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WORKING DOCUMENT

on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009

COMMISSION STAFF WORKING DOCUMENT – DOES NOT NECESSARILY REPRESENT THE VIEW OF THE COMMISION SERVICES

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Document history

Version	Date	Comment
9	21 March 2014	
10	25 January 2021	Partial update: Section 2[1], Section 3, Annex I and II were revised in view of implementation of the Transparency Regulation[2]. Applies to all applications submitted after 27 March 2021.
11	12 July 2023	Partial update: Section 2.4, first paragraph was revised.

[1] Not all Member States agreed with the last four paragraphs of Section 2.1 concerning the possibility of the coexistence of approval as a basic substance and as an active substance approved in accordance with Articles 7 to 13 of Regulation (EC) 1107/2009.

[2] Regulation (EU) No 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency of the EU risk assessment in the food chain and amending Regulations (EU) No 178/2002, (EC) No 1829/2003, No 1831/2003, (EC) No 2068/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283, and Directive 2001/18/EC, (OJ L 231, 6.9.2019, p. 1).

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Background

This document aims to provide guidance for the submission of applications concerning active substances which could be approved as "basic substances" according to provisions laid down by Regulation (EC) No 1107/2009[3] on placing plant protection products on the market ('PPP Regulation'). In addition, it aims to clarify the procedural steps for approval.

Regulation (EC) No 1107/2009 introduces the new category of "basic substances" which are defined by recital 18 as "certain substances which are not predominantly used as plant protection products may be of value for plant protection, but the economic interest of applying for approval may be limited. Therefore, specific provisions should ensure that such substances, as far as their risks are acceptable, may also be approved for plant protection use".

On this basis, specific provisions are set to ensure that such active substances, as far as they do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment, can be legally used in the EU after having been approved as "basic" under Regulation (EC) No 1107/2009.

In particular, Article 23 of the PPP Regulation lays down specific criteria to identify an active substance as eligible as basic:

a) is not a substance of concern as defined in Article 3(4) of the PPP Regulation; and

b) does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects; and

c) is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent; and

d) is not placed on the market as a plant protection product.

In addition, Article 23 of the PPP Regulation further states that "*an active substance which fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002[4] shall be considered as a basic substance*".

According to Article 2 of Regulation (EC) No 178/2002, 'food' (or 'foodstuff') means

> "*any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.*
>
> *"Food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes*

[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] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC[5].

'Food' does not include: (a) feed; (b) live animals unless they are prepared for placing on the market for human consumption; (c) plants prior to harvesting; (d) medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC; (e) cosmetics within the meaning of Council Directive 76/768/EEC; (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC; (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971; (h) residues and contaminants."

Therefore, ingredients such as food additives or flavourings are considered food and benefit from the provisions of Article 23 (1) of the PPP Regulation.

A basic substance should comply with the approval conditions of Article 23(2) of the same Regulation. In particular the substance should benefit from a previous evaluation under EU law and have no harmful effect on human or animal health and no unacceptable effect on the environment.

The basic substance will be then approved by the Commission and listed in a separate list in Regulation 540/2011[6], before its use is legal for plant protection purposes.

Finally, the PPP Regulation establishes that when a substance is approved as a basic substance, it is approved for an unlimited period of time and no authorisations will be required for sale and use of products consisting exclusively of basic substances.

[5] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. OJ L 330, 5.12.1998, p. 32–54.

[6] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

1 Compliance with established criteria on basic substances and their products

Information to be provided with the application must demonstrate the compliance of the substance with criteria of Article 23 of the PPP Regulation. The applicant will have to demonstrate that the substance is not a substance of concern; that it is not known to have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects and any immediate or delayed harmful effect on human or animal health nor any unacceptable effect on the environment, deriving from the use of the substance, either directly or in a mixture consisting of the substance and a simple diluent. Finally, the basic substance is not placed on the market as plant protection product.

The applicant must substantiate that the substance at issue complies with all criteria of Article 23(1) by means of information included in the application.

In order to be approved as a basic substance, it should also comply with Article 23(2) of the same Regulation, which means that the substance should have already been evaluated in view of other uses. The applicant must provide within the application all information on the assessments carried out under other legislative frameworks and a detailed description of the intended use pattern to exclude unacceptable risks. The substance must fulfil the specifications set under the other Union legislative frameworks. Those assessments should be collated, summarised and analysed to support the approval of the substance as "basic substance". The referenced studies should be submitted when available, at least an electronic reference should be provided.

1.1 Food or foodstuffs as defined in Regulation (EC) No 178/2002

In case of food or foodstuffs as defined in Regulation (EC) No 178/2002, the applicant should include all available assessments. When food grade specifications have been set, as in the case of additives, and such assessment is used to support the basic substance identification, again evidence should be provided to demonstrate compliance with those specifications (see Section 3 below). Nevertheless, in the case no specific assessment nor authorisation is required under EU food law, assessments may not be available. In this case, it is considered that the assessments are not necessary for the purpose of the Article 23, as the principle is that food does not present a risk for human health and does not require an assessment before being marketed, hence the qualification as food under Regulation (EC) No 178/2002 stands for a relevant evaluation (with respect to human health).

On the other hand, for all basic substances, it means that all evaluations carried out for example in the context of approval of food additives, pharmaceuticals and veterinary drugs, cosmetic, novel foods should be provided to support the identification and evaluation of the substance as basic substance under the PPP Regulation. However, additional risk assessment may be needed due to the specific use in plant protection. Risks can result from the manner of application, including possible outdoor uses of the substances, so that human and animal health, the environment and non-target organisms can be affected.

To substantiate a claim that a substance has no immediate or delayed harmful effect on human and animal health, nor an unacceptable effect on the environment, justifications can be included instead of studies and information, wherever appropriate. For example: it would be not necessary to supply an assessment of a specific risk, when the exposure by the plant protection use would only add a little to an existing exposure not subject to any limit. In that case the use

for plant protection would not pose any specific risk. In case of foodstuff the applicant will compile the application for the parts concerning description of the substance, the preparation of the substance (e.g. plant extracts) and of the product to be applied, the details of envisaged uses for plant protection, including information on the absence of any potential harmful effect on human and animal health or unacceptable effect on the environment and legal references to substantiate the claim that the substance is foodstuff.

For any application, the applicant is requested to submit all available information which might have also an influence on the setting of conditions for use according to Article 6 of the PPP Regulation.

Compliance with criteria of Article 23 (1) (c) and (d) of the same Regulation would need to be demonstrated under Section 2 of the Application (see Application template in Annex II). Section 3, below, will provide further clarification on these issues.

1.2 Products on the market containing exclusively one or more "basic substances" Article 28 (2) (a)

Since products falling under Article 28 (2) (a) of the PPP Regulation (products containing exclusively one or more basic substances) do not require any authorisation for use as they are on the market not as plant protection products, hence they do not profit from data protection under the Regulation, it can be anticipated that many applications will be mainly based on information which is already available, such as:

- unprotected studies
- scientific literature or
- a bibliographic review of safety data collated, for example in compliance with other Community regulatory frameworks together with an expert analyses complemented or supplemented by any data considered necessary to fulfil criteria.

Considering that no authorisation under the PPP Regulation will be necessary for placing a product on the market containing exclusively one or more basic substances (Art. 28 (2) (a)) as they are not plant protection products, it is the producer's responsibility to ensure that its product is safe in accordance with provisions of Product Safety Directive 2001/95/EC[7] and its respective national implementations.

The product shall not be placed on the market as a plant protection product, but the label on the product may indicate that the basic substances it contains are approved under Article 23 of the PPP Regulation.

Whenever, the producer will add a reference on the label of the product to Article 23 of PPP Regulation 9, it is recommended to add also any information related to conditions of approval of the basic substances of which the product consists of. However, it must be borne in mind that the product cannot be sold as plant protection product.

[7] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety. OJ L 11, 15.1.2002, p. 4–17.

It is recognised that the producer of such product may choose not to add such reference to the label. This may particularly be the case where the producer (under the other Union regulatory framework) is not the applicant for the approval as a basic substance. Hence, the Commission as well as Member States will have to put measures into place to inform the public of basic substance approvals and their respective conditions.

1.3 Products made of "basic substances" and other substances

Any other products deviating from the definition of Article 28 (2) (a) of the PPP Regulation containing for example an already approved "basic substance" and a co-formulant shall have to be considered as plant protection product. Therefore, in compliance with Article 2 of the same Regulation in that case the substance will constitute the "active substance". In such case, the substance need to be approved as active substance. An application accompanied by a dossier in compliance with Article 8 of the PPP Regulation will have to be submitted.

