Pesticide Action Network Europe

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

Brussels, 16 May 2024

Subject: EU Standing Committee on Plants, Animals, Food and Feed; 22-23 May - position of Pesticide Action Network (PAN) Europe

Dear members of the PAFF committee,

On 22 and 23 May, 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 for renewal of the approval of captan
2. Proposal for renewal of the approval of metconazole
3. Proposal to withdraw the approval of acibenzolar-S-methyl
4. Proposal to withdraw the conditions of use of metalaxyl-M
5. Proposal for extension of the approval period of amisulbrom, s-abscisic acid, thiencarbazone and valifenalate
6. Proposal for renewal of the approval of metrafenone
7. Proposal for renewal of the approval of folpet
8. EFSA conclusions: mecoprop-P, 8-hydroxyquinoline
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1. Proposal for renewal of the approval of captan (B.01)

In January 2024, EFSA published a statement aiming to refine the environmental risk assessment of captan taking into account the new classification recommended by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) namely toxic to reproduction Category 2, STOT RE1 and Aquatic Chronic Category 1. This statement does not demonstrate that the substance meets the safety requirements of Regulation (EC) 1107/2009 to be renewed. In this respect, PAN Europe would like to highlight the following:

- First, as mentioned in our previous communication, one of our main concerns is that a restriction of the use of captan to permanent greenhouses will not eliminate the identified risks to non-target species, as these are not closed systems. A report by PAN Europe - compiling scientific alarms about the environmental impact of the use of pesticides in greenhouses and field test data- demonstrated that greenhouses do not control and certainly do not prevent pesticide emissions into the environment. This means they cannot protect non-targeted organisms from the unacceptable effects of pesticide substances such as captan. This is not addressed by EFSA which brings no indication that permanent greenhouses are closed spaces in its statement.

- This EFSA statement highlights a genuine risk to consumers *via* drinking water consumption following the classification of captan as toxic for reproduction (category 2), which comes on top of its exciting classification as carcinogenic (category 2). The new classification means that the groundwater metabolites THPI and THPAM become toxicologically relevant since their potential for reproductive toxicity has not been investigated. According to the EFSA's conclusion from 2020, while the metabolites THPI and THPAM were found above 0.1 µg/L for the use for strawberries in greenhouses, this threshold was exceeded in the majority of the FOCUS groundwater scenarios for other uses. Furthermore, the metabolites THPI and THPAM are expected to occur in groundwater, particularly if crops are grown in soil in permanent greenhouses.

In this context, the new Commission's proposal for renewal is inevitably failing to ensure the protection of consumers, 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.

2. Proposal for renewal of the approval of metconazole (B.02)

PAN Europe reiterates 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 its metabolite 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 could not finalise the consumer risk assessment of metconazole and its triazole metabolites, is of high concern and should preclude the renewal of the substance's approval. 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, the definition of which includes "*pregnant and nursing women, the unborn, infants and children*" (Article 3(14)). 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"* (point 3.6.4 of Annex II). According to 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"*. Therefore, a high level of protection should also be expected from metabolites that are toxic to the vulnerable groups of our population, such as 1,2,4 triazole. In light of the above provisions and considering the precautionary principle, the approval of metconazole should not be renewed.

2) Endocrine-disrupting substance per mode of action: according to EFSA conclusions, metconazole does not meet 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 because the substance is approved as a growth regulator on oilseed rape, these conclusions are very disconcerting. Especially as recent scientific literature supports 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 received a mandate 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 another 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.

3. Proposal to withdraw the approval of acibenzolar-S-methyl (B.03)

PAN Europe reiterates its support of 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 foetuses 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 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 Guidance (2018), 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.

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

4. Proposal to withdraw the conditions of use of metalaxyl-M (B.04)

PAN Europe would like to express concerns about the current attempts to lower the protection from metalaxyl-M, for which EFSA has already concluded a high acute and long-term risk for birds and mammals for all representative uses. Furthermore, we disagree with the declassification of the relevant metabolite NOA409045 as non-relevant based on the negative *in vivo* micronucleus study submitted by the applicant. The substance has undergone a limited assessment particularly for long term toxicity, and in relation to toxicological endpoints such as developmental toxicity and neurotoxicity and therefore its safety cannot be concluded.

