CropLife Europe Proposed strategy to set specific protection goals (SPGs) for non-target terrestrial organisms (NTTOs) in preparation for the upcoming EFSA guidance on NTPs, NTAs and soil organisms

Aim of this document

In 2024, the EU Commission mandated EFSA (the authority in charge of evaluating the risk of plant protection products to humans and the agricultural environment) to make proposals on how to better protect plants outside of the cropped fields, and insects and soil organisms both in the cropped field and outside of the field, which are not the target of weed, pest and disease control methods. In this mandate[1], the EU Commission requests EFSA to consider the agricultural practices and agronomic aspects, to ensure that the new regulation will not further hinder agricultural production. The conservation of particular species, habitats or environments is out of scope of the mandate, since this is covered by other specific EU legislations (e.g., Habitats Directive, Birds Directive, Sustainable Use of Pesticides Directive).

EFSA has recently released their proposed strategy to fulfill this mandate (EFSA, 2025[2]). In this document we set the recently shared document of EFSA into context of the mandate by the EU Commission and the agricultural practice.

CropLife Europe (CLE) appreciates the transparent and well-structured approach by EFSA for setting up the specific protection goals. However, since this discussion needs in-depth understanding of various complex matters like agronomy, ecology, ecotoxicology, land management as well as the regulatory, legal and political processes we think it might be very helpful for other stakeholders to consider our arguments on the proposal from EFSA. Therefore, we tasked a group of experts to link the proposal of EFSA to agronomic practice and current regulation and assess the realism, complexity and pragmatism of the EFSA approach. Since decisions are improved by transparency of such a process, we would be very happy to see similar documents from other stakeholders soon to allow for a fact-based discussion.

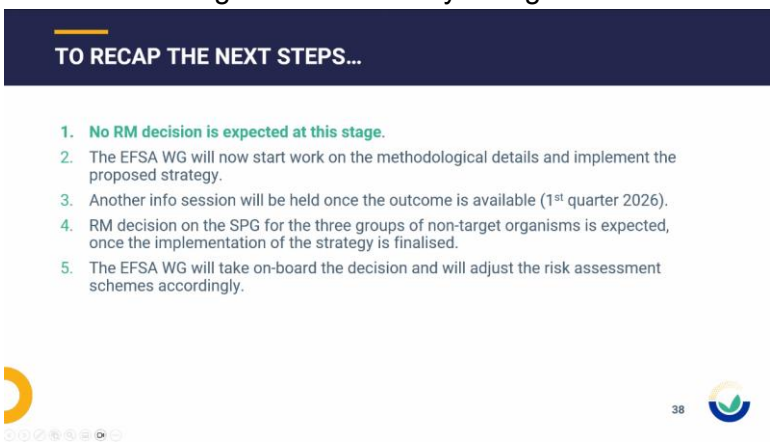
[1] EC, 2024b, M-2024-00086, https://open.efsa.europa.eu/question/EFSA-Q-2024-00464
[2] EFSA, 2025: https://doi.org/10.2903/j.efsa.2025.9501

Table of Contents

Aim of this document 1
General consideration from the stakeholder call before official release of the scientific report (EFSA, 2025) 3
General process 5
Ecological Threshold Option (ETO) and Ecological Recovery Option (ERO) 14
Indirect effects 16
Non-target terrestrial plants (NTTP) 18
Non target arthropods (NTA) = insects 23
In Soil organisms 27
Lines of evidence to set effect thresholds and time to recovery 31
References 33
Glossary: 33

General consideration from the stakeholder call before official release of the scientific report (EFSA, 2025)

- EFSA conducted a stakeholder consultation on 8th of May in which a draft of the scientific report was shared with stakeholders and discussed
- In the stakeholder consultation EFSA stated (Slide 38) that at this stage no decision of risk managers needs to be taken. EFSA will work out the details in the upcoming months and stakeholders will get involved next year again.



- However, as CLE has already raised during this stakeholder call, we do not agree with this statement. EFSA has prescribed the SPGs already so much that only the most conservative approach is envisaged (selecting the population as entity in-field, allowing only small effects for a very restricted time frame in-field and the using solely Ecological Threshold Option (ERO) off-field i.e. natural recovery processes are disregarded in spite of the explicit mention of it in the EU Commission mandate; see details below). This leaves no room for the risk managers to decide about the appropriate conservatism level of the risk assessment.
- With the currently proposed SPG for NTAs (page 13 of EFSA, 2025) of allowing only small effects (10-35%) on population of insects in the field, all insecticides in the market will fail any upcoming risk assessment. This proposal is not compatible with the provisions of regulation 1107/2009 which request that insecticides must be highly efficacious to be registrable in the EU. This includes both synthetic insecticides and biocontrol products (see details below).
- The “streamlined SPGs” in-field are unfortunately not considering normal agricultural practice. Indeed, any farmer intervention in-field (preparation of soil for seed bed, crop watering, crop protection, harvest, etc.) will lead to effects on both target and non-target species that are higher than negligible or small. This is ignored in the current approach from EFSA, which is not in line with the mandate from the EU Commission. Thus, the streamlined SPGs for the in-field are not a good starting point for further discussions. We urge EFSA to bring agronomic realities in their approaches for the setting the in-field SPGs. The fact that EFSA misses agronomic expertise in their panels was already brought up several times by stakeholders and is identified by EFSA themselves as a limitation (PERA[3] & EFSA Editorial about advancing regulatory science[4]).

[3] PERA scientific report: https://doi.org/10.2903/sp.efsa.2022.EN-7546
[4] EFSA Editorial: https://doi.org/10.2903/j.efsa.2025.e220401

- The approach from EFSA favours land sharing (biodiversity needs to be protected in-field) although a better level of protection of biodiversity can often be reached in the off-field (land sparing). Which approach is most effective depends on the species requirements and the landscape. Therefore, SPGs need to be set for many different situations along the trajectory of land-sparing and land sharing approach[5, 6, 7].

[5] Phalan et al. 2011: https://doi.org/10.1126/science.1208742
[6] Edwards et al. 2014: https://doi.org/10.1111/gcb.12353
[7] Grass et al. 2019: https://doi.org/10.1002/pan3.21

General process

In the table below, we review the strategy EFSA proposed to set specific protection goals (SPGs)[8]. In the left column the original EFSA text is shown and our considerations are added in the right column. In this chapter we focus on the general process of the SPG setting and setting the strategy of EFSA in line with the mandate[9] and the recently published guidance on problem formulation for Regulation (EC) No 1107/2009 (EC, 2024a[10]).

Page	Original EFSA-Text	Consideration
Page 5	The scope of this document is to illustrate the strategy proposed by the WG for supporting Risk Managers (RM) in the definition of the SPGs. The methodology, which will be further detailed at a later stage, uses as a starting point the scientific opinions of the PPR panel on Non-Target Terrestrial Plants (EFSA PPR Panel, 2014a), Non-Target Arthropods (EFSA PPR Panel, 2015) and In-Soil Organisms (EFSA PPR Panel, 2017), where SPG options were comprehensively explored, in line with the PPR panel opinion (EFSA PPR Panel, 2010) and EFSA Scientific Committee GD (2016).	We welcome that EFSA follows the cited guidance in their approach for setting SPGs. However, the previous step of prioritizing ecosystem services to be delivered in-field and off- field is missing, which leads to the over conservatism of the approach EFSA follows to define the SPG quantitively (all ecosystem services have to be protected everywhere all the time). This step of prioritizing the ecosystem services is indeed not in EFSA's remit, and therefore, a consultation with risk managers at the beginning of the process is needed to define what to protect where, before EFSA can start their work on setting SPGs (which are enablers for ensuring that the priority ecosystem services will indeed be delivered where/when they are required). In addition, EFSA used the ecosystem services stated in the EFSA scientific opinion as basis for SPG setting. Some of the ecosystem services are no more within the scope of the mandate and some others are used in a "ecocentric" approach (rather than anthropocentric), thus failing to meet an essential requirement of the ecosystem services concept.

