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Guidance to provide justifications as referred in point 1.5 of the Introduction of the Annexes of Regulations (EU) No 283/2013 and No 284/2013: Problem formulation for environmental risk assessment in the context of Regulation (EC) No 1107/2009

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Version	Applicable from	What
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Table of contents

1 Foreword and objectives 4

2 When to implement point 1.5 of the Introduction to the Annex of the Data Requirements? 6

3 How to implement point 1.5 of the Introduction to the Annex of the Data Requirements?..... 8

 3.1 Introduction 8

 3.2 Template for problem formulation 8

Annex I: How was the template for problem formulation developed? 14

 1. Introduction 14

 2. Identifying the relevant ecosystem services for problem formulation..... 18

 3. Linking the relevant ecosystem services to the data requirements of the current regulatory framework..... 29

Annex II: Case studies conducted during the commenting phase of the draft document. 33

1 Foreword and objectives

Regulation (EC) No 1107/2009¹ lays down rules for the placing on the market of plant protection products in the EU. Such products can only be placed on the market if, inter alia, they shall have no unacceptable effects on the environment, as defined in Art 4.3.e of that regulation which is understood as the protection goal². Complementing the Regulation (EC) No 1107/2009, Regulations (EU) No 283/2013 and No 284/2013³ define data requirements for active substances and plant protection products, respectively.

For a fair, healthy and environmentally friendly food system, the Green Deal⁴ and the Farm to Fork Strategy⁵ introduced measures to reduce the risk, use, and dependency on chemical plant protection products, as well as to stimulate the use of non-chemical alternatives and low risk plant protection products. Facilitating the placing on the market of biological active substances such as micro-organisms or of plant protection products applications that reduce the exposure (e.g., precision application techniques) is expected to contribute achieving these targets. Microorganisms or botanicals represented 30% of the active substances submitted for approval/renewal under Regulation (EC) No 1107/2009 in the period 2019-2022 and this number is likely to increase in the coming years.

There are several actions that can be undertaken to ensure more availability of such products and their uses on the market. One action may be to move to a fit for purpose risk assessment defined by a problem formulation step⁶, which will determine the studies needed for each particular scenario. Scenarios where conventional chemical pesticides are applied with a conventional sprayer in the open field are considered a worst case. For such conventional scenarios, impacts could be expected for all the environmental compartments and non-target species. Therefore, all the data requirements must be addressed in an application dossier and conducting problem formulation might not be of an added value for those conventional scenarios.

The method described in this document allows to provide in a harmonised manner justifications as referred to 1.5 of the introduction of the Annexes of Regulations (EU) No 283/2013 and No 284/2013 (hereafter referred to as the Data Requirements) in cases where experimental data would not be necessary owing to the nature of the active substance or the representative uses of the plant protection product containing it. This is also in line with Directive 2010/63/EU⁷ on the protection of animals used for scientific purposes, in particular reducing testing on vertebrate animal species.

How plant protection products impact the environment (compartments and/or non-target organisms) varies largely on their intrinsic properties and use. The risk is defined by the hazard properties of the

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R1107-20221121>

² Discussions to further define the protection goals set in Regulation (EC) No 1107/2009 and Regulation 546/2011 are not in the scope of this document.

³ [EUR-Lex - 32013R0283 - EN - EUR-Lex \(europa.eu\)](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0283-20221121) and [EUR-Lex - 32013R0284 - EN - EUR-Lex \(europa.eu\)](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0284-20221121)

⁴ https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en

⁵ https://ec.europa.eu/food/horizontal-topics/farm-fork-strategy_en

⁶ Devos Y, Craig W, Devlin RH, Ippolito A, Leggatt RA, Romeis J, Shaw R, Svendsen C and Topping CJ, 2019. *Using problem formulation for fit-for-purpose pre-market environmental risk assessments of regulated stressors*. *EFSA Journal* 2019;17(S1): e170708, 31 pp. <https://doi.org/10.2903/j.efsa.2019.e170708>

⁷ Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02010L0063-20190626>

substances in the plant protection product (PPP) and the exposure of the environment to the PPP (Risk = Hazard X Exposure). Low environmental effects may occur either because the substances are not hazardous and/or the exposure is low, in particular when comparing to a scenario where conventional chemical pesticides are applied with a conventional sprayer in the open field.

Some specific guidance for expert judgement has already been set out in case of substances as pheromones and botanicals. However, the current Environmental Risk Assessment (ERA) is not sufficiently flexible to accommodate scenarios for other types of applications (e.g., precision application techniques), for active substances of particular nature (e.g., volatile chemicals and microorganisms with very specific host range) or for new technologies (e.g., RNAi, peptides and antibodies). Furthermore, application methods that may reduce the environmental exposure, such as precision application technologies and drift reduction techniques, need to be considered in the environmental risk assessment.

For such scenarios, conducting an explicit problem formulation would help to have a more fit-for-purpose environmental risk assessment. This was confirmed at the Workshop “Specific Protection Goals for the Environmental risk assessment of Plant Protection Products - moving forward”⁸ held with Member States and stakeholders in February 2020. During this workshop, participants asked to develop scenarios considering different methods of PPP application and different types of active substances for framing and strengthening the ERA. However, to agree on scenarios would be lengthy and never complete as plant protection products and their uses are evolving and diverse.

Following that request, **this document provides a method to conduct problem formulation to determine which experimental ecotoxicological, fate and/or behaviour data would not be necessary for the ERA of representative uses with potentially low environmental effects** (or as defined by the Regulation (EU) No 1107/2009 “non unacceptable” effects). For instance, microorganisms, pheromones, botanicals, plant extracts, and application methods like indoor uses (e.g., permanent greenhouses or storage rooms) precision application techniques, localised applications (e.g., burrows), or drip irrigation, may lead to lower environmental effects when comparing to a scenario in which a conventional chemical pesticide is applied with a conventional sprayer in the open field. The method presented in this document may also help support the argumentation for the approval of basic substances and increase the transparency and harmonization of the assessment by EFSA in the corresponding Technical Reports.

It is important to note that the method provides harmonised guidance to implement the provisions set in point 1.5 of the Introduction of the Annexes of the Data Requirements and to identify and provide scientific justification as regards the fate and behaviour and ecotoxicological studies that may not be required for the risk assessment. Human health risk assessment is not in the scope of this document.

⁸ https://food.ec.europa.eu/document/download/f466cf50-dad7-46f3-b6cd-472a54cf13fb_en?filename=pesticides_auth-ppp_workshop_20200204_reprt.pdf

2 When to implement point 1.5 of the Introduction to the Annex of the Data Requirements?

The method described in this document was developed to be used in the context of approval (or renewal of approval) of active substances including their representative uses at the EU level. It may be also useful at Member States level for the authorization of plant protection products.

The template aims to provide **harmonised guidance for applicants, Rapporteur Member State (RMS), co- RMS and European Food Safety Agency (EFSA) on how to apply the provision set in point 1.5 of the Introduction to the Annex of the Data Requirements.**

The template may be of added value during the discussions of the pre-submission meetings^{9,10}, which are not legally binding. For instance, according to Article 3(2) of Regulation (EU) 2020/1740¹⁰, the pre-submission advice for the renewal of an active substance shall take into account any existing experience and knowledge relevant for the active substance, including, where appropriate, available studies from the earlier approval or renewal of approval. However, the pre-submission meetings usually take place at least three years before the submission of the dossier and that stage, the information provided by the applicants in the template might be limited (i.e., they do not have a complete dossier).

For the assessment of an active substance/representative uses at the EU level, each type of applications (spraying, greenhouse, etc.) of the representative uses may have a different influence on the environment, and thus, would imply different problem formulations and environmental risk assessments.

When conducting problem formulation, i.e., filling in the template, for exposure scenarios in which the exposure is expected to be lower (e.g., indoor uses) than when a conventional chemical is applied with a conventional sprayer the open field, applicants might propose to exclude from the ERA certain studies on fate and behaviour and/or studies on non-targeted groups of organisms. If an applicant decides to make use of point 1.5 of the Introduction to the Annex of the Data Requirements, this needs to be duly justified in the dossier. The burden of proof always remains on the applicants, who is expected to complete the template of problem formulation providing information to demonstrate the absence of hazard or exposure for a specific environmental compartment and/or organisms under the proposed conditions of use.

The completed template of problem formulation should be part of application dossier and/or peer review documentation and therefore included in the IUCLID dossiers. It is proposed to include the template in IUCLID Section 13. *Summary and evaluation*. When completing the IUCLID dossier, the applicant may cross refer to this document as one element of its justification that would need to be submitted for each of the IUCLID sections and subsections where data is not provided. For example, if the applicant proposes not to perform guideline studies for non-target organisms at the time of the pre-

⁹ Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain

¹⁰ COMMISSION IMPLEMENTING REGULATION (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances.

submission meeting because of absence of hazard and explain this in the Problem Formulation template), the absence of hazard should be demonstrated in the dossier as a justification for not providing studies (for example based on a literature search) and this justification is evaluated by the RMS.

