu
[65] In accordance with Article 16 of Regulation (EC) No 1107/2009, as amended by the GFL Regulation.
[66] By sending an email to: apdesk.applications@efsa.europa.eu, Cc: pesticides.peerreview@efsa.europa.eu
[67] Universal Unique Identifier generated by IUCLID for each dossier submitted.
[68] Link to a specific dossier in IUCLID.
[69] Unique identifier to link all dossiers in the regulatory action (e.g. original dossier and all subsequent updates).

2.7. Transparency and confidentiality requirements

This section aims at giving an overview to applicants on the procedure governing transparency requirements and confidentiality requests, in accordance with the relevant provisions of the GFL Regulation and Article 63 of Regulation (EC) No 1107/2009, as amended by the Transparency Regulation. It is to be read in conjunction with Regulation (EC) No 1049/2001[70], Regulation (EC) No 1367/2006[71], as well as with:

- EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009 (EFSA, 2021b);
- EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a)

The Practical Arrangements, available on EFSA's website, provide a comprehensive description of the applicable procedures and provisions.

It is important to note that under Regulation (EC) No 1107/2009, as amended by the Transparency Regulation:

- Confidentiality requests pertaining to dossiers and updated dossiers submitted as part of an application for the **approval of a new active substance**[72] **or the amendment to the conditions of approval** of an active substance **are assessed by the RMS, in consultation with EFSA**. In case one or more requests for confidentiality are rejected pursuant to RMS' confidentiality decision, the applicant is responsible to implement the confidentiality decision on the dossier by updating the information in IUCLID accordingly.
- Confidentiality requests on the **DAR, updated DAR**[73], on the peer review report and EFSA's conclusions **are processed by EFSA**. In case one or more requests for confidentiality are rejected pursuant to EFSA's confidentiality decision, EFSA will implement the confidentiality decision on the DAR, updated DAR, on the peer review report and EFSA's conclusions.
- Confidentiality requests pertaining to renewal dossiers and updated renewal dossiers submitted as part of applications for the **renewal** of the approval of an active substance[74] **are assessed by EFSA**. In case one or more requests for confidentiality are rejected pursuant to EFSA's confidentiality decision, the applicant is responsible to implement the confidentiality decision on the renewal dossier by updating the information in IUCLID accordingly.
- Confidentiality requests on the **RAR and updated RAR**[75], on the peer review report and EFSA's conclusions **are processed by EFSA**. In case one or more requests for confidentiality are rejected pursuant to EFSA's confidentiality decision, EFSA will implement its confidentiality decision on the RAR, updated RAR, on the peer review report and EFSA's conclusions.

To ensure consistency of those assessments by the RMS and EFSA, in the context of applications as part of the processes for the approval of an active substance and the renewal of an approval, EFSA has laid down Practical Arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009 (EFSA, 2021b), applicable when analysing confidentiality requests presented by applicants for their application.

Please note that when the approval (or renewal of approval) of an active substance is subject to the condition of the submission of further confirmatory information to Member States, the European

[70] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents. OJ L 145, 31.5.2001, p. 43–48.
[71] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies. OJ L 264, 25.9.2006, p. 13–19.
[72] or in the context of addressing confirmatory information, if any, following the approval of an active substance.
[73] including updates carried out in the context of the assessment of confirmatory information, if any, prepared following the approval of an active substance.
[74] or in the context of addressing confirmatory information, if any, following the renewal of approval of an active substance.
[75] including updates carried out in the context of the assessment of confirmatory information, if any, prepared following the renewal of approval of an active substance.

Commission and EFSA, the confidentiality requirements also apply to information provided to meet that condition.

2.7.1. Transparency requirements applicable to information shared by applicants with EFSA

The GFL Regulation as amended by the Transparency Regulation introduced a general principle of proactive disclosure and transparency of information, studies and data submitted to EFSA for scientific evaluation. In light of this principle, and of the related provisions, EFSA must proactively disseminate all information shared by applicants for the purposes of EFSA's scientific evaluation of regulated products, including the information submitted during the assessment process as well as confirmatory information. Specifically, EFSA is to make publicly available[76] *inter alia* the following information[77]:

- all its scientific outputs;
- scientific data, studies and other information supporting applications, including additional information required by the RMS or EFSA during the assessment process for the applicant to complement the dossier initially submitted to prove compliance of the active substance with Regulation (EC) No 1107/2009, as well as other scientific data and information supporting requests from the European Commission and the Member States for a scientific output;
- the information on which its scientific outputs are based;
- a summary of the advice provided to potential applicants at pre-submission phase.

By derogation from the general principle of proactive disclosure and transparency, EFSA, or the RMS depending on the procedure as detailed above, may grant confidential status to certain elements of applications dossiers, provided applicants submit a verifiable justification, and EFSA/the RMS accepts the confidentiality request. For this purpose, and for each document for which confidentiality is requested, applicants are required to provide:

- **a request to treat certain item(s) as confidential**, specifying: the confidentiality ground(s) and conditions, justification, excerpt of the text, location in the file. These requests should be inserted in IUCLID at the time of submission of the information. Multiple requests can be submitted per file, but only with regard to the specific items listed in Article 63 of Regulation (EC) No 1107/2009 (see Section 2.7.3);
- **a version of the concerned document with all information visible and no blackening applied**. In this version, all information claimed to be confidential by the applicant should be boxed or earmarked (confidential version, not for public disclosure);
- **a non-confidential version with all elements claimed to be confidential blackened** (public version). This version will be made publicly available in the public IUCLID and through the OpenEFSA portal as soon as the application is declared admissible. This non-confidential version provided by the applicant and made publicly available will be replaced by an updated version pursuant to EFSA's or the RMS' confidentiality decision, in case one or more confidentiality requests are rejected. Applicants should note that the 'public version' should have all the names and addresses of individuals involved in testing on vertebrate animals or in obtaining toxicological information blackened as these elements must not be disclosed. Furthermore, the public version should also have all the personal data the applicants consider should not be disclosed pursuant to its confidentiality requests, equally blackened. For more information, see Section 2.7.3 and EFSA's Practical Arrangements.[78]

[76] The proactive disclosure of the above information does not imply permission or licence for their re-use, reproduction, or exploitation in breach of the relevant existing rules concerning intellectual property rights or data exclusivity. EFSA cannot be held liable or responsible for any use of the disclosed data by third parties in breach of any existing intellectual property rights.

[77] For an exhaustive list of the types of information, documents or data which is made proactively available, please refer to Articles 5 and 6 of Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality (EFSA, 2021a).

[78] For approval of new active substances, please refer to Article 12 of EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009. For renewals, please refer to Article 4(5) of EFSA's Practical Arrangement concerning transparency and confidentiality.

Please note that when applicants submit additional information requested by the RMS or EFSA during the assessment of an application or when the approval (or renewal of approval) of an active substance is subject to the condition of the submission of further confirmatory information to Member States, the European Commission and EFSA, the above transparency requirements also apply to information provided to meet those conditions.

2.7.2. How to submit a confidentiality request

For requests pertaining to information provided in the dossiers, applicants are required to submit confidentiality requests in IUCLID, using the dedicated functionality by providing reasoning supporting each request and addressing the requirements set out in EFSA's Practical Arrangements.[79]

It is fundamental that applicants submit all relevant confidentiality requests at the time of submission of the related piece of information (e.g. dossiers, renewal dossiers, information submitted following a request for additional information, etc.).

For requests pertaining to the assessment reports, applicants should use the justification forms provided in Appendix B –.

After submission, applicants may not modify confidentiality requests anymore, unless requested to do so by EFSA/the RMS.

If EFSA/the RMS requests the applicant to provide clarifications on the information initially provided to justify a confidentiality request, and the applicant does not react by the given timeline, the confidentiality request will be rejected.

2.7.3. Parts of the application or information for which a confidentiality request can be submitted

Applicants may submit confidentiality requests only regarding the following items of the application or submissions, as per Article 63 of Regulation (EC) No 1107/2009 and EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a):

- the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety[80];
- commercial links between a producer or importer and the applicant or the authorisation holder, where applicable[81];
- commercial information revealing sourcing, market shares or business strategy of the applicant[82];
- quantitative composition of the subject matter of the request, except for information which is relevant for the assessment of safety[83];
- the specification of impurity of the active substance and the related methods of analysis for impurities in the active substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant and the related methods of analysis for such impurities[84];

[79] For approval of new active substances, please refer to Articles 5 and 6 of Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009 (EFSA, 2021b). For renewals, please refer to Articles 9 and 10 of Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality (EFSA, 2021a).
[80] Article 63(2)(a) of Regulation (EC) No 1107/2009 (making reference to Article 39 of the GFL Regulation).
[81] Article 63(2)(a) of Regulation (EC) No 1107/2009 (making reference to Article 39 of the GFL Regulation).
[82] Article 63(2)(a) of Regulation (EC) No 1107/2009 (making reference to Article 39 of the GFL Regulation).
[83] Article 63(2)(a) of Regulation (EC) No 1107/2009 (making reference to Article 39 of the GFL Regulation).
[84] Article 63(2)(b) of Regulation (EC) No 1107/2009.

- results of production batches of the active substance including impurities[85];
- information on the complete composition of a plant protection product.[86]

Personal data are processed in accordance with Regulation (EU) 2016/679[87], applicable to RMS, and Regulation (EU) 2018/1725[88], applicable to Union Institutions, bodies and agencies. The following personal data must be made by law proactively available by EFSA:

a. the name and address of the applicant;

b. the names of authors of published or publicly available studies supporting the application;

c. the names of all participants and observers in meetings of the Scientific Committee and the Scientific Panels, their working groups and any other ad hoc group meeting on the application.

In contrast, personal data (names and addresses) of individuals involved in testing on vertebrate animals or in obtaining toxicological information must not be made publicly available by EFSA.[89]

2.7.4. Processing of confidentiality requests

The RMS/EFSA, depending on the applicable procedure, will assess each confidentiality request, by performing an individual examination of the information claimed as being confidential by the applicant and of the relevant justification provided.

Confidentiality requests are processed by EFSA and RMS in accordance with EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a) for renewal applications, or in accordance with EFSA's Practical Arrangements on confidentiality pursuant to Articles 7 and 16 of Regulation (EC) No 1107/2009 for new active substances (EFSA, 2021b), as well as with Regulation (EC) No 1367/2006 and Regulation (EC) No 1049/2001, insofar as applicable.

The notification of the confidentiality decision or the decision itself will also inform the applicant of its right to ask for a review of its confidentiality decision (confirmatory application).[90]

2.7.5. Possibility of commenting on, or challenging, a negative decision on a confidentiality request

Applicants have several opportunities to participate in the decision-making process regarding confidentiality requests made in respect to their dossiers and to put forward their views and observations.

Applicants have the opportunity to comment draft decisions on their confidentiality requests and challenge the decisions, once adopted:

a. **prior to the adoption of a decision** rejecting the applicant's confidentiality request in part or in full, by being consulted on the draft decision;

b. **after the adoption of a confidentiality decision**, by making use of the possibility of submitting a confirmatory application;

[85] Article 63(2)(c) of Regulation (EC) No 1107/2009.
[86] Article 63(2)(d) of Regulation (EC) No 1107/2009.
[87] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). OJ L 119, 4.5.2016, p. 1–88.
[88] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98.
[89] Article 39(e)(2) of the GFL Regulation.
[90] In accordance with Article 39b(2) of the GFL Regulation.

c. **after the adoption of a decision on a confirmatory application**, by having the possibility of bringing an action for annulment against the decision on the confirmatory application pursuant to Article 263 of the Treaty on the Functioning of the European Union.[91]

A comprehensive description of the applicable procedures and provisions is available in EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a) and EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009 (EFSA, 2021b).

2.7.6. Implementation of RMS's and EFSA's confidentiality decision

For each application document and any information and data submitted as part of the dossier, renewal dossier or in reply to a request for additional information, the RMS or EFSA, must implement their respective confidentiality decisions without delay. As a temporary solution pending the adaptation of the available software package, EFSA and the RMS must ensure that the applicant implements their confidentiality decisions.

EFSA implements its confidentiality decisions on the assessment reports, on its conclusions and peer-review reports.

2.7.7. Implications of the award of confidential status to certain information

Information for which RMS's or EFSA's decision on confidentiality is still pending or for which confidential status has been granted will not be made public. EFSA makes such information available to the European Commission and the Member States in the IUCLID platform for the purpose of carrying out the risk assessment, or participating to the peer review process.

All professionals having access to information for which decision on confidentiality is still pending or for which confidential status has been granted are subject to the obligation of professional secrecy and bound to not disclose information for which confidential status has been granted. These obligations continue to apply even after their duties have ceased.

2.7.8. Proactive disclosure of information contained in the application

During the life-cycle of the application, EFSA will proactively disclose information contained in the application dossier. Specifically for applications for the approval of an active substance or the amendment to the conditions of approval of an active substance:

- The non-confidential version of the dossier provided by the applicant as well as the non confidential version of the summary dossier are published as soon as after the application is declared admissible;
- If confidentiality requests are rejected, an updated non-confidential version of the dossier is published upon implementation of the RMS's confidentiality decision;
- During the RMS's risk assessment, a non-confidential version of additional information provided at the RMS's request is published as soon as received;
- If confidentiality requests presented on the additional information are rejected, the non-confidential version of the additional information is published after implementation of RMS's confidentiality decision;
- During the EFSA's peer-review, a non-confidential version of additional information provided at EFSA's request is published as soon as received;
- If confidentiality requests presented on the additional information are rejected, the updated non-confidential version of the information is published after implementation of the RMS's confidentiality decision, once EFSA's conclusion is adopted.

[91] Consolidated version of the Treaty on the Functioning of the European Union. OJ C 326, 26.10.2012, p. 47–390.

For applications for the renewal of the approval of an active substance:

- The non-confidential version of the renewal dossier is published as soon as the application is declared admissible;
- If confidentiality requests are rejected after admissibility, an updated non-confidential version of the renewal dossier is published upon implementation of EFSA's confidentiality decision;
- During the RMS's risk assessment, a non-confidential version of additional information provided at the RMS's request is published as soon as received;
- If confidentiality requests presented on the additional information are rejected, the non-confidential version of the updated additional information is published after implementation of EFSA's confidentiality decision, at publication of the sanitised draft RAR;
- During the EFSA's peer-review, a non-confidential version of additional information provided at EFSA's request is published as soon as received;
- If confidentiality requests presented on the additional information are rejected, the updated non-confidential version of the information is published after implementation of EFSA's confidentiality decision, once EFSA's conclusion is adopted.

2.8. Public consultation on information contained in the application

In accordance with Article 32c(2) of the GFL Regulation, in order to ensure that the RMS and EFSA have access to all relevant scientific data and studies available on an active substance subject to an application, EFSA consults stakeholders and the public ('consultation of third parties') on the scientific data, studies and other information part of, or supporting, the submitted application to identify whether other relevant scientific data or studies are available.

Upon publication by EFSA of the non-confidential version of the application dossier, and following the implementation of the relevant confidentiality decision (see Section 2.7), EFSA will launch a public consultation on its website. The consultation on the application for new active substances and amendment of approval conditions lasts 3 calendar weeks[92], the one on renewal applications lasts 60 days.[93]

All comments received from third parties will be made public by EFSA upon the closure of the consultation of third parties and will be brought to the attention of the RMS.[94] Relevant comments should be considered by the RMS during the risk assessment and preparation of the assessment report. The assessment report should clearly report in an annex how the comments received have been taken into account.

For a comprehensive description of applicable procedures and provisions, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c).

2.9. Preparation and submission of the assessment report by the RMS

A 'report generator' is available in IUCLID and the RMS can take advantage of this functionality to prepare parts of the assessment report.

Editorial check

As a general good working practice, the RMS should consider sending the assessment report to the applicant and the co-RMS for performing an editorial check before its submission to EFSA for peer review. A slot of 2 to 4 weeks is considered sufficient for this task. The scope of the commenting should be clearly defined to the applicant, also indicating that no additional information can be accepted. The

[92] In accordance with Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021c).
[93] In accordance with Article 10 of Commission Implementing Regulation (EU) 2020/1740.
[94] The public disclosure of the comments received during the public consultation is done pursuant to Article 5(2), letter (g) of Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality (EFSA, 2021a).

RMS should also inform the applicant whether or not the RMS intends to provide a response to the comments received.

The applicant should note that new or additional information can only be submitted if it had been formally requested by the RMS during the preparation of the assessment report.

Submission of assessment report

The RMS must make available to EFSA the assessment report at the latest 12 months[95] after admissibility of the dossier in case of application for approval or amendment of approval conditions, or 13 months after submission of the application for renewal.[96]

To allow full alignment of the EFSA peer review and ECHA classification processes, an assessment report prepared according to Regulation (EC) No 1107/2009 and a proposal for Harmonised Classification and Labelling (CLH Report) according to Article 37(1) of Regulation (EC) No 1272/2008 should be prepared by the RMS, where relevant, using the joint DAR/RAR/CLH report template (SANCO/12592/2012, latest revision) and submitted to both ECHA and EFSA.