[8] EFSA, 2025: https://doi.org/10.2903/j.efsa.2025.9501
[9] EC, 2024b, M-2024-00086, https://open.efsa.europa.eu/question/EFSA-Q-2024-00464
[10] EC, (2024a): Problem formulation for environmental risk assessment in the context of Regulation (EC) No 1107/2009.

Page 5	For the groups of NTOs considered in this document, previous work related to the definition of SPGs is already available. The Scientific Opinions of the PPR Panel (EFSA PPR Panel, 2014a, 2015, 2017) all include sections dedicated to this topic. More concretely, each of the Scientific Opinions lists the Ecosystem Services (ES) that may be impaired by the use of plant	EFSA based their whole proposal on scientific opinions which are partially more than 10 years old. Science developed in the last 10 years was mainly ignored. Industry contributed a significant amount of data which is useable to set specific protection goals for terrestrial non-target species in the agricultural landscape. This valuable data is ignored.
Page 10	In determining SPGs, some of the dimensions are restricted to a limited number of possible options (e.g. entity and attribute to be protected, and to some extent the spatial scale). For those, the options proposed by the PPR Panel are considered as fixed, simply because: (I) they make sense from an ecological viewpoint and/or (II) of the way the different SPUs provide the services associated to them.	EFSA skipped the steps to define the ecological entity, attribute and spatial scale of the SPGs and fixed it to settings conducted 10 years ago by a group of experts behind closed doors without any stakeholder discussion. EFSA focused their entire work on the last step only: defining the magnitude of tolerable effects (for the ecological threshold option (ETO) and ecological recovery option (ERO)) and the related temporal scale for the ERO. Thereby, they shift the discussion for the risk managers into these risk assessment specific topics. However, the much more important decision for the risk managers is what needs to be protected in-field, edge of the field and on landscape level. Different ecosystem services might be relevant at the different spatial scales as laid down the problem formulation guidance by the EC (EC, 2024a). In-field is a production area to produce food and therefore food production has to be prioritized as the main ecosystem service to deliver there (EC, 2024b).
		It is not the decision of EFSA what needs to be protected at which spatial scale, this is a risk managers decision that requires to be proportionate. Risk-benefit approaches for the agricultural landscape need to be taken into account and ecosystem services like food production vs. protection of biodiversity need be weighted.

		The ecological viewpoint EFSA refers to is based on the concept of land sharing, so biodiversity needs to be protected in the agricultural landscape and in-field. Recent scientific publications have highlighted that protection of biodiversity is much more efficient in the land sparing than in the land sharing approach[11, 12, 13] . Which approach is most effective depends on the species requirements and the landscape. There is no "one size fits all" option. Therefore, SPGs need to be set for many different situations along the trajectory of land-sharing and land-sparing. In the end Risk managers need to decide in which regions or under which agricultural conditions land-sharing or land-sparing is better suited.
Page 10	The EFSA Scientific Committee (2016) gives guidance on how to set specific protection goals that cover the general protection goals set in the Regulation 1107/2009, i.e., 'non target organisms' 'biodiversity and the ecosystem' using the framework of the 'ecosystem service approach'. The ES concept is inherently linked to the functioning of the ecosystems. However, the EFSA Scientific Committee (2016) indicates that most types and categories of ES have elements that either depend on or are influenced by biodiversity.	It is not controversial that biodiversity and ecosystem services are linked. However, maintaining ecosystem services (e.g. soil structure and soil function) in field does not require to protect the whole biodiversity of soil organisms in the field, due to the functional redundancy of the single species. As shown by Pamminger et al 2021[14], even large effects (up to 80% effect on total abundance) on, e.g., springtails and mites, with a duration of up to 6 months after treatment were shown to have no relevant impact on the function ´organic matter degradation` in arable field soil, one of the agronomically most relevant services provided by soil organisms.

[11] Phalan et al. 2011: https://doi.org/10.1126/science.1208742
[12] Edwards et al. 2014: https://doi.org/10.1111/gcb.12353
[13] Grass et al. 2019: https://doi.org/10.1002/pan3.21
[14] Pamminger et al. 2021: https://doi.org/10.1002/ieam.4563

Page 10	Functional groups were often mentioned by the PPR Panel as the appropriate ecological entity to be protected. Nonetheless, the three Scientific Opinions summarised in section 2.1 put a great deal of attention also to structural elements of the ecosystem, namely: • By including 'provision of biodiversity' and other associated items (i.e. cultural, aesthetic, availability of genetic resources) in the list of ecosystem services. • By suggesting more structure-related ecological entities to be protected (e.g. population, communities), especially for off-field assessments, even for those ecosystem services which are a direct consequence of the composition of functional groups (e.g. food web support, pest control, pollination, maintenance of soil structure).	The problem formulation guidance of the EC, which is referenced in the mandate, states that the ES listed here are not in scope of 1107. "Maintenance of genetic diversity": • 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. "Cultural & Aesthetic services": 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. Based on the EC commission mandate, the risk management decision on these ecosystem services was already taken. Therefore, these argument should not be used to set specific protection goals under Regulation (EC) No 1107/2009. In the EFSA colloquium 28 on assessing indirect effects of pesticides in environmental risk assessment, professor L. Maltby addressed the question of the importance of structure vs. function for delivering ecosystem services in detail in a keynote presentation[15]. She concluded that the most relevant approach for the risk assessment (protecting either structure or function) depends on the ecosystem service which we want to ensure the delivery of. This emphasizes again

[15] https://www.efsa.europa.eu/en/events/efsas-scientific-colloquium-28-assessing-indirect-effects-pesticides-environmental-risk

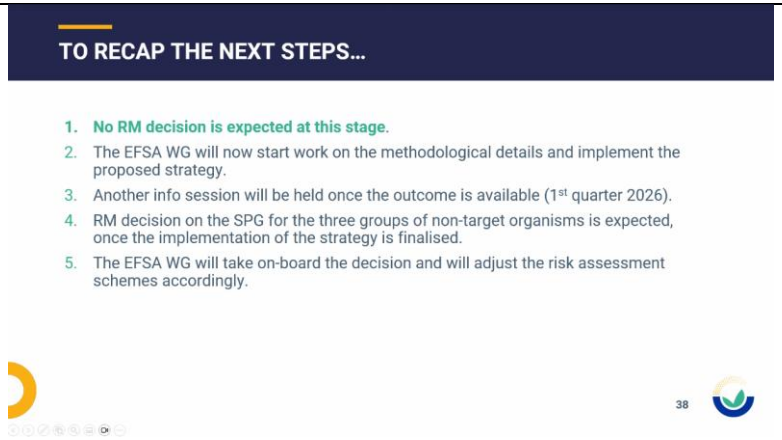
		the need for prioritizing which ecosystem services to prioritize where (in-field and off-field), and the identification of the service providing units (i.e. the steps which EFSA has skipped) before starting to work on defining SPGs that support the ecosystem service delivery.
		The idea to create different SPGs for the different ecosystem services to give options to risk managers is good, but it is not implemented in the current EFSA proposal. • In the mandate (EC, 2024b) it is stated that EFSA should provide the necessary support to risk managers for setting the SPGs and not that EFSA takes already decisions on the SPGs themselves. • In the guidance on SPG setting (EFSA, 2016) it is stated: "Moreover, in the context of defining SPGs, risk assessors may elaborate different options for the SPG as specified by its dimensions. Risk managers then decide which option(s) need to be set as SPG(s)." By not presenting different options for the ecosystems services and the resulting service providing units to be protected to the risk managers, EFSA (as the risk assessor) - and not the risk managers - has decided on the SPG.