In the hypothetical case of a substance already listed as "basic" where an applicant would submit an application for an approval as "active", the applicant will provide evidence in conformity with data requirements for the "active" substance, including efficacy data. Moreover, for example in the case of a basic substance being a plant extract the "active" can often be linked to a specific component, hence related to a purified extract not yet available on the market and having own specifications different from the basic substance already approved. In this last case, the two compounds having different specifications will potentially be listed separately.

On the contrary, a basic substance may be used in a formulation of plant protection product together with one or more active substances, as it has already been clarified in the document Questions and Answers on Regulation (EC) No 1107/2009 available at the DG SANTE webpage (https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_legis_qanda_regulation_1107-2009.pdf).

Therein, it is stated: *" ...If a basic substance is mixed with an active substance and it is intended to be used for one of the purposes listed in Article 2(1) paragraphs a) to e) of Regulation (EC) No 1107/2009, the mixture will be considered as a plant protection product. This plant protection product may not be placed on the market or used unless it has been authorised in the Member State concerned.*

The active substance contained in the plant protection product needs to be approved as described in Articles 4 to 13 of Regulation (EC) No 1107/2009. The basic substance which is contained in the plant protection product does not need to be approved as an active substance following the procedure described in Articles 7 to 12, nor according to the procedure described in Article 23. In fact, in case of a product containing at least one active substance, it is irrelevant if the other components are basic substances or not.

When a Member State receives an application for the authorisation of a plant protection product consisting of a mixture of a basic substance with an active substance, it will evaluate the plant protection product containing the basic substance in the same way as in the case of a plant protection product containing a co-formulant."

For sake of clarity, with respect to plant protection products assessment, any substance has to be evaluated for its specific function in the formulation as being in the scope of the PPP Regulation laid down in its Article 2(3). On the basis of its function, it is added to the formulation itself and such function must be duly substantiated with scientific evidence.

2 How to apply for approval of a basic substance

Applications for the approval of a basic substance may be submitted to the European Commission by Member States or any other interested party.

2.1 Responsibilities of the applicant

The applicant is responsible for:

- Providing sufficient information to show that the substance complies with the criteria of Article 23 of the PPP Regulation to be approved as a basic substance, taking into account the guidance provided in this document;
- Providing only trustworthy information and to include in the application any relevant information on any foreseeable negative effects;
- Seeking general pre-submission advice from EFSA when considered relevant;
- Notifying EFSA without delay of information related to scientific study/ies [8] commissioned or carried out to support his/her application (see Section 2.2.2);
- Submitting a complete application in accordance with the recommended template and format (see Section 2.2.2) and ensuring that all references used are valid, relevant and available in the bibliography. The applicant should examine and summarise each reference used (in accordance with Section 3.5 of this document);
- Submitting requests to treat certain parts of the information as confidential, pursuant to Article 63 of the PPP Regulation and EFSA's Practical Arrangements concerning transparency and confidentiality[9], outlining the reasons why they consider such a request is justified[10];
- Responding timely to requests for further information by the Commission or EFSA.

The applicant needs to be aware that it is not allowed to market basic substances as plant protection products and therefore they may not be placed on the market as such, i.e. they need to have another primary purpose. Applicants wishing to place (products containing) basic substances on the market solely for the purpose of plant protection must apply for approval of the active substance in accordance with Articles 7 to 13 of the PPP Regulation.

The applicant needs to be aware that in case a substance is approved as a 'regular active substance' (i.e. approved in accordance with Articles 7 to 13 of the PPP Regulation), no application for approval as basic substance for the same substance will be accepted.

[8] As defined in Section 3 of Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations. Available on EFSA's website

[9] Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality. Available on EFSA's website

[10] The applicants should note that for basic substances only a few confidentiality requests have been accepted up to date. See also section 2.2.2.

The applicant needs to be aware that in case an application for approval as a 'regular active substance' is pending, this substance will be evaluated as a regular active substance in accordance with Articles 7 to 13 of the PPP Regulation. No application for approval as basic substance for the same substance will be accepted.

In case the approval of a regular active substance has expired, plant protection products containing the active substance are eventually no longer authorised in the EU. If the active substance itself complies with the criteria for approval as a basic substance, then an applicant could apply for the approval as a basic substance for this previously approved regular active substance.

2.2 Overview of the approval procedure

Applications for the approval of a basic substance may be submitted to the European Commission by Member States or any other interested party.

The approval procedure consists of the following steps:

1. Pre-submission phase
    - General pre-submission advice (optional)
    - Notification of studies (mandatory if such studies are commissioned or carried out)
2. Submission of the application
3. Validity check of the application
4. Confidentiality decision
5. Public consultation and possibility to propose additional uses
6. Consultation of Member States and publication of EFSA Technical Report
7. Decision making in Standing Committee on Plants, Animals, Food and Feed and adoption and publication of review report and (non-)approval regulation

The flowchart of the process of approval as basic substance and indicative timelines are included in Annex I.

2.2.1 Step 1. Pre-submission phase

The information included in this guidance only aims at providing an overview to applicants on the procedure to be followed in the pre-submission phase and it should be read in conjunction with Regulation (EC) No 178/2002, Regulation 1107/2009 and EFSA's Practical Arrangements on pre-submission phase and public consultations, available on EFSA's website[11], which provide comprehensive information and instructions on that matter.

Before submitting an application for approval of a basic substance, a potential applicant shall first register in EFSA's portal supporting pre-submission activities, available on EFSA's

[11] Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations. Available on EFSA's website

website[12]. 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, to be used for any activity related to the pre-submission phase, if applicable:

- possibility to request general pre-submission advice from EFSA (optional);
- notification of information related to studies commissioned/carried out (mandatory if such studies are commissioned or carried out);

The pre-application identification reference, if any, shall be provided when submitting the application (see Section 2.2.2).

2.2.1.1. General pre-submission advice (optional)

Specific provisions establishing the procedures for the provision of general pre-submission advice and, the relevant modalities to be followed by applicants are set in EFSA's Practical Arrangements on pre-submission phase and public consultations which are available on the website of EFSA[13].

A potential applicant for the approval of a basic substance may, at any time after having obtained a pre-application identification and before the submission of the envisaged application, request general pre-submission advice (GPSA) from EFSA. The GPSA is optional for the potential applicant and aims at providing guidance on the rules applicable to, and the content required for, the application.

The following items are considered out of the scope of the GPSA:

- design of studies intended 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, scientific opinions, guidance documents or guidelines applicable to applications.

Requests for general pre-submission advice should be submitted to EFSA by filling in the dedicated general pre-submission advice online form ('General Pre-submission Advice form') available on the EFSA website[14]. The request may be submitted at any time before submitting the corresponding envisaged application but it is recommended to submit the request for such an advice at least six months before the envisaged submission date of the application[15].

Following an administrative check EFSA will provide its feedback on whether the submitted request is accepted or rejected within 15 working days from the receipt of the General Pre-submission Advice form. For accepted requests, EFSA will decide upon the most appropriate

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

[13] Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements on pre-submission phase and public consultations. Available on EFSA's website

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

[15] See in particular Article 7 of the EFSA's Practical Arrangements on pre-submission phase and public consultations. Available on EFSA's website

manner to address the questions posed through the General Pre-submission Advice form, by implementing the following working procedures:

- where possible, EFSA will answer the questions in writing;
- in case EFSA considers that a discussion with the potential applicant might be useful to clarify specific aspects of the request, EFSA will organise a meeting by teleconference or video conference. In exceptional circumstances, EFSA may decide to organise a physical meeting.

EFSA will provide its advice to the potential applicant in accordance with the timelines indicated in Article 9 of the Practical Arrangements:

a) for requests, or questions included in a request, in response to which EFSA has decided to reply in writing, the written advice should be provided within 15 working days as of the date of the acceptance of the request;

b) for requests, or questions included in a request, in response to which EFSA has decided to organise a meeting, the meeting should be organised within 20 working days as of the date of the acceptance of the request. The advice shall be provided during the meeting.

EFSA may decide to consult the Commission where considered appropriate. EFSA will draw up a summary of the advice and will send this summary to the potential applicant(s) for information. Following the submission of the application for which general pre-submission advice was requested, in order to allow for the public disclosure of the summary, the Commission will inform EFSA without delay of any positive conclusion as regards the validity of that application.

Any general pre-submission advice provided to a potential applicant shall be without prejudice and non-committal as to the subsequent assessment of an application by EFSA, the Member States and the Commission.

2.2.1.2. Notification of studies (mandatory if such studies are commissioned or carried out)

The information included in this guidance only aims at providing an overview to applicants on the procedure and it should be read in conjunction with Regulation (EC) No 178/2002, Regulation 1107/2009, and EFSA's Practical Arrangements setting out specific and comprehensive provisions establishing the notification procedures.[16]

Experience to date has shown that applications for basic substances are mainly based on information which is already publicly available, such as unprotected studies, scientific literature or a bibliographic review of safety data collated, for example in compliance with other Union regulatory frameworks together with an expert analysis complemented or supplemented by any data considered necessary to fulfil the criteria under Article 23 of the PPP Regulation.