It is important to note that further data may always be requested by the RMS, co- RMS and EFSA during the admissibility of the application or the peer-reviewed process within the corresponding legal provisions in Regulation (EU) 1107/2009 or Regulation 2020/1740.

If experimental data was not submitted for certain environmental compartments or non-target organisms due to expected reduced exposure (e.g., indoor uses), the regulatory decisions are likely to limit the approval/renewal of approval to only low exposure representative uses. Consequently, uses for plant protection products outside these restrictions and leading to higher exposure cannot be authorised at Member State level. For uses of plant protection products outside these restrictions, the applicant may have to submit a request for the modification of conditions of approval in accordance with Article 7 of Regulation (EC) No 1107/2009 as a first step.

3 How to implement point 1.5 of the Introduction to the Annex of the Data Requirements?

3.1 Introduction

A scenario is defined by the properties of the active substance contained in the plant protection product and its conditions of use. The conditions of use are defined by the representative uses in the respective dossier. The potential effects on the environmental compartments and on the organisms living in it of a PPP scenario will be triggered by the hazard properties of the active substance contained in the PPP and its representative use and the environmental exposure to the active substance with this representative use (See Figure 1).

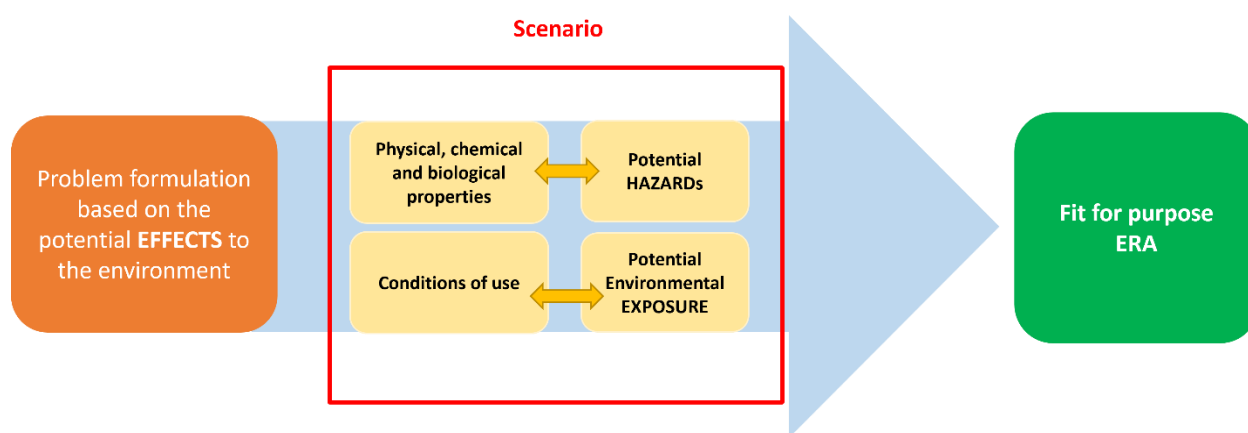


Figure 1. Strengthening problem formulation for a more target oriented, focused and fit for purpose Environmental Risk Assessment.

3.2 Template for problem formulation

The template for problem formulation can be found at the end of this Section.

Section 1 of the template contains a qualitative description of the plant protection use scenario: hazard properties of the active substance and the representative use of the formulated plant protection product in the GAP table. Each representative use (e.g., indoor and outdoor uses) would need to be assessed independently. Section 1 provides for the necessary information for the arguments in Section 2 and 3 to be robust and scientifically justified.

Section 2 contains a qualitative description of the fate and behaviour of the substance in the different environmental compartments. It also includes a column in which, based on this description and the information on Section 1, the applicant can propose to exclude studies on fate and behaviour.

Section 3 looks at the potential effects on non-target organisms based on the hazard properties of the active substance/representative use, its behaviour on the environment and the expected exposure in

case of each representative use. This section lists all relevant¹¹ ecosystem services and the corresponding service providing units. Service providing units or SPUs are organisms that support relevant ecosystem services (for more explanation see Figure 4 of Annex I). These organisms are not the organisms to be targeted by the PPP. Section 3 needs to be completed with justifications for the potential effect (or its absence) on the relevant ecosystem services and in particular, the SPUs. Using these justifications, the applicant can propose to exclude studies on non-target organisms.

Annex I contains explanation on the SPUs and the related test species. The Data Requirements define the current relevant test species and Table 3 of Annex I shows the list of the existing mandatory test species for the assessment of an active substance/representative use at EU level. These test species represent typical organisms of a functional group (e.g., arthropods that act as predators or parasitoids to pests) for which standardised ecotoxicological test protocols are available.

It is important to note that the EU legislation provides that farmers and other professional users are trained (Article 5 of Directive 2009/128/EC¹²) and that pesticide applications equipment is regularly inspected and calibrated so that it delivers the recommended application rates (Article 8 of Directive 2009/128/EC). These provisions need to be kept in mind when conducting problem formulation of representative uses for professional uses such as in agriculture and forestry (e.g., farming, crop production), preserving agricultural plant products (storage applications), maintenance of industrial or amenity areas (e.g., railways), maintenance of public green areas (e.g., parks and sports fields).

In addition, specific environmental parameters such as topography or climate conditions are not considered for conducting problem formulation because they are considered by the different exposure models (e.g., FOCUS) during the proper risk assessment. Multiple stressors cannot yet be taken into account as scientific developments are not yet ready. Research is ongoing and will be incorporated in problem formulation and risk assessment when available.

¹¹ See Annex for background information on the determination of relevant ecosystem services.

¹² <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009L0128-20091125>

Section 1 -DESCRIPTION OF THE SCENARIO

1.Description of the properties and conditions of use of the active substance / representative use of the formulated plant protection product

1.1. Physical and chemical and biological properties of the active substance/ representative use of the formulated plant protection product

e.g., volatility- deposition, solubility in water, mode of action, impurities... (for chemical substances), biology and ecology including host range, growing conditions, ... (for microorganisms)





Please state any other type of information that might be relevant (e.g., if a substance has been authorised as food additive, flavouring etc.)

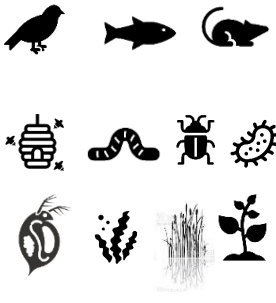
1.2. Description of the conditions of use - Representative uses in the GAP table

Section 2 -FATE AND BEHAVIOUR

Describe how the substance behaves in: E.g., information on persistence, mobility, etc...	Based on Section 1, are there any studies that may be excluded the ERA on the representative use? Please justify.
Soil	
Water: Effects on biological method for sewage treatment systems (very relevant for greenhouse uses and indoor uses) -Can the representative use potentially trigger an effect on the sewage treatment plants? If so, are there any routes of environmental exposure to consider, e.g., the application of sludge in the field coming from the sewage plant?	
Groundwater:	
Air:	

Section 3- POTENTIAL EFFECTS ON NON-TARGET ORGANISMS

Relevant Ecosystem Services	Service Providing Unit for the relevant Ecosystem Services ¹³	Are the properties of the active substance/ representative use of the formulated plant protection product and/or its exposure (considering all possible routes deriving from the representative use) expected to lead to unacceptable effects on...	If no, please justify. If yes, list the species to be tested. Current test species are listed in Annex I of this document. Additional ad-hoc test may also be proposed.
Fresh water		...this ES and in particular, algae, non-target aquatic plants and aquatic invertebrates? Yes/No.	
Erosion prevention and maintenance of soil fertility		...this ES and in particular, terrestrial invertebrates, earthworms, and soil micro-organisms? Yes/No.	
Pollination		...this ES and in particular, bees and other terrestrial invertebrates? Yes/No.	
Biological control		...this ES and in particular the biological control agents such as certain terrestrial invertebrates, soil micro-organisms and aquatic invertebrates? Yes/No.	

<p>Habitats for species¹³</p>		<p>... on food, water or shelter needed to maintain soil micro-organisms micro, aquatic invertebrates, algae, non-target aquatic plants, non-target arthropods, earthworms, bees, non-target terrestrial plants, birds, fish, mammals and on any of these species? Yes/No.</p>	
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¹³To include a widest possible range of taxa under the ES habitats for species while making the link to the current test species, species which benefit from this ES were added to the service providing units identified by EFSA in 2010. For further explanation, please see section 3 of Annex I and pg. 30.