Page 11	When the issue is viewed from such perspective, it should be clear that protecting the most vulnerable structural elements of the ecosystem (i.e. maintaining the level of biodiversity) also ensures its functioning, and the delivery of services (while the opposite might not necessarily be true), somehow resolving the dichotomy between biodiversity and ecosystem services. Such consideration is very much aligned with the philosophy underpinning the suggestions related to SPGs contained in the three Scientific Opinions from the PPR Panel.	We agree with the statement of EFSA that protecting the most vulnerable structural elements of the ecosystem will likely ensure the functioning of the ecosystem. However, this approach is leading to an unnecessary level of conservatism. Indeed, science can inform which SPUs are supporting which ecosystem services, and if structure or function matters most in each case (see keynote presentation from Pr. L. Maltby in the EFSA Scientific colloquium 28[16]). Based on this information, EFSA could have a more balanced approach that protects ecosystem services delivery without introducing unnecessary conservatism in the risk assessment. Unfortunately, doing this is an overwhelming task under the current EFSA approach because the priority ecosystem services to deliver have not been prioritized, and we feel that's why EFSA comes back to the "most vulnerable" approach.
Page 11	From the analysis of the SPGs proposed by the three PPR Scientific Opinions summarised in Section 2.1, it appears that, while in the off-field only negligible effects are suggested, in-field some effects higher than negligible could be considered acceptable, if recovery is attained within a suitable timeframe. This seems sensible, as most pesticides are not so specific as to only affect the target species. Nonetheless, the concept of recovery in agricultural landscapes is not straightforward and may warrant further considerations	In the mandate the EC has tasked EFSA to assess "recolonization and/or recovery as a normally occurring ecological process". In other words, the risk managers have decided that they want to be able to assess the ecological recovery option (ERO). However, the specific protection goals which will be further investigated by EFSA will cover only the ecological threshold option (ETO) for the edge of the field and the recovery option will be evaluated only for in-field assessment. Therefore, EFSA does not meet the mandate requirements with this proposal.

[16] https://www.efsa.europa.eu/en/events/efsas-scientific-colloquium-28-assessing-indirect-effects-pesticides-environmental-risk

Page 11	The spatial aspect of SPGs has so far been described as a sort of matrix with two dimensions: the scale (i.e. local field/edge-of-field vs. landscape) and the separation between in-field and off-field. Further considerations on the interaction between those two axes are given in Section 2.2.3.	The "streamlined SPGs" in-field are unfortunately not considering normal agricultural practice. Indeed, any farmer intervention in-field (preparation of soil for seed bed, crop watering, crop protection, harvest, etc.) will lead to effects on both target and non-target species that are higher than negligible or small. This is ignored in the current approach from EFSA. Therefore, we feel that the streamlined SPGs for the in-field are not a good starting point for further discussions. We urge EFSA to bring agronomic realities in their approaches for the setting the in-field SPGs.
Page 14	As summarised in section 2.1 of this document, the PPR Panel already put significant effort into the topic of identifying SPG options for non-target terrestrial organisms. In its Scientific Opinions, the PPR Panel used a consistent scale for classifying the magnitude of effects (negligible: <10%;small: 10-35%; medium 35%-65%; large >65%) and made concrete proposals based on it. Similarly, in case of effects larger than negligible, the Opinions often proposed concrete temporal scales for recovery, based on the ecology of the SPU of interest. The thresholds proposed in the Scientific Opinions are largely based on information on population growth rates, distribution, recovery and recolonisation potential as available at that time, the consequent expert judgment and further qualitative considerations.	EFSA creates the impression as if this were scientifically and societally agreed decisions and thresholds. This is not the case. Not all elements from scientific opinions by EFSA are scientifically justified. Furthermore, these scientific opinions were not agreed by stakeholders, they are not peer-reviewed (as would be the case for a scientific publication) nor commented by stakeholders. It is the sole opinion of the PPR panel dated back to 2014-2015, and the process to establish it was not proportionate. Several publications, presentation and posters have challenged these scientific opinions, which were not assessed or taken into account by EFSA while now drafting specific protection goals. We do not think that the proposals from the scientific opinions (SO) are sufficiently sound to be "taken as is". Indeed, the mapping of ecosystem services to SPGs to test endpoints was not always done properly. Ecosystem services to be delivered were not prioritized (in the current EFSA approach, we protect everything everywhere all the time). This leads to the "misidentification" of the entities and attributes to be addressed in the ERA. Furthermore, we identified a confusion between relevant entities, attributes and assessment endpoints for these attributes (e.g. see below an example of mismatch in the NTP area). We welcome the attempt to use existing endpoints as far as possible to avoid complexifying the ERA, however, the ERA will not work if the endpoints at various tiers and SPG are not connected correctly. We encourage EFSA to

		have a second look at how the mapping of SPG to test endpoints was done in the SOs. Example of a "mapping mismatch": for NTP, the protection goal is set for the ecological entity "population" and the attribute are defined a mix of population attributes (biomass) and individual attributes (reproduction, visual health) [whereas only population relevant attribute should be looked at if the entity to protect is population]. ERA is recommended to be based on the 5th percentile of the distribution of ER10, which distribution relates to species sensitive distribution [SSD is an attribute of a community, not a of population]. Thus, in this approach, there is a lack of coherence between the entity to protect, its attributes and the test endpoints related to these attributes: we are unduly mixing individual, population and community levels. In this mismatch situation, how can we identify which entity will be protected by the final assessment endpoint (individual? population? community?), and how this relates to the delivery of an ecosystem service? We encourage EFSA to engage in a proportionate, open and transparent discussion about this specific protection goals including current state of scientific knowledge and all relevant stakeholders.
Page 14	Thus, the overall strategy proposed in this document consists in building lines of evidence (hereafter LoE) of different types (see section 3.1.2) to substantiate the quantification of such thresholds. Some lines of evidence will mainly be relevant for defining the ETO option (both in-field and off-field) while others target more specifically the ERO option (in-field).	In the mandate (EC, 2024b) it is stated that EFSA should take Recolonization/Recovery as a normally occurring ecological processes. Therefore, the ERO option should also be addressed for the off-field.

		We disagree with the approach that risk managers are not involved in the discussions from the start, and that EFSA themselves has made already a lot of decisions without a proportionate consultation of stakeholders. EFSA made already decision what to protect where and what are acceptable effects (negligible or small), they want the Risk Managers only to decide about the magnitude of these effect categories. With this paradigm EFSA is pushing already the risk assessment scheme outside the mandate, since they ignore the agricultural practices and agronomic aspects. As an example (see NTA section below) they propose to protect NTAs in field allowing only small effects (~25%) on insects: this is not possible for insecticides, which needs to have a high efficacy against insects (>90%) to be registrable under regulation 1107/2009. With this approach, the track of the risk assessment is already set in a way that the new guidance will systematically make it impossible to register any kind of insecticides (synthetic or organic) in agriculture. EFSA will now start their work to give options how much effects are negligible, small or medium and what are appropriate time to recovery. However, this leaves almost no room for risk managers to really decide on what to protect where, and which level of effects is acceptable under which situations.

Ecological Threshold Option (ETO) and Ecological Recovery Option (ERO)

In the mandate the EC has tasked EFSA to assess “recolonization and/or recovery as a normally occurring ecological process” (EC, 2024b). In other words, the risk managers have decided that they want to be able to assess the ecological recovery option. However, the specific protection goals which will be further investigated by EFSA will cover only the ecological threshold option (ETO) for the edge of the field and the recovery option will be evaluated only for in-field assessment.

Recovery could occur from inside of the population which is defined as intrinsic recovery. The speed of this process depends on the life-cycle and reproductive strategy of the organism, e.g. a univoltine insect (only reproducing once a year) will need at least one year for recovery if the effect occurred after the breeding season. Another mechanism of recovery is recolonization from other areas (meta-population, sink-source dynamics). The speed of this process is normally much faster (days-weeks) and depends on the mobility, behavior of the species and the distance to the area from which recolonization occurs. Whether recolonisation occurs and on which temporal scale depends major on the dispersal mechanism of a species and the composition and complexity off-field habitat, so the landscape structure[17].