Importantly, metalaxyl-M is still detected in surface waters in the Netherlands and Belgium, indicating that the 2020 restriction of its use in seeds grown in greenhouses is not sufficient to protect environmental exposure and unacceptable effects on the environment (see 2023 PAN Europe report "It rains pesticides from greenhouses"). The proposed restrictions fail to ensure the safe use of metalaxyl-M, and therefore the approval requirements laid down in Article 4(1 to 3) of Reg. (EC) 1107/2009 are not met. Evidently the approval of metalaxyl-M should be withdrawn.

We call on you to **reject the Commission's proposal to partly waive the condition of approval of metalaxyl-M** and call instead for a **withdrawal of the substance.**

5. Proposal for extension of the approval period of amisulbrom, s-abscisic acid, thiencarbazone and valifenalate (B.07)

Once again, PAN Europe deplores the Commission's proposal to extend their approval period of four active substances for two or more years. While the approval period for these four substances is to expire at the end of September 2024, the proposal foresees extending their approval until the end of 2026/beginning of 2027. Hence, this proposal will grant Member States and EFSA almost twice the time foreseen in the applicable regulations to carry out their re-evaluation (2 years and a half); prolonging in the meantime the exposure of citizens and the environment to these harmful substances.

Indeed, the four concerned active substances have already been classified as suspected or known to cause harm to human health and the environment under Regulation (EC) 1272/2008. This makes their reassessment in light of the most recent scientific knowledge urgent to ensure the substances comply with the approval criteria of Regulation (EC) 1107/2009.

- Amisulbrom is classified as suspected of being carcinogenic (category 2) and as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1/Aquatic Chronic 1).
- Valifenalate is also classified as suspected of being carcinogenic (category 2) and as toxic to aquatic life with long-lasting effects (Aquatic Chronic 2). Moreover, the compliance of the batches tested in the mammalian toxicology and ecotoxicology data packages with the proposed specification could not be demonstrated back in 2013, raising some significant concerns about the reliability of its assessment.
- S-abscisic acid is classified as very toxic to aquatic life with long-lasting effects (Aquatic Acute 1/Aquatic Chronic 1).
- Thiencarbazone: is classified as very toxic to aquatic life with long- lasting effects (Aquatic Acute 1/Aquatic Chronic 1).

Given the above, we call on you to embrace a precautionary risk management approach and oppose any delay in the assessment of these substances to ensure that no active substances, possibly failing to comply with the approval requirements of Regulation (EC) 1107/2009, remain on the EU market.

We call on you to **reject the Commission's proposal to extend the approval of amisulbrom, s-abscisic acid, thiencarbazone and valifenalate.**

6. Proposal for renewal of the approval of metrafenone (C.02)

PAN Europe deplores that the European Commission maintains its proposal of January 2024 to renew the approval of metrafenone despite the concerns identified, as we highlighted previously. 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"* has no unacceptable effects on the environment, namely no endocrine-disrupting (ED) effects on non-target organisms. In 2023, EFSA published the conclusions on its endocrine disrupting assessment of metrafenone in line 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 for humans, 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 concerning 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 was needed to conclude on the ED potential of the substance.

The results of the XETA test showed positive and statistically significant effects (ANOVA) at the lowest tested concentration but discrepancies in results were obtained when applying other statistical methods recommended in the OECD TG 248. Experts highlighted that it should not be concluded that the XETA is negative (shows no effect) based on other statistical methods. Furthermore, the experts considered that individual runs should be further investigated for reproducibility of the dose-response curve and examine whether the test has to be repeated. In its conclusions, EFSA points to 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))*". Given this clear consensus and because endocrine disruption posed by active substances for non-target organisms 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. A similar level of protection against endocrine disruptors is required for non-target species as for humans.