[16] See Chapter IV on notification on studies of the Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations. Available on EFSA's website

Nevertheless, in case the potential applicant commissions or carries out one or several scientific study/ies[17] to support his/her application after 27 March 2021, he/she shall, without delay, notify to EFSA certain information[18] related to those studies in accordance with Article 32b of Regulation (EC) No 178/2002[19]. The same obligation applies to the laboratories and other testing facilities located in the EU[20] which carry out the studies commissioned by potential applicants.

Study notifications shall be submitted in the database of study notifications available on the EFSA website[21] without delay before the starting date of the study. The database will assign a unique study identification to each study notification. For any study notification submitted after the starting date of the study, at application submission phase, the applicant shall provide justifications for the delay.

The obligations on notifications of studies also apply to any additional study commissioned or carried out after the submission of the initial application and submitted during the assessment of the application as part of the updated application.

2.2.2 Step 2. Submission of the application

The information included in this guidance only aims at providing an overview to applicants on the submission procedure and it should be read in conjunction with Regulation (EC) No 178/2002, Regulation 1107/2009, and EFSA's Practical Arrangements on confidentiality and transparency available on EFSA's website[22], which provide comprehensive information and instructions on that matter.

In order to support an application, the applicant has to submit an application dossier, containing scientific information and studies. Applications should be submitted electronically through a central submission system using the IUCLID (International Uniform ChemicaL Information Database) software package (freely available online) [23], which allows to share them automatically among the European Commission, the Member States and EFSA.

[17] As defined in Section 3 of Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations. Available on EFSA's website.

[18] This information includes: title and scope of the study, laboratory or testing facility carrying out the study, starting and planned completion dates of the study. The full list of information to be notified for each study is provided in Annex II to EFSA's Practical Arrangements on pre-submission phase and public consultations.

[19] Regulation (EU) 2019/1381 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, OJ 6.9.2019 L 231/1.

[20] 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 Regulation (EC) No 178/2002.

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

[22] Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality. Available on EFSA's website

[23] IUCLID is a software application to record, store, maintain and exchange data on intrinsic and hazard properties of chemical substances and is used to prepare application dossiers in a structured format. Available at: https://iuclid6.echa.europa.eu/it/download

More information on how to submit an IUCLID application dossier via the central submission system is available on the EFSA webpages[24].

Where pre-submission activities have been carried out (see Section 2.2.1) in relation to the application for approval of the basic substance, applicants should provide the pre-application identification received.

The application dossier should include the following elements:

- the application template filled in by the applicant, as set out in the Annex II to this guidance;
- the summary of intended uses for plant protection purpose (Good Agricultural Practices (GAP));
- the full text of each cited literature reference;
- the full text of each test/study report if such reports are submitted,
- if the applicant intends to request to treat certain information as confidential in accordance with Article 63 of the PPP Regulation, such request will need to be included using the relevant IUCLID functionality by complying with EFSA's Practical Arrangements concerning transparency and confidentiality;
- a non-confidential (i.e. sanitised) version of each document submitted in the dossier for which confidentiality is requested;
- if studies were commissioned or carried out, all information needed to comply with obligations related to study notifications[25] (see Section 2.2.1.2.), in particular:
  - pre-application identification provided to the applicant at pre-submission phase; and
  - the study notification identifications generated by the database for each study submitted in the application.
  - if necessary, the justifications explaining the divergences between the information notified in accordance with Section 2.2.1.2. and the studies included in the application dossier[26], linked, where applicable, to the study identifications.

For a comprehensive description of the information to be provided when submitting applications to allow verification of compliance with study notifications obligations, the applicant should refer to the Practical Arrangements on pre-submission phase and public consultations[27] available on EFSA's website.

For further information on how to fill in specific sections in IUCLID, and on the content of the application, the applicant is advised to refer to Section 3 and Annex II of this guidance and the IUCLID user manual.[28]

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

[25] In accordance with Article 32b of Regulation (EC) 178/2002 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'.

[26] In particular, the justification should be provided if studies included in the application were not previously notified in the database and if studies previously notified in the database were not included in the application.

[27] See in particular Chapter IV on notification of studies of the Decision of the Executive Director of the European Food Safety Authority laying down the practical arrangements on pre-submission phase and public consultations.

[28] IUCLID users manual is available at https://www.efsa.europa.eu/en/applications/toolkit

Confidentiality

According to Article 38 (1) (c) of Regulation (EC) No 178/2002, all scientific and other information, including studies submitted by an applicant to support an application for the approval of active substances shall be made publicly available by EFSA in a dedicated section of EFSA's website, once an application is found valid, except for information that has been claimed confidential by the applicant and granted confidential status pursuant to Article 63 of the PPP regulation.

Even though experience to date has shown that applications for the approval of basic substances rarely contain information that can be considered confidential, the applicant may include a request for certain information to be treated as confidential in accordance with Article 63 of the PPP Regulation and provided that such information falls within the scope of information items for which confidentiality treatment may be claimed. In that case, the applicant shall provide verifiable justification demonstrating that the public disclosure of such information potentially harms its interests to a significant degree, in accordance with EFSA's Practical Arrangements concerning Transparency and Confidentiality[29].

It should be noted that the concept of basic substances implies that no commercial interest is involved in the approval as a basic substance, since this substance should already be placed on the market for purpose(s) other than for plant protection. Therefore, it is in generally expected that applications for approval of basic substances contain very limited information that could be considered as compliant with Article 63 of the PPP Regulation and EFSA's Practical Arrangements concerning Transparency and Confidentiality.

Article 63 of Regulation (EC) No 1107/2009[30] identifies the closed positive lists of the items for which confidentiality requests may be introduced.

EFSA's Practical Arrangements concerning Transparency and Confidentiality [31] set out comprehensive information about substantive and procedural requirements applicable to the confidentiality requests and decision making.

IUCLID 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).

[29] Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality. Available on EFSA's website

[30] 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. OJ L 231, 6.9.2019.

[31] Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality. Available on EFSA's website

Consequently, for each confidentiality request submitted, applicants are required to provide:

- the reasoning for the request, 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.
- a confidential version of the concerned document (not for public disclosure) with all information visible. In this version, all information claimed to be confidential by the applicant should be boxed or earmarked;
- a non-confidential (i.e. sanitised) version of the concerned document (for public disclosure) with all elements claimed to be confidential blackened (i.e. sanitised). This version will be made publicly available in the dissemination portal[32] as soon as the application is declared valid and will be later replaced by an updated version pursuant to EFSA's confidentiality decision, in case one or more requests for confidentiality are rejected.

2.2.3 Step 3. Validity check of the application

The Commission will perform a check of the application submitted *via* the central submission system in IUCLID format prior to its assessment. Checking the validity of an application will cover two main aspects:

- verification of compliance with the definition of basic substances, the level of information provided in the application and the references to studies/documentation. In the event that the application is incomplete and thus considered not suitable for commencing the evaluation, the applicant will be given the possibility to provide additional information and complete the application within 3 months.

- verification of compliance with the obligation of study notifications (see Section 2.2.1.2.) concerning the notified studies, if any, and the justification provided in case less or more studies are included in the application compared to those notified. In particular, an application will not be considered valid where it is supported by studies that have not been previously notified, unless the applicant provides a valid justification for the non-notification of such studies, or it does not contain studies which were previously notified in the database, unless the applicant provides a valid justification for the non-inclusion of such studies.

  In the event that the application is not considered compliant with respect to the obligations of study notifications, the Commission will invite the applicant to notify in the database the studies which have not been previously notified or to submit the missing studies and to re-submit the application. The assessment of the validity of such a re-submitted application will commence six months after re-submission.[33]

Once an application has been found valid for further evaluation, the Commission will inform the applicant and EFSA accordingly.

[32] OpenEFSA portal available at: https://open.efsa.europa.eu

[33] Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements on pre-submission phase and public consultations. Available on EFSA's website

Upon receipt of the confirmation of the validity of the application by the Commission, EFSA will make public the non-confidential version of the application dossier provided by the applicant in a dedicated section of EFSA's website[34,35] and at the same time, the Commission will register the application in the Pesticides Database[36].

2.2.4 Step 4. Confidentiality decision making

In case an applicant has requested confidentiality for certain elements in the application, EFSA will assess the requests and decide which information is to be treated as confidential. The confidentiality decisions taken by EFSA will be adopted in accordance with EFSA's Practical Arrangements concerning Transparency and Confidentiality available on EFSA's website[37].

