Pesticide Action Network Europe

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

Brussels, 24 January 2024

**Subject**: EU Standing committee on Plants, Animals, Food and Feed - 30-31 January - position of Pesticide Action Network (PAN) Europe

Dear members of the PAFF committee,

On 30 and 31 January, you are invited to the EU Standing Committee on Plants, Animals, Food and Feed to discuss and/or adopt opinions on several proposals of the European Commission. In advance of this meeting, please find below PAN Europe's position on certain issues that relate to the protection of human health and the environment, for which we kindly request your particular attention.

**Agenda issues:**

1. Proposal defining data requirements for the approval of safeners and synergists and establish a work programme for the gradual review of safeners and synergists on the market
2. Proposal for renewal of approval of trinexapac as trinexapac-ethyl
3. Proposal for renewal of approval of metconazole
4. Proposal for renewal of approval of captan
5. Proposal for non-renewal of the approval of dimethomorph
6. Proposal for non-renewal of the approval of mepanipyrim
7. Proposal to withdraw the approval of acibenzolar-S-methyl
8. Proposal to renew the approval of metrafenone
9. EFSA conclusions
10. Renewal report on metribuzin
11. Confirmatory information
12. Guidance documents: article 53
13. PFAS
14. Working groups: comparative assessment, negligible exposure
15. PAN Europe’s contributions on other issues

1. **Proposal defining data requirements for the approval of safeners and synergists and establish a work programme for the gradual review of safeners and synergists on the market (B. 01)**

PAN Europe welcomes the Commission's long overdue (9 years) draft Regulation by which it intends to fulfil its obligations under Article 26 of Regulation (EC) 1107/2009. However, we are concerned by the sudden rapid progress of this process, casting doubt on the possibility of constructive dialogue. While the public consultation was ongoing, Member States at SCoPAFF were already invited to discuss the Commission's draft. Just a month after the end of the public consultation, an amended draft Regulation is already being submitted for possible opinion under Section B. It appears that the Commission has overlooked the issues raised in our contribution to the public consultation, as well as those of other environmental NGOs, in contrast to the ones raised by the pesticide industry and animal welfare groups. We therefore reiterate these comments below and ask you to urge the Commission to include them in the draft proposal before it is adopted.

While PAN Europe considers the draft Regulation satisfactory in terms of setting data requirements at the same high level as for active substances, several limitations must be addressed:.

1) The proposed timeline for the work programme for the gradual review of safeners and synergists currently on the market is unacceptably long: 6.5 years. In view of the gap in the risk-assessment of safeners and synergists and the 9-years delay in implementing Article 26 of Regulation (EC) 1107/2009, **the complete review period should be reduced to a maximum of 3 years.**
2) The data requirements include the identification and proposal of a residue definition for safeners and synergists, where relevant (Article 9(1) §c). However, the draft Regulation does not foresee setting Maximum Residue Levels (MRLs) in food for safeners and synergists. **The legal text should include a reference to establish MRLs for safeners and synergists to comply with the provisions of Article 4(2) of the Regulation (EC) 1107/2009.**
3) The draft Regulation would allow for pesticide products containing a safener or synergist not included in the work programme for gradual review to remain on the market for an additional 5 years after the work programme's adoption. This applies to substances without an application for inclusion in the work program or whose application have been deemed inadmissible. **Pesticide products containing such safeners and synergists must be withdrawn at the national level upon the adoption of the work programme.**
4) Although the draft Regulation refers to Article 4 of Regulation (EC) 1107/2009, it is important to **specify in the legal text that the general provisions of Article 1 in terms of high level of protection and implementation of the precautionary principle are applicable to the assessment of safeners and synergists.**
5) A clear reference to Article 4(2) of Regulation (EC) 1107/2009 and the protection of groundwater is missing. Similarly as to active substances, safeners and synergists, their metabolites and degradation products may spread in different environmental compartments and reach the groundwater. **The draft Regulation should establish the same limit value of 0.1 µg/L in groundwater for safeners and synergists and their relevant metabolites, as set for active substances.**

We call on you to **address the present limitations in the proposals before endorsing it.**