Annex I: How was the template for problem formulation developed?

1. Introduction

This document builds on the outcome of the Workshop “Specific Protection Goals for the Environmental risk assessment of Plant Protection Products - moving forward” held with Member States and stakeholders in February 2020. The document was developed by the European Commission together with the Working Group on environmental relevant topics in the context of Regulation (EC) No 1107/2009¹⁴. The draft document was consulted with approximately 80 experts from Member States, relevant stakeholders, the Biopesticides Working Group as well as experts of European H2020 projects of ERA of low-risk substances, who were invited to provide case studies. Comments were received from 11 Member States and 6 stakeholders. In addition, 23 case studies (see Annex II) that put in practice the method to conduct problem formulation were provided by Member States and stakeholders. The feedback and case studies received were used to review the consulted draft document.

The rationale used to develop the method for problem formulation is based on Step 1 and 2 of a method developed by EFSA¹⁵¹⁶ and on the currently established data requirements.

It consists of different steps:

- Step 1: the identification of the relevant ecosystem services (ES) that can be affected by a stressor (e.g., the use of a plant protection product).
- Step 2: the identification of service providing units (SPUs) that support relevant ecosystem services identified in step 1.
- Step 3: the specification of the level/parameters of protection of the potentially impacted SPUs identified in step 2, using interrelated dimensions.

Based on the method developed by EFSA, the method for problem formulation makes use of the concept of ES to predict how the environment may potentially be affected by a stressor.

In this document, **ES is used as conceptual bridge to link the concepts of hazard, exposure and the data requirements currently in place.**

Discussions to further define the protection goals set out in Regulation (EC) No 1107/2009 and Regulation 546/2011 are not in the scope of this document.

¹⁴ Terms of Reference_Working Group of environmental topics under the Reg 1107/2009 <https://webgate.ec.testa.eu/Ares/documentInfo/documentInfoDetails.do?documentId=080166e5f49081d1& f=ext>

¹⁵ EFSA Scientific Committee, 2016. Guidance to develop specific protection goals options for environmental risk assessment at EFSA, in relation to biodiversity and ecosystem services. EFSA Journal 2016;14(6):4499, 50 pp. doi:10.2903/j.efsa.2016.4499

¹⁶ EFSA Panel on Plant Protection Products and their Residues (PPR); Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002). EFSA Journal 2010;8(10):1821. [55 pp.] doi:10.2903/j.efsa.2010.1821 .

The concept of Ecosystem Services

ES is a holistic framework that serves as a connecting concept between ecosystem assets and the services that the environment provides to society. The use of ES is considered transparent, easy to understand for non-experts and therefore particularly suitable for stakeholder involvement and policy decision making. Furthermore, the use of the ES concept allows to have a systemic and holistic view on the environment, and it can be applied for assessing different kinds of environmental stressors, and thus for comparison among them.

The concept of ES is broadly used in international, European and national environmental policy making. In recent years, significant research developments took place to translate the concept of ES into operational frameworks for environmental decision-making at the EU level (e.g., OpenNESS¹⁷, OPERAs¹⁸, BESAFE¹⁹, EnRoute²⁰). As a result, the EU established relevant guidance on integrating ecosystems and their services into decision-making²¹ as well as an integrated system of ecosystem accounts for the EU that contains examples of ES accounts and existing policy applications²². The Framework to Facilitate Sustainable Investment²³ and the EU pollinators Initiative²⁴ are examples of policies initiatives of the European Commission where the concept of ES has been recently used. The EU Biodiversity Strategy for 2030²⁵ includes actions to develop natural capital accounting in the EU, with a focus on ecosystems and their services.

In practice, ES are divided into provisioning services, regulating services, habitat or supporting services, and cultural services. Provisioning services are those ES representing the contributions to benefits that are extracted or harvested from ecosystems. Regulating and supporting services are those ES resulting from the ability of ecosystems to regulate biological processes and to influence climate, hydrological and biochemical cycles, and thereby maintain environmental conditions beneficial to plant and animal species as well as to human society. Cultural services are the experiential and intangible services related to the perceived or actual qualities of ecosystems whose existence and functioning contribute to a range of cultural benefits.

There are different internationally recognised lists of ES developed over the years that are interconvertible: Millennium Ecosystem Assessment (MEA)²⁶, the Economics of Ecosystems and

¹⁷ <http://www.openness-project.eu/about>

¹⁸ <https://www.operas-project.eu/>

¹⁹ <https://cordis.europa.eu/project/id/282743/reporting/es>

²⁰ <https://oppla.eu/groups/enroute>

²¹ https://ec.europa.eu/environment/nature/ecosystems/pdf/SWD_2019_305_F1_STAFF_WORKING_PAPER_EN_V2_P1_1042629.PDF

²² https://ec.europa.eu/eurostat/documents/7870049/12943935/KS-FT-20-002-EN-N.pdf/de44610d-79e5-010a-5675-14fc4d8527d9?t=1624528835061https://ec.europa.eu/environment/nature/ecosystems/pdf/SWD_2019_305_F1_STAFF_WORKING_PAPER_EN_V2_P1_1042629.PDF

²³ Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R0852&from=EN>

²⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0395&from=EN>

²⁵ https://ec.europa.eu/info/sites/default/files/communication-annex-eu-biodiversity-strategy-2030_en.pdf

²⁶ Millennium Ecosystem Assessment (MEA), 2005. Ecosystems and Human Well-being: Synthesis. Island Press, Washington, DC, 160 pp.

Biodiversity (TEEB)²⁷, the Common International Classification of Ecosystem Services (CICES)²⁸ and the “reference list” of ecosystem services of the System of Environmental-Economic Accounting—Ecosystem Accounting (SEEA EA) report published in 2021²⁹.

EFSA used the MEA list in the Guidance Document (GD) (2016) and in a Scientific Opinion (2010). However, the method presented in this document uses the TEEB list as it was found more complete than MEA but -compared to CICES- easier to use with stakeholders. Definitions of each ES according to the TEEB List (17 ES divided into 4 categories: provisioning services, regulating services, habitat or supporting services and cultural services) and a correlation between the ES of the TEEB list and the MEA list (31 ES divided into the same 4 categories as the TEEB list) can be found in table 1.

The template included in this document contains the ES that are relevant for the problem formulation of ERA for the approval/renewal of approval of active substances/representative use at EU level and then link them with the current test species (see Figure 2). The following subsections describe this link with more details.

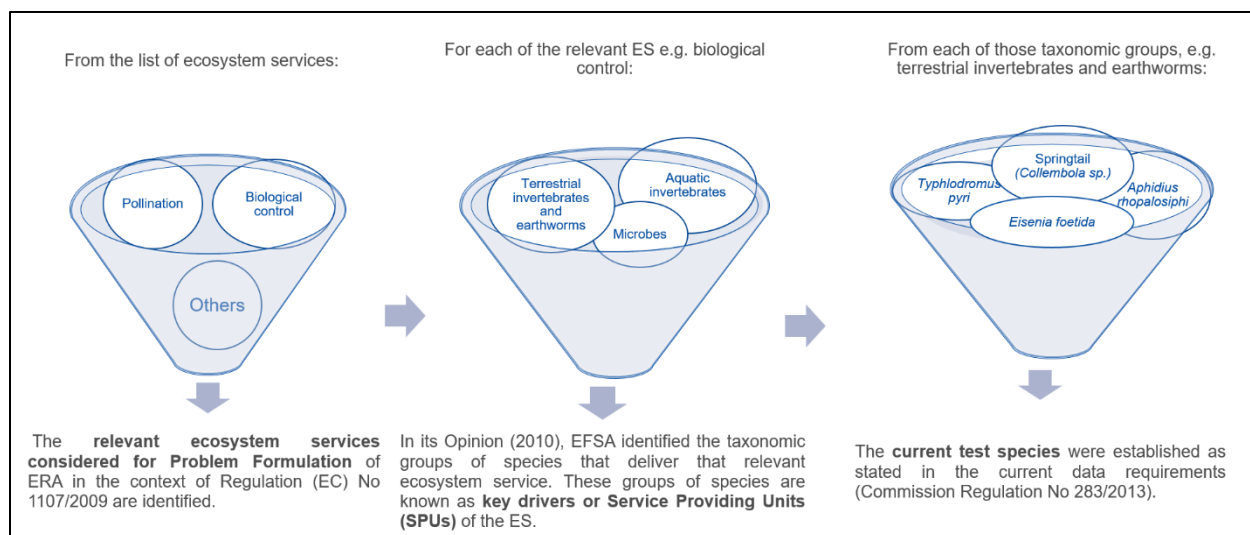


Figure 2. Link between relevant ecosystem services for problem formulation of plant protection product use and the current test species.