In the table below, we review the strategy EFSA proposed to set specific protection goals (SPGs)[18]. In the left column the original EFSA text is shown and our considerations are added in the right column.

[17] Chaplin-Kramer et al (2011) https://doi.org/10.1111/j.1461-0248.2011.01642.x, Mazzi et al. (2012) https://doi.org/10.1111/j.1744-7348.2012.00533.x, Vasseur et al., (2013) https://doi.org/10.1016/j.agee.2012.08.013 Martin et al (2019) https://doi.org/10.1111/ele.13265, Peer et al. (2025): https://doi.org/10.1111/j.1461-0248.2011.01642.x

[18] EFSA, 2025: https://doi.org/10.2903/j.efsa.2025.9501

Page	Original EFSA-Text	Consideration
Page 11	From the analysis of the SPGs proposed by the three PPR Scientific Opinions summarised in Section 2.1, it appears that, while in the off-field only negligible effects are suggested, in-field some effects higher than negligible could be considered acceptable, if recovery is attained within a suitable timeframe. This seems sensible, as most pesticides are not so specific as to only affect the target species.	The mandate (EC, 2024b) stated: good agricultural practice and the use of plant protection products. For this, EFSA is requested to maintain established approaches such as separation of the assessment for the target application area (e.g. in-field area destined to crop production) and the areas outside the production area (e.g. off-field), and as regards the possibility of recolonisation and/or recovery as normally occurring ecological processes. EFSA shall Therefore, EFSA should provide options to the risk managers to decide. If recovery is a normally occurring ecological process, as stated in the mandate, at least one option for the SPGs should include the recovery option for the off-field area.
Page 11	Specifying SPGs for both ETO and ERO in-field would facilitate discrimination of situations where an explicit consideration of recovery could be considered vs. those where only negligible effects are expected.	Negligible effects on NTTO organisms in-field are impossible during normal agricultural practice (e.g. irrigation, ploughing, harvesting), which, once more, demonstrates the need of agronomic expertise within the EFSA working group.
Page 11	Nonetheless, that kind of reasoning does not stand for the ERO option. Apart from microorganisms like bacteria, for most NTOs recovery within days, weeks or months is likely to be driven by recolonization from unexposed areas, rather than by internal recovery due to local recruitment of new individuals within the affected area. Whenever recovery is determined by 'source-sink' dynamics, it becomes impossible to neglect the landscape level. One possible way forward would be to only allow the ERO option in the presence of a suitable landscape configuration defined a priori, i.e. a certain balance of treated vs. untreated vegetated areas. This balance could also be attained by modifying the destination of use of some land as a mitigation measure.	The experience with the chick food index and the results of the wildlife trust demonstrates that the impact of indirect effects of pesticide heavily depends on the landscape. Will EFSA assume only a worst-case landscape or will different landscapes characteristics, e.g. differ between MS be assessed? If source-sink dynamics are triggered by landscape level, how important is this to judge about safe use of a specific pesticide in the context of Regulation (EC) 1107/2009? Will EFSA prepare different scenarios with different in-field/off-field areas (like the FOCUS scenarios for surface water) and member states select which of the scenarios are representative for their agricultural area? Who certifies the farmer that his field is in an area which has the right balance between in-field and off-field areas?

Indirect effects

In our point of view for the in-field situation, the target groups (non-crop plants, fungi and bacteria, nematodes and non-beneficial insects) should not be part of the [indirect effects] risk assessment: These groups will be affected by either the use of herbicides, fungicides or insecticide/nematicides. Building an indirect effects assessment on absence or reduction of these groups is rendering the concept of agricultural production ad absurdum, like not registering an antibiotics because it could disturb the intestinal microbiome. PPPs are required to be particularly efficacious on targets resulting in a better performance of the crop to be protected or cured (e.g., in terms of yield). Methods other than synthetic PPPs (e.g., weed burning, tillage, organic insecticides, copper, sulfur) also affect NTTPs, NTAs and soil organisms in-field. In fact, **all crop protection methods** (apart from some genetically modified organisms (GMOs) and a few biologicals, and irrespective of the farming system) **will have some direct effects on either NTTPs or NTAs in the field, which could result in indirect effects depending on other circumstances (the main determinant being the presence and quality of off-field habitats).** Whether the farmer removes weeds with an herbicide or with a plough has the same end-result for NTTPs and NTAs in field (weeds are removed and NTTPs and NTAs are removed with them), and thus the same, or even higher, potential risk of generating indirect effects via trophic interactions[19]. Therefore, it does not make sense to evaluate the risk of indirect effects from a single PPP use in isolation: A proper assessment of indirect effects via trophic interaction requires considering all farmer's interventions for weed/pest control and harvest to set an appropriate baseline.

Experts concluded that an indirect effect assessment for trophic interactions should not be part of Regulation (EC) 1107/2009, since the outcome cannot be attributed to a single active ingredient and is therefore not relevant to assess a safe use as defined in this regulation. In contrast, more than just single products need to be accounted for and the resulting indirect effect will vary based on land management. In addition, ecological data are lacking to sufficiently inform, as well as appropriate tools to support, such assessments. Therefore, adding an indirect effect assessment step in the current risk assessment will trigger unnecessary work and complexity, aggravating the workload for authorities and increasing the delays for (re)-registration of PPPs, without any (or only limited) direct improvement for biodiversity. **Instead, we recommend not to unnecessarily increase EU bureaucracy, but leveraging from the already existing and fit-for-purpose agricultural policies** like the Sustainable Use Directive and the Common Agricultural Policy (CAP) and implementing these in Member States via National Action Plans or CAP Strategic Plans. **If this is planned and managed correctly, the improvement for biodiversity will be much higher with the same or lower resources need.**

In the table below, we review the strategy EFSA proposed to set specific protection goals (SPGs)[20]. In the left column the original EFSA text is shown and our considerations are added in the right column.

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[19] H. M. Cunningham et al., Non-inversion tillage and farmland birds: a review with special reference to the UK and Europe, https://doi.org/10.1111/j.1474-919X.2004.00354.x
[20] EFSA, 2025: https://doi.org/10.2903/j.efsa.2025.9501

Page	Original EFSA-Text	Consideration
Page 15	For the present strategy, explicit consideration of indirect effects is relevant for the definition of ETO/ERO thresholds. Specifically, because: • for an effect to be considered negligible, it is expected that it does not trigger indirect effects larger than negligible to other organisms. Should this not be the case, the proposed thresholds for defining 'negligible' may have to be recalibrated.	In order to assess whether a negligible effect on species A might trigger indirect effects that are not negligible in species B, elaborated food web models with retroaction loops are needed. These models are currently not available. We are concerned about the EFSA strategy that consists in pushing more conservatism to the ERA on the classically used ecotoxicological endpoints, which are not fit for the purpose of assessing effects on food webs at the landscape level. We recommend starting with a lower level of complexity that if negligible effects can be demonstrated on species A, then it is unlikely that an indirect effect on another species will be triggered. In natural systems, and in view of natural variability, it is indeed very unlikely that negligible effects on a species (less then 10% as currently defined for "negligible"!) will trigger an effect on another species. This level of complexity in a ERA is not needed, because it does not match the functioning of real ecological systems More generally, towards the EFSA strategy for addressing indirect effects: In circumstances when indirect effects via trophic interaction might occur (as defined from the risk assessment), the main factor that decides whether indirect effect will manifest or not is the presence and quality of off-field habitat. Scientific literature shows that the use of a weed/pest control method (or any other human disturbance) might lead to higher indirect effects on biodiversity in simplified landscape[21]. A specific intervention may lead to indirect effects in a homogenous landscape, which has only limited suitable off-field habitats, but it might not lead to indirect effects in heterogenous landscape where sufficient habitat of good quality is available in the off-field[22] [23]. Therefore, appropriate mitigation measures for such indirect effects via trophic interactions have to be defined at the landscape level, e.g., by changing the ratio of in-field and suitable off-field areas. One of the possible solutions often proposed for habitat creation is setting aside (productive) land. How much land should be set aside will depend on the local circumstances of the farm. This is a risk management question that

