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REVIEW

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Assessing in-field pesticide effects under European regulation and its implications for biodiversity: a workshop report

Magali Solé^{1*†}, Stephan Brendel^{1*†}, Annette Aldrich², Jens Dauber³, Julie Ewald⁴, Sabine Duquesne¹, Eckhard Gottschalk⁵, Jörg Hoffmann⁶, Mathias Kuemmerlen⁷ , Alastair Leake⁸, Steffen Mätzki¹, Stefan Meyer⁹, Moritz Nabel⁷ , Tiago Natal-da-Luz¹⁰ , Silvia Pieper¹¹, Dario Piselli¹², Stanislas Rigal^{13,14}, Martina Roß-Nickoll¹⁵ , Andreas Schäffer¹⁵ , Josef Settele^{16,17}, Gabriel Sigmund¹⁸ , Nick Sotherton⁸, Jörn Wogram¹ and Dirk Messner¹⁹

Abstract

Background Biodiversity loss is particularly pronounced in agroecosystems. Agricultural fields cover about one-third of the European Union and are crucial habitats for many species. At the same time, agricultural fields receive the highest pesticide input in European landscapes. Non-target species, including plants and arthropods, closely related to targeted pests, are directly affected by pesticides. Direct effects on these lower trophic levels cascade through the food web, resulting in indirect effects via the loss of food and habitat for subsequent trophic levels. The overarching goals of the European pesticide legislation require governments to sufficiently consider direct and indirect effects on plants and arthropods when authorising pesticides. This publication provides an overview of a workshop's findings in 2023 on whether the current pesticide risk assessment adequately addresses these requirements.

Results Effects due to in-field exposure to pesticides are currently not assessed for plants and inadequately assessed for arthropods, resulting in an impairment of the food web support and biodiversity. Deficiencies lie within the risk assessment, as defined in the terrestrial guidance document from 2002. To overcome this problem, we introduce a two-step assessment method feasible for risk assessors, that is to determine (i) whether a pesticide product might have severe impacts on plants or arthropods and (ii) whether these effects extend to a broad taxonomic spectrum. When each step is fulfilled, it can be concluded that the in-field exposure of the pesticide use under assessment could lead to unacceptable direct effects on non-target species in-field and thus subsequent indirect effects on the food web. While our primary focus is to improve risk assessment methodologies, it is crucial to note that risk mitigation measures, such as conservation headlands, exist in cases where risks from in-field exposure have been identified.

Conclusions We advocate that direct and indirect effects caused by in-field exposure to pesticides need to be adequately included in the risk assessment and risk management as soon as possible. To achieve this, we provide

[†]Magali Solé and Stephan Brendel have contributed equally to the manuscript.

*Correspondence:

Magali Solé

magali.sole@uba.de

Stephan Brendel

stephan.brendel@uba.de

Full list of author information is available at the end of the article

recommendations for the authorities including an evaluation method. Implementing this method would address a major deficiency in the current in-field pesticide risk assessment and ensure better protection of biodiversity.

Introduction

Agricultural landscapes are experiencing declines in biodiversity attributed to multifactorial causes [1–3]. Among these causes, pesticide uses (defined here as agricultural pesticides, i.e., plant protection products) have persistent negative effects on biodiversity in agroecosystems [4–6] and adjacent areas [7–9]. In typical agricultural landscapes, a substantial proportion of the total area might be the agricultural fields themselves, referred to as “in-field areas”. These areas not only serve as cultivation areas but are also crucial habitats for a variety of species typical of agricultural and open lands, which include also untreated “off-field” areas. Only a few of these species represent targets of pest control measures. For all other species, such as non-target terrestrial plants (NTTP) and arthropods (NTA), unacceptable effects of pesticide use should be avoided or at least minimized. The legal framework (Regulation (EC) No. 1107/2009 [10]) stipulates that pesticides “shall have no unacceptable effects on the environment”, with specific considerations for the “impact on non-target species” and the “impact on biodiversity and the ecosystem”. According to Regulation (EU) 283/2013 [11], this includes “potential indirect effects via alteration of the food web”. Although the indirect effects of pesticides are diverse and not limited to food web alteration, in this publication we refer specifically to the indirect effects defined in Regulation (EU) 283/2013, i.e., food web alteration due to ecotoxicological effects. In addition, we focus on the terrestrial agroecosystems, as in-field applications of pesticides in waterbodies are limited in the EU to rice cultures; these are therefore considered to be of minor relevance in relation to the whole European agricultural area.

Plants and arthropods are an essential part of terrestrial biodiversity and ecological communities. Any decline of their in-field diversity and abundance can have repercussions on the whole ecosystem by also affecting the off-field area through source-sink dynamics as demonstrated in studies with NTA [12, 13]. Additionally, NTTP and NTA are important components of terrestrial food webs. Thus, declines in their populations, both in-field and off-field, can have cascading indirect effects on consumer species, including farmland birds and mammals [14–16].

To address this concern, alternative and more sustainable solutions are being explored, such as for instance expanding organic farming and implementing agroecological methods [17, 18]. Among other objectives, these approaches not only aim to reduce the use

of pesticides but also prevent or mitigate their adverse effects on biodiversity. Despite ongoing efforts, a fundamental change in the current agricultural practice, along with its associated pesticide use, appears unlikely in the short term. Focussing on the European Union (EU), it is therefore crucial to further develop the best possible protection of biodiversity already within the current European legal framework for pesticides. However, in the current EU environmental risk assessment of pesticides, the direct effects of exposure of NTTP to pesticides in-field (i.e., in-field effects) are not assessed and the direct effects of exposure on NTA in-field are considered to be severely underestimated [19, 20]. Moreover, the potential indirect effects via alteration of food webs are largely ignored [21].

