CropLife Europe proposal for specific protection goals for non-target soil organism risk assessment for PPPs in Europe under Regulation (EC) No 1107/2009

For the registration of plant protection products under Regulation (EC) No 1107/2009, the absence of unacceptable effects on the environment for safe use must be demonstrated in a thorough regulatory process. The general protection goal needs to be translated into specific protection goals (SPGs) for the respective non-target organisms. Options for SPGs for soil organisms have been proposed in the past (EFSA, 2017[1]) and are expected to be further scrutinized and refined during the development of an updated risk assessment guidance. This is required as the European Commission mandated EFSA (EC, 2024[2]) to review the risk assessment methodology for soil organisms as part of the revision of the guidance document on terrestrial ecotoxicology SANCO/10329/2002 (EC, 2002[3]).

CropLife Europe would like to share considerations for SPGs for soil organisms as summarized in this document for the development of the soil guidance document in general and by risk assessors and risk managers on a country level.

- SPGs should be separately established for **key ecosystem services (ESS)** related to the respective non-target soil organisms in scope of production and non-production areas. In EFSA (2017) this discrimination is considered by SPGs categorized into in-field and off-field goals.

- **From CropLife Europe's perspective, further discrimination between primary and supportive ESS should be made. For example, the primary ESS of agricultural ecosystems (in-field) is 'agricultural production'.** This is briefly acknowledged in EFSA (2017, point 6.2) but can conflict with some of EFSA's proposed regulating and supporting ESS linked to soil organisms, i.e. biodiversity, genetic resources and cultural services. As a result, trade-offs between ESS might have to be considered in the defined SPG options, and focus should lie on primary ESS for decision making.

- **In the off-field area, the primary and supportive ESS can largely vary in practice as they are dependent on the given land uses.** Detailed investigation and categorization of land uses is required to compile different land use types and to define frequent characteristics associated with these. Based on the results, the proposed SPGs of EFSA (2017) need to be evaluated and put into context.

- The definition of SPGs is only possible for organism groups currently considered in risk assessment (earthworms, collembola, mites). For these, a high amount of field data from standardized test protocols allows the setting of SPGs and calibrating risk assessment approaches[4]. For newly proposed organism groups, such data must be first generated before SPGs can be defined.

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[1] EFSA, 2017. Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms. EFSA Journal 2017;15(2):4690, 225 pp. doi:10.2903/j.efsa.2017.4690
[2] EC, 2024: *Request to EFSA to review the Guidance Document on Terrestrial Ecotoxicology. Mandate M-2024-0086*
[3] EC, 2002: *Guidance Document on Terrestrial Ecotoxicology*. SANCO/10329/2002
[4] Christl et al. 2016: Recalibration of the Earthworm Tier 1 Risk Assessment of Plant Protection Products. IEAM 12(4), pp 643-650

CropLife Europe thus believes that the setting of SPGs by EFSA needs to consider both sustainability of agriculture and practicability of approaches to ensure availability of required plant protection tools for farmers contributing to a stable crop production in the future.

SPGs for the In-field (crop production) area

In the past years, climate change, diseases and military conflicts have increased pressure on the EU to take measures for ensuring nutritional security. The latter requires a balance between a reliable agricultural production system and sustainable cropping practices for long-term success. European agricultural performance and crop yields significantly improved over time and need to be maintained or even further increased to satisfy population demands. Thus, for the determination of SPGs **for in-field, the primary aim and ESS 'agricultural production' should be in focus**. This ESS is interlinked with further supporting ESS like 'soil structure' and 'soil function' which promote fulfillment of the primary ESS. However, they may be in contradiction to other proposed ESS linked to soil organisms, i.e., biodiversity, genetic resources and cultural services proposed by EFSA (2017). For the fulfillment of the primary ESS the interlinked ESS, i.e., functional groups or parameters associated with soil function should be in focus in agreement with the EC mandate instead of individual species or biodiversity related endpoints. Protection of biodiversity in-field will result in protection of the pests in-field which jeopardizes the ESS ´food production`.

In the determination of thresholds for SPGs the ecology of key drivers of the relevant ESS (namely the service providing units) needs to be considered. The definition of fixed effect thresholds for acceptable effects is not scientifically justified for (semi)field data-based evaluations. From an ecological perspective, an organism's response can exhibit high natural fluctuations due to interactions with various (a)biotic factors and species-specific aggregation behavior. Different taxa as investigated in (semi)field studies will also show a different seasonal extent of interactive responses. Based on environmental factors, naturally high variability in responses cannot be diminished by adjusted test designs or replication in a practicable way. A specific threshold value or range would disregard the performance range of various taxa. It is highlighted that the proposed threshold of 10% as derived for pollinators in the new bee guidance (EFSA, 2023[5]) was conservatively derived from data for managed honeybees only. As a result, from statistical perspective >1000 fields would be needed to conclude on low effect (<10%) with a high statistical power (Annex C) in field studies, highlighting the impracticability of this protection goal. Even large effects (up to 80% effect on total abundance) on, e.g., springtails and mites, with a duration of up to 6 months were shown to have no relevant impact on the function ´organic matter degradation` in arable field soil[6], one of the agronomically most relevant services provided by soil organisms. **For soil organisms, medium to large transient effects** should therefore be acceptable **as long as recovery can be demonstrated within an agreed time period.** The determination of recovery in (semi)field studies further require a specific definition and methodology.

SPGs for off-field landscapes (with various land uses)

Setting SPGs for the off-field area (including biodiversity protection) poses challenges due to the diverse landscapes and land uses across Europe and the influence of various regulations such as the Sustainable Use of Pesticides Directive, the Habitats Directive, the Nature Restoration Regulation or the implementation of the EU Common Agricultural Policy, as well as on farmers' decision and agricultural practices. To establish an agronomic baseline for the impact of agronomic practices on soil organisms outside the treated area, it is necessary to define scenarios of "typical landscapes" at default scales. A fundamental understanding of the natural spatial and temporal variability of soil communities within these landscapes scenarios is essential for providing SPG levels at landscape scale; this is a research gap from the perspective of CLE that needs specific attention. Without this pre-work, determination of realistic ESS is not possible.

The acceptable duration and magnitude of effects will depend on the chosen scenarios and defined baseline.

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[5] 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
[6] Pamminger et al. 2021: Investigating the role of soil mesofauna abundance and biodiversity for organic matter breakdown in arable fields. IEAM 18(5) pp 1423-1433