If there is a discrepancy between EFSA's decision on confidentiality and the applicant's confidentiality requests, for the time being, pending the adaptation of the available software package (IUCLID), the applicant will be required to implement EFSA's confidentiality decision by making the necessary changes to the non-confidential version of the dossier submitted.

With the development of more advanced IUCLID functionalities, the implementation of the confidentiality decision will be performed by EFSA.

2.2.5 Step 5. Public consultation and possibility to propose additional uses

Public consultation

In order to ensure access to all relevant scientific data and studies available on the subject matter of an application, EFSA will consult stakeholders and the public[38] ('consultation of third parties'). EFSA will do so by making publicly available the non-confidential version of the application dossier updated so as to implement EFSA's confidentiality decision.

The consultation of third parties will remain open for a period of 3 calendar weeks. For further details, please refer to Chapter V on Public consultation on submitted applications of the Practical Arrangements of EFSA[39].

Extension of the application to support additional uses

During the public consultation period, Member States or any interested party may provide also additional information on uses of the basic substance which are beyond the uses supported by the applicant. These additional uses will be included in the assessment under the following considerations:

[34] As specified in Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements on pre-submission phase and public consultations. See in particular Chapter V on Public consultation on submitted applications. Available on EFSA's website

[35] OpenEFSA portal available at: https://open.efsa.europa.eu

[36] EU Pesticides Database – available at : https://ec.europa.eu/food/plant/pesticides/eu-pesticides-db_en

[37] Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements concerning transparency and confidentiality. Available on EFSA's website

[38] in accordance with Article 32c(2) of Regulation (EC) No 178/2002 and with the relavant EFSA's practical arrangements

[39] Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements on pre-submission phase and public consultations. Available on EFSA's website

- If additional uses proposed by Member States or interested third parties are less or equally critical as the uses included in the original application (i.e. they are within the same "risk envelope[40]"), no additional data are needed for including them in the assessment.

- For additional uses which are not covered by the original application, leading to potentially higher risk to humans, animals or the environment (e.g. uses where the supported application rates are higher), the Member States or interested parties proposing the additional uses shall provide evidence that the proposed additional uses meet all the approval criteria of Article 23 of the PPP Regulation (see also Section 2.3 on an application for an extension of use). If no additional data are provided to support such additional uses, those uses may not be included in the assessment.

The comments received in the framework of the public consultation performed in accordance with Article 32c (2) of Regulation (EC) No 178/2002 will be made public by EFSA without delay after the closure of the public consultation.[41]

Further detailed information is available in the corresponding Practical Arrangements established by EFSA.[42]

2.2.6 Step 6. Consultation of Member States and publication of EFSA Technical Report

After the closure of the public consultation, EFSA will collate all comments received during the public consultation, including information on proposed additional uses if any, and provide them to the Member States together with the application for their assessment. EFSA will allow a period of two months for Member States experts to comment.

At the end of that period, EFSA experts will also provide observations, and EFSA will collate all the comments (received during the public consultation and from the Member States and EFSA) in a structured reporting table and forward it to the applicant within a period of three weeks.

The applicant will be required to respond to the comments received in the reporting table and, where relevant, to provide an application updated accordingly through the central submission system using the IUCLID software package within a period of 60 days. The non-confidential version of the updated application will be made public by EFSA.

After that period, on the basis of a specific mandate from the Commission, EFSA will consider the responses from the applicant, finalise the reporting table on each specific point raised and, based thereon, provide its scientific opinion to the Commission in accordance with Article 23 of the PPP Regulation.

EFSA will deliver its scientific opinion within 3 months from the reception of the specific mandate from the Commission. The scientific opinion of EFSA will be in the form of a Technical Report with a brief discussion of the main findings and outcome for each section,

[40] 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

[41] See Sections 26(6) and 27 of the Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements on pre-submission phase and public consultations.

[42] Decision of the Executive Director of the European Food Safety Authority laying down practical arrangements on pre-submission phase and public consultations. Available on EFSA's website

including consideration of the comments in the completed reporting table. This Technical Report will include information on the identity and (biological) properties of the substance and on the Good Agricultural Practices (GAP) for all intended uses for plant protection purpose and will include the finalised reporting table.

Applicants should note that if EFSA, following a more extensive verification of the data submitted by the applicant, detects during its risk assessment that studies previously notified in the database were not submitted in full, will require the applicant to provide a justification to that effect. In case the justification is considered not valid, EFSA will inform the applicant that the time-limits within which EFSA is required to deliver its scientific output are suspended. The suspension will end six months after the submission of all data of those studies.

EFSA will make the Technical Report (including the finalised reporting table) available to the public.

On the basis of the Technical Report, the Commission may decide to request EFSA to organise a complete or focused peer review, or to deliver its conclusion on certain specific open points.

2.2.7 Step 7. Decision making and publication of (non-)approval regulation

The standard procedures for decision making as set out in Article 13 of the PPP Regulation will apply.

The Commission, within 6 months from the delivery of the Technical Report or finalisation of a complete or focused peer review by EFSA (if requested), will prepare a draft review report on whether the criteria for the approval of the basic substance are met. The applicant will be given the possibility to comment on the draft report.

The Commission will submit the review report and, if applicable, a draft Regulation for approval (or non-approval) of the substance as a basic substance to the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF).

In line with the examination procedure laid down in Regulation (EU) No 182/2011[43], following a vote on the draft Regulation in SCoPAFF, the Commission will adopt a Regulation to approve and include the basic substance in Part C of the Annex to Regulation 540/2011, or not to approve the basic substance. Conditions and restrictions of approval can be set as appropriate in accordance with Article 6 of the PPP Regulation and, where relevant, are included in the approval Regulation and the review report.

After publication in the Official Journal, the (non-)approval Regulation and the review report will then also be made public in the EU Pesticides Database.

Considering that basic substances are not subject to any further authorisation assessment, the approval of a basic substance and its conditions of use will have to be communicated by the competent authorities to the general public and professionals, by means of their national

[43] Regulation (EU) No 182/2011 of the Euroepan Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers. O.J. L 55, 28.2.2011, p. 13.

websites and/or by any other form of communication appropriate to ensure the information will reach potential users.

2.3 Application for an extension of use

Basic substances are approved for specific intended uses supported by the applicant in the submitted application or by Member States or other interested parties during the public consultation period.

At any time, Member States or any other interested party (including the applicant who submitted the original application for approval) can apply for an extension of use through the same procedure as described under Sections 2.2.1 and 2.2.2.

The applicant for the extension of use shall in his/her application provide evidence that the proposed extension of use meets all the approval criteria of Article 23 of the PPP Regulation. The applicant can make use of the original application and the available EFSA Technical Report, and shall provide additional information as required to demonstrate that the substance is still compliant with the criteria for the additional uses. The application for an extension of use as basic substance should be submitted electronically through a central submission system using the IUCLID software package.

Two cases can be foreseen:

1. Additional uses are covered by the original GAP of the application. The risk assessment already performed for the uses included in the original application and presented in the already published Technical Report of EFSA can be easily extrapolated to the additional uses (i.e. the risk envelope approach can be applied, see Section 2.2.5. The applicant for extension of use does not have to provide additional data supporting the risk assessment but shall provide the necessary rationale to demonstrate that the additional uses are covered by the original GAP.

2. Additional uses are not covered by the original GAP of the application. Applicants who want to support additional uses should compile the necessary data to support those uses and submit them as part of an application.

Following the procedure as described in Sections 2.2.3 to 2.2.6, the Commission will present a revision of the review report, including consideration on whether the substance meets the criteria of Article 23 of the PPP Regulation for the extended uses and, if applicable, a draft Regulation amending the conditions of approval, to the Standing Committee for Plants Animals Food and Feed (SCoPAFF). The procedure described in Section 2.2.7 will follow.

2.4 Withdrawal of an application

A withdrawal of an application is possible at all stages of the procedure preceding the moment when the Member States represented in SCoPAFF will have voted on the Commission's proposal for approval (or non-approval) of the substance. The withdrawal of the application interrupts the procedure and a decision by the Commission is only required when the withdrawal occurs after the adoption of the EFSA output.

The withdrawal of an application after the adoption of an EFSA Technical Report has no effect on the adopted output, which will be in any case published, and remain published, on the EFSA website. For the effects of the withdrawal on information made publicly available on EFSA's dissemination portal[44], refer to EFSA's Practical Arrangements concerning Transparency and Confidentiality.

The withdrawal is effective when the applicant submits to the Commission a letter or an e-mail clearly expressing his/her decision to withdraw the application, notifying *via* e-mail also EFSA. The address to which such a withdrawal request should be sent is: sante-consult-e4@ec.europa.eu (Commission) and pesticides.peerreview@efsa.europa.eu (EFSA).