According to the Regulation (EC) No. 1107/2009 [10] risk assessment methodologies should be harmonised between European Member States. This means, for example, that Member States can include a specific evaluation in the risk assessment scheme of pesticides only if a corresponding scientific assessment method is available and accepted by “the Authority”, i.e., the European Food Safety Authority (EFSA). It should be noted that mandatory acceptance by EFSA is subject to current legal interpretation. However, there is no such scientific assessment method accepted by EFSA that would allow risk assessors to address the gap between the assessment of in-field effects on NTTP and NTA and their repercussions on biodiversity in a harmonised manner.

A workshop was held on the 3rd and 4th of July 2023 at the German Environment Agency (Umweltbundesamt—UBA, in Dessau-Roßlau, Germany) to bridge the gap between science and regulation. The workshop focused on describing the risks of in-field pesticide exposure within the current legislative framework. Potential risk mitigation measures, as well as measures outside the legislative framework, were raised but not explored in-depth. It was organised by a consortium of three parties: the UBA, the UK Game and Wildlife Conservation Trust (GWCT) as well as experts from the German Academy of Sciences Leopoldina. Participants were representatives from various European research institutions and regulatory bodies with expertise in ecological risk assessment of pesticides, farmland biodiversity, and agronomy (see list of participants in supporting information).

The objectives of the workshop were to (1) discuss the importance of the “in-field” habitat within

agroecosystems in the context of pesticide uses on biodiversity, (2) review the current ecological risk assessment of pesticides in the light of the acceptability criteria set out by the European Regulation (EC) No. 1107/2009 [10], especially considering in-field exposure, (3) discuss the need for a methodological approach developed by UBA and (4) formulate recommendations to improve the in-field pesticide assessment for better protection of biodiversity.

The discussions at the workshop led to the identification of gaps in the risk assessment of pesticides to address direct impacts on in-field habitats and associated flora and fauna and their indirect effects on the food web. The participants highlighted the need to increase awareness of these existing gaps. The main outcomes and recommendations, to better protect biodiversity from pesticide impacts and satisfy the legal requirements of Regulation (EC) No. 1107/2009 [10], are presented here.

Scientific reflections

Value of the in-field habitat and farmland species in agroecosystems

Farmland covers nearly half (46.4%) of the European land area, of which 38.4% (157.4 million hectares) is composed of utilised agricultural area [22]. Given that the EU covers over 400 million hectares it results that approximately one-third of the total European surface is covered by cropped areas where pesticides are regularly applied and which are referred to as in-field habitat in this paper.

Agroecosystems are the habitat of plants and animal species that are particularly adapted to traditionally managed agricultural areas, i.e., areas characterized by small-scale, diverse and labour-intensive practices excluding chemical pesticides [23]. Arable plants, (i.e., segetal plants, which thrive exclusively amongst crops, and facultative arable plants, which thrive predominantly in cultivated fields but can also form larger populations in other habitats) are generally less competitive and less prone to spreading. Hence, these NTTP find optimal conditions in regularly disturbed in-field habitats. At higher trophic levels, farmland birds like the grey partridge (*Perdix perdix*), the Eurasian skylark (*Alauda arvensis*), or the corn bunting (*Emberiza calandra*), along with small mammals like the European hamster (*Cricetus cricetus*) and the brown hare (*Lepus europaeus*) are typical vertebrate species occurring in such ecosystems. These farmland species are adapted to the nesting and foraging conditions provided by traditional agroecosystems, making these habitats essential for their survival. In addition, numerous invertebrate species contribute significantly to the biodiversity of agroecosystems and play essential functional roles in maintaining these ecosystems. Soil micro-, meso-, and macrofauna are drivers of soil fertility and

soil formation [24], while bees, syrphid flies, moths, and butterflies ensure the essential pollination of crops and wild plants [25]. They also provide benefits to farmers by improvements in soil health, insect pollination, and pest control through natural enemies [26]. Notably, species such as ladybirds and parasitoid wasps are effective biological controls against pests [27, 28]. The ecological functions of NTA are discussed in the EFSA scientific opinion addressing the state of the science on risk assessment of pesticide products [20]. EFSA (2015) [20] particularly stresses the need to protect NTA at an adequate temporal and spatial scale to ensure the provision of NTA as a food source for higher trophic levels, including amphibians, reptiles, birds, and small mammals.

All species living in and around agricultural fields define the biodiversity of agroecosystems [29]. They have a functional and intrinsic value and are often the subject of nature conservation demands and efforts (e.g., birds Directive 79/409/EEC [30] amended in 2009 in the Directive 2009/147/EC [31]). However, their occurrence and abundance are directly linked to agricultural practices.

Biodiversity decline across agricultural landscapes and effects of pesticides

Over the last 70 years, there has been a massive loss of biodiversity across taxa and ecological guilds [1, 2, 32]. In Europe, this decrease is particularly pronounced in agricultural landscapes—for arable plants [33–37], as well as for vertebrates (especially farmland birds [38–40]) and invertebrate species [41–45]. For terrestrial insects, the decline in diversity was also associated with a decrease in biomass observed across Europe [46] with a recorded reduction of more than 75% within nature reserves in Germany [8].

Pesticides are consistently detected beyond the agricultural fields where they are intended to be applied, extending into the landscape on a broader scale, including protected areas [47–49]. Most pesticides display a low selectivity, and they therefore have the capacity to affect their intended target species (pests) but also various non-target species. More specifically, the effects of pesticides can be either direct or indirect. Direct effects are those that occur when non-target species are directly exposed to overspray, residues, or off-field drift, influencing their population abundance. Indirect effects may arise through altered food web interactions or changes in competition and facilitation processes. Within food webs, NTTP and NTA play a crucial role in the functioning of ecosystems due to their key positions at the base of the trophic network. Declines in their populations, whether in-field (cropped area) and off-field (outside the cropped area), trigger cascading effects on consumer species [16, 50]. For example, the in-field application of herbicides often

leads to a significant reduction in both plant diversity and abundance as well as a reduction in flowers available for insects [34, 37, 51]. Thus, pollinator insects are deprived of pollen and nectar, while herbivorous invertebrates and vertebrates are deprived of essential food sources and NTA lose their habitats. This, in turn, leads to an expected decrease in the abundance of NTA, affecting insectivorous species.