[21] P. Batery et al., The former Iron Curtain still drives biodiversity–profit trade-offs in German agriculture, https://doi.org/10.1038/s41559-017-0272-x
[22] T. Tscharntke et al., Landscape Perspectives on Agricultural Intensification and Biodiversity – Ecosystem Service Management, https://doi.org/10.1111/j.1461-0248.2005.00782.x
[23] I. Litovska, Arthropod abundance is most strongly driven by crop and semi-natural habitat type rather than management in an intensive agricultural landscape in the Netherlands, https://doi.org/10.1016/j.agee.2024.109298

		requires a holistic appraisal of all farming interventions. Thus, it cannot be solved in the context of the risk assessment of a single PPP under Regulation (EC) 1107/2009.
Page 15	• for any 'recovery option', it has to be considered that while it may be feasible for a certain population to completely recover within the time limits proposed by the PPR Panel in their opinions (Section 2.1), it is important to check whether this does not cause any unacceptable indirect effect. It must be noted in this respect that the PPR Panel already posed some time limitations to such recovery options (e.g. for NTAs during bird breeding season and during flowering period).	An indirect effect assessment for in-field effects needs to be judged against the baseline of other agronomics practices (crop choice, other pesticides, mechanical or thermal treatment). Basic data for such an agronomic baseline are currently missing and need to be gathered in a systematic approach. However, CLE experts agreed that it could be possible to assess the indirect effects of a pesticide on some key or umbrella species. For example, the existing chick food index[24] for grey partridge could be adapted to assess the indirect effects of a PPP on farmland birds at landscape level. However, all this complexity will not add to the decision about safe use of a specific pesticide in the context of Regulation (EC) 1107/2009, since the same indirect effects could result from other actives or other farming interventions with the same aim.

Non-target terrestrial plants (NTTP)

In 2014, EFSA identified several, rather nature/ecosystem-centric ESS (*e.g.,* nutrient cycling, water regulation, food web, *etc.*) as relevant for in-field and off-field scenarios. However, according to a recent EC guidance (EC, 2024a[25]), the only relevant ESS assigned to NTTPs in the context of PPPs is the regulating service "habitat for species" (providing everything that an individual plant or animal needs to survive: food, cover). CLE supports and follows this approach. "Habitat for species" is a functional ESS which is more resilient to unintended effects of PPPs than structural

[24] J.M. Holland et al, *Farmland bird invertebrate food provision in arable crops*, https://doi.org/10.1111/j.1744-7348.2011.00521.x.
[25] EC, (2024a): Problem formulation for environmental risk assessment in the context of Regulation (EC) No 1107/2009.

aspects. Higher resilience is based on ecological redundancy whereby effects on individuals or species can be compensated by non-affected individuals or species. Such redundancy is frequently given in plant communities. Accordingly, protecting this ecological entity of NTTPs will ensure the ESS of habitat for species.

In the table below, we review the strategy EFSA proposed to set specific protection goals (SPGs)[26]. In the left column the original EFSA text is shown and our considerations are added in the right column.

Page	Original EFSA-Text	Consideration
Page 6	**TABLE 1** Summary of specific protection goals (SPGs) for non-target terrestrial plants (NTTPs) as proposed by EFSA PPR Panel (2014a). **ES** / **Entity** / **Attribute** / **Magnitude and temporal scale (local scale)** / **Magnitude (landscape scale)** **In-field** Food web support / Functional group / Biomass / Medium effects up to weeks (few days during breeding/chick phase) / Negligible effects Aesthetic value / Population / Visual health / Large effects up to weeks / Negligible effects Genetic resources/ Aesthetic value / Population / Reproduction / Large effects up to weeks / Negligible effects Meta-population / Reproduction / Medium effects up to weeks / Negligible effects **Off-field** Nutrient cycling / Population / Reproduction / Negligible effects / N/A Biomass / Negligible effects Water regulation / Population / Biomass / Small to medium effects / N/A Food web support / Population / Reproduction / Negligible effects / N/A Biomass Biodiversity / Population / Reproduction / Negligible effects / N/A Biomass / Negligible to small effects Aesthetic value / Population / Visual health / Small effects up to days / N/A Reproduction / Small temporary effects / N/A Genetic resources / Population / Reproduction / Small temporary effects / N/A	The ecosystem service “aesthetic values” have been clearly ruled out of the scope of this guidance by the EC commission mandate. 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. Therefore, “visual health” is not a relevant attribute to protect in the scope of this guidance. Also, it would be very difficult to include this attribute in a ERA because: - test endpoints related to visual health are not directly connected with the entity to protect i.e. plant population. - it is unclear how to consider the agronomic baseline (e.g. monocultures, mowed field margins, roads etc.) when assessing impacts on aesthetic values are considered?

[26] EFSA, 2025: https://doi.org/10.2903/j.efsa.2025.9501

		- visual injuries caused by plant diseases and arthropod/nematode infestation would need to be considered too, because they also decrease the aesthetic values. In terms of protectiveness of the ERA, scientific evidence shows that effects from visual injury are often happening at higher concentration than effects on biomass, and thus they are already covered in the risk assessment in most instances. Adding complexity here does not improve the risk assessment and does not serve the purpose of informing the SPG.
Page 12	While different magnitudes of tolerable effects were proposed for different ES, this is not practical for the risk assessment.	EFSA should stop making risk management decisions. It is a risk management decision which ES needs to be protected where. According to the mandate EFSA should develop a risk assessment method fit-for-purpose informing risk managers appropriately. This can be interpreted in a way that the SPGs for different ES are different and will result in different risk assessments, which ES and thereby which risk assessment needs to be applied is a risk manager decision and might be different from zone to zone or MS by MS.
Page 12	By considering the strictest magnitude, an overall SPG for the off-field could be summarised as follows: the off-field could be summarised as follows: Ecological entity: **population** Attribute: **biomass, reproduction, visual health** Spatial scale: **local (edge-of-field)** Magnitude of effects: **negligible effects (small effects for visual health)** Temporal scale: **not applicable (up to days for visual health)**	EFSA should stop making risk management decisions by only laying out the SPGs for the strictest magnitude (see above). Based on their own scientific opinion (EFSA, 2014) the ecological entity can be: • the **functional group**/community with **biomass** as attribute for primary production, provision of habitat and food for other non-target organisms According to the EC problem formulation guidance (EC,2024) these are the ES relevant for assessment under 1107. The off-field SPGs in this scientific opinion were not separated according to the ES.

		The attributes reproduction and visual health are no attributes which can be selected for the entity population (EFSA, 2016). These are attributes if the individual needs to be protected. Setting the magnitude of effects to “negligible” would not allow for consideration of the recovery option which is recommended by the EC mandate (2024), as a risk manager decision, and would not consider the capacity of many species to outgrow damages within their typical life cycle which is best reflected by “weeks to months” as many plant species found in agricultural areas (like herbs and grasses) have a short life cycle and high reproduction rates. // How does the SPG fit a) the Commissions mandate and b) to the Ecosystem services assigned for plants in the Commissions 2024 Guidance on the “Problem Formulation”? The latter document assigns to NTTP’s only one single Ecosystem service: Habitat for species. Habitat for species provided by off-field vegetation structures should be the basis for the SPG setting. Off-field vegetation structures can be described as structural elements e.g. hedge, grassy strips, grassland/meadows, woods, etc. Some of these structures may be further defined by (regionally) typical plant communities. If the service habitat provision is key functional aspects of a vegetation structure are most efficient to describe this ESS. Hence it needs to be identified which features of a vegetation structure around a field are driving habitat provision. The ecological entity may therefore apply to the population (e.g. woody species in a hedge) as proposed by EFSA but it could as well be the plant community (e.g. grassy field margins). Furthermore, additional function of vegetation structures adjacent to the field need to be respected in the SPG setting: vegetation installed primarily as filter/windshield/drift shield are meant to absorb as much of