In case of renewals, at the latest at the time of submission of the draft renewal assessment report the RMS must submit a proposal to ECHA[97] to obtain an opinion on a harmonised classification of the active substance at least for the hazard classes defined in Article 11(9) of Commission Implementing Regulation (EU) 2020/1740, or to confirm the existing classification, where applicable, or for re-classification of the active substance in accordance with the criteria of Regulation (EC) No 1272/2008.

Where the RMS considers that there is no need to change the existing classification, it should duly justify[98] why the existing classification/RAC opinion remains valid.[99] Member States should keep both EFSA and ECHA informed on the progress and planned submission dates of the assessment report and corresponding CLH report. In all cases the RMS should notify ECHA as soon as possible (preferably already at the stage of the pre-submission meeting/completeness check) with a notification - and proposal - in the ECHA 'Registry of intention' and inform also EFSA in order to permit planning and coordination of the upcoming activities by both EFSA and ECHA.

- For the RMS's consideration:

EFSA will make available a folder in its document management system that can be used for exchanges of files with the co-RMS during the preparation of the assessment report (see Section 3.14 for consideration about the role of the RMS vs the role of the co-RMS).

Once the assessment report is finalised, the RMS should upload the final version of all volumes in PDF format to the dedicated space in the document management system.

The RMS is invited to submit any supporting Excel files together with the assessment report.

In cases where the applicant has also submitted via IUCLID an MRL application, the assessment report should contain an assessment of the MRL(s) proposed. The MRL(s) for the representative use(s) are part of the assessment by default (see also Section 3.13).

As soon as the full set of documents is uploaded, the RMS should notify EFSA[100] that the submission is complete.

The PDF version of the assessment report is considered as the reference one and will be used for all next steps of the procedure. The assessment report in Word format may also be provided in addition, however this is not subject to any check.

[95] In accordance with Article 11(1) of Regulation (EC) No 1107/2009. When the RMS needs additional information, the 12-month period can be extended for a maximum of 6 months in accordance with Article 11(3) of Regulation (EC) No 1107/2009.
[96] In accordance with Article 11 of Commission Implementing Regulation (EU) 2020/1740.
[97] In accordance with Article 37(1) of Regulation (EC) No 1272/2008.
[98] The RMS is expected to provide solid argumentation taking into account all available relevant scientific data and evidence why a classification is not changing.
[99] In accordance with Article 11(9) of Commission Implementing Regulation (EU) 2020/1740.
[100] Notification should be sent via email to both apdesk.applications@efsa.europa.eu and pesticides.peerreview@efsa.europa.eu

For the naming of the files, the RMS is recommended to follow the naming convention given in European Commission, 2013a. Some examples are given below in case of a RAR:

Active substance_RAR_01_CLH_Volume_1_yyyy-mm-dd

Active substance_RAR_nn_Volume_3CP_Product_B-1_yyyy-mm-dd

In case of appendices or multiple Volumes 3 or 4, the use of an incremental numbering is recommended in order to make clear the final number of volumes composing the assessment report:

Active substance_RAR_nn_Volume_4_Applicant1_yyyy-mm-dd

Active substance_RAR_nn+1_Volume_4_Applicant2_yyyy-mm-dd

The assessment report will be distributed to the applicant(s) and Member States in PDF format, therefore the RMS needs to ensure the highest quality of this version. Before submitting the assessment report, the RMS is invited to check in particular the following:

- volumes should not be saved in track changes mode. All volumes should be in their final version when uploaded, without comments and revisions remaining;
- page numbers should be included. It is important to check that they are not missing from a volume or from a part of it;
- bookmark errors or reference source errors should not appear in the text. This error is displayed after the conversion of documents from MS Word to PDF. The RMS is advised to always check the PDF version, once generated;
- files should not be inserted in the main text as embedded files, since it is not possible to open these files from the PDF version (which is the one distributed and published for the consultation). Instead, they should be included in the respective volume, e.g. as full text in an appendix. Alternatively, they can be submitted as separate files;
- it is recommended that Excel files are provided separately as additional files.[101] Other documents (e.g. PDF documents) may be submitted as separate annexes. Alternatively, they can be included in the volume, e.g. as full text in an appendix;
- highlighting should be limited to updates introduced in the RAR compared to the previous version, and its use should be clarified at the beginning of the relevant volume in the versioning table.

2.10. Completeness check of the assessment report

On receipt, EFSA checks the assessment report to verify that it contains the necessary information, according to the Completeness checklist for assessment reports provided in Appendix A – to this guidance and taking into account the recommendations provided in Chapter 3. EFSA contacts the RMS in case the assessment report is considered incomplete or if it requires amendments. Issues raised during completeness check can be related to:

- the correct format of the DAR/RAR;
- incomplete information on the assessment of MRL(s), when needed;
- Article 4(7), negligible exposure assessment;
- presentation of endocrine disruptor (ED) assessment;
- re-assessment of old studies in the RAR, which should be robust and transparently presented;
- presentation of the studies, including presentation of results in tabular format;

[101] For the naming of appendixes (e.g. Excel files), it is recommended to follow the naming convention described above in the paragraph, without adding the incremental number: Active substance_RAR_Title of the appendix_yyyy-mm-dd. For example: Active substance_RAR_Appendix E_yyyy-mm-dd.

- presentation of the results of the public consultation on the submitted application in an annex which should clearly report how comments have been considered by the RMS.

EFSA may consider that the peer review should start only when the assessment report is satisfying the requirements listed in the checklist (Appendix A –).

- For RMS's consideration:

The checklist provided in Appendix A – is a useful reference during the preparation of the assessment report. Read in conjunction with Chapter 3 of this guidance, the completeness checklist gives indications on how data need to be presented in the assessment report and how the information will be checked by EFSA when the assessment report is received.

The RMS is strongly recommended to use the completeness checklist when preparing the assessment report and submit the checklist, duly filled in, together with the assessment report.

2.11. Procedural steps from the dispatch of the assessment report to the launching of the commenting period

2.11.1. Procedure for the approval of a new active substance and amendment of approval conditions

Dispatch of the draft DAR

In accordance with Article 12 of Regulation (EC) No 1107/2009, EFSA provides the applicant and the Member States with the draft DAR for the active substance under evaluation and notifies them of the dispatch of the draft DAR. The version of the DAR made available at this stage following EFSA's completeness check is to be used for the next steps of the procedure.

At this stage, the applicant has the possibility to submit confidentiality requests for certain information in the draft DAR originating from its application, pursuant to Article 12 of Regulation (EC) No 1107/2009.

The confidentiality requests should be made exclusively related to the set of files made available by EFSA. The sanitised documents must be submitted in a format that allows users to search for specific words within the document (i.e. searchable PDF document).

Confidential information should be precisely identified as such and the request for its removal duly justified using the template provided in Appendix B –. Applicants should fill in the justification form indicating each sanitisation individually.

The sanitised documents and the respective justification form including all requests for confidentiality must be provided by the applicant within two weeks of the date of receipt of EFSA's communication ("call for removal of confidential information"). In the communication to the applicant, the deadline for providing the sanitised documents and related justification form will be clearly set out.

EFSA assesses each confidentiality request, following the principles described under Section 2.7.

Once the confidentiality decision-making process is concluded, the sanitised draft DAR is published on the OpenEFSA portal for the public consultation[102] (see Section 2.12).

Updated Dossier

In the context of the risk assessment and preparation of the draft DAR, the RMS may ask the applicant to provide additional information. This additional information must be submitted in the form of an updated dossier in IUCLID, following the instructions of the IUCLID user manual. In this way, the additional information is automatically made available to EFSA, the European Commission and Member States.

[102] In accordance with Article 12(1) of Regulation (EC) No 1107/2009.

It is important to note that if new studies are submitted in the updated dossier, the provisions of the GFL Regulation on the notification of studies apply, if such studies are commissioned or carried out as of 27 March 2021 (see Section 2.5).

Confidentiality requests presented by applicants within the updated dossier following request for additional information are assessed by the RMS in accordance with EFSA's Practical Arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009 (EFSA, 2021b) as described in Section 2.7. The non-confidential version of the updated dossier is proactively disclosed by EFSA on the public IUCLID and retrievable through the OpenEFSA portal.

The updated dossier is not subject to public consultation.

2.11.2. Procedure for the renewal of an active substance

Dispatch of the draft RAR

In accordance with Regulation (EC) No 1107/2009 and Commission Implementing Regulation (EU) 2020/1740, EFSA provides the applicant and the Member States with the draft RAR for the active substance under evaluation and notifies them of the dispatch of the draft RAR. The version of the draft RAR made available at this stage following EFSA's completeness check is to be used for the next steps of the procedure.

At this stage, the applicant has the possibility to submit confidentiality requests to EFSA for certain information in the draft RAR originating from its application, pursuant to Commission Implementing Regulation (EU) 2020/1740.

The confidentiality requests should be made exclusively related to the set of files made available by EFSA. The sanitised documents must be submitted in a format that allows users to search for specific words within the document (i.e. searchable PDF document).

Confidential information should be precisely identified as such and the request for its removal duly justified using the template provided in Appendix B –. Applicants should fill in the justification form indicating each sanitisation individually and referring to the electronic page number where the confidential information is given.

The sanitised documents and the respective justification form including all requests for confidentiality must be provided by the applicant within two weeks of the date of receipt of EFSA's communication ('call for removal of confidential information'). In the communication to the applicant the deadline for providing the sanitised documents and the related justification form is clearly set out.

EFSA assesses each confidentiality request, in accordance with Commission Implementing Regulation (EU) 2020/1740.

Once the confidentiality decision-making process is concluded, the sanitised draft RAR is published on the OpenEFSA portal for the public consultation[103] (see Section 2.12).

Updated renewal dossier

In the context of the risk assessment and preparation of the draft RAR, the RMS may ask the applicant to provide additional information. This additional information must be submitted in the form of an updated renewal dossier in IUCLID, following the instructions of the IUCLID user manual.[104] In this way, the additional information is automatically made available to EFSA, the European Commission and Member States.

It is important to note that if new studies are submitted in the updated renewal dossier, the provisions of the GFL Regulation on the notification of studies apply, if such studies are commissioned or carried out as of 27 March 2021 (see Section 2.5).

[103] In accordance with Article 12(2) of Commission Implementing Regulation (EU) 2020/1740.
[104] https://www.efsa.europa.eu/en/applications/toolkit

Confidentiality requests presented by applicants within the updated renewal dossier following request for additional information are assessed by EFSA in accordance with EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a) as described in Section 2.7. The non-confidential version of the updated renewal dossier is published on the public IUCLID and retrievable through the OpenEFSA portal at the same time as the sanitised RAR.[105]

The updated renewal dossier is not subject to public consultation.

2.12. Commenting period

Applicants, Member States and the public are invited to submit comments on the draft assessment report produced by the RMS. The date on which a consultation is planned is published in advance in EFSA's public consultation calendar.[106]

The public version of the draft assessment report (sanitised draft DAR/RAR) is made available on the OpenEFSA portal, and comments from the public can be submitted using the online tool for providing comments available on EFSA's website within 60 days from the opening of the public consultation.

Applicants and Member States are informed with a dedicated communication when the commenting period starts. The commenting period is 60 days from the date of EFSA's communication ("call for comments"). Comments from applicants and Member States should be provided exclusively using the dedicated tool available on EFSA's website.[107]

Comments received after the expiry of the commenting period cannot be taken into account unless data that identifies a concern (i.e. 'adverse' data) is identified. All comments received during the commenting phase will be made available to the public.

A parallel consultation on the CLH proposal, where relevant, is launched on the ECHA website.[108] Consequently, applicants, Member States and the public should submit their comments related to the risk assessment of the substance to EFSA, while those related to the CLH report should be submitted directly to ECHA.

- For applicant's consideration:

Additional data must not be submitted at this stage but such availability can be indicated in the comments provided. After consultation with the Member States and following the consideration of any data requirements essential for the risk assessment the applicant may be requested by EFSA to submit further specified data.

2.13. Peer-review and publication of EFSA's conclusion

The EFSA Pesticide Peer-review Unit and Member States comprehensively peer review the draft assessment report prepared by the RMS to guarantee the highest possible standards. At the beginning of the peer review process, the comments provided by Member States, the public, the applicant(s) and EFSA are forwarded to RMS. The applicant is invited by the RMS to react on the comments compiled. Then, the RMS evaluates the comments and the applicant's responses and EFSA concludes on the way forward for each of them (addressed i.e. point closed and no further action required, data requirement i.e. additional information is to be requested, open point i.e. point to be further considered by RMS, or experts' consultation i.e. point to be discussed in an experts' meeting). The main actions (such as the expert consultation points and data requirements requests) are agreed in the kick-off teleconference organised between EFSA-(co)-RMS-(ECHA-EC).

Applicants are reminded that if, following a more extensive verification of the data submitted by the applicant in the application dossier, EFSA detects that the studies previously notified in accordance with Article 32b(2) and (3) of the GFL Regulation (See Sections 2.5, 2.6.1, 2.6.2) are not included in full in

[105] In accordance with Article 12(4) of Commission Implementing Regulation (EU) 2020/1740.
[106] EFSA public consultation calendar: https://open.efsa.europa.eu/calendar/public-consultation. The dates as published in the calendar may be subject to change.
[107] https://www.efsa.europa.eu/en/applications/toolkit
[108] https://echa.europa.eu/public-consultations

the submitted application dossier, EFSA requests the applicant to provide justifications regarding any missing data.

The applicant is informed that the time limit within which EFSA is required to deliver its conclusion is suspended, pending the provision of valid justifications for the absence of certain data of studies previously notified. EFSA assesses the justifications provided by the applicant.

If the justifications are considered valid, the peer review re-starts and the applicant is informed accordingly.

If the justifications provided by the applicant are not considered valid, the applicant is requested to submit the missing data of the notified study/ies. The applicant is also informed that the peer review will remain suspended for six months after the submission of any missing data relating to any supporting notified studies.[109]

For details on implications and duration of the suspension, please consult EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c).

Moreover, during the peer-review process, EFSA may request the applicant to submit additional information according to Article 12(3) of Regulation (EC) No 1107/2009, or according to Article 13(2) of Commission Implementing Regulation (EU) 2020/1740 in case of renewal of approval.[110]

In case EFSA considers that additional information is necessary, EFSA notifies the request for additional information to the applicant, specifying which information is to be provided and the deadline for submitting the information. Information received without having been requested or beyond the deadline specified by EFSA cannot be taken into account in the peer review unless it is data that identifies a concern (i.e. 'adverse' data).

In case of a request for additional information, the time limit to deliver EFSA's conclusion is extended ("stop-the-clock procedure").

When responding to EFSA's request for additional information , the applicant must upload the additional information using the IUCLID format and the central submission system through which the additional information is made available to EFSA, to the RMS, all Member States and the European Commission.

It is important to note that if the applicant submits new studies when addressing the request for additional information, the provisions of the GFL Regulation on the obligations of study notifications apply, if such studies are commissioned or carried out as of 27 March 2021 (see Section 2.5 and EFSA, 2021b).

Confidentiality requests presented by applicants on the additional information are assessed in accordance with EFSA's Practical Arrangements (EFSA, 2021a and 2021b). EFSA will proactively disclose the non-confidential version of the updated dossier/updated renewal dossier on the public IUCLID upon receipt. The link to this version will be also made available through the OpenEFSA portal upon receipt.

The RMS assesses the additional information submitted by the applicant and includes it in a revised draft assessment report, clearly identifying the amended parts. The RMS sends the revised draft assessment report to EFSA who takes care of launching a written procedure with Member States on the RMS's assessment of the additional information and when needed, organises Pesticides peer-review experts' meetings with the scientific experts from the regulatory authorities of the Member States and from EFSA. Experts' meeting reports are made publicly available after the meetings take place.[111] Where relevant, the RMS updates the draft assessment report in the light of the outcome of the written procedure or experts' meetings.

[109] In accordance with Article 32b(6) of the GFL Regulation.
[110] Applicants should note that Commission Implementing Regulation (EU) 2020/1740 foresees a time period of maximum one month for the applicant to provide the requested information.
[111] https://www.efsa.europa.eu/en/pesticidespeerreview/peerreviewexpertsmeetings

EFSA, following the last update of the draft assessment report by the RMS, drafts its conclusion summarising the outcome of the peer review process and sends it to the RMS for a first review and then subsequently to the other Member States for comments.

As an additional consultation step, applicable only to the procedure for renewal of approval, before finalisation of the peer review, EFSA communicates the draft conclusion to the applicant.

Applicants have 2 weeks to submit comments on the draft EFSA Conclusion.[112] In particular, where in the draft EFSA Conclusion critical issues and/or critical data gaps have been identified to an extent that it is expected that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are not fulfilled for at least one representative use, which the applicant could not have known about at the time of submission of the application and did not have the possibility to address during the first 'clock stop procedure' because they emerged only after that period, the applicant may also submit additional information or clarifications on those issues within the period of 2 weeks. When communicating the draft conclusion to the applicant, EFSA will specify the critical issues and/or critical data gaps for which the applicant may submit additional information.

The purpose of this provision is to provide a short window for applicants to submit comments and further information on the draft EFSA Conclusion, aimed to address critical issues impacting on the decision-making that were raised late in the peer review process for the first time (e.g. after the expert meetings or at the stage of drafting the Conclusion) and could not be foreseen by applicants, in order to increase the completeness and robustness of the final EFSA Conclusion.

