Pesticide Action Network Europe

To: members of the PAFF Committee - Section "Phytopharmaceuticals - Legislation"

Brussels, 27 November 2024

Subject: EU Standing Committee on Plants, Animals, Food and Feed (PAFF); 4-5 December - position of Pesticide Action Network (PAN) Europe

Dear members of the PAFF committee,

On December 4th and 5th, you are invited to the EU Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) to discuss and/or potentially adopt opinions on several proposals from the European Commission. Ahead of this meeting, we would like to share PAN Europe's position on specific issues related to the protection of human health and the environment. We kindly request that you give these matters your particular attention.

Agenda issues

1. Draft Commission Regulations amending Commission Regulation (EU) No 283/2013 and 284/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009
2. Proposal for non-renewal of flufenacet
3. Proposal for non-renewal of flutolanil
4. Draft review/renewal reports: pydiflumetofen, 8-hydroxyquinoline (quinolin-8-ol), fenoxaprop-P-ethyl
5. EFSA conclusions: mecoprop-p, pirimicarb, fludioxonil
6. Confirmatory information: difenoconazole
7. AOB. Concerns on EFSA's misguided approach for revising the EU Guidance Document on non-target arthropods - new PAN Europe report.

1. **Draft Commission Regulations amending Commission Regulation (EU) No 283/2013 and 284/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009**

PAN Europe views this review of data requirements as a missed opportunity to expand the assessment of active substances and plant protection products (PPPs) in order to ensure a higher level of protection for humans, animals and the environment from potential harm caused by these chemicals. For example, additional tests should have been added to assess their potential for developmental neurotoxicity and immunotoxicity as compulsory, as well as the genotoxic and endocrine-disrupting properties of the PPPs.

Considering the scientific and epidemiological evidence of the neurotoxic effects of pesticides[1], it is evident that the current pesticide risk assessment falls short in protecting humans from exposure to substances that can harm brain development. A significant reason for this failure is the lack of a mandatory requirement for applicants to submit developmental toxicity or additional neurotoxicity studies that address long-term exposure. This gap persists even for those insecticides, whose mode of action is through the nervous system. Although there is an explicit requirement to provide sufficient information on potentially harmful effects of active substances to evaluate neurotoxic risks to humans, a recent publication[2] highlighted that this requirement does not ensure that applicants consistently submit data on the developmental neurotoxic potential of their substances. In light of this, PAN Europe urges that the submission of developmental toxicity studies be made a systematic requirement for all synthetic active substances.

A second major concern is the growing epidemiological evidence that pesticides may also act as immunosuppressive agents. This is of concern as the immune response plays a pivotal role in the progression of chronic diseases such as cancer. PAN Europe argues that the draft Regulations should be revised to include, at a minimum, the OECD *in vitro* Test No. 444A.

Finally, the European Court of Justice clarified in 2019[3] that PPPs should be assessed for their long-term toxicity and carcinogenicity, and in 2024[4] that they should be tested for their endocrine disruptive properties. Therefore, data requirements to assess these endpoints of toxicity should be included.

---

[1] Inserm, Collective Expert Report, 2021. https://presse.inserm.fr/en/inserm-publishes-its-latest-collective-expert-review-on-the-health-effects-of-pesticides/60325/; Potential neurotoxicity of acetamiprid in children https://www.pan-europe.info/blog/neurotoxic-pesticides-affect-children%E2%80%99s-brain-global-restrictions-urgently-needed

[2] Mie, A., Rudén, C. Non-disclosure of developmental neurotoxicity studies obstructs the safety assessment of pesticides in the European Union. Environ Health 22, 44 (2023). https://doi.org/10.1186/s12940-023-00994-9

[3] Judgement of the Court Case C-616/17

[4] Judgement of the Court Cases C-309/22 and C310/22

2. Proposal for non-renewal of flufenacet

On behalf of the 49 environmental and health organizations supporting a swift ban on flufenacet[5], PAN Europe welcomes the Commission's proposal for its non-renewal. According to EFSA's conclusions, flufenacet does not comply with the approval criteria set in Regulation (EC) No 1107/2009, in particular:

- Firstly, flufenacet was considered to meet the endocrine disruption criteria for humans and non-target organisms. The substance was found to alter the thyroid-stimulating hormone leading to changes in thyroid weight and thyroid histopathology. A clear mode of action was identified in line with Regulation 2018/605. Moreover, alterations of the thyroid hormone could induce developmental neurotoxicity as observed in a developmental neurotoxicity study about flufenacet according to EFSA. These conclusions also apply to wild mammals as non-target organisms. In accordance with Article 4(1) as well as points 3.6.5 and 3.8.2 of Annex II of the Pesticide Regulation, a substance having endocrine-disrupting properties for humans and/or non-target organisms shall not be approved.
- Secondly, flufenacet was found to be highly toxic to algae in virtually all the relevant scenarios.
- Finally, EFSA's conclusions raised additional concerns, including the failure to complete the consumer risk assessment and to address the toxicological relevance of certain metabolites, such as trifluoroacetic Acid (TFA), a common metabolite of several PFAS pesticides. Although this last point has not been identified by EFSA as a critical area of concern, TFA is another crucial reason supporting the substance ban. Flufenacet meets the OECD definition of PFAS as it contains a C-CF3-group. In addition to being persistent, it breaks down into the concerning metabolite TFA. TFA is an ultra-short PFAS, which highly contaminates our water resources all across Europe, including our groundwater and drinking water. It is even detected in mineral waters and most pristine water resources[6]. This is of significant concern as knowledge about the substance's toxicity is increasing. TFA has been proposed for hazard classification as toxic for reproduction category 1B, acute toxic 3, very persistent and very mobile (vPvM) and persistent, mobile and toxic (PMT), which makes it a toxicologically 'relevant metabolite'. In line with the Pesticide Regulation, an active substance shall not be approved if its relevant metabolite(s) are likely to contaminate groundwater above the legal limit of 0.1 µg/L set out in Annex I of Directive 2006/118/EC on groundwater. In its conclusions, EFSA found that the use of flufenacet would result in TFA levels exceeding not only the limit for relevant metabolites (0.1 µg/L) but even the one for non-relevant metabolites (10 µg/L). Therefore, the Commission's proposal for the non-renewal of flufenacet should identify TFA as the relevant metabolite and mention contamination of groundwater with TFA above the legal limit as the third critical point for which flufenacet shall no longer be approved in the EU.

[5] PAN Europe, Top-Selling PFAS Herbicide Flufenacet Confirmed Harmful by EFSA: 49 Environmental Groups Call for Emergency Ban | PAN Europe (November 2024)
[6] PAN Europe, TFA in Water: Dirty PFAS Legacy Under the Radar (May 2024); TFA: The Forever Chemical in the Water We Drink (July 2024).

Given the well-documented toxicity of flufenacet, the urgent need to eliminate TFA sources, and the fact that flufenacet's approval has been extended for over 11 years, we strongly urge an immediate EU-wide ban. **This ban must proceed without delay or grace periods** for the sale, distribution, disposal, storage, or use of existing stocks. We demand decisive and timely action.

3. Proposal for non-renewal of flutolanil

PAN Europe welcomes the Commission's proposal for non-renewal of the approval of flutolanil. According to the OECD definition of PFAS and as confirmed by EFSA's peer review from June 2023, flutolanil belongs to this group of particularly problematic "forever pollutants". Under its European Green Deal, the EU committed to phase out PFAS due to the unacceptable risk they pose to humans and the environment. According to EFSA, flutolanil is a persistent (P) to very persistent (vP) substance and forms the very persistent and very mobile metabolite trifluoroacetic acid (TFA). TFA is also proposed for classification as toxic for reproduction 1B and acute toxic 3, which makes it a relevant metabolite for groundwater and consumer risk assessment. This is worrying since numerous publications highlight high and widespread contamination of EU water bodies with this metabolite, at levels which largely exceed the 0.1 µg/L threshold for groundwater and drinking water for relevant metabolites. No data on the potential for groundwater contamination with TFA were submitted for flutolanil by the applicant and renewing the substance would further increase the already high exposure to TFA. Moreover, the consumer risk assessment could not be finalised because of lacking data on the presence and toxicity of relevant metabolites, including TFA, for the purpose of residue definition in plants and animals. The concerns for consumers apply equally to the consumption of drinking water due to missing information on the effect of water treatment processes on the nature of the residues of flutolanil and metabolite M-11. The latter might also be present in surface water when it is abstracted for the production of drinking water.