²⁷ <http://teebweb.org/>

²⁸ Haines-Young, R. and M.B. Potschin (2018): Common International Classification of Ecosystem Services (CICES) V5.1 and Guidance on the Application of the Revised Structure. Available at www.cices.eu

²⁹ https://unstats.un.org/unsd/statcom/52nd-session/documents/BG-3f-SEEA-EA_Final_draft-E.pdf

Table 1: TEEB list versus MEA list.

Economics of Ecosystems and Biodiversity (TEEB) as used in the February 2020 workshop	Millennium Ecosystem Assessment (MEA) used by EFSA in the 2010 and 2016 Guidance
Provisioning services	
Food	Food
Raw materials	Fibre and fuel Ornamental resources
Fresh water	Fresh water
Medicinal resources	Biochemical/natural medicines
Regulating services	
Local climate and air quality	Air quality regulation
Carbon sequestration and storage	Climate regulation
Moderation of extreme events	Natural hazard regulation (other than water regulation, e.g., avalanches and landslides) Water regulation (quantitative aspects)
Waste water treatment	Water purification/waste treatment
Erosion prevention and maintenance of soil fertility	Erosion regulation Soil formation and retention soil remediation
Pollination	Pollination
Biological control	Pest and disease regulation Invasion resistance
Habitat or supporting services	
Habitats for species	Primary production Photosynthesis Provision of habitat Nutrient cycling Water cycling
Maintenance of genetic diversity	Genetic resources/biodiversity
Cultural services	
Recreation and mental and physical health	Education and inspiration
Tourism	Recreation and ecotourism
Aesthetic appreciation and inspiration for culture, art and design	Cultural heritage Aesthetic values
Spiritual experience and sense of place	Spiritual and religious values Sense of place
Others	Energy (hydroelectric and cooling water) Transport (waterways, e.g. boat traffic)

2. Identifying the relevant ecosystem services for problem formulation

Plant protection products may be used and applied in different areas such as agricultural fields, forests, storage rooms, greenhouses, or even on railways. These application areas present different ecological characteristics and are managed in different ways. For this document, agricultural fields are chosen as example to refer to this method as it is the most widespread plant protection product application area in the EU.

The use of plant protection products as well as other agricultural practices influence the ES the agricultural field provides. On one hand, the use of plant protection products enhances the provision of some ecosystem services. For example, plant protection products contribute to the provision of food and feed, can reduce invasive alien species and can thus contribute to the maintenance of habitats of other local species. On the other hand, their use may diminish the provision of some ES as the provision of fresh water.

It is acknowledged that trade-offs between the positive and negative effects of the use of a pesticide on the provision of ES by an agricultural field should be considered by looking at them at a broader scale (local, regional level) or in the framework of other EU regulations. However, trade-offs and socio-economics aspects of the use of pesticides are currently not criteria to consider when evaluating an active substance/representative use for its approval/renewal of approval. Data on trade-offs and socio-economics aspects of the use of pesticides do not need to be submitted under Regulation (EC) No 1107/2009 for an application for approval/renewal of approval of active substances/representative use at EU level. Trade-offs and socio-economics aspects of the use of pesticides are not considered in the uniform principles either.

For the approval/renewal of approval of active substances/representative use at EU level, ERA should ensure that the use of at least one PPP containing the active substance under consideration is not leading to any unacceptable effect on the environment (Article 4.3 Regulation (EC) No 1107/2009). This is also referred to as the “one safe use “concept. Therefore, only potential negative effects on the environment should be considered when conducting problem formulation.

Considering the above and during the consultations for this document, some ES from the complete TEEB list of ecosystem services were considered not relevant for a problem formulation for active substance/representative use environmental risk assessment at EU level as explained in detail in Table 2 on the next page.

These non-relevant ecosystem services are food, raw materials, medicinal resources, local climate and air quality, carbon sequestration and storage, moderation of extreme events, waste water treatment, maintenance of genetic diversity and the cultural services. The ES fresh water, erosion prevention and maintenance of soil fertility, pollination, biological control, and habitats for species are the relevant ecosystem services of the TEEB list maintained to conduct problem formulation for the environmental risk assessment needed for the approval/renewal of approval of an active substance/representative use at EU level (see Figure 3). Some of them were renamed or redefined for the purpose of this document as explained in Table 2.

To conduct problem formulation for the evaluation of an active substance/representative use, the potential effects to species that provide the five relevant ES need to be assessed looking at the routes of exposure to be evaluated. The relevant ES were included in the template for problem formulation. If the template is applied for other contexts than agricultural fields such as railways, the relevant ES will be the same as for agricultural fields.

Table 2. Relevance of Ecosystem Services for conducting problem formulation of ERA for the approval/renewal of approval of active substances/representative use at EU level. The first column shows the complete list of ES and their definitions as used in the February Workshop 2020. The second column explains if an agricultural field provides (if so, how) or not each of the ES listed. The third column explains whether an ecosystem service as defined by the TEEB list can be potentially impacted by the use of plant protection products and if so how, which triggers its relevance or not for problem formulation.

Economics of Ecosystems and Biodiversity (TEEB) as used in the February 2020 workshop		Does the agricultural field provide this ES? (yes/no, and if yes, how?)	Is this ES relevant for the problem formulation of ERA for the approval/renewal of approval of an active substance/representative use ³⁰ at EU level?
Ecosystem Service	Definition		
Provisioning services			
Food	Ecosystems provide the conditions for growing food. Food comes principally from managed agro-ecosystems but marine and freshwater systems or forests also provide food for human consumption. Wild foods from forests are often underestimated.	Yes, agricultural fields are managed to grow food for human consumption (edible crops) and feed for animal production.	<p>Not relevant in the context of ERA which considers unacceptable effects (as provided for in Regulation (EC) No 1107/2009), because the use of PPP is expected to have a positive effect on this ES (production of edible crops or feed).</p> <ul style="list-style-type: none"> • It is acknowledged that PPP have positive effects on food or feed production, however this is out of scope of ERA. PPPs are applied for controlling pests to ensure that crops can grow and be harvested. Therefore, the direct effect on crop production (that results in the production of tangible items as edible crops, fibre, medicinal resources) can be considered positive as the provision of edible crops is ensured. • Potential negative impacts on the yield from the use of plant protection products is already covered in the efficacy assessment. • Potential negative impacts on the edible crops or feed are already covered by Regulation (EC) 396/2005 that ensures a high-level consumer protection relating to maximum levels of plant protection product residues on food.
Raw materials	Ecosystems provide a great diversity of materials for construction and fuel including wood, biofuels and plant oils that are directly derived from wild and cultivated plant species.	Yes, agricultural fields are managed to grow diversity of materials for construction and fuel including wood, biofuels and plant oils from cultivated plant species. Also production of tree nursery crops and perennials, floriculture and ornamentals, etc... is possible.	<p>Not relevant in the context of ERA which considers unacceptable effects (as provided for in Regulation (EC) No 1107/2009), because the use of PPP is expected to have a positive effect on this ES.</p> <p>The direct effect on raw materials production can be considered positive as the provision of non-edible crops is ensured.</p>

³⁰ When referring to the active substance, it is meant also its representative use(s) at the EU level. This applies for all the entries of Table 2 and the following sections of this document.