A withdrawal of an application for approval of a basic substance is without prejudice to a new application for the same substance by the same or other applicants.

2.5 Review of approved basic substances

Approvals of basic substances are for an unlimited period of time. However, the Commission may review the approval of a basic substance at any time in accordance with Article 23(6) of the PPP Regulation. This may lead to the withdrawal of approval or to a revision of the conditions of approval of the basic substance.

[44] OpenEFSA portal available at: https://open.efsa.europa.eu

3 Content of the application

3.1 Elements of the application dossier

The application dossier should be submitted *via* IUCLID and should include the following elements:

1. the application template filled in by the applicant as set out in the Annex II to this guidance, submitted in pdf or Word format;
2. the summary of the intended uses for plant protection purpose (Good Agricultural Practices (GAP), to be to be filled in directly in IUCLID);
3. the full text of each cited literature reference;
4. the full text of each test/study report if such reports are submitted;
5. if the applicant requests to treat certain information as confidential in accordance with Article 63 of the PPP Regulation , such request will need to be included using the relevant IUCLID functionality;
6. a non-confidential (sanitised) version of each document submitted in the dossier for which confidentiality is requested;
7. if studies were commissioned or carried out for the purpose of the application, all information needed to comply with the obligations related to study notifications (see Section 2.2.1.2.), in particular:
   - the pre-application identification provided to the applicant at pre-submission phase; and
   - the study notification identifications generated by the database for each study submitted in the application.
   - if necessary, the justifications explaining the divergences between the information notified in accordance with Section 2.2.1.2. and the studies included in the application dossier, linked, where applicable, to the study identifications.

3.2 General remarks

In general, Article 23(3) of the PPP Regulation requires that:

"The application shall be accompanied by the following information:

- any evaluations of its possible effects on human or animal health or the environment carried out in accordance with other Union legislation regulating the use of the substance; and
- other relevant information on its possible effects on human or animal health or the environment."

The application template is based on the structure of the EU assessment report that is compiled for active substances to be used in plant protection products. It refers to all areas of the risk assessment usually evaluated in regulating uses of plant protection products and has to be considered as a structured template to elaborate a file collating and assessing all possible information to demonstrate that basic substances criteria[45] are fulfilled.

[45] Article 23 of the PPP Regulation lays down specific criteria to identify an active substance as eligible as basic; see also Background section to this guidance.

The applicants should note that the legal frameworks under which substances are regulated in accordance with other Union legislation provide for specific approval criteria and may differ in the level of protection of human or animal health and the environment. Therefore, in the assessment of the application, the level of protection of human and animal health and the environment as ensured by the PPP Regulation will be taken as a reference.

The amount of information to be provided with the application will depend on the properties of the substance and its intended uses. The application template, which is included as Annex II to this Guidance, is therefore quite comprehensive, but the application should be completed in a proportionate manner and matters which are not relevant need not to be addressed. In cases where an item is considered not applicable or not appropriate by the applicant, the applicant will restrict his contribution under this item to "Not applicable" together with a justification why he deems this item not to be applicable/appropriate for the substance in question.

While preparing the dossier, the applicant is advised to refer to the relevant technical guidance documents related to the approval of regular active substances issued by the European Commission and to EFSA's guidance documents and opinions available on the Commission's and EFSA's websites[46]. The comprehensive explanation of the type of information to be preferably submitted to support the application can be found in the data requirements included in Regulation (EU) No 283/2013[47] and the accompanying Communication[48] and Regulation (EU) No 284/2013[49].

Information related to basic substances available on the market as foodstuffs

For basic substances that are foodstuffs[50], the risks are supposed to be inherently low for human health. However, this assumption applies only to cases where exposure resulting from the use in plant protection is comparable to the use as foodstuff. Human and animal health, the environment and non-target organisms can be affected since risks can result from the manner of application and given the possible outdoor uses of the substances.

Therefore, it is important to provide a detailed description of the intended use pattern and results of any assessment carried out on the substance to demonstrate that this substance has no immediate or delayed harmful effect on human or animal health and no unacceptable effects on the environment (Art (4) of the PPP Regulation). A comparison should be made of the exposure to the substance when used as a foodstuff and the exposure when it is used for plant protection

[46] https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en
[47] Commission Regulation (EU) No 283/2013 of 1 March 2013setting 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.
[48] Commission Communication in the framework of the implementation of 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 C 95, 3.4.2013, p. 1–20.
[49] Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, 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. 85–152.
[50] 'Foodstuff'is defined in Article 2 of Regulation (EC) No 178/2002. See also the Background section of this guidance.

purposes, and all routes of exposure need to be addressed. The identity and specification of the basic substance used in plant protection should be compared to its identity as specific foodstuff.

3.3 Supporting evidence, references and bibliography

The statements included in the application should be supported by scientific data and/or relevant references to study reports, scientific publications, regulatory evaluations finalised in the context of authorisation for other uses e.g. food additive assessments, as well as evaluations available in OECD or other countries etc. These references should be examined, summarised and used in an argumentation showing that the proposed uses meet the criteria for a basic substance.

All relevant available information submitted with the application (studies, scientific publications, regulatory evaluations etc.) should be submitted in digital form *via* IUCLID and always listed in Section 10 of the application template as reference relied upon. References should be ordered by section of the application template (in alphabetical order or by order of appearance) and bear filenames that correspond to the references as made in the application.

To include peer-reviewed open literature, the applicant should follow the recommendations of the specific European Food Safety Authority (EFSA) Guidance on submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009[51].

For EU assessments, such as opinions of the EFSA, a reference with a link to the electronic version of the report is sufficient. For all other publications or reports referred to in the application, an electronic copy, preferably in PDF format, should be included with the application. Preferably all quoted publications should be available in English to facilitate the commenting by Member States during the consultation process.

The applicant must ensure that terms and conditions asserted by any copyright holder of publications or information submitted to EFSA are fully satisfied. The applicant should consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing copyright licenses to reproduce any publications provided to EFSA. The applicant remains solely responsible and liable for obtaining all necessary authorisations and rights to use, reproduce and share the publications provided to EFSA.

3.4 Information to be filled in directly in IUCLID

The applicant will be asked to provide certain information by filling in the relevant sections in IUCLID, in addition to filling in the template provided in Annex II. This includes among others contact details of the applicant, some information on the identity of the substance, some information on the preparation to be used for plant protection and a summary of intended uses.

[51] EFSA Journal 2011; 9(2):2092.doi:10.2903/j.efsa.2011.2092; available online: www.efsa.europa.eu

Information related to the summary of intended uses

The applicant should provide detailed information on the uses of the substance for plant protection. This includes the description of the typical practices of applying the substance (Good Agricultural Practices - GAP).

For each of the uses intended to be included in the application, the applicant should provide a separate entry for each combination of crop, treated object, target organism and application details (method, timing, application rate etc.). It should be also indicated if post application exposure may occur, for example to workers re-entering a field/greenhouse after application etc.

A comprehensive explanation of how to fill in this section in IUCLID is provided in the IUCLID manual[52].

3.5 Specific guidance per section of the application template

1. Purpose of the application

Describe briefly the reasons to support the substance as basic substance and the envisaged uses in plant protection. Add when possible, information on its traditional use in agriculture (e.g. interest for organic agriculture). Indicate whether the application concerns an approval of a new substance or an extension of use of an already approved basic substance.

2. Identity of the substance as available on the market and its predominant use(s)

Provide information demonstrating that criteria of Article 23 (1) (c) and (d) of the PPP Regulation are fulfilled: information on the substance, the type and specification of the substance as available on the market, information on how it is normally used (for purposes other than plant protection) and on the use for plant protection, whether it is used directly or in a simple diluent preparation.

The information provided should be sufficient to clearly allow the identification of the basic substance as present on the market and planned to be used for plant protection.

Coherence must be ensured in terms of specifications as the substance should respect the same specifications as assessed and, as appropriate, set under other Union legislation. Provide a comparison of the specification/identity of the substance to be used as a basic substance to the specific foodstuff or substance evaluated in accordance with other Union legislation. It should be also demonstrated that the specification proposed for the substance intended to be used as a basic substance for plant protection purposes corresponds to the sources of the substance available on the market. This is especially important for substances for which specifications have not yet been laid down in another legal framework.

[52] IUCLID users manual is available at https://www.efsa.europa.eu/en/applications/toolkit

2.1. Predominant uses for purposes other than plant protection

Describe the predominant use(s) of the substance and provide evidence that these are not for purposes of plant protection. Provide arguments why they shall be considered as predominant compared to the intended use in plant protection.

2.2. Relevant evaluations, carried out in accordance with other Union legislation as referred to in Article 23 of Regulation (EC) No 1107/2009

Include any relevant evaluations, carried out in accordance with other Union legislation regulating the use of that substance for purposes other than for plant protection (e.g. food additives, (traditional) medicine, etc.), demonstrating that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment.