While the direct toxicity of pesticides to terrestrial vertebrates has constantly decreased over the last decades in Germany and the US, it has increased for terrestrial plants and remained approximately consistent for terrestrial arthropods—with the exception of pollinators in the US also experiencing an increase in direct toxicity [52, 53]. Such sustained, and in some cases increasing, direct toxic pressure on lower trophic levels may imply trophic cascade effects, potentially undermining efforts to reduce direct toxicity, as has been well-documented for amphibians [54] and birds [50, 55]. For instance, in southern England, the Game & Wildlife Conservation Trust has monitored, through the Sussex Study, farmland biodiversity and pesticide applications for over 50 years. The study started in 1968 to investigate the causes of the drastic decline of the grey partridge in this area [56]. The main reason for the decline in grey partridge numbers was the poor levels of chick survival driven by agricultural intensification, especially the use of herbicides firstly and latterly insecticides [57, 58]. Pesticide use reduced the number of insects available as food sources for the young chicks firstly by reducing the host plants that support these chick-food insects. Insecticides reduced the number of chick-food insects directly. This reduction in chick-food led to the starvation of partridge chicks as they are heavily dependent on insect availability in a narrow time window, as are many chicks of other farmland birds [14, 15, 59–62]. Various mitigation measures to overcome these direct and indirect effects were developed and evaluated. This has been aided by the fact that long-term monitoring of the farmed environment has identified what NTTP will provide NTA food resources for the chicks of farmland birds [63]. Considering in-field habitats, tested mitigation measures include beetle banks, wildflower plots, and floristically enhanced grass strips [64–67]. One option, demanding less long-term commitment to land cover change, is conservation headlands, which have been shown to restore invertebrate numbers [68]. In conservation headlands, the edges of cereal crops receive only selective or seasonably restricted inputs of pesticides. Conservation headlands do allow farmers to use graminicides to remove the very worst of grass weeds but limit pesticides to those that do not remove the valuable NTTP

[63]. Installing conservation headlands, in tandem with beetle banks and wild bird cover, as undertaken on a portion of the Sussex Study since 2003, shows that around 15% of the total managed area was sufficient to restore the grey partridge populations [56, 69]. Other demonstration projects have used between 5 and 20% of habitat provision to restore grey partridge numbers [70, 71]. Such measures have now been made available (i.e., funded) in the UK's agri-environment scheme and will be funded post-Brexit by the UK Government [72]. Other management options based on so-called sustainable regenerative farming or newer agroecological techniques and including efficient Integrated Pest Management (IPM) are successfully minimising pesticide use, and might efficiently support the recovery of insect populations [73–75] as well.

Effects of pesticides and implications for biodiversity assessment

In light of the scientific evidence, including but not limited to the studies described above, the risk assessment of pesticides should extend beyond their direct effects to cover also their indirect and subsequent cascading effects. However, realistic quantification, particularly of the indirect effects, poses a major challenge due to various uncertainties related to the multifactorial causes of biodiversity losses, e.g., numerous anthropogenic and natural stressors that are additional to the pesticide applications. Nevertheless, this challenge should not be a reason to exclude risks caused by indirect effects from the risk assessment, especially as they are known and highly relevant for the achievement of the legal environmental protection goals. A sound description of the risks to biodiversity and the agroecosystem from pesticides should cover the potential impact on the diversity and abundance of non-target species in the whole agricultural landscape. This should include the consequences of in- and off-field exposure and the ecological role (function) of non-target species in the agroecosystems, such as their supporting roles in food webs. This is all the more important because NTTP and NTA are generally exposed to several pesticides simultaneously or subsequently through the application of tank mixtures or via spray series. This multiple exposure is not explicitly taken into account in the prospective risk assessment, which is performed for each single pesticide and intended use [76]. Currently, one major obstacle to a more protective risk assessment is the inadequate description of in-field risks. The need for an appropriate in-field risk assessment is even more important when considering that the in-field area accounts for one third of the entire European landscape and is of inestimable value to biodiversity.

Regulatory reflections

Limitations of the risk assessment framework

In the European Union, the process for placing pesticides on the market is dual: first, the approval of active substances at the EU level; second, the authorisation of pesticide products containing approved active substances at the national level. The rules for this process are defined by Regulation (EC) No. 1107/2009 [10] which states that pesticide products placed on the market must not exert harmful effects on human or animal health, nor have unacceptable impacts on the environment. Environmental considerations mainly focus on the impact on non-target species, biodiversity and ecosystems. Commission Regulation (EU) No 283/2013 explicitly lists that “The potential impact of the active substance on biodiversity and the ecosystem, including potential indirect effects via alteration of the food web, shall be considered”

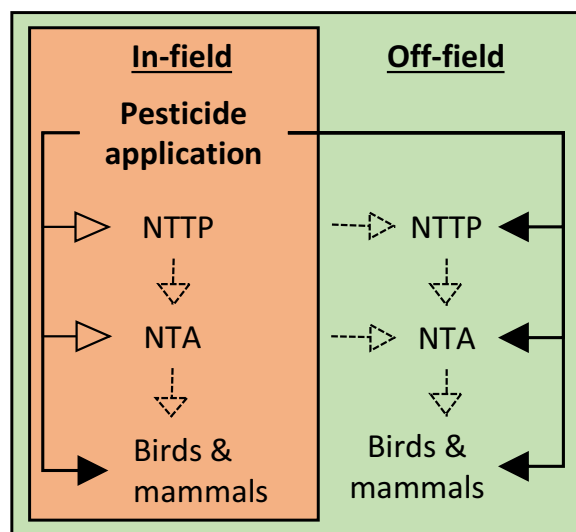
The protection goals set in Regulation (EC) No. 1107/2009 [10] imply that any risk assessments should consider biotic and abiotic interactions including trophic chain interactions. However, such a holistic view on the interrelationships occurring in agroecosystems is missing. The current risk assessment framework is based on environmental scenarios that tend to create so-called assessment silos. Single environmental compartments (air, soil, aquatic) and organism groups (e.g., birds, mammals, NTA, NTTP, aquatic organisms) are assessed in isolation. The assessment focuses primarily on the direct toxic effects of single pesticide uses on these groups of organisms and the consideration of systematic links between single environmental scenarios (neither spatial nor temporal) is often missing. Another critical shortcoming of the current risk assessment framework is the insufficient consideration of the in-field risk to NTTP and NTA.