		plant protection products as possible to prevent their overspill to non-target areas. Therefore, such vegetation structures are part of the managed area in support of the field's productivity. It is not in all cases necessary to assign these areas also to the in-field, but their function as filter justifies lower level of protection for SPG setting.
Page 12	EFSA PPR (2014) does not make an explicit quantification of 'negligible effects'. Nonetheless, in mapping specific protection goals to test endpoints, there are explicit references to the 5th percentile of the distribution of ER10 (effect rates resulting in a 10% effect). Additional assessment factors were suggested to account for uncertainties, but not for targeting a higher level of protection. Thus, it can reasonably be speculated that 'negligible effects' were translated into effects below 10% for 95% of the species.	The current NTP RA is based on the 5% percentile of the ER50 (not ER10). However, this says nothing about what a negligible effect is in the real world. Typical agricultural practices like mowing, trampling or use of fertilizers can significantly impact NTTPs and accordingly it must be considered that this impacts the variability in NTTPs (both, on population and community level). Plant communities in field margins are often species-poor and mostly contain species that are very abundant (such as grasses). Accordingly, it is essential to take into account the baseline of what needs to be protected when setting SPGs.
Page 12	Note that this is consistent with the interpretation given in Appendix A of EFSA Scientific Committee (2016).	This is a circular reference, since the Appendix A of EFSA, 2016 was copied from EFSA PPR (2014).

Non target arthropods (NTA) = insects

Regulation services that enhance agricultural production, namely pest regulation and pollination, are the key ecosystem services provided by NTAs living in the vegetation or on the soil in both production and non-production areas. In areas outside the production zones, supporting services such as secondary production (i.e., provision of habitat) and nutrient cycling also play a significant role.
With the currently proposed SPG for NTAs (page 13 of EFSA, 2025[27]) of allowing only small effects (10-35%) on population of insects in the field, all insecticides in the market will fail any upcoming risk assessment. This proposal is not compatible with the provisions of regulation 1107/2009 which requests that insecticides must be highly efficacious to be registrable in the EU. This includes both synthetic insecticides and biocontrol products. (details see below). Anything which EFSA now conducts to find out if the small effects are 10 or 35% will not help to create an environmental risk assessment which is feasible, flexible and proportionate to address good agricultural practices for the in-field assessment (EFSA, 2024b[28]).

The “streamlined SPGs” in-field are unfortunately not considering normal agricultural practice. Indeed, any farmer intervention in-field (preparation of soil for seed bed, crop watering, crop protection, harvest, etc.) will lead to effects on both target and non-target species that are higher than negligible or small. This is ignored in the current approach from EFSA, which is not in line with the mandate from the EU Commission. Thus, the streamlined SPGs for the in-field are not a good starting point for further discussions. We urge EFSA to bring agronomic realities in their approaches for the setting the in-field SPGs.

In the table below, we review the strategy EFSA proposed to set specific protection goals (SPGs)[27]. In the left column the original EFSA text is shown and our considerations are added in the right column.

[27] EFSA, 2025: https://doi.org/10.2903/j.efsa.2025.9501
[28] EC, 2024b, M-2024-00086, https://open.efsa.europa.eu/question/EFSA-Q-2024-00464

<table>
<tr><th>Page</th><th>Original EFSA-Text</th><th>Consideration</th></tr>
<tr><td>Page 7</td><td>

TABLE 2 Summary of specific protection goals (SPGs) for non-target arthropods other than bees (NTAs) as proposed by EFSA PPR Panel (2015).

ES	Entity	Attribute	Magnitude and temporal scale (local scale)	Magnitude (landscape scale)
In-field				
Genetic resources and biodiversity	(Meta) Population	Abundance	Small effects up to 6 months	Not specified
Cultural services	(Meta) Population	Abundance	Small effects up to 6 months	Not specified
Pest control	Functional group	Abundance	Medium effects up to 4 weeks	Not specified
Food web support	Functional group	Abundance	Medium effects up to 4 weeks	Not specified
		Biomass	Small effects up to 6 months[a] No shortfall below the limits given by chick-food indices	
Pollination	Functional group	Abundance	Medium effects up to 4 weeks (outside flowering period) Small effects up to 6 months[a]	Not specified
Off-field				
Genetic resources and biodiversity	Population	Abundance	Negligible effects	Negligible effects
Cultural services	Population	Abundance	Negligible effects	Negligible effects
Pest control	Population	Abundance	Negligible effects	Negligible effects
Food web support	Population	Abundance	Negligible effects	Negligible effects
		Biomass		
Pollination	Population	Abundance	Negligible effects	Negligible effects
		Biomass		

[a]Note that the recovery time given for different effect levels is not additive. On the contrary, the maximum allowed recovery time given for a certain effect level includes the duration of effects above such effect level as well. For example, if medium effects are recorded, the maximum allowed recovery time given for small effects (i.e. 6 months) includes the time during which effects are in the medium level.

</td><td>The ES evaluated were not in line with the **EC Problem formulation guidance** (2024) in which the ES of the category cultural services and genetic resources and biodiversity are seen as out of scope for 1107.

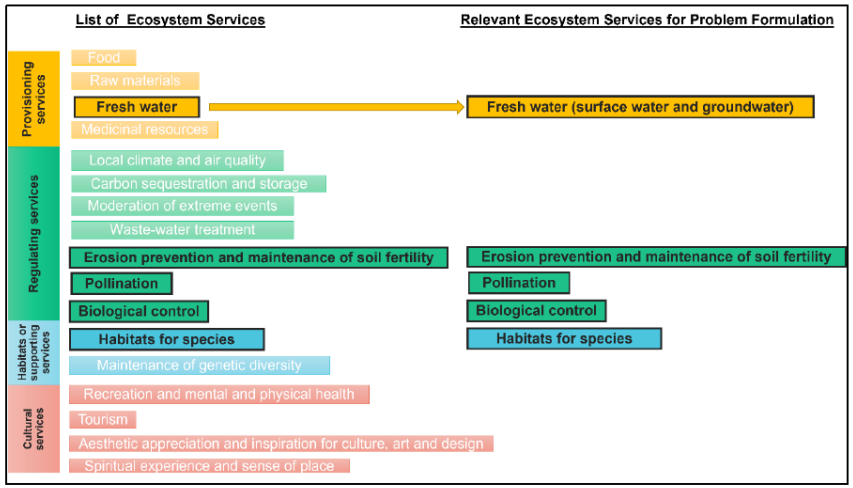

Figure 3. On the left the ecosystem services according to the TEEB List (17 ES divided into 4 categories). In bold and highlighted black boxes: the relevant ecosystem services identified for problem formulation. On the right, the five relevant ecosystem services for problem formulation according to the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

In the mandate (EC, 2024b) it is stated that EFSA should take Recolonization/Recovery as a normally occurring ecological process. This seems not to be reflected in the SPG setting for the edge of the field.</td></tr>
<tr><td>Page 13</td><td>For the **in-field**, the entity to be protected is generally the **functional group**, while for biodiversity/genetic resources/aesthetic value is the **(meta) population**. The attribute is</td><td>EFSA should take into account only the relevant categories of ES according to the problem formulation guidance (EC, 2024a[29]). For which the ES “Genetic resources and biodiversity” and “Cultural</td></tr>
</table>

[29] EC, (2024a): Problem formulation for environmental risk assessment in the context of Regulation (EC) No 1107/2009.

