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# LICENCE TO KILL

an EU guideline with far-reaching consequences



Pesticide  
Action  
Network  
Europe

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# Abstract

Europe is facing a catastrophic collapse of biodiversity, with arthropod populations plummeting at an alarming rate. In some regions, insect biomass has declined by an alarming 75% over approximately 25 years. The scientific evidence is clear: habitat loss, industrial agriculture, and rampant pesticide use are the primary drivers of this decline.

The EU Pesticide Regulation states that pesticide products should have no unacceptable effects on the environment and non-target species, taking into account their impact on biodiversity and ecosystems. In practice, however, pesticides that are highly toxic to insects and other bugs, and negatively impact biodiversity continue to be systematically approved in the European Union. This is possible due to an outdated and biased “Guidance Document”, which details how the impact of pesticides on 'non-target' arthropods should be assessed in the EU. Essentially, it allows for the killing of arthropods with almost no limits. Adopted in 2002 and never revised since, it was heavily influenced by industry representatives. Hence, the tests required for assessing the impact of pesticides on arthropods are very limited and insensitive, allowing the killing of as much as 50% of the population with the spraying of a single pesticide. Unscientific concepts such as "recovery" provide exceptions even for 100% mortality of test arthropods, based on the reasoning that 'they will come back'. In agriculture, the reality is that arthropods are exposed to cocktails of pesticide substances and other chemical stressors; this

is not taken into account in the assessment. Hence, hardly any 'arthropod' life can survive with this guideline and they have little chance of 'coming back'.

This flawed document has been instrumental in the dramatic collapse of arthropods we are currently witnessing in Europe. For many years it has been criticised by both scientists, as well as by EU Member States, without undergoing any revision. After years of delay, the European Commission has finally granted the European Food Safety Authority (EFSA) the green light to revise the Guidance Document in June 2024. However, undisclosed documents obtained by PAN Europe, show that EFSA and its partner, Wageningen University (WUR), have no intention of increasing the level of protection of insects or of biodiversity as a whole. New and even worse concepts are introduced that will - if they have their way - lead to an equally ineffective or even worse new guideline that allows to finish off the life that still manages to survive in agricultural fields and their surroundings. EFSA and WUR create a fantasy world that has little to do with reality. Their work on non-target arthropods is the opposite of what they claim it to be—transparent, scientific, and independent, while they actively undermine current EU rules to protect the environment. EFSA’s work on non-target arthropods should be put to a halt and a new panel of completely independent scientists and entomologists should be appointed to start developing a new guideline from scratch.



# Executive Summary

Arthropods are the diverse range of insects and other small ‘invertebrate’ animals, such as spiders, beetles, millipedes, butterflies, crustaceans, and springtails, that account for over 80% of all known animal species on Earth. Although they are often perceived as ‘pests’, they are absolutely essential to life on Earth as we know it. Arthropods support the intricate balance of our environment by performing countless ecological functions, such as pollination, crop pest regulation, decomposition, nutrient cycling and soil aeration. They are the linchpins that sustain our ecosystems and the foundation of our food webs. Through their incredible diversity, they are a testament to the wonder of evolution and the richness of our natural world. Yet, industrial agricultural practices—especially pesticide use—have driven a dramatic decline in their populations and diversity, with insect biomass plummeting by 75% in Europe over the past 25 years. Even in nature reserves, the insect collapse occurred while—not coincidentally—cocktails of pesticides could be analysed.

In this report, PAN Europe critically analyses the EU’s 2002 “Guidance Document on Terrestrial Ecotoxicology”, which defines the agreed protection standards and methodology for assessing pesticide impacts on non-target arthropods (NTAs, i.e., the arthropods present in the environment that are not intended to be affected by pesticides). Our investigation reveals that for the past 22 years, the EU pesticide risk assessment system has not only failed to protect NTAs but has also actively contributed to their decline

**by enabling the approval of pesticides representing a "high risk" to these vital species.** This failure stems from the guidance document’s shockingly weak protection standards, unscientific methods, and flawed testing protocols, which were directly taken from the “ESCORT 2” report—a document drafted primarily by agrochemical industry representatives back in 2000.

Despite calls for revision from EU Member States as early as 2019, progress has been alarmingly slow, with the European Commission only granting EFSA the mandate to begin the revision process in June 2024. Meanwhile, EFSA has been laying the groundwork for the revision by developing its own approach to protecting environmental organisms. The Authority has been closely collaborating with a handful of like-minded experts, primarily from a unit at Wageningen University (Wageningen Environmental Research, formerly known as Alterra), along with subcontractors from the UK, Portugal, and Germany. Notably, another part of the same Wageningen unit is conducting similar work for the chemical industry (CEFIC), raising concerns about potential industry influence on EFSA’s proposals.

In a quest for transparency, PAN Europe filed 'access-to-documents' requests to uncover EFSA's preparatory work on the NTA guidance update, including preliminary reports from Wageningen University’s research project on NTAs. Our analysis reveals a troubling truth: if their approach is implemented, NTAs protection will amount to little more than smoke and



**mirrors. The updated guidance could pose significant risks that may even surpass the flaws of its 2002 predecessor**, allowing for the continued mass killing of these vital organisms through pesticide use.

On one hand, key shortcomings from the previous guidance remain, most notably the lack of scientific rigour. This includes a failure to account for the impact of pesticide cocktails on NTAs, even though NTAs are exposed to multiple pesticide substances in the environment. By only assessing the effects of exposure to a single pesticide substance on NTAs, the true extent of the harm inflicted on NTAs will remain grossly underestimated in the risk assessment of pesticides. Additionally, EFSA and WUR continue to rely on the discredited concept of “recovery”, which is used to justify a high level of mortality, as long as there are indications that the population will bounce back within one year. Recovery is an unvalidated assumption that lacks support from field tests, particularly in areas where refuges for NTAs are insufficient, leaving them vulnerable to pesticide exposure. Lastly, once again, the recommended species for testing do not include the most sensitive species of arthropods. As a result, even if the assessment shows no harm to the tested species, there is no guarantee that the same conclusion holds true for all arthropod species.

On the other hand, EFSA and WUR introduce new shortcomings that will further compromise the protection of non-

target arthropods in the EU. Their approach contravenes EU Law by focusing narrowly on protecting only specific aspects of ecosystems and biodiversity, prioritising only those that provide ‘services’ to humans. Alarmingly, they propose to elevate agricultural production as the most important ‘service’ (“trade-off”), while disregarding the known detrimental impact of current industrial agricultural practices on ecosystems and biodiversity. EFSA and WUR’s approach turns the protection of biodiversity upside down, suggesting that arthropods do not require safeguarding, unlike agricultural practices and pesticides. Furthermore, EFSA and WUR introduce the classification of “disservice” for organisms like grasshoppers, mites, and thrips, thus voluntarily leaving entire groups of creatures devoid of any protection under this misguided framework.

EFSA's claim of developing a "next-generation, holistic" risk assessment is misleading. In reality, it serves as a smokescreen for the ongoing destruction of NTAs. By favouring single-minded experts, ignoring the effects of chemical mixtures, and permitting the flawed recovery option, EFSA is violating its commitment to scientific excellence and independence. The stakes are high: if implemented, WUR and EFSA’s approach will further undermine the provisions of the EU Pesticide law by prioritising ecosystem services for humans over the protection of biodiversity, further exacerbating the biodiversity crisis.





# Chapter 1

## Creeping crisis: the impact of pesticides on arthropod populations

Imagine a world where the delicate balance of nature falters: decomposing organic matter piles up, crops fail due to dead soils and countless species face extinction. These are some of the consequences that would occur if arthropods were to disappear. These bugs are underappreciated, and often branded as pests; however, the survival of life on Earth as we know it depends completely on their existence.

### 1. What are arthropods?

Arthropods belong to a large group of animals (phylum<sup>1</sup>) called Arthropoda, which includes a vast diversity of invertebrate species, ranging from minuscule mites measuring less than 0.1 millimetres to 3-metre-long crabs. Unlike vertebrate groups, such as mammals and birds, they do not have a backbone (a vertebral column). Arthropods' particular feature is that they have a hard protective outer shell, an exoskeleton, providing structural support and protection. Their bodies typically consist of segments, usually equipped with pairs of jointed legs known as appendages, from which the name arthropod derives<sup>2</sup>. Appendages vary in

number and function across arthropod species. They are used for eating, feeling, sensing, mating, breathing, walking, or defence. The exoskeleton, coupled with the jointed appendages, functions much like a suit of armour.

Arthropods inhabit nearly every habitat on Earth, from deserts to tropical rainforests, and everything in between. This phylum is subdivided into four main groups: Chelicerata (including arachnids), Crustacea (which include crustaceans), Myriapoda (comprising millipedes and centipedes) and Hexapoda (insects).

<sup>1</sup> The animal kingdom is divided into 39 major groups called 'phyla.' Organisms within each phylum share common morphological traits and/or evolutionary ancestry. By grouping organisms in this way, scientists can better understand how different species are related and track their evolutionary history. Amongst the 39 phyla, arthropods form the most diverse phylum, followed by mollusks and vertebrates.

<sup>2</sup> The word arthropod comes from the Greek root words arthro-, meaning joint and -pod meaning foot.



Arthropods comprise more species and individuals than all other animal groups combined, accounting for over 80% of all known animal species, with more than 1.02 million species discovered, including around 1 million described and named insect species, which are by far the largest subgroup and the most abundant life form known to science (Giribet & Edgecombe, 2019; Noordijk et al., 2010). In comparison, there are only about 5,400 mammalian species on Earth. Within this subgroup, beetles (part of the Insect class) alone represent approximately 400,000 species and makeup about 25% of all known animal species (Stork et al., 2015).

Despite this diversity and abundance, arthropods are significantly understudied compared to vertebrates, such as mammals, plants, birds, amphibians, reptiles and fish (Samways, 2015). Scientific studies suggest that only a very small fraction of all the arthropod species inhabiting our world has been discovered. On average, the most recent estimates indicate there could be around 1.5 million species of beetles, approximately 5.5 million species of insects, and about 7 million species of terrestrial arthropods worldwide—thus far exceeding the number of species discovered to date (Stork, 2018).

Arthropods, including insects, rarely attract public attention or media coverage and are seldom the focus of policy measures. In recent years, only managed honeybees have captured public interest. They have emerged as a flagship species for other pollinating insects, such as wild bees, hoverflies, butterflies and moths, reflecting a heightened public awareness of their ecological significance and the alarming decline many wild pollinators face. This increased awareness has been driven by a growing number of high-profile scientific studies indicating their decline due to chemical pollution and habitat destruction, particularly in proximity to agricultural zones, and extensive media coverage highlighting these issues. As a result, citizens have displayed a great interest in conservation actions to support bees, engaging in a variety of ways to “save the bees”<sup>3</sup>. Faced with this significant public

pressure to protect bee and other pollinator populations, the EU restricted the use of neonicotinoids in 2013. Later, in 2018, it launched the Pollinators initiative to safeguard pollinators across Member States<sup>4</sup> and started banning all outdoor uses of several neonicotinoid pesticides, such as imidacloprid, due to their high toxicity to bees and other pollinators<sup>5</sup>. In the recently adopted European Nature Restoration Law (Regulation (EU) 2024/1991), an article is dedicated to pollinators, aiming to improve pollinator diversity and reverse the decline of pollinator populations at the latest by 2030. While these measures represent progress, they fall short of effectively safeguarding bee populations. More critically, there is a notable lack of any similar initiatives for other, often less charismatic, arthropod species, which are also declining<sup>6</sup> but remain largely unaddressed by EU policies. Despite some Mem-

<sup>3</sup> Colla, S. R. (2022). The potential consequences of ‘bee washing’ on wild bee health and conservation. *International Journal for Parasitology: Parasites and Wildlife*, 18, 30–32. <https://doi.org/10.1016/j.ijppaw.2022.03.011>.

<sup>4</sup> European Commission, Communication from the Commission to the European Parliament, The Council, the European Economic and Social Committee and the Committee of the Regions: EU Pollinators Initiative (2018). [https://ec.europa.eu/environment/nature/conservation/species/pollinators/documents/EU\\_pollinatorsinitiative.pdf](https://ec.europa.eu/environment/nature/conservation/species/pollinators/documents/EU_pollinatorsinitiative.pdf).

<sup>5</sup> EFSA. Neonicotinoids. [https://food.ec.europa.eu/plants/pesticides/approval-active-substances-safeners-and-synergists/renewal-approval/neonicotinoids\\_en](https://food.ec.europa.eu/plants/pesticides/approval-active-substances-safeners-and-synergists/renewal-approval/neonicotinoids_en)

<sup>6</sup> See sub-section 3, “Fading buzz: the alarming European insect collapse”.





ber States implementing general biodiversity conservation measures, protection efforts across the European Union are still limited and inadequate in curbing their decline. This disparity highlights a significant oversight by European policymakers, who

have underestimated the importance of all arthropods for ecosystem stability, not just that of pollinators. Furthermore, by law, biodiversity, including arthropod populations, must be protected against the harm of pesticides.

## 2. The unsung importance of arthropods

Arthropods' value to our ecosystems is not defined by their appearance; even the least attractive species play crucial roles. Beetles, centipedes, mites, and other arthropods are foundational to ecosystems, agriculture, and food security. These often-overlooked creatures perform a variety of essential ecological functions, making them indispensable workers in our environment.

Among their many roles, arthropods are key pollinators. Alongside honeybees, wild bees, wasps, beetles, hoverflies, moths and other flower-visiting insects ensure the pollination of a vast majority of flowering plant species. In the EU alone, it is estimated that around 84% of cultivated species and 78% of wildflower species depend, at least in part, on animal pollination<sup>7</sup>.

Less known but equally important is their contribution to soil health. Species like woodlice and burrowing beetles break down plant and animal detritus, preventing the buildup of dead organic matter. This decomposition process recycles nutrients back into the soil, thereby maintaining soil health and making nutrients available to plants and primary producers—the base of our food chain. Other arthropod species, such as ants and dung beetles, help to create soil structure and facilitate soil aeration and water infiltration, which are crucial for healthy plant root development, as well as ensuring the sponge role of soil and preventing floods.

Additionally, many arthropods are effective predators or parasitoids that regulate the populations of other insects. Ladybirds, lacewings, hoverflies, praying mantises, spiders, and various predatory bugs all play a vital role in maintaining ecological balance. Parasitoid wasps and flies play a role of similar importance. They are also beneficial predators in agriculture as they provide natural pest control.

These few examples highlight the diverse and indispensable ecological roles fulfilled by arthropods in our ecosystems. Their value becomes even more apparent when considering that many species perform multiple functions simultaneously. For example, hoverflies not only contribute to plant pollination but also serve as effective predators (i.e., of aphids).



<sup>7</sup> Potts, S., et al., (2015), Status and Trends of European Pollinators (Statut et tendances des pollinisateurs européens). Key Findings of the STEP Project (Principales conclusions du projet STEP), Pensoft Publishers, Sofia, p.72. Cited in: <https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A52018DC0395>



It is important to recognise that the value of arthropods goes far beyond the services they provide. They are integral to the intricate web of life on Earth. Over millions of years, arthropods have adapted to countless environments, evolving into a dazzling array of colours, patterns, and unique survival strategies. Their diversity and complexity are a testament to the wonder of evolution and the richness of our natural world. They form the link that holds the food web together, as they play a role at almost every level of the food chain in ecosystems. Herbivorous arthropods, like caterpillars and grasshoppers, are primary consumers that feed on plants. These herbivores are then preyed upon by various predators, including other arthropods, such as spiders and predatory beetles, as well as birds, mammals, reptiles, and amphibians. In turn, these predators themselves become prey for other higher-level consumer species. This intricate web of interactions highlights the importance of arthro-



pods in transferring energy through the food web and supporting the overall ecosystem. In addition, many of these higher-trophic species, such as birds or amphibians, also play a crucial role in reducing crop pest pressure.

Hence, any changes in the diversity and abundance of arthropods can have significant ecological impacts. We may picture an intricate and delicate lacework, where each thread represents a different species within an ecosystem. Arthropods are the master threads woven throughout this lace. If the threads were to weaken or break, the entire lacework would fall apart. If they were to decline dramatically or, worse, go extinct, the repercussions for the planet's ecosystems would be catastrophic<sup>8;9</sup>. A vast tract of the plant kingdom—both wild and cultivated—would not survive without arthropod-pollinating species. This would lead to a subsequent loss of habitat and food sources for herbivores, their predators, and for human consumption. The many insect-eating animals—especially birds—would starve to death or experience a lower reproduction rate<sup>10</sup>; those feeding on these insectivores would also perish. Progressively, the entire food web would be disrupted. Soil health and plant growth would be impaired as decaying matter would pile up, impacting soil fertility and nutrient availability. In short, the stability and health of ecosystems hinge on arthropods. Hence, the decline in arthropod populations observed in recent decades warrants serious attention and policy action. This is particularly evident in France, where farmland birds have experienced a 60% decline over the past 40 years, partly attributed to the lack of available insects (Rigal et al., 2023<sup>11</sup>).

<sup>8</sup> Sánchez-Bayo, F., & Wyckhuys, K. A. G. (2019). Worldwide decline of the entomofauna: A review of its drivers. *Biological Conservation*, 232, 8–27. <https://doi.org/10.1016/j.biocon.2019.01.020>.

<sup>9</sup> WILSON, E. O. (1987). The little things that run the world\* (the importance and conservation of invertebrates). *Conservation Biology*, 1(4), 344–346. <https://doi.org/10.1111/j.1523-1739.1987.tb00055.x>.

<sup>10</sup> See for instance: Grames, E. M., Montgomery, G. A., Youngflesh, C., Tingley, M. W., & Elphick, C. S. (2023). The effect of insect food availability on songbird reproductive success and Chick body condition: Evidence from a systematic review and meta-analysis. *Ecology Letters*, 26(4), 658–673. <https://doi.org/10.1111/ele.14178>.

<sup>11</sup> Rigal, S., Dakos, V., Alonso, H., & Devictor, V. (2023). Farmland practices are driving bird population decline across Europe. *Proceedings of the National Academy of Sciences*, 120(21), e2216573120. <https://doi.org/10.1073/pnas.2216573120>.



### 3. Fading buzz: the alarming European insect collapse

Since the early 2000s, an increasing number of citizens across the European Union have noticed troubling signs: fewer insects around lights on summer nights, a quieter evening chorus of crickets and other nocturnal insects, significantly fewer insect splatters on car windshields than in the past, a strong decline in the populations of most butterflies and many bird species... Far from being trivial, these observations are indicators of how arthropod populations are faring. The scientific community is united in its concern: global arthropod populations are declining rapidly, and the situation is extremely alarming. Studies consistently show a swift decline in both species diversity and abundance worldwide (Habel et al., 2019<sup>12</sup>), resulting in significant biomass loss and changes in species composition, with some species becoming increasingly rare.

However, there is no scientific consensus on the precise rate of decline, as estimates vary due to incomplete data. According to a landmark review of 72 long-term insect surveys, around 40% of insect species are rapidly declining, and one-third are globally threatened with extinction (Sánchez-Bayo & Wyckhuys, 2019)<sup>13</sup>. The authors estimate that, over the past 25 to 30 years, the total mass of insects globally has decreased by an average of 2.5% each year. For some groups mentioned (i.e., hoverflies), average decline rates are even higher<sup>14</sup>. Hence, if the current rates of decline continue, many insect species could face extinction. These conclusions were mostly driven by data from the United Kingdom, Germany, the Netherlands, and

other European countries, where the declines in insect species diversity and abundance are well-documented, thanks to the work of collectors and dedicated naturalists<sup>15</sup>.

In short, there is substantial evidence that arthropod species in European countries are in significant and ongoing decline<sup>16</sup> (Habel et al., 2016<sup>17</sup>; Simons et al., 2017<sup>18</sup>). However, our understanding of the decline varies significantly from one species to another. From the available data, species of butterflies, moths, bees, wasps, and dung beetles appear to be among the most affected (Sánchez-Bayo & Wyckhuys, 2019). Among land-dwelling insects, dung beetles in Mediterranean countries are experiencing the biggest biodiversity losses, with over 60% of species in decline and a large portion considered threatened.