**2. Proposal for renewal of approval of trinexapac as trinexapac-ethyl (B.04)**

PAN Europe takes note of EFSA's updated peer review conclusion that trinexapac-ethyl does not meet the endocrine disrupting criteria set out in points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) 1107/2009. However, the conclusions of this ED assessment do not address all concerns about the substance, namely those identified by EFSA as of 2018. EFSA identified two critical areas of concern, which indicate that the conditions set out in Article 4 and Annex II of Regulation (EC) 1107/2009 are not met. Firstly, EFSA could not determine whether the batches used to conduct the mammalian toxicity studies were representative of the technical specification proposed by the applicant due to data gaps. Further information was deemed necessary to exclude the relevance of some impurities (5 and 9) suspected of being genotoxic. As a result, no safe use could be identified for any of the representative uses. Secondly, EFSA could not finalise the consumer risk assessment for water and food consumption. These two critical areas of concern preclude the renewal of trinexapac as trinexapac-ethyl with no room for appreciation on the part of risk managers in accordance with Regulation (EC) 1107/2009. In addition to this, the substance is classified as very toxic to aquatic life with long lasting effects under Regulation (EC) 1272/2008.

We call on you to **reject the Commission's proposal to renew the approval of trinexapac-ethyl** and support its non-renewal.

**3. Proposal for renewal of approval of metconazole as candidate for substitution (C.01)**

PAN Europe would like to express its concerns about the proposal for renewal of the broad-spectrum fungicide metconazole for a series of reasons.

1) Reprotoxicity of metconazole and its metabolite 1,2,4 triazole: metconazole is suspected of damaging the unborn child (toxic for reproduction category 2) while 1,2,4 triazole is presumed to damage fertility and the unborn child (toxic for reproduction category 1B) in accordance with Regulation (EC) 1272/2008. Therefore, the fact that EFSA claims it could not finalise the consumer risk assessment of metconazole and triazole metabolites is of high concern and should not allow the substance's renewal. Article 4(1) to (3) of Regulation (EC) 1107/2009 provides that a pesticide including its active substance and residues, shall only be approved/authorised when it has no harmful effects on human health, including that of vulnerable groups such as pregnant and nursing women, the unborn, infants and children. Namely, *"an active substance shall only be approved if (...) it is not or has not to be classified (...) as toxic for reproduction category 1A or 1B"* according to point 3.6.4 of Annex II. In accordance with Article 3(1), *"'residues' means one or more substances present in or on plants or plant products, edible animal products, drinking water or elsewhere in the environment and resulting from the use of a plant protection product, including their metabolites, breakdown or reaction products"*. In light of the above provisions and considering the precautionary principle, the approval criteria listed in point 3 of Annex II must also be applied to metabolites to meet the requirements of Articles 4(2) and ensure a high level of protection of human health.

2) Endocrine disrupting substance per mode of action: according to EFSA conclusions, metconazole is not meeting the endocrine disrupting criteria set out in Commission Regulation (EU) 2018/605. Yet, the primary mode of action of the substance is the blocking of ergosterol biosynthesis through inhibition of cytochrome P450 sterol 14-demethylase (CYP51). For this reason, and considering the fact that the substance is approved as a growth regulator on oilseed rape, these conclusions are very disconcerting for PAN Europe. Especially since some articles from scientific literature support the opinion of an A-mediated endocrine effect.
3) Increasing prevalence of azole-resistant strains in *A. fumigatus*: there is growing evidence that azole-resistant *Aspergillus spp.* is diminishing the effectiveness of medicinal azole treatments, leading to harmful consequences for patients. The use of azole fungicides stands as a significant source of the increasing incidence of environmental resistance to *Aspergillus spp* (Zhang J et al, 2021; Danish GW on resistance, Snelders et al, 2012 etc). We note that the EFSA has been mandated to assess the impact of the use of azole fungicides on the development of azole resistant *Aspergillus spp* and that its opinion is expected in Fall 2024. Therefore, in light of existing evidence, we find it highly problematic to propose to renew a fungicide belonging to the triazole group for seven years just a few months before the publication of EFSA's opinion.

