Pesticide Action Network Europe

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

Brussels, 6th July 2023

Subject: EU Standing committee on Plants, Animals, Food and Feed - 11-12 July 2023 - position of Pesticide Action Network (PAN) Europe

Dear members of the PAFF committee,

On 11th and 12nd July, 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 to extend the approval's period of 25 active substances
2. Proposal to renew the approval of captan
3. Proposal to renew the approval of ethephon
4. Proposals for non-approval of asulam sodium and non-renewal of the approvals of metiram, benthiavalicarb, clofentezine and triflusulfuron-methyl
5. Proposal for non-renewal of the approval of s-metolachlor
6. EFSA conclusions on flutolanil and dimethomorph
7. Confirmatory information on flutianil
8. EFSA Guidance Document on the risk assessment of plant protection products on bees
9. Working group on comparative assessment

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1. Proposal to extend the approval's period of 25 active substances, including flufenacet and chlorotoluron (B. 04)

PAN Europe reiterates its concerns to see a proposal for the approval period of no less than 25 active substances to be extended. This proposed prolongation is coming on top of many past ones and includes active substances whose reapproval can reasonably be questioned in the light of the strict safety requirements of Regulation (EC) 1107/2009.

With this proposal, flufenacet's approval (2004-2013) will be prolonged for an eighth time and chlotoroluron's approval (2006-2016) for a seventh time. Both substances were added to the list of candidates for substitution in 2015 because of their persistent and bioaccumulative properties. Furthermore, chlorotoluron is classified as both suspected of causing cancer (carcinogen category 2) and of damaging the unborn child (toxic for reproduction category 2). In fact because of its toxic potential the European Parliament has already objected three times in the previous prolongations of the approval period of chlorotoluron. Until recently, it was considered as meeting the interim criteria of endocrine disruption for humans in accordance with point 3.6.5 of Annex II, and therefore did not comply with the conditions of approval under Article 4. Instead of a non-renewal decision, the interim classification was waived with the adoption of the new scientific criteria of 2018, and the finalisation of its assessment based on these new criteria is still pending. It is unacceptable that due to these delays this harmful substance is now proposed to remain in the market for yet another year. On its side, flufenacet was added to the list of PFAS active substances in the proposed PFAS restriction of February 2023, raising additional concerns regarding its environmental toxicity.

These two examples support PAN Europe's claim that the ever-increasing risk assessment delays are working against the general purpose and requirements of Regulation (EC) 1107/2009 of ensuring a high level of protection of human health, animal health and the environment and applying the precautionary principle.

We call on Member States to **reject this Commission's proposal in line with the precautionary principle and to increase their resources** to remedy these structural delays.

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2. Proposal to renew the approval of captan (C. 01)

Since March 2023, PAN Europe has been expressing its concerns on the Commission's proposal to renew the approval of captan, under the restriction to be used in permanent greenhouses. To us, 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 has been classified as suspected of causing cancer (carcinogenic category 2) and which poses long-term high risks to birds, mammals, aquatic organisms, bees and non-target arthropods other than bees for all its representative uses according to EFSA. Furthermore, important data gaps regarding contamination of surface and drinking water remain. As a result, it cannot be expected that captan meets the approval requirements of Regulation (EC)1107/2009, namely due to its unacceptable effects on the environment. These unacceptable effects cannot be addressed by restricting the use of captan to permanent greenhouses. Both field studies and monitoring data have shown that greenhouses are not closed systems. To PAN Europe, this proposal is bypassing the approval requirements of Regulation (EC) 1107/2009.

We call on you **to reject the Commission's proposal to renew the approval of captan with restrictions and support instead its non-renewal** to ensure the protection of water systems, the environment and its species.

3. Proposal to renew the approval of ethephon (C. 04)

PAN Europe has serious reservations about the Commission's proposal to renew the approval of ethephon. These concerns relate to the assessment of its endocrine disrupting properties on non-target organisms in accordance with point 3.8.2 of Annex II of Regulation (EC) 1107/2009. According to the EFSA's conclusions of January 2023, ethephon has unanimously been considered as not meeting the endocrine disruption criteria laid down in point 3.6.5 of Annex II for humans. However, no consensus has been reached between experts, EFSA and the rapporteur Member States regarding its properties for non-target species *via* the EAS modalities. In its conclusions, EFSA seems to have opted for the least precautionary option, contrary to what the experts had agreed. To PAN Europe, a serious scientific doubt remains, which requires the implementation of the precautionary principle in decision-making while further scientific investigation is carried out.