<sup>12</sup> Habel, J. C., Samways, M. J., & Schmitt, T. (2019). Mitigating the precipitous decline of terrestrial European insects: Requirements for a new strategy. *Biodiversity and Conservation*, 28(6), 1343-1360. <https://doi.org/10.1007/s10531-019-01741-8>

<sup>13</sup> Sánchez-Bayo, F., & Wyckhuys, K. A. G. (2019). Worldwide decline of the entomofauna: A review of its drivers. *Biological Conservation*, 232, 8-27. <https://doi.org/10.1016/j.biocon.2019.01.020>

<sup>14</sup> Zeegers, Reemer, Smit & van Steenis 2024. Strong decline of hoverflies (Diptera, Syrphidae) in the Netherlands over the last decades. 12th. International Symposium on Syrphidae. [https://www.researchgate.net/publication/384103669\\_Hoverflies\\_in\\_strong\\_decline](https://www.researchgate.net/publication/384103669_Hoverflies_in_strong_decline).

<sup>15</sup> Wagner, D. L. (2020). Insect declines in the anthropocene. *Annual Review of Entomology*, 65(1), 457-480. <https://doi.org/10.1146/annurev-ento-011019-025151>.

<sup>16</sup> This phenomenon is observed globally, but the wealth of studies is more limited outside of the EU and North America.

<sup>17</sup> Habel, J. C., Seegerer, A., Ulrich, W., Torchyk, O., Weisser, W. W., & Schmitt, T. (2016). Butterfly community shifts over two centuries. *Conservation biology : the journal of the Society for Conservation Biology*, 30(4), 754-762. <https://doi.org/10.1111/cobi.12656>.

<sup>18</sup> Simons, N. K., Lewinsohn, T., Blüthgen, N., Buscot, F., Boch, S., Daniel, R., Gossner, M. M., Jung, K., Kaiser, K., Müller, J., Prati, D., Renner, S. C., Socher, S. A., Sonnemann, I., Weiner, C. N., Werner, M., Wubet, T., Wurst, S., & Weisser, W. W. (2017). Contrasting effects of grassland management modes on species-abundance distributions of multiple groups. *Agriculture, Ecosystems & Environment*, 237, 143-153. <https://doi.org/10.1016/j.agee.2016.12.022>



Butterflies, moths, hoverflies and bees are among the most thoroughly studied groups, with reliable long-term data on their population sizes and species abundances. In contrast, for many other species, such data are either limited or completely lacking. This is the case for many species of beetles, flies, ants, aphids, shield bugs, and crickets for instance. Nevertheless, scientists suggest that these species are likely not faring any better than the studied species, as there is no evidence to suggest otherwise. Most worrying is the fact that the decline affects not only specialist insects<sup>19</sup> but also many common and generalist species<sup>20</sup>. Concurrently, the abundance of very few adaptable, generalist species is rising, as they move into the niches left vacant by the declining species and thrive in

these new areas. As a result, insect communities are becoming increasingly uniform and less diverse (Sánchez-Bayo & Wyckhuys, 2019).

Worryingly, populations of insects in protected natural areas are also declining rapidly. A landmark study by Hallmann et al. (2017)<sup>21</sup>, which analysed insect-trapping data from 63 nature reserves in Germany, found that the mass of flying insects across all habitat types had dropped by 76 to 82 per cent over 27 years up to 2016. The authors show that the decline observed occurred regardless of the habitat, and therefore must be driven by large-scale factors. Notably, almost all locations (94%) are enclosed by agricultural fields, leading the authors to consider that agricultural intensification, including pesticide use, is a plausible cause.

### 4. The role of pesticides in arthropod population decline

Today, a large part of Europe's land area is used for agricultural purposes, with a large portion of it being dedicated to intensive farming. In these landscapes, the decline in biodiversity — particularly among plants<sup>22</sup>, birds<sup>23;24</sup>, and insects — has become increasingly obvious over the last few decades. Regarding insect decline, the ever-grow-

ing body of scientific literature consistently concludes that agricultural intensification is an important driver. For instance, it has been identified as a primary threat in all of the studies evaluating the losses of butterflies and moths in the United Kingdom, Finland, the Netherlands and Sweden (Wagner, 2020<sup>25</sup>).

<sup>19</sup> Specialist insects are species that thrive only in particular environments or on specific resources. Unlike generalist insects, which can adapt to a wide range of conditions and resources, specialists are highly dependent on certain factors such as host plants, niche habitats, interactions with other species... Their narrow ecological requirements make them highly sensitive to changes in their environment.

<sup>20</sup> Generalist insects are species that can thrive in a wide range of environments and utilise various resources for survival, such as multiple types of food sources or diverse habitats. Their broad adaptability allows them to survive and reproduce in changing conditions, making them more resilient to environmental changes compared to specialists.

<sup>21</sup> Hallmann, C. A., Sorg, M., Jongejans, E., Siepel, H., Hofland, N., Schwan, H., Stenmans, W., Müller, A., Sumser, H., Hörrén, T., Goulson, D., & de Kroon, H. (2017). More than 75 percent decline over 27 years in total flying insect biomass in protected areas. *PLOS ONE*, 12(10), e0185809. <https://doi.org/10.1371/journal.pone.0185809>.

<sup>22</sup> Carmona, C. P., Guerrero, I., Peco, B., Morales, M. B., Oñate, J. J., Pärt, T., Tschardtke, T., Liira, J., Aavik, T., Emmerson, M., Berendse, F., Ceryngier, P., Bretagnolle, V., Weisser, W. W., & Bengtsson, J. (2020). Agriculture intensification reduces plant taxonomic and functional diversity across European arable systems. *Functional Ecology*, 34(7), 1448–1460. <https://doi.org/10.1111/1365-2435.13608>.

<sup>23</sup> Donald, P. F., Green, R. E. & Heath, M. F. Agricultural intensification and the collapse of Europe's farmland bird populations. *Proc. Biol. Sci.* 268, 25–29 (2001). <https://doi.org/10.1098/rspb.2000.1325>.

<sup>24</sup> Reif, J. & Vermouzek, Z. Collapse of farmland bird populations in an Eastern European country following its EU accession. *Conserv. Lett.* 12, 1–8 (2019). <https://onlinelibrary.wiley.com/doi/pdf/10.1111/conl.12585>.

<sup>25</sup> Wagner, D. L. (2020). Insect declines in the Anthropocene. *Annual Review of Entomology*, 65, 457–480. <https://doi.org/10.1146/annurev-ento-011019-025151>.



Among the various farming practices associated with agricultural intensification, the systematic and widespread use of pesticides has been singled out as a key factor in the decline of insects<sup>26,27</sup>. A landmark study by Geiger et al. (2010)<sup>28</sup> investigated the effects of agricultural intensification on biodiversity in eight European countries. Out of the 13 studied components of agricultural intensification, the authors concluded that the use of pesticides, especially insecticides and fungicides, had the most consistent negative effects on the species diversity of carabids and ground-nesting farmland birds and reduced the potential of natural enemies to control pest organisms. Among the farms studied, organic farms harboured more wild plant and carabid species than conventional farms. Similarly, Sánchez-Bayo and Wyckhuys (2019) conclude that pollution, mainly by synthetic pesticides and fertilisers, is reported as the second leading cause of species declines in studies, right after habitat loss by conversion to intensive agriculture and urbanisation. Additionally, agricultural intensification, particularly pesticides and fertiliser use, has been identified as the main pressure behind most bird population declines, especially for invertebrate feeders (Rigal et al., 2023<sup>29</sup>)

Pesticides are toxic chemicals with specific modes

of action commonly used in agricultural and urban environments to target and kill specific invertebrate “pests”, fungi, and weeds. However, when pesticides are applied, they equally expose pests and non-target species present in both the treated area and surrounding habitats. This exposure occurs via various pathways: direct spray on their bodies, direct contact with treated surfaces, inhalation of droplets, ingestion of contaminated food such as pollen, pesticide drift, etc... As a result, arthropods that are not intended to be affected by the use of pesticides (non-target arthropods), are continuously exposed to cocktails of various pesticide residues in agricultural landscapes. A 2021 study found that insects collected from nature conservation areas near conventional farms had an average of 16.7 pesticide residues on their bodies, with 47 different pesticide residues detected in all insect samples (Brühl et al., 2021<sup>30</sup>). The constant exposure of bees to mixtures of pesticide residues in agricultural landscapes is also well-documented<sup>31</sup> and has been suggested as a potential factor in their decline and that of other flower-visiting insects<sup>32,33</sup>.

Pesticide exposure negatively affects non-target arthropods and is linked to a wide range of direct negative effects (both lethal and non-lethal) (Bartling et al., 2024<sup>34</sup>), as well as to indirect effects

<sup>26</sup> Dudley, N., & Alexander, S. (2017). Agriculture and Biodiversity: A Review. *Biodiversity*, 18(2–3), 45–49. <https://doi.org/10.1080/14888386.2017.1351892>.

<sup>27</sup> Sánchez-Bayo, F., & Wyckhuys, K. A. G. (2019). Worldwide decline of the entomofauna: A review of its drivers. *Biological Conservation*, 232, 8–27. <https://doi.org/10.1016/j.biocon.2019.01.020>.

<sup>28</sup> Geiger, F., Bengtsson, J., Berendse, F., Weisser, W. W., Emmerson, M., Morales, M. B., Ceryngier, P., Liira, J., Tschardtke, T., Winqvist, C., Eggers, S., Bommarco, R., Pärt, T., Bretagnolle, V., Plantegenest, M., Clement, L. W., Dennis, C., Palmer, C., Oñate, J. J., ... Inchausti, P. (2010). Persistent negative effects of pesticides on biodiversity and biological control potential on European farmland. *Basic and Applied Ecology*, 11(2), 97–105. <https://doi.org/10.1016/j.baae.2009.12.001>.

<sup>29</sup> Rigal, S., Dakos, V., Alonso, H., Auniņš, A., Benkő, Z., Brotons, L., Chodkiewicz, T., Chylarecki, P., de Carli, E., del Moral, J. C., Domşa, C., Escandell, V., Fontaine, B., Foppen, R., Gregory, R., Harris, S., Herrando, S., Husby, M., Ieronymidou, C., ... Devictor, V. (2023). Farmland practices are driving bird population decline across Europe. *Proceedings of the National Academy of Sciences*, 120(21), e2216573120. <https://doi.org/10.1073/pnas.2216573120>.

<sup>30</sup> Brühl, C. A., Bakanov, N., Köthe, S., & others. (2021). Direct pesticide exposure of insects in nature conservation areas in Germany. *Scientific Reports*, 11, 24144. <https://doi.org/10.1038/s41598-021-03366-w>.

<sup>31</sup> Nicholson, C.C., Knapp, J., Kiljanek, T. et al. Pesticide use negatively affects bumble bees across European landscapes. *Nature* 628, 355–358 (2024). <https://doi.org/10.1038/s41586-023-06773-3>

<sup>32</sup> Botías, C., David, A., Hill, E. M. & Goulson, D. Quantifying exposure of wild bumblebees to mixtures of agrochemicals in agricultural and urban landscapes. *Environ. Pollut.* 222, 73–82 (2017). <https://doi.org/10.1016/j.envpol.2017.01.001>.

<sup>33</sup> Uhl, P., & Brühl, C. A. (2019). The Impact of Pesticides on Flower-Visiting Insects: A Review with Regard to European Risk Assessment. *Environmental toxicology and chemistry*, 38(11), 2355–2370. <https://doi.org/10.1002/etc.4572>.

<sup>34</sup> Bartling, M.-T., Brandt, A., Hollert, H., & Vilcinskis, A. (2024). Current insights into sublethal effects of pesticides on insects. *International Journal of Molecular Sciences*, 25(11), 6007. <https://doi.org/10.3390/ijms25116007>.



(Sánchez-Bayo, 2021). For instance, carnivorous arthropods are likely to be more prone to higher impacts from pesticides than their prey<sup>35</sup>. Direct toxic effects range from acute and chronic mortality to sub-lethal effects, such as the disruption of vital behaviours, including foraging, nesting, and mating. The effects depend on many factors, such as the insect species, age, sex, caste, physiological condition, as well as the type and concentration of the active ingredients and the exposure route (Bartling et al., 2024). Indirect effects involve broader consequences that can impact entire ecosystems, including changes in food webs and biodiversity<sup>36</sup>. These complex effects, however, are less studied and consequently, less understood. In a review of studies on insects and other arthropods, Sánchez-Bayo (2021) discusses a range of these indirect effects and concludes that pesticides released into the environment can indirectly affect target and non-target species in ways that are often contrary to their intended use. For instance, the *“application of insecticides to agriculture often results in subsequent pest outbreaks due to the elimination of natural enemies. The loss of floristic diversity and food resources that result from herbicide applications can reduce populations of pollinators and natural enemies of crop pests. (...) Fungicides and systemic insecticides also reduce nutrient recycling by impairing the ability of detritivorous arthropods. Herbicides also decrease vegetation biodiversity both within crops and in surrounding areas due to drift and runoff, which indirectly impacts arthropod species that depend on wild plants, causing these plants to either disappear or significantly decline in numbers”*<sup>37</sup>. Indirect effects can create negative interactions between different organism groups. For example, while an herbicide may not acutely harm insects or birds, its use can reduce food sources for pollinators and herbivorous insects, ultimately im-

acting bird populations that rely on these insects for nourishment<sup>38</sup>.

The EU law on Pesticides (Regulation (EC) 1107/2009) states that pesticide products should cause no unacceptable effects on the environment. It states clearly that *“Substances should only be included in plant protection products where it has been demonstrated that they present a clear benefit for plant production and they are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment”* (Regulation (EC) 1107/2009, recital 10).

One might expect that, to protect the survival of non-target arthropod species in fields and surrounding habitats, both the direct and indirect effects of active substances would be thoroughly considered during the authorisation process at the European level. However, this is far from the case in practice. The current methodology used to assess the impact of pesticides on non-target arthropods relies on an outdated guidance document that is fundamentally flawed and inadequate for ensuring their protection.



<sup>35</sup> Zeegers, van Steenis, Reemer & Smit 2024. Drastic acceleration of the extinction rate of hoverflies (Diptera: Syrphidae) in the Netherlands in recent decades, contrary to wild bees (Hymenoptera: Anthophila). *Journaal van Syrphidae* 3(1): 1-11. <https://doi.org/10.55710/1/YDSJ1547>.

<sup>36</sup> Calvo-Agudo, Tooker, Dicke & Tena 2022. Insecticide-contaminated honeydew: risks for beneficial insects. *Biological Reviews* 97: 664-678. <https://doi.org/10.1111/brv.12817>.

<sup>37</sup> Sánchez-Bayo, F. (2021). Indirect effect of pesticides on insects and other arthropods. *Toxics*, 9(8), 177. <https://doi.org/10.3390/toxics9080177>.

<sup>38</sup> Brühl, C. A., & Zaller, J. G. (2019). Biodiversity decline as a consequence of an inappropriate environmental risk assessment of pesticides. *Frontiers in Environmental Science*, 7. <https://doi.org/10.3389/fenvs.2019.00177>.





# Chapter 2

## The EU's guidance document for assessing the impact of pesticides on non-target arthropods: an 'industry recipe' for weak protection

### 1. "Guidance Documents" explained

The first 18 years of pesticide approval in the European Union were governed by the (EEC) Directive 91/414, adopted in 1991. This directive required that authorisation be granted only if a pesticide product had *"no unacceptable influence on the environment"* with particular regard to non-target species (Art. 4.1.b.iv). In 2009, this directive was replaced by the (EC) Regulation 1107/2009 (hereafter the EU Pesticide Regulation), which mandates that pesticide products *"shall have no unacceptable effects on the environment"* (Art.4.3.e), including on non-target species and their ongoing behaviour (Art. 4.3.e.ii) and also regarding *"its impact on biodiversity and the ecosystem"* (Art. 4.3.e.iii), where the scientific methods accepted by the European Food Safety Authority (EFSA) for assessing such effects are available. Unfortunately, these legal improvements aimed at increasing environmental protection have not led to any concrete changes on the ground.

These scientific methods referred to in the Regulation are known as "Guidance Documents". They provide technical and scientific recommendations to applicants (agrochemical companies) and Member States to harmonise decision-taking on individual pesticides. Guidance Documents complement the EU Pesticide Regulation by specifying how some of its provisions should be implemented in practice. For instance, these documents can detail the criteria and methodology for assessing the risks of pesticides to specific non-target species, such as birds and mammals, or bees. While not legally binding, the recommendations of Guidance Documents are widely followed in practice because they outline harmonised accepted methods and standards for conducting pesticide risk assessments. By adhering to these guidelines, regulators consider that the assessments meet regulatory expectations and align with best practices. Hence, Guidance Documents significantly impact the effectiveness of the EU Pesticide Regulation.



When it comes to the risk assessment of pesticides on non-target arthropods (i.e., the arthropods present in the environment that are not intended to be affected by the pesticide, hereafter “NTA”), the scientific methodology is laid out in Section 5 of the “*Guidance Document on Terrestrial Ecotoxicology*”<sup>39</sup> (hereafter “Guidance Document on NTA”). This guideline was drafted and adopted in 2002—22 years ago—by DG SANCO (formerly DG SANTE) in the context of Directive 91/414/EEC, as EFSA did not exist at the time. Since then, the document has never been revised. Therefore, it contains references to standards and procedures that are no longer applicable since the adoption of the EU Pesticide Regulation in 2009. The latter now incorporates biodiver-

sity protection as a new requirement (Art. 4.3.e.iii) and the obligation to take into account new scientific and technical knowledge (Art. 4.1). Consequently, the criteria and methodologies described to assess the risk posed by pesticides to NTA are outdated and do not reflect the current legal requirements or the current state of scientific and technical knowledge on the topic. Moreover, since its inception, this guideline has consistently failed to safeguard non-target arthropods due to its flawed risk assessment methodology and lax protection standards, as further detailed. Because of this failing document pesticides that present an unacceptable risk to arthropods—and thus to the environment—are continuously authorised.

## 2. The agrochemical industry: the ghostwriter of the EU's guidance document on NTA

Before the adoption of the current EU Pesticide Regulation in 2009, the drafting of EU guidance documents took place in opaque conditions. The process was often led by ad-hoc working groups composed of both Member States' representatives and industry experts, without including independent academic or NGO experts. The documents resulting from these working groups were subsequently included in the EU's guidelines for pesticide risk assessment. However, the groups were frequently dominated by industry representatives, largely due to the absence of conflict-of-interest policies at the time<sup>40</sup>. Non-expert public servants relied on the expertise of the industry to draft such guidelines.

Several of the EU guidelines on pesticide risk assessment, for instance, have been drafted during and following meetings organised by the Society of Environmental Toxicology and Chemistry (SETAC). SETAC presents itself as a not-for-profit, worldwide professional organisation dedicated to advancing environmental science and environmental management<sup>41</sup>. This organisation organises publications, awards, education programs, meetings and workshops to provide a forum to exchange information and ideas, as well as offering collaboration and networking opportunities amongst environmental professionals<sup>42</sup>.

<sup>39</sup> European Commission (2002). Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC, p.19-24. [https://food.ec.europa.eu/document/download/424e71a2-5beb-4fa3-9198-89be916c1789\\_en?filename=pesticides\\_ppp\\_app-proc\\_guide\\_ecotox\\_terrestrial.pdf](https://food.ec.europa.eu/document/download/424e71a2-5beb-4fa3-9198-89be916c1789_en?filename=pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf)

<sup>40</sup> PAN Europe (2018). Report: “Industry writing its own rules”. p.4. <https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/industry-writings-its-own-rules-pdf.pdf>.

<sup>41</sup> Society of Environmental Toxicology and Chemistry, <https://www.setac.org/>.