2.3 Identity of the substance

2.3.1. – 2.3.3. Name(s) and identifiers

Provide common name or ISO-accepted and synonyms, chemical name (IUPAC and CA nomenclature), CAS, EC and CIPAC numbers. Provide molecular and structural formula, molar mass. For plant extracts, a different approach may be taken if adequately justified.

2.3.4. Manufacturer(s) and name(s) of substance as put on the market

Indicate some of the trade names under which the substance is normally marketed. For each of the trade names, indicate the names of the manufacturers.

2.3.5. Method or methods of manufacture of the substance

Provide information on the methods of manufacturing (synthesis pathway) of the substance. Where relevant, provide specific information on how any possible sources of contamination are excluded.

2.3.6. – 2.3.7. Specification

Provide specification data related to the substance: specification of purity of the substance in g/kg, identity and content of any additives (such as stabilisers) and impurities. A case should be made that the specification covers the available sources of the substance.

Where relevant, provide information that demonstrate compliance with the specifications already assessed and set under other Union legislation (e.g. food additives, (traditional) medicine, etc.). Reference to specifications set by other relevant international institutions such as FAO could also be included.

When specifications are not yet set under other legislative frameworks, provide enough information to characterise the substance in terms of purity and impurities. The identity of significant impurities must have been assessed and their toxicity verified. For complex

substances, e.g. plant extracts[53], provide identification of all compounds as feasible, and include a description of the major components, concentration range and any possible contaminants. To fulfil these requirements, please consult the specific data requirements on active substances included in Regulation (EU) 283/2013.

2.3.8. Physical and chemical properties

If possible, provide relevant physical and chemical properties of the substance such as appearance, melting point, boiling point, solubility in water and organic solvents, *n*-octanol/water partition coefficient, dissociation in water etc. Please consult the relevant specific data requirements on active substances included in Regulation (EU) No 283/2013.

2.3.9. Methods of analysis

If possible, provide reference to a validated method for analysing the substance. In case of plant extracts, when not all components can be identified, provide validated methods of analysis of the markers of the extract.

If any toxic impurity, relevant for human or animal health and the environment could be present, validated methods of analysis must be available.

Provide reference to validated methods of analysis in body fluids and tissues for any 'toxic' component (e.g. impurity, metabolite). Provide reference to validated methods for analysing the substance in water, soil and air if exposure of the respective compartment is likely and if the additional contribution compared to natural exposure levels is relevant and detectable.

2.4 Type of preparation of the substance

Describe the type of preparation (formulation) of the substance and how it is presented when placed on the market for purposes other than plant protection (e.g. dispersible concentrate, granules, decoction, wettable powder, etc.). Indicate the source where the different types of preparation can be found. The applicant should be aware that according to Art. 23 (1) (c) of the PPP Regulation basic substances should be useful in plant protection either directly or in a product consisting of the substance and a simple diluent.

2.5 Description of the preparation of the substance for use in plant protection

Describe in detail the recipe (or dilution process) for the preparation of the substance as it will have to be applied for use in plant protection.

According to Art. 23 (1) (c) of the PPP Regulation basic substances should be useful in plant protection either directly or in a product consisting of the substance and a simple diluent. In some cases, the substance can be used as such. When the substance is not to be used directly, sufficient information should be provided for the mixture(s) which is (are) expected to be prepared by the users. Describe all the ingredients (including diluents) as well as the process

[53] For plant extracts, the applicant is advised to consult also Guidance Document on botanical active substances used in plant protection products SANCO/11470/2012 available on the website of European Commission

itself so that it can be easily reproduced by a user. All the required transformation steps have to be thoroughly explained, as a sort of recipe for the preparation and/or the use. The recipe for the preparation of the substance for use will become an integral part of the specifications for the use of the basic substance and will be included in the Review Report.

3. Uses of the substance for plant protection

The summary on the intended uses of the substance for plant protection (information on typical practices of applying the substance - Good Agricultural Practices - GAP) should be inserted directly into the relevant section of the IUCLID template (see point 3.4 above 'Information to be filled in directly in IUCLID'). The format for introducing the relevant information covers standardized picklists. A comprehensive explanation of how to fill in this section in IUCLID is provided in the IUCLID manual[54].

For comprehensive explanation of the type of information to be preferably submitted to support points 3.1 to 3.3 please consult the relevant specific data requirements included in Regulation (EU) No 284/2013.

3.1 Field of use/function

Describe globally the proposed field of use (function) of the substance/product in plant protection (e.g. as a fungicide, insecticide, herbicide, elicitor, etc.).

3.2 Effects on harmful organisms or on plants (including mode of action)

Describe the mechanism of action against pests, diseases or plants or if the substance has any eliciting properties or barrier mechanism. Where there is uncertainty, a putative mechanism should be suggested.

3.3 Usefulness in the framework of plant protection

Describe the usefulness of the substance/product for plant protection purposes and specifically for the intended uses. Provide a comparison of the proposed GAP (application rate) with the dose at which effect (efficacy) can be expected. Support your statements with evidence, citing studies or literature. Such information can also be supported by the statement(s) from growers' associations and/or agricultural extension services.

4. Classification and labelling of the substance

[54] IUCLID users manual is available at https://www.efsa.europa.eu/en/applications/toolkit.

Provide information of any classification or proposed classification under Regulation (EC) No 1272/2008[55]. Information available on the website of the European Chemicals Agency (ECHA) should be described and referred to.

5. Impact on human and animal health

In this section, provide information that shows that the substance complies with the criteria in Article 23(1) (a) and (b) and Article 23(2):

- It is not a substance of concern;
- It does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects;
- It does not have an immediate or delayed harmful effect on human and animal health.

As required in Article 23(2) the substance should have already been evaluated in view of other uses, except for certain foodstuffs for which no specific assessment nor authorisation is required under EU food law.

In the particular case of a foodstuff, the risks from ingestion are supposed to be inherently low for human health. However, different risks for human health can result from the manner of application for purposes of plant protection (e.g. dermal or inhalatory exposure during use), exposure of environmental compartments from the outdoor uses of the substance or from exposure being higher than the exposure from the use as foodstuff.

Therefore, both for foodstuffs and other substances regulated under other legislative frames, it very often will be necessary to demonstrate or prove that exposure from the intended use(s) as a basic substance for plant protection purposes does not lead to significantly higher exposure than already resulting from the other (regulated) uses. All routes of exposure must be addressed, including the relevant dermal and inhalation exposure (i.e. non-dietary exposure).

Examine and summarise all toxicological information available, including studies, scientific publications, and relevant evaluations carried out in accordance with other Union legislation regulating the use of that substance for purposes other than for a plant protection, but also evaluations done under regulatory reviews performed by OECD or other countries.

Immunotoxicity, neurotoxicity and endocrine disruption need to be specifically addressed according to Article 23 (1) (b) of the PPP Regulation.

When applicable, compile and provide information and an assessment on the acceptable daily intake (ADI), the acute reference dose (ARfD) and the (acute) acceptable operator exposure level/concentration (AOEL/AOEC).

For a more detailed explanation of points 5.1 to 5.3 of the template in Annex II please consult the data requirements included in Regulations (EU) 283/2013 and 284/2013. It should be noted

[55] 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.

that not all points necessarily need to be addressed. Provide proper justification why certain points do not apply.

It is important that the available information from the different references provided is used to discuss the possible risk from the use of the substance as a basic substance under point 5.4 of the template. Point 5.4 should contain a rationale, discussing all references provided, on why the use of the substance as a basic substance is considered acceptable with regard to human health. To achieve this, the toxicity needs to be considered in relation to the expected exposure.

6. Residues

No need for setting Maximum Residues Levels (MRLs) should arise, as this would not allow for approval of the substance as basic.

The extent of exposure due to the pesticide use must be compared to the natural exposure and/or to the exposure arising from other uses and/or to the exposure via food if the substance itself is part of the normal human diet. For example, if a substance is used as a food additive, a comparison should be provided of intakes from the use as food additive and the use as basic substance. The assessment of consumer intake should be done by using EU consumption data (available *via* the EFSA Comprehensive European Food Consumption Database[56]).

The setting of MRLs are not needed in the specific case where the intended use leads to an exposure below the natural exposure. In case it cannot be demonstrated that the exposure due to the intended use is lower/negligible compared to the natural background levels, a complete residue data package[57] should be provided.

If applicable, provide information on the residue behaviour of the substance (e.g. metabolism in/on plants, behaviour during processing operations; depending on the properties of the substance, also further data might be required). If available and considered relevant, based on ADI and ARfD values and the expected exposure both from pesticide uses and other sources, conduct a consumer risk assessment to demonstrate that no unacceptable effects on humans have to be anticipated.