We call on Member States to **reject this Commission's proposal in line with the provisions of Regulation (EC) 1107/2009 and the precautionary principle.**

7. Proposal for renewal of the approval of folpet (C. 03)

PAN Europe is highly concerned to observe that the Commission is moving forward with a proposal to renew the approval of folpet. While EFSA did not list any critical area of concern and unfinalised issues, 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 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 call on you to reject the Commission proposal for renewal of approval of folpet.**

8. EFSA conclusions (A.06)

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 for children.

b) 8-hydroxyquinoline

PAN Europe is pleased to see that EFSA's conclusions on the peer review of the reprotoxic substance 8-hydroxyquinoline were finally published at the end of March 2024. It clarifies that negligible exposure of humans cannot be demonstrated for that "cut-off" substance, including when used in permanent greenhouses (current conditions of approval). It confirms that the substance does not meet the approval criteria of Regulation (EC) 1107/2009, namely Article 4(1) and point 3.6.4 of Annex II. As a result, it is crucial that the Commission and Member States immediately proceed with banning 8-hydroxyquinoline, which has been classified as damaging the unborn child since September 2019 (i.e. toxic for reproduction 1B), on top of being very toxic to aquatic life with long-lasting effects (Aquatic Acute 1/Aquatic Chronic 1). It also highlights the crucial need to improve the current procedures for the Commission and Member States to comply more strictly with the hazard-based requirement of Article 4(1) by immediately banning substances that meet one of the "cut-off" criteria. Acting differently, as done in the case of 8-hydroxyquinoline, leads to the exposure of citizens (workers in this case) and the environment to a harmful substance. It was the responsibility of risk managers to prevent such a detrimental situation and swiftly address it now banning 8-hydroxyquinoline.

In line with Article 20(2) of Regulation (EC) 1107/2009, PAN Europe would like to remind the Commission and Member States that when the approval of an active substance is not renewed because of immediate concerns for human health, all products containing that substance shall be withdrawn from the market immediately. We thus call the Commission to request Member States not to grant any transitional and grace periods for products containing 8-hydroxyquinoline and withdraw them from the market with immediate effect. .

We call on you to request from the Commission to **propose a regulation on the non-renewal of 8-hydroxyquinoline and require an immediate withdrawal from the EU market of products containing the substance, in accordance with Article 20(2)-(3) of Regulation (EC) 1107/2009.** This proposal should be submitted to vote during the next SCoPAFF meeting planned on 28th June.

9. Draft review/renewal reports (A.05)

a) Pydiflumetofen

PAN Europe is calling upon the Commission and Member States to ban the approval of the active substance pydiflumetofen, a succinate dehydrogenase inhibitor fungicide, by considering its very high persistence as an unacceptable effect. This demand is in line with the scientific recommendation that chemicals should be regulated based on their persistence alone to prevent irreversible impacts on human health and the environment. The fact that this substance is a biologically active fungicide further strengthens this argument. Moreover, pydiflumetofen has a difluoromethyl group and therefore is a PFAS according to the OECD 2021 definition of PFAS (contains at least one saturated CF2 or CF3 part).

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 into the environment, such as dichlorodiphenyltrichloroethane (DDT), chlordane and recently PFAS, due to an underestimation of their impacts during their risk assessment. The release of highly persistent substances can lead to particularly high concentrations in the environment, thereby increasing the risk of causing adverse effects on human health and other species. In the case of pydiflumetofen, there are already some toxicity concerns. 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 (i.e. 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 be addressed very carefully by risk managers for such a persistent substance to which concentration levels might be high for humans and the environment. Moreover, the 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 levels of the tested substance.

Finally, pydiflumetofen is a succinate dehydrogenase inhibitor (SDHI) fungicide. The potential adversity relative to a SDHI fungicide mode of action in humans was found inconclusive by EFSA, raising valid concerns. The latter is supported by the results of independent peer-reviewed studies published in 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 (Kerhoas *et al*, 2024). It was also found to enhance CYP3A4 mRNA expression in human hepatic HepaRG cells and primary human hepatocytes (Kerhoas *et al*, 2024). Lastly, a study has pointed out the acute and developmental toxicity of pydiflumetofen toward embryos, larvae, and adult zebrafish (Wang *et al*, 2022).

Another concern with persistent substances is the time it takes to reverse contamination and relevant costs once they are found to be more toxic than originally anticipated. 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 future 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 contamination and protect human health and the environment from future harm.

b) Flutolanil

According to the proposal for a REACH restriction, aiming at phasing out PFAS in the EU and the list of PFAS pesticides it provides, flutolanil belongs to the group of PFAS. This is confirmed by EFSA in its conclusions published in June 2023. According to EFSA, flutolanil is persistent (P) to very persistent (vP) and forms the very persistent and very mobile metabolite trifluoroacetic acid (TFA). Moreover, the potential for immunotoxicity of flutolanil could not be excluded based on existing data and should be further investigated according to EFSA. Another significant concern about flutolanil is that the consumer risk assessment could not be finalised because of lacking data on the presence and toxicity of relevant metabolites (including TFA) for the 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 be present in surface water when surface water is abstracted for the production of drinking water.