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The concerns result from the changes in the gonad histopathology for species of both sexes and an increase of mineralisation observed in the Fish Short-Term Reproduction Assay (FSTRA, OECD TG 230) performed. These effects evidenced a weak but positive endocrine disrupting activities of ethephon for the EAS modalities, as reported in the summary of the meeting TC 88 which took place in August 2022. As a result, the majority of the experts agreed that an additional study was required to draw conclusions. In line with the Guidance Document for the identification of endocrine disruptors in the context of Regulations (EU) 528/2012 and (EC) 1107/2009, a level 5 study was needed but eventually experts agreed on a level 4 study (OECD TG 234 - FSDT). Yet, we observe that this agreement is not reflected in EFSA conclusions, which instead refer to the "*weight of evidence and the analysis of uncertainties*" to dismiss any pattern of endocrine activity and the need for further study (including the level 4 study experts had agreed on). This does not appear to be in line with the precautionary principle laid down in Article 1(4) of Regulation (EC) 1107/2009. PAN Europe considers there is at present no sufficiently robust evidence to state that the ethephon has no unacceptable effects on the environment as required by Article 4(1) to (3) and has no endocrine disrupting properties that may cause harm to non-target organisms as required by point 3.8.2 of Annex II of Regulation (EC) 1107/2009.

We ask you to **reject this Commission's proposal** to renew the approval of ethephon.

4. Proposals concerning the non-approval of asulam sodium and the non-renewal of the approvals of metiram, benthiavalicarb, clofentezine and triflusulfuron-methyl (C. 06 to C.10)

PAN Europe would like to give its full support to the Commission's five proposals to ban a series of active substances identified as endocrine disruptors according to the new scientific criteria of 2018. The active substances in question - asulam sodium, benthiavalicarb, clofentezine, metiram and triflusulfuron-methyl - were all found to meet the endocrine disrupting criteria for humans. Triflusulfuron-methyl was additionally found to disrupt the endocrine system of wild mammals as non-target organisms. As a result, these substances do not meet the approval criteria set out in Article 4(1) to (3) of Regulation (EC) 1107/2009 and in point 3.6.5. of Annex II, and in point 3.8.2. of Annex II in the case of triflusulfuron-methyl. Yet, the ban of these cut-off substances has been delayed, sometimes by several years, initially due to delays in risk assessment, and then

due to lengthy discussions on the possibility of applying Article 4(7) to approve these harmful substances by a way of derogation.

The possibility to apply Article 4(7) is restricted to circumstances where the "*active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods*". However, in recent years, EFSA has published protocols on Article 4(7) which are not aligned with these strict legal requirements and lead to inconsistencies in its individual conclusions on these five substances. On the one hand, chemical and non-chemical alternatives are clearly acknowledged by EFSA, but on the other hand, these solutions are dismissed on the basis of a methodology which diverges from the provisions of Article 4(7), and thus from the general purpose of ensuring a high level of protection for human and animal health and the environment of Regulation (EC) 1107/2009. As alternatives have been identified by EFSA itself for all uses of these five active substances, these proposals by the Commission reflect a compliant interpretation of Article 4(7) of Regulation (EC) 1107/2009. These are also aligned with the European Green Deal commitments to better protect its citizens and future generations from endocrine disrupting chemicals and to cut by 50% the use of more hazardous pesticides by 2030.

We call on you **to uphold the Commission's interpretation of Article 4(7)** and **support these five Commission's proposals.**

5. Proposal for non-renewal of the approval of s-metolachlor (C. 11)

PAN Europe reminds its support to the Commission's proposal for non-renewal of the approval of the active substance s-metolachlor, as we expressed in our letter to Commissioner Kyriakides. The risk assessment conclusions published by EFSA in February 2023 have confirmed the presence of several critical areas of concern, already identified in 2022, which prevents the substance to meet the approval requirements of Regulation (EC) 1107/2009. Namely, EFSA's conclusions have shown the potential of the substance and its toxicologically relevant metabolites to exceed the parametric drinking water limit of 0.1 µg/L, and cause groundwater contamination, for all representative uses, as indicated by monitoring data. For some of these metabolites there were concerns or data gaps in relation to genotoxicity and/or carcinogenicity. Furthermore, s-metolachlor is also posing a high risk to earthworm-eating mammals. Based on

these results, it is evident that the substance does not meet the requirements laid down in Article 4(1) to (3) of Regulation (EC) 1107/2009.

We ask you to **support this proposal** for non-renewal of approval of S-metolachlor to swiftly ensure the protection of consumers, groundwater and biodiversity.

6. EFSA conclusions on dimethomorph, flutolanil and glyphosate (A. 04)

a) EFSA conclusions on Dimethomorph

Since September 2019, dimethomorph is classified as damaging to fertility (toxic for reproduction category 1B). 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 appears clearly that both dietary exposure (food intake and drinking water) and non-dietary exposure (operators and residents) are not negligible for the representative uses and can't 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 article 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 invite the **Commission to propose a non-renewal of the approval of** dimethomorph to ensure a high level of protection of human health.

b) EFSA conclusions on flutolanil

EFSA conclusions on flutolanil were published in June 2023. It is emphasised that four areas of the risk assessment could not be finalised as a result of data gaps regarding:

- the representativeness of the used test material,
- the immunotoxicity potential of flutolanil,
- the toxicity to humans and the environment of several metabolites (M-101, M-102, M-02, TFA) of flutolanil,

- the lack of information on the effect of water treatment processes on the nature of the residues of flutolanil and metabolite M-11.