However, it is not intended to revisit/reopen issues for which the applicant had the opportunity to submit additional information during the first clock stop, even if the risk assessment that took account of that information results in a concern.

EFSA will consider the submitted comments and information, in cooperation with the RMS and/or co-RMS as appropriate before finalising the EFSA Conclusion.

After the finalisation of the Conclusion, EFSA notifies it to the applicant, the Member States and to the European Commission.

- For the applicant's consideration:

EFSA's Conclusion and background documents are exchanged through EFSA's document management system. The applicant may request that certain information in EFSA's Conclusion and background documents is kept confidential pursuant to Article 63 of Regulation (EC) No 1107/2009. Confidential information should be precisely identified as such and the request for its removal duly justified using the template provided in Appendix B – of this guidance. Applicants should fill in the justification form indicating each sanitisation individually and referring to the page number in the EFSA Conclusion and background documents where the confidential information is given. The sanitised documents should be submitted in a format that allows users to search for specific words within the document (i.e. searchable PDF document).

In the notification to the applicant, EFSA will clearly set out the deadline for providing the sanitised documents and the related justification form.[113]

Following EFSA's decision on the confidentiality requests and upon implementation of the confidentiality decision (see Section 2.7), EFSA's conclusions and background documents are published in the EFSA Journal.[114]

Should the EFSA Conclusion identify foreseeable effects regarding public health, animal health or the environment, and should these effects regard items that were granted confidential status pursuant to EFSA's Practical Arrangements above, EFSA will have to review the initial confidentiality decision in accordance with Article 39c of the GFL Regulation.

[112] In accordance with Article 13(4) of Commission Implementing Regulation (EU) 2020/1740.
[113] In accordance with Article 13(6) of Commission Implementing Regulation (EU) 2020/1740 for renewal applications the applicant is given two weeks for presenting confidentiality requests.
[114] http://www.efsa.europa.eu/en/publications

2.14. Withdrawal of an application

An applicant can withdraw its application at any time during the assessment or peer review process.

Once the withdrawal of the application is submitted, all aspects related to the application process stop (e.g. RMS risk assessment, EFSA peer-review, assessment of confidentiality).

When an applicant withdraws its application prior to the adoption of a confidentiality decision (see Section 2.7 and EFSA, 2021a and 2021c), EFSA, the European Commission and the Member States must not make public the information for which confidential status had been requested.

In case an applicant withdraws its application after the adoption of a confidentiality decision, the European Commission, RMS, EFSA and other national authorities having access to the relevant information must comply with the confidentiality decision. For the effects of the withdrawal on information made publicly available through the OpenEFSA portal, please refer to EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a), which give a comprehensive overview of the applicable procedure.

The withdrawal of an application after the adoption of an EFSA Conclusion has no effect on the Conclusion, which will be in any case published, and remain published, in the EFSA Journal. It is also without prejudice to any ensuing regulatory decision at risk management level concerning the active substance or plant protection products containing that substance.

3. Practical guidance for applicants and Member States for preparing dossiers and assessment reports under Regulation (EC) No 1107/2009

3.1. Introduction

This section aims to provide additional instructions and guidance for both applicants and RMS on how data should be presented in the (summary) dossier and assessment report. It is the applicant's responsibility to provide a good quality (summary) dossier and to compile all information as required by the risk assessors and in line with the relevant legislation and guidance documents in force at the time of submission, taking into account the latest scientific and technical knowledge. The RMS has to ensure that the information is clearly presented in the assessment report. The objective of this practical guidance is to facilitate an efficient, transparent and comprehensive peer review and to avoid extensive revisions to the assessment report late in the peer review process.

The RMS is the author of the assessment report. However, it is acknowledged that the peer review process is based on the data and information provided by the applicant(s) and assessed by the RMS, therefore certain elements of the assessment report may be taken from the applicant's dossier (for reasons of efficiency), with a clear indication that the RMS agrees with those parts. The views and conclusions of the RMS (and co-RMS, where relevant) should always be clearly and transparently reported to differentiate the view of the applicant from that of their own.

This document covers many areas related to the assessment of active substances used in plant protection products, in particular those areas where experience in the peer review has highlighted particular problems or the need for additional guidance and clarification. Advice relevant for applicants and/or for the RMS is provided in each section, as appropriate.

This section is to be read in conjunction with the technical reports published following experts' meetings on general recurring issues in several areas currently available on EFSA's website.[115] Recommendations on topics where harmonisation was sought in the EU were compiled based on the discussion and conclusions achieved at the meetings on general recurring issues. These recommendations will be applied during EFSA's peer review of the active substances and they are expected to provide additional clarifications to applicants and RMSs regarding the scientific interpretation of the relevant issues when preparing the dossiers and the assessment reports.

All the relevant templates to support both applicants and RMS on how data should be presented as well as further details and instructions on data formats related to the dossier are made available in the IUCLID user manual.

3.2. Representative uses, the GAP, risk envelope approach, risk mitigation measures

3.2.1. Representative uses and the GAP

The applicant should provide information with respect to one or more representative uses which should contain at least one widely grown crop for each zone of at least one plant protection product containing the active substance, demonstrating that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are fulfilled. The representative uses should include whenever possible the uses evaluated for the first approval or subsequent renewals. In case the information submitted does not cover all zones or does not concern a widely grown crop, a justification should be submitted. At least one plant protection product for a representative use should contain no other active substance, where such a product exists.

The GAP (i.e. Good Agricultural Practice) is a fundamental element of the dossier and assessment report since it sets out the details of the representative uses which are being applied for. It is essential that

[115] http://www.efsa.europa.eu/en/applications/pesticides/regulationsandguidance

the GAP form is completed accurately and unequivocally to ensure that the correct risk assessments are undertaken.

- For the applicant's consideration:

The applicant should describe the representative uses in the IUCLID dossier, using the 'GAP form'. The GAP form has been developed to ensure that GAP information is submitted in a harmonised way serving the needs of both EU and MS assessment processes. Separate GAP forms should be completed for each individual GAP. To ensure consistency, applicants should use the available pre-defined terminology provided in picklists, where available. Further instructions are available in the IUCLID user manual. If relevant, appropriate risk mitigation measures should be described for the individual GAPs.

Applicants should pay attention to the following specific considerations in the GAP information:

- the difference in risk to bees/pollinators for a crop when harvested before flowering or when harvested after flowering in case of seed production;
- the type or types of greenhouse of the intended use should be defined in accordance with the relevant EFSA guidance (EFSA, 2014a), using the codes offered in the picklist; this defines which exposure assessments need to be carried out and for which groups of non-target organisms risk assessments need to be conducted. More specifically, in case of greenhouse uses, the GAP should specify what kind of structures are intended: permanent or non-permanent structures. The definitions of different structures and wording used should be in line with the above-mentioned EFSA guidance and the relevant picklists. This may be in particular important for relevant sections (i.e. ecotoxicology and bystander/resident exposure). If the use is not restricted to a permanent greenhouse then exposure to non-target organisms is anticipated and a full risk assessment will be needed. Should the type of protected structures include both walk-in tunnel and permanent glasshouses, the applicant should present an exposure and risk assessment for each situation separately, allowing also the RMS to prepare the draft DAR/RAR to clarify the greenhouse uses accordingly.
- if the intended use(s) defined in the GAP refer to cultivation in growing media other than soil, this information should be specified in the field on restrictions (e.g. other compost or soil-less (e.g. hydroponic or rock-wool)).
- For indoor use details should be described in the remarks, e.g. post-harvest storage room or silo, potato store, mushroom shed, witloof shed or rhubarb forcing house.
- Special consideration should be given for specific cases, e.g. the use on maize for sweet corn production will require a different GAP than the one for maize production. It should be also specifically highlighted whether the GAP for cereals and pulses and oilseeds (rape seed) is intended for grain/seed production and/or forage production (winter and spring cereal, rape seed).
- Restriction to use every X number of years.

Changing the GAP forms is not permitted during the ongoing peer review except for providing clarifications (e.g. as regards to the types of protected cropping systems / greenhouse structures) or correction of errors (e.g. correction in case of obvious mismatch between growth stage of last application and the proposed PHI, or error in calculation of concentration e.g. due to mismatch of units).

- For the RMS's consideration:

The RMS should check whether the GAP forms submitted in the IUCLID dossier are clear and complete.

Efficiency can be improved if incorrect/incomplete GAP information is corrected at the beginning of the process and not after the commenting stage.

The GAP compilation containing all the GAPs provided by the applicant in the individual GAP forms is part of the list of endpoints (LoEP) and should be also presented in Level 1 of Volume 1 of the draft assessment report; it should not be repeated in other parts of the draft assessment report to avoid that different GAP information is presented in different sections of the draft assessment report. Risk assessments should be performed consistently in each section for the GAPs compiled in Volume 1 and the LoEP.

3.2.2. Risk envelope approach

In case the risk envelope approach[116] is applied and thus the risk assessment is presented for the worst case GAP, it is recommended to also present the risk assessment for the less critical representative uses covered by other GAP forms, in particular if the risk assessment is close to the accepted trigger values or if there are indications that endpoints may change and thus this could impact the risk assessment. However, if for the same crop there are different GAPs, when a low risk is concluded, a risk assessment performed with the most critical GAP is sufficient. If a low risk is not concluded or mitigation measures are identified, the risk assessment should be performed also for the other, less critical, representative uses on the same crop (e.g. considering the lower application rate). Consideration of less critical GAPs by the applicant as well as risk mitigation measures, if appropriate, may facilitate identification of possible safe (sub)uses by risk managers during the decision-making phase. It is pointed out that only representative uses identified by the applicant should be considered in the draft assessment report and changes to the GAP forms should not be accepted during the evaluation or peer review.

3.2.3. Risk mitigation measures

- For the applicant's consideration:

Mitigation measures should be proposed by the applicant in the dossier in order to be considered/evaluated by the RMS in the draft assessment report. The applicant should consider proposing all possible risk mitigation measures in cases where there is doubt about the acceptability of the approaches taken in the risk assessment or about whether endpoints may be lowered during the review. Commission Implementing Regulation (EU) No 2020/1740 on renewals explicitly states that the applicant should provide consideration and proposal for any necessary and appropriate risk mitigation measures in the application dossier.

- For the RMS's consideration:

The RMS should consider any mitigation proposed, or any additional measures that may be required based on the risk assessment carried out. In fact, Commission Implementing Regulation (EU) No 2020/1740 on renewals explicitly prescribes that the RMS should also identify and consider, where appropriate, risk mitigation measures and take into account the written comments received during the public consultation on the dossier.

Finally, EFSA will reflect in its conclusion the risk mitigation options identified in the draft assessment report or during the peer review. This will facilitate identification of possible safe (sub)uses by risk managers during the decision-making phase. Final decisions on the need for risk mitigation measures to ensure the safe use of plant protection products containing the concerned active substance will be taken by risk managers during decision-making. Consideration of the validity and appropriateness of the risk mitigation measures remains the responsibility of MSs at product authorisation, taking into account their specific agricultural, plant health and environmental conditions.

3.3. Metabolites

- For the applicant's consideration:

A summary table for all metabolites is made available (see template 'Substances and metabolites; structures, codes, synonyms'[117] available in the IUCLID user manual) in order to identify all the metabolites and all possible codes/acronyms/names used in the different study reports and peer reviewed publications making up the dossier, as well as the compartments where the metabolites are

[116] For further details see the Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach" SANCO/11244/2011 https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en

[117] Corresponding to the previous 'Document N-3' in SANCO/10181/2013, last revision.

detected, and the detected levels (in percent of application rate (AR) or total radio-active residue (TRR), or expressed as mg/kg).

Applicants should fully complete and submit the table 'Substances and metabolites; structures, codes, synonyms'[118] as part of the dossier. The applicant should ensure that in the (summary) dossier, each individual metabolite or transformation product is referred to by a consistent unique identifier (code/acronym/name). This unique identifier should be included in bold in the key summary table 'Substances and metabolites; structures, codes, synonyms'. Further metabolite key summary tables should not be added in the different sections of the (summary) dossier to avoid creating inconsistencies in the naming of metabolites between different sections. All dossier sections should use the unique bold identifier from this key summary table 'Substances and metabolites; structures, codes, synonyms'.

This approach should be followed for both chemicals and microorganisms, even though for microorganisms the availability of details regarding detected metabolite levels will often be limited. Applicants should also bear in mind that the information in the dossier (for both chemical and microorganism active substances) on metabolites, needs to be sufficient to provide the necessary evidence to permit the establishment of their toxicological, ecotoxicological or environmental relevance. This is an approval criterion laid down in Regulation (EC) No 1107/2009.

- For the RMS's consideration:

The RMS should provide in Volume 1 of the draft assessment report one overview table containing all information on the metabolites (using the table 'Substances and metabolites; structures, codes, synonyms' from the dossier, after it has been checked by the RMS) to act as a 'key' for the whole draft assessment report. The Volume 3 documents of the draft assessment report should not contain any additional metabolite key tables to avoid inconsistencies in naming of the metabolites between the different sections. Where tables or text refer to metabolites or transformation products in the respective Volume 3 documents, the RMS should pay particular attention that only the code/acronym/name in bold from the overview table 'Substances and metabolites; structures, codes, synonyms' included in Volume 1 be used (to ensure consistency with regard to codes/acronyms/names). Structural formula in the draft assessment report should be labelled with just the bold code/acronym/name included in the Volume 1 overview table.

Following this process is important as in different study reports and peer reviewed publications various codes/acronyms/names may have been used for the same metabolite. Details like % AR, % TRR or mg/kg should only be presented in the metabolite overview table included in Volume 1 of the draft assessment report to ensure consistency and not in other overview summary tables (since such values may change as a result of the evaluation). This approach should be followed for both chemical and microorganism assessments, even though for microorganisms the availability of details regarding detected metabolite levels may be limited.

In addition, for presentation of the toxicological profile of metabolites in the draft assessment reports by the RMS, a table summarising and integrating the evidence for genotoxicity and an additional table summarising all available data on metabolites found in residues of plant and animal origin and/or in groundwater are available based on the outcome of the pesticides peer review meeting on general recurring issues in mammalian toxicology (EFSA, 2020). Further information on the pertinent templates is available in the IUCLID user manual.

3.4. Specification and impurities

- For the applicant's and the RMS's consideration:

The proposed specification of the technical material as manufactured should be clearly presented in the dossier submitted as described in the IUCLID user manual[119]) and in the assessment report Volume 4. The site(s) of manufacture should be clearly identified, the age of the 5-batch analysis data should be considered and in the case of renewals changes in the method(s) of manufacture and methods of analysis and starting materials should be presented, as these will be subject to detailed scrutiny by the

[118] It should be noted that pending on IUCLID developments, relevant data might be entered directly in IUCLID.
[119] Corresponding to the previous Document J in SANCO/10181/2013, last revision. It should be noted that pending on IUCLID developments, relevant data might be entered directly in IUCLID.

RMS. In case of renewals, both the specification of the reference source agreed during the previous EU assessment and the newly proposed specification should be mentioned.

The RMS should evaluate the new data related to the substance identity to assess whether the new data is in compliance with the reference specification or if the reference specification may require an update. In particular, the following should be considered:

- whether a new (relevant) impurity has been identified i.e. the detection of previously undetected (relevant) impurity, or an existing impurity is considered relevant based on new information, or a new impurity is formed due to the change in the manufacturing process and considered relevant;
- whether the reference specification is covered by the batches used in the toxicological and ecotoxicological studies or sufficient information is available to conclude that the reference specification does not have any harmful effect on human or animal health or any unacceptable effects on the environment;
- if a new reference specification is proposed, whether this specification is covered by the batches used in the toxicological and ecotoxicological studies.

The available information on the impurity profile of the batches used in the ecotoxicological and toxicological studies should be included in the draft assessment report Volume 4, as well. The assessment of the representativeness of the batches used for ecotoxicology and toxicology testing for an already existing reference specification and/or to a newly proposed specification should be clearly presented. This is important in order to clarify if the impurities have been tested in relevant studies at the levels proposed in the technical specification. Further to the representativeness of the batches used for ecotoxicology and toxicology testing, the toxicological relevance of each impurity should be assessed separately and any relevant impurities should be clearly indicated with the corresponding maximum level.

For renewals, the RMS should include in the draft RAR a recommendation as to whether the reference specification agreed during the previous approval (renewal) process requires an update or if the old specification is still applicable. When the old reference specification is not covered by the batches used in the toxicological and ecotoxicological studies, or when there is insufficient information that the old reference specification does not have any harmful effects on humans and the environment, then a new reference specification might be proposed. The RMS should also clearly identify the proposed reference specification in Volume 4 of the draft RAR and provide the location of the proposed reference specification in the list of endpoints in order to facilitate future equivalence checks.

These considerations will also be reflected in EFSA's Conclusion, together with an indication of the minimum purity and the maximum level of relevant impurity(ies) and a proposal for the reference specification(s). A decision on the reference specification will be taken subsequently by risk managers during the decision-making phase at EU level.

A flowchart of the assessment of the proposed specification is presented in of the Technical Report 'Outcome of the pesticides peer review meeting on general recurring issues in physical and chemical properties and analytical methods' (EFSA, 2017e).