In line with Article 1 (3) and (4) and the above, we call on you to **reject the Commission's proposal to renew the approval of metconazole** and support its non-renewal.

**4. Proposal for renewal of approval of captan (C.02)**

Since March 2023, PAN Europe has been expressing its concerns on the Commission's intent to renew the approval of captan, under the restriction to be used in permanent greenhouses. This proposal fails to provide the high level of human, animal and environmental protection required by Regulation (EC) 1107/2009. Captan is an active substance that is suspected of causing cancer (carcinogenic category 2) and which poses long-term high risks to wild mammals, fish, aquatic invertebrates and non-target arthropods. According to EFSA, these ecotoxicological issues stand as critical areas of concern, and thus should preclude the renewal of substance, unless captan's use is restricted to closed spaces. While permanent greenhouses are defined as a closed system in Regulation (EC)1107/2009, in practice they should not be considered closed spaces resulting in no emissions, e.g. where unacceptable effects on the environment can be controlled and prevented. Scientific literature has indeed, on multiple occurrences, raised concerns about greenhouse pesticide emissions into the environment, *via* different pathways (water, air, soil etc). These scientific alarms have been compiled and confirmed by field tests around greenhouses in a report by PAN Europe (read below). In this context, the new Commission's proposal for renewal is inevitably failing to ensure the protection of water systems, the environment and its species as required by Regulation (EC)1107/2009.

We call on you to **reject the Commission's proposal to renew the approval of captan** and support instead its non-renewal.

**5. Proposal for non-renewal of the approval of dimethomorph (C.03)**

PAN Europe strongly supports the long-awaited Commission's proposal for non-renewal of approval of dimethomorph. Since September 2019, dimethomorph is classified as damaging fertility (toxic for reproduction category 1B) under Regulation (EC) 1272/2008. Based on EFSA's conclusions published in May 2023, it is now also considered to have endocrine disrupting effects on both humans and wild mammals as non-target organisms. In accordance with points 3.6.4, 3.6.5 and 3.8.2 of Annex II of Regulation (EC) 1107/2009, such a harmful substance cannot be approved unless exposure to humans and non-target organisms is found negligible. From EFSA's conclusions, it is clear that both dietary exposure (food intake and drinking water) and non-dietary exposure (operators and residents) are not negligible for the representative uses, which cannot be deemed to be addressed by any risk mitigation measures. As a result, it is clear that dimethomorph does not meet the approval requirements laid down in A rticle 4(1) to (3) Regulation (EC) 1107/2009. Namely, the substance meets three cut-off criteria. Its presence on the market thus runs counter to the obligation for Commission and Member States of ensuring a high level of protection of human, animal health and the environment of Regulation (EC) 1107/2009.

**We call on you to endorse the Commission's proposal for non-renewal of approval of dimethomorph.**

**6. Proposal for non-renewal of the approval of mepanipyrim (C. 04)**

PAN Europe supports the Commission's proposal for non-renewal of the approval of mepanipyrim. In August 2023, EFSA published its conclusion on the updated peer review of the risk assessment of the active substance mepanipyrim. This update results from a Commission's request from 2019 to assess the active substance in light of the new scientific criteria to identify endocrine disrupting properties of active substances, laid down in Commission Regulation (UE) 2018/605. According to EFSA's findings, mepanipyrim meets the endocrine disruption criteria for the EAS-modalities for both human health and non-target organisms. This stands as a first critical area of concern. Namely, mepanipyrim was found to induce histopathological changes in the testicular seminiferous epithelium in male rats, deregulate oestrus cycle and ovarian follicular cysts in female rats, as well as to lead to the occasional occurrence of uterine endometrial hyperplasia, hydrometra and uterine adenocarcinoma, and decrease the prostate weight in male dogs. No evidence showing that the conditions of negligible exposure or of the derogation under Article 4(7) could be met was provided by the applicants or any Member States during the periods of submissions specified in Article 14(1)(a) of Commission Implementing Regulation 844/2012. Therefore, in line with Article 4 (1) to (3) and points 3.6.4, 3.6.5 and 3.8.2 of Annex II of Regulation (EC) 1107/2009, mepanipyrim does not meet the approval criteria. Furthermore, a second critical area of concern by EFSA points out a high long-term risk for wild mammals for all representative uses *via* dietary exposure. These findings come on top of mepanipyrim's harmonised classification as suspected of being carcinogen (category 2) and as particularly toxic for aquatic organisms with long term effects (Aquatic acute category 1; Aquatic chronic category 1) under Regulation (EC) 1272/2008. Therefore, it is clear that mepanipyrim causes both harmful effects on the human health and animal health and unacceptable effects on the environment, which must preclude its renewal in accordance with Regulation (EC) 1107/2009. Yet, the approval period of mepanipyrim has been repeatedly extended over the last decade and is now due to expire in March 2025 (initially expiring in October 2014). In accordance with Regulation (EC) 1107/2009