In addition, the potential for immunotoxicity of flutolanil could not be excluded based on existing data and should be further investigated according to EFSA.

We call on you to **support the Commission's proposal for the <u>non-renewal</u> of flutolanil** to protect European citizens from <u>direct and deliberate exposure to this PFAS substance</u>.

4. Draft review/renewal reports: pydiflumetofen, 8-hydroxyquinoline (quinolin-8-ol), fenoxaprop-P-ethyl

a) Pydiflumetofen

PAN Europe is calling upon the Commission and Member States to ban the approval of pydiflumetofen, a succinate dehydrogenase inhibitor fungicide, by considering above all its very

high persistence as an unacceptable effect. This demand is in line with the scientific recommendation[7] that chemicals should be regulated based on their persistence alone to prevent irreversible impacts on human health and the environment.

The history of chemical regulation has indeed demonstrated that a number of chemical pollution problems we are facing nowadays result from the release of highly persistent chemicals, such as dichlorodiphenyltrichloroethane (DDT), chlordane and PFAS, due to an underestimation of their impacts during their risk assessment. The use of highly persistent substances leads to the risk of reaching particularly high concentrations when released in the environment, increasing thereby the risk of causing adverse effects on human health and the environment. In the case of pydiflumetofen, some toxicity concerns already exist. Namely, concerns remain regarding the genotoxic potential of its metabolite 2,4,6-TCP and the toxicity of three of its impurities. Moreover, while EFSA concluded that pydiflumetofen does not meet the criteria for endocrine disruption, some adverse effects were observed in fish (decreased VTG at all concentrations, decreased fecundity, change in female gonad histopathology, i.e. increased oocyte atresia), raising some clear "uncertainties" for its impact on non-target organisms other than mammals. These uncertainties and remaining unaddressed issues should have been considered very carefully by risk managers for such a persistent substance to which concentration levels might be of high risk for humans and the environment. Moreover, chronic toxicity of persistent substances is insufficiently addressed in the context of pesticide risk assessment as such chronic studies are not designed to particularly consider persistence and exposure to increasing background levels of the tested substance.

Finally, pydiflumetofen is a succinate dehydrogenase inhibitor (SDHI) fungicide. The potential adversity relative to an SDHI fungicide mode of action in humans was found inconclusive by EFSA, raising valid concerns. The latter is supported by the results of peer-reviewed studies published in independent scientific journals. Namely, pydiflumetofen was found to interact with drug transporters, notably by strongly reducing the activity of the renal organic anion transporter (OAT) 3, in a concentration-dependent manner[8]. It was also found to enhance CYP3A4 mRNA expression in human hepatic HepaRG cells and primary human hepatocytes[9]. Lastly, a study has pointed out the acute and developmental toxicity of pydiflumetofen toward embryos, larvae, and adult zebrafish[10].

---

[7] Cousins IT *et al*. Why is high persistence alone a major cause of concern? Environ Sci Process Impacts. 2019 May 22;21(5):781-792. doi: 10.1039/c8em00515j. Erratum in: Environ Sci Process Impacts. 2019 May 22;21(5):904. doi: 10.1039/c9em90019e. PMID: 30973570.