<sup>42</sup> <https://www.setac.org/learn-about-setac.html>





However, SETAC is not an independent expert network; on the contrary, some of its members and partners have clear economic interests. It has a tripartite structure and involves professionals from academia, government as well as the industry. For instance, the board of the SETAC Europe Council currently has 19 members, amongst whom four are professionals from academia, six with government affiliation, and four from industry<sup>43</sup>. Two board members are employees of the agrochemical companies Corteva Agriscience and Bayer Crop Science, while a third one previously served as a Senior Ecotoxicologist at the Agricultural Research Centre of the German chemical group BASF and is currently working for a consulting group specialised in ecotoxicology. Interestingly, the current Europe Executive Director<sup>44</sup>, Albertus T.C. Bosveld, used to be the head of the Ecotoxicology section of ALTERRA<sup>45</sup> at Wageningen University in early 2000<sup>46</sup> (discussed in Chapter 4). SETAC Europe also counts amongst its partners the pesticide lobby group CropLife Europe and the umbrella lobby for chemical industries in Europe, CEFIC<sup>47</sup>. Partners pay a membership fee to access exclusive advantages, such as up-to-date contact information of SETAC members, delegate lists from SETAC Europe meetings, invitations to networking events, and more.

One could say that SETAC meetings serve as a "marketplace" for consultants and university em-

ployees<sup>48</sup> to secure funding for their research, programmes, ideas, and models on the risk assessment of chemicals, including from the agrochemical industry. Representatives of EFSA and other national authorities are also present. Hence, SETAC meetings are a crucial networking platform for the agrochemical industry to communicate ideas that could lead to more favourable risk assessments for their products and connect with like-minded experts who share their ideology that the use of pesticides is safe<sup>49</sup>. Agrochemical companies either financially support 'favourable' ideas for the sales of their products or create consortiums with consultants and university employees to apply for important EU research programmes, such as the multi-million Horizon 2020<sup>50</sup>. By supporting these research efforts, they can influence the development of favourable new risk assessment models and methodologies that favour their business. The outcome of this research is then used to influence the EFSA and push for the adoption of their findings in official EU guidelines. This strategy has been highly successful in shaping regulatory outcomes in the past<sup>51</sup>.

While the NTA Guidance Document was officially drafted by DG SANCO, it is based on and refers back to the recommendations established in a document known as the "ESCORT 2", short for "*Guidance document on regulatory testing and risk assessment procedures for plant protection products*

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<sup>43</sup> <https://www.setac.org/setac-where-you-live/europe/meet-your-leadership.html>

<sup>44</sup> <https://www.setac.org/setac-where-you-live/europe/meet-your-leadership.html>.

<sup>45</sup> <https://www.sciencedirect.com/science/article/abs/pii/S0045653502001613>.

<sup>46</sup> Wageningen University (section Environmental Research, the former Alterra Institute) has been contracted by EFSA on an important scientific project on NTA, related to the upcoming revision of the NTA Guidance Document. See Chapter 4 for a detailed explanation on why this is relevant.

<sup>47</sup> <https://www.setac.org/setac-where-you-live/europe/become-a-europe-partner.html#:~:text=SETAC%20Europe%20Partners%20are%20for,to%20foster%20the%20society's%20purposes>.

<sup>48</sup> University employees are encouraged, or even forced sometimes by governments, to get part of their finances 'from the market'.

<sup>49</sup> A case in point is Wageningen University Acropolis project leader Van Klaveren (later moved to Dutch RIVM when he was project leader at EFSA) who stated at the start of the programme that the aim is "to prove that the use of pesticide residues is safe", see flyer [https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/articles/Acropolis%20to%20prove%20that%20use%20of%20pesticides%20is%20safe%20-%20Van%20Klaveren%20ILSI%20\(1\).pdf](https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/articles/Acropolis%20to%20prove%20that%20use%20of%20pesticides%20is%20safe%20-%20Van%20Klaveren%20ILSI%20(1).pdf)

<sup>50</sup> An example is the Acropolis program of industry/Freshfel on cumulative assessment that was embraced by EFSA. The project leader of Acropolis was hired by EFSA as a manager of its cumulative assessment work. See: PAN Europe (2014). Report: "HOW INDUSTRY TRIES TO WATER DOWN THE RISK ASSESSMENT OF PESTICIDE MIXTURES IN EVERYDAY FOOD". <https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/pane-2014-a-poisonous-injection.pdf>.

<sup>51</sup> See for instance the Acropolis program in PAN Europe (2014). Report: "HOW INDUSTRY TRIES TO WATER DOWN THE RISK ASSESSMENT OF PESTICIDE MIXTURES IN EVERYDAY FOOD". <https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/pane-2014-a-poisonous-injection.pdf>. See also an industry program to avoid animal testing in PAN Europe (2016). Report: "AOP THE TROJAN HORSE FOR INDUSTRY LOBBY TOOLS?" <https://www.pan-europe.info/sites/pan-europe.info/files/pan-aop-report-nov-16.pdf>



with non-target arthropods"<sup>52</sup>. The document states it clearly: the guidance provided "is in line with the recommendations of ESCORT 2"<sup>53</sup> which details how the risk-assessment of pesticides on NTA should be performed.

The ESCORT 2 document, "endorsed" by DG SANCO, was drafted in 2000 following a workshop organised by BART, EPPO/CoE<sup>54</sup>, the OECD, and IOBC, alongside SETAC and the European Commission. The stated purpose of this workshop was to address gaps and update the 1994 guidelines on non-target arthropod (NTA) testing and pesticide risk assessment. However, the details of this workshop reveal a concerning level of industry involvement. The workshop was sponsored by 14 organisations—11 of which were leading

agrochemical companies, including Bayer and Novartis<sup>55</sup>. Of the 53 participants<sup>56</sup>, there were more representatives from agrochemical companies (15 people<sup>57</sup>) than from regulatory authorities of EU Member States (14 people)<sup>58</sup>. Worryingly, this trend extended to the drafting of the ESCORT 2 guidance itself. Of the 10 editors involved in the drafting of the ESCORT 2 guidance document, a striking half were employees of the pesticide industry—including companies such as Bayer, Zeneca Agrochemicals<sup>59</sup>, and Novartis—or worked for contract research and consulting firms close to the industry, such as Huntington Life Sciences and JSC International. The lead editor of the ESCORT 2 guidance was no other than Marco Candolfi, the head of the Ecotoxicology team at Novartis (now Syngenta<sup>60</sup>), who also served as Chairperson of the work-



<sup>52</sup> Candolfi MP, Barrett KL, Campbell P, Forster R, Grandy N, Huet M-C, Lewis G, Oomen P A, Schmuck R, Vogt H. 2000. Guidance document on regulatory testing and risk assessment procedures for plant protection products with nontarget arthropods. Report of the SETAC/ESCORT 2 Workshop, Wageningen, The Netherlands, SETAC-Europe, Brussels, Belgium. [https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/\\_ESCORT%20%20\\_non-target%20arthropods.pdf](https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/_ESCORT%20%20_non-target%20arthropods.pdf)

<sup>53</sup> European Commission (2002). Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC, p.20. [https://food.ec.europa.eu/document/download/424e71a2-5beb-4fa3-9198-89be916c1789\\_en?filename=pesticides\\_ppp\\_app-proc\\_guide\\_ecotox\\_terrestrial.pdf](https://food.ec.europa.eu/document/download/424e71a2-5beb-4fa3-9198-89be916c1789_en?filename=pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf)

<sup>54</sup> It is interesting to note that the EPPO's conflict of interest policies has been qualified as very limited by the EU Ombudsman, which acknowledged the heavy representation of the industry within the organisation. See point 63-64: European Ombudsman, Decision on how the European Commission adopted a guidance document on comparative assessment in the context of the substitution of hazardous substances in pesticides (case 177/2023/VB). <https://europa.eu/!rVmVFC>

<sup>55</sup> The 11 companies include American Cyanamid, Aventis, BASF, Bayer, Dow, Du Pont, FMC, Monsanto, Novartis Crop Protection AG, Uniroyal, and Zeneca Agrochemicals. See page 28 (Appendix I -workshop sponsors) of ESCORT 2: [https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/\\_ESCORT%20%20\\_non-target%20arthropods.pdf](https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/_ESCORT%20%20_non-target%20arthropods.pdf).

<sup>56</sup> See page 29-30 (Appendix II - participants list) of ESCORT 2: [https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/\\_ESCORT%20%20\\_non-target%20arthropods.pdf](https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/_ESCORT%20%20_non-target%20arthropods.pdf).

<sup>57</sup> American Cyanamid Company (1), Aventis CropScience GmbH (2), BASF AG (2), Bayer AG (2), Dow AgroSciences (1), DuPont Agricultural Products (1), Monsanto Europe SA (1), Novartis Crop Protection AG (2), Uniroyal Chemical Ltd. (1), Zeneca Agrochemicals (2).

<sup>58</sup> Other participants were affiliated with the Commission of the European Communities (1 participant), the OECD (1 participant), the EPPO (1 participant), contract research organisations and academia.

<sup>59</sup> Around 2000, AstraZeneca was the third largest producer of agrochemicals, after Novartis and Monsanto. Zeneca Agrochemicals was one of the constituent parts of AstraZeneca, together with AstraZeneca Pharmaceuticals. In 2000, Zeneca Agrochemicals merged its activities with the agricultural activities of Novartis to form the company Syngenta.

<sup>60</sup> Novartis AG is a Swiss multinational pharmaceutical company. Prior to 2000, the company had an agrochemical and genetically modified crops division. In 2000, Novartis and the Anglo-Swedish company AstraZeneca merged their agricultural activities into a new company, known as Syngenta, in order to focus on their activities related to human health.



shop's organising committee. Five public officials participated in the editing process: one representative each from the EU, German and Dutch regulatory authorities, and two from the OECD.

The industry's heavy influence within the workshop, the conflict of interests amongst the participants and editors of the ESCORT 2 guidance document created a seriously biased document. An agrochemical company's primary goal is to secure market approval for its products, giving it a clear interest in influencing pesticide risk assessment

methods to lower protection standards. Lower standards increase the likelihood of potentially harmful synthetic pesticides gaining authorisation. By adopting the industry-driven ESCORT 2 recommendations, methodology, and criteria, DG SANCO has created a fundamentally flawed and inadequate Guidance Document. Consequently, non-target arthropods in the European Union have been left vulnerable to the harmful effects of pesticides for the past two decades. We will elaborate on this in the following paragraphs.

## 3. The flaws and failures of the EU guidance document on NTA

The risk assessment of NTA takes place at two levels. The first level (first tier) aims at calculating a 'hazard quotient' (HQ), based on the Lethal Rate 50 (LR50) (i.e. the concentration of a pesticide that causes death in 50% of a test population of organisms). For arthropods, the LR50 is measured in glass plates in laboratory studies using two insect species deemed "most sensitive" in ESCORT 2. However, this claim regarding the sensitivity of the selected species is, once again, based on pesticide industry scientists' work, led by Novartis employee M. Candolfi<sup>61</sup>. If the toxicity of the pesticide tested exceeds this certain threshold, the LR50, it is considered that there is a potential risk to non-target arthropods. In this case, the industry can conduct a more detailed assessment (higher-tier testing), which they do in the vast majority of instances, to further refine the risk evaluation unless appropriate 'risk mitigation measures' can be identified. This takes the form of additional toxicity tests (higher-tier testing) with the two "most sensitive" species and one or two additional insect species that are less sensitive to pesticides. The Guidance Document on NTA provides that the industry can choose from several test options for higher-tier testing, detailed in ESCORT 2.

### ● Giving the industry the choice of which species to test

The guidance document lists several species for testing, based on the recommendations of ESCORT 2. In the first tier, producers are only required to test two insect species deemed "most sensitive": *Aphidius rhopalosiphi* (a parasitic wasp species) and *Typhlodromus pyri* (a predatory mite species). In higher-tier testing, the applicant must perform additional toxicity tests with the two first-tier species and add one or two more species from a predetermined list, deemed "less sensitive", which includes *Orius laevigatus* (a predatory bug), *Chrysoperla carnea* (a green lacewing), *Coccinella septempunctata* (a seven-spotted ladybird) and *Aleochara bilineata* (a rove beetle).

One major issue with the current list of test species is the overall lack of diversity. The list is very narrow, featuring only six species, with a maximum of four to be tested. Different species can respond very differently to pesticides—some may show minimal effects, while others could suffer severe harm. Hence,

<sup>61</sup> M.P. Candolfi, F. Bakker, V. Cañez, M. Miles, Ch. Neumann, E. Pilling, M. Primiani, K. Romijn, R. Schmuck, S. Storck-Weyhermüller, A. Ufer, A. Waltersdorfer, Sensitivity of non-target arthropods to plant protection products: Could *Typhlodromus pyri* and *Aphidius* spp. be used as indicator species?, *Chemosphere*, Volume 39, Issue 8, 1999, Pages 1357-1370, ISSN 0045-6535, [https://doi.org/10.1016/S0045-6535\(98\)00489-5](https://doi.org/10.1016/S0045-6535(98)00489-5).



testing only two to four species is problematic because it provides a very limited understanding of how the vast diversity of arthropods in nature may respond to pesticide exposure. This is all the more a problem since ESCORT 2 did not choose the most ecologically relevant species or those most likely to encounter the pesticide in the environment. Instead, it selected species that are predators or parasitoids of "pest" arthropods, used for biological pest control in IPM systems ("beneficial" species). Why? Because these species are cheap and easy to grow in the laboratory. No decomposer, pollinator, or herbivorous arthropod is included in the assessment. Hence, the selection of test species in the current testing approach fails to accurately account for the impact of pesticides on the diverse range of non-target arthropods. The assessment is incomplete and unreliable, and poses the risk of reducing functional diversity in insects.

Additionally, the guidance document allows pesticide companies to choose which additional species to present in higher tier. While they are mandated to provide tests for one or two additional species in higher-tier testing, the pesticide companies are allowed to perform the tests on all six species from the provided list. However, they are not required to submit all results; they can choose which data to include in the pesticide's dossier. Hence, the guidance document creates an opportunity for selective reporting, where companies can potentially exclude less favourable results and only present studies for the species that show minimal harmful effects while disregarding those that reveal more severe toxicity. This "cherry-picking" approach allows the pesticide companies to submit data that presents their products as safer than they may be. As a result, the risk assessment may not fully reflect the pesticide's true impact on non-target arthropods. This selective reporting can lead to an even more incomplete and biased understanding of the pesticide's effects, compromising the reliability of the risk assessment and potentially overlooking significant risks.

- **No assessment of chronic effects, behavioural effects, indirect effects, or cocktail effects**

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The guidance document only provides for the assessment of acute (short-term) effects of pesticide exposure on non-target arthropods. These tests are designed to measure specific endpoints, such as mortality, that occur within a short time frame. Hence, the current testing framework cannot establish the full extent of a pesticide's impact on non-target arthropods. For instance, chronic effects (i.e., the long-term or delayed adverse effects that occur as a result of prolonged or repeated exposure to a pesticide), are not taken into account. This is a critical limitation as continuous exposure could reveal harmful effects on non-target arthropods that cannot be established through testing for short-term effects, such as developmental abnormalities. Additionally, the current guidance document does not include testing for behavioural effects (i.e., changes in feeding patterns, mating behaviours, navigation, or predator-prey interactions). Behavioural changes may not cause immediate death or visible harm; yet they can significantly affect an insect's survival and reproductive success, hence the survival of a species. The guideline neither provides for the assessment of indirect effects. These effects occur when the presence of a pesticide affects an organism indirectly through changes in its environment or food sources, i.e., food web alterations due to ecotoxicological effects or habitat modifications. If a herbicide depletes the density of a certain plant species that is food for a butterfly, this is an indirect effect. Overlooking these indirect effects can lead to a false impression that a pesticide is safe, as the overall impact on the ecosystem is not accounted for. Lastly, the guidance document does not provide for the testing of combined effects resulting from the exposure of NTA to multiple pesticides (the cocktail effect), while non-target arthropods are often exposed to a mixture of different pesticides and chemicals simultaneously<sup>62</sup>.

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<sup>62</sup> See Chapter 1.4 of the report.



- Using the misleading concept of "recovery" to justify approving harmful pesticides

The guidance document embraces the concept of "recovery", which was introduced for use in environmental risk assessment in guidelines published in the late 1990s, following SETAC meetings (HARAP<sup>63</sup>, CLASSIC<sup>64</sup>, ESCORT<sup>65</sup>). Commonly in use, notably in aquatic<sup>66</sup> and arthropod risk assessments, this concept refers to the idea that if organisms are harmed or killed following a pesticide application, their population can bounce back within a certain period, thanks to the surviving individuals or those from nearby areas that will move back to the affected area, reproduce and re-establish the population close to its previous levels. It thus implies that it is acceptable for a pesticide to have harmful effects on non-target species, as they can potentially recover.

The recovery concept is very convenient, as it is used to justify setting a high benchmark for acceptable pesticide risk to NTA. According to the NTA Guidance Document, if a pesticide kills up to 50% of the tested arthropods in extended laboratory and semi-field tests (high-tier tests), it should be considered to present an acceptable level of risk<sup>67</sup>. A pesticide that wipes out as much as half of the beetles,

butterflies, or other key species is thus concluded to represent a low-risk<sup>68</sup> to non-target arthropods. The ESCORT 2 suggests that in-crop recovery for arthropods should take place at least within one year.

On top of this, no consideration is given to the potential ecosystem impact if half the population of non-target arthropods is missing for an entire year. The ESCORT 2 provides no scientific evidence to support the assumption that such a prolonged absence of these crucial species does not pose a serious threat to ecosystem stability and health. For recovery in the off-crop situation, it is merely stated that the duration of the effect of the pesticide on NTA and the range of taxa affected by the pesticide should be taken into consideration. However, it is specified that where a significant off-field effect is detected, it should not necessarily result in the denial of authorisation of the pesticide active substance but should instead be addressed in industry-promoted risk management options<sup>69</sup>. It is important to note that in many cases, recovery is not tested experimentally in the exposed fields but with short-term tests on artificial substrates. This is even more problematic because sublethal effects (behaviour, reproduction) are not tested.

The NTA Guidance Document lacks scientific justification for both the high benchmark and the reliance

<sup>63</sup> Campbell PJ, Arnold DJS, Brock TCM, Grandy NJ, Heger W, Heimbach F, Maund SJ, Strelake M. 1999. Guidance document on higher-tier aquatic risk assessment for pesticides (HARAP). Brussels (BE): SETAC-Europe.

<sup>64</sup> SETAC, 2002. Community-Level Aquatic System Studies - Interpretation Criteria (CLASSIC). Proceedings from workshop held at Fraunhofer Institute - Schmallenberg, Germany, 30 May-2 June, 1999. [https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/Community\\_Level\\_Aquatic\\_System\\_Studies\\_Interpretation\\_Criteria%20\(1\).pdf](https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/Community_Level_Aquatic_System_Studies_Interpretation_Criteria%20(1).pdf).

<sup>65</sup> Guidance document on aquatic ecotoxicology, Sanco/3268/2001 rev.4 (final) 17 October 2002. <https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/Guidance%20Document%20on%20Aquatic%20Ecotoxicology.pdf>.

<sup>66</sup> EFSA Panel on Plant Protection Products and their Residues (2013). Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2013.3290>

<sup>67</sup> European Commission (2002). Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. Section 5, Other arthropods, p.23. [https://food.ec.europa.eu/document/download/424e71a2-5beb-4fa3-9198-89be916c1789\\_en?filename=pesticides\\_ppp\\_app-proc\\_guide\\_ecotox\\_terrestrial.pdf](https://food.ec.europa.eu/document/download/424e71a2-5beb-4fa3-9198-89be916c1789_en?filename=pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf)

<sup>68</sup> ESCORT 2, <https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/ESCORT%20%20non-target%20arthropods.pdf>.