and Article 14(2) of Commission Implementing Regulation 844/2012, the Commission proposal for a non-renewal of the approval of this substance should take effect as soon as possible.

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| We call on you to **endorse the Commission's proposal for non-renewal of the approval of mepanipyrim.** |

**7. Proposal to withdraw the approval of acibenzolar-S-methyl (C.05)**

PAN Europe supports the Commission's decision to review and withdraw the approval of acibenzolar-S-methyl in line with Article 21 of Regulation (EC) 1107/2009. The approval of acibenzolar-S-methyl was renewed in 2016 on the condition that the applicant submits additional information. This information was related to the relevance and reproducibility of the morphometric changes observed in the cerebellum of fetuses linked to exposure to acibenzolar-S-methyl and to examine whether these changes may be produced via an endocrine mode of action. In addition, the applicant was requested to submit further data by 2019 to carry out its endocrine disrupting assessment in light of Regulation (UE) 2018/605. In 2020, EFSA and the Rapporteur Member States (France) considered the confirmatory data were incomplete and could not conclude on the endocrine disrupting properties of the substance. As a result, the Commission requested EFSA to carry out a peer review to further assess the endocrine disrupting properties of acibenzolar-S-methyl. Conclusions, published in June 2021, show that based on the extraordinarily incomplete data set provided by the applicant compared to what is asked in EFSA/ECHA (2018) Guidance, none of the suspected endocrine disruption modalities can be ruled out for humans (E, A, S and T) and for non-target organisms. On the contrary, valid concerns remain, namely because of the outcome of the developmental neurotoxicity study, which showed morphometric changes in the cerebellum and increased auditory startle amplitude. Thus, the applicant has failed to provide the data required in time for its substance to continue to be approved in the EU. It is important that, after all these years, the identified concerns lead to a ban of the substance according to the approval criteria of Regulation (EC) 1107/2006 and the precautionary principle.

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| We call on you to **endorse the Commission's proposal to withdraw acibenzolar-S-methyl** |

**8. Proposal to renew the approval of metrafenone (C.06)**

PAN Europe expresses its disagreement with the European Commission's proposal to renew the approval of metrafenone. This is contrary to Regulation (EC) 1107/2009 and the underpinning precautionary principle, which requires that it *"has been established with respect to one or more representative uses of at least one plant protection product containing that active substance"* that it has no unacceptable effects on the environment, including no endocrine disrupting effects on non-target organisms. In 2023, EFSA published the conclusions on its endocrine disrupting assessment of metrafenone in accordance with the criteria established in Regulation (EU) 2018/605. While it concluded that the criteria according to point 3.6.5 of Annex II of Regulation (EC) No 1107/2009 were not met for the EAS- and T-modalities, EFSA highlighted that further data were required to investigate the endocrine activity through the T-modality for non-target organisms. Hence, no conclusion could be drawn with regard to the endocrine disrupting

properties of metrafenone on non-target organisms, contrary to point 3.8.2 of Annex II of Regulation (EC) 1107/2009. Indeed, according to all peer review experts and in line with OECD TG 248, the results from the Xenopus eleuthero embryonic thyroid signalling assay (XETA) provided by the applicant to investigate the T-modality of metrafenone for non-target organisms, was equivocal and additional information were needed to conclude on the ED potential of the substance.