Please also refer to the proposed templates for presentation of impurities assessment, made available in the IUCLID user manual, and the 'Technical Report on general recurring issues in mammalian toxicology' (EFSA, 2016a) for further details.

3.5. Literature search

According to Article 8(5) of Regulation (EC) No 1107/2009, the dossier must contain scientific peer-reviewed open literature in accordance with EFSA's guidance document on Submission of scientific peer-reviewed open literature for the approval of pesticide active substance under Regulation (EC) No 1107/2009 (EFSA, 2011). Based on the experience collected since the publication of the guidance document, an Appendix to the guidance has been published as 'Supporting information' to the guidance in the EFSA Journal. This Appendix is a supportive document that aims to provide additional instructions and guidance for both applicants and RMS on how the literature search should be presented in the

(summary) dossier and draft assessment report. Further information for presenting the literature search is also available in the IUCLID user manual.

3.6. Weight of Evidence (WoE)

According to the guidance on the use of the weight of evidence (WoE) approach in scientific assessments (EFSA Scientific Committee, 2017a), the WoE assessment should transparently document all steps of the procedure in sufficient detail to be repeated, to explain how the conclusion has been drawn, and making clear where and how expert judgement has been used.

The WoE approach has been specifically described in the scientific opinion related to genotoxicity assessment (EFSA Scientific Committee, 2017b) for the evaluation and interpretation of genotoxicity data, taking into account not only the quality and availability of the data on genotoxicity itself, but also all other relevant data that may be available. The WoE approach should also be applied for all other endpoints as, for instance, the data from the literature search, old studies or the results from QSAR models should be considered in a WoE approach to conclude on the endpoint for which they have been provided (EFSA, 2016a, 2018).

3.7. Availability of assessments from other European authorities and/or international bodies

- For the applicant's and the RMS's consideration:

In case other assessments are available from different European authorities and/or international bodies, references should be provided in the dossier and included in part 1.1.4 of Volume 1 of the draft assessment report (see SANCO/12592/2012). In case of divergence with other scientific bodies, a clear and transparent explanation should be added explaining the reasons for the divergence in the relevant section in Volume 3.

3.8. Analytical methods

- For the applicant's consideration:

The Guidance for generating and reporting methods of analysis (European Commission, 2019) should be followed. Analytical methods used in tests in all areas of the dossier (excluding monitoring methods), including validation data and LOQ, should be presented by the applicant in the pertinent part of the IUCLID dossier, including the presentation in tabular format of the 'Overview table for analytical methods used for risk assessment'. Further instructions and information on the pertinent template are available in the IUCLID user manual.

- For the RMS's consideration:

The 'Overview table for analytical methods used for risk assessment' should be presented in Volume 3 B5 of the draft assessment report and a reference to this table should be included in the relevant sections to avoid unnecessary duplication and inconsistencies.

3.9. Reference lists for the renewal of approval

Applicants should use the template provided in Volume 2 of the draft assessment report, so that studies submitted for the first approval of a substance ('Annex I inclusion'), including the old OECD annex points and the new EU points for comparison, or submitted at national level for product authorisation can easily be differentiated from new studies submitted for the renewal. This would facilitate handling the consideration of data protection at Member State level. In case additional studies are submitted during a clock-stop phase, the applicant should provide the revised reference list to the RMS through IUCLID and the RMS should check/amend it as necessary and include it in the revised draft assessment report. The guidance document on preparing lists of test and study reports should be used (SANCO/12580/2012). [120]

[120] It should be noted that with the IUCLID developments, the reference lists would be generated by IUCLID directly.

3.10. QSAR data

There is no particular EFSA guidance on the use of (Q)SAR models. The documents which should be considered by the applicant and the RMS are: guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA PPR Panel, 2013); guidance on establishment of residue definition for dietary risk assessment (EFSA PPR Panel, 2016); external scientific report on applicability of QSAR analysis to the evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for dietary risk assessment (European Commission-JRC, 2010); as well as ECHA (2008, 2016) and OECD (2007) guidance documents related to the use of (Q)SAR models for regulatory purpose.

- For the applicant's consideration:

The applicant should always provide raw data from QSAR as they are generated by the software tool used (output file) and a summary of the results with a detailed reasoning of acceptance or rejection of the predictions. The output file generated by the tool should be included in the dossier. If larger datasets have been analysed by the applicant, the input file should be also provided in a format (e.g. Excel) that would allow the RMS to reproduce the simulation. The input file should be included in the dossier as a stand-alone document (for further information refer to the IUCLID user manual).

- For the RMS's consideration:

The RMS should include the summary and justification of the prediction in the draft assessment report (in Volume 4 of the draft assessment report for QSAR on impurities or in Volume 3 CA B6 of the draft assessment report for QSAR on metabolites – as an appendix).

Further details on the minimum documentation / information to be provided to support the predictions by QSAR analysis are provided in the Technical Report on the outcome of the pesticides peer review meeting on general recurring issues in mammalian toxicology (EFSA, 2018). The most recent version of the tool should be used unless a scientific justification is provided (e.g. the latest update of the software is not related with the model used). It should be stressed that the recommendations and the references are also applicable to environmental fate and ecotoxicology sections where any summary and justification of the prediction in the assessment report needs to be included in Volume 3 CA B8 and/or B9 as applicable. If larger datasets have been analysed by the applicant, the input file should be included as a stand-alone file (e.g. Excel) as an annex to the draft assessment report.

During the pesticides peer review meeting on general recurring issues in mammalian toxicology (EFSA, 2020), a template and example on how to report QSAR assessment in the DAR/RAR was agreed. The template is based on the OECD principles for validation of QSARs and on the ECHA guidance used in the framework of REACH (ECHA, 2008). The template including the example is made available in the IUCLID user manual.

3.11. Non-submission of particular studies required by the regulation

In some cases, agreed test methods or guidance documents are not yet available for particular data requirements. In these cases, the non-submission of particular studies required by the EU legislation should be thoroughly justified and statements (often referred to as 'position papers') should be substantiated with data or information provided by the applicant in the dossier and evaluated by the RMS in the draft assessment report.

- For the applicant's consideration:

It should be ensured that position papers and references cited by applicant(s) in them, or if relevant supporting calculations have been included in the dossier and summarised under the applicable data point in the IUCLID dossier. Additional instructions are available in the IUCLID user manual. Statements limited to just the argumentation that finalised guidance is not available or no study guideline is available (e.g. residue trials on pollen and bee products, *in vitro* metabolism studies in mammalian toxicology section) is as such not considered sufficient by EFSA in the scientific conclusion on the peer review. Further explanation and justification should always be provided to allow for a meaningful consideration in the peer review.

Examples of cases of non-submission of data/studies may include: study not technically feasible when the nature of the substance does not allow it to be tested for that endpoint; study scientifically not

necessary/other information available. Applicants should always have in mind that the information in the dossier needs to be sufficient to provide the necessary evidence to inform on the criteria for the approval of an active substance that amongst others includes that the uniform principles have been satisfied and would enable the authorisation of at least one product for at least one representative use.

- For the RMS's consideration:

The RMS should include justification for each case of non-submission of data/studies in place of the usual study summary under the relevant data point in the respective part of the draft assessment report, along with the RMS conclusion on the appropriateness of the case. Where needed, the RMS should include under the relevant data point a clear summary and an evaluation of any supporting material used in the case. The view and conclusion of the RMS should be clearly presented.

3.12. Read across

- For the applicant's and the RMS's consideration:

For each data requirement where read across to data obtained with a different active substance/microorganism or formulation is used, e.g. in field studies and dermal absorption studies, a detailed justification needs to be provided supporting read across for that specific data requirement. It should be clearly justified why the data is considered representative and in case adjustments of values are needed due to the read across approach, these should also be clearly justified. The read across statement should be supported by information on the chemical compositions of both formulations for plant protection products (PPPs). In case of read across for common biotransformation products, the relevant degradation pathways should be presented as well.

In general, there is not a particular EFSA guidance on read across, however the documents which might be considered are documents related with chemical group formation and read across (see the ECHA Read-Across Assessment Framework (RAAF) (ECHA, 2017) and the Guidance on Grouping of Chemicals by OECD (2017)). More details on the minimum documentation/information to be provided to support the read across are provided in the Technical Report on general recurring issues in mammalian toxicology (EFSA, 2018).

3.13. MRL application submitted as part of the peer-review

See European Commission (SANTE/2015/10595, latest revision) and the relevant information on submitting MRL applications under the peer review (Section 2.6.1 on applications for approval of new active substances and Section 2.6.2 on applications for renewal). The above SANTE document includes information on requests for inclusion of an active substance/microorganism in Annex IV of Regulation (EC) No 396/2005 as well as requests to set or modify MRL(s).

- For the applicant's consideration:

When the applicant submits an MRL application as part of an approval or renewal process, a separate dossier (MRL submission) should be created in IUCLID. The dossier supporting the approval or renewal process and the one supporting the MRL application should be provided at the same time but submitted separately in the EFSA central submission system.[121]

The purpose of the MRL application should be indicated in the dossier header of the MRL submission following the instructions in IUCLID. The link between the active substance dossier and the MRL dossier should be indicated in both dossier headers (i.e. active substance and MRL). In the dossier headers, the applicant should tick the check box under the section "Other submission related information" and specify the submission number of the other dossier.

For example, if the purpose of the MRL application is either to set MRL(s) related to intended new use(s) (or authorised uses in the case of import tolerance MRL application) or to modify the existing MRL(s) for a representative use or for already authorised European uses, or to address the confirmatory data following the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005, this

[121] For technical reasons, the MRL submission will have to be done before the dossier submission to allow the system to link the two items.

should be indicated in the dossier header of the MRL submission following the instructions in IUCLID. In case the applicant considers that some Article 12 confirmatory data will never be submitted (e.g. if the use is no longer supported) this should be clearly indicated in the commenting box next to the purpose of application defined in the dossier header.

The GAPs to be assessed in the MRL application should always be reported in the MRL dossier created in IUCLID.

The assessment of these MRLs will be included in the draft assessment report prepared by the RMS and will be subsequently peer-reviewed by EFSA.

- For the RMS's consideration:

The assessment of the data submitted to support the MRL application should also be presented in a specific chapter in the different parts of the draft assessment report (resp. in Volume 1, level 1, 1.1.1 and 1.5.3; and level 2 residues section, Volume 3 B.7 and LoEP). If confirmatory data following an Article 12 MRL review are included in the RAR that are not related to the representative uses, this should be clearly outlined and separated from the representative uses assessment and not mixed and merged. If the confirmatory data are also relevant for the representative uses then the data should not be separated but it should be clearly flagged in Volume 1 that the RAR also addresses (part of) the Article 12 confirmatory data. A conclusion on the Article 12 confirmatory data assessment (context of data gap and whether sufficiently addressed by the new submission) should be provided in Volume 1, residues section. If part of the Article 12 confirmatory data will never be submitted (e.g. if the use is not supported any longer) this should be clearly flagged in Volume 1.

3.14. Role of RMS vs co-RMS

The co-RMS support is crucial during the preparation of the draft assessment report. However, currently Member States apply different approaches in terms of the level of cooperation. Overall, full flexibility is provided for sharing work between the RMS and co-RMS and there is no legal basis to enforce cooperation by the co-RMS. The co-RMS could either draft directly parts of the draft assessment report or could entirely or partly peer review the work done by the RMS in case the co-RMS is not involved in the drafting.

In view of enhancing the quality of the draft of the assessment report and peer review process it is recommended as good practice to have a more clearly described role of RMS vs co-RMS from the start of the evaluation process. The following points may be considered as best practices for sharing work between RMS/co-RMS and therefore are recommended.

- During the evaluation, if the RMS identifies particular problematic or novel approaches that require further consideration, an early discussion between the RMS and co-RMS should be arranged in order to avoid divergent views later in the peer review. EFSA can also be invited to participate in such discussions if considered appropriate;
- The co-RMS should provide scientific/technical comments on the draft assessment report (slot of 2 to 4 weeks) before it is submitted to EFSA for the peer review;
- The RMS should provide clear responses to the co-RMS comments in the format of a commenting table to be submitted when the draft assessment report is submitted for peer review. This commenting table can be a stand-alone document. For transparency reasons, it may be useful to address the co-RMS comments already in the draft assessment report and avoid that the co-RMS repeats the comments during the public consultation, if they have already been addressed by the RMS before submitting the draft assessment report;
- Issues that are considered still open because of disagreements between the RMS and co-RMS at the beginning of the peer review should be clearly presented in Volume 1 of the draft assessment report, part 3.1.9 and included by the RMS during the compilation of the Reporting Table. In this way they will be considered in the evaluation of comments in the reporting table.

It is also noted that the co-RMS can be involved in the pre-submission meetings and during the evaluation process when further discussion is needed on issues raised during the evaluation.

3.15. Assessment and presentation of studies

This section provides instructions for both applicants and RMSs on the assessment and presentation of studies.

- For the applicant's consideration:

The assessment of the validity of old studies that are critical to the risk assessment may trigger the need for repeating the studies. The study summaries (for both laboratory and higher tier studies) reviewed in the original assessment report and/or revisions to such reports where applicable, should be updated in order to have a similar level of information as in the summaries of the new studies submitted for the renewal procedure (i.e. the tables of biological findings, tables of analytical findings and validity criteria should be added). The applicant should ensure that any corrections and comments made to the original study summaries in the previous DAR/RAR and in the available EFSA conclusion are reflected in the updated study summaries of old studies.[122] IUCLID provides for the possibility to insert directly the endpoint study records of the studies according to OECD Harmonised Templates (OHTs). Therefore, the applicant should provide an assessment of old studies (submitted in the original dossier or for last renewal) against current criteria, guidelines and requirements (including updated statistical analyses) submitted through updated study records (OHT) and study summary endpoints that are self-standing, sufficiently detailed and transparent, as part of the renewal dossier.

In particular, according to Article 6(2)(d) of Commission Implementing Regulation (EU) No 2020/1740, the renewal dossier should include data and risk assessments which are necessary, *inter alia*: (i) to reflect changes in legal requirements which have occurred since the approval or last renewal of the approval of the active substance concerned; (ii) to reflect changes in scientific and technical knowledge since the approval or last renewal of the approval of the active substance concerned. Accordingly, the renewal dossier should include an assessment according to the current scientific and technical knowledge of all information submitted, including, where relevant, a re-assessment of studies and information that were part of the approval dossier or subsequent renewal dossiers.

For this purpose, all efforts should be made by the applicant to obtain access to and provide the full text of each test and study report and robust study summaries for the studies, which were part of the approval dossier or subsequent renewal dossiers. Access to old dossiers can also be facilitated by the original RMSs. The Member State that acted as rapporteur for the approval and/or subsequent renewals should endeavour to make available such studies when the applicant provides evidence that its attempts to obtain access from the study owner have failed.

- For the RMS's consideration:

The RMS should prepare a complete new assessment report, as one single, stand-alone document including the assessment of both new and old data. It is not acceptable for the RMS to only make reference to an old study which was considered as acceptable in the framework of the previous assessment and peer review. The draft assessment report should contain the RMS's current evaluation of the old studies according to new relevant validity criteria reported in updated or new guidelines, if available; there is no need to present the previous conclusion. It should be checked for instance if biological effects and parameters observed and measured in the old studies are still in accordance with the current data requirements, applicable guidance documents and current scientific knowledge. The RMS should assess the individual studies for their acceptability and deviations from Test Guidelines, and clearly present the RMS's view on each of them together with their conclusions on the validity of the results.

The RMS should take into account all the information submitted as part of the application, including the dossiers submitted for the approval and subsequent renewals of approval and where relevant information submitted as part of an application for amendment to approval conditions or to address confirmatory information requirements. Where despite the best efforts made, the applicant could not submit the full text and summary of each test and study report, which was part of the approval dossier

[122] It should be noted that with the IUCLID developments, the previous document M from the SANCO/10181/2013, last revision, would be generated by IUCLID automatically.

or subsequent renewal dossiers and required for the assessment, the RMS should ensure that the respective studies are evaluated and taken into account in their overall assessment.

Written comments received during the public consultation on the non-confidential version of the dossier should also be taken into account.

Overall, the conclusion in the draft assessment report should address whether the requirements of Article 4 of Regulation (EC) No 1107/2009 are satisfied.

- For the applicant's and the RMS's consideration:

Detailed instructions on the presentation of study summaries are given in the IUCLID user manual.

It is important to distinguish and clarify what is taken from the applicant's dossier and what is the RMS's assessment, thus increasing the transparency of the evaluation. The RMS should also indicate whether they agree with the results and conclusions drawn by the applicant. In addition, the deviations from current guidelines and whether the study was assessed in the previous evaluation should also be mentioned in the conclusions of the RMS.

In case the applicant/RMS considers that a study is not acceptable anymore according to current guideline or guidance criteria, a substantiated justification should be provided in the dossier/RAR and the study can be summarised more briefly or just the assessment why it is unacceptable presented (e.g. *the old kinetic assessment was not presented as it was superseded by the study report xx where a new assessment following FOCUS kinetics guidance was provided*).