<sup>69</sup> The risk management options are detailed in another pesticides industry publication: Candolfi, M., Bigler, F., Campbell, P., et al. (2000). Principles for regulatory testing and interpretation of semi-field and field studies with non-target arthropods. *Journal of Pest Science*, 73(3), 141-147. <https://doi.org/10.1007/BF02956449>.



on the recovery concept, simply referring back to the ESCORT 2 document. The ESCORT 2 document claims the 50% benchmark is appropriate because the test designs are not sensitive enough to detect smaller differences in impact<sup>70</sup>. Interestingly, this limited justification is retrieved from an older document<sup>71</sup> written following a workshop that involved the same organisations as the ESCORT 2. Authored by Novartis's Candolfi and several other industry representatives, among others, this guidance further adds that the 50% benchmark is a level where arthropod recovery between seasons is usually not impeded, without offering any supporting evidence to back this claim. This raises serious doubts that the benchmark has been set arbitrarily.

Even more worryingly, the 50% benchmark is not a strict limit. The ESCORT 2 document allows for exceptions, stating that if an acceptable potential for recovery of the NTAs studied can be demonstrated, a pesticide may still be considered low-risk to the habitat, even if effects above the threshold value (50%) are measured<sup>72</sup>. The NTA Guidance Document embraces these recommendations without reserves. Hence, mortality percentages above 50% and as high as 100% can still result in a pesticide being considered to present an acceptable level of risk for NTA, meaning that it fulfils the criteria to be approved. For example, EFSA identified a high risk to certain non-target arthropods for the active substance sulfoxaflor, both in and outside of treated fields across all the representative uses assessed. However, it was considered that it posed an accept-

able risk to non-target arthropods as the potential for in-field population recovery was considered demonstrated, although field studies were missing for some of the uses assessed<sup>73</sup>. Its authorisation has since then been restricted to use in greenhouses only, due to the risk identified to bees and bumblebees<sup>74</sup>.

In the same vein, exposure of the two first-tier species to a glyphosate formulation led to 100% mortality. As the industry itself acknowledged, this is probably due to the toxicity of the co-formulants present in the herbicide. Even though 100% of these two beneficial insect species were wiped out, EFSA concluded that it was safe for insects, based on the second-tier tests carried out on much less sensitive species<sup>75</sup>.

In 2016, EFSA started reviewing the issue of 'recovery' in ecological risk assessment. It commissioned a scientific report summarising academic literature. This report<sup>76</sup> concludes that 'recovery' can only be expected in specific and rare cases. If the environment is already under stress, as in agricultural areas, external recovery (from outside the fields) cannot be expected to occur. On the contrary, ecological stress may increase due to the synergistic effects of different pesticides used, which should be taken into account.

However, this is currently not taken into consideration, and the EFSA keeps applying a recovery principle in pesticide risk assessment for NTA that

<sup>70</sup> ESCORT 2, p.20. <https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/ESCORT%20%20non-target%20arthropods.pdf>.

<sup>71</sup> Candolfi, M., Bigler, F., Campbell, P., et al. (2000). Principles for regulatory testing and interpretation of semi-field and field studies with non-target arthropods. *Journal of Pest Science*, 73(3), 141–147. <https://doi.org/10.1007/BF02956449>

<sup>72</sup> ESCORT 2, p.14-15. <https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/ESCORT%20%20non-target%20arthropods.pdf>

<sup>73</sup> See p.15, EFSA Panel on Plant Protection Products and their Residues (PPR). (2014). Conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor. *EFSA Journal*, 12(5), 3692. <https://doi.org/10.2903/j.efsa.2014.3692>

<sup>74</sup> European Commission. (2022). Commission Implementing Regulation (EU) 2022/686 of 28 April 2022 amending Implementing Regulations (EU) 2015/1295 and (EU) No 540/2011 as regards the conditions of approval of the active substance sulfoxaflor (Text with EEA relevance). *Official Journal of the European Union*. C/2022/2583. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R0686&qid=1726067190747>

<sup>75</sup> Glyphosate Renewal Assessment Report 29, p.477. <https://open.efsa.europa.eu/study-inventory/EFSA-Q-2020-00140>.

<sup>76</sup> M. Kattwinkel, J. Römbke, M. Liess; Ecological recovery of populations of vulnerable species driving the risk assessment of pesticides. Supporting Publications 2012:EN-338. [98 pp.]. <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2016.4313>.



it declared inapplicable in most cases since 2016. The potential for recovery is assessed in studies based on the application of a single pesticide substance, whereas in reality, arthropods are exposed to the application of multiple pesticides throughout the year<sup>77</sup>, as well as to residues of pesticides and other chemicals in the environment. The tests to measure the potential for recovery do not replicate the real ecological stress to which arthropods are effectively exposed in the environment. This is a critical gap in the risk assessment process that leads to underestimating the risks. Hence, any conclusion that an acceptable potential for re-colonisation of NTAs has been demonstrated is strictly unreliable.

In practice, even when a high risk for non-target arthropods is identified for a pesticide, this does

not prevent its approval in the EU. For instance, the marketing authorisation of the active substance esfenvalerate was renewed in the EU in 2015<sup>78</sup>, even though a high risk to NTA was identified during its risk assessment<sup>79</sup> and EFSA considered that the studies provided in the dossier were not sufficient to demonstrate in-field recovery for some species, concluding on a data gap. In its renewal decision for esfenvalerate<sup>80</sup>, the European Commission merely stated that the Member States shall pay particular attention to the risk to honeybees and non-target arthropods when risk-assessing esfenvalerate-based pesticide products for authorisation at the national level. Similarly, a high in-field risk was concluded for all representative field uses of the active substance captan<sup>81</sup>, yet its marketing authorisation in the EU was reapproved this year



<sup>77</sup> See Chapter 1.4 of this report.

<sup>78</sup> The active substance is approved in the EU until May 2026. See COMMISSION IMPLEMENTING REGULATION (EU) 2023/2592 of 21 November 2023 amending Implementing Regulation (EU) No 540/2011. [https://eur-lex.europa.eu/eli/reg\\_impl/2023/2592/oj](https://eur-lex.europa.eu/eli/reg_impl/2023/2592/oj).

<sup>79</sup> EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance esfenvalerate. EFSA Journal 2014;12(11):3873. <https://doi.org/10.2903/j.efsa.2014.3873>.

<sup>80</sup> COMMISSION IMPLEMENTING REGULATION (EU) 2015/2047 of 16 November 2015 renewing the approval of the active substance esfenvalerate, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. <https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32015R2047>

<sup>81</sup> EFSA (European Food Safety Authority). (2020). Conclusion on the peer review of the pesticide risk assessment of the active substance captan. EFSA Journal, 18(9), 6230, 28 pp. <https://doi.org/10.2903/j.efsa.2020.6230>.



until 2039, with some restrictions of uses<sup>82</sup>. Another example is the active substance lambda-cyhalothrin, currently authorised until 2026<sup>83</sup>, although EFSA, in its last peer review, identified either a high risk or a data gap for most of the representative uses assessed<sup>84</sup>.

To our knowledge, never has the identification of a 'high risk' to non-target arthropods prevented the authorisation of an active substance in the EU.

#### 4. Recognised shortcomings by Member States, the European Commission, and EFSA

There is clear evidence that both the Member States and the European Commission have been aware for several years of the significant flaws in the pesticide risk assessment scheme for non-target arthropods and are undermining the serious ecological consequences of continuing to use this outdated guidance document.

In 2019, 11 Member States and Norway<sup>85</sup> wrote to the Pesticides and Biocides Unit of the European Commission's DG SANTE, in a letter titled "Request to revise the Guidance Document for Non-target arthropods"<sup>86</sup>, which was also shared with EFSA. Therein, the Member States indicate that the ecotoxicology experts of several Member States responsible for the risk assessments of pesticide products had already expressed their concerns in

2018 that the current risk assessment scheme for non-target arthropods was not 'fit for purpose'. Hence, the Member States' letter "*intends to underline the urgency to up-date the current Guidance Document on terrestrial ecotoxicology*."

It is important to note that in their letter, the Member States draw a clear link between arthropod decline and the use of pesticides. They express concerns about the ecological impacts of continuing to use the current risk assessment, stating that it "*does not protect insects as it should*" under the EU legal framework on pesticides<sup>87</sup>. Indeed, the EU pesticide law mandates consideration of impacts on non-target species, their behaviour, biodiversity, and ecosystems, including potential indirect effects resulting from food web alterations. The

<sup>82</sup> European Commission. (2024). Commission Implementing Regulation (EU) 2024/2186 of 3 September 2024 renewing the approval of the active substance captan in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011. Official Journal of the European Union. <https://eur-lex.europa.eu/eli/reg/impl/2024/2186/oj>.

<sup>83</sup> European Commission. (2024). Commission Implementing Regulation (EU) 2024/324 of 19 January 2024 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benzovindiflupyr, bromuconazole, buprofezin, cyflufenamid, fluazinam, fluopyram, flutolanil, lambda-cyhalothrin, mecoprop-P, mepiquat, metsulfuron-methyl, phosphane, and pyraclostrobin. Official Journal of the European Union. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32024R0324>.

<sup>84</sup> EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance lambda-cyhalothrin. EFSA Journal 2014; 12(5):3677, 170 pp. <https://doi.org/10.2903/j.efsa.2014.3677>.

<sup>85</sup> Austria, Belgium, Czech Republic, Germany, Finland, Hungary, Lithuania, Netherlands, Poland, Sweden, Slovakia and Norway.

<sup>86</sup> 12 EU Member States. (2019). Letter to DG SANTE: Request to revise the Guidance Document for non-target arthropods [Letter]. European Commission. [https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/12%20MS%20urge%20COM%20to%20revise%20insect%20guideline%20\(2\).pdf](https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/12%20MS%20urge%20COM%20to%20revise%20insect%20guideline%20(2).pdf).

<sup>87</sup> Commission Regulation (EC) No 1107/2009, Commission regulation (EU) No 283/2013 and Commission regulation (EU) No 284/2013.





12 countries state that *“Considering the obvious deficiencies in the current scheme, it becomes increasingly difficult to justify performing the current risk assessment against better knowledge”*. The letter specifically mentions that the current risk assessment *“tolerates large reductions of arthropod populations in the agricultural fields and does not aim to prevent food web effects of PPPs [plant protection products] that threaten farmland birds.”* Hence, the Member States acknowledge that the guidance document is both outdated and misaligned with the latest scientific understanding and the legal requirements set by EU Law. The specific deficiencies of the guidance document highlighted in the letter include the lack of protection goals, the selection of the standard species (need to focus on the impact on beneficial insects in agricultural landscapes), the use of the vegetation distribution factor, design and use of field studies, consideration of recovery and indirect effects, landscape level effects and multiple stressors.

The Member States conclude by asking the Commission to initiate the process for EFSA to revise the Guidance Document for non-target arthropods as soon as possible and to supply EFSA with appropriate funds, no later than by the end of 2019.

In its short and incomplete reply to the letter<sup>88</sup>, DG SANTE indicates that several of the NTA Guidance Documents' shortcomings cited by the Member States will be covered by the DG's project to define specific protection goals (SPG) for the environmental risk assessment for pesticide products.

The SPGs are presented as a prerequisite to a swift update of the relevant guidance documents, including the NTA Guidance Document.

More than five years have passed since Member States called for an urgent revision of the Guidance Document for non-target arthropods, yet little progress has been made. In January 2023, a Commission staff working paper listed this revision as a 'top priority' and indicated that preparatory work is ongoing within EFSA and the Commission<sup>89</sup>. Finally, in June 2024, EFSA received an official mandate from the European Commission to revise the Guidance document on terrestrial ecotoxicology<sup>90</sup>. This will result in three separate guidance documents: one on non-target arthropods, one on non-terrestrial-target plants, and one for in-soil organisms. EFSA has also received another mandate to produce a guidance document to assess indirect effects on biodiversity<sup>91</sup>.

The process for the revision of the NTA Guidance Document has barely started; however, EFSA has been preparing the ground for the revision of the guidance document in the last three years. To understand the approach EFSA is taking with the revision of the NTA guidance, it is important to examine the work EFSA has undertaken to define its policy on environmental protection since 2010 (Chapter 3). Once this is established, it will be clear why EFSA's current approach to the revision of the NTA Guidance Document will not provide a high level of protection for non-target arthropods, as required by EU law (Chapter 4).

<sup>88</sup> DG SANTE. (2024). *Reply to letter from MS: request to revise the Guidance Document for Non-target arthropods* [Letter]. SANTE/E4/ZsK/gb(2019) 3299480. [https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/SANTE%20answer%20to%2012%20MS%20on%20insects%20-%20first%20SPG%20-%20non%20promises%20-%20terrestrial%20guideline%202019%20\(3\).pdf](https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/SANTE%20answer%20to%2012%20MS%20on%20insects%20-%20first%20SPG%20-%20non%20promises%20-%20terrestrial%20guideline%202019%20(3).pdf).

<sup>89</sup> DG SANTE. (2023). *Proposed priority list for development and updates of guidance documents (in the context of Regulations (EC) No 1107/2009 and Regulation (EC) No 396/2005)* [Commission staff working document], p.4. [https://food.ec.europa.eu/document/download/f383f32c-1e42-468c-a70a-85cc51337fe4\\_en?filename=pesticides\\_ppp\\_app-list-guidance\\_priority-list.pdf](https://food.ec.europa.eu/document/download/f383f32c-1e42-468c-a70a-85cc51337fe4_en?filename=pesticides_ppp_app-list-guidance_priority-list.pdf).

<sup>90</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2024-00464>

<sup>91</sup> <https://open.efsa.europa.eu/questions/EFSA-Q-2024-00463?search=indirect+effect>





# Chapter 3

## EFSA's approach undermines the legal protection of ecosystems and biodiversity against the harms of pesticides

EFSA was mandated by the European Commission to work on the protection of NTAs in June 2024. However, EFSA started defining its policy on environmental protection in general, earlier in 2010. This chapter summarises EFSA's work and gives a critical view of the EFSA approach to environmental protection.

### 1. EFSA's history of low priority in protecting the environment, and again SETAC

While EFSA was established in 2004 at its Parma offices, it dedicated little, if any, resources to the protection of the environment and the revision of the outdated and biased environmental guidelines until 2010. Curiously, EFSA's environmental strategy started in SETAC. A SETAC working group<sup>92</sup> formed in 2009 was chaired by Fred Heimbach, a former Bayer employee. The group included employees from BASF, Syngenta, and Bayer, as well as French regulator Anne Alix (who later moved to Dow Agroscience, now Corteva), university staff

working on industry-funded projects (e.g. Prof. Lorraine Maltby ; Theo Brock from Wageningen University's (WUR) section of Environmental Research, formerly known as Alterra), and two EU civil servants, Wolfgang Reinert (DG SANTE) and Karin Nienstedt (EFSA, who later moved to DG SANTE). There was no involvement of civil society and no transparency in the process. This working group likely functioned as a pressure group towards EFSA, supported by an EFSA self-mandate; ultimately, the ideas of this SETAC group were embraced by EFSA.

<sup>92</sup> <https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/articles/SETAC%202009%20on%20ERA%20Maltby%20Hardy%20Luttik%20Wheeler%20Heimbach%20.pdf>



## 2. No protection of ecosystems and biodiversity

In 2010, EFSA published a scientific opinion, on environmental risk assessment (ERA) and Specific Protection Goals (SPG)<sup>93</sup>. The same 'experts' who were part of the SETAC working group were at the basis of this EFSA opinion, providing the preparatory work. However, this time only university employees or civil servants from the SETAC-group were included in the EFSA working group (i.e. Theo Brock, Anne Alix, Karin Nienstedt, Lorraine Maltby, Tony Hardy, and Paulo Sousa), leaving the industry employees out. This EFSA document introduced a new strategy to protect only "ecosystem services for humans" (ESH) as "an overarching concept" for environmental risk assessment (ERA). No explanation is provided as to why the protection of the environment and biodiversity was limited to services for humans, nor for dropping the protection of the entire ecosystem, as specified in the EU Pesticide Regulation 1107/2009. This is a significant omission given the evidential illegality of this concept<sup>94</sup>. To make matters worse, another new element was included (compared to the 2009 SETAC group), stating that "trade offs between production and biodiversity need to be considered and not all biodiversity can be protected in every location all the time". This reduces the protection of the environment even further. DOW Chemical (now Corteva) already anticipated these new changes and published a document in support of this 'trade off' concept<sup>95</sup> concluding that the 'aesthetic value' of citrus fields overrules the damage done by the use of the brain-harming pesticide chlorpyrifos<sup>96</sup>. No-

where in the Regulation is there any mention of trade-offs. On the contrary, recital 24 of the Pesticide Regulation 1107/2009 states: "the objective of protecting human and animal health and the environment should take priority over the objective of improving plant production". There is little doubt that the specific SETAC group had a certain ideology that favours industry and intensive agricultural production over the protection of the environment. It is more than remarkable that EFSA embraces these ideas, which are in contradiction with EU law.

The 2010 EFSA publication<sup>97</sup> includes several more questionable 'ideas'. Protection of in-field non-tar-



<sup>93</sup> Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002)1, EFSA Journal 2010;8(10):1821.

<sup>94</sup> Art. 4.3.e of Regulation 1107/2009.

<sup>95</sup> Ecosystem Services in Pesticide Risk Management: A Wider Perspective for Decision-Making, Samantha Deacon, Gregory Reu, Gretchen Greene, Joe Nicolette and Steve Norman, ENVIRON UK Limited, Box House, Box, Wiltshire, SN13 8AA, United Kingdom, ENVIRON International Corporation, USA and Dow AgroSciences, 3 Milton Park, Abingdon, OX14 4RN, United Kingdom, Fresenius meeting,, Germany, 2011.

<sup>96</sup> Chlorpyrifos is known for reducing children's IQ when exposed in the womb, it was banned because of its developmental neurotoxicity in the EU in 2021

<sup>97</sup> Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002)1, EFSA Journal 2010;8(10):1821.



get species (those present within the field crop areas that are treated with pesticides) is reduced: *“There is no legal distinction made between in-crop effect and off-crop effects, but it is considered practical to make this distinction in the risk assessment because of differences in the socio-economic and ecological functions of in-crop and off-crop areas”*. The text goes on to *“consider the field margin and buffer strip of agricultural fields as areas to which the in-crop specific protection goals apply (keep it simple)”* and *“A distinction in the risk assessment should be made because of differences in the socio-economic and ecological functions of what are named in-crop and off-crop areas”*. Socio-economic functions (economic and business interests) are, however, not part of the Regulation and therefore the EFSA approach is not in line with the EU Pesticide Regulation.

### 3. The 2015 EFSA opinion

A consecutive 2015 EFSA opinion echoed most of the elements of the industry-written 2002 Guideline designed by ESCORT/SETAC (see Chapter 2). It looks only at the two predator species in the first-tier assessment and a few other predators if there is an exceedance in Tier 1 (the first level of risk assessment). The ecosystem services for humans policy is still supported in the opinion while the questionable concept of 'recovery' is also promoted. There are, though, some updates, on testing suggestions (including testing on reproduction, not only the basic -acute- 'LD50' tests with glass plates), and the main proposal illustrated is to perform landscape analysis. This means they will try to identify communities of NTAs in the landscape that will be assessed for 'acceptable effects'. ('one should ask where is the community protection

Another new idea is the application of “functional redundancy” to substitute a non-target organism that is harmed by another: *“Most species, however, are at least partly substitutable for the ecosystem functioning and their loss can be compensated for by other species”* (EFSA, 2010).

Numerous ways, therefore, are included to enable a claim that the use of pesticides is safe despite the harm observed. The EFSA opinion will be one of the building blocks of the future NTA and environmental risk assessment guideline and is a gift to the agro-industry.

At the same time, another 'unscientific' approach of EFSA is that they assume a non-target organism is exposed to only one pesticide at a time. This denial of the reality of multiple pesticide exposure is seen throughout the 2010 'scientific' opinion.

interest for this specific protection goal?'). EFSA applied landscape modelling in its attempt to design the bee guidance document, but it failed. It applied it to the (non-validated and industry-developed) model called Beehave<sup>98</sup>, made to examine the impact of different stressors on bee population levels. Worryingly, by statistically calculating what would be 'acceptable' damage (or the 'Normal Operation Range', the NOR), it was concluded that it would be acceptable to have around 25% mortality in a honey bee colony<sup>99</sup>.