A need to improve risk assessment to ensure sufficient protection level in-field

Guidance documents translate the legal requirements into practical applications within risk assessment schemes. However, the terrestrial guidance document in force [77] does not fully reflect the current scientific state and does not sufficiently consider the provision of Regulation (EC) No. 1107/2009 [10], as it dates from 2002. EFSA has acknowledged these shortcomings in its review of the current state of scientific knowledge for the terrestrial risk assessment of non-target organisms exposed to pesticides [20, 78]. Both scientific opinions clearly highlight the importance of NTA and NTTP as part of the overall biodiversity of agroecosystems. They recognise the value of in-field areas for agricultural production, proposing different specific protection goals

for both in-field and off-field areas regarding NTA and NTTP. Additionally, the opinions emphasize the crucial role of NTA and NTTP as drivers of various ecosystem services, including ‘food web support’ in in-field areas for species at higher trophic levels. This aligns well with the general protection goals of the (EC) 1107/2009 and related legislative documents; it represents a significant regulatory advancement, as the current EU risk assessment framework does not adequately address the direct in-field effects of pesticides nor their impairment of the ‘food web support’ [77]. However, none of the opinions presents a methodology for carrying out such an in-field risk assessment. In this paper, we propose a feasible method to close this gap within the current pesticide risk assessment framework.

The current terrestrial guidance document [77] defines NTTP as “non-crop plants located outside the treatment area” for which the “continuance of populations” should be ensured. Accordingly, the risk assessment is based on studies with the pesticide products and considers only off-field exposure via spray drift – omitting the in-field habitat (Fig. 1). In comparison, both off-field and in-field risk assessments are foreseen for NTA, but in



Pesticide effect: — direct ----- indirect

Protection goal:
 ► addressed ▷ not (sufficiently) addressed

Fig. 1 Direct (solid arrows) and indirect (dashed arrows) effects of pesticides on non-target terrestrial plants (NTTP), non-target arthropods (NTA), birds and mammals in-field (orange rectangle) and off-field (green rectangle). Arrowheads indicate implementation (filled) or absence/insufficient implementation (unfilled) of protection goals in guidance documents currently in force

our view they result in a low level of protection, mostly due to several shortcomings linked to the in-field assessment (Fig. 1). For example, for NTA exposed in-field the acceptability criterium is fulfilled with up to 50% initial effects on reproduction or mortality in laboratory studies. Even greater effects are accepted if a "potential for recolonisation or recovery at least within one year" is indicated by higher-tier field studies. However, as illustrated in the scientific publications cited above, chicks of farmland birds depend on sufficient insect availability as a food source within a critical few-week time window in spring and early summer [50, 57, 61]. This emphasises that a one-year NTA recovery period is too long when considering indirect effects acting via alteration of the food web. Moreover, as outlined by Landis [79], intensive agricultural practices can lead to homogenised landscapes that do not contain refugia such as hedge rows and field margins. Consequently, pesticide-driven losses of NTA in-field might not be compensated by off-field populations, for which the proximity of refuges is a crucial factor [80]. Finally, Knillmann et al. [81] discussed that the frequent use of broad-spectrum pesticides increases effects on non-target species, either directly or indirectly, due to the cumulative impact of multiple pesticide products, whereby the single contributions of co-formulants and adjuvants to these effects is generally difficult to determine. These landscape-scale conditions, which are not considered in the NTA in-field risk assessment, impede a realistic risk description. They question whether the assumption of the current in-field risk assessment, allowing for potential recolonisation of the in-field habitat by the off-field NTA populations, is justified.

For comparison, the guidance document for aquatic organisms in edge-of-field surface water [82] acknowledges that "none of the direct effects should lead to unacceptable indirect effects" in case that direct effects are accepted for the recovery options (Table 14, [82]). In contrast, the recent EFSA guidance document for risk assessment for birds and mammals [83] also acknowledges that "indirect effects of pesticides on birds and mammals are likely to be important". However, the risk assessment proposed does not cover the issue of indirect effects due to treatment-related shifts in food availability (i.e. alteration of the food web); this issue is postponed to the future revision of the terrestrial guidance document.

Beyond the improvement of the current risk assessment framework

Improving the current pesticides risk assessment framework can enhance biodiversity protection and is the focus of this publication. However, such improvement will not be enough to drive a transformation towards a more sustainable agriculture, as this requires more profound

changes, including measures to reduce pesticide use and risk at national and farm level [84–86]. Mitigating the impacts of pesticides by increasing the use in contained environments, such as greenhouses, or relying exclusively on technological innovations like precision farming, is not sufficient to reach a more sustainable agriculture. For example, greenhouses and other contained environments reduce pesticide drift and exposure, but they may not decrease broader ecological impacts on wildlife due to habitat loss or ecosystem disruption (e.g., [87]). Similarly, limited advantages for the environment may be expected from precision farming if it is only aimed at optimizing existing systems for more efficiency rather than accompanying a real transformation towards sustainable agroecosystems [88, 89].