More detailed justifications are provided regarding the need for reassessment of old studies for the specific sections below. It is noted that the issue on re-evaluation of old studies was also discussed in the general meetings on mammalian toxicology and ecotoxicology (EFSA, 2015, 2016a).

Chemical active substances

Physical-chemical properties, Methods of analysis

- Physical-chemical properties of the active substance: if an old study was performed under GLP and according to the correct method, there is no need to re-evaluate the study.
- Physical-chemical properties of the formulations: usually new studies are submitted. If an old study was performed under GLP and according to the correct method, there is no need to re-evaluate the study.
- Re-evaluation of the analytical methods used in the studies of the other sections is needed to be able to judge on the acceptability of the studies. See also Section 3.8 on Analytical methods, and further information and applicable templates made available in the IUCLID user manual.

Mammalian toxicology

Overall summaries of the various toxicology sections (acute toxicity, short-term toxicity, ADME etc.) should be included in Volume 1 of the draft assessment report. It is up to the RMS to include them in each subsection of Volume 3 B.6.

Further to a quality check of the studies against current standards, old studies often lack investigating parameters/endpoints that should be carefully addressed according to the new data requirements (such as toxicokinetics data, potential neurotoxic and immunotoxic effects or genotoxicity by way of micronuclei formation in short-term studies and endocrine sensitive parameters in reproductive studies). In these cases, the whole dossier should be checked by the applicant and a summary/references should be made to studies where these endpoints have been investigated elsewhere before a consideration of conducting new studies is undertaken. The RMS should verify what has been reported by the applicant and may discuss it during pre-submission meetings, as appropriate. The repeat or duplication of studies using vertebrate animals should always be avoided.

Residues

The main reason for the need of re-evaluation of old studies is because OECD guidelines are now available and should be followed, i.e. the adequacy of an old study to address the purpose and requirements laid down in current guidelines has to be assessed. Corrections of certain parameters have

been made as for instance, the number of required storage stability studies to cover a crop category (e.g. high water content category) has been changed compared to the old data requirements. In addition, the models have evolved e.g. animal dietary burden model, PRIMo. Therefore, attention should be paid to use always the latest version of the models by checking the version status as reported on the European Commission's website.[123]

Environmental fate and behaviour

Changes in data requirements: all fate and behaviour studies need re-evaluation as the trigger levels for identifying and assessing metabolites have had changes made except for aqueous photolysis. Triggers for field soil dissipation studies have also had amendments so have to be checked, meaning there is a need to reconsider field data.

Changes in guidance: the need to follow FOCUS kinetics guidance means that even aqueous photolysis has to be revisited. Kinetics in all degradation/transformation studies has to be reassessed and the DegT50 guidance followed (EFSA, 2014b). There is also an OECD field soil dissipation guidance (OECD, 2016) for which the DegT50 study design chapter is identical to the analogous section of the DegT50 guidance. Regarding soil adsorption, re-evaluation following the OECD 106 checklist (EFSA, 2017b) is warranted. Regarding lysimeter field leaching and groundwater monitoring data there is new groundwater guidance, so previous evaluations have to be reassessed. Other environmental fate studies in the dossier have to be reassessed to ensure they are fit for purpose in light of the guidelines prescribed at the time of submission of the dossier (usually OECD), when previously SETAC guidance had been the standard that was assessed against. In addition, it has to be noted that this re-assessment could impact also on the risk assessment by retaining or not a study or a number of studies done according to an old guideline.

Ecotoxicology

According to the data requirements, when the study design allows to do so, it is necessary to provide an effective concentration (EC_x) value. If an EC_x value cannot be provided then a justification as to why it could not be determined should be given. In evaluating the EC_x value, or the justification as to why it could not be calculated, it is necessary to re-consider the study for this purpose in addition to whether the study is still valid according to the latest scientific knowledge. See also the Technical Reports on the outcome of the pesticides peer review meetings on general recurring issues in ecotoxicology (EFSA, 2015; EFSA, 2019b).

When re-evaluating old studies, it is important to establish whether any subsequent changes introduced by e.g. new guidelines, have fundamentally changed the scientific robustness of the endpoint.

For algae it was noted that there were problems in the past with variation of the controls undermining the ability to detect effects and hence new validity criteria were introduced in the latest version of the OECD test guideline.[124]

Microorganism active substances

The study summaries and evaluations in old DARs/RARs are usually found not fit for purpose. Furthermore, this is often the case for any underpinning study reports. Publicly available data can only be accepted for endpoint setting when they originate from the peer reviewed scientific literature. As has always been the case, in order to be relied on, unpublished study reports need to have been generated in facilities with appropriately certified quality systems in place (GLP certified or certified officially recognised testing organisations depending on the category of the study, all as specified in the data requirements). The guidance document on the risk assessment of metabolites produced by microorganisms should be followed (SANCO/2020/12258). Where a metabolite needs to be assessed and fulfils the criteria for the data requirements set out in part A of Commission Implementing

[123] https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en. For PRIMo please refer to the following website: https://www.efsa.europa.eu/de/applications/pesticides/tools

[124] Refer to OECD Guidelines for the Testing of Chemicals, Section 2, OECD Test No. 201: Freshwater Alga and Cyanobacteria, Growth Inhibition Test, OECD Publishing, Paris, https://doi.org/10.1787/9789264069923-en.

Regulation (EU) No 283/2013[125] to be applicable (as set out in part B of the data requirements or SANCO/2020/12258), then metabolite assessments need to cover applicable updates made to the part A data requirements and associated guidance documents.

3.16. Guidance on presentation of the results

For applicants, it is imperative that the results are reported in a tabular format in the study records (OHT) of the IUCLID dossier and these should be checked by the RMS; results presented in a text format are not sufficient to ensure an independent, transparent evaluation. If necessary, revised study records should be provided by the applicant for the request of the RMS to subsequently allow an independent and transparent evaluation by the RMS. Detailed instructions and pertinent templates for presentation of results in tabular format are available in the IUCLID user manual. Applicants also need to always carry out and present the statistical analyses of results from within individual study reports as well as results from different related studies, all in line with the relevant study guidelines and guidance that are applicable to the various data requirements sections.

Specific guidance for the various sections is also provided below.

Efficacy

Concerning new active substances: results of e.g. the performance of the active substance against named targets, representative of proposed uses at the proposed dose, results of crop safety, observations on other undesirable or unintended side-effects as well as information on the development of resistance should be presented by the applicant in the dossier, as part of study summaries for all field trials, and where appropriate, in tabular format. Data should be verified and confirmed by the RMS, overall results and a summary should be included in Volume 1 of the draft assessment report (point 2.3. "data on application and efficacy" as well as in the list of endpoints (chapter "further information and efficacy"). The guidance document on data requirements on efficacy for the approval of active substances should be used (European Commission, 2013b).

For the renewal of approval of an active substance, the dossier should include an overview of the efficacy information (effectiveness of the active substance against target pests, crop safety, observations on other undesirable or unintended side-effects as well as information on the development of resistance) concerning the representative uses and an overview of the uses already authorised in Member States, according to the format provided in the template 'Further information on the active substance'[126] and 'Data on application'[127] made available in the IUCLID user manual. Information about the current authorisation status is to be reported in the 'List of currently authorised uses and extent of use'.[128] The information provided by the applicant should be checked by the RMS and the appropriate sections in the RAR should be completed..

Mammalian toxicology

As a general rule, tables regarding individual parameters examined should be presented where there are toxicologically relevant (e.g. dose-response relationship) and equivocal findings, also addressing those reported in the text as not relevant/adverse by the applicant/RMS but that could be interpreted differently by other Member States' experts on the basis of the summary table of results (e.g. effects showing dose-response relationship). They should be tabulated with indication of the magnitude and direction of change as well as statistical significance. Detailed instructions and pertinent templates for the presentation of results in tabular format are given in the IUCLID user manual.

[125] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, p. 1–84.

[126] Corresponding to the previous 'Document MCA Section 3' in SANCO/10181/2013, last revision. It should be noted that pending on IUCLID developments, relevant data might be entered directly in IUCLID.

[127] Corresponding to the previous 'Document MCP Section 3' in SANCO/10181/2013, last revision.

[128] Corresponding to the previous 'Doc D-2' in SANCO/10181/2013, last revision. It should be noted that pending on IUCLID developments, relevant data might be entered directly in IUCLID.

An exception to this rule are acute toxicity studies where it may be useful but is not mandatory to present the results in tabular format. In the case of multi-generation studies, a table of the achieved daily doses according to the study phase (e.g. premating, gestation, lactation, offspring growth) should be provided.

- **Historical Control Data (HCD)**

HCD are necessary to follow changes in the biology of the used test species and to differentiate the way to evaluate test results. HCD represent a summary of the observations made on the untreated or control groups from individual studies and a complete assessment of their relevance should be provided by the applicant in the dossier based on the criteria as set out in Commission Regulation (EU) No 283/2013[129]:

- the incidence of effects for control animals in studies with the same design conducted by the same laboratory; summarised by species, strain, sex, route of administration and vehicle. If study via diet, the diet should be mentioned with reference to the diet characteristics.
- the data for control animals compiled from the concurrent five-year period.

Therefore the following information should be provided:

- the mean, the median, the standard deviation (SD) and range of incidences among studies of the effect,
- the number and the dates of studies summarised,
- the use of percentiles could be further considered for HCD of growth or survival (presented as curves),
- single values (mean, median, SD and range) from those studies that fulfil criteria as set out in Commission Regulation (EU) No 283/2013.

Note that this document only refers to the expected minimum amount of details when reporting HCD. However, if the HCD are intended to be used for the evaluation of the appropriateness of the study's control group, the applicant should refer to OECD GD 116 for the data set that should be reported and included in the statistical analysis when using HCD.

- **Genotoxicity**

Results obtained in genotoxicity studies should be presented in tables. For instance, results for each strain ± metabolic activation (e.g. S9 mix) in an Ames test should be tabulated. When negative results are obtained *in vivo*, the evidence for target tissue exposure (and thus the adequacy of the test) should be fully considered and discussed. It is reminded that the data requirements on genotoxicity listed in Commission Regulation (EU) No 283/2013 should be addressed. For the assessment and interpretation of the genotoxicity studies, EFSA recommends following EFSA's Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment (EFSA Scientific Committee, 2011) and respective update on how EFSA evaluates genotoxicity (e.g. EFSA Scientific Committee, 2017b).

- **Dermal absorption**

Study summaries of dermal *in vitro/in vivo* absorption studies should include tabulated individual data (e.g. absorption rates/per cent absorption for the different cells/animals). The EFSA guidance on dermal absorption (EFSA, 2017a) provides a template to be used for presenting the results as well as a template xls file to be used for calculation of dermal absorption value(s) based on results from *in vitro* study. The assessment of dermal absorption needs to cover applicable updates made to the EFSA guidance on dermal absorption.

- **Assessment of endocrine disrupting properties**

The 'Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009' (ECHA/EFSA, 2018) contains more details on how to present the assessment of endocrine studies. Furthermore, in Volume 1 of the assessment report template

[129] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, p. 1–84.

(SANCO/12592/2012) instructions are given on how to present the assessment of the endocrine disrupting (ED) properties. Additionally, further instructions and the pertinent template are available in the IUCLID user manual. The assessment of ED properties (for both human health and non-target organisms) should be included into Volume 1 (chapter 2.10) of the draft assessment report in line with the template for presentation of the assessment of ED properties (available in the IUCLID user manual). Study summaries of individual mammalian toxicology ED studies need to be presented in Volume 3 B.6, whereas study summaries of individual ecotoxicology ED studies need to be presented in Volume 3 B.9 respectively. The Excel file (Appendix E.1 to the ECHA/EFSA 2018 Guidance), completed in line with the instructions for reporting the available information relevant for ED assessment, checked and where needed corrected by the RMS, should be submitted as annex to the assessment report Volume 1.

- **Epidemiological data**

Epidemiological studies on active substances and their relevant metabolites published within the last ten years before the date of the submission of the dossier should be retrieved from the literature according to the EFSA Guidance on 'Submission of scientific-peer reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009' (EFSA, 2011). The Scientific Opinion of the PPR Panel (EFSA PPR Panel, 2017) should be consulted for further support in the peer review process.

- **Metabolism studies in laboratory animals (e.g. rat)**

Metabolism studies should be entered using the Data Evaluation Record (DER) composer of the Metapath software package. The metabolism data should then be uploaded as xml files, generated by the DER composer software, in the respective sections in IUCLID. Additional instructions are available in the IUCLID user manual.

- **Non-dietary exposure estimates**

Non-dietary exposure estimates should be provided at least for the most critical representative use (GAP). The EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA, 2014c) should be considered, together with the annexed exposure calculation spreadsheet. If the scenario is not covered by this guidance, *ad hoc* approaches and/or relevant field studies need to be adequately justified and assessed and may be discussed during pre-submission meetings, as appropriate. The assessment of non-dietary exposure needs to cover applicable updates made to the current EFSA guidance (EFSA, 2014c).

Residues

The results of the key studies investigating the metabolism and the magnitude of residues should be presented in tabular format. This includes studies on metabolism in plants (primary crops, rotational crops, processed commodities) and livestock and on the magnitude or residues in plants (residue trials), in processed commodities (processing trials) and in livestock (feeding studies).

Metabolism studies should be entered using the MSS composer of the Metapath software package. The metabolism data should then be uploaded as xml files, generated by the MSS composer software, in the respective sections in IUCLID. Using the full functionalities of Metapath, applicants may also generate summary reports of the available metabolism studies in a human readable format; these reports can be uploaded in the endpoints summaries of the respective sections in IUCLID. Additional instructions are available in the IUCLID user manual.

The results of residue field trials should be summarised as described in the IUCLID user manual. The summarised results uploaded in IUCLID do not replace the comprehensive assessment of the data according to the current test guidelines, which should be provided for each study independently as well as in the summary of the respective sections.

The Excel sheets related to the livestock (Animal Model) and consumer dietary intake calculations (PRIMo) should be completed and uploaded as xls file attachments in the respective sections in IUCLID. Attention should be paid to using the appropriate version of the PRIMo model and, for the calculation of livestock burden, the latest version of the animal dietary burden model (cf. IUCLID user manual).

Relevance of metabolites in groundwater

The RMS should ensure that the draft assessment report Volume 1, Section 2.12 (relevance of metabolites in groundwater) has been coherently completed regarding all sub headings and that none of these has been deleted. If an assessment of a sub section is not triggered, this should be stated explaining why it was not triggered or explanations of other sub sections in Section 2.11 of Volume 1 of the draft assessment report that explain this should be cross-referenced. A template for presenting the relevance of metabolites in groundwater is available in the IUCLID user manual.

Environmental fate and behaviour

The results of kinetic fitting for studies on degradation in soil and water should be presented by the applicant in the dossier, in table form in sufficient detail as part of the study summaries for all field and laboratory soil and water degradation studies (the template for presenting the kinetic fitting is available in the IUCLID user manual). In addition, also plots and residual plots for all fits should be provided in a format that allows them to be copied directly into the assessment report.

The RMS should make sure that these results are presented in the same table format in the respective Volume 3 B8 part of the draft assessment report. The RMS should include the visual fit(s) that was (were) selected by them as the reliable endpoints for each experiment in the assessment report. It is only necessary to present other kinetic fits where the decision on which to select was less clear and presenting the other fits allows reviewers to understand the RMS selection.

The results of soil adsorption studies should be presented by the applicant in line with the Technical report on OECD 106 evaluators' checklist (see Section 4 template for reporting results in the Technical Report (EFSA, 2017b)). A template for this is available in the IUCLID user manual. Freundlich plots (as presented in the Worked example of Appendix A of EFSA, 2017b) should also be included.

The RMS should make sure that these results are presented in the same table format in the respective Volume 3 B8 part of the draft assessment report.

Results from available monitoring data on occurrence of residues in soil, surface water, sediment and groundwater as required by the data requirements need to be included in the dossier, as described in the IUCLID user instructions. The applicant should provide as far as they are able an accompanying consideration of the patterns of authorised uses in the regions monitored and how these might have changed over the period for which the sourced monitoring data were available. The RMS should report their assessment of this information and contextualise it as far as possible in relation to what is known about authorised uses in the areas for which monitoring information is available. They should clearly report if they identify that relevant monitoring data is missing from the applicant's dossier. They should also discuss the available monitoring results by providing a comparison from what was known about uses pertaining to the results and the representative uses being assessed / supported by the applicant.

Ecotoxicology

- Results from analytical verification of the test substance should be presented in tabular format. For aquatic studies, resulting endpoints should be expressed as recommended in the Technical Report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology (EFSA, 2015). Where relevant, test concentrations on which the endpoints are based (e.g. mean measured) should be reported for each tested concentration in the tables of results. A similar approach may be applied for terrestrial studies, where relevant.
- In the study summaries, the results (i.e. biological findings) should be presented in tabular format. In addition to the absolute numbers, percentages of effects (when applicable) and statistical significance should be reported for all tested rates (concentration).
- For those studies as indicated in Appendix F of EFSA, 2015, in addition to the no effect level (concentration), EC_{10}, EC_{20} values are also required. If EC_x values could not be determined, a justification needs to be provided.
- In case the dossier contains data for several formulations, a corresponding Volume 3 for the formulation (i.e. CP document) is prepared by the RMS for each formulation. However, the peer review has to conclude on the active substance and on each representative use in the GAP list. Therefore, Volume 1 of the draft assessment report and the LoEP should present the outcome of

the risk assessment based on each representative use and avoid concluding on the basis of each formulation. This will ensure consistency in the LoEP with the conclusion text.