[8] Kerhoas *et al.* 2024. Inhibition of human drug transporter activities by succinate dehydrogenase inhibitors, Chemosphere, Volume 358:142122 https://doi.org/10.1016/j.chemosphere.2024.142122

[9] Kerhoas *et al.* 2024. Induction of human hepatic cytochrome P-450 3A4 expression by antifungal succinate dehydrogenase inhibitors, Ecotoxicology and Environmental Safety, Volume 276:116261, https://doi.org/10.1016/j.ecoenv.2024.116261

[10] Wang *et al.* 2022. Comprehensive study of pydiflumetofen in *Danio rerio*: Enantioselective insight into the toxic mechanism and fate, Environment International, Volume 167: 107406 https://doi.org/10.1016/j.envint.2022.107406

Another concern with persistent substances is that it takes significant time and resources to reverse contamination when these are found to be way more toxic than originally concluded in chemical assessment. For this reason and given the already high background exposure levels of chemicals for humans and the environment, a more precautionary approach from regulators is crucial to protect our health and that of the next generations. It would also be consistent with the current work on the proposal for a universal restriction of PFAS based on the persistence properties of this class of chemicals.

We call on you to invite the Commission to **propose the non-approval of pydiflumetofen** to prevent poorly reversible future impacts on human health and the environment.

b) 8-hydroxyquinoline (quinolin-8-ol)

PAN Europe urges you to oppose the renewal of 8-hydroxyquinoline, a “cut-off” substance classified as presumed to "damage the unborn child" (i.e. toxic for reproduction 1B) since 2015. The Pesticide Regulation clearly establishes that reprotoxic substances cannot be approved in the EU unless negligible exposure to humans can be demonstrated under realistic conditions of use (Article 4(1), point 3.6.4 of Annex II). This provision and its exemption of negligible exposure must be interpreted very restrictively to ensure that the level of protection remains high, as foreseen by the EU Pesticide Regulation. Therefore, negligible exposure to all exposure groups should be clearly demonstrated. This demonstration should be based on an objective, robust and comprehensive dataset. Worryingly, EFSA’s peer review on 8-hydroxyquinoline from March 2024 shows that these conditions for scientific rigour were not achieved due to the lack of reliable and realistic data. Particularly, we would like to highlight the following shortcomings in the assessment:

- Workers and operators: the field study submitted by the applicant to assess non-dietary exposure for operators and workers had several limitations and could only be considered as ‘supportive’ evidence for negligible exposure. In fact, it was considered non-reliable for quantitative risk assessment according to EFSA. Yet, this “unreliable” study was the main basis for concluding that workers’ and bystanders’ exposure is negligible. Even when applying an additional factor of 10, this situation does not ensure sufficient confidence in the assumption that workers and operators will be protected from this reprotoxic substance.

- Bystanders and resident children: the assessment of non-dietary exposure of bystanders and resident children could not be finalised due to a data gap for the representative use. Based on the best existing data (spray application), EFSA pointed out that the exposure of these vulnerable groups to vapour of 8-hydroxyquinoline is predicted to exceed the threshold for negligible exposure (120% of Acceptable Observed Effect Level). While this estimation may overestimate the level of exposure in the case of drip irrigation, it cannot be proven that residents’ and bystanders’ exposure will be negligible in that condition of use. Particularly, the risks of exposure *via* volatilisation cannot be ruled out based on the workers’ and bystanders' study (mentioned above) as suggested in the Commission’s

renewal report. This is particularly worrying in that it concerns groups of the population that are particularly vulnerable, including pregnant women and children.

In its renewal report, the Commission is proposing to request as confirmatory data a new non-dietary exposure study for workers and operators, this time under realistic conditions of use, which confirms the lack of robustness of the assessment carried out based on the current data. This proposal for confirmatory information about negligible exposure is unacceptable and fails to comply with point 3.6.4 of Annex II. Moreover, taking into consideration the precautionary principle, in line with Article 1(4) and Article 13(2), risk managers are entitled to issue a non-approval for this hazardous substance.