While sustainable farming practices, including modified tillage strategies, crop diversification, and the principles of agroecology, are in development, their adoption is still limited. Establishing and refining guidelines or directives and providing incentives to promote sustainable farming techniques is necessary to facilitate their adoption. Examples include the Common Agricultural Policy of the EU, the Sustainable Use Directive [90] and the EC Habitats Directive [91]. Adopting a more holistic and systems-based approach for ecological risk assessment, including better collaboration among various stakeholders, is vital to develop a more sustainable agricultural paradigm [92–94].

There are a number of EU investments and supporting projects aiming at strengthening European research and innovation for a better protection of human and environment health from chemicals, such as projects developing a new paradigm of systems-based approach in environmental risk assessment to move towards a future new generation risk assessment (e.g. in the EU Partnership for the Assessment of Risks from Chemicals (PARC)). These include the consideration of a broad range of possible improvements of the risk assessment to better protect biodiversity within and beyond the current legal framework. The proposed approach in this paper adopts a systems view by integrating the impact assessment across taxa, providing the opportunity to link the outcome of the assessment to risk mitigation measures at ecosystem-level. As the proposed method also makes use of already existing data, it provides an example on how systems thinking can be implemented within the current regulatory framework as well as support a transition to future systems-based environmental risk assessment.

Urgency for action

There is thus a great urgency for action from a scientific as well as regulatory point of view. Direct and indirect effects caused by in-field exposure need to be adequately

included in the risk assessment and subsequently in the risk management as soon as possible. Besides other shortcomings of the current risk assessment, as outlined in various documents [20, 78, 92, 93], the revision of the terrestrial guidance document [77] must tackle this issue. However, considering the efforts required for completely revising and implementing the new terrestrial guidance document, it is imperative to establish an effective interim solution.

Ideally, the prospective assessment, and the effectiveness of the subsequent implemented, risk mitigation measures should be verified [95] and, if needed, adjusted based on biological and chemical post-authorisation monitoring [96]. However, in the current case, effective measures exist to mitigate in-field risk on NTTP [97] and NTA as reported in the examples of scientific publications above. Therefore, the establishment of such a feedback system should not delay the introduction of risk assessment and risk management for in-field effects.

Method for assessing the risks from in-field exposure

General considerations

Addressing knowledge gaps is a key challenge in pesticide and chemical regulations, especially in regard to environmental impacts. These gaps might emerge from complex, often difficult to predict, effects of chemical exposure on the environment, leading to uncertainties and deficiencies in environmental risk assessment. For pesticides, the insufficient regulation of direct effects on in-field NTTP and NTA leads to the propagation of indirect effects, mostly due to alterations in the food web. We foresee two different approaches for improvement.

The first approach could be to reproduce indirect effects in multi-species test systems to better characterise their impact. Such complex test systems exist for some compartments and are sometimes used to refine risks identified with standard laboratory tests, e.g., aquatic mesocosms or terrestrial model ecosystems. However, although more realistic, these studies are not part of the first-tier data requirements and they do not reproduce the whole food chain of field communities. Their assessment stays restricted to the environmental compartment of concern. The potential cascading effects on groups of organisms from other environmental compartments and from higher trophic levels are ignored (e.g. no fish in mesocosm, no mammals in terrestrial model ecosystems). Addressing this gap with an assessment method that attempts to fully model the complex interactions between trophic levels and aims to accurately predict all possible indirect effects would be hardly feasible and impractical for validation.

The second approach—which is in our opinion the simplest way to address indirect effects in food webs—could be to better regulate direct effects, for which information from standard laboratory tests is available. Ideally, the assessment of direct effects should be calibrated, by the implementation of appropriate assessment factors covering for field situations, in such a way that possible indirect effects are also prevented. The assessment schemes established in environmental risk assessment for the authorisation of pesticides all aim to follow this second approach.

Proposed method

With the present proposed method (Fig. 2) we expand the focus of the current risk assessment to also cover the overall impact on the ecosystem and biodiversity. The approach is to consider the in-field effects of pesticides in such a way that the impairment of NTTP and NTA as drivers of ‘food web support’—a relevant ecosystem function—can be appropriately addressed in product authorisations. In our method, this aim is operationalized by considering a simplified but also scientifically reliable relationship:

In the first step, we consider that if the available toxicity data of the pesticide product indicates toxic effects of more than 50% on in-field NTTP or/and NTA species

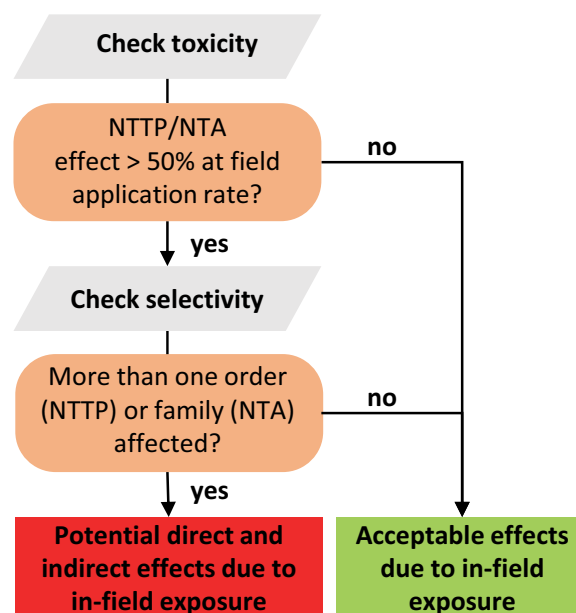


Fig. 2 Proposed assessment scheme of direct and indirect effects of in-field exposure. The scheme involves two steps: Checking for toxic effects on non-target terrestrial plants (NTTP) or non-target arthropods (NTA) and evaluating if these effects extend to a broader range of species. If both conditions are fulfilled, potential direct and indirect effects due to in-field exposure are indicated

for the intended field rate, a potential for unintentional adverse effect on species at higher trophic level and overall biodiversity has to be expected. Decision-relevant effects are based on endpoints reported in the current data requirements, i.e., reproduction and mortality for NTA and biomass, phytotoxicity and emergence for NTTP. The effect threshold of 50% has the aim of being on the one hand not overly conservative, but on the other hand not resulting in clear “false negative” results failing to identify effects in the field. The effect threshold of 50% reflects the current harmonised approach in the present risk assessment. In the second step, a high likelihood for a significant impairment of the ‘food web support’ is concluded, if the product under evaluation has a broad-spectrum activity, i.e., if the effects on NTTP or NTA communities are non-selective. This may occur if available toxicity or efficacy data show more than one NTTP family or NTA order is affected, potentially impacting a range of food items for species at higher trophic levels.