	again **abundance** alone or in combination with **biomass.**	services" are seen as not relevant. Therefore, the entity to protect in-field in the streamlined proposal should be the **functional group and not the population for NTAs**
Page 13	A magnitude of tolerable effects and related temporal scale are only proposed at the local scale, and they vary. The most conservative selection was made for biodiversity/genetic resources/aesthetic value, for which only **small effects up to 6 months** were proposed in the Scientific Opinion.	EFSA should take into account only the relevant categories of ES according to the problem formulation guidance (EC, 2024a). For which the ES "Genetic resources and biodiversity" and "Cultural services" are seen as not relevant. If only the relevant ES for the in-field assessment are taken into account EFSAs own conclusion (Table 2, Page 8 or Slide 12) would be Small effects up to 6 Month and Medium effects up to 4 weeks for the functional group. Natural pest predators, parasitoids (beneficial arthropods) and pollinating arthropods are the key SPUs for the ESS pest regulation and pollination. It is highlighted that the main pollinator groups relevant for pollination are managed honeybees, bumblebees and solitary bee species, covered by the bee guidance document (EFSA, 2023[30]). In integrated pest management the objective is keeping pest damage below economically viable levels for agricultural production, while natural pest control and PPPs are complementary tools. At the economic threshold level, where intervention is necessary, trade-offs between the protection of natural enemies and limiting pest damage by applying PPPs arise. In pollination, a trade-off arises when adult insect stages provide pollination, while the herbivore larval stage acts as pest.
Page 13	Thus, in order to provide a consistent SPG that covers all possible impacts on the different ES, the following is proposed:	EFSA should take into account only the relevant categories of ES according to the problem formulation guidance (EC, 2024a), in which

[30] EFSA, 2023: *Revised guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. And solitary bees).* https://doi.org/10.2903/j.efsa.2023.7989

	Ecological entity: **population/meta-population** Attribute: biomass, abundance Spatial scale: local (field/edge-of-field)/landscape4 Magnitude of effects: negligible effects (off-field)/small effects (in-field) Temporal scale: not applicable (off-field)/recovery within 6 months (in-field) EFSA PPR (2015) provides a tentative quantification of 'negligible' (< 10%), 'small' (10-35%), 'medium' (35-65%) and 'large' (> 65%) effects.	the ES "Genetic resources and biodiversity" and "Cultural services" are seen as not relevant. Therefore, the entity to protect in-field in the streamlined proposal should be the **functional group and not the population for NTAs as shown on this slide.** The scope of Regulation (EC) No 1107/2009 and the goal conducting ERA at EU level is to ensure that plant protection produ shall not have unacceptable effects on the environment (Article Regulation (EC) No 1107/2009) and not the conservation biodiversity hotspots or individual species. In the mandate (EC, 2024b) it is stated that EFSA should take Recolonization/Recovery as a normally occurring ecological process. This seems not to be reflected in the SPG setting for the edge of the field.
	Based on the question of CLE representatives in the stakeholder meeting why the most conservative SPGs were selected and not the functional group as entity and the EC guidance on problem formulation (EC, 2024) was ignored EFSA replied: "*indirect effects from the direct effects on the NTAs will lead to reduction of biodiversity outside of the field. Therefore this much stricter SPGs were chosen.*"	Indirect effect for trophic interactions might occur from direct in-field effects, depending on the landscape. However, also for this indirect effect, a functional group (e.g. biomass for bird) can be defined and the protection in-field does not need to be on single species level. We need to be aware that already the intended use (reducing the pest insects) affects this ecosystem in-field.

In Soil organisms

Soil organisms provide important ecosystem services in-field as well as in the off-field area, namely nutrient cycling, pest and disease control, soil structure formation and water retention, support of food webs. It has to be taken into account that the farmer is managing the field and disruption of important ecosystem services like nutrient cycling would be disrupted impacts on yield should be expected. In contrast soil structure is changed by the farmer on purpose with good agricultural practices without the use of pesticides. Therefore, an agronomic baseline is mandatory to set the specific protection goals for in-field effects. Without such a baseline the specific protection goals cannot achieve to create an environmental risk assessment which is feasible, flexible and proportionate to address good agricultural practices for the in-field assessment (EFSA, 2024b[31]).

Thus, the streamlined SPGs for the in-field are not a good starting point for further discussions. We urge EFSA to bring agronomic realities in their approaches for the setting the in-field SPGs.

In the table below, we review the strategy EFSA proposed to set specific protection goals (SPGs)[32]. In the left column the original EFSA text is shown and our considerations are added in the right column.

[31] EC, 2024b, M-2024-00086, https://open.efsa.europa.eu/question/EFSA-Q-2024-00464

[32] EFSA, 2025: https://doi.org/10.2903/j.efsa.2025.9501

<table>
<tr><th>Page</th><th>Original EFSA-Text</th><th>Consideration</th></tr>
<tr><td>Page 7</td><td>According to the EFSA PPR Panel (2017) opinion on in-soil organisms, the main ecosystem services potentially impacted are:

• Provision of genetic resources and biodiversity
• Maintenance of cultural services
• Nutrient cycling
• Pest and disease control
• Natural attenuation
• Soil structure formation (and water retention)
• Support of food webs

TABLE 3 Summary of off-field specific protection goals (SPGs) for in-soil organisms as proposed by EFSA PPR Panel (2017).

<table><tr><th>SPU</th><th>Ecological entity</th><th>Attribute</th><th>Magnitude (local scale)</th></tr><tr><td>Earthworms</td><td>Population</td><td>Abundance/biomass</td><td>Negligible effects (comparable to 10%)</td></tr><tr><td>Enchytraeids</td><td></td><td></td><td></td></tr><tr><td>Microarthropods</td><td></td><td></td><td></td></tr><tr><td>Macroarthropods</td><td></td><td></td><td></td></tr><tr><td>Gastropods</td><td></td><td>Abundance</td><td></td></tr><tr><td>Nematodes</td><td>Population/community</td><td>Abundance/community structure</td><td></td></tr><tr><td>Mycorrhiza, other fungi and protozoa</td><td>Community</td><td>Structure</td><td></td></tr><tr><td>Soil bacteria and Archaea</td><td></td><td>Diversity</td><td></td></tr></table></td><td>The ES evaluated were not in line with the EC Problem formulation guidance (2024) in which the ES of the category cultural services and genetic resources and biodiversity are seen as out of scope for 1107.

 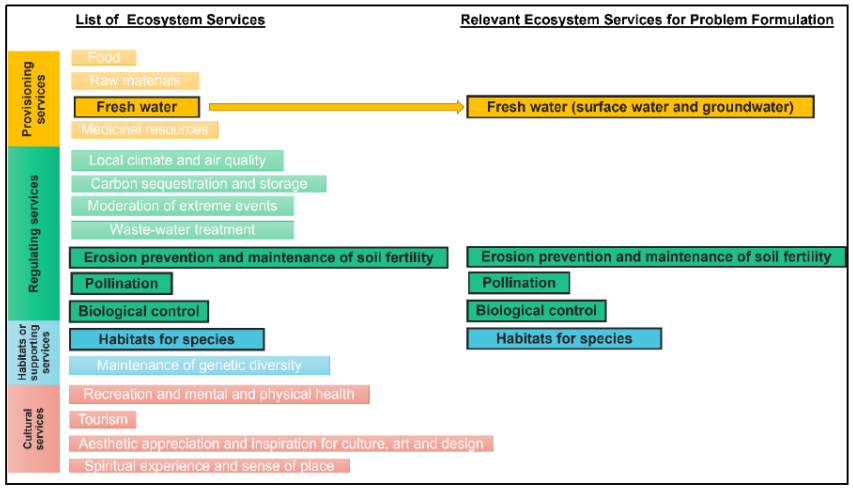

Figure 3. On the left the ecosystem services according to the TEEB List (17 ES divided into 4 categories). In bold and highlighted black boxes: the relevant ecosystem services identified for problem formulation. On the right, the five relevant ecosystem services for problem formulation according to the explanations given in Table 2.</td></tr>
<tr><td>Page 13</td><td>For soil macro and mesofauna, the ecological entity is generally the population. If this is protected, the functional group is automatically addressed as well. The attributes are abundance and biomass. For the off-field, only negligible effects (comparable to a No effect level or 10%) were suggested. For the in-field, small effects (quantified as in the range 10-35%) up to 6 months were proposed as possible for all SPUs. Medium effects (quantified as 35-65%) up to 4 weeks were suggested for all SPUs except earthworms and gastropods.</td><td>EFSA should take into account only the relevant categories of ES according to the problem formulation guidance (EC, 2024), in which the ES “Genetic resources and biodiversity” and “Cultural services” are seen as not relevant. Therefore, the entity to protect in-field in the streamlined proposal should be the functional group and not the population for in-soil organisms as shown in Table 5 (page 9).</td></tr>
</table>