We call on you to reject the Commission proposal for renewal of 8-hydroxyquinoline, requesting instead a **non-renewal of 8-hydroxyquinoline and an immediate withdrawal from the EU market of products** containing this substance, in line with Article 20(2,3) of Regulation (EC) 1107/2009.

c) Fenoxaprop-P-ethyl

PAN Europe urges your support for the non-renewal of fenoxaprop-P-ethyl, given its endocrine-disrupting properties and in compliance with Article 4(1) and point 3.6.5 of Annex II of Regulation (EC) 1107/2009. According to EFSA's conclusions, published on 13 November 2024, fenoxaprop-P-ethyl has been identified as an endocrine disruptor for humans through the A (androgen)-modality. Specifically, it was shown to induce changes in the weights of the prostate, epididymis, and testes, alongside alterations in testicular weight.

EFSA's conclusions highlight significant data gaps in ED assessment, including the absence of a level 5 study, even though this was required by the applicant under the ECHA/EFSA Guidance Document and explicitly requested by the peer review experts in 2019. This data gap is particularly unacceptable, given that the applicant was granted three years (2019–2022) to address it. This resulted in multiple extensions of the approval period for fenoxaprop-P-ethyl, which was initially set to expire in 2018.

Therefore, PAN Europe fully supports the view of EFSA's peer review experts, who emphasized the need to accept a higher level of uncertainty and conclude that fenoxaprop-P-ethyl meets the criteria for endocrine disruption.

For non-target organisms, these data gaps were found to be too significant to determine the endocrine-disputing potential of fenoxaprop-P-ethyl via the EAS modalities. Further data gaps have resulted in unfinalised issues in the assessment of EFSA's peer review making it impossible to conclude i) whether the proposed levels of all impurities are toxicologically acceptable; ii-iii) the consumer risk assessment and iv) the risks for aquatic organisms. Nevertheless, there is no reason to request additional data to address these data gaps. The substance is an endocrine disruptor for humans and therefore does not meet the approval criteria laid down in Article 4 (1) of 1107/2009.

We call on you to invite the Commission to propose **the non-renewal of fenoxaprop-P-ethyl**, ensuring a high level of protection for human health and the environment.

5. EFSA conclusions: mecoprop-p, pirimicarb, fludioxonil

a) Mecoprop-p

In October 2023, EFSA published its updated peer review on mecoprop-p with its endocrine disruption assessment. Overall, EFSA concluded that the endocrine-disrupting criteria of points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) 1107/2009 were not met for the EATS-modalities for humans and non-target organisms. However, mecoprop-p cannot be considered to comply with the approval criteria of Regulation (EC) 1107/2009 with regard to the critical area of concern identified by EFSA in 2023: the predicted exposure to residents is above the AOEL for children entering treated areas (75th percentile), even by applying a buffer strip of 10 m and drift reduction nozzles during application. This critical area of concern indicates that the conditions set out in Article 4 of Regulation (EC) 1107/2009 are not met, particularly regarding those provisions aiming to ensure that products placed on the market and their residues "*shall not have any harmful effects on human health, including that of vulnerable groups"* (Recital 24; Article 4(2) & (3)). Moreover, mecoprop-p is classified as very toxic to aquatic life with acute and long-lasting effects (Aquatic Acute 1 and Aquatic Chronic 1) as well as harmful if swallowed and causing serious eye damage under Regulation (EC) 1272/2007. Therefore, it cannot be concluded that the use of the substance does not cause any harm to human health or does not have any unacceptable effects on the environment. Nevertheless, so far the approval of mecoprop-p has been repeatedly extended for a total of 9 years and a half. It is high time that citizens, including agricultural workers and their families, as well as the environment stop being exposed to this hazardous substance.

We call on you to invite the Commission to propose **the non-renewal of mecoprop-p** to ensure a high level of protection for children.

b) Pirimicarb

In September 2024, EFSA published its conclusion on the peer review of the candidate for substitution pirimicarb. Despite multiple prolongations of the substance's approval (8 years), these conclusions now raise concerns as they highlight that pirimicarb fails to comply with the approval criteria of Regulation (EC) 1107/2009 including Article 4(1).