For low-risk uses (according to Annex II, point 5 of Regulation (EC) No. 1107/2009 [10]) or for the application of pesticides at a smaller scale or with lower intensity, such as grassland, home gardening and specific single-plant treatments (irrespective of the crop), potential direct and indirect effects cannot be excluded (e.g., [98]). However, since a lower risk is expected in this case due to a lower probability of sink-source effects at the landscape scale, we currently do not recommend applying the proposed method to low-risk and smaller-scale uses. Further considerations may be required in the future.

We believe that the proposed method is suitable for evaluating both direct and indirect effects resulting from in-field exposure within the current risk assessment framework. Additionally, the proposed method is designed to meet the current data requirement and other legislative requirements set in Regulation (EC) No. 1107/2009 [10] without requiring additional testing. It also provides a feasible assessment for risk assessors since no additional expert knowledge is needed. However, there are several other crucial issues directly linked to the established risk assessment framework that remain unresolved by the proposed method. The main limitations are detailed in the coming section.

Limitations of the proposed method

The proposed method aims to address the alteration of the food-web support of NTA and NTTP in-field within the existing regulatory framework to fill a significant gap in the current risk assessment. However, it does not address several inherent shortcomings of the regulatory framework currently in force. These include:

(i) The limited scope of the effects and exposure routes assessed. Current risk assessments consider only certain effects and exposure routes relevant to the maintenance of NTA and NTTP populations [77]. For instance, they do not include oral exposure by ingestion of contaminated food, direct overspray and growth effects for NTA, nor run-off exposure and reproductive endpoints for NTTP [20, 78].

(ii) The restricted information on species sensitivities. The two standard NTA species tested at Tier 1—a mite and a parasitic wasp—are used as surrogate species for the invertebrate kingdom, raising concern about their ecological representativeness. Additional species are only assessed if a risk is indicated in the first-tier. For plants, assessments typically include at least six species, mostly crops, thereby neglecting wild species and groups like ferns, mosses, lichens, and woody species [78].

(iii) The impact of additional environmental stressors. Endpoints used for risk assessments are typically from single-species tests performed under ideal laboratory or greenhouse conditions. These tests do not account for intra and inter-species interactions, predators, and other stressors. Consequently, these ecotoxicological studies do not adequately reflect the potential increased sensitivities of species in natural habitats compared to laboratory conditions, as demonstrated in aquatic environments [99] and supported by studies performed with terrestrial plants [100, 101].

(iv) The consideration of the application of a single pesticide product in isolation and in standardized environmental scenarios, excluding the effects of spray series, tank mixtures, and specific landscape contexts.

Addressing these shortcomings would require significant fundamental changes beyond introducing a new methodological approach [93]. As these limitations are currently not addressed, uncertainties associated with the proposed method exist. For instance, the proposed 50% effect threshold might result in much higher effects under field situations. In our view, setting the effect thresholds to 50% ensures a high likelihood of identifying pesticides causing indirect effects, while minimizing the risk of false negatives. We acknowledge that this threshold is higher than the recommendations of the uniform principles laid down in Regulation (EU) No 546/2011 [95] that state that effects on beneficial arthropods should not exceed 30%. Broad-spectrum insecticides and herbicides, however, are assumed to result in more than 50% effect at field application rate, as shown by efficacy studies. Moreover, given the steep slope of dose–response relationships

around the effective concentration that produces a 50% response, the difference between 50 and 30% effect is not expected to be of relevance. Therefore, the 50% threshold has also been chosen as the most pragmatic approach, since 50% effect levels are currently derived and reported within the risk assessment framework [78]. It should be noted that this threshold falls within the range of the tolerable magnitude of effects proposed in EFSA 2014 [20] for the assessment of non-target arthropods as food web support (i.e., 35% to 65% of effects for up to four weeks outside the breeding season).

Impact analysis

For an impact analysis, UBA assessed products submitted for authorisation in Germany in the period from 05.11.2018 to 04.09.2019. This time period was pragmatically chosen, as the product assessments according to the proposed assessment scheme were already available. The impact analysis shows that from a total of 106 products, 4 out of 30 fungicides, all 64 herbicides and 10 out of 12 insecticides were identified as having potential direct and indirect effects due to in-field exposure and, thus the authorisation of these products would warrant risk mitigation (Table S1). These results are predictable, given that the modes of action for most herbicides and insecticides are inherently broad-spectrum. Pesticide products containing microorganisms are an exception, as they do not usually have broad-spectrum adverse effects on NTTP and NTA. Accordingly, the two insecticides not identified in the impact analysis as having the potential for exerting indirect effects are (i) the product that contains the bacterium *Bacillus thuringiensis*, and (ii) flonicamid, that is specifically acting against aphids. Some fungicides also have severe, broad-spectrum direct effects on NTTP and NTA due to in-field exposure. Due to data confidentiality, no details on the toxicity data on non-target plants and arthropods related to pesticide product authorisations can be presented here. The supporting information includes details on the active substances in the products (Table S1) and specific examples based on representative formulations from publicly available active substance evaluations (Table S2).