Economics of Ecosystems and Biodiversity (TEEB) as used in the February 2020 workshop		Does the agricultural field provide this ES? (yes/no, and if yes, how?)	Is this ES relevant for the problem formulation of ERA for the approval/renewal of approval of an active substance/representative use at EU level?
Ecosystem Service	Definition		
Fresh water (surface water and groundwater)	Ecosystems play a vital role in the global hydrological cycle, as they regulate the flow and purification of water. Vegetation and forests influence the quantity of water available locally.	<p>Agricultural fields can provide fresh water (e.g. percolation of rain by the field will provide drinking water via groundwater).</p> <p>At local level or regional scale, the provision of fresh water is affected by many factors such as the topography, type of soil and vegetation, local climate (rainfall patterns).</p>	<p>Relevant in the context of ERA because:</p> <ul style="list-style-type: none"> • The provision of fresh water by water sources that are off field (irrigation channels, rivers, ponds, wetlands) might be affected by the drift, drainage* and run off* of plant protection product from the field. Specific animals and plants contribute to the provision of fresh water (e.g., wetlands) because of their biological functions e.g., green algae, aquatic grass, aquatic invertebrates (see Figure 5 on Service Providing Units). Therefore, if the water sources are affected by the use of a plant protection product, these animals and plants might be affected too, and they should be considered for the ERA. • The potential effect of plant protection products on fish, which would have fresh water as a habitat would be covered under the ES habitats. • The potential effect of groundwater contamination by a pesticide use is addressed under fate and behaviour and it will be part of the data submitted in dossier. • The fate and behaviour of the active substance in the soil and water compartments will also indicate if the active substance shows potential to interfere the quality of drinking water and with the surface and groundwater (see Template, pg. 7). • *Drainage: artificial removal of the water from the land. The drained water can be sourced from the percolation of rainwater, groundwater or surface water into upper layers of soils down to the draining system before the water reaches groundwater bodies or runs off to surface water bodies. This results in water running to ditches, then to rivers, etc. <p>*Run-off: physical phenomenon by which water sourced from rainwater or surface water bodies is leaving the area of the field without percolating through the soil hence not reaching the groundwater bodies but rather other surface water bodies, including ditches and rivers.</p>

Economics of Ecosystems and Biodiversity (TEEB) as used in the February 2020 workshop		Does the agricultural field provide this ES? (yes/no, and if yes, how?)	Is this ES relevant for the problem formulation of ERA for the approval/renewal of approval of an active substance/representative use at EU level?
Ecosystem Service	Definition		
Medicinal resources	Ecosystems and biodiversity provide many plants used as traditional medicines as well as providing the raw materials for the pharmaceutical industry. All ecosystems are a potential source of medicinal resources.	The provision of medicinal resources by an agricultural field (in- field) would be already covered by the provision of raw materials (non- edible crops).	<p>Not relevant as use of PPP has a neutral or positive effect on growing medicinal crops. Same as for food and raw materials.</p> <ul style="list-style-type: none"> Medicinal plants could be provided also by off-field areas but the protection of these via this rationale is already covered by protecting their habitats (this protection is covered by the inclusion of habitats for species as a relevant ES).
Regulating services			
Local climate and air quality	Trees provide shade whilst forests influence rainfall and water availability both locally and regionally. Trees or other plants also play an important role in regulating air quality by removing pollutants from the atmosphere.	<p>In comparison with other areas like forests; agricultural fields contribute marginally to the regulation of air quality. Local climate is regulated at a scale significantly higher than an agricultural field.</p> <p>Other factors affect directly the provision of this ES such as the type of vegetation (trees, forests), the local patterns of temperature and precipitation.</p>	<p>Not relevant based on the definition of ES because:</p> <ul style="list-style-type: none"> The fate and behaviour of the active substance in the air compartment will indicate if the active substance shows potential to interfere the air quality and therefore affect certain animal species as birds. The potential effect of plant protection products on animals and plant that need good air quality would be covered under the ES habitats.
Carbon sequestration and storage	Ecosystems regulate the global climate by storing and sequestering greenhouse gases. As trees and plants grow, they remove carbon dioxide from the atmosphere and effectively lock it away in their tissues. In this way forest ecosystems are carbon stores. Biodiversity also plays an important role by improving the capacity of ecosystems to adapt to the effects of climate change.	<p>Forests, e.g. boreal forests, where plant protection products are also applied, do sequester and store carbon through the microbial biomass of the soil.</p> <p>Agricultural fields do sequester and store carbon in a limited level compared to forests.</p> <p>It is recognized that some agroecosystems such as</p>	<p>Not relevant as:</p> <ul style="list-style-type: none"> Other factors affect directly the provision of this ES such as the type of vegetation in field and off field, the type of soils, the type of agricultural practices applied...etc. Because of the previous reasons, the contribution of this ES is usually considered at landscape level and not only at farm level. Other policy instruments than PPP legislation are better suited to address / develop more sustainable farming practices with regards to carbon storage in agricultural soil. Plant protection product applications are intended to ensure the growth of trees (= positive effect to carbon sinks). However, there is a potential impact to forest soil ecosystems, and specifically to

Economics of Ecosystems and Biodiversity (TEEB) as used in the February 2020 workshop		Does the agricultural field provide this ES? (yes/no, and if yes, how?)	Is this ES relevant for the problem formulation of ERA for the approval/renewal of approval of an active substance/representative use at EU level?
Ecosystem Service	Definition		
		agroforestry or permanent ley cultivations contribute to this service, however this is more linked to type of planting/cultivars rather than to the use of plant protection product.	symbiotic fungi which contribute to the nutrient intake of forest trees. These effects on carbon sequestration of forests (and agricultural soils) are already covered by the inclusion of erosion prevention and maintenance of soil fertility as relevant ES. See Figure 4 and 5, where soil micro-organisms are identified as key driver/SPUs of erosion prevention and maintenance of soil fertility (if a plant protection product impact the forest soil, soil micro-organisms would need to be tested).
Moderation of extreme events	Extreme weather events or natural hazards include floods, storms, tsunamis, avalanches and landslides. Ecosystems and living organisms create buffers against natural disasters, thereby preventing possible damage. For example, wetlands can soak up flood water whilst trees can stabilize slopes. Coral reefs and mangroves help protect coastlines from storm damage.	No	<p>Not relevant as:</p> <ul style="list-style-type: none"> • use of plant protection products do not affect directly mitigation of weather events or natural hazards including floods, storms, tsunamis, avalanches and landslides. • The provision of this ES is affected for other stressors as land uses, local climate conditions etc.
Waste and water treatment	Ecosystems such as wetlands filter both human and animal waste and act as a natural buffer to the surrounding environment. Through the biological activity of microorganisms in the soil, most waste is broken down. Thereby pathogens (disease causing microbes) are eliminated, and the level of nutrients and pollution is reduced.	Agricultural fields are acting as natural filters to treat water that will end up in fresh water sources, and also they treat waste/pollution through the activity of soil organisms (decomposition of organic materials).	<p>Not Relevant as:</p> <ul style="list-style-type: none"> • The international definition of this ES only refers to the natural process that provide certain soil organisms, soil micro-organisms, aquatic organisms and algae of treating waste and water. Because the effects of pesticide on those organisms are looked at by other ES such as the provision of fresh water, ground water and soil erosion and maintenance of soil fertility this ES is not considered relevant for conducting problem formulation. • However, the potential effects on pesticides on the artificial wastewater treatment facilities should be considered when conducting problem formulation in particular when assessing an active substance that is going to be used in greenhouses or storage rooms. These potential effects will be addressed describing the fate and behaviour of the substance and providing information on the effects on

Economics of Ecosystems and Biodiversity (TEEB) as used in the February 2020 workshop		Does the agricultural field provide this ES? (yes/no, and if yes, how?)	Is this ES relevant for the problem formulation of ERA for the approval/renewal of approval of an active substance/representative use at EU level?
Ecosystem Service	Definition		
			biological method for sewage treatment systems (see Template, Annex X, pg. x). Please read the information below the table on the impact of plant protection products on the effects of plant protection products on the artificial waste water treatment facilities and how this is considered for conducting problem formulation.
Erosion prevention and maintenance of soil fertility	Soil erosion is a key factor in the process of land degradation and desertification. Vegetation cover provides a vital regulating service by preventing soil erosion. Soil fertility is essential for plant growth and agriculture. Well-functioning ecosystems supply the soil with nutrients required to support plant growth.	Yes, agricultural fields are very relevant for the provision of maintenance of soil fertility. In addition, a healthy soil helps to prevent erosion.	Relevant <ul style="list-style-type: none"> Because the type of active substance and the way of application (e.g. soil application, granules, spraying) can have a direct impact on the soil compartment and the organism that live on it (surface, rhizosphere and below). However, it is important to consider that soil is affected by many factors such as the type of soil and vegetation, agricultural practices, etc. Erosion prevention is mostly affected by the more general management of the field.
Pollination	Insects and wind pollinate plants and trees which is essential for the development of fruits, vegetables and seeds. Animal pollination is an ecosystem service mainly provided by insects but also by some birds and bats. Some 87 out of the 115 leading global food crops depend upon animal pollination including important cash crops such as cocoa and coffee (Klein et al. 2007).	Yes	Relevant