We call on you to invite the Commission to **propose the non-renewal of flutolanil** to protect European citizens from a direct and deliberate exposure to this PFAS substance.

c) Tritosulfuron

According to the proposal for a REACH restriction, aiming at phasing out PFAS in the EU, 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) Metribuzin

In August 2023, EFSA published its conclusion of the peer review of the pesticide risk assessment of metribuzin. It listed 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) and 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 in line with the approval criteria set out in Article 4(1) to (3), metribuzin must not 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 as soon as possible. It came to PAN Europe's attention that the "Metribuzin Task Force" is questioning the critical areas of concern identified by EFSA and that the Commission requested EFSA to update its conclusions on metribuzin. PAN Europe, in turn, is questioning the legal basis of such a procedure and would like to raise concerns on any additional delays, resulting in the continuous exposure of citizens and the environment to a substance which clearly does not meet the approval criteria laid down in Article 4 of Regulation 1107/2009 to remain in the market. When it comes to assessment for endocrine disruption, we would like to stress that in accordance with Article 13 (3a) of Commission Implementing Regulation 844/2012, information to assess approval criteria set out in point 3.6.5 and point 3.8.2 of Annex II and the conditions for the application of the derogation under Article 4(7) had to be submitted in a strict legal timeline. It follows, in line with Article 13(5) that information submitted by the application after the expiry of this period for submission or without having been requested shall not be taken into account.

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

10. Confirmatory information (A.06)

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 purposes 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.

11. Guidance Documents (A.07)

Emergency authorisations - Article 53

PAN Europe considers that the Court ruling C-162/21 of the European Court of Justice should be fully implemented. Substances that have been banned, not renewed, or not approved (such as 1,3-dichloropropene) because of health and environmental concerns, should not be given derogations to be used in emergency situations under Article 53. **The new guidance document should mention 'non-approved substances' and not only 'non-approved uses'**. In the same vein, substances for which no renewal was requested by the industry, or for which the renewal request was withdrawn during the reapproval procedure, should also not be given a derogation. Indeed, providing derogations to substances that are harmful to human health and/or the environment but were not re-assessed by EFSA, is not in line with the precautionary principle. In some cases, the withdrawal even takes place after a negative opinion has been concluded from EFSA, identifying numerous data gaps or critical areas of concern. Providing derogations to such substances would be in opposition to the Court ruling. **This is particularly unacceptable in cases such as 1,3-dichloropropene: this substance is highly toxic to humans and the environment, and its application dossier was rejected twice. Nevertheless, Member States, such as Spain, provide yearly derogations to a pesticide that is easily replaced by simple alternatives such as crop rotation.**

Furthermore, PAN Europe recommends taking into account the opinion of the Advocate General. Only complete and detailed dossiers should be accepted, enabling national competent authorities

to carry out an in-depth evaluation of the real needs of a derogation. The dossiers should provide information on the economic threshold that justifies the need for the specific derogation as well as details on the available alternatives, whether used alone or in combination. Those must be thoroughly assessed by staff that are knowledgeable on alternatives to synthetic pesticides.

PAN Europe would also like to take the opportunity of the revision of the guidance document to ask for clarification about the meaning of the "Authorisation holder". Indeed, it appears that some Member States indicate the name of the pesticide company that produces and sells the pesticide, while others put the entity applying for the derogation. An emergency authorisation to sell a pesticide is evidently given to the pesticide industry, but this doesn't provide information about the end-user, which it should. PAN Europe would suggest renaming this category to "Applicant for emergency authorisation".

More specifically, PAN Europe asks to make it clear that derogations should be asked for by end-users only, e.g. by farmers or farmers associations or eventually by public authorities (in case of use of non-authorised biocontrol in public areas) but in no case by the pesticide industry itself, that has a strong conflict of interest.

Finally, PAN Europe has identified that a series of Member States submit the information to the E-Submission Food Chain (ESFC) platform sometimes months after the derogation period is over. To improve transparency on this important environmental information, PAN Europe asks to add a deadline to submit the information, e.g. maximum of 2 weeks after the decision to grant the derogation is taken.