On top of this series of issues, PAN Europe would like to bring to your attention the recent identification of flutolanil as a PFAS (TFA precursor) as part of the proposed restriction of PFAS in the EU. Active substances used in pesticides are not covered by the scope of this proposed restriction on the grounds that Regulation (EC) 1107/2009 is better suited than Regulation (EC) 1907/2006 ("REACH") to tackle the presence of PFAS in pesticides. To that end, the restriction's proposal came with the recommendation that further measures to regulate PFAS should be considered in the context of Regulation (EC) 1107/2009. PAN Europe observes that the EFSA's conclusions do not mention this commitment to ban group of PFAS chemicals as a whole and the explicit identification of flutolanil as a PFAS. Likewise, EFSA does not put any particular emphasis on the high persistence of metabolite M-11. Therefore, PAN Europe believes this PFAS identification should be a point of discussion between Member States and the Commission, on top of the other issues raised by EFSA and reported above.

We call on you to invite the **Commission to propose a non-renewal of the approval of** flutolanil in line with the EU commitment to ban PFAS.

c) EFSA conclusions on glyphosate

PAN Europe will communicate separately on EFSA's conclusions on glyphosate renewal on 6th July.

7. Confirmatory information on flutianil (C. 06)

PAN Europe's concerns regarding the handling of the submitted confirmatory information on endocrine disruption of flutianil by the Commission remain unchanged. Flutianil was approved in April 2019 providing that confirmatory data were submitted by the applicant, in line with Article 6(7) of Regulation (EC) 1107/2009. To our concern, this included data regarding its endocrine disrupting potential for humans and non-target organisms. Based on the information submitted in 2021, EFSA concluded that flutianil does not meet the criteria for endocrine disruption for humans. However, no conclusion was reached on its endocrine disrupting potential for non-target organisms because of flaws in the design of the study submitted by the applicant. More specifically, this study contained a solvent, which undermined the assessment of the solubility properties of the substance. It led EFSA's experts to conclude that the highly debatable

design of this study was making it impossible to draw conclusions on whether flutianil met the criteria for endocrine distortion for non-target organisms laid down in points 3.8.2 of Annex II of Regulation (EC) 1107/2009.

As a result, we stress again that the submitted confirmatory information has failed to address at least one of the points raised in the approval Regulation of flutianil. At the end of this confirmatory information procedure, it cannot be expected that flutianil still meets the approval requirements of Regulation (EC) 1107/2009. This requires action from the Commission and Member States. Indeed, in accordance with article 21(3) of Regulation (EC) 1107/2009, where *"the approval criteria provided for in article 4 are no longer satisfied, or the further information required in accordance with article 6(f) has not been provided, a Regulation to withdraw or amend the approval shall be adopted"*. This important provision is reflected in the guidance document SANCO/5634/2009 on confirmatory information. Article 21(3) also echoes Article 4, as well as the precautionary principle set out in Article 1(3) of Regulation (EC) 1107/2009.

Consequently, we ask to oppose the continuous approval of flutianil and call **to withdraw the approval** of flutianil as required by Regulation (EC) 1107/2009.

8. EFSA Guidance Document on the risk assessment of plant protection products on bees (A. 07)

PAN Europe welcomes the updated version of the Bee Guidance Document recently published by EFSA. Since the first alerts on the decimation of honey bee hives due to neonicotinoids, and the failure of the risk assessment procedure, it is evident that risk assessment of pesticides on bees is of major importance. Pollination ecosystem services represent ~15 billion euros while they also ensure the perennity of wild plants.

Ten years after the publication of the first version of this guidance document, PAN Europe reiterates its call on the Member States to **endorse this new guidance document without delay**. Nevertheless, we would also like to reiterate our criticism of the 10% mortality accepted by Member States. Considering the fact that bees are exposed to a cocktail of pesticides, simultaneously with other stressors such as pathogens or lack of resources, PAN Europe considers that this figure is unsustainable and might reduce the positive impact of the

progress made with the new Bee Guidance Document. We therefore ask Member States to **review their position and reduce it to 3%.**

9. Working group on comparative assessment (A. 16)

PAN Europe welcomes the resumption of the Working Group on Comparative Assessment and Substitution, while strongly criticising the lack of transparency that surrounds this work. Following the first working group's meeting in May, the Commission shared with Member States an amended proposal for Annex IV of Regulation 1107/2009. While we welcome this substantial progress, we consider the current proposal maintains several shortcomings.

Thus, 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.

We have asked the Commission to share PAN Europe's detailed comments on its proposal on CIRCAB. We hope they will stimulate your reflections and future discussions on comparative assessment.

From beforehand, thank you for your consideration.

Sincerely yours,

Angeliki Lysimachou
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