Economics of Ecosystems and Biodiversity (TEEB) as used in the February 2020 workshop		Does the agricultural field provide this ES? (yes/ no, and if yes, how?)	Is this ES relevant for the problem formulation of ERA for the approval/renewal of approval of an active substance/representative use at EU level?
Ecosystem Service	Definition		
Biological control	Ecosystems are important for regulating pests and vector borne diseases that attack plants, animals and people. Ecosystems regulate pests and diseases through the activities of predators and parasites. Birds, bats, flies, wasps, frogs and fungi act (all) as natural controls.	Yes, agricultural fields are the habitat of many species (mainly insects) that play a key role on pest control because they act as natural predators of other insects thus regulating pests and diseases. In addition, diverse plant associations (e.g. cover crops) can also suppress noxious weeds.	Relevant for agroecosystems where PPP used against a certain pest could impact regulators of other pests and diseases.
Habitat or supporting services			
Habitats for species	Habitats provide everything that an individual plant or animal needs to survive: food; water and shelter. Each ecosystem provides different habitats that can be essential for a species' lifecycle.	Yes , for those species adapted to agroecosystems. This includes for instance invertebrates ³¹ , vertebrates (e.g. farmland birds), etc.	Relevant , in the context of ERA in the context of Regulation of (EC) No 1107/2009 the ES is interpreted as: <i>Plant protection products shall not have an unacceptable effect on food, water and shelter so that animals and plants population have everything to support their lifecycle.</i> It is important to recognize that other factors and stressors impact this ES e.g. landscape structure, climate change, dynamics of invasive species.
Maintenance of genetic diversity	Genetic diversity is the variety of genes between and within species populations. Genetic diversity distinguishes different breeds or races from each other thus providing the basis for locally well-adapted cultivars and a gene pool for further developing commercial crops and livestock. Some habitats have an exceptionally high number	Maybe, for specific cases.	Not relevant for maintenance of gene pool of cultivars and commercial crops For the broader interpretation of maintenance of genetic diversity: <ul style="list-style-type: none"> • Biodiversity at species level would be covered by the ES "Habitats for species". • The scope of Regulation (EC) No 1107/2009 and the goal of conducting ERA at EU level is to ensure that plant protection products shall not have unacceptable effects on the environment (Article 4.3 Regulation (EC) No 1107/2009) and not the conservation of biodiversity hotspots or individual species. • In case of vulnerable and endangered species, other instruments

³¹ Update and expansion of the database of bio-ecological information on non-target arthropod species established to support the environmental risk assessment of genetically modified crops in the EU. <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2016.EN-956>

Economics of Ecosystems and Biodiversity (TEEB) as used in the February 2020 workshop		Does the agricultural field provide this ES? (yes/ no, and if yes, how?)	Is this ES relevant for the problem formulation of ERA for the approval/renewal of approval of an active substance/representative use at EU level?
Ecosystem Service	Definition		
	of species which makes them more genetically diverse than others and are known as “biodiversity hotspots”.		<p>apply for their protection from plant protection product use (e.g., Sustainable Use Directive restricting or prohibiting the use of plant protection products in specific circumstances, areas like the Natura 2000 network to ensure the long-term survival of the species and habitats and implementing guidance avoiding the use of plant protection products in these areas). At the European level, most valuable and threatened animal, plant species and habitats are protected in their own right, e.g., the Birds or the Habitats Directives. These provisions would be relevant at Member State level for the PPP authorization and use.</p> <ul style="list-style-type: none"> • Variety of genes within species need to be considered at population level in some cases at landscape scale that is larger than an agricultural field and it is not feasible to address genetic diversity by the current environmental risk assessment framework. • It is important to recognize that there are many other stressors that have strong direct effects on this ES.
Cultural services			
Recreation and mental and physical health	Walking and playing sports in green space is not only a good form of physical exercise but also contributes to people’s relaxation/recreation. The role that green space plays in maintaining mental and physical health is increasingly being recognized, despite difficulties of measurement.	Yes, but not at EU but local scale.	<p>Not relevant at EU level but it may be relevant at local scale and specific locations (e.g. based on specific national legal provisions such as protection of rare species or restriction of use in nature conservation areas) because:</p> <ul style="list-style-type: none"> • Recreation, aesthetic enjoyment, mental health benefits and spiritual experiences are not part of the approval criteria of ERA of the approval/renewal of approval of the active substance under Regulation (EC) No 1107/2009. Therefore, cultural services are not considered relevant for the ERA needed for the approval/renewal of approval of active substance at EU level. • There is not a known or agreed quantitative link between plant protection products use and its effect on cultural services at the EU level. • The provision of cultural services is affected by many other factors that cannot be currently operationalized in the selection of test species for ERA at EU level.
Tourism	Ecosystems and biodiversity play an important role for many kinds of tourism which in turn provide considerable economic benefits and are a vital source of income for many countries. Cultural and eco-tourism can also educate people		

Economics of Ecosystems and Biodiversity (TEEB) as used in the February 2020 workshop		Does the agricultural field provide this ES? (yes/ no, and if yes, how?)	Is this ES relevant for the problem formulation of ERA for the approval/renewal of approval of an active substance/representative use at EU level?
Ecosystem Service	Definition		
	about the importance of biological diversity.		
Aesthetic appreciation and inspiration for culture, art and design	Language, knowledge and the natural environment have been intimately related throughout human history. Biodiversity, ecosystems and natural landscapes have been the source of inspiration for much of our art, culture and increasingly for science.		
Spiritual experience and sense of place	In many parts of the world natural features such as specific forests, caves or mountains are considered sacred or have a religious meaning. Nature is a common element of all major religions and traditional knowledge, and associated customs are important for creating a sense of belonging.		

Important remarks:

- It is acknowledged that under the TEEB list there is not a proper reference to the provision of groundwater. Therefore, it is difficult to see how the potential effects of the use of a plant protection product in groundwater are going to be addressed by the ES framework. In any case, the possible groundwater contamination by a pesticide use is addressed under fate and behaviour and it will be part of the data submitted in dossier. In general, groundwater can be exposed to a PPP in different ways:
 - Field use – direct impact of PPPs on surface waters and from there to groundwater (green arrow)
 - Field use – direct impact on soil, infiltration and then contamination of groundwater (yellow arrow)
 - Reuse of water from the sewage plants

In this basis and with the purpose of conducting problem formulation for ERA of an active substance at the EU level, a specification is added to relevant ES of **fresh water (surface water and groundwater)**.

- The TEEB definition of the ES of **waste water treatment** only refers to the natural process that provide certain soil organisms, microorganisms, aquatic organisms and algae of treating waste and water. Because the effects of plant protection products on those organisms are looked at by other ES such as the provision of fresh water, ground water and soil erosion and maintenance of soil fertility this ES is not considered relevant for conducting problem formulation. However, the potential **effects of plant protection products on the artificial waste water treatment facilities** should be considered when conducting problem formulation in particular when assessing an active substance that is going to be used in greenhouses or storage rooms. These potential effects will be addressed describing the fate and behaviour of the substance and providing information on the effects on biological method for sewage treatment systems (See template, Section 2).

After considering these remarks, The ES of **fresh water (surface water and groundwater), erosion prevention and maintenance of soil fertility, pollination, biological control, and habitats for species** are the five **relevant ecosystem services** to conduct problem formulation for the environmental risk assessment needed for the approval/renewal of approval of an active substance at EU level (see Figure 3).

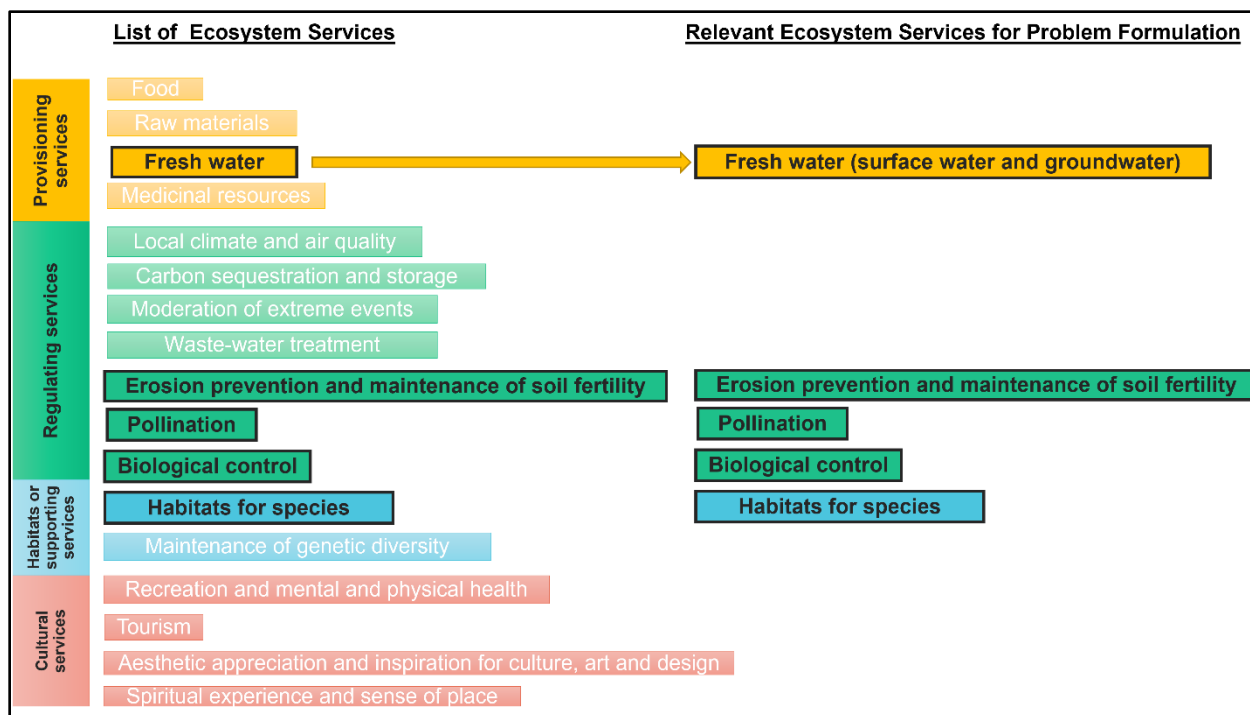


Figure 3. On the left the ecosystem services according to the TEEB List (17 ES divided into 4 categories). In bold and highlighted black boxes: the relevant ecosystem services identified for problem formulation. On the right, the five relevant ecosystem services for problem formulation according to the explanations given in Table 2.