Firstly, the developmental neurotoxicity potential of pirimicarb remains unresolved due to concerns linked to its neurotoxic mode of action and evidence of neurotoxicity in the available dataset. The substance is also associated with potential phototoxicity and photomutagenicity. Moreover, the consumer risk assessment, including for drinking water, has not been finalised, due to various data gaps, including some regarding the toxicological profile of several metabolites. This is of concern since pirimicarb is classified as a carcinogen category 2 under Regulation (EC) 1272/2007. Moreover, this is despite repeated extensions of its approval

period, during which the applicants could have provided the missing data. According to a report by PAN Europe published in May 2022[11], pirimicarb stood as the third most detected candidate for substitution in fruit grown in the European Union. Secondly, pirimicarb was found to pose a high risk to aquatic organisms in the majority of the assessed scenarios with maximum risk mitigation measures, leading EFSA to establish a critical area of concern. This clearly means that no safe use of pirimicarb could be identified. Further ecotoxicological concerns result from the impossibility of EFSA to conclude on the risk to honeybees, soil-dwelling organisms and on the endocrine-disrupting properties of pirimicarb for non-target organisms.

Given the above concerns, we call on you to urge the Commission to propose the **non-renewal of pirimicarb**.

c) Fludioxonil

On 4 November 2024, EFSA finally published its conclusion on the peer review of the candidate for substitution fludioxonil. While the substance's approval was initially due to expire in late 2018, its approval has been extended to June 2025 as a result of several delays in risk assessment. The EFSA conclusions show that the substance does not meet the requirements of Article 4(1) of Regulation (EC) 1107/2009 to be approved in the EU. Alarmingly, this further demonstrated that -in contradiction with the purpose of Regulation (EC) 1107/2009 of ensuring a high level of protection- delays in risk assessment and approval prolongations lead to continued exposure to substances for which there is evidence indicating they are harmful to humans and pose unacceptable effects on the environment. In the case of fludioxonil, it is all the more concerning that the substance was the most often detected candidate for substitution in European fruit between 2009 and 2019 according to data from the EU Multiannual Control Programme analysed by PAN Europe[12].

The most prominent concern identified by EFSA is that fludioxonil meets the endocrine disruption criteria for the EAS-modalities for humans and non-target organisms as laid down in points 3.6.5 and 3.8.2. of Annex II to Regulation (EC) 1107/2009. Namely, fludioxonil was found to decrease testosterone synthesis and increase estradiol leading to delayed sexual maturation, decreased anogenital distance in males and increased oestruscycle in females. Evidence suggests an anti-androgenic mode of action but other modes of action, affecting steroidogenesis and/or oestrogenic pathways, are also plausible. These conclusions for humans also apply to wild mammals as non-target organisms. Moreover, other important issues of fludioxonil risk assessment could not be finalised according to EFSA. Alarmingly, the batches used in toxicity studies could not be concluded to be representative of the originally and newly proposed reference specification for the active substance fludioxonil and associated impurities. Additionally, EFSA consumer risk assessment could not be finalised (dietary and drinking water). Last, the groundwater exposure assessment was not finalised for the possible metabolites unidentified MF2 and D9.

[11] PAN Europe, Forbidden Fruit (May 2022).
[12] Idem.

Considering the above, we call on you to invite the Commission to propose **the non-renewal of fludioxonil.** Moreover, fludioxonil's harmful properties, combined with this prolonged approval process, highlight the need for more stringent enforcement of regulatory deadlines to prevent similar cases in the future.

6. Confirmatory information: difenoconazole

PAN Europe acknowledges EFSA's peer review of difenoconazole in light of confirmatory data, which concluded that no immediate concerns were identified for consumers. However, we regret to see that these findings do not address all outstanding concerns regarding the substance. Earlier this year, PAN Europe voiced concerns[13] regarding the delayed decision on the non-renewal considering the overwhelming evidence of difenoconazole's endocrine-disrupting properties and associated risks to reproductive and developmental health. We pointed to independent studies and research showing the chemical's harmful effects on fish, mammals, and potentially humans, including disruption of sex hormone synthesis, thyroid hormones, and other crucial endocrine functions. Moreover, we raised issues with the metabolite 1,2,4-triazole, a breakdown product of difenoconazole, which is classified as toxic for reproduction category 1B. Last, we highlighted that the use of azole fungicides, other than as human medicines, contributes to the development of azole-resistant *Aspergillus spp.* Considering these elements, difenoconazole's approval should be withdrawn under Article 21 of Regulation (EC) 1107/2009 without further risk assessment delays.