- Assessment of endocrine disrupting properties: The 'Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009' (ECHA/EFSA, 2018) contains templates on how to present studies that might elucidate endocrine disrupting properties of pesticides. Furthermore, in Volume 1 of the assessment report template (SANCO/12592/2012) instructions are given on how to present the assessment of endocrine disrupting (ED) properties. Additionally, further instructions and the pertinent template are available in the IUCLID user manual. The assessment of ED properties (for both human health and non-target organisms) should be included into Volume 1 (chapter 2.10) of the draft assessment report in line with the template for presentation of the assessment of ED properties (available in the IUCLID user manual). Study summaries of individual mammalian toxicology ED studies need to be presented in Volume 3 B.6, whereas study summaries of individual ecotoxicology ED studies need to be presented in Volume 3 B.9 respectively. The Excel file (Appendix E.1 to the ECHA/EFSA 2018 Guidance), completed in line with the instructions for reporting the available information relevant for ED assessment, checked and where needed corrected by the RMS, should be submitted as annex to the assessment report Volume 1.

3.17. Application invoking negligible exposure and/or derogation in accordance with Article 4(7) of Regulation (EC) No 1107/2009

The applicant and RMS have to examine the compliance with the approval criteria as laid down in Article 4 of Regulation (EC) No 1107/2009 and when the criteria set out in points 3.6.2, 3.6.3, 3.6.4 and 3.7 of Annex II to Regulation (EC) No 1107/2009 are not satisfied (including consideration of negligible exposure, where relevant - see below), the RMS should limit the draft assessment report to that part (as laid down in Article 11(4) of Commission Implementing Regulation (EU) No 2020/1740 for renewals and in Article 11(2) of Regulation (EC) No 1107/2009 for new active substances).

In fact, for substances meeting the hazard criteria in points 3.6.3 and 3.6.4, approval may still be possible if it can be demonstrated that exposure to the substance under realistic conditions of use is negligible[130]. Therefore, an examination of data provided to demonstrate negligible exposure should also be undertaken before limiting the assessment. In addition, the draft assessment report may need to be completed despite the possible non-compliance with the approval criteria of Annex II points 3.6.3, 3.6.4, 3.6.5 and 3.8.2 in case the applicant submitted documentation to demonstrate that the derogation of Article 4(7) of Regulation (EC) No 1107/2009 could be met, provided the RMS agrees that this derogation possibility could apply.

If an application for negligible exposure is submitted as part of the dossier, the relevant documents should be clearly presented in the respective substance and/or product sections of the dossier. Volume 1 of the draft assessment report should clearly mention that the applicant submitted a negligible exposure application. Furthermore, the assessment and outcomes should be presented by the RMS in the draft assessment report Volume 1, Volumes 3 B6, B7 and/or where appropriate. The "Draft Technical guidance on points 3.6.3 to 3.6.5 of Annex II to Regulation (EC) No 1107/2009, in particular regarding the demonstration of negligible exposure to an active substance in a plant protection product under realistic conditions of use", the latest version available from PAFF Section Pesticide Legislation (European Commission, 2015), could be considered for the assessment.

If an application under Article 4(7) of Regulation (EC) No 1107/2009 is submitted as part of the dossier, the respective documents should be filed as the 'List of currently authorised uses and extent of use'[131]. Volume 1 of the draft assessment report should clearly mention that the applicant submitted an application under Article 4(7), however the assessment should not be included as part of the assessment report as a separate procedure will be run by EFSA to evaluate the application under Article 4(7). The RMS should mention in Volume 1 of the draft assessment report that an application under Article 4(7)

[130] In addition, consideration of negligible exposure is also relevant for substances meeting the criteria in points 3.6.5 and 3.8.2 (endocrine disrupting properties) of Annex II to Regulation (EC) No 1107/2009.

[131] Corresponding to the previous 'Doc D-2' in SANCO/10181/2013, last revision. It should be noted that pending on IUCLID developments, relevant data might be entered directly in IUCLID.

has also been submitted. A separate Annex to EFSA's conclusion for reflecting the assessment on Article 4(7) will be drafted. The EFSA protocols that should be used in the assessment of Article 4(7) submissions are listed in the reference list (EFSA, 2016b, 2017c and 2017d).

Information to demonstrate that the active substance may be used such that exposure is negligible, and/or documentary evidence for the application of the derogation under Article 4(7) of Regulation (EC) No 1107/2009 may also be provided by the applicants at the time of EFSA's request for additional information during the peer review, if possible non-compliance with the relevant approval criteria is indicated based on the comments received.

For the assessment of negligible exposure, the representative uses (GAPs) **should not be changed** i.e. the applicant/RMS should consider negligible exposure for the representative use(s) only. For Article 4(7) the situation is different as the applicant and the MSs should identify all authorised uses to be considered (in line with the protocols on this subject mentioned above).

4. Guidance on the provisions of the Transparency Regulation for MRL applications

This chapter is specifically addressing maximum residue level (MRL) applications and confirmatory data submitted within the scope of Regulation (EC) No 396/2005[132].

It provides guidance to applicants and Evaluating Member States (EMS) on the provisions introduced by the GFL Regulation, as amended by the Transparency Regulation[133], and their implementation in the MRL application procedure according to the Practical Arrangements[134] laid down by EFSA.

The chapter should be read in conjunction with the above-mentioned Regulations, EFSA's Practical arrangements implementing the provisions of the Transparency Regulation, i.e. the Practical arrangements on pre-submission phase and public consultations[135] (EFSA, 2021c) and those concerning transparency and confidentiality[136] (EFSA, 2021a), as well as with the EC guidance document on the MRL setting procedure (European Commission, 2018) and the Commission Working Document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs (SANTE 10235/2016 - Rev. 4).

In case of discrepancy between the content of this chapter and applicable legal acts, or EFSA's Practical Arrangements, the legal acts and the latter prevail.

This administrative guidance is not replacing the relevant guidance documents issued by the European Commission, which remain to be consulted for the preparation of dossiers and evaluation reports but it complements these documents with the related provisions set out by the Transparency Regulation for MRL applications.[137]

The provisions presented in this chapter apply to all MRL applications submitted as of 27 March 2021. Therefore, this guidance should be used for the preparation of all applications intended to be submitted from that date onwards. For all applications submitted before 27 March 2021, the previous guidance document on MRLs applies (SANTE/2015/10595 Rev. 5.4).

This section does not apply to MRL applications submitted as part of the peer review. For the procedure applicable to these cases, please refer to Section 3.13 of this guidance.

The tools that applicants are expected to use in the preparation of the application and subsequent phases (e.g. EFSA's system for pre-submission activities, database of study notifications, IUCLID software) are available on EFSA's website[138], together with a brief description of each tool, how to access it and dedicated user manual/guide where available. IUCLID is also accessible to Member States.

[132] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

[133] 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, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

[134] EFSA's Practical arrangements are available online at: https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements

[135] See Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations

[136] See Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality

[137] https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en

[138] https://www.efsa.europa.eu/en/applications/toolkit

Pre-submission phase

Before submitting an application for setting or changing maximum residues levels or submitting confirmatory data in order to access pre-submission activities, a potential applicant should first register in EFSA's portal supporting pre-submission activities available on EFSA's website.[139] The registration is needed only in case the potential applicant intends to request pre-submission advice and/or studies must be notified. Potential applicants should in any case inform the EMS of the intention to submit an MRL application.

Upon request addressed to EFSA, potential applicants are given a reference i.e. pre-application identification 'ID' (EFSA-ID-YYYY-NNNNNN[140]), to be used for any activity related to the pre-submission phase (see Sections 4.1, 4.2), as introduced by the GFL Regulation:

- possibility to request general pre-submission advice from EFSA (optional, applicable to all types of MRL applications);
- notification of information related to studies commissioned or carried out (mandatory, applicable to all types of MRL applications).

The pre-application ID may be also requested by a potential applicant on behalf of a group of potential applicants in relation to all the pre-submission activities, which are envisioned to support a future joint application.

If given, the pre-application ID(s), if any, must be provided when submitting the application (see Sections 4.3).[141]

The sections below provide an overview to applicants on the procedure governing the pre-submission phase. They should be read in conjunction with binding Union legal acts, in particular with EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c), which provide comprehensive information and instructions on that matter.

4.1. General pre-submission advice

In accordance with Article 32a(1) of the GFL Regulation, potential applicants may request general pre-submission advice (GPSA) from EFSA at any time before submitting the envisaged application. The GPSA is optional for the potential applicant. Within the framework of GPSA, EFSA provides advice on the rules applicable to, and the content required for, an application prior to its submission.

In particular, the following items are considered outside of the scope of the GPSA:

- design of the studies to be submitted and questions related to hypotheses to be tested, unless the advice concerns guidance documents developed by EFSA in which study design is addressed;
- risk management questions;
- any aspects going beyond the information available in the legislation, rules, guidance documents or guidelines applicable to applications.

EFSA recommends submitting the request at least six months before the envisaged submission date of the application.

Requests for general pre-submission advice must be submitted to EFSA by filling in the dedicated general pre-submission advice online form ('GPSA form') available on EFSA's website.[142]

[139] https://www.efsa.europa.eu/en/applications/toolkit
[140] YYYY corresponds to the year and NNNNNN is a progressive number.
[141] In accordance with Article 5 of Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021c).
[142] https://www.efsa.europa.eu/en/applications/toolkit

The GPSA is given by EFSA in close collaboration with the intended or designated EMS.[143] To this end:

- in case of intended applications for MRLs within the EU, the requester must provide the indication of the intended EMS in the GPSA form. If the intended EMS is not indicated, the GPSA will be provided by EFSA alone; the applicant is informed accordingly;
- in case of intended applications for import tolerance[144], the requester must provide the indication of the designated RMS/co-RMS in the GPSA form. If the potential applicant fails to indicate the designated RMS/co-RMS, the request is rejected. The requester can submit a new request.

Upon receipt, the request for GPSA is transmitted to the intended EMS or designated RMS.[145] All the exchanges will take place electronically in the tool supporting pre-submission activities available through EFSA's website.[146]

Following an administrative check, EFSA informs the intended EMS or designated RMS whether the request for GPSA is accepted and whether a reply will be provided in writing or in the context of a meeting. The intended EMS/designated RMS is requested to confirm within 5 working days if it is willing to prepare the draft written advice or the preliminary assessment in case of a meeting.

GPSA requests for which the reply is provided in writing

- In the event that the intended EMS/designated RMS is willing to prepare the draft written advice: the intended EMS/designated RMS prepares the draft written advice and sends it to EFSA for consultation within 15 working days from the confirmation that the request is accepted by EFSA (i.e. up to 5 working days at the latest for confirming willingness to prepare the draft advice + up to 10 working days for preparing the draft). Within 5 working days as of the date of receipt of the draft written advice, EFSA provides the intended EMS/designated RMS with its comments on such draft and with a draft summary of the advice (to be later published).
- In the event that the intended EMS/designated RMS is not willing to prepare the draft written advice: within 10 working days from receipt of a reply from the intended EMS/designated RMS, EFSA prepares the draft written advice and related summary and shares them with the intended EMS/designated RMS for possible comments. In case no comments are received within 5 working days, EFSA will provide the advice to the potential applicant, as previously communicated to the intended EMS/designated RMS.
- within 20 working days as of the date of the acceptance of the request, EFSA provides the written advice and the related summary agreed by EFSA and the intended EMS/designated RMS to the requester.[147] In case the intended EMS/designated RMS disagrees with EFSA about one or more replies, the written advice and the summary will reflect both opinions.
- EFSA shares the written advice and the summary with the competent authorities of all Member States for information purposes.

GPSA requests for which the advice is provided in a meeting

- In the event that the intended EMS/designated RMS is willing to prepare the preliminary assessment: the intended EMS/designated RMS prepares its preliminary assessment of the questions to be addressed during the meeting and sends it to EFSA within 15 working days from the confirmation that the request is accepted by EFSA (i.e. up to 5 working days at the latest for confirming willingness to prepare the preliminary assessment + up to 10 working days

[143] EFSA is committed to providing the most helpful support possible by way of general pre-submission advice in close cooperation with the relevant national competent authorities. However, in situations where the relevant national competent authorities do not consent to such collaboration, EFSA may not be held liable for any divergences between the general pre-submission advice provided by EFSA and that possibly provided separately by the relevant national competent authority.
[144] Applications under Article 6(4) of Regulation (EC) No 396/2005.
[145] 'designated RMS' is used in reference to applications for import tolerance.
[146] https://www.efsa.europa.eu/en/applications/toolkit
[147] In this context, EFSA does not provide any advice outside the scope of Article 7(1) and (2) of Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021c).

for preparing the preliminary assessment). EFSA and the intended EMS/designated RMS have 5 working days to exchange views before the meeting takes place;

- in the event that the intended EMS/designated RMS is not willing to prepare the preliminary assessment: within 10 working days from receipt of a reply from the intended EMS/designated RMS, EFSA prepares its preliminary assessment of the questions to be addressed during the meeting and shares it with the intended EMS/designated RMS. EFSA and the intended EMS/designated RMS have 5 working days to exchange views before the meeting takes place;
- the meeting is organised within 20 working days as of the date of the acceptance of the request; both EFSA and intended EMS/designated RMS must attend;
- the advice is provided by EFSA, in collaboration with the intended EMS/designated RMS during the meeting[148];
- after the meeting, EFSA provides the intended EMS/designated RMS with a summary of the advice. In case the intended EMS/designated RMS disagrees with EFSA about one or more replies provided to the potential applicant during the meeting, the summary will reflect both opinions. The summary is sent for information to the requester;
- EFSA shares the summary with the competent authorities of all Member States for information purposes.

The summary of the GPSA is kept by EFSA and made public together with the non-confidential version of the application dossier once the application is declared admissible. To this end, it is important that the EMS notifies EFSA as soon as the application is declared admissible.

For a comprehensive description of applicable procedures and provisions, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c, see in particular the section 'Special and exceptional provisions applicable to the area of plant protection products and maximum residue levels of pesticides').

4.2. Notification of studies

In accordance with Article 32b of the GFL Regulation, potential applicants[149] commissioning or carrying out studies as of 27 March 2021 in view of a MRL application have the obligation to notify EFSA without delay of the following information[150] related to those studies:

- title and scope of the study;
- laboratory or testing facility carrying out the study;
- starting and planned completion dates of the study.

The same obligation applies to the laboratories and other testing facilities located in the EU[151] for studies commissioned by potential applicants and carried out by such laboratories and other testing facilities. Therefore, both potential applicants and laboratories/testing facilities have the obligation to notify information about all studies commissioned or carried out to support an application. Study notifications must be submitted in EFSA's database of study notifications available on EFSA's website[152] without delay before the starting date of the study. The database will assign a unique study identification 'ID' to each study notification (i.e. study ID: EFSA-YYYY-NNNNNNNN[153]).

[148] In this context, EFSA does not provide any advice outside the scope of Article 7(1) and (2) of Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021c).
[149] If an application is submitted by the EMS, the obligations of study notifications do not apply.
[150] The full list of information to be notified for each study is provided in Annex II to Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021c).
[151] The same obligation applies to laboratories and testing facilities located in third countries insofar as set out in relevant agreements and arrangements with those third countries, including as referred to in Article 49 of the GFL Regulation.
[152] https://www.efsa.europa.eu/en/applications/toolkit
[153] YYYY corresponds to the year and NNNNNNNN is a progressive number.

For any study notification submitted after the starting date of the study, the applicant must provide justifications for the delay in the application dossier when submitting the application.

The obligations on notifications of studies apply to any additional study provided after the submission of the application either during the admissibility check of the application by the EMS or in relation to the EMS' evaluation or EFSA's assessment, if such studies are commissioned or carried out as of 27 March 2021.

Applicants should be aware that non-compliance with the obligations for notifications of studies may result in the non-admissibility of the application (see Section 4.4) or in delays in the EMS' evaluation or EFSA's assessment.

Studies submitted to support a MRL application are not subject to the obligation of study notifications if they were commissioned or carried out before 27 March 2021.

For a comprehensive description of applicable procedures and provisions, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c).

The EMS is responsible for checking the compliance with respect to obligations of study notifications during the admissibility check.

The EMS will not have direct access to EFSA's database of study notifications. EFSA will extract the relevant information from the database and share it with the EMS, strictly on a need-to-know basis and for the period necessary to complete the assessment.

From submission of the application to the adoption of EFSA's reasoned opinion

4.3. Preparation and submission of an application

In order to support an application, the applicant has to submit an application dossier, containing all required scientific information and studies. The dossier must be prepared using the IUCLID (International Uniform ChemicaL Information Database) software, which is a software application to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances and the standard data format to be used for pesticides. Please refer to the instructions of the IUCLID user manual[154] for information on how to prepare and submit an application dossier.

Once prepared, the applicant must submit the dossier through the EFSA central submission system and in IUCLID format, indicating the evaluating Member State who will perform the assessment of the application. Via IUCLID, the valid dossier[155] is automatically made available to the European Commission, the Member States (including the one receiving the application), and to EFSA.