Negligible exposure

PAN Europe welcomes the Commission's resumption of work on negligible exposure and emphasizes the importance of conducting such assessments promptly, based on guidelines agreed upon by risk managers. These guidelines should ensure a high level of protection from harmful pesticides, as foreseen in Regulation (EC) 1107/2009. In this context, PAN Europe is concerned about the lack of transparency and inclusiveness surrounding the ongoing work, and the risk of lowering the level of protection. Therefore, it's important to take into consideration the following:

- In accordance with points 3.6.3. to 3.6.5. of Annex II, all the conditions of use that fail to qualify as a closed system (preventing any release), or to exclude contacts with humans, cannot be regarded as negligible. Residues in food must not exceed the default value (of 0.01 mg/kg or below). This means that all **situations which fail to prevent any release of a substance to the environment or/and that result in direct or indirect human exposure to that substance** should lead to the conclusion that the substance does not meet the requirement of negligible exposure and therefore should be banned.
- **Safeners and synergists**: the negligible exposure requirements also apply to safeners and synergists found to be toxic for reproduction 1A/B, carcinogen 1A/1B or having

endocrine disrupting properties. This means that food residues of these substances shall not be found above 0.01 mg/kg of the relevant Level of Quantification. While the EU recently adopted an implementing regulation to approve safeners and synergists in the EU, this text does not foresee the setting of MRLs for those substances. Likewise, the concentration of safeners and synergists and their relevant metabolites in groundwater and drinking water shall not exceed the limit value of 0.1 µg/L in line with the rules applicable to active substances. In the absence of such regulatory values in food and water, PAN Europe considers that negligible exposure of humans to safeners and synergists cannot be demonstrated.

- Margin of Exposure: 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. These are intended to establish an acceptable level of potential exposure of humans and wildlife for substances that do not fall under the hazard class criteria of Article 4(1). Their use can reduce exposure but should not be assumed that these will result in no contacts with humans and/or non-target species.
- Risk mitigation measures are meant to minimise contact and should not be assumed that their application will result in "no contact" 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.
- **Non-target organisms**: Clear conditions should be established of what negligible exposure to an endocrine-disrupting substance would mean both for humans and non-target organisms to ensure a harmonised approach complying with the requirements of point 3.8.2 of Regulation 1107/2009. A guidance that does not address both requirements should be considered incomplete and should not be adopted.

12. **Carbendazim (A.18)**

PAN Europe is opposed to the Commission's and Member States' approach of keeping the MRLs above the default value of 0.01mg/kg or the relevant Level of Quantification (LOQ) for active substances that meet one of the cut-off criteria of Regulation (EC) 1107/2009 for human health, especially once their ban has entered into force. This practice contradicts the joint purpose of Regulations (EC) 1107/2009 and 396/2005 to ensure a high level of protection of EU citizens from pesticides and their residues.

Carbendazim is classified as mutagenic category 1B and toxic for reproduction category 1B. Following points 3.6.2-3.6.6 of Annex II of Regulation 1107/2009, it has been banned in the EU since 2014 to protect human health, particularly that of the most vulnerable groups. Pregnant women, babies and children shall not be exposed to that hazardous substance or its residues. Article 32(2) of Regulation (EC) 396/2005 makes clear that import tolerances are "MRL(s) set for imported products (...) where the use of the active substance in a plant protection product on a given product is not authorised in the Community **for reasons other than public health reasons**". It follows that import tolerances cannot be set when a substance is banned in the EU because it harms human health (explained in details here).

Allowing residues of banned and hazardous pesticides in food contradicts the Farm to Fork commitment to eliminate double standards between the EU and third countries and drive the global transition towards a sustainable food system. In a letter, PAN Europe urged the Commission to lower the MRLs to the default value of 0.01 mg/kg or to the relevant LOQ the MRLs of all food products for all reprotoxic substances no longer approved in the EU. We also highlighted that a similar approach should be adopted for all hazardous substances falling under the cut-off criteria of Article 4(1) and Annex II, including those with endocrine-disrupting properties.

From beforehand, thank you for your consideration.

Sincerely yours,

On behalf of PAN Europe

Angeliki Lysimachou
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Pesticide Action Network Europe