For non-target organisms, the main proposal in the 2015 opinion is to ensure that negligible effects occur off-field, to enable recovery in-field. While it is acknowledged that 'multiple stressors' is a reality in agriculture and should be taken into account in the 'recovery' decision, EFSA states that

<sup>98</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/4125>

<sup>99</sup> In the end, the EFSA outcome was disregarded and a political decision was taken in the EU Council (10% mortality is 'normal').



methods are still lacking. EFSA also recognises the relevance of indirect effects on the different trophic levels of the ecosystem, but—again—claims that methods are lacking to assess this effect. It is also acknowledged that several species have an inherently low capacity for recovery (only one generation per year, spending their whole life cycle in the fields, low offspring production levels), but this is currently not taken into consideration in the recovery decision either. Furthermore, for mobile organisms, field tests cannot be used for recovery.

The 2015 opinion might be integrated into a future revised guideline on NTAs, but for now, all risk

assessments for NTAs remain based on the biased, unscientific 2002 guideline. As mentioned earlier, eleven member states (and Norway) acknowledge the urgency and already sent a letter to the European Commission on April 5, 2019, to speed up the revision of the 2002 guideline on non-target arthropods. Five years later, nothing has changed.

It is evident that the SETAC industry-dominated working group's concepts on Ecosystem Services strongly influenced the EFSA scientific opinion. Therefore, the resulting work from EFSA fails to address the requirements of the EU law.

### 4. DG SANTE embraces the unlawful concept of SETAC/EFSA

It is more than surprising that the Commission's health service, DG SANTE, uncritically started promoting the SETAC/EFSA concept of ecosystem services for humans and 'trade-offs'. DG SANTE, led by the Head of sector of the Pesticides and Biocides Unit Ms. Karin Nienstedt, tried to 'sell' the idea to the Member States in a series of workshops where 'industry consultant' Prof. Lorraine Maltby was presented as the main expert. The 'Nienstedt-Maltby' tandem has been active since 2009 at SETAC, EFSA and now DG SANTE. Prof. Maltby is known to have significant conflicts of interest. She worked for sev-

eral years with the industry on ERA (with the industry umbrella group CEFIC<sup>100</sup>), organised meetings for the sector on the topic (CARES<sup>101;102</sup>), was part of an industry taskforce<sup>103</sup> (ECOTOC), and has published articles with industry employees from Bayer, BASF, Syngenta, Exxon, DOW<sup>104</sup>.

The entire environmental risk assessment on non-target arthropods shows a clear pattern of 15 years of conflicts of interest at all levels in the EU: EFSA and DG SANTE.

<sup>100</sup> Christopher M. Holmes, Colin D. Brown, Mick Hamer, Russell Jones, Lorraine Maltby, Leo Posthuma, Eric Silberhorn, Jerold Scott Teeter, Michael St J Warne, and Lennart Weltje, Prospective Aquatic Risk Assessment for Chemical Mixtures in Agricultural Landscapes, *Environmental Toxicology and Chemistry*—Volume 37, Number 3—pp. 674–689, 2018

<sup>101</sup> Maltby Lorraine, van den Brink Paul J., Faber Jack H., Marshall Stuart, Advantages and challenges associated with implementing an ecosystem services approach to ecological risk assessment for chemicals, *Science of The Total Environment*, Volume 621, 15 April 2018, Pages 1342-1351

<sup>102</sup> CARES II Stakeholder Workshop Invitation: <https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/Invitation%20CARESII%20stakeholder%20workshop1.pdf>.

<sup>103</sup> A Ross Brown, Graham Whale, Mathew Jackson, Stuart Marshall, Mick Hamer, Andreas Solga, Patrick Kabouw, Malyka Galay-Burgos, Richard Woods, Stephanie Nadzialek, and Lorraine Maltby, Toward the Definition of Specific Protection Goals for the Environmental Risk Assessment of Chemicals: A Perspective on Environmental Regulation in Europe, *Integr. Environ Assess Manag* 2017:17–37 (SETAC).

<sup>104</sup> Alison R. Holt, Anne Alix, Anne Thompson, Lorraine Maltby, Food production, ecosystem services and biodiversity: We can't have it all everywhere, *Science of The Total Environment* Volume 573, 15 December 2016, Pages 1422-1429.



## 5. Member states are not convinced

In 2019, DG SANTE organised a workshop to discuss ongoing work on Specific Protection Goals (SPGs) with risk managers across Member States. It was explained that they should agreed upon SPGs for the protection of organisms and ecosystems. Specific Protection Goals are defined by EFSA as *“The specific goals of an environmental risk assessment in terms of what to protect, where to protect it, over what time period and with what degree of certainty”*<sup>105</sup>. SPGs are the level of protection that is granted to key features of sensitive ecological components, such as specific organisms (NTAs) or ecosystems, and are the basis of the legal term “unacceptable effects”. They aim at discerning what level of harm or adverse effects is acceptable versus unacceptable. However, the ‘acceptable’ standard is more of a political decision rather than a scientific one, as there is often insufficient data available on what constitutes “acceptable” harm levels for NTAs, let alone for ecosystems as a whole. The regulators will have to choose a ‘representative’ NTA-organism to assess this ‘acceptable effect’. And EFSA’s approach, embraced by the Commission’s DG SANTE, is the ‘ecosystem services for humans’ (ESH) policy- a controversial approach focusing on human-relevant services, not on the entire ecosystem.

During the SPGs 2019 workshop organised by DG SANTE, to which PAN Europe attended, Prof. Maltby participated as a key academic expert. Attend-

ees were not informed about her previous collaborations with the chemical industry and pesticide producers. PAN Europe filed a complaint to the Ombudsman about her involvement. In her conclusions, the Ombudsman clarified that the Commission should have been required *“to submit a ‘declaration of interests”* for the expert in question, and urged the Commission *“to require declarations of interest from experts invited in their personal capacity to future events, and to assess and publish such declarations”*<sup>106</sup>. In the meantime, the Commission requested a declaration of interest from Prof. Maltby, but she remained involved in the project nonetheless.

The Commission also invited JRC (EU Joint Research Centre<sup>107</sup>) to provide scientific validation for the ESH approach. However, following a series of questions from PAN Europe, the JRC confirmed that there is no scientific proof that protecting ecosystem services for humans will truly protect biodiversity.

Some Member States raised critical questions in written comments following the meeting. The Netherlands, for instance<sup>108</sup>, questioned the Ecosystem Services for Humans (ESH) approach concerning ecosystem protection: *“Starting point in ecology is that the greater the biodiversity, the more stable the ecosystem and thus automatically the better the services that can be delivered. By*

<sup>105</sup> <https://www.efsa.europa.eu/en/glossary/specific-protection-goals-era-pesticides#:~:text=Description%3A,with%20what%20degree%20of%20certainty.>

<sup>106</sup> Ombudsman Case 1402/2020/TE How the European Commission involved stakeholders and managed conflicts of interest in reviewing the ‘specific protection goals’ for assessing environmental risks of pesticides. <https://europa.eu/!j37YV>

<sup>107</sup> [https://commission.europa.eu/about-european-commission/departments-and-executive-agencies/joint-research-centre\\_en](https://commission.europa.eu/about-european-commission/departments-and-executive-agencies/joint-research-centre_en)

<sup>108</sup> Document not published; a copy can be obtained from PAN Europe on request.



considering vulnerable organisms, the protection of biodiversity is best guaranteed and by that also the ecosystems and the services they provide”.

Germany stated<sup>109</sup>, “The ESH approach has an anthropocentric view. This might not adequately address all protection goals which need to be considered in the risk assessment, e.g. the intrinsic value of biodiversity.”

Sweden<sup>110</sup> referred to the Commission staff document ‘EU guidance on integrating ecosystems and their services into decision-making’ and wrote:

“The document describes e.g. how biodiversity is a prerequisite for a strong resilient ecosystem that can provide ecosystem services both today as well as in the future and we would welcome more emphasis on this important question in the ongoing work of defining SPG for environmental risk assessment”.

Although Member States’ opinions varied between support and opposition to ESH, DG SANTE claimed they had received support and proceeded further defining and detailing the ESH policy.

## 6. Expert scientists have been highly critical of the current risk assessment

Topping et al. (2020<sup>111</sup>) criticise the assumptions underlying the current Guideline on NTAs, specifically, they state it: “relies on the assumption that managing risks through single-product, single-crop assessments provides sufficient ecosystem protection, and where harm is unavoidable, such as insecticide applications, that the ecosystem is sufficiently robust to recover”. They state that their monitoring data demonstrates that this assumption is wrong.

They also criticise the lack of consideration of multiple pesticide exposure: “Risk assessments are based on the use of a single pesticide in a specific crop. Yet, the number of mixtures and sequential treatments with pesticides in the landscape can be very high and is the norm across Europe. Any organism spending time in a single field is unlikely to face a single-product scenario, necessitating the consideration of the application sequence in the ERA”.

They criticise as well the recovery approach, noting: “the ERA requires recovery experiments to demonstrate recovery potential. For most species, recovery in the contaminated area is by emigration from source habitats. However, this assumes a balanced source-sink dynamic that does not reflect intensive modern agriculture. The experiment, conducted for single fields or plots within an untreated area, does not represent the real ratio of source and sink habitat, something constantly changing because of continued agricultural intensification. The consequence is an underestimation of the risk in the long term as source areas become depleted owing to dispersal of organisms into the sinks contaminated with pesticides”.

Similarly, regarding temporal dynamics: “current ERA also does not consider temporal dynamics. A declining population will be less resilient to future stressors, and thus, a spiral of decline may ensue”.

<sup>109</sup> Document not published; a copy can be obtained from PAN Europe on request.

<sup>110</sup> Document not published; a copy can be obtained from PAN Europe on request.

<sup>111</sup> C. J. Topping, A. Aldrich, P. Berny, Overhaul environmental risk assessment for pesticides, Science, 24 JANUARY 2020 • VOL 367 ISSUE 6476.



Additionally, other stressors are ignored: “ERA ensures that assumptions regarding population health will be incorrect because multiple (regulated and non-regulated) stressors are ignored entirely”.

A similar critique was expressed by the Chief Scientific Advisors in 2018<sup>112</sup>, who argued for modernising risk assessment and including the consideration of the effects of mixtures of substances and aggregate exposure<sup>113</sup>.

The study of Topping et al. (2020) is preceded by many other authors reaching similar conclusions. For example, Bruhl and Zaller (2019<sup>114</sup>) describe the current ERA as ‘inappropriate’, and Liess et al. (2016<sup>115</sup>) criticise the lack of consideration for multiple stressors and synergies. Just to name a few scientific researchers.

EFSA and DG SANTE clearly have chosen a pathway that has no support in the scientific community.



## 7. Towards a new guideline for non-target arthropods

While DG SANTE has been stalling for five years since the Member States asked the Commission to grant EFSA a mandate to start drafting the Guideline<sup>116</sup>, the Authority has not remained inactive. As it was pointed out, EFSA has been working since 2010 on environmental risk assessment (ERA). In 2020, it launched its strategy called PERA<sup>117</sup>, aimed at guiding the implementation of environmental risk assessment. However, PERA, given its lack of

concrete elements, is more a smokescreen than an actual guidance. Together with Wageningen University, EFSA started a Framework Partnership Agreement that will shed some light on the underlying intentions of EFSA. It seems EFSA is attempting to create a ‘fait accompli’ by producing reports behind closed doors. This work will be discussed in the next chapter.

<sup>112</sup> Scientific Advice Mechanism (SAM), INDEPENDENT SCIENTIFIC ADVICE FOR POLICY MAKING Group of Chief Scientific Advisors, Scientific Opinion 5, (Supported by SAPEA Evidence Review Report No. 3), Brussels, 4 June 2018, EU authorisation processes of Plant Protection Products from a scientific point of view.

<sup>113</sup> Expand, strengthen and provide stable support for an adequate expert network in the EU to address the changing nature of PPPs, scientific and technological developments in risk assessment methods, the effects mixtures of substances and aggregate exposure

<sup>114</sup> Brühl CA and Zaller JG (2019), Biodiversity Decline as a Consequence of an Inappropriate Environmental Risk Assessment of Pesticides. *Front. Environ. Sci.* 7:177.

<sup>115</sup> Matthias Liess, Kaarina Foit, Saskia Knillmann, Ralf B. Schäfer & Hans-Dieter Liess, Predicting the synergy of multiple stress effects, *Nature Scientific Reports*, 6:32965, 2016

<sup>116</sup> After years of delay, a mandate was finally sent to EFSA in June 2024.

<sup>117</sup> The European Partnership for next generation, systems-based Environmental Risk Assessment







# Chapter 4

## EFSA's cosmetic reforms will not protect non-target arthropods

### 1. EFSA's strategy on the environment (PERA), a smokescreen?

While a mandate from DG SANTE to EFSA to work on a Guideline for NTAs was still pending<sup>118</sup>, EFSA, in 2020, launched an overarching programme for environmental risk assessment (ERA) called PERA through its own mandate<sup>119</sup>. PERA stands for “*Building a European Partnership for next generation, systems-based Environmental Risk Assessment*”. Few people beyond the Authority's leadership understand the intended practical implications of the programme. We understand it has become a contested arena in which welcome progress is being made by some in and around EFSA, while others are using it to advance an agenda further at odds with the EU law on pesticides and NTA protection than exists today. This second group is about to conclude a four-year programme under PERA called AENEAS. The acronym AENEAS stands for “*Advancing ERA of non-target arthropods for PPPs*<sup>120</sup>”. The stated aim of this programme is to

generate various methods that will form the basis of the new NTA guideline, a programme we expand on below.

In PERA, EFSA acknowledges existing issues, noting that the “*current ERA might not be sufficiently protective for the wider biodiversity*”. It introduces a ‘roadmap’ for implementing ERA, featuring ambitious concepts such as “*a holistic vision for a future systems-based ERA*”, “*overcoming regulatory silos*”, and “*transition to a next generation ERA*”. The proposed Environmental Risk Assessment (ERA) process is presented as a concentric circular model with 4 circles or layers (see below): moving outward from the inner circle, these include (1) the current substance approach, (2) the landscape/ecosystem relation to ERA, (3) the interconnectivity to agricultural production, and (4) political, economic, and social parameters.

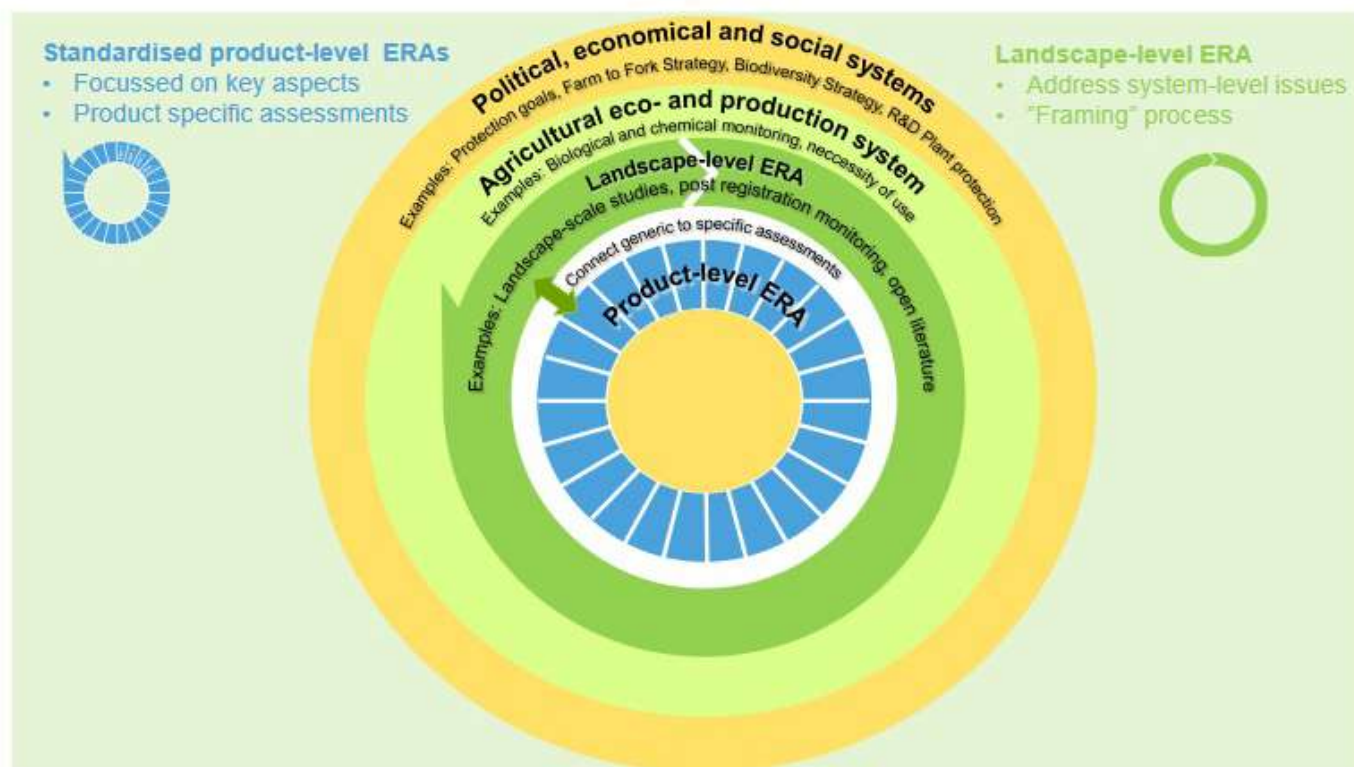
<sup>118</sup> A mandate was submitted in June 2024 (M-2024-00086) on terrestrial ecotoxicity with specific reference on NTA «A review of the risk assessment methodology and guidance document for NTA other than bees».

<sup>119</sup> Sousa JP, Aldrich A, Axelman J, Backhaus T, Brendel S, Dorronsoro B, Duquesne S, Focks A, Holz S, Knillmann S, Pieper S, Schmied-Tobies M, Silva E, Topping C, Wipfler L, Williams J, 2022. Building a European Partnership for next generation, systems-based Environmental Risk Assessment (PERA). EFSA supporting publication 2022: EN-7546.

<sup>120</sup> i.e., plant protection products, a term commonly used in EU law to refer to pesticide products.



Graphical abstract (vision for a system-based and holistically framed ERA)



For PAN Europe, it is unclear what are the objectives behind this work. Considering the track record of EFSA's work on environmental risk assessment, PAN Europe oftentimes questions the intentions behind this work. In this chapter, we will explore this by examining the research done for EFSA in the past few years together with Wageningen University, through the documents that EFSA reluctantly provided to PAN Europe, after a series of access-to-documents requests.