While the results of the XETA test showed positive effects at the lowest tested concentration when using mixed effects ANOVA (statistical method), experts highlighted that it should not be concluded that the XETA is negative (shows no effect). Indeed, discrepancies of results were obtained when applying other statistical methods recommended in the OECD TG 248. Furthermore, and in line with OECD TG 248, experts considered that individual run should be further investigated for reproducibility of the dose response curve and that it should be considered whether the test has to be repeated. In its conclusions, EFSA points at the need for "*Additional information to fully investigate the endocrine activity through the T-modality for non-target organisms (i.e. a valid and reliable XETA). If the XETA is positive, a mode of action (MoA) should be postulated and further data would be needed to further investigate adversity (i.e. a Larval Amphibian Growth and Development Assay (LAGDA))*" In view of this clear consensus, and given that endocrine disruption posed by active substances stands as one of the cut off criteria laid down in Regulation (EC) No 1107/2009, it is unacceptable that the Commission is proposing to renew the approval of the substance metrafenone.

We call on Member States to **reject this Commission's proposal in line with the Regulation (EC) 1107/2008 and the precautionary principle.**

**9. EFSA conclusions**

**a) Mecoprop-p**

In October 2023, EFSA published its updated peer review on mecoprop-p following 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. Regardless of these conclusions, mecoprop-p cannot be considered to meet 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 a drift reduction during application. This critical area of concern, which indicates that the conditions set out in Article 4 of Regulation (EC) 1107/2009 are not met, particularly regarding the provisions of the Regulation 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 (Aquatic Acute 1) and very toxic to aquatic life with long lasting effects (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, 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 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 of children.

b) **Folpet**: while we note that EFSA did not list any critical area of concern and unfinalised issues, we consider that the neurotoxic potential of flopet as well as its carcinogenicity were insufficiently investigated and its toxicity is therefore underestimated. In a recent study by Paul, K.C. et al, folpet was classified as a Parkinson-relevant pesticide. This finding echoes those of previous research (Fitzmaurice AG et al, 2014). Pesticide-related neurological diseases are rising in the EU and specialists have called policymakers to action to address what they describe as an upcoming "Parkinson's epidemic". Moreover, folpet is classified as suspected of causing cancer (carcinogen category 2) because although intestinal tumours were observed in mice, it was assumed that a safe dose can be established. However, there is no scientific consensus that a safe dose for carcinogens can be established. Moreover, according to an independent analysis of the industry studies submitted in the course of the carcinogenicity assessment, folpet's cancer action is not limited to the intestine of mice. Exposure to folpet induced tumour incidences also in rats and therefore it should have been classified as a presumed to be carcinogen (category 1B) according to Regulation (EC) No 1272/2008. According to Regulation (EC) 1107/2009, substances falling under this category shall not be approved. Last but not least, folpet has also been classified as very toxic to aquatic life .

To ensure the protection of human health, primarily that of the most vulnerable groups of our population and of agricultural workers, and the environment and in accordance with the precautionary principle and the requirement to take account of the most recent scientific evidence and ECHA/OECD guidelines, **we ask you to invite the Commission to propose the non-renewal of approval of folpet.**

c) **Tritosulfuron:** according to the proposal for a REACH restriction, aiming at phasing out PFAS in the EU and the list of PFAS pesticides it provides, tritosulfuron belongs to the group of PFAS. The concerns that arise from this identification are confirmed in the EFSA conclusions published in August 2023. EFSA indeed highlights that tritosulfuron is persistent as well as particularly toxic for aquatic organisms with long term effects (Aquatic acute category 1; Aquatic chronic category 1) according to Regulation (EC) 1272/2008. Moreover, tritosulfuron is metabolised to the very persistent Trifluoraceticacid (TFA) whose toxicity assessment for consumers, birds and mammals, aquatic and soil organisms could not be finalised by EFSA.