When submitting a MRL application, the applicant must submit the following documentation through a **dossier**, prepared using the **IUCLID** software[156], including amongst other elements listed in Regulation (EC) No 396/2005[157]:

- for each of the data requirements: the full text of each test/study report, and a sanitised version if the full text version contains confidential material and a completed endpoint study record;
- completed endpoint study records and a comprehensive overview of relevant concerns raised in the available scientific literature about the plant protection product and/or its residue;
- summaries for each endpoint and analysis where multiple studies are used to inform the evaluation;

[154] https://www.efsa.europa.eu/en/applications/toolkit
[155] A dossier is considered valid (i.e. successfully submitted) once it has gone through and passed the automatic submission checks.
[156] Available at: https://iuclid6.echa.europa.eu/it/download
[157] Full list of requirements is given in Article 7 of Regulation (EC) No 396/2005.

- requests for confidentiality, using the relevant IUCLID functionality;
- non-confidential version of each attached document in the dossier for which confidentiality is requested;
- the relevant GAP applying to the specific use of the active substance;
- all information needed to comply with obligations of study notification[158] (see Section 4.2).

IUCLID provides for the possibility to insert directly the endpoint study records of the studies according to OECD Harmonised Templates (OHTs).[159] IUCLID also has functionalities to flag confidential information, insert requests for confidentiality and generate automatically the sanitised summary dossier and **a non-confidential version of the dossier** (meaning the dossier where confidential documents are replaced by their non-confidential version, as provided by the applicant).

Regarding the study notification obligations of Article 32b(2) and (3) of the GFL Regulation, when submitting an application, the applicant must provide the following information:

- **pre-application ID(s)** provided to the applicant at pre-submission phase, in case pre-submission advice was requested and/or or new studies have been notified;
- **study ID** generated by EFSA's database of study notifications for each study submitted in the application;
- if necessary, **justifications** explaining the divergence between the information notified in accordance to Section 4.2 and the studies included in the application, linked, where applicable, to the study ID.

For a comprehensive description of the information to be provided when submitting applications to allow verification of compliance with study notification obligations, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c).

- For the applicant's consideration:

The results of the key studies investigating the metabolism and the magnitude of residues should be presented in tabular format. This includes studies on metabolism in plants (primary crops, rotational crops, processed commodities) and livestock and on the magnitude or residues in plants (residue trials), in processed commodities (processing trials) and in livestock (feeding studies).

Metabolism studies should be entered using the MSS composer of the Metapath software package. The metabolism data should then be uploaded as xml files, generated by the MSS composer software, in the respective sections in IUCLID. Using the full functionalities of Metapath, applicants may also generate summary reports of the available metabolism studies in a human readable format; these reports can be uploaded in the endpoints summaries of the respective sections in IUCLID. Additional instructions are available in the IUCLID user manual.

The results of residue field trials should be summarised as described in the IUCLID user manual. The summarised results uploaded in IUCLID do not replace the comprehensive assessment of the data according to the current test guidelines, which should be provided for each study independently as well as in the summary of the respective sections.

The Excel sheets related to the livestock (Animal Model) and consumer dietary intake calculations (PRIMo) should be completed and uploaded as xls file attachments in the respective sections in IUCLID. Attention should be paid to using the appropriate version of the PRIMo model and, for the calculation of livestock burden, the latest version of the animal dietary burden model (cf. IUCLID user manual).

[158] In accordance with Article 32b of GFL Regulation and in line with Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021c).

[159] Where the nature of the information, documents or data is technically not compatible with OHT, semi structured data may be submitted.

4.4. Admissibility check of the application by EMS

In the context of the admissibility check of the application, the EMS should assess the compliance of the application with all relevant requirements, including with the obligations of study notifications laid down in Article 32b(2) and (3) of the GFL Regulation.

The EMS is expected to consider the application as not admissible if during the admissibility check it concludes that:

- a submitted study was not previously notified in EFSA's database of study notifications or was notified after the starting date of the study (i.e. non-notification regulated by Article 32b(4) of the GFL Regulation) and the applicant has provided no valid justification; and/or
- a study previously notified in EFSA's database was not included in the application and the applicant has provided no valid justification (i.e. non-inclusion of a study regulated by Article 32b(5) of the GFL Regulation);
- a notification of a study was withdrawn and the applicant has provided no valid justification (Article 21(b)(iii) of EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c)).

The application may be re-submitted, provided that:

- the applicant notifies in the database the studies that were not previously notified; and/or
- the applicant submits all the studies which were previously notified in the database or, in case of unjustified withdrawal of a notification of a study, the data delivered by the relevant laboratory or testing facility even without having the study completed.

The admissibility check will commence six months after the submission of the latter studies or data.

Upon receipt of the notification of admissibility from the EMS, the application is displayed in the OpenEFSA portal.

Once the application is found admissible by the EMS, EFSA makes available on the OpenEFSA portal a link to the non-confidential version of the dossiers in 'public' IUCLID, which is the version accessible by the public.[160] To this end, it is important that the EMS notifies EFSA[161] as soon as the application is declared admissible.

The EMS should include in the notification the following information, retrievable in IUCLID:

- Dossier UUID[162]
- Dossier URL[163]
- European Reference number[164]
- Dossier subject/Substance name
- Pre-application identification(s)
- Purpose of application

In addition, when sending the notification, the EMS is expected to make available to EFSA the following documents: validation assistant report, notification of studies report. These documents can be automatically generated by IUCLID following the instructions provided in the IUCLID user manual.

The validation report can be exported from IUCLID in standardised Excel format. The studies report can be generated from IUCLID in Word or PDF format. It is also possible to make a request to EFSA for an extraction from the notification studies database in order to make a comparison.

[160] https://open.efsa.europa.eu
[161] By sending an email to: apdesk.applications@efsa.europa.eu, Cc: pesticides.mrl@efsa.europa.eu
[162] Universal Unique Identifier generated by IUCLID for each dossier submitted.
[163] Link to a specific dossier in IUCLID.
[164] Unique identifier to link all dossiers in the regulatory action (e.g. original dossier and all subsequent updates).

The non-confidential version of the application proactively disclosed on the public IUCLID and through the OpenEFSA portal upon declaration of admissibility may be republished at a later stage, should EFSA reject any of the confidentiality requests presented by the applicant (see Section 4.6).

Following the implementation of the confidentiality decision, the non-confidential version of the application dossier is subject to public consultation (see Sections 4.6 and 4.7).

The applicant must ensure that terms and conditions asserted by any rightsholder of studies, information or data submitted to EFSA are fully satisfied. The applicant may consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing the appropriate licenses to provide studies, information or data to EFSA, taking into account the proactive disclosure requirements as detailed below. For publications already available to the public upon payment of fees (e.g. studies published in scientific journals) for which the applicant does not have or cannot obtain intellectual property rights for the purposes of the proactive public disclosure requirements, the applicant must provide (a) a copy of the relevant publications along with the relevant bibliographic references/ citations for scientific assessment purposes only, in the confidential version of its application and (b) these relevant bibliographic references/citations where these publications are available to the public in the non-confidential version of its application for public dissemination on the OpenEFSA portal.

4.5. Transparency and confidentiality requirements

This section gives an initial overview to applicants on the procedure implementing transparency and confidentiality requirements, in accordance with relevant provisions of the GFL Regulation and EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a). It is to be read in conjunction with Regulation (EC) No 1049/2001, Regulation (EC) No 1367/2006, as well as with EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a), which provide a comprehensive description of applicable procedures and provisions.

4.5.1. Transparency requirements applicable to information shared by applicants with EFSA

The GFL Regulation as amended by the Transparency Regulation introduced a general principle of proactive disclosure and transparency of information, studies and data submitted to EFSA for scientific evaluation. In light of this principle, and of the related provisions, EFSA must proactively disseminate all information submitted by applicants for the purposes of EFSA's scientific evaluation of regulated products, including the information submitted during the assessment process.

Specifically, EFSA is to make publicly available[165] *inter alia* the following information[166]:

- all its scientific outputs;
- scientific data, studies and other information supporting applications, including additional information requested during an assessment, as well as other scientific data and information supporting requests from the European Commission and the Member States for a scientific output;
- the information on which its scientific outputs are based;
- a summary of the advice provided to potential applicants at pre-submission phase.

By derogation from the general principle of proactive disclosure and transparency, EFSA may grant confidential status to certain elements of application dossiers, provided applicants submit a verifiable justification, and EFSA accepts the confidentiality request. For this purpose, and for each document for which confidentiality is requested, applicants are required to provide:

[165] The proactive disclosure of the above information does not imply permission or licence for their re-use, reproduction, or exploitation in breach of the relevant existing rules concerning intellectual property rights or data exclusivity. EFSA cannot be held liable or responsible for any use of the disclosed data by third parties in breach of any existing intellectual property rights.

[166] For an exhaustive list of the types of information, documents or data which is made proactively available, please refer to Articles 5 and 6 of Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality (EFSA, 2021a).

- **a request to treat certain item(s) as confidential**, specifying: the confidentiality ground(s) and conditions, justification, excerpt of the text, location in the file. These requests should be inserted in IUCLID at the time of submission of the information. Multiple requests can be submitted per file, but only with regard to specific items as indicated in the relevant Union law (see Section 4.5.3);
- **a version of the concerned document with all information visible and no blackening applied**. In this version, all information claimed to be confidential by the applicant should be boxed or earmarked (confidential version, not for public disclosure);
- **a non-confidential version of documents with all elements claimed to be confidential blackened** (public version). This version will be made publicly available in public IUCLID and through the OpenEFSA portal as soon as the application is declared admissible. This non-confidential version provided by the applicant and made publicly available will be replaced by the one sanitised by EFSA pursuant to its confidentiality decision, in case one or more confidentiality requests are rejected. Applicants should note that the 'public version' should have all the names and addresses of individuals involved in testing on vertebrate animals or in obtaining toxicological information blackened as these elements must not be disclosed. Furthermore, the public version should also have all the personal data the applicants consider should not be disclosed pursuant to its confidentiality requests, equally blackened. For more information, see Section 4.5.3 as well as EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a).

4.5.2. How to submit a confidentiality request

Applicants are required to submit confidentiality requests in IUCLID using the dedicated functionality, by providing reasoning supporting each request and addressing the requirements set out in Article 10 of EFSA's Practical Arrangement concerning transparency and confidentiality.

It is fundamental that applicants submit all relevant confidentiality requests at the time of submission of the related piece of information (e.g. application dossier, information submitted following a request for additional information, etc.). After submission, applicants may not modify confidentiality requests anymore, unless requested to do so by EFSA.

If EFSA requests the applicant to provide clarification on the information initially provided to justify a confidentiality request, and the applicant does not react by the given timeline, EFSA will reject the confidentiality request.

A comprehensive description of applicable procedures and provisions is available in EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a).

4.5.3. Parts of the application or information for which a confidentiality request can be submitted

Applicants may submit confidentiality requests only regarding the following items of the application or submissions, as indicated in the relevant Union law and specified in Annex A of EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a):

- the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety[167];
- commercial links between a producer or importer and the applicant or the authorisation holder, where applicable[168];

[167] Article 39(2)(a) of the GFL Regulation.
[168] Article 39(2)(b) of the GFL Regulation.

- commercial information revealing sourcing, market shares or business strategy of the applicant[169];
- quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety[170].

Personal data are processed in accordance with Regulation (EU) 2018/1725[171]. The following personal data must be made by law proactively available by EFSA:

a. the name and address of the applicant;

b. the names of authors of published or publicly available studies supporting an application; and

c. the names of all participants and observers in meetings of the Scientific Committee and the Scientific Panels, their working groups and any other ad hoc group meeting on the application.

In contrast, personal data (names and addresses) of individuals involved in testing on vertebrate animals or in obtaining toxicological information must not be made publicly available by EFSA.[172]

4.5.4. Processing of confidentiality requests

EFSA will assess each confidentiality request, by performing an individual examination of the information claimed as being confidential by the applicant and of the relevant justification provided.

Confidentiality requests are processed in accordance with EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a).

The notification of the confidentiality decision or the decision itself will also inform the applicant of its right to ask for a review of EFSA's confidentiality decision (confirmatory application).[173]

A comprehensive description of applicable procedures and provisions is available in EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a).

4.5.5. Possibility of commenting on, or challenging, a negative decision on a confidentiality request

Applicants have several opportunities to participate in the decision-making process regarding confidentiality requests made in respect to their dossiers and to put forward their views and observations.

Applicants have the opportunity to comment draft decisions on their confidentiality requests and challenge the decisions, once adopted:

a. **prior to the adoption of a decision** rejecting the applicant's confidentiality request in part or in full, by being consulted on the draft confidentiality decision;

b. **after the adoption of a confidentiality decision**, by making use of the possibility of submitting a confirmatory application;

c. **after the adoption of a decision on a confirmatory application**, by having the possibility of bringing an action for annulment against the decision on the confirmatory application pursuant to Article 263 of the Treaty on the Functioning of the European Union.[174]

A comprehensive description of applicable procedures and provisions is available in EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a).

---

[169] Article 39(2)(c) of the GFL Regulation.
[170] Article 39(2)(d) of the GFL Regulation.
[171] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98.
[172] Article 39(e)(2) of the GFL Regulation.
[173] In accordance with Article 39c of the GFL Regulation.
[174] Consolidated version of the Treaty on the Functioning of the European Union. OJ C 326, 26.10.2012, p. 47–390.

4.5.6. Implementation of EFSA's confidentiality decision

EFSA implements its confidentiality decisions without delay in accordance with its Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a). EFSA is responsible to implement the confidentiality decision in all documents, including the Evaluation report before publication. As regards the implementation of EFSA's confidentiality decision on the dossier, as a temporary solution pending the adaptation of the available software package, EFSA must ensure that the applicant implements EFSA's confidentiality decisions.

4.5.7. Implications of the award of confidential status to certain information

Information for which EFSA's decision on confidentiality is still pending or to which confidential status has been granted will not be made public. EFSA makes such information available to the European Commission and the Member States upon request, or if required as per Article 10(2) of Regulation (EC) No 396/2005.

All professionals having access to information for which EFSA's decision on confidentiality is still pending or to which confidential status has been granted are subject to the obligation of professional secrecy and bound to not disclose information to which confidential status has been granted. These obligations continue to apply even after their duties have ceased.

4.5.8. Proactive disclosure of the information contained in the application

During the life-cycle of the application, EFSA will proactively disclose information contained in the application dossier. Specifically:

- The non-confidential version of the dossier is published upon declaration of admissibility of the application;
- If confidentiality requests are rejected, an updated non-confidential version of the dossier is published upon implementation of EFSA's confidentiality decision;
- During the EMS's risk assessment or EFSA's peer-review, a non-confidential version of information provided at the EMS's or EFSA's request for supplementary information is published as soon as received;
- If confidentiality requests presented for the supplementary information are rejected, the updated non-confidential version of the information is published after implementation of EFSA's confidentiality decision, once EFSA's reasoned opinion is adopted.

4.6. Public consultation on information contained in the application

In accordance with Article 32c(2) of the GFL Regulation, in order to ensure that the EMS and EFSA have access to all relevant scientific data and studies available on the subject matter of an application, EFSA consults stakeholders and the public ('consultation of third parties') on the scientific data, studies and other information part of, or supporting, the submitted application to identify whether other relevant scientific data or studies are available.

Upon publication by EFSA of the non-confidential version of the application dossier, and following the implementation of the confidentiality decision (see Section 4.6), EFSA will launch a public consultation on its website. The consultation will last 3 calendar weeks.[175]

[175] In accordance with Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations (EFSA, 2021c).

All comments received from third parties will be made public by EFSA upon the closure of the consultation of third parties and will be brought to the attention of the EMS.[176] Relevant comments are considered by the EMS during the risk assessment and preparation of the evaluation report. The evaluation report should clearly report in an annex how the comments received have been taken into account.

For a comprehensive description of applicable procedures and provisions, please refer to EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c).

4.7. EFSA's assessment and publication of EFSA's reasoned opinion

The Pesticide Residues Unit, in close cooperation with the EMS assesses the MRL applications, performs a consumer risk assessment and determines the recommended MRLs.

If, in the context of EFSA's assessment, following a more extensive verification of the data submitted by the applicant in the application dossier, EFSA detects that the studies previously notified in accordance with Article 32b(2) and (3) of the GFL Regulation (See Sections 4.2 and 4.3) are not included in full in the submitted application dossier, EFSA requests the applicant to provide justifications regarding any missing data.

The applicant is informed that the time limit within which EFSA is required to deliver its opinion is suspended, pending the provision of valid justifications for the absence of certain data of studies previously notified. EFSA assesses the justifications provided by the applicant.

If the justifications are considered valid, EFSA's assessment re-starts and the applicant is informed accordingly.

If the justifications provided by the applicant are not considered valid, the applicant is requested to submit the missing data of the notified study/ies. The applicant is also informed that EFSA's assessment will remain suspended for six months after the submission of any missing data relating to any supporting notified studies.[177]

For details on implications and duration of the suspension, please consult EFSA's Practical Arrangements on pre-submission phase and public consultations (EFSA, 2021c).