Given the fact that the PERA-strategy is quite theoretical, the best PAN Europe could get out of all the language on this 'next generation' risk assessment is that PERA includes: integrating landscape effects, extrapolation from laboratory to higher-tier studies, extrapolation across species, integrating NAMs ('New Approach Methods' based on non-animal testing), mechanistic effect modelling, model suitability, and background variability. These

are all very theoretical elements of a future environmental risk assessment. However, a concrete way forward for environmental risk assessment is still lacking. Many of these concepts fit with a general (hidden) policy of EFSA to reduce costs for the industry by trying to abandon expensive animal testing. This is evident from EFSA's work on (generally) non-scientifically validated assumptions on Modes of Action (MoA) (the mechanism through which a pesticide causes harm in organisms), non-validated models for extrapolation from "in vitro" to "in vivo" experiments, and assumptions regarding safe exposure levels of pesticides for organisms (see PAN Europe report on Adverse Outcome Pathways -AOP<sup>121</sup> for further information). But is it EFSA's mission to lower costs for industry? Not according to the 'mission<sup>122</sup> and tasks' of EFSA laid down in the General Food Law Regulation (EC) 178/2002. However, using freedom of information laws, PAN eventually obtained, on appeal, dozens

<sup>121</sup> [AOP the Trojan Horse for Industry Lobby Tools?](#)

<sup>122</sup> Mission of EFSA, e.g. Article 22 (7) «The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it.



of confidential documents relating to the AENEAS programme<sup>123</sup>. The most noteworthy are four documents called 'deliverables' that are the programme's main output, providing EFSA with a suite of updated risk assessment tools, and some entirely new ones, to benchmark pesticide impacts on NTAs. These were devised for EFSA by a contractor from the Wageningen University (section Environmental Research, the former Alterra Institute), and some subcontractors, such as Sheffield University (United Kingdom), University of Coimbra (Portugal) and University of Osnabrück (Germany). The individual researchers are not acknowledged by name, but PAN was able to identify most of them through their institutions and pattern of similar work. Most are close to the (pesticide) industry and have a history of cycling between business, academia and regulatory roles (see the end of this chapter). PAN expects them to gain official roles in the process of EFSA and SANTE adoption of the new NTA guidelines, a process with no deadline and which is expected to take years to conclude. EFSA will explain this process in a 'roadmap', to be published in January 2025. The costs of these projects are particularly high: PERA<sup>124</sup> is costing tax-payers 16.5 million, and AENEAS 1 million<sup>125</sup>. This significant investment was one of the early clues that made the purpose of the AENEAS programme clear from the start: to serve as a template for the new NTA guide-

lines. This was eventually confirmed in writing at a late-stage presentation on 8/9 October 2024<sup>126</sup>. Among the cache of documents handed over to PAN are numerous emails showing that EFSA took a close interest in the work as it was being developed, at places offering WUR line-by-line input. The AENEAS programme's terms of reference, signed by WUR, state that EFSA must achieve institutional approval of the deliverables before the work is considered complete. That is to say that EFSA understood and approved the programme in detail. We understand the deliverables will be published after the programme's formal conclusion, before the end of 2024.

The deliverables PAN Europe obtained in the documents it obtained (it is unknown what we did not obtain) are the following: deliverable 1.3 (drafted by Univ. of Sheffield and Univ. of Osnabruck) on ecosystem services, deliverable 1.4 (all four universities involved) on selecting representative NTA-species, deliverable 1.5 (Univ. Osnabrück) on finding a baseline level of NTAs, and deliverable 3.2 (Univ. Wageningen) on the routes of exposure of NTAs to pesticides. Officially AENEAS is commissioned to deliver scientific reports, that is to say, based on current scientific insights. What can we learn from AENEAS?



<sup>123</sup> <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/tender-details/8625>.

<sup>124</sup> <https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/3.%20Launch%20of%20the%20call%20for%20the%20Stakeholder%20Discussion%20Group%20on%20ERA%20-%20D.%20Auteri.pdf>, p.3.  
<https://www.efsa.europa.eu/sites/default/files/2024-10/introduction-mandates.pdf>, p.8.

<sup>125</sup> <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/tender-details/8625>.  
<https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/3.%20Launch%20of%20the%20call%20for%20the%20Stakeholder%20Discussion%20Group%20on%20ERA%20-%20D.%20Auteri.pdf>, p.4.

<sup>126</sup> <https://www.efsa.europa.eu/en/events/workshop-revision-terrestrial-ecotoxicology-guidance-document-pesticides-risk-assessment>.



## 2. Ecosystem services for humans policy

The old 2002 industry-designed Guideline on NTAs only granted protection for a few predators and parasitoids, both beneficial organisms for agriculture (see Chapter 2). From the 1 million known arthropod species on Earth and potentially 5 million other unknown<sup>127</sup>, this leaves more than 99.99% of species untested and therefore unprotected. The industry-dominated working group that influenced the drafting of the guideline<sup>128</sup> (that was entirely adopted by the Commission) introduced crop production as a major interest, overruling all other interests of the ecosystem. At that time, in 2002, the EU Directive 91/414 on pesticide authorisations was still in force and already provided that the protection of the environment should take priority over the objective of improving crop production. Therefore, the 2002 Guideline was unlawfully conceived and failed to ensure the protection of the arthropod species. Remarkably, despite the higher level of protection of the consecutive Pesticide Regulation (EC) 1107/2009, nowadays, EFSA still tries to maintain this focus by embracing the 'Ecosystem Services for humans' (ESH) policy<sup>129</sup>, designed by the industry (see Chapter 3 of this report), and putting agricultural interests (again) on a platform. Regulation 1107/2009 does not provide for such a priority. The Regulation is crystal clear: the impact on ecosystems and biodiversity needs to be taken into account (Art. 4.3). Furthermore, the protection of the environment has priority over

the improvement of crop production. This was recently confirmed in a ruling from the Court of Justice of the EU in 2023<sup>130</sup>, settling a case brought by PAN and others.

If we take a look at the AENEAS documents (deliverable 1.5<sup>131</sup>), the programme focuses only on beneficial organisms for agriculture when discussing the 'normal operation range' - NOR- (for a detailed explanation, see later in this chapter). Much data is lacking and only one article, an EFSA publication (Rieder et al., 2016<sup>132</sup>) provides information on the abundance of non-target arthropods (NTAs) in agricultural areas. However, the AENEAS documents indicate that "*not all of them are relevant 'service' providing NTAs*". This raises the question: how can NTAs be irrelevant in ecosystems that have evolved over millions of years? If they were truly irrelevant, evolution would have wiped them out. This Wageningen statement does not rely on any scientific insights. Furthermore, in their effort to derive abundance graphs, the study selected 20 NTA families and example species were chosen 'randomly' based on available data (based on Rieder's study only). There was no search for vulnerable species, nor were there any attempts to protect ecosystems and biodiversity by testing vulnerable species, while the approach is still adhering to the old paradigm of prioritising agriculture.

<sup>127</sup> Nigel E. Stork, How Many Species of Insects and Other Terrestrial Arthropods Are There on Earth?, *Annu. Rev. Entomol.* 2018. 63:31–45.

<sup>128</sup> Candolfi MP, Barrett KL, Campbell P, Forster R, Grandy N, Huet M-C, Lewis G, Oomen P A, Schmuck R, Vogt H. 2001. Guidance document on regulatory testing and risk assessment procedures for plant protection products with nontarget arthropods. Report of the SETAC/ESCORT 2 Workshop, Wageningen, The Netherlands, SETAC-Europe, Brussels, Belgium.

<sup>129</sup> Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002)1, *EFSA Journal* 2010;8(10):1821.

<sup>130</sup> Judgment C-162/21 of the Court, PAN Europe and others v Etat belge, 19 January 2023

<sup>131</sup> AENEAS deliverable 1.5, on the Normal Operation Range.

<sup>132</sup> Riedel J, Romeis J, Meissle M, 2015. Update and expansion of the database of bio-ecological information on non-target arthropod species established to support the environmental risk assessment of genetically modified crops in the EU. EFSA supporting publication 2016.



In another AENEAS deliverable<sup>133</sup> (e.g., Prof. Maltby, Prof. Focks), the same approach is taken. While they briefly mention other ‘ecosystem services’ provided by other NTAs, the focus quickly shifts again to predators and parasitoids. Shockingly, they even consider that agriculture itself is an ecosystem service<sup>134</sup>, one that overrides NTAs, at least within the agricultural fields. This approach is unscientific and unlawful.

The 2002 Guideline already allowed for 100% killing of NTAs (provided that they ‘recover’), and now, the new proposal for the ‘Ecosystem services for humans’ approach (ESH), leads to the same policy, given the text in the deliverable 1.3, — with even fewer constraints. Intensive agriculture is given priority, and the rest of the ‘services’ have to make way. Worse still, the AENEAS-conclusions of ‘dis-services’ are introduced. Herbivorous NTAs such as grasshoppers, mites, and thrips are all considered harmful and must be considered a disservice, according to this deliverable (1.5). This reflects a vision of the world designed with industrial agriculture as the backbone, and all other organisms marginalised or deemed undesirable.

These consultants are providing a roadmap to change the legal obligation for the protection of biodiversity in order to preserve current intensive agricultural production! It is just like saying: “Smok-

ing causes cancer, so to prevent cancer, it is okay to keep smoking”. It is astonishing to see such reasoning in a supposedly ‘scientific report’ commissioned by EFSA. Even more surprising is that EFSA, which closely follows and comments on these reports, accepts these unlawful and unscientific views<sup>135</sup> that are not grounded in current scientific knowledge. This is a serious issue. If these experts are promoting arguments that undermine the standards of the Regulation and are disconnected from current scientific insights, favouring agroindustry both now and in previous opinions<sup>136</sup>, it raises serious concerns about why they continue to be contracted by authorities and institutions meant to carry out independent and objective work based on scientific consensus. It is unacceptable that the Authority allows the work to take such an unscientific and unlawful direction, while it is supported with public money.

Remarkably, the European Commission’s health service, DG SANTE, is supporting EFSA’s work on ESH and has already drafted a Regulation to ‘waive’ obligatory studies from the ‘data requirements’<sup>137</sup>, resulting in the pesticide industry being able to skip expensive testing, based on the Ecosystem Services for humans policy<sup>138</sup>. Germany, for instance<sup>139</sup>, pointed out that this approach is unlawful: “the concept represents a shift from a purely ecocentric to an anthropocentric approach as well

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<sup>133</sup> AENEAS deliverable 1.3, on ecosystem services and effects.

<sup>134</sup> Agriculture should be a human activity that relies on ecosystems (soil fertility, pollination, soil nutrient cycling etc.). However, current intensive agriculture is based on external inputs (fertiliser, rockwool, heating, artificial light, etc.) and generally leads to the destruction of natural elements and ecosystems. It cannot be considered to be a service an ecosystem service.

<sup>135</sup> EFSA needs to approve every report, it is a requirement in the tender. See SPECIFIC AGREEMENT No 3, UNDER FRAMEWORK PARTNERSHIP AGREEMENT No GP/EFSA/PREV/2020/02. See EFSA framework on partnership agreements 2023-2027: <https://www.efsa.europa.eu/sites/default/files/2023-06/financial-aspects-of-the-framework-partnership-agreement-2023-2037-l.brovall.pdf>

<sup>136</sup> EFSA Panel on Plant Protection Products and their Residues (PPR); Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002). EFSA Journal 2010; 8(10):1821. [55 pp.] doi: [10.2903/j.efsa.2010.1821](https://doi.org/10.2903/j.efsa.2010.1821).

Holt, A. R., Alix, A., Thompson, A., & Maltby, L. (2016). Food production, ecosystem services and biodiversity: We can’t have it all everywhere. *The Science of the total environment*, 573, 1422–1429. <https://doi.org/10.1016/j.scitotenv.2016.07.139>

<sup>137</sup> Indeed, DG Sante is actively trying to reduce the level of environmental protection against a series of ‘low risk’ pesticides

<sup>138</sup> Document not published; a copy can be obtained at PAN Europe on request.

<sup>139</sup> SCoPAFF January 2024, Pt A 06.01 – Problem Formulation, Comments from Germany.



as from an emphasis on structural to functional endpoints. Given the fact that (i) not all populations of non-target organisms can be assigned to a specific service and (ii), as a general rule, structural endpoints tend to be more susceptible than functional endpoints, the concept is accompanied by a significant lowering of the ecological protection standard, which is no longer compatible with the protection standard stipulated by the regulation and is therefore unlawful". Lowering of standards is what we get if ESH is implemented by DG SANTE in regulations.

This approach supported by EFSA's policy of Ecosystem services involves lowering standards, which is not only problematic but also illegal. The 'ecosystem services for humans' approach is not part of Regulation 1107/2009 and the entire ecosystem needs to be protected. Furthermore, the EU Biodiversity Strategy<sup>140</sup> does not refer to human services of the ecosystem either, instead, it aims at "protecting nature and reverse the degradation of ecosystems".

### 3. Not the most sensitive (service-providing) NTAs will be protected, but only the NTAs left in degraded agri-industrial landscapes

In traditional risk assessment, the standard procedure is to assess the effects on the most vulnerable species within a family to guarantee that less sensitive species are also protected. This is not the case with NTAs and pesticides<sup>141</sup>. Out of millions of arthropod species, only two species—beneficial to agriculture (predator, parasitoid)—are assessed<sup>142</sup>. Will EFSA's proposed 'holistic, system-based, next generation ERA' repair this mistake in the current guideline? Unfortunately, it appears not to be the case. In AENEAS deliverable 1.4, 'habitat scenarios' [authored by Louise Wipfler (Wageningen University), Lorraine Maltby (University Sheffield), Andreas Focks (University of Osnabrück) and Paulo Sousa (University of Coimbra)], the selection of NTAs is based solely on their presence in the agricultur-

al landscapes (crops), which is already limited to predators and parasitoids (see Chapter 3.1 of 1.4 'vulnerability analysis'). If an NTA is not found on the crop, it is deemed not relevant (page 23 of deliverable 1.4). This means that the authors consider the fully degraded agricultural landscape, with its "collapsed" biodiversity, as the basis for protection. After decades of pesticide use, sensitive NTAs are likely to be decimated. Protecting ecosystems and restoring biodiversity, as outlined in the EU Biodiversity Strategy, is left off the agenda for WUR/EFSA. Only a few resistant or mobile NTAs might remain, and the vulnerable species will be missed. Having EU strategies that contradict and undermine each other will be completely ineffective.

<sup>140</sup> Brussels, 3.5.2011, COM(2011) 244 final, COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS.

<sup>141</sup> DEFRA, 2007. Methods of addressing variability and uncertainty for improved pesticide risk assessments for non-target arthropods. Report for United Kingdom Department of Environment Food and Rural Affairs project PS2307. Their conclusion is that it is 'potentially misleading to refer to *T. pyri* and *Aphidius spp.*' as 'sensitive indicator species'.

<sup>142</sup> The 2002-guideline uses a default (CF=correction factor) to account for species sensitivity, but only off-field; the CF is nullified by another factor, VDF, Vegetation Distribution Factor.



PAN Europe considers it both unscientific and unlawful to base protection measures on the remnants of biodiversity in industrial agricultural landscapes, which can hardly be qualified as ecosystems or considered 'biodiverse'. As discussed in Chapter 1, the current type of agricultural practices is precisely what is driving biodiversity collapse. Instead, such assessments should be conducted in untreated organic fields, not in degraded agri-industrial fields. This EFSA/WUR approach violates the Rio Declaration<sup>143</sup>, the EU Biodiversity Strategy<sup>144</sup>, the Convention on Biological Diversity<sup>145</sup> and the Habitat Directive<sup>146</sup>.

EFSA's comments on the AENEAS deliverables are generally positive and —as expected— support the central elements of the programme, including the ecosystem services, recovery, focusing on beneficial arthropods, and —apparently— even the extremist conclusions on giving agricultural production the highest level of interest. However, on certain points EFSA criticises WUR's work for being limited to only a few general or model species<sup>147</sup> with WUR attributing this to a lack of data and time. AENEAS, on the topic of species distribution in habitats, relied on

just one (non-peer-reviewed) publication on NTAs<sup>148</sup> for its work on the NOR (Normal Operation Range, this is a theoretical assumption on the 'normal' level of a species mortality), while the planned literature search was not conducted. The report, by Judith Riedel, Jörg Romeis and Michael Meissle—an EFSA publication<sup>149</sup>—, provides a description of NTAs to support Environmental Risk Assessment (ERA) for GMOs (Genetically Modified Organisms). The Riedel report lists NTAs that have been observed in agricultural fields that are generally heavily sprayed with pesticides. This EFSA-commissioned work is inspired by an ILSI (an industry lobby group<sup>150</sup>) initiative on GMOs<sup>151</sup> that tried to promote their approach to 'protection goals' for environmental species: *"it is necessary to initially select appropriate species that can be tested under worst-case conditions in the laboratory; these species serve as surrogates for the broader diversity of ecologically and economically desirable organisms"*. No field tests are conducted. This is an industry proposal for cheap testing of (economically) 'desirable' organisms. What should have been done is to identify NTAs in organic fields and assess which ones are the most sensitive to pesticide exposure.

<sup>143</sup> "States shall cooperate in a spirit of global partnership to conserve, protect and restore the health and integrity of the Earth's ecosystem".

<sup>144</sup> Aiming at "protecting nature and reverse the degradation of ecosystems".

<sup>145</sup> Protection goal: "Protecting and restoring structural as well as functional biodiversity (Malawi-principles)".

<sup>146</sup> Habitat Directive "Those species (and their local populations, respectively) need special protection that are vulnerable due to their given unfavourable state of conservation".

<sup>147</sup> EFSA comments: *"In the tender specifications it was indicated that the contractor should collect and collate data to build the typical species composition of different habitats (e.g. orchards, cereal fields, bare soil), in relation to farm management (conventional vs. organic) and landscape complexity. Also, in the technical offer, it was stated that data on NTA assemblages will be collected to develop habitat scenarios that combine crop and management type. However, the interim report states that due to the scarcity of information regarding NTAs composition under different management regimes and the lack of representation of organic management within the ALMaSS windows, it would not be meaningful or comprehensive to present incomplete results regarding management"*.

<sup>148</sup> Riedel J, Romeis J, Meissle M, 2015. Update and expansion of the database of bio-ecological information on non-target arthropod species established to support the environmental risk assessment of genetically modified crops in the EU. EFSA supporting publication 2016.

<sup>149</sup> Riedel J, Romeis J, Meissle M, 2015. Update and expansion of the database of bio-ecological information on non-target arthropod species established to support the environmental risk assessment of genetically modified crops in the EU. EFSA supporting publication 2016.

<sup>150</sup> <https://ilsi.org/>.

<sup>151</sup> See publication with numerous industry employees and agroscope employee Romeis: <https://ainfo.cnptia.embrapa.br/digital/bitstream/doc/697271/1/Formulacao-de-Problema-em-Analise-de-Ris-1.pdf>.



#### 4. Indirect effects on the ecosystem are not taken seriously

For a long time, Member States have requested for the indirect effects of pesticides on biodiversity to be taken into account in the risk assessment. These effects can include negative impacts on the ecosystem food chain, such as birds consuming contaminated NTAs (or lacking NTAs for their chicks) and birds of prey feeding on contaminated

birds or amphibians. Germany<sup>152</sup> and Sweden<sup>153</sup>, in 2021 and 2022, even proposed interim solutions to EFSA to address these negative impacts of pesticides, but EFSA dismissed them due to a supposed lack of 'consensus'<sup>154</sup>, despite no real effort being made to reach one.

#### 5. Trade-off between protection of the environment and agricultural interest is not in line with the pesticides regulation

The desire for a 'trade-off' between the protection of the environment and the interests of intensive agriculture has been highlighted on several occasions in EFSA's work on SPGs (Specific Protection Goals) setting the levels of 'acceptable' harm to organisms, and by Prof. Maltby (see Chapter 3 of this report). This concept is echoed in a previous EFSA report<sup>155</sup> drafted by Wageningen University employee Pauline Adriaanse, who states that, *"A trade-off needs to be made between the importance of ecosystem services and the magnitude of effects, thus weighing the value of crop protection as a provisioning service against that of protecting biodiversity and other ecosystem services"*. It is further noted in the Adriaanse-report that, *"In recognition of this, different SPGs are defined for in-field and off-field habitats", and "in-field effects on individuals, populations, and biodiversity may be accepted while still aiming to protect the ecosystem service"* (page 57). This clearly lays the foundation for EFSA/WUR to sacrifice the protection of ecosystems, at least within the fields. It is crucial to note that Regulation 1107/2009 does not allow for such trade-offs in favour of the interests of agri-industrial production. It provides for "no unacceptable

effects" to environmental organisms (Art. 4.3), ensuring a certain state of health for organisms, irrespective of whether they are in the field or off-field. There seems to be a clear intention from EFSA, and WUR, to silently change the law. This is not within their remit. They should limit their research to the most recent scientific evidence, yet the necessary scientific rigour is glaringly absent in these reports. This is a serious issue that undermines regulatory integrity and environmental protection.