Conclusions

To fulfil the protection requirements of the EU pesticide legislation, we recommend that the authorities (i.e., the European Commission, EFSA, competent authorities of Member States, and others) should evaluate and accept these outlined science-based reflections to better protect biodiversity from the in-field exposure to pesticides and to satisfy the protection requirements of the EU pesticide

legislation. As a concrete regulatory measure, we advocate for the adoption of the proposed method to assess the risks of in-field exposure to NTTP and NTA. We also suggest conducting a second workshop in the near future involving a broader range of participants, including risk managers and farmers, to discuss the feasibility of implementing the risk mitigation measures presented in this report.

Main outcomes of the workshop

- Need for a risk assessment covering for direct and indirect effects

Considering the general biodiversity losses across agricultural ecosystems and beyond, the regulatory framework should, as soon as possible, improve the risk assessment for in-field exposure to better cover direct effects and to include indirect effects on all trophic levels.

- Suitability of the proposed assessment to address the impact on biodiversity and ecosystem

Within the existing regulatory framework and with currently available data, the evaluation of direct effects on plants and arthropods of a single pesticide use occurring at field rate, combined with the selectivity of a pesticide, is an expedient option to address possible indirect effects and their impact on biodiversity and ecosystem due to in-field exposure.

Available ecotoxicological data for NTTP and NTA, in addition to the information provided in the efficacy studies, should be used to characterise, in a standardised transparent assessment method, the impact on biodiversity and ecosystem due to in-field exposure to uses of the individual pesticide (as in 1107/2009).

- Implementation of the proposed assessment scheme

Despite the challenges (e.g., selected threshold value might not be sufficiently protective, not covering all indirect effects; representativeness of tested species in general) raised during the workshop, the proposed approach would be a workable assessment scheme within the current risk assessment. The successful implementation of the method is one first step in reducing the in-field impact of pesticide products on biodiversity and ecosystems.

Further recommendations

- Value of agroecosystem and farmland species

Cropped fields are a relevant part of the agroecosystem. They are not only production areas for food and feed but also habitats for farmland and other species. Those farmland species—including vegetal flora, soil fauna, insects, and farmland birds—are a significant fraction of the biodiversity of arable landscapes that cover a substantial part of Europe. Farmland species also have functional roles in agroecosystems. Some are considered pest species (of the crops); most are essential to support the agroecosystems (e.g., pollination, natural biocontrol). Some of these farmland species are the focus of nature conservation demands and efforts.

- Pesticides impact food webs in terms of direct and indirect effects

Owing to their low selectivity, many pesticides impact not only target species but also many non-target species. Effects can be direct or indirect, for instance via food web interactions or changed competition. This makes pesticides one of the main relevant stressors within a multitude of anthropogenic and natural stressors contributing to a continuous decline of farmland species recorded over the last half-century.

- Keys of scientifically sound assessment of pesticides' risks

A scientifically sound assessment of pesticides' risks to biodiversity and the agroecosystem should cover (i) the potential impact on the diversity and abundance of non-target species due to in-field exposure, (ii) the functional role of non-target species in the agroecosystems (e.g., food web support), and (iii) the delivery of ecosystem services by non-target species.

- Need for a better description of the risk

For risk managers to make sound decisions, the risk assessment should provide all information on the impact of single pesticide uses due to their application in-field. This information should be complete to allow the identification of the necessary risk mitigation measures for specific uses. However, this is not yet the case. For NTTP and NTA, the descrip-

tion of the in-field risks associated with direct effects is either missing or insufficient, respectively. The potential indirect effects via food web interactions are not addressed at all. Hence, the guidelines for a risk assessment in the process of the authorisation of pesticides should be supplemented accordingly.

- Possible compensation measures

There exist effective risk mitigation measures—including compensation measures—to be applied in-field or off-field for risks arising from in-field pesticide exposure. For instance, conservation headlands and other habitat provisions investigated in the Sussex Study and in other areas show that between 5 to 20% of the total managed area, depending on the quality of the management, are sufficient for risk mitigation. The applicability of these results to other areas of Europe is a matter of debate. Their implementation could avoid a non-authorisation due to unacceptable effects.

- Other deficits of the current pesticides risk assessment framework

The current risk assessment framework is characterised by several issues, which partly hamper its ability to identify risks to biodiversity and the ecosystem. These include: potential shortcomings to assess the persistence of pesticides and their transformation products; changed degradation rates of pesticides in mixtures compared to those of individual substances; inadequate evaluation of mixture toxicity (sequential application of pesticide products in spray series and tank mixtures) and potential effects of co-formulants and adjuvants; non-systematic consideration of stressors other than pesticides, e.g., both natural stressors such as interactions between species and anthropogenic stressors such as habitat fragmentation and climate change; possible non-representativeness of standard test species for assessing the risk to the protection goal; non-disclosure of all relevant information on pesticide safety data to authorities.

- More actions needed for a sustainable use of pesticides

Improvement of the current regulatory framework of pesticides based on the authorisation of single pesticide uses is an important component, but is

not enough to drive a transformation towards more sustainable agriculture. Additionally, more profound changes including measures outside the current scope of the pesticide regulation are necessary. Some examples are given below:

- (i) Reducing the use and thus also the impact of pesticides is an important measure. But doing this by increasing their use in enclosed structures (e.g., greenhouses and crops under cover) is not a solution, nor is the sole reliance on technological advances such as precision farming;
- (ii) More sustainable farming practices are under development but not yet widely used (e.g. culture-dependent changes in tillage, crop diversification, agroecology);
- (iii) The development of guidance/directives for more sustainable farming practices as well as the improvement of their use are needed.

- Advantages of using the current dataset

The approach we proposed uses the available ecotoxicological data and therefore does not increase the regulatory burden, nor does it entail additional animal testing.

- Complexity

From a regulatory and scientific perspective, the risk assessment should be as simple as possible and as complex as necessary, which is largely fulfilled by the proposed method.

- Risk communication

The risk assessment should provide information on the options and level of mitigation needed in-field for the pesticides under evaluation.