Page 1	For soil micro-organisms, the ecological entity differs depending on the organisms considered and is more variable. When this is the population or the functional group, the attribute to protect is generally the abundance or the biomass and/or the activity. When the ecological entity is the community, then the attributes are structure and diversity. The magnitude and timescale of tolerable effects are similar to those proposed for the macro and mesofauna for both in-field and off-field, with the exception that, for bacteria, large effects (> 65%) up to 7 days were suggested as tolerable.	The scope of Regulation (EC) No 1107/2009 and the goa conducting ERA at EU level is to ensure that plant protection prod shall not have unacceptable effects on the environment (Article Regulation (EC) No 1107/2009) and not the conservation biodiversity hotspots or individual species. In the mandate (EC, 2024b) it is stated that EFSA should take Recolonization/Recovery as a normally occurring ecological processes. This seems not to be reflected in the SPG setting for the edge of the field.
Page 13-14	Overall, for soil macro and mesofauna, the following comprehensive SPG could be proposed: Ecological entity: population Attribute: biomass, abundance Spatial scale: local (field/edge-of-field) Magnitude of effects: negligible effects (off-field)/small effects (in-field, earthworms and gastropods)/medium effects (in-field, all other SPU) Temporal scale: not applicable (off-field)/recovery within 4 weeks from medium effects; recovery within 6 months from small effects5 (in-field)	This SPG were derived on the wrong ecosystem service which are ruled ouf from the problem formulation guidance (EC, 2024), in which the ES "Genetic resources and biodiversity" and "Cultural services" are seen as not relevant. See comments above. If only relevant ESS are assessed the ecological entity to protect should be the function group (Table 5 page9-10), with the attribute Abundance/Biomass/Activity. Also the mandate (EC, 2024b) to assess recolonization/recovery as a normally occurring ecological process is ignored for setting the SPGs in off-field.
	For nematodes and soil microorganisms: Ecological entity: population/functional group/community	

	Attribute: biomass, abundance, activity/diversity Spatial scale: local (field/edge-of-field) Magnitude of effects: negligible effects (off-field)/medium effects (in-field)/large effects (in-field, bacteria) Temporal scale: not applicable (off-field)/recovery within 7 days (bacteria only, in-field) from large effect/ recovery within 4 weeks from medium effects; recovery within 6 months from small effects(in-field) Also in this case, the tentative quantification scale of 'negligible' (< 10%), 'small' (10-35%),'medium' (35-65%) and 'large' (> 65%) effects is adopted.	

Lines of evidence to set effect thresholds and time to recovery

The streamlined SPGs for the in-field are not a good starting point for further discussions and the off-field SPGs are not in the line of the mandate to take recolonization/recovery as a normal occurring process. The lines of evidence EFSA works out will not change this overall, they will just add more details what means small and negligible and therefore not be helpful to define feasible, flexible and proportionate to environmental risk assessment as was the mandate of (EFSA, 2024b[33]).Nevertheless, there we would like to make some general considerations on the lines of evidence EFSA now will dive into.

EFSA proposes to work on replication in higher tier studies (LoE#1, page 15-18). The current approach is trying to solve the question: what level of effects we can detect, and can we modify the field study design to measure effects as low as 10% (i.e. negligible effects)". This is not the right question for setting ecologically relevant SPG and managing risk. The right question which a risk manager will want to answer is: does a 10% change in an endpoint really matter for the biomass of the population, in view of the natural variability of population biomass?
It is crucial to have a good understanding of natural variability of the entity to protect when setting SPGs, and only then work on the technical aspects how can we measure a relevant effect in view of natural variability. Not the other way around….

If different studies/designs are available, they might also show that higher replication does not automatically improve (decrease) variability. It might be the other way round from an ecological perspective. In any case, a situation like for the bees should be omitted, where an unrealistically high required replication for field data hinders any realistic data generation, and thus, makes higher tier options completely irrelevant with significant impact on risk assessment and product registrations.

On page 16 EFSA stated that feasibility will not be assessed – so whether their proposal connects with basic reason will not be judged. We assume that most scientists on the panels are probably underinformed on what field studies for NTA and earthworms look like. If the analysis will not include any consideration of the actual feasibility of certain designs (e.g. number and size of plots, regional replication). Who will evaluate then these considerations as they are an essential element for practicability which is the mandate of EFSA?

On page 16 EFSA reference Moller et al. (2019) to support their claim about indirect effects caused by toxic effects on plants/inverts. This is not appropriate – the study looks at the decline in insects and a consequent decline in insectivorous birds, but there is no actual link to pesticide use. The author hypothesizes (but have no evidence) that the observed declines in insects could be due to pesticide use on crops (even though the land use at the study site did not change at all in the 20 years of study), but also mosquito control was pointed at.

The aim would be to evaluate what level of food deprivation affecting individuals is relevant for population dynamics – this is THE question, what is a biologically and population-relevant effect? Whether a certain individual effect will be visible in populations will depend very much on other processes, primarily density dependence and there is no mention of that.

Where it becomes even more concerning is their suggestion on Holling's functional responses (section 3.3.2, page 17): here they provide some description and justification as to why they should use type I. I have not seen in any ecological studies that type I is observed or used in modelling, might be there are examples, but in principle all ecologists working on trophic interactions and food webs never assume type I. More importantly, using type I in a food web or network results in highly

[33] EC, 2024b, M-2024-00086, https://open.efsa.europa.eu/question/EFSA-Q-2024-00464

unstable networks as even very small perturbations result in food web collapses (there is much more buffering capacity in type II and III) which means that even the smallest effect can have detrimental impacts on stability (this is relevant for LoE #4).

Finally, simplified assessments of effects of food deprivation on populations have been done via modelling, e.g., in Galic et al. 2017 and 2018 (Galic et al. 2017, Galic et al. 2018) we look at high different levels of food deprivation (as well as other effects on individuals) translate to populations and ecosystem function. It is relevant to emphasize here that a reduction in feeding can result in different population outcomes depending on population regulation (density dependence), but this is not acknowledged here.

A more complex example of evaluating indirect effects is a modelling study conducted for US listed species assessment: a population model of an endangered fish species was combined with an ecosystem model representing the food base of this omnivorous fish. Here it was clear that understanding species dependence on its food base is crucial for assessing any indirect impacts of chemicals on its food. Here the case was with detritus, where a high reliance on detritus buffered any impacts on other components of the fish food base ((Schmolke et al. 2019).

References

EC, (2024b): M-2024-00086, https://open.efsa.europa.eu/question/EFSA-Q-2024-00464

EC, (2024a): Problem formulation for environmental risk assessment in the context of Regulation (EC) No 1107/2009. PAFF-PPL-January 2024-Doc.A.07.01

EFSA, 2025: https://doi.org/10.2903/j.efsa.2025.9501

NTA SO

NTP SO

Soil SO

Glossary:

ERA: Environmental risk assessment

ERO: Ecological recovery option (allow effects which will recover in a specific period of time, a normal occurring process in the landscape by intrinsic recovery and recolonisation)

ETO: Ecological threshold option (allowing only negligible effects, no recovery needed no indirect effect assumed)

NTP: Non-target plants

NTA: Non-target arthropods (insects)

NTTO: Non target terrestrial organisms

SPG: Specific protection goals