Pesticide Action Network Europe

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

Brussels, 4th October 2023

Subject: EU Standing committee on Plants, Animals, Food and Feed - 12/13 October 2023 - position of Pesticide Action Network (PAN) Europe

Dear members of the PAFF committee,

On 12st and 13rd October, 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 renew the approval of glyphosate
2. Proposal to renew the approval of ethephon
3. Proposals for non-approval of asulam sodium and non-renewal of the approvals of metiram, benthiavalicarb, clofentezine and triflusulfuron-methyl
4. Proposal for non-renewal of the approval of s-metolachlor
5. Proposal to renew the approval of captan
6. EFSA conclusions on flutolanil, dimethomorph, metribuzin, and mepanipyrim
7. Confirmatory information on pendimethalin
8. PFAS
9. EFSA Guidance Document on the risk assessment of plant protection products on bees
10. Working groups on comparative assessment and negligible exposure

1. Proposal to renew the approval of glyphosate (B. 03)

PAN Europe has repeatedly expressed its concerns on the re-approval of glyphosate, due to the identified potential impacts on human health and biodiversity. Glyphosate is currently the most popular herbicide in Europe, it's used for agricultural and non-agricultural purposes, and recent monitoring data confirm that it is widely detected in the urine of European citizens, including children, and it is ubiquitous in the environment. Therefore, any scientific evidence linking exposure to health effects should be taken carefully into consideration and should lead to strict regulatory measures aiming at ensuring a high level of protection of human health and the environment in line with Regulation (EC) 1107/2009.

The Commission's proposal as it stands is concerning. It entails the renewal of the EU approval of glyphosate for 10 years, with no restrictions included in the text to minimise its use apart from pre-harvest desiccation, which is already restricted in certain Member States. This decision is alarming in light of the considerable amount of scientific knowledge on its toxicity, both through independent research, as well as through industry data. Particularly, scientific evidence shows that glyphosate can potentially cause carcinogenicity and genotoxicity, as well as oxidative stress. It disrupts people's microbiome and potentially the endocrine system, causes neurotoxicity and massively harms biodiversity. Below we provide a summary of these findings.

We've previously highlighted that the evidence from animal studies and epidemiology studies, combined with the evidence that glyphosate may cause DNA damage in certain organs (other than bone marrow), indicate the potential of glyphosate to cause cancer, according to the EU (CLP) and international guidelines (OECD Guidance document 116). We also indicated that two genotoxicity studies were absent from that applicant's dossier, as confirmed by ECHA. Nevertheless, Member State authorities, ECHA and EFSA have downplayed all this evidence, while renowned independent institutes such as International Agency for Research on Cancer, the French Health Institute Inserm and the Belgian Health Council have concluded that based on all the available evidence a probable link between glyphosate exposure and cancer development is undeniable.

Recent scientific studies show that even low levels of exposure to glyphosate and the representative formulation MON 52276 (0.05 to 50 mg/kg), far lower than those tested in animal carcinogenicity studies, may cause oxidative stress and toxicity in certain organs and/or induce genotoxicity biomarkers- which may support the evidence on the non-Hodgkin lymphoma development in humans. Disregarding this evidence, the EU authorities have concluded on the genotoxicity of the formulation, based solely on 2 in vitro genotoxicity tests, despite having indications that certain of its components (formaldehyde, glyphosine) are carcinogenic or potentially genotoxic, and there are missing toxicity data for one of the co-formulants. The EU case law (Case C-616/17) indicates that the applicants have to show that the active substance as

well as the product that contains it cause no long-term toxicity and carcinogenicity. Not only this has not been demonstrated by the applicants for glyphosate, but scientific findings clearly indicate that the glyphosate formulation is genotoxic.

However, genotoxicity and carcinogenicity may be only the tip of the iceberg. Recent research shows that low levels of glyphosate and the representative formulation (MON 52276) that are considered safe, disrupt the microbiome. Glyphosate interfering with human and animal microbiomes should not come as a surprise, since it's also an antibiotic agent. Nevertheless, it is extremely worrying considering the number of health impacts and diseases that microbiome disruption is linked to. EFSA acknowledges the impact of glyphosate and glyphosate-based products on microbiome and the possible consequences on health but wrongfully stated that in the absence of standardised protocols conclusions cannot be drawn. This was clarified recently by Advocate General Medina in her opinion on case C-308/22, stating that "*that if there are no guidance documents… then the Member States are obliged under that regulation to carry out the assessment and adopt authorisation decisions based on other available sources that do contain most recent scientific and technical knowledge*".

In relation to the neurotoxicity potential of glyphosate, the applicants missing out to submit the DNT study on glyphosate trimesium salt revealing adversity in pups, is a violation of the EU law, for which we hope that you follow with an infringement procedure. Glyphosate has the capacity to pass the blood-brain barrier and has been detected in the brain of exposed animals, where it induces inflammation markers, linked to the development of Alzheimer's disease and other neurodegenerative disorders. Moreover, exposure to glyphosate has been linked to autism spectrum disorders in children exposed from prenatal age, Amyotrophic lateral sclerosis (ALS) and Parkinson's disease in adults. The two acute and two subchronic neurotoxicity studies submitted by the applicants are insufficient to examine such long-term neurodegenerative effects. EFSA acknowledges that there are indications that glyphosate-based herbicides cause neurodevelopmental toxicity, but wrongfully missed to identify this as a critical area of concern.