In recent years, the persistence of PFAS has led to dangerous levels of pollution of our environment and living organisms, which the EU has recognised as an unacceptable risk and has taken action to address this under the REACH restriction. Similarly, **we ask you to invite the Commission to propose the**

**non-renewal of approval of tritosulfuron** to protect human health and the environment from this deliberate and direct source of PFAS pollution.

d) **Isoflucypram:** EFSA conclusions on isoflucypram are seriously worrisome, according to PAN Europe. First, EFSA identified two critical areas of concern precluding the renewal of the substance. On the one hand, the toxicological profile of isoflucypram relied upon toxicity studies that were not representative of the proposed technical specification for the active substance and associated impurities. On the other hand, there is a high potential for groundwater contamination by the relevant metabolite M12 in all FOCUS scenarios when spring sown and in 8 out 9 FOCUS scenarios when autumn sown. Moreover, the assessment of the endocrine disruption properties of isoflucypram for humans for the T-modality and for non-target organisms for all EATS-modalities could not be finalised because of significant data gaps. As a result it is not possible, for example, to assess the thyroid hormone system toxicity in the most sensitive population of concern. Yet, there is evidence of some adverse effects and of an endocrine mode of action. As a result, it cannot be concluded that isoflucypram has no endocrine disrupting properties as required by point 3.6.5. Considering the cut off nature of ED properties, this unfinalised assessment should stand as a third critical area of concern precluding the substance's reapproval. Last but not least, isoflucypram is classified as suspected of damaging the fertility (toxic to reproduction category 2) under Regulation (EC) 1272/2008.

In the light of the above, **we ask you to invite the Commission to propose the non-renewal of approval of isoflucypram** to protect human health and the environment.

**10. Renewal reports**

**a) Metribuzin**

In August 2023, EFSA published its conclusion of the peer review of the pesticide risk assessment of metribuzin. It lists three critical areas of concern, which in line with Article 4(1) to (3), preclude the reapproval of metribuzin:

- Metribuzin meets the endocrine disruption criteria for humans for the T-modality according to point 3.6.5 of Annex II of Regulation (EC) 1107/2009 and Commission Regulation (EU) 2018/605. No information was submitted by the applicant to demonstrate that dietary and non-dietary exposure to metribuzin is negligible or to demonstrate that the conditions for derogation under Article 4(7) of Regulation 1107/2009 are met during the eligible period for submission set out in Article 14(1)(a) of Commission Implementing Regulation 844/2012.
- Bystander and resident exposure estimates exceed the AOEL value.
- A high risk to bees could not be excluded based on the available studies.

Moreover, metribuzin is classified as acutely toxic when ingested (category 4, H302) particularly toxic for aquatic organisms with long term effects (Aquatic acute category 1; Aquatic chronic category 1) under Regulation (EC) 1272/2008. To ensure a high level of protection of human health, animal health and the environment, and line with the approval criteria set out in Article 4(1) to (3), metribuzin cannot be

renewed. Considering its approval period was initially due to expire in September 2017 and has been continuously extended (now until February 2025), a non-renewal decision should occur in the shortest delay.

**We call on you to invite the Commission to propose a non-renewal of the approval of metribuzin.**

### 11. Confirmatory information: pendimethalin

**Pendimethalin**: PAN Europe is very disappointed that the Commission requests EFSA to organise a peer review on the B potential of pendimethalin, instead of proposing a withdrawal of the approval of this PBT substance. As expressed in our letter and in a previous SCoPAFF position, the Commission should have used the highest bioconcentration factor (BCF) for regulatory purpose to ensure the swift ban of this PBT substance, in line with point 3.7.2 of Annex II of Regulation (EC) 1107/2009 and to make the best use of EFSA's limited resources.