<sup>152</sup> UBA, IMPACT OF PESTICIDES ON IN-FIELD NON-TARGET PLANTS AND ARTHROPODS WITH CONSEQUENCES FOR 'FOOD-WEB-SUPPORT' – EXPANDED RISK ASSESSMENT METHOD FOR NATIONAL PRODUCT AUTHORISATION IN GERMANY, 2022.

<sup>153</sup> KEMI, Methods for assessing the effects of plant protection products on biodiversity, 2021.

<sup>154</sup> EFSA letter to the Ombudsman, April 2024 after complaint PAN Europe.

<sup>155</sup> Adriaanse, PI, Buddendorf, WB, Holterman, HJ, ter Horst, MMS, 2022. Supporting the development of exposure assessment scenarios for Non-Target Terrestrial Organisms to plant protection products. Development of Exposure Assessment Goals. EFSA supporting publication 2022:EN-7661.





## 6. Multiple stressors are not taken into account

In the previous work of Adriaanse<sup>156</sup> for EFSA on exposure to NTAs, only a few routes of exposure (direct and via food) are considered, while other potential exposures of NTAs, such as those from additional pesticides in the same crop and other chemical stressors (like soil contamination with pesticides<sup>157</sup>, as well as other chemicals like PFAS and chlorinated compounds, or aerial deposition of pesticides<sup>158</sup>) are ignored. This oversight is evident throughout all of the Wageningen documents (AENEAS deliverables<sup>159</sup>). The long-standing and blatantly unscientific bias of assessing the effects of a single pesticide as if it were applied in an entirely uncontaminated and completely “healthy” environment continues. It is hard to believe that such a significant scientific oversight has not been corrected in EFSA's ‘next generation ERA’s’. Unfortunately, the error remains unaddressed, even though the EU Pesticide Regulation requires assessing cumulative and synergistic effects (Art. 4.2.a). Several studies<sup>160;161</sup> demonstrate that the combined effects of pesticides and other stress-

ors can far exceed the impact of a single pesticide. Synergism, (i.e., the combined effects of chemicals that increase each other's toxicity) which could go far beyond additive effects, is also a potential effect that continues to be disregarded. For example, research by Professor Vijver<sup>162</sup> from the University of Leiden demonstrated that the pesticide thiacloprid was 2,456 times more toxic under natural conditions (with multiple stressors) than when measured in isolation. Liess et al.<sup>163</sup> (on aquatic organisms) showed that the presence of environmental stressors increases individual sensitivity to toxicants (such as pesticides, trace metals) by a factor of up to 100.

The European Academies Science Advisory Council (EASAC) also considers that the unrealistic one-substance assumption fails to account for the potential for combined (additive or interactive) toxic effects in mixtures<sup>164</sup>. In 2018, the EU Chief Scientific Advisors (SAM<sup>165</sup>) already requested that cumulative and synergistic effects be taken into

<sup>156</sup> Adriaanse, PI, Buddendorf, WB, Holterman, HJ, ter Horst, MMS, 2022. Supporting the development of exposure assessment scenarios for Non-Target Terrestrial Organisms to plant protection products. Development of Exposure Assessment Goals. EFSA supporting publication 2022:EN-7661

<sup>157</sup> Bruhl et al. , 2022 noted that in their research they analysed 20-30 pesticides being present all year round at low concentrations in soil.

<sup>158</sup> Mayer, L., Degrendele, C., Šenk, P., Kohoutek, J., Přibylková, P., Kukučka, P., Melymuk, L., Durand, A., Ravier, S., Alastuey, A., Baker, A. R., Baltensperger, U., Baumann-Stanzer, K., Biermann, T., Bohlin-Nizzetto, P., Ceburnis, D., Conil, S., Couret, C., Degórska, A., Diapouli, E., ... Lammel, G. (2024). Widespread Pesticide Distribution in the European Atmosphere Questions their Degradability in Air. *Environmental science & technology*, 58(7), 3342–3352. Advance online publication. <https://doi.org/10.1021/acs.est.3c08488>.

<sup>159</sup> For instance deliverables 1.3, 1.4, 1.5 and 2.3.

<sup>160</sup> Matthias Liess, Kaarina Foit, Saskia Knillmann, Ralf B. Schäfer & Hans-Dieter Liess, Predicting the synergy of multiple stress effects, *Nature Scientific Reports*, 6:32965, 2016.

<sup>161</sup> Rohr JR, Raffel TR, Halstead NT, McMahon TA, Johnson SA, Boughton RK, Martin LB. 2013 Early-life exposure to a herbicide has enduring effects on pathogen induced mortality. *Proc R Soc B* 280: 2013.

<sup>162</sup> S. Henrik Barmantlo, Elinor M. Parmentier, Geert R. de Snoo, and Martina G. Vijver, Thiacloprid-Induced Toxicity Influenced by Nutrients: Evidence from In Situ Bioassays in Experimental Ditches, *Environmental Toxicology and Chemistry—Volume 37, Number 7—pp. 1907–1915*, 2018.

<sup>163</sup> Matthias Liess, Kaarina Foit, Saskia Knillmann, Ralf B. Schäfer & Hans-Dieter Liess, Predicting the synergy of multiple stress effects, *Nature Scientific Reports*, 6:32965, 2016.

<sup>164</sup> EASAC, Neonicotinoids and their substitutes in sustainable pest control, EASAC policy report 45, 2023.

<sup>165</sup> European Commission, Group of Chief Scientific Advisors, Scientific Opinion 5/2018, EU authorisation processes of Plant Protection Products.



account: “different substances can have similar negative effects on health or the environment, resulting in a cumulative increase of negative effects. In addition, some substances have the potential to interact with other substances, which can synergistically change their toxicity. Exposure to the same substance can occur via multiple routes, referred to as ‘aggregate exposure’, as some substances used

in PPPs are also used in other products, resulting in a higher than expected exposure”. Six years later, nothing has changed.

Yet overlooking the broader scientific consensus, both EFSA and WUR continue to proceed with the unrealistic and unscientific ‘one-chemical’ approach.

### 7. Level of protection: services focused primarily on crop production and pest control

While EFSA advocates for the ‘Ecosystem Services for humans’ approach (ESH), which is unconditionally adopted and implemented by AENEAS as demonstrated in previous chapters, it creates significant confusion about what should be protected. There is even a specific training for policy officers on ESH conducted by many of the same consultants hired for AENEAS<sup>166</sup>, such as Louise Wipfler, Theo Brock, Lorraine Maltby, Andreas Focks, etc. Therefore, the level of ecosystem protection remains an open question. Officially, the decision on the protection level falls to risk managers, specifically, the members of the Standing Committee on Plant, Animals, Food and Feed<sup>167</sup>, meaning the representatives of the EU Ministries of Agriculture. However, Wageningen University in a related report written by Theo Brock, Louise Wipfler, Ivo Roessink (who are all experts at WUR/Alterra) has established their own standards of protection<sup>168</sup>

with Theo Brock being a long-time expert on EFSA’s panels and working groups<sup>169</sup>.

The report, which is mentioned in the AENEAS programme<sup>170</sup>, outlines four levels of protection, ranging from low to high. Level 4 (the highest) is relatively minimalistic and not in line with EU law. The Brock-report is based on EFSA’s 2015 opinion on SPGs<sup>171</sup> and considers not only the ecosystem service ‘crop production’ and the regulatory ecosystem services like ‘pest control’ and ‘pollination’ as being important, but also ‘supporting’ ecosystem services (though at a lower level of interest) such as ‘food-web support for insectivorous birds and mammals’ and cultural ecosystem services like ‘protection of biodiversity for educational, aesthetic and conservation purpose’. This highest level allows for in-field “temporal effect of average size” (though ‘average’ is undefined), provided there

<sup>166</sup> Louise Wipfler, Theo Brock, Andreas Focks, Lorraine Maltby, Gianni Gilioli, Anna Simonetto, Boet Glandorf, Laura Padovani, 2022. Training on Environmental Risk Assessment as a component of EFSA’s risk assessments. EFSA supporting publication 2022:EN-7221.

<sup>167</sup> [https://food.ec.europa.eu/horizontal-topics/committees/paff-committees\\_en](https://food.ec.europa.eu/horizontal-topics/committees/paff-committees_en).

<sup>168</sup> Theo Brock, Paulien Adriaanse, Ivo Roessink, (reviewed by Louise Wipfler), Non-target terrestrial arthropods in prospective environmental risk assessment for plant protection products, Specific protection goal options, WUR report, 2021.

<sup>169</sup> EFSA Declaration of Interest, <https://open.efsa.europa.eu/scientific-panel/12>, ao. Vice-Chair-PPR Panel 2012-2015 (PPR), Member-WG Aquatic Ecotoxicology (PPR), Chair-EFSA WG on Revision of the EFSA (2009) Guidance Document Risk assessment for Birds and Mammals (PREV)

<sup>170</sup> Correspondence between WUR and EFSA on a deliverable we did not obtain (2.4) indicates that the ‘Brock’ SPGs are included in AENEAS.

<sup>171</sup> <https://www.efsa.europa.eu/en/efsajournal/pub/4499>.



are “*no significant direct toxic effects*” at the field's edge, thus considering only acute effects and ignoring potential chronic effects. The population is assessed on a landscape level, aiming for negligible effects on the spatial occupancy and overall abundance of vulnerable non-target arthropods. While some aspects, like bird poisoning and the protection of butterflies for their aesthetic value, may

be considered in the future, there is no serious consideration of what an NTA-ecosystem needs, also not in level 4, nor on how to align with the EU Biodiversity strategy's goal of ‘*protect[ing] nature and revers[ing] the degradation of ecosystems, nor with the obligation from the pesticides regulation to protect ecosystems globally*’.

### 8. Normal Operation Range

Normal Operation Range, a theoretical level of mortality for a species under ‘normal’ conditions, is an invention of EFSA, which was applied (unsuccessfully) by EFSA in the drafting of the bee guidance document. However, it appears that EFSA is trying to integrate this concept again, given the AENEAS deliverable 1.5. If an assessment is conducted on exposed NTAs, a control level (a threshold) must be established. Any effect above the control level should be considered harmful to NTAs. EFSA is not doing this by working with a normal control test where NTAs are not exposed in the field, but through the approach entitled, ‘Normal Operation Range’ (NOR). For the revision of the bee guidance document, EFSA attempted to establish a NOR based on an industry-funded landscape model (Beehave) that aims to represent a ‘real’ agricultural landscape; however, this turned out to be an embarrassing mistake. The outcome—up to 25% of bees dying according to the NOR—might result in the collapse of beehives with such a permanent loss. Despite the fact that the EFSA approach was rejected a few years ago, EFSA and WUR are trying again to put in place a NOR with another model. Several existing landscape models are discussed with their pros and cons, but no choice is made in the AENEAS reports<sup>172</sup>. Considering the lack of field data for NTAs, it is unlikely that the model for NOR of pesticides, with regards to NTA, will be im-

plemented anytime soon; however, the intention in AENEAS is clear. The fact that they continue to push for this non-validated methodology in deliverable 1.5 raises serious concerns about the integrity of the work of WUR/EFSA.

Current regulatory testing of pesticides compares the impact of exposing organisms to non-treated versus treated crops. By defining NORs based on models, one attempts to become independent of field trials and carry out risk assessment in silico (use of computer models). While PAN Europe agrees that there is an interest in using models to better understand population dynamics and include other stressors in the risk assessment, we question if such models are appropriate for setting thresholds in the risk assessment. A long way remains to validate these models and use them to support risk managers' decisions.

The question remains: why rely on a Normal Operation Range, a theoretical level of ‘normal’ mortality? Any scientist would agree on including a control group without pesticide exposure in a field test to clearly determine whether there is an effect in your pesticide-treated field compared to the control. However, EFSA prefers to develop its own ‘regulatory’ procedures while disregarding established scientific methods. The NOR is essentially a copy-paste concept borrowed from another

<sup>172</sup> AENEAS, deliverable 1.5, Defining normal operating range.



EFSA approach related to Historical Control data (HCD<sup>173</sup>), which has been strongly promoted by the pesticide industry<sup>174</sup>. Adopting questionable tools is a pattern at EFSA. The industry did not like to see negative effects in animal exposure studies that exceeded those of the control group, so they sought ways to reconsider exceedances or change the outcome. One approach was to combine control data from all unexposed test animals in a given laboratory over time in different tests and to create a wider range of 'normal' control values. These wider control ranges are then used as a reference instead of using the results from a single, specific control group in a particular experiment (concurrent control). This automatically increases the control range, making it possible to disregard previously observed adverse effects since the broader control range makes those effects appear less significant. For NTAs and other organisms, WUR/EFSA advocate the NOR, which estimates the abundance of a species in a landscape based on landscape modelling. Interestingly, the variation in abundance is significant (for instance a factor of more or less six for the species *Erigone atra*<sup>175</sup>). This approach enables EFSA to abandon real controls based on

real-world measurements and design an artificial control, NOR, and do this with a lot of questionable statistics. This is likely to again result in ridiculously high levels, as was the case for bees. Like HCD, NOR is not utilised by scientists. It is an artificial method of disregarding the hazardous effects of pesticides on NTAs, ultimately clearing the path for pesticide approval.



## 9. Recovery: ecological nonsense but regulatory reality

In the current 2002 NTA guideline, 'recovery' (recolonisation) of NTAs (arthropods) is considered to be achieved in one year's time. However, it is generally not tested experimentally in the exposed fields but rather on artificial substrates using short-term tests<sup>176</sup>. For several pesticides, like esfenvalerate (EFSA peer review 2014<sup>177</sup>), it was found that

recolonisation was not proven by the applicant (which was subsequently considered only an 'in field' data gap). Yet, after 23 years, this pesticide remains on the market without being reassessed by the relevant Standing Committee of Member States (ScoPAFF<sup>176</sup>). Similarly, the EU approval of acetamiprid (EFSA peer review 2016<sup>177</sup>) was re-

<sup>173</sup> <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2022.EN-7558>.

<sup>174</sup> See for instance: Nolte et al., RITA—Registry of Industrial Toxicology Animal data: The application of historical control data for Leydig cell tumors in rats, *Experimental and Toxicologic Pathology* 63 (2011) 645–656. Or: Greim et al., Evaluation of historical control data in carcinogenicity studies, *Human & Experimental Toxicology* (2003) 22: 541–549.

<sup>175</sup> AENEAS, deliverable 1.5, Defining normal operating range.

<sup>176</sup> 2002-Guideline: "Generally, it has to be demonstrated that there is a potential for recolonisation/recovery at least within one year but preferably in a shorter period depending on the biology (seasonal pattern) of the species. The assessment may be based on field studies or other evidence (e.g. results of aged-residue studies, environmental fate information). In any case the data and assumptions should be fully justified".

<sup>177</sup> EFSA Journal 2014;12(11):3873.



newed in 2018, although it showed 100% mortality for NTAs, and the recovery in the field within a year was not sufficiently demonstrated. This was merely noted as a 'data gap' again (while Member States must pay "particular attention" to the risks for NTA). The same occurred with lambda-cyhalothrin (EFSA peer review 2014<sup>178</sup>), where in-field recovery was not demonstrated, yet it remains on the market 10 years later. In a national authorisation of acetamiprid in 2020<sup>179</sup>, there was no indication that this data gap had been addressed or that particular attention was paid to NTAs. In another national authorisation in the Netherlands for esfenvalerate, the authority only warned the farmers in the authorisation decision "to avoid unnecessary exposure" of NTAs while spraying.<sup>182</sup> In practice, the requirement to 'pay particular attention' is not taken seriously, raising concerns about its ecological and legal relevance. If organisms are absent for a full year, what does this mean for the ecosystem?

A study<sup>183</sup>, for instance, points to the direct and indirect effects of pesticides and the 'narrow window' on which bird chicks rely on for their food (insects): *"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"*. Along with other similar studies<sup>184,185,186,187</sup> this again demonstrates that a full year without insects will block bird reproduction. EFSA itself<sup>188</sup> even considers that 'small effects, 10-35%' should not last longer than a month during the breeding/chick phase. Certainly not 100% mortality for an entire year.

Another element to consider with regards to 'recovery' is whether refuges for NTAs still remain, now that pesticides are abundantly found in nature conservation areas and considerable insect biomass loss is observed even there<sup>189</sup>. Other scientists also criticised the approach as unprotective<sup>190</sup>. In one study<sup>191</sup>, 23 years after an agricultural field was converted into a conservation area, recovery did not occur.

<sup>178</sup> [https://food.ec.europa.eu/horizontal-topics/committees/paff-committees/phytopharmaceuticals\\_en](https://food.ec.europa.eu/horizontal-topics/committees/paff-committees/phytopharmaceuticals_en)

<sup>179</sup> EFSA Journal 2016;14(11):4610

<sup>180</sup> EFSA Journal 2014;12(5):3677

<sup>181</sup> <https://toelatingen.ctgb.nl/nl/authorisations/25081>

<sup>182</sup> [https://ctgb-prd.s3.eu-central-1.amazonaws.com/cc569aa4cad9b93c786ad7a60377635\\_20211647\\_14880\\_P+WG.pdf](https://ctgb-prd.s3.eu-central-1.amazonaws.com/cc569aa4cad9b93c786ad7a60377635_20211647_14880_P+WG.pdf)

<sup>183</sup> Magali Solé, Stephan Brendel, Annette Aldrich, Jens Dauber, Julie Ewald, Sabine Duquesne, Eckhard Gottschalk, Jörg Hoffmann, Mathias Kuemmerlen, Alastair Leake, Steffen Matezki, Stefan Meyer, Moritz Nabel, Tiago Natal-da-Luz, Silvia Pieper, Dario Piselli, Stanislas Rigal, Martina Roß-Nickoll, Andreas Schäffer, Josef Settele, Gabriel Sigmund, Nick Sotherton, Jörn Wogram and Dirk Messner, Assessing in-field pesticide effects under European regulation and its implications for biodiversity: a workshop report, Environmental Sciences Europe (2024) 36:153.

<sup>184</sup> Boatman ND, Brickle NW, Hart JD, Milsom TP, Morris AJ, Murray AWA, Murray KA, Robertson PA (2004) Evidence for the indirect effects of pesticides on farmland birds. *Ibis* 146:131–143.

<sup>185</sup> Potts G (1986) *The partridge: pesticides Predation and Conservation*, Collins, London.

<sup>186</sup> Southwood TR, Cross DJ (2002) Food requirements of grey partridge, *Perdix perdix* chicks. *Wildl Biol* 8(3):175–183

<sup>187</sup> G. Benton et al. (2002). Linking agricultural practice to insect and bird populations: a historical study over three decades. *Journal of Applied Ecology* 39: 673-687.

<sup>188</sup> Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target arthropods, EFSA Journal 2015;13(2):3996.

<sup>189</sup> Bruhl et al., Direct pesticide exposure of insects in nature conservation areas in Germany, *Nature Scientific Reports*, 2022, 11:24144.

<sup>190</sup> Christopher John Topping, Lene Jung Kjaer, Udo Hommen, Toke Thomas Høye, Thomas G Preuss, Richard M Sibly, Peter van Vliet, Recovery based on plot experiments is a poor predictor of landscape-level population impacts of agricultural pesticides, *Environ Toxicol Chem*. 2014 Jul;33(7):1499-507.

<sup>191</sup> Siepel, H., 1993. Recovering of natural processes in abandoned agricultural areas: decomposition of organic matter. In: Zombori, L. & L. Peregovits (eds) *Proc. 4th European Congress of Entomology, Gödöllő*, 374-380.