7. AOB Concerns on EFSA's misguided approach for revising the EU Guidance Document on non-target arthropods - new PAN Europe report

PAN Europe wishes to express its deep concern regarding EFSA's preparatory work for the upcoming revision of the EU Guidance Document on non-target arthropods.

Alarmingly, insect populations have collapsed across Europe in the last 25 years. Intensive agriculture and the widespread use of pesticides are an important cause according to scientists[14;15;16]. PAN Europe's latest report[17] shows that this is partly due to the continued reliance of the pesticide risk assessment on the current 2002 Guidance Document on Terrestrial Ecotoxicology[18] (NTA guidelines). The critical analysis of the guidelines' significant shortcomings shows how its application has resulted in the approval and widespread use of pesticides, which represent a high risk to arthropods. This regulatory shortcoming contributes to an ecological crisis that threatens the health of our ecosystems and, consequently, of European food security.

---

[13] PAN Europe, Request to withdraw the approval of difenoconazole (May 2024).
[14] Dudley, N., & Alexander, S. (2017). Agriculture and Biodiversity: A Review. *Biodiversity*, *18*(2–3), 45–49. https://doi.org/10.1080/14888386.2017.1351892.
[15] 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.
[16] Geiger, F. *et al* (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.
[17] PAN Europe, Licence to kill: an EU guideline with far-reaching consequences (November 2024).
[18] European Commission (2002). Section 5 of the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC, p.19-24.

While PAN Europe welcomes the European Commission's mandate to EFSA (in June 2024) to develop a new guidance document on NTAs[19], we wish to voice our concerns about the approach taken by EFSA. EFSA's preparatory work for the NTA guideline revision is conducted under the AENEAS program—a Framework Partnership Agreement with Wageningen University. The outcomes of this research - presented as EFSA's input in a stakeholder meeting held on October 8-9, 2024-, together with our analysis, indicate that this work will fail to provide the level of protection for biodiversity foreseen by the EU law.

The approach of the AENEAS program focuses on providing protection only for elements of the ecosystem that allow the use of pesticides and directly generate profit for companies, rather than safeguarding biodiversity as a whole. This is in line with EFSA's "ecosystem services for humans" ongoing policy, which is not aligned with the requirements of the EU pesticide Regulation. According to the Regulation pesticide products *"shall have no unacceptable effects on the environment*" (Art.4.3.e) with particular regard to *"its impact on biodiversity and the ecosystem".* Remarkably, the program promotes the idea of elevating 'agricultural production' as one of the main ecosystem 'services' that deserve protection and goes as far as suggesting that agricultural production could overrule ("trade-off") other 'services', such as the protection of non-target arthropod species. The framework ultimately proposes classifying certain species of our ecosystem as a 'disservice', thereby excluding them from protection despite their essential role as the foundation of vast food webs.

The AENEAS program also raises serious questions about EFSA's selection policy of experts. Several of the consultants involved in the AENEAS programme, selected by EFSA, have a documented history of close collaboration with the agrochemical industry.

In light of the troubling concepts for arthropod protection introduced by the AENEAS framework and of the background of the consultants involved in the programme, we strongly urge you to reconsider EFSA's ongoing work and its reliance on potentially biased consultants in drafting a revised guideline. Instead, we advocate for assembling a new panel of entirely independent scientists, ecologists and entomologists to ensure an objective and science-driven approach.

From beforehand, thank you for taking into consideration our remarks and I wish you a constructive discussion.

Sincerely yours,

On behalf of PAN Europe

Angeliki Lysimachou
Head of Science and Policy
Pesticide Action Network Europe

[19] https://open.efsa.europa.eu/questions/EFSA-Q-2024-00464