### 12. Guidance document on emergency authorisation (Article 53)

PAN Europe welcomes that the Commission has undertaken work to amend the guidance document on emergency authorisations to comply with the opinion of the EU Court of Justice on the scope of Article 53(1). Namely, the amended guidance document must clarify that:

- no derogation under Article 53 can be provided to EU-banned or EU-restricted pesticides;
- no derogation under Article 53 can be provided to treat seeds with an EU-banned pesticide, no matter where the treated seeds will be marketed (e.g. for EU export);
- any emergency authorisation which does not comply with the opinion of the Court will be cancelled by the Commission. This should start with a cancellation of the Romanian emergency authorisations granted to imidacloprid and thiamethoxam to treat sunflower and maize seeds from January to May 2024, as we wrote to the Commission.
- Member States must thoroughly evaluate if the requests to provide an emergency authorisation are truly needed, in the light of Integrated Pest Management (IPM) and Sustainable Use of pesticides Directive 2009/128/EC. Namely, Member States must carry out a full agronomic assessment, with scientific evidence, a list of non-chemical and chemical alternatives etc. This information must be provided in their notifications to the Commission.

### 13. PFAS (A.12)

In November 2023, a report by PAN Europe and Générations Futures looked at the presence and toxicity of PFAS among EU-approved active substances in pesticides**.** It revealed that 37 active substances currently approved for use in pesticides are PFAS, representing 12% of all synthetic substances approved. The analysis of the approval dossiers of the 10 PFASs with the highest sales in France demonstrated that the majority of these substances are persistent in the environment or give rise to persistent metabolites such as TFA. In addition to being persistent, some of these PFAS AS have other toxic properties. For others, uncertainty remains due to a lack of thorough assessment of their metabolites, their endocrine disrupting properties and their impact on the environment and ecosystems. This gives rise to concerns for

their impact on the environment and/or human health. Therefore, we ask for a **phasing out of the PFAS active substances approved for use in pesticide products in the EU.**

Namely, we call for:

1. the improvement of the implementation of Regulation 1107/2009 until the restriction enter into force, namely by:

- considering **persistence of active substances & their metabolites as an "unacceptable effect on the environment"**, in line with the REACH restriction proposal.
- strictly applying the approval requirement and the precautionary principle by precluding/putting an end to the approval of active substances meeting a cut off criterion or for which EFSA identified critical areas of concerns or for which the assessment of the approval criteria was not finalised due to data gaps.

2. the **inclusion of pesticide active substance within the scope of the PFAS restriction** to ensure a comprehensive phasing out of PFAS pesticides' manufacture, marketing and import in Europe.

**14. Working groups (A.16)**

**Comparative assessment**

While PAN Europe welcomes the substantial progress made by the Commission on the revision of Annex IV, we consider the current proposal maintains several shortcomings. We propose to change the following elements:

- The resistance approach based on the need to have a minimum number of modes of action (MoA) available per crop is actually one of the causes of the ever-increasing resistance of pests and increasing use of pesticide (cocktails) in agriculture. Pesticide reduction will not be possible if we continue down this alley. We ask you to drop the general minimum number of (3) MoA per crop. The chemical diversity in the Annex shall be applied to yearly change a MoA of the existing formulations available, not as an argument for further authorising the candidate for substitution.
- In this proposal it is assumed that resistance always exists, and therefore chemical diversity is essential. Yet, this is not the case. We ask you to include in the proposal the obligation to first assess whether there is resistance of the pests in the crop/candidate for substitution combination. If there is no resistance or hardly any resistance, the diversity element can be directly disregarded. In other words, chemical diversity cannot be a cut-off criterion.
- We welcome the identification of non-chemical methods as the best option. However, non-chemical methods are different from chemical treatment and therefore some elements cannot be compared. For instance, synthetic herbicides kill for nearly 100%, while mechanical weeding doesn't and sometimes has to be repeated. It is not possible to always expect a non-chemical alternative to kill 100% of weeds. We urge you to include in the text that these differences are not a reason to disqualify non-chemical methods as alternatives.
- If non-chemical methods and practices are applied by non-organic farmers, one can claim that the alternative is economically acceptable and has no significant higher costs. We propose to include that if 2% of the non-organic farmers use a non-chemical method or practice, it shall count as a viable alternative in the comparative assessment.
- Since 2014, all farmers are expected to apply IPM as the basis for their crop protection. From this we deduce that the basis of a comparative assessment is IPM. Hence, all available IPM methods

and practices must be included as a legal obligation for farmers who are spraying a candidate for substitution on their fields.