For a more detailed explanation on Section 6 please consult the data requirements included in Regulation (EU) 283/2013.

7. Fate and behaviour in the environment

Based on the description of the intended uses, the potential consequences of increased exposure with respect to natural exposure levels of water, soil or air or to exposure due to other uses should be considered. An estimation of the predicted environmental concentrations in soil, water (both surface and groundwater) and air resulting from the intended uses should be given. For naturally occurring substances, the predicted environmental concentrations should be

[56] https://www.efsa.europa.eu/en/data-report/food-consumption-data

[57] As set out in Technical Guideline on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin SANTE/2019/12752 available on the website of European Commission

compared to the natural background concentrations. It should be demonstrated that the substance will not have "an unacceptable effect on the environment".

Examine and summarise all information available including studies, scientific publications, relevant evaluations carried out in accordance with other Union legislation regulating the use of that substance for purposes other than for plant protection, but also evaluations done under regulatory reviews performed in OECD or other countries.

For a more detailed explanation on Section 7 please consult the data requirements included in Regulations (EU) 283/2013 and 284/2013 regarding the calculation of predicted environmental concentrations.

8. Effects on non-target organisms

Examine and summarise all the information available that allow understanding of the potential hazard to non-target organisms. This information should include available studies, publications, relevant evaluations carried out in accordance with other Union legislation regulating the use of that substance for purposes other than for plant protection, including evaluations done in OECD or other countries.

Based on the description of the intended uses, the potential consequences of increased exposure with respect to natural exposure levels or to exposure due to other uses should be considered. It should be demonstrated that the substance has "neither an immediate or delayed harmful effect on animal health nor unacceptable effects on environment" (which includes non-target organisms). This means that a risk assessment (either quantitative or qualitative) is needed for all groups of non-target organisms (birds, mammals, aquatic organisms, bees, non-target arthropods, soil macro-organisms including earthworms, soil micro-organisms and non-target terrestrial plants. Such risk assessment may include information on natural exposure levels, information from the scientific literature or scientifically supported argumentation. The applicant should be aware that if the risk mitigation measures are considered necessary, this may lead to a non-approval as a basic substance.

It is important that the available information from the different references provided is used to discuss the possible risk from the use of the substance as a basic substance under point 8.8 of the template. All references used in the respective risk assessments should be transparently summarised together with an evaluation of their reliability and relevance.

Point 8.8 should contain a rationale, discussing all references provided, on why the use of the substance as a basic substance for plant protection purposes is considered acceptable with regard to the risk for non-target species. To achieve this, the potential adverse effects need to be discussed in relation to the expected exposure.

For a more detailed explanation on Section 8 please consult the data requirements included in Regulations (EU) 283/2013 and 284/2013.

9. Overall conclusion with respect to eligibility of the substance for approval as basic substance

Present a synthesis of the information presented in the application that concludes how the substance fulfils the following criteria to identify that the basic substance:

- is not a substance of concern; and
- does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects; and
- is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent; and
- is not placed on the market as a plant protection product.

Also include a synthesis of the conclusions of the evaluation demonstrating that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment and therefore could be approved as "basic substance".

10. List of references relied upon

Section 10 should list all references relied upon. References shall be ordered by section of the application template, in alphabetical order or by order of appearance. A template table is included. This section should include also the description of methodology used to perform the literature search. For this, the applicant is advised to follow the recommendations of the specific EFSA guidance[58].

3.6 Tools and sources of information on substances

Basic substance applications usually rely mainly on information available in public literature and databases. This chapter suggests a list of sources that provide information to be considered to support the application.

Standards and regulatory status

FAO Codex Alimentarius international food standards database[59]

FAO JECFA food additives compendium[60]

Food additives: Regulation (EC) 2008/1333, Annex II (Community list of food additives) and database[61]

Flavourings: Regulation (EC) 2008/1334, Annex I (Union list of flavourings) and database[62]

[58] European Food Safety Authority; Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092. Available online: www.efsa.europa.eu

[59] http://www.fao.org/fao-who-codexalimentarius/codex-texts/all-standards/en/

[60] http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/

[61] https://ec.europa.eu/food/safety/food_improvement_agents/additives_en

[62] https://ec.europa.eu/food/safety/food_improvement_agents/flavourings/eu_lists_flavourings_en

Food supplements: Directive 2002/46/EC[63] (Minerals and vitamins)

Traditional herbal medicine: Decision 2008/911/EC[63]

Novel foods: the novel food catalogue[64] can be used to find out whether a foodstuff is a novel food or not. If it is a novel food, then it can be checked in the list[65] whether it is authorised (and thus evaluated). This information can also be used to substantiate claims on whether a substance is a foodstuff.

European Pharmacopeia[66]

Union evaluations

Several EU agencies perform risk assessments and evaluations of substances which can be helpful to substantiate the application for a basic substance. Detailed information and publications are available on their websites.

European Food Safety Authority (EFSA[67])

EFSA publishes all its scientific outputs including conclusions, scientific opinions and technical reports on its website. They cover a wide range of topics, such as food additives, flavourings, feed additives, contaminants in food, nutrition and health claims and plant protection. The applicant is advised to perform a search of the substance on EFSA's website and use the information available in the relevant publications. For example, EFSA Compendium of botanicals[68] reports information on naturally occurring substances of possible concern for human health when used in food and food supplements.

European Chemicals Agency (ECHA[69])

The website of the ECHA contains information on chemicals in general and biocides in particular. The information on chemicals includes the harmonised classification and reports on which these classifications are based. Especially useful when available is the REACH registration dossier. The applicant is advised to perform a search of the substance applied for on ECHA's website and use the information available.

European Medicine Agency (EMA[70])

The website of EMA contains information on pharmaceuticals, including the EU herbal monographs[71] on herbal substances used as medicine and the underlying assessment reports.

[63] https://eur-lex.europa.eu/homepage.html?locale=en
[64] https://ec.europa.eu/food/safety/novel_food/catalogue_en
[65] https://ec.europa.eu/food/safety/novel_food/authorisations_en
[66] https://www.edqm.eu/en
[67] https://www.efsa.europa.eu/
[68] https://www.efsa.europa.eu/en/efsajournal/pub/2663
[69] https://echa.europa.eu/
[70] https://www.ema.europa.eu/en
[71] https://www.ema.europa.eu/en/human-regulatory/herbal-products/european-union-monographs-list-entries

Other evaluations and information sources

Cosmetics: US Cosmetics Ingredient Review[72]

EPA (USA): conventional low risk pesticide program[73]

OECD eChemPortal[74] contains links to information collected under various regulatory frameworks (US, EU…) related to chemicals.

Council of Europe, three books[75] on natural sources of flavourings.

Assessment tools

Several tools are available on how to perform the assessment of exposure to the basic substance when used for plant protection. These tools can also be used to compare this exposure to the background exposure, if sufficient information on this is available:

- EFSA Comprehensive food consumption database

This database[76] provides information on the consumption of different foodstuffs within the EU. It may be used to obtain information on the chronic and acute exposure to substances that may be found in the food chain. For basic substances this may be useful to obtain information on the background dietary exposure to the substance.

See also under Pesticide Evaluation tools for EFSA's PRIMO model, which is specifically focused on the dietary exposure to pesticides residues.

- Eurostat agricultural production in the EU

Eurostat provides information on crop yields per hectare, which can be useful when estimating residues or background exposure. The webpage[77] on agricultural production provides further links to the relevant Eurostat database.

- EFSA Pesticide Evaluation Tools

EFSA provides several tools for the assessment of exposure of operators, workers, bystanders, residents (non-dietary exposure), the exposure to consumers (dietary exposure) and the exposure to the environment. They can be found here[78].