3. Linking the relevant ecosystem services to the data requirements of the current regulatory framework

After identifying the five relevant ES the link between those and the existing test species needs to be established as the Step 2 of the EFSA method explains (see pg. 14) . This link is established via the key drivers and service providing units (SPUs).

EFSA (2010, 2016)^{15 16} defines key drivers and SPUs as synonyms concepts that link groups of organisms or species with the ecosystem services they provide; changes in – for instance abundance - of these groups of organisms are expected to have implications for the ES provision. EFSA identified in its opinion (EFSA, 2010) seven **key drivers** covering all ecosystem services which could potentially be affected by the use of plant protection products: vertebrates, bees, terrestrial invertebrates, aquatic invertebrates, algae, non-target plants and micro-organisms (see Figure 4).

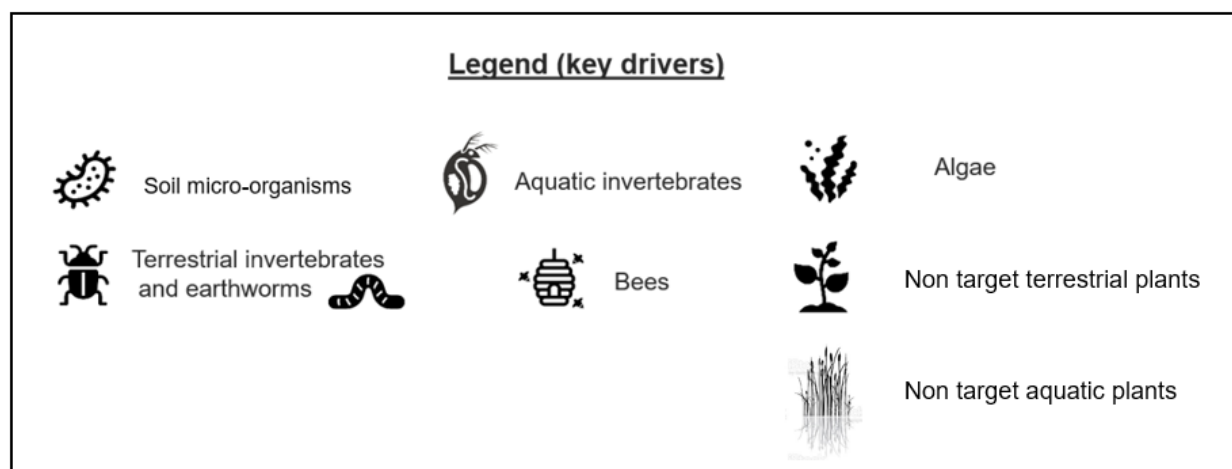
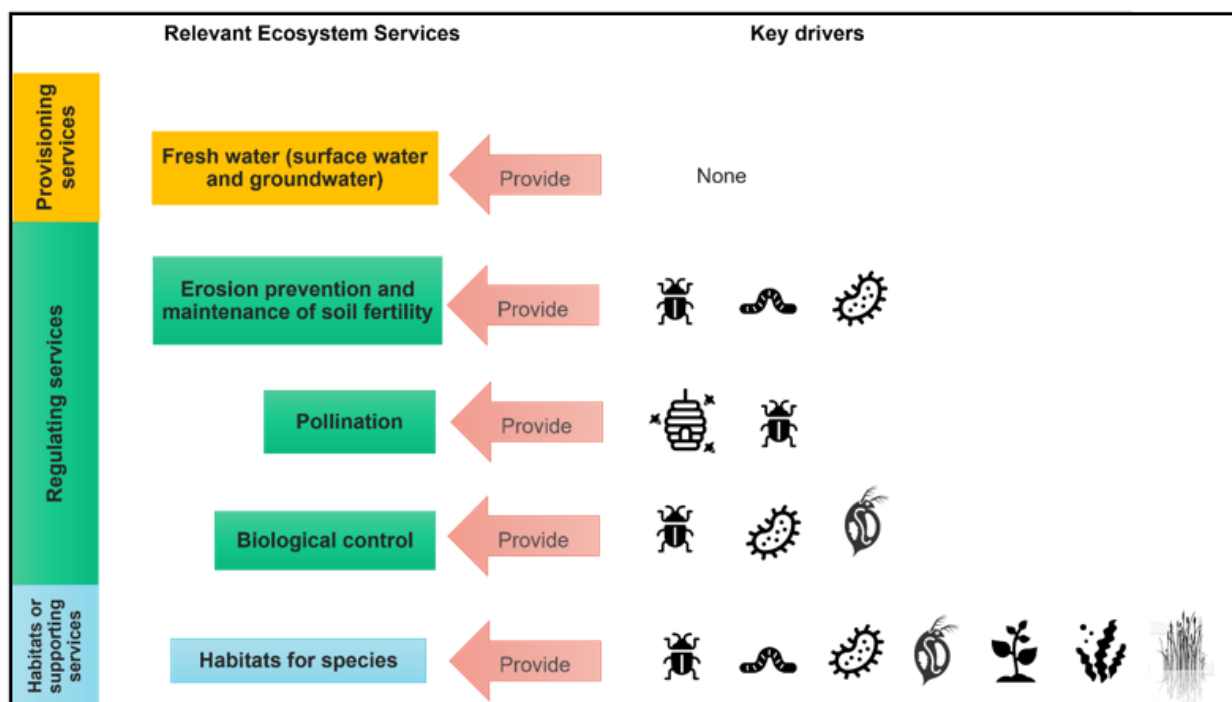


Figure 4. Key drivers for the Ecosystem Services identified by EFSA (2010).

To cover the current data requirements and ensure the protection of the environment under Regulation (EC) No 1107/2009, some additions to the SPUs identified by EFSA (2010) are proposed. For fresh water, SPUs were added considering current aquatic test species. Furthermore, to include a widest possible range of taxa under the ES habitats for species while making the link to the current test species, species which benefit from this ES were added to the service providing units identified by EFSA in 2010. Figure 5 presents all the SPUs for the relevant ES.