- Although we welcome the lowering of the Toxicity Exposure Ratio (TER) factor, we consider that "at least 5" for chemical alternatives is still too high. We propose replacing it with "at least 2".
- Minor uses must be better controlled, as they open the door to derogations that are unfounded in the current proposal.

**Negligible exposure**

According to PAN Europe, the work on the technical guidance document to assess negligible exposure should be driven by the followed principles:

- **Conditions of use for which negligible exposure is not demonstrated:** in accordance with points 3.6.3. to 3.6.5. of Annex II, all the conditions of use which fail to qualify as a closed system (preventing any release), or to *exclude contacts* with humans, cannot be regarded as negligible. This includes greenhouses and automatic spraying methods, which result in leakage and exposure of the environment and the general population.

- **Reference values**: assuming that the use of reference/safety values will achieve a negligible exposure in certain conditions of use is an inaccurate understanding of the role of reference values in risk assessment. Reference values are intended to achieve an acceptable level of potential exposure of humans and wildlife. Their use can *reduce exposure* but certainly not that they can completely avoid contacts with humans.

- **Risk mitigation measures** are meant to *minimise contact*, not to exclude it as required by Regulation EC 1107/2009. Furthermore, they are adopted at the national level at the Member State's discretion without any EU monitoring scheme to ensure their effectiveness.
- **Environmental exposure**: the above comments also apply to point 3.8.2. The use of natural background level which is insufficient to fulfil the "negligible exposure" requirement.

For further details, we invite you to consult our position paper on negligible exposure.

**15. PAN Europe's contributions on other issues: New report by PAN Europe and partners, "*It Rains Pesticides from Greenhouses*", December 2023**

PAN Europe carried out an analysis and published a report that looks at the pesticide emissions released from greenhouses and how their impacts are currently overlooked by the pesticide approval procedure. In doing so the report provides a review of the scientific literature on the environmental impact of the use of pesticides in greenhouses and carries out some testing, by collecting surface and rainwater samples near greenhouse fields in four member states.

Our report confirms that greenhouses do not operate as closed systems and that harmful pesticides are leaking from them. The main findings are the following:

- Scientific literature has, on multiple occurrences, raised concerns about greenhouse pesticide emissions into the environment, via different pathways (water, air, soil etc);

- The collection of rain and surface water samples reveals an alarmingly high number of pesticides detected: 35 different pesticides in one rainwater sample from the Netherlands and 23 in a surface water sample from Spain.
- Combined concentrations of up to 90 µg/l in Belgian surface water and 21 µg/l in rainwater samples, 180 and 42 times higher than the recently proposed 0.5 µg/l total pesticide threshold in surface waters, were recorded.
- Common pesticides detected include the PFAS pesticide fluopyram, the metabolite 2,6-dichlorobenzamid of dichlobenil, banned since 2008, the endocrine disruptor dimethomorph, classified as toxic to fertility, the PFAS pesticide fluopicolide, the endocrine disruptor boscalid and metalaxyl-M, which has been linked to thyroid cancer.

Our policy demands:

1. **Greenhouses are not a closed space:** Greenhouses should not be considered closed spaces where emissions can be controlled and prevented.
2. **Phasing out active substances approved in greenhouses:** Immediately withdraw the current approval of active substances that are considered toxic in light of the approval criteria laid down in Article 4 of Regulation 1107/2009 and have been banned for use in open fields.
3. **Improve the risk assessment procedure:** The European Commission and Member States need to develop a better understanding of pesticide emissions routes in greenhouses and should provide an adequate risk assessment on the use of pesticides in greenhouses, taking into account their emissions into the environment and potential impacts on human health and environmental species.
4. **Redefine the concept of greenhouses:** A correct definition of greenhouses should be applied, to ensure adequate and harmonised risk assessment for this area of pesticide application in the context of active substance approval, product authorisation and mutual recognition of product authorisations.

From beforehand, thank you for your consideration.

Sincerely yours,

On behalf of PAN Europe

Angeliki Lysimachou
Head of Science and Policy
Pesticide Action Network Europe