- Feedback loop/monitoring

To establish a feedback system of the prospective assessment and the effectiveness of the risk mitigation measures implemented in the courses of the authorisation, biological and chemical monitoring of the agroecosystems is needed and can be established in parallel to the risk assessment. The establishment of such a feedback system should not delay the introduction of risk assessment and risk management for in-field effects.

Any monitoring action should also require that available information on pesticide use and applied mitigation measures be made publicly available, ideally following FAIR (findability, accessibility, interoperability, and reusability) data principles.

- Suggestions for managers

In the context of the revision of the terrestrial guidance document (SANCO/10329/2002), it is recommended that risk managers consider that the protection goals for NTTTP and NTA should cover the indirect effects/food web support.

Methods

A literature review was conducted to identify pertinent information on the impact of pesticides on the agroecosystem, farmland species, and the impact of pesticides. The discussion on these issues and possible improvements to the regulatory system took place at a workshop in Dessau-Roßlau in July 2023. This event was organised by the German Environment Agency (UBA), in collaboration with the Game and Wildlife Conservation Trust (GWCT) and the German Academy of Sciences (Leopoldina). Participants included European scientists and regulatory experts from EU member states and Switzerland and the European Environment Agency (EEA). In the role of observers participated the European Food Safety Authority (EFSA) and the German Federal Office of Consumer Protection and Food Safety.

Abbreviations

EEA	European Environment Agency
EFSA	European Food Safety Authority
GWCT	Game & Wildlife Conservation Trust
NTA	Non-target arthropods
NTTP	Non-target terrestrial plants
UBA	German Environment Agency

Supplementary Information

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Supplementary material 1.

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Author contributions

MS: Workshop participation and organisation, Conceptualisation, Writing—Original Draft, Visualisation SB: Workshop participation and organisation, Conceptualisation, Writing—Original Draft, Visualisation AA: Workshop participation, Writing—Review and Editing JD: Workshop participation, Writing—Review and Editing SD: Workshop participation, Conceptualisation, Writing—Review and Editing, Visualisation JE: Workshop participation,

Conceptualisation, Writing—Review and Editing. EG: Workshop participation, Writing—Review and Editing JH: Workshop participation, Writing—Review and Editing MK: Workshop participation, Writing—Review and Editing AL: Workshop participation, Conceptualisation, Writing—Review and Editing. SMatezki (UBA): Workshop participation and organisation, Conceptualisation, Writing—Review and Editing SMeyer: Workshop participation, Writing—Review and Editing TNL: Workshop participation, Writing—Review and Editing SP: Workshop participation, Conceptualisation, Writing—Review and Editing DP: Workshop participation, Writing—Review and Editing SR: Workshop participation, Writing—Review and Editing MRN: Workshop participation, Writing—Review and Editing AS: Workshop participation, Conceptualisation, Writing—Review and Editing. JS: Workshop participation, Conceptualisation, Writing—Review and Editing. GS: Workshop participation, Writing—Review and Editing NS: Workshop participation, Writing—Review and Editing JW: Workshop participation and organisation, Conceptualisation, Writing—Review and Editing DM: Workshop participation, Conceptualisation, Writing—Review and Editing.

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Author details

¹Department Plant Protection Products, German Environment Agency, Umweltbundesamt (UBA), Wörlitzer Platz 1, 06844 Dessau-Roßlau, Germany. ²Federal Office for the Environment (FOEN), Monbijoustrasse 40, 3011 Bern, Switzerland. ³Thünen Institute of Biodiversity, Bundesallee 65, 38116 Braunschweig, Germany. ⁴Game and Wildlife Conservation Trust, Burgate Manor, Hampshire, Fordingbridge SP6 1EF, UK. ⁵Department of Conservation Biology, University of Göttingen, Bürgerstraße 50, 37073 Göttingen, Germany. ⁶Sustainable Agriculture and Biodiversity, Julius Kühn-Institut (JKI) Federal Research Centre for Cultivated Plants Institute for Strategies and Technology Assessment, Stahnsdorfer Damm 81, 14532 Kleinmachnow, Germany. ⁷Federal Agency for Nature Conservation, Konstantinstraße 110, 53179 Bonn, Germany. ⁸Game and Wildlife Conservation Trust, Loddington House, Loddington, Leicestershire LE7 9 XE, UK. ⁹Department of Plant Ecology and Ecosystems Research, Albrecht-von-Haller-Institute for Plant Sciences, University of Göttingen, Untere Karspüle 2, 37073 Göttingen, Germany. ¹⁰Centre for Functional Ecology (CFE), Science for People and the Planet, Associate Laboratory TERRA, Department of Life Sciences, University of Coimbra, Calçada Martim de Freitas, 3000-456 Coimbra, Portugal. ¹¹Department Soil State and Soil Monitoring, German Environment Agency, Umweltbundesamt (UBA), Wörlitzer Platz 1, 06844 Dessau-Roßlau, Germany. ¹²European Environment Agency, Kongens Nytorv 6, 1050 Copenhagen K, Denmark. ¹³Swedish University of Agricultural Sciences, Uppsala, Sweden. ¹⁴UMR Tetis, INRAE, Montpellier, France. ¹⁵Institute for Environmental Research, RWTH Aachen University, 52074 Aachen, Germany. ¹⁶Department of Conservation Biology and Social-Ecological Systems, UFZ—Helmholtz Centre for Environmental Research, Permoserstraße 15, 04318 Leipzig, Germany. ¹⁷German Centre for Integrative Biodiversity Research (iDiv) Halle-Jena-Leipzig, Leipzig, Germany. ¹⁸Environmental Technology, Wageningen University and Research, 6700 AA Wageningen, The Netherlands. ¹⁹German Environment Agency, Umweltbundesamt (UBA), Wörlitzer Platz 1, 06844 Dessau-Roßlau, Germany.

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