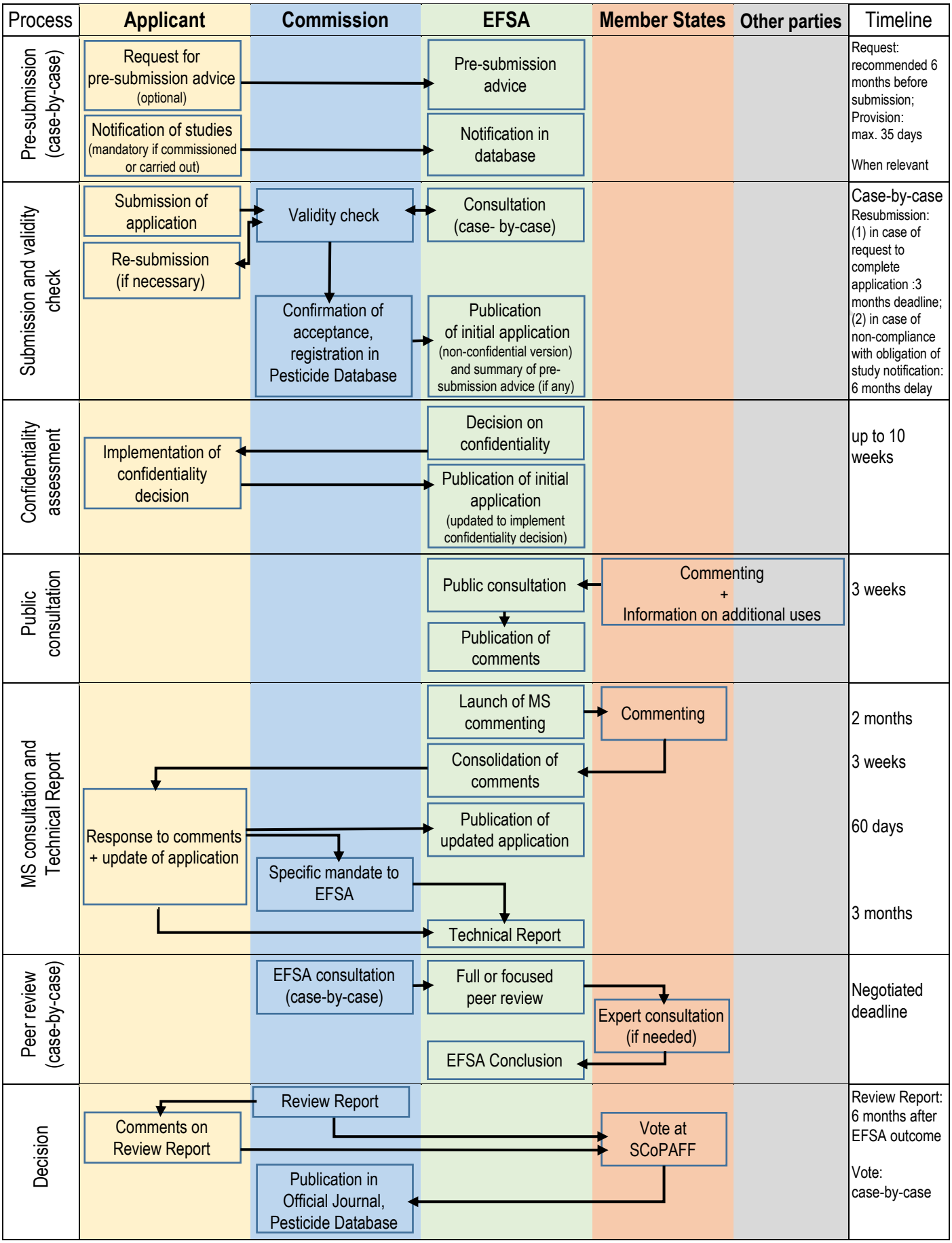
Information on approved basic substances

A list of approved basic substances is available in the EU Pesticides Database[79].

[72] https://www.cir-safety.org/
[73] https://www.epa.gov/pesticide-registration/conventional-reduced-risk-pesticide-program
[74] https://www.echemportal.org/echemportal/
[75] https://book.coe.int/en/83-health-protection-of-the-consumer
[76] https://www.efsa.europa.eu/en/data/food-consumption-data
[77] https://ec.europa.eu/eurostat/statistics-explained/index.php/Agricultural_production_-_crops
[78] https://www.efsa.europa.eu/en/applications/pesticides/tools
[79] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-db_en

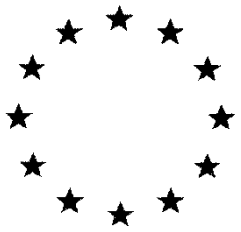
Successful applications for approval as basic substance may provide interesting examples to applicants. They are published on EFSA's website as background documents to the EFSA Technical Reports.

ANNEX I - Flowchart and timelines of the process of approval as basic substance



ANNEX II – Application template

European Commission



Application for approval of a basic substance, in the context of Regulation (EC) N°1107/2009

NAME of substance

BASIC SUBSTANCE APPLICATION TEMPLATE

Date:

Table of Contents

1. Purpose of the application

This report is submitted to support the application for the approval/extension of use of XXXXXXX as a basic substance according to Article 23 of Regulation (EC) No 1107/2009 of the European Parliament and Council.

2 Identity of the substance as available on the market and its predominant use(s)

2.1 Predominant uses for purposes other than plant protection

2.2 Relevant evaluations, carried out in accordance with other Union legislation as referred to in Art 23 of Regulation (EC) No 1107/2009

2.3 Identity of the substance

2.3.1 Common name of the substance and its synonyms

Proposed name:
ISO common name:
Synonyms:

2.3.2 Chemical name with CAS, EC and CIPAC numbers

Chemical name (IUPAC):
CAS number:
EC number:
CIPAC number:

2.3.3 Molecular and structural formula, molar mass

2.3.4 Manufacturer(s) and name(s) of substance as put on the market

2.3.5 Method or methods of manufacture of the substance

2.3.6 Description and specification of purity of the substance

2.3.7 Identity of inactive isomers, impurities and additives

2.3.8 Physical and chemical properties

2.3.9 Methods of analysis

Methods of analysis for determination of the substance as manufactured
Analytical methods for determination of relevant impurities
Analytical methods for determination of residues

2.4 Type of preparation of the substance

2.5 Description of the preparation of the substance for use in plant protection

3 Uses of the substance for plant protection

The summary on the intended uses of the substance for plant protection (information on typical practices of applying the substance - Good Agricultural Practices - GAP) should be inserted directly into the relevant section of the IUCLID template (see Section 3.4 of this guidance: 'Information to be filled in directly in IUCLID'). The format for introducing the relevant information covers standardized picklists. A comprehensive explanation of how to fill in this information in IUCLID is provided in the IUCLID manual.

3.1 Field of use/function

3.2 Effects on harmful organisms or on plants (including mode of action)

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4 Classification and labelling of the substance

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5.1.1 Toxicokinetics and metabolism in humans

5.1.2 Acute toxicity

5.1.3 Short-term toxicity

5.1.4 Genotoxicity

5.1.5 Long-term toxicity and carcinogenicity

5.1.6 Reproductive toxicity

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5.1.11 Medical data: adverse effects reported in humans

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5.3.2 Background exposure (exposure to the substance through uses other than plant protection)

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5.4 Impact on human and animal health arising from exposure to the substance or impurities contained in it

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5.6 Additional information related to use as food

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6.2.1 Exposure through the use for plant protection purposes

6.2.2 Background exposure (exposure to the substance through uses other than for plant protection)

6.2.3 Comparison of exposure through use for plant protection and the background exposure

7 Fate and behaviour in the environment

7.1 Fate and behaviour in the environment

7.2 Estimation of the short and long-term exposure of relevant environmental compartment (soil, ground water, surface water and air)

7.2.1 Exposure through the use for plant protection purposes

7.2.2 Background exposure (exposure to the substance through uses other than for plant protection purposes)

7.2.3 Comparison of exposure through use for plant protection and the background exposure

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8.2 Effects on aquatic organisms

8.3 Effects on bees and other arthropods species

8.4 Effects on earthworms and other soil macro-organisms

8.5 Effects on soil micro-organisms

8.6 Effects on other non-target organisms (flora and fauna)

8.7 Effects on biological methods of sewage treatment

8.8 Overall conclusion on effects on non-target organisms

9 Overall conclusions with respect to the eligibility of the substance to be approved as basic substance

10 List of references relied upon

Include here all references to studies and assessment reports cited in the various chapter of application template. Please describe briefly the methodology used to perform the literature search.

Author(s)	**Year**	**Title** **Source** **Company, report N°** **GLP or GEP status** **Published or not**
SECTION 1: Purpose of the application		

Author(s)	**Year**	**Title** **Source** **Company, report N°** **GLP or GEP status** **Published or not**
SECTION 2: Identity of the substance as available on the market and its predominant use(s)		

Author(s)	**Year**	**Title** **Source** **Company, report N°** **GLP or GEP status** **Published or not**
SECTION 3: Uses of the substance for plant protection		

Author(s)	**Year**	**Title** **Source** **Company, report N°** **GLP or GEP status** **Published or not**
SECTION 4: Classification and labelling of the substance		

Author(s)	Year	Title Source Company, report N° GLP or GEP status Published or not
SECTION 5: Impact on human and animal health		

Author(s)	Year	Title Source Company, report N° GLP or GEP status Published or not
SECTION 6: Residues		

Author(s)	Year	Title Source Company, report N° GLP or GEP status Published or not
SECTION 7: Fate and Behaviour in the environment		

Author(s)	Year	Title Source Company, report N° GLP or GEP status Published or not

SECTION 8: Effects on non-target organisms		