Even EFSA itself criticised the recovery approach in the 2002 guideline<sup>192</sup>. It concluded:

- Environmental stress generally acts in addition to or in synergy with pesticide stress; hence recovery must be evaluated within the ecological context. This is particularly true for endangered species, which are under particular stress.
- Internal recovery strongly depends on the reproductive capacity of the species.
- If recovery from external sources is assumed for mobile species, it must be ensured that the magnitude of recolonisation from such sources is a realistic estimation, particularly in Population Recovery.
- Indirect effects based on, for example, competition and predation can play an important role in the magnitude and duration of effects, as well as in recovery processes. This is especially true for taxa at higher levels of the food web (e.g., the lack of food for birds caused by the decrease in arthropod populations after the use of insecticides).
- Compensation for losses is only possible if certain minimum requirements are fulfilled, including the provision of enough food, a high enough density of mating partners, a suitable distance to unaffected sites, and others.
- In agricultural landscapes, pesticide exposure recurs every year and consists of a mixture of different substances applied various times throughout the year. Hence, even if a species

can recover in experimental studies within a reasonable time, this must be related to realistic exposure scenarios in terms of short-term exposure profiles within a year and long-term exposure profiles over multiple years.

These EFSA conclusions again show that the recovery approach<sup>193</sup>, still used to this day, is highly unscientific.

Recovery is a major element of the new guideline design, as seen in the WUR AENEAS programme (deliverable 1.3). Subcontractor Prof. Maltby<sup>194</sup> even suggests halting testing on 'recovery' altogether, proposing instead a theoretical evaluation based on traits/characteristics (for instance, body size), claiming that *"70% of the vulnerability can be explained by traits."* Testing or assuming, as is currently common in NTA risk assessment would be replaced by a theoretical assessment of vulnerability (traits) and recovery. This view is even more unscientific, for the reasons EFSA developed in its opinion on ecological recovery (see above).

Similarly, WUR (Alterra<sup>195</sup>) has long proposed moving away from animal testing by substituting the assessment with 'mechanistic effect modelling'. While they claim this approach is more realistic, these assertions lack supporting validation data. Moreover, WUR ignores the elephant in the room: NTAs' current exposure to dozens of pesticides and co-formulants simultaneously. As mentioned before, this cocktail exposure, a well-documented scientific reality, is ignored, resulting in a significant underestimation of the harm caused by pesticides—a serious scientific mistake.

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<sup>192</sup> Mira Kattwinkel, Jörg Römbke, Matthias Liess, Ecological recovery of populations of vulnerable species driving the risk assessment of pesticides, EFSA Supporting Publications 2012:EN-338.

<sup>193</sup> WUR AENEAS deliverable 1.3, Methodology to link effects and impact on ecosystem services.

<sup>194</sup> Rico et al. 2016, Developing ecological scenarios for the prospective aquatic risk assessment of pesticides, Integr Environ Assess Manag. 2016 Jul;12(3):510-21 (WUR-Alterra).

<sup>195</sup> Internal recovery (where you do not rely on any recovery from sources) is theoretically possible, but recovery from sources outside the fields is not something that can be assumed. It depends on the landscape and scale of use. Both of which in modern systems are not giving this support.



This system, like many 'mechanistic systems' used by EFSA, and proposed by AENEAS (deliverable 1.3) is hampered by a significant lack of data and validated model systems against real-life scenarios, making it unsuitable for use in at least the coming years, if ever. If applied, it will likely rely on the personal views of the 'experts' involved (the WUR/EFSA group) due to the absence of data and validated models, which may be substituted by opinions, non-validated models, or reasoning. The recovery approach lowers the level of protection of NTAs since the 50% mortality threshold in the old 2002 guideline can be overruled and as high as a 100% mortality is allowed. Given the complexity, it may ultimately become incomprehensible. As a result, other scientists will not be able to scrutinise the assessment (or might refuse to read the 'pseudoscience'), leaving only a handful of experts, likely, with a certain common view, to decide on pesticide approvals.

WUR<sup>196</sup> claims to work: *"through the incorporation of biological trait information and landscape parameters to assess individual, population and/or community-level effects and recovery"*. For the requirements, it says: *"the development of ecological scenarios will require ecotoxicological data for different life-stages of the selected focal species and the chemical stressor of concern, as well as sufficient ecological information of the focal spe-*

*cies selected and of the habitats where they dwell"*. However, these methods are still in their infancy and have not been validated with real experimental exposure data in the field. It is also highly questionable whether this approach will ever result in a meaningful assessment. A sense of urgency seems to be lacking if EFSA and WUR engage on such a risky pathway that could take years to develop while disregarding the urgently needed improvements in the way the current risk assessment is carried out. If WUR and EFSA's efforts fail to deliver a robust and validated method for recovery that effectively protects biodiversity, it will result in many years of delay (in addition to the lack of protection since 2002) and cause further NTA decline, driving additional species to extinction.

EFSA's decision to disregard scientific approaches to risk assessment raises critical concerns about its intention to urgently protect NTAs. Why not derive 'safe' exposure values for different pesticides, based on testing a range of sensitive organisms, as is done for water organisms under the Water Framework Directive? This established method could just as effectively be applied to NTAs. It has been shown to be protective and should be considered to quickly remedy the current disastrous situation. In parallel, a complementary system-based approach could be developed.

## 10. Chronic testing

In a deliverable on routes of exposure of pesticides to NTAs<sup>197</sup>, Wageningen University (WUR) proposes to limit exposure of NTAs to 48 hours in the tests to see if a new pesticide should be given market access. While generally agreeing with WUR's idea, in this case even EFSA was critical in its comment on the draft deliverable, stating: *"one*

*of the driving forces behind the idea of this request [tender] was to verify whether chronic contact exposure tests may be needed in some cases. If the uptake is stopped after 48 hours, we will probably never have an answer to that - unless we perform some extrapolations"*. WUR, on the other hand, proposed to conduct the tests in the laboratory

<sup>196</sup> Rico et al. 2016, Developing ecological scenarios for the prospective aquatic risk assessment of pesticides, Integr Environ Assess Manag. 2016 Jul;12(3):510-21 (WUR-Alterra).

<sup>197</sup> Deliverable 3.2, AENEAS testing protocol.



using inert material (glass-fibre based filter paper), while EFSA, in its comment, insisted they should be performed on a more realistic substrate: “*The idea here would be to use environmental matrices (e.g. soil, leaves)*”. Performing tests for only 48 hours has an unknown relation to real-world conditions in the field. It seems evident that the WUR con-

sultants keep trying to simplify the risk assessment in an unscientific way. The Wageningen approach is also undermining Regulation (EU) 546/2011, the pesticide Uniform Principles, which states that pesticides should not have any long-term repercussions for the abundance and diversity of non-target species<sup>198</sup>.



### 11. Industry influence and conflicts of interest

If the AENEAS work would be turned into a guideline it is quite clear that no pesticide will ever be banned because it harms NTAs. There will always be a life stage, habitat, crop, part of the season, recovery for the selected species, where the applied model suggests a ‘safe’ and therefore ‘acceptable’ exposure. For the industry, this AENEAS-based system is a golden opportunity to maintain the status quo; pesticides that harm NTAs would continue to be authorised.

It is difficult to understand why WUR employees work on research that violates EU rules and current scientific knowledge (limiting biodiversity to human/agricultural needs). We can only speculate why they do this. Maybe WUR desperately needs

financial resources<sup>199</sup> and overlooks scientific insights. Maybe some of its employees have ideological views in line with the ‘ecosystem services for humans’ ideology. We have no means to find out. In any case, they seem to have forgotten about their own WUR mission: “*To explore the potential of nature to improve the quality of life.*”

It is also important to note that parallel research on the ‘ecosystem services for humans’ policy (with Prof. Maltby and WUR<sup>200</sup>, see Chapter 3.4) was also being conducted by CEFIC, the chemical companies’ umbrella association. Here we see the same construction, parallel research, on environmental risk assessment (on NTAs) in a CEFIC programme called “Chimera<sup>201</sup>”, while the chemi-

<sup>198</sup> Regulation (EU) 546/2011 states “Since the evaluation is to be based on data concerning a limited number of representative species, Member States shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species.”

<sup>199</sup> Bayer also hired a professor seat, see <https://www.pan-europe.info/press-releases/2013/05/silent-takeover-dutch-wageningen-university-moves-sell-their-independence>.

<sup>200</sup> <https://cefic-lri.org/projects/eco-45-chemicals-assessment-of-risks-to-ecosystem-services-cares-ii/>.

<sup>201</sup> <https://cefic-lri.org/projects/lri-eco19-rug-chimera-an-integrated-modelling-tool-for-ecological-risk-assessment/>.





cal giant Bayer also works on it individually<sup>202</sup>. Remarkably, CEFIC also hires experts from WUR/Alterra<sup>203</sup>, at the same time, raising obvious concerns about potential conflicts of interest. In EFSA's 'declarations of interest', one of the subcontractors of AENEAS, Andreas Focks (University of Osnabrück), mentions that he was part of an advisory group of the chemical umbrella association CEFIC from 2015 to 2018<sup>204</sup>. EFSA warned him that this would constitute a conflict of interest, leading Focks to step down from CEFIC (EFSA ignoring its own 2-year 'cooling-off' period rule). However, for Prof. Maltby, who worked for many years with the industry<sup>205</sup> and is now a subcontractor for AENEAS while also connected to Chimera<sup>206</sup>, this presents a conflict of interest that EFSA has chosen to overlook. The fact that Wageningen Environmental Research is working—through generally different colleagues—both in the EFSA AENEAS programme and the CEFIC Chimera programme at the same time should

also be considered a conflict of interest. In general, it can be observed that the WUR experts closely cooperate with the industry, frequently collaborating and regularly publishing with industry experts, as highlighted by a few examples in the footnotes<sup>207;208;209;210;211</sup>. This raises concerns about the impartiality of their work.

We observe that the chemical industry is conducting research similar to that of EFSA. EFSA often follows previous industry ideas and views<sup>212;213</sup>. This was the case for instance with the policy on 'Ecosystem services for humans' (ESH), designed at a SETAC meeting in 2009<sup>214</sup> and promoted by CEFIC<sup>215</sup>. The same pattern is now apparent in ERA, Environmental Risk Assessment (CEFIC programme since 2013, with a budget of 700K<sup>216;217</sup>). SETAC serves as a key venue where these parallel efforts come together, acting both as a meeting place and a place where these projects are brokered.

<sup>202</sup> [https://esdac.jrc.ec.europa.eu/public\\_path//shared\\_folder/PesticidesModelling/EMW-11/26-Wang-Magnus-xPP\\_Presentation\\_EUModelingWorkshop\\_v1.0.11aug20231.pdf](https://esdac.jrc.ec.europa.eu/public_path//shared_folder/PesticidesModelling/EMW-11/26-Wang-Magnus-xPP_Presentation_EUModelingWorkshop_v1.0.11aug20231.pdf).

<sup>203</sup> <https://research.wur.nl/en/publications/the-chimera-project-coupling-mechanistic-exposure-and-effect-mode>.

<sup>204</sup> <https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/other/Focks%20-%20WUR%20-%20CEFIC%20-%20SETAC%20-%20env%20modelling%202020.pdf>. Document obtained by PAN Europe through its access to document requests; this information is not publicly available on the declaration of interest of Andreas Focks available on EFSA's website, available via this link: <https://open.efsa.europa.eu/expert/300000014515826>.

<sup>205</sup> Prof. Maltby was the main promoter of the Ecosystem services for humans approach and was consultant for industry umbrella CEFIC and industry research group ECETOC and published with many industry employees such as from Bayer, Syngenta, Dupont, DOW, etc.

<sup>206</sup> <https://cefic-lri.org/projects/lri-eco19-rug-chimera-an-integrated-modelling-tool-for-ecological-risk-assessment/>

<sup>207</sup> WUR expert Brock: <https://corporateeurope.org/en/pressreleases/2012/06/conflicts-interest-still-evident-new-esfa-expert-panels>.

<sup>208</sup> WUR subcontractor Maltby: <https://cefic-lri.org/projects/eco-45-chemicals-assessment-of-risks-to-ecosystem-services-cares-ii/>; [https://www.sciencedirect.com/science/article/pii/S0048969716315844?via%3Dihub](https://cefic-lri.org/projects/eco-45-chemicals-assessment-of-risks-to-ecosystem-services-cares-ii/); <https://setac.onlinelibrary.wiley.com/doi/full/10.1002/etc.4049>

<sup>209</sup> Maltby, Rico and Van den Brink: <https://www.sciencedirect.com/science/article/pii/S0048969718336544?via%3Dihub>; <https://cefic-lri.org/projects/lri-eco19-rug-chimera-an-integrated-modelling-tool-for-ecological-risk-assessment/>

<sup>210</sup> Focks: CEFIC task force 2015-2018 (EFSA DoI).

<sup>211</sup> Wipfler: [https://www.researchgate.net/publication/341370430\\_Stepwise\\_development\\_of\\_catchment\\_hydrology\\_for\\_effect\\_modelling\\_in\\_regulatory\\_landscape-scale\\_aquatic\\_risk\\_assessment/link/62fe49b4eb7b135a0e43a049/download](https://www.researchgate.net/publication/341370430_Stepwise_development_of_catchment_hydrology_for_effect_modelling_in_regulatory_landscape-scale_aquatic_risk_assessment/link/62fe49b4eb7b135a0e43a049/download); <https://tip.wur.nl/Project.php?ProjectID=5498>

<sup>212</sup> <https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/pane-2011-a-toxic-mixture-industry-bias-found-in-efsa-working-group-on-risk-assessment-for-toxic-chemicals.pdf>

<sup>213</sup> <https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/pane-2014-a-poisonous-injection.pdf>

<sup>214</sup> <https://www.pan-europe.info/sites/pan-europe.info/files/public/resources/articles/SETAC%202009%20on%20ERA%20Maltby%20Hardy%20Luttik%20Wheeler%20Heimbach%20.pdf>

<sup>215</sup> For instance (see also chapter 3); Maltby Lorraine, van den Brink Paul J., Faber Jack H., Marshall Stuart, Advantages and challenges associated with implementing an ecosystem services approach to ecological risk assessment for chemicals, Science of The Total Environment, Volume 621, 15 April 2018, Pages 1342-1351.

<sup>216</sup> <https://cefic-lri.org/projects/lri-eco19-rug-chimera-an-integrated-modelling-tool-for-ecological-risk-assessment/>

<sup>217</sup> For instance: De Laender et al., The ChimERA project: coupling mechanistic exposure and effect models into an integrated platform for ecological risk assessment, Environ Sci Pollut Res (2014) 21:6263–6267





# Chapter 5

## Conclusions on the AENEAS work (Wageningen/EFSA)

1. EFSA/WUR intend to protect only restricted elements of the ecosystem (selected human services), which is a clear violation of Regulation 1107/2009, as the regulation includes no provisions for such a limitation. Given the centrality of arthropods to the natural world and therefore to the law, this is a major erosion of Europe's central pesticide regulation;
2. The limitation of ecosystem services to that for humans is in stark contrast with the scientific ecological insights on the protection of biodiversity, which suggests that greater biodiversity contributes to ecosystem stability and thereby enhances the delivery of ecosystem services.
3. The impact of pesticides on the most sensitive and vulnerable non-target arthropods (NTAs) will not be assessed with such an approach, failing to guarantee protection for NTA populations at large;
4. Despite available methods to assess indirect effects on ecosystems, EFSA refuses to apply these methods and differs protection in the future;
5. Ultimately, the protection of NTAs is turned upside-down by the consideration that agricultural production is the main ecosystem service that can overrule other services (via trade-offs). Such a trade-off is not included in the Regulation; note that current agricultural production is not an ecosystem service; rather, it destroys ecosystems;
6. Not taking into account the daily reality of exposure to multiple pesticides is a major scientific mistake that leads to greatly underestimating risks;
7. The WUR/EFSA experts attempt to define the level of protection at a very low threshold (for instance, no chronic assessment is considered), which is outside their remit;



8. **The EFSA concept of recovery or recolonisation is an ecological nonsense but remains a major element of the assessment in the EFSA/WUR documents;**
9. **EFSA and CEFIC are working in parallel, both employing experts from the same institute (Wageningen University, WUR, formerly Alterra), creating a recipe for conflicts of interest;**
10. **From this WUR/EFSA work, it can be derived that the new Guidance Document to protect NTAs is likely to be equally ‘unfit for purpose’—if not worse—and will provide no protection at all.**

The “next generation ERA” as framed by EFSA is being designed in parallel by EFSA and the chemical industry (CEFIC) through the same institute (Wageningen Environmental Research, the former Alterra). This assessment system for NTAs has little scientific basis and benefits pesticide-intensive agriculture, rather than protecting biodiversity as it should. It is an artificial construct, created by a closed circle of like-minded experts, a ‘bubble’, without democratic oversight. The complexity of the approaches proposed in the assessment system in development might be a way to confuse policymakers who lack the time to read the documents thoroughly or the expertise, allowing EFSA to create a *fait accompli*.

The work of EFSA/WUR should be halted. A completely independent panel of scien-

tists (entomologists) should be put in place to write a truly protective guideline for NTA from scratch. The European Commission and Member States, which will have the opportunity to scrutinise the future guidelines, should also demand a change at EFSA toward a more independent scientific approach. Additionally, the EU Parliament has a say and could veto the guideline when it is implemented in the data requirement Regulation<sup>218</sup> and the Uniform Principles<sup>219</sup>. Implementing yet another ineffective guideline would lead to the continued decline of non-target arthropods, resulting in the irreversible extinction of arthropod species.

In the meantime, PAN and its members will continue exposing the clear contradiction between European law and the NTA guidelines by challenging, where possible, pesticide authorisations in court. The guidelines are central to PAN Europe’s most recent legal challenge, starting with a request for internal review to the European Commission (registered on 25 October 2024) on the authorisation of a widely used Swiss-invented fungicide known as captan, a suspected carcinogen and reprotoxic substance, harmful to the environment including insects. In December, PAN will ask the European Court of Justice to overturn Glyphosate authorisation throughout Europe, again highlighting the broken NTA guidelines and poor ERA. We will not stop challenging pesticides until very sensible legal protections for the living world are respected. We do this because, in crude terms, the security of animal and hu-

<sup>218</sup> COMMISSION REGULATION (EU) No 283/2013 of 1 March 2013

<sup>219</sup> COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011



man food webs are at stake, and with them, our future.

This report exposes how a simple law has spawned a byzantine world of obscure functionaries devising complex formulations that few understand. The complexity hides a simple purpose. This architecture is designed to overturn the law, to blur a clear line drawn by lawmakers to separate those pesticides that are safe for humans and the environment from those that are not. This is a form of corruption, of the law, hiding in the shadows. The record shows that this work is in the service of the chemical industry, work that is paid for and approved in detail by the public agency that is supposed to guarantee food safety in Europe; EFSA. All of this stands in stark contrast to what EFSA claims to be. According to its strategy<sup>220</sup>, EFSA claims its mission is centred on excellence: *“We deliver rigorous and reliable risk assessments, building on the latest scientific advancements”*; independence: *“We ensure impartiality of our scientific outputs. Staff and experts, free of conflicts of interests, analyse data and apply methods objectively”*; and openness: *“Our risk assessments ... are produced via transparent processes, enhanced by an open dialogue with all interested parties”*. As this report has shown, this is far from the truth.

Today, the law has not stopped a single pesticide being authorised because of its threat to arthropods, to the best of our knowledge. If Europe is already a *carte blanche* for pesticide makers, it is reasonable to ask why the rules are being further weakened. Our conclusion is they are making a first appearance in the arthropod guidelines as a precedent, from which they can be more easily adopted in other legal arenas. For instance, an EFSA guidance document meant to shield amphibians from dangerous pesticides will be revised in the upcoming years. This new guidance document and the others to come, we fear, will be twisted out of shape by the priorities of the chemical industry.

But we do not want to conclude this report on a negative note. EFSA has rigged the game to suit the pesticide industry and is trying to rig it still further. But the game is not over and other players will soon join, not least society’s representatives in Brussels, the European Parliament. The environment Ministries and agencies across Member States should also intervene in support of the protection of biodiversity and its species. Revision of the arthropod guidelines is a golden opportunity to overhaul these obscure rules so they do what the law intends: protect the natural world and, by extension, us.

<sup>220</sup> <https://www.efsa.europa.eu/en/corporate-pubs/efsa-strategy-2027-science-safe-food-sustainability>





# LICENCE TO KILL

an EU guideline with far-reaching consequences

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