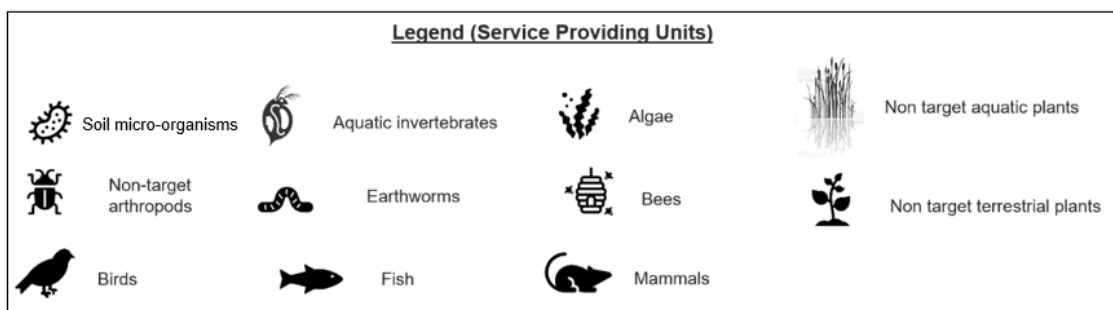
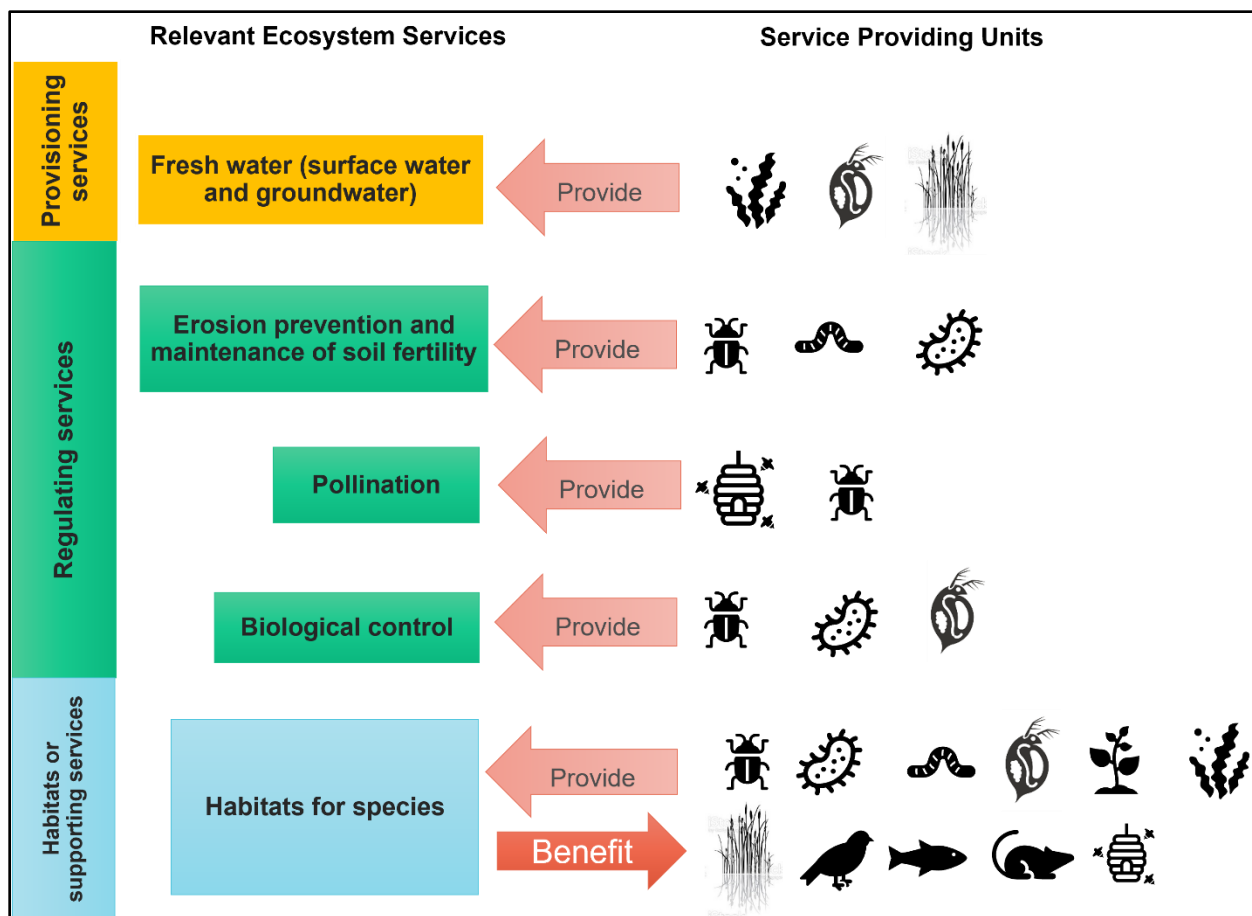










Figure 5. Service providing units that link the relevant ES and the current test species. For the ES habitats for species, the species that benefit from this ES have been included.

For each of the SPU, ultimately test species need to be selected. Commission Regulations (EU) No 283/2013 and (EU) No 284/2013 set out the data requirements for active substances and plant protection products, respectively, and define the current relevant test species. These test species represent typical organisms of a functional group (e.g., arthropods that act as predators or parasitoids to pests) for which standardised ecotoxicological test protocols are available. Table 3 shows the list of the existing mandatory test species for the assessment of an active substance/representative use at EU level. Nevertheless, the applicant can always perform additional tests, using ad-hoc protocols, to show a safe use.

Table 3 List of existing test species for the EU assessment of active substances and plant protection products and its link to the Service Providing Units.

Service Providing Unit to which the test species belongs to	Current species that can be tested based on Commission Regulations No 283/2013 and 284/2013 and relevant guidance documents
Terrestrial and aquatic vertebrates 	Mouse (<i>Mus musculus</i>) Rat (<i>Rattus sp.</i>) Rabbit (<i>Lepus sp.</i>) Dog (<i>Canis sp.</i>) Quail species (<i>Coturnix spp.</i>) Mallard duck (<i>Anas sp.</i>) Feral pigeon (<i>Columba sp.</i>) Zebra finch (<i>Taeniopygia guttata</i>) Budgerigar (<i>Melopsittacus undulates</i>) Rainbow trout (<i>Oncorhynchus mykiss</i>)
Bees 	Honeybee (<i>Apis mellifera</i>) Bumblebee (<i>Bombus sp.</i>) Solitary bee (<i>Osmia sp.</i>)
Non-target arthropods (Terrestrial invertebrates) 	<i>Aphidius rhopalosiphi</i> , aphid parasitoids that are small wasps and kills aphids, largely used in biological control <i>Typhlodromus pyri</i> , predatory mites that feed largely on other mites, used in biological control <i>Coccinella septempunctata</i> <i>Chrysoperla carnea</i> <i>Folsomia candida</i> , springtail (Collembolans) in leaf litter, compost piles and soil, recycling dead plant material into nutrients
	<i>Hypoaspis aculeifer</i> , soil dwelling mite which feeds on small arthropods and nematodes.
Earthworms (terrestrial invertebrates) 	Earthworms (<i>Eisenia foetida</i>)
Aquatic invertebrates and sediment dwelling organisms 	<i>Daphnia magna</i> , small aquatic crustaceans <i>Chironomus riparius</i> , insects which larvae live in sediment Mysid shrimp
Algae 	<i>Lumbriculus spp.</i> , sediment dwelling worms Green algae - unicellular
Non-target terrestrial and aquatic plants 	Six different species including both mono and dicotyledons <i>Lemna sp.</i> , aquatic plant <i>Myriophyllum sp.</i> , aquatic plant Aquatic grass such as <i>Glyceria maxima</i>
Soil micro-organisms 	Microflora (soil microorganisms for nitrogenation and oxigenation) – part of the soil

Annex II: Case studies conducted during the commenting phase of the draft document.

A draft of this document was consulted with Member States and stakeholders during June and July 2022. Consulted experts were invited to comment on the document on the basis of case studies developed by themselves, in order to test the template and to provide comments which were based on concrete and “hands on” experience. These case studies concluded that some or all studies on non-target organisms would have not been required for the ERA of certain representative uses.

These case studies have so far not been validated nor peer-reviewed, however provided useful insights to experts commenting on the document. Further developments might be possible with increasing experience.

For transparency reasons, below an overview of the 23 case studies submitted by the consulted experts is provided. They are listed considering the plant protection product use and the type of the active substance.

1. Permanent greenhouse by drenching or spraying / chemical fungicide
2. Permanent greenhouse soil application via the drip irrigation system / botanical active substance – nematicide
3. Greenhouse by foliar spraying / botanical active substance
4. In door - gas-tight storage structures/ chemical fumigant insecticide & rodenticide
5. In door by drenching or dipping / botanical active substance -fungicide / bactericide
6. In door by drenching or spraying / chemical fungicide
7. In door by dipping or drenching / lipopeptide - fungicide
8. Seed treatment in an ESTA certified site³² / chemical fungicide
9. Seed treatment in a non-ESTA certified site /micro-organism
10. Outdoor by foliar spraying/ botanical active substance
11. Outdoor spraying / glucose
12. Outdoor in a container-insect trap / chemical insecticide
13. Outdoor by burrow application / chemical fumigant insecticide & rodenticide
14. Outdoor by localised application -plant detection/chemical herbicide
15. Outdoor by broadcast application on established grassland / chemical – antibody based
16. Outdoor by broadcast application / chemical herbicide
17. Outdoor by localised application - precision technique/chemical insecticide
18. Outdoor by localised application – precision sprayer / chemical – selective herbicide
19. Outdoor by spraying/ micro-organism (entomopathogenic)
20. Outdoor by spraying / formulation that reduces drift
21. Outdoor by spray application / lipopeptide fungicide
22. Outdoor by spraying / RNA insecticide
23. Outdoor pre-emergence application after drilling /chemical herbicide

³² https://euroseeds.eu/app/uploads/2020/02/20.0051_ESTA-Standard_v2.5.pdf