Moreover, during the assessment, EFSA may request the applicant to submit supplementary information.[178] In case of a request for supplementary information, the time limit to deliver EFSA's reasoned opinion is extended ("stop-the-clock procedure").[179]

When responding to EFSA's requests, the applicant must upload the supplementary information using the IUCLID format and the EFSA central submission system through which the supplementary information is made available to EFSA, to the EMS, all Member States and the European Commission.

It is important to note that if the applicant submits new studies when addressing the request for supplementary information, the provisions of the GFL Regulation on the obligations of study notifications apply, if such studies are commissioned or carried out as of 27 March 2021 (see EFSA, 2021b and Section 4.2).

Confidentiality requests presented by applicants on the supplementary information are assessed in accordance with EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a). Upon receipt, EFSA will proactively disclose the non-confidential version of the supplementary information on the public IUCLID. The link to this version will be also made available through the OpenEFSA portal. If confidentiality requests presented on the supplementary information are rejected,

[176] The public disclosure of the comments received during the public consultation is done pursuant to Article 5(2), letter (g) of the Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality (EFSA, 2021a).
[177] In accordance with Article 32b(6) of the GFL Regulation.
[178] In accordance with Article 11(2) of Regulation (EC) No 396/2005.
[179] In accordance with Article 11 of Regulation (EC) No 396/2005.

the updated non-confidential version of the supplementary information is published after implementation of EFSA's confidentiality decision, once EFSA's reasoned opinion is adopted.

Following EFSA's decision on the confidentiality requests and upon implementation of the confidentiality decision (see Section 4.5), EFSA's reasoned opinion is published in the EFSA Journal.[180]

Should the reasoned opinion identify foreseeable effects regarding public health, animal health or the environment, and should these effects regard items that were granted confidential status pursuant to EFSA's Practical Arrangements above (EFSA, 2021a), EFSA will have to review the initial confidentiality decision in accordance with Article 39c of the GFL Regulation.

4.8. Withdrawal of an application

An applicant can withdraw its application at any time. Once the withdrawal of the application is submitted, all aspects related to the application process stop (e.g. EMS assessment, EFSA assessment, assessment of confidentiality).

When an applicant withdraws its application prior to the adoption of a confidentiality decision (see Section 4.5 and EFSA, 2021c), EFSA, the European Commission and the Member States must not make public the information for which confidential status had been requested.

In case an applicant withdraws its application after the adoption of a confidentiality decision, the European Commission, EMS, EFSA and other national authorities having access to the relevant information must comply with the confidentiality decision.

For the effects of the withdrawal on information made publicly available through the OpenEFSA portal, please refer to EFSA's Practical Arrangements concerning transparency and confidentiality (EFSA, 2021a), which give a comprehensive overview of the applicable procedure.

The withdrawal of an application after the adoption of an EFSA reasoned opinion has no effect on the adopted opinion, which will be in any case published, and remain published, in the EFSA Journal.

[180] http://www.efsa.europa.eu/en/publications

5. Interaction with EFSA staff during the life-cycle of the application

EFSA has implemented several initiatives to support applicants in understanding the evaluation process of applications for regulated products and to engage with them during all phases of the life-cycle of applications (i.e. pre-submission phase, preparation and submission of the application, the peer review of pesticide active substances or the risk assessment for MRL applications, adoption of EFSA's conclusions, or EFSA's reasoned opinions for MRL applications, and post-adoption phases).

For the different possibilities of interaction with EFSA in the different phases of the application life-cycle, please consult EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products (EFSA, 2021d).

The Catalogue also describes the dedicated support EFSA offers to small and medium-sized enterprises (SMEs).

References

ECHA (European Chemicals Agency), 2008. Guidance on information requirements and chemical safety assessment Chapter R.6: QSARs and grouping of chemicals. May 2008. Available online https://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9

ECHA (European Chemicals Agency), 2016. Practical guide How to use and report (Q)SARs. Version 3.1, July 2016. Reference: ECHA-16-B-09-EN; ISBN: 978-92-9247-809-4; Available online: https://echa.europa.eu/documents/10162/13655/pg_report_qsars_en.pdf/407dff11-aa4a-4eef-a1ce-9300f8460099

ECHA (European Chemicals Agency), 2017. Read-Across Assessment Framework (RAAF), March 2017. Reference: ECHA-17-R-01-EN; ISBN: 978-92-9495-758-0; available online: https://echa.europa.eu/documents/10162/13628/raaf_en.pdf/614e5d61-891d-4154-8a47-87efebd1851a

ECHA (European Chemicals Agency) and EFSA (European Food Safety Authority) with the technical support of the Joint Research Centre (JRC), Andersson N, Arena M, Auteri D, Barmaz S, Grignard E, Kienzler A, Lepper P, Lostia AM, Munn S, Parra Morte JM, Pellizzato F, Tarazona J,Terron A and Van der Linden S, 2018. Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA Journal 2018;16(6):5311,135 pp. doi:10.2903/j.efsa.2018.5311

EFSA (European Food Safety Authority), 2011. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092, 49 pp. doi:10.2903/j.efsa.2011.2092.

EFSA (European Food Safety Authority), 2014a. EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3):3615, 43 pp. doi:10.2903/j.efsa.2014.3615

EFSA (European Food Safety Authority), 2014b. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp. doi.org/10.2903/j.efsa.2014.3662

EFSA (European Food Safety Authority), 2014c. EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp. doi:10.2903/j.efsa.2014.3874.

EFSA (European Food Safety Authority), 2015. Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology. EFSA Supporting Publication 2015; 12(12):EN- 924. 62 pp. doi:10.2903/sp.efsa.2015.EN- 924

EFSA (European Food Safety Authority), 2016a. Technical report on the outcome of the pesticides peer review meeting on general recurring issues in mammalian toxicology. EFSA supporting publication 2016: 13(8):EN- 1074. 24 pp. doi:10.2903/sp.efsa.2016.EN- 1074

EFSA (European Food Safety Authority), Dehnen- Schmutz, K., Bastiaans, L., Chauvel, B., Gardi, C., Heppner, C., Koufakis, I., 2016b. Protocol for the evaluation of data concerning the necessity of the application of herbicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non- chemical methods. EFSA supporting publication 2016: 13(8):EN- 1060. 18 pp. doi: 10.2903/sp.efsa.2016.EN- 1060

EFSA (European Food Safety Authority), Buist H, Craig P, Dewhurst I, Hougaard Bennekou S, Kneuer C, Machera K, Pieper C, Court Marques D, Guillot G, Ruffo F and Chiusolo A, 2017a. Guidance on dermal absorption. EFSA Journal 2017;15(6):4873, 60 pp. doi:10.2903/j.efsa.2017.4873

EFSA (European Food Safety Authority), 2017b. Technical report on the outcome of the pesticides peer review meeting on the OECD 106 evaluators checklist. EFSA supporting publication 2017:EN-1326. 17pp. doi:10.2903/sp.efsa.2017.EN-1326

EFSA (European Food Safety Authority), Grégoire J.C., Jaques Miret J.A., González-Cabrera J., Heimbach U., Lucchi A., Gardi C., Erdos Z., Koufakis I., 2017c. Protocol for the evaluation of data concerning the necessity of the application of insecticide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods. EFSA supporting publication 2017:14(4):EN-1201. 26 pp.

EFSA (European Food Safety Authority), 2017d. Protocol for the evaluation of data concerning the necessity of the application of fungicide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods. EFSA supporting publication 2017:14(12):EN-1345. 30 pp. doi: 10.2903/sp.efsa.2017.EN-1345

EFSA (European Food Safety Authority), 2017e. Technical Report on the outcome of the pesticides peer review meeting on general recurring issues in physical and chemical properties and analytical methods. EFSA supporting publication 2017:EN-1221. 19 pp.doi:10.2903/sp.efsa.2017.EN-1221

EFSA (European Food Safety Authority), 2018. Technical report on the outcome of the pesticides peer review meeting on general recurring issues in mammalian toxicology. EFSA supporting publication 2018:EN-1485. 11 pp. doi:10.2903/sp.efsa.2018.EN-1485

EFSA (European Food Safety Authority), 2019a. Administrative guidance on submission of dossiers and assessment reports for the peer- review of pesticide active substances, EFSA supporting publication 2019: 16(4): EN- 1612. 49 pp. doi: 10.2903/sp.efsa.2019.EN- 1612

EFSA (European Food Safety Authority), 2019b. Technical report on the outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2019:EN-1673. 117 pp. doi:10.2903/sp.efsa.2019.EN-1673

EFSA (European Food Safety Authority), 2020. Technical report on the outcome of the pesticides peer review meeting on general recurring issues in mammalian toxicology. EFSA supporting publication 2020:EN-1837. 26 pp. doi:10.2903/sp.efsa.2020.EN-1837

EFSA (European Food Safety Authority), 2021a. Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality. Available online: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-transparency-and-confidentiality.pdf

EFSA (European Food Safety Authority), 2021b. Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009. Available online: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-confidentiality-Artt-7-and-16-of-regulation-1107-2009.pdf

EFSA (European Food Safety Authority), 2021c. Decision of the Executive Director of the European Food Safety Authority laying down the Practical Arrangements on pre-submission phase and public consultations. Available online: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/210111-PAs-pre-submission-phase-and-public-consultations.pdf

EFSA (European Food Safety Authority), 2021d. EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products. EFSA Supporting Publication 2021:EN-6472. 36 pp. doi:10.2903/sp.efsa.2021.EN-6472

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 268 pp doi:10.2903/j.efsa.2013.3290.

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2016. Guidance on the establishment of the residue definition for dietary risk assessment. EFSA Journal 2016;14(12):4549, 129 pp. doi:10.2903/j.efsa.2016.4549

EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), Ockleford C, Adriaanse P, Berny P, Brock T, Duquesne S, Grilli S, Hougaard S, Klein M, Kuhl T, Laskowski R, Machera K, Pelkonen O, Pieper S, Smith R, Stemmer M, Sundh I, Teodorovic I, Tiktak A, Topping CJ, Wolterink G, Bottai M, Halldorsson T, Hamey P, Rambourg M-O, Tzoulaki I, Court Marques D, Crivellente F, Deluyker H and Hernandez-Jerez AF, 2017. Scientific Opinion of the PPR Panel on the follow-up of the findings of the External Scientific Report 'Literature review of epidemiological studies linking exposure to pesticides and health effects'. EFSA Journal 2017;15(10):5007, 101 pp. doi.org/10.2903/j.EFSA.2017.5007

EFSA Scientific Committee (European Food Safety Authority Scientific Committee), 2011. Scientific Opinion on genotoxicity testing strategies applicable to food and feed safety assessment. EFSA Journal 2011;9(9):2379, 68 pp. doi:10.2903/j.efsa.2011.2379

EFSA Scientific Committee (European Food Safety Authority Scientific Committee), 2017a. Guidance on the use of the weight of evidence approach in scientific assessments. EFSA Journal 2017;15(8):4971, 69 pp doi:10.2903/j.efsa.2017.4971

EFSA Scientific Committee (European Food Safety Authority Scientific Committee), Hardy A, Benford D, Halldorsson T, Jeger M, Knutsen HK, More S, Naegeli H, Noteborn H, Ockleford C, Ricci A, Rychen G, Silano V, Solecki R, Turck D, Younes M, Aquilina G, Crebelli R, Gurtler R, Hirsch-Ernst KI, Mosesso P, Nielsen E, van Benthem J, Carfi M, Georgiadis N, Maurici D, Parra Morte J and Schlatter J; 2017b. Scientific Opinion on the clarification of some aspects related to genotoxicity assessment. EFSA Journal 2017;15(12):5113, 25 pp. doi: 10.2903/j.efsa.2017.5113

European Commission - Joint Research Centre, Computational Toxicology Group, Institute for Health and Consumer Protection, Ispra, Italy, 2010. Scientific report submitted to EFSA on the applicability of QSAR analysis to the evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for dietary risk assessment. EFSA supporting publication 2010.EN-50. 311 pp. doi:10.2903/sp.efsa.2010.EN-50

European Commission, 2012. Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009. SANCO/10597/2003 - rev. 10.1, 13 July 2012

European Commission, 2013a. Guidance document on rules for revision of assessment reports. SANCO/10180/2013 - rev. 1, March 2013

European Commission, 2013b. Guidance document on data requirements on efficacy for the dossier to be submitted for the approval of new active substances contained in plant protection products. SANCO/10054/2013 - rev. 3, 11 July 2013

European Commission, 2015. Draft Technical Guidance Document on assessment of negligible exposure of an active substance in a plant protection product under realistic conditions of use (points 3.6.3 to 3.6.5, and 3.8.2 of Annex II of Regulation (EC) No 1107/2009). SANCO/2014/12096), November 2015

European Commission, 2018. Guidance document MRL setting procedure in accordance with articles 6 to 11 of Regulation (EC) No 396/2005 and article 8 of Regulation (EC) No 1107/2009. SANTE/2015/10595 Rev. 5, 27 November 2018

European Commission, 2019. Technical Active Substance and Plant protection products: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex (Section 4) of Regulation (EU) No 283/2013 and Annex (Section 5) of Regulation (EU) No 284/2013. SANCO/3030/99 - rev. 5, 22 March 2019

OECD (Organisation for Economic Co-operation and Development), 2007. Guidance document on the validation of (quantitative) structure-activity relationships [(Q)SAR] models. ENV/JM/MONO(2007)2, 30 March 2007.

OECD (Organisation for Economic Co-operation and Development), 2016. Guidance Document for Conducting Pesticide Terrestrial Field Dissipation Studies, OECD Series on Testing and Assessment, No. 232. ENV/JM/MONO(2016)6, 4 March 2016.

OECD (Organisation for Economic Co-operation and Development), 2017. Guidance on Grouping of Chemicals, Second Edition, OECD Series on Testing and Assessment, No. 194. ENV/JM/MONO(2014)4, 14 April 2014.

Useful links

- Applicant toolkit:
  https://www.efsa.europa.eu/en/applications/toolkit
- IUCLID software:
  https://iuclid6.echa.europa.eu/it/download
- EFSA's Practical Arrangements:
  https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements
- EFSA Journal:
  http://www.efsa.europa.eu/en/publications
- Minutes of the pesticides working groups and composition of the working groups:
  https://www.efsa.europa.eu/en/pesticides/working-groups
- Panel on plant protection products and their residues:
  https://www.efsa.europa.eu/en/panels/ppr
- Pesticides peer-review experts meetings:
  http://www.efsa.europa.eu/en/pesticidespeerreview/peerreviewexpertsmeetings
- Networks supporting the Pesticides Peer-review Unit:
  http://www.efsa.europa.eu/en/pesticides/networks
- APDESK section on pesticides:
  http://www.efsa.europa.eu/en/applications/pesticides
- Overview of regulations and guidance documents for pesticide applications:
  https://www.efsa.europa.eu/en/applications/pesticides/regulationsandguidance
- Frequently Asked Questions:
  https://connect.efsa.europa.eu/RM/s/faq
- Ask a question webform:
  https://connect.efsa.europa.eu/RM/s/new-ask-efsa-request
- OpenEFSA portal:
  https://open.efsa.europa.eu
- Pesticides topic:
  http://www.efsa.europa.eu/en/science/pesticides
- European Commission's website on pesticides:
  https://ec.europa.eu/food/plant/pesticides_en
- List of National Competent Authorities and contacts:
  https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_legis_national-authorities_en.pdf

Abbreviations

ADME	Absorption, distribution, metabolism, excretion
APDESK	EFSA Applications Desk
AR	Application rate
CLH	Harmonised Classification and Labelling
Co-RMS	Co-Rapporteur Member State
DAR	Draft Assessment Report
DER	Data Evaluation Record
EC	European Commission
ECHA	European Chemicals Agency
ECX	Effective concentration
ED	Endocrine disruptor
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European Union
FOCUS	Forum for the co-ordination of pesticide fate models and their use
GAP	Good Agricultural Practice
GLP	Good Laboratory Practice
GPSA	General pre-submission advice
HCD	Historical control data
IUCLID	International Uniform ChemicaL Information Database
LoEP	List of endpoints
LOQ	Limit of quantification
MRL	Maximum residue level
OECD	Organisation for Economic Co-operation and Development
OHT	OECD Harmonised Templates
PDF	Portable Document Format
PPR	EFSA's Scientific Panel on Plant Protection Products and their Residues
PPP	Plant protection product
PRES	EFSA Pesticide residues Unit
PREV	EFSA Pesticide Peer-review Unit
PRIMo	Pesticide Residue Intake Model
QSAR	Quantitative structure–activity relationship
RAR	Renewal Assessment Report
RMS	Rapporteur Member State
RPSA	Renewal pre-submission advice
SD	Summary dossier (in Chapter 2)
SD	Standard deviation (in Chapter 3)

SME	Small and Medium-sized Enterprise
SSD	Sanitised summary dossier
TRR	Total radio-active residue
WoE	Weight of evidence

Appendices A and B can be found in the online version of this output (‘**Supporting information**’ section): https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2021.EN-6464

Appendix A – Completeness checklist for assessment reports

Appendix B – Justification form for confidentiality requests pertaining to the draft DAR/RAR, EFSA’s conclusions and background documents