In relation to the impact on environmental non-target species and biodiversity, a big volume of scientific literature indicates that glyphosate & the representative formulation cause adverse effects, therefore glyphosate doesn't meet the criteria to be approved laid in Regulation 1107/2009. EFSA's peer review acknowledges some of the adverse effects, such as the long-term impact on macrophytes, amphibians, herbivorous small mammals, as well as the impact on biodiversity via indirect effects and trophic interactions. In fact, in mammals, a low risk was identified at uses of the representative formulation towards the lower range of application rates (0.54-0.72 kg a.s./ha), indicating that exceeding those would cause higher toxicity. The impact on amphibians was not thoroughly investigated by the applicant. In relation to biodiversity impact, EFSA and Member State experts have wrongfully concluded that conclusions cannot be

drawn in the lack of harmonised methodologies, as was recently clarified by AG opinion in C-308/22.

Considering the above-mentioned remarks, it is unacceptable that the current proposal intends to reauthorise glyphosate for 10 years, overlooking the plethora of toxicity studies, particularly from independent literature, indicating the toxic potential of glyphosate and the representative formulation. It completely contradicts the provisions of the EU law and the precautionary principle. The applicants have clearly failed to demonstrate the long-term safety of glyphosate and/or the representative formulation. Furthermore, the Commission is now passing the responsibility to Member States, who do not test the long-term toxicity and carcinogenicity of the products, which will inevitably lead to misleading conclusions about their safety. The additional non-binding recommendations of use are simply insufficient to ensure any protection of the health of workers and residents of agricultural zones, including children, as well as of the environmental ecosystems and biodiversity.

PAN Europe asks you to **reject the Commission's proposal to renew** the approval of glyphosate for 10 years with hardly any restrictions on use.

2. Proposal to renew the approval of ethephon (B. 02)

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.

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 indicate a weak but positive endocrine disrupting activity 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 is not 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.

3. Proposals concerning the non-approval of asulam sodium (B. 04) and the non-renewal of the approvals of metiram (B. 07), benthiavalicarb (B. 05), clofentezine (B. 06) and triflusulfuron-methyl (B. 09)

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. These five substances all present additional issues of concerns ranging from a CMR category 1 classification, worrying consumer exposure to high risk for the environment. Yet, the ban of these very hazardous 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.

In this respect, we reiterate that the use of 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). Furthermore, the alleged serious danger to plant health is systematically insufficiently demonstrated. The proposals for non-approval/renewal of these five substances by the Commission reflect a compliant interpretation of the conditions to

apply 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 the Commission's proposals for non-approval of asulam sodium and the non-renewal of the approvals of metiram, benthiavalicarb, clofentezine and triflusulfuron-methyl.**

4. Proposal for non-renewal of the approval of s-metolachlor (B. 08)

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 conclusions of the risk assessment published by EFSA in February 2023 have confirmed the presence of several critical areas of concern, already identified in 2022, which precludes 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.

5. 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.

6. EFSA conclusions on dimethomorph, flutolanil, mepanipyrim and metribuzin (A.05)

a) EFSA conclusions on 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 the light of the new scientific criteria to identify endocrine disrupting properties of active substances laid down in Commission Regulation 2018/605. According to EFSA's findings, mepanipyrim meets 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 in female rats and ovarian follicular cysts in female rats, decrease the prostate weight in male dogs and to lead to the occasional occurrence in female rats of uterine endometrial hyperplasia, hydrometra and uterine adenocarcinoma. 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. 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 appears clearly 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 should propose a non-renewal approval of the substance taking effect as soon as possible.

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

b) EFSA conclusions on 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 acute 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 was 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**.

c) EFSA conclusions on dimethomorph

Since September 2019, dimethomorph is classified as damaging 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 promptly propose a non-renewal of the approval of** dimethomorph to ensure a high level of protection of human health.

d) 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 persistence of the active substance in water (DT 224 days) and the very high persistence of metabolite M-11 (DT50 1000 days in soils, waters and sediments). 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.

7. EFSA Guidance Document on the risk assessment of plant protection products on bees (A. 07-5)

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%.**

8. Confirmatory information on pendimethalin (A. 06)

In 2017, pendimethalin was reapproved as a candidate for substitution as it fulfilled the criteria as persistent (P) and toxic (T) set out in points 3.7.2.1 and 3.7.2.3 of Annex II to Regulation (EC) 1107/2009. However, in its peer review which preceded this renewal decision, EFSA could not exclude the bioaccumulation (B) potential of the substance. As a result, and in accordance with Article 6(f) of Regulation (EC) 1107/2009, this renewal of pendimethalin's approval was conditioned on the submission of further confirmatory information regarding the potential for bioaccumulation (B) of pendimethalin. In particular, the applicant was requested to provide a reliable BCF value for bluegill sunfish *(Lepomis macrochirus)* by 31 December 2018. Considering that active substances meeting the PBT criteria cannot be approved in the EU, the submission of this information was crucial to ensure the substance's approval is in line with the approval requirements of Regulation (EC) 1107/2009.

The supporting publication published in light of the submitted confirmatory data published by EFSA in 2021 shows that the BCF value for *Lepomis macrochirus* was found to exceed the trigger value of 2,000 L/kg for a B classification. It was highlighted that this BCF value might underestimate the degree of the bioaccumulation potential of pendimethalin as the TOC of the exposure medium was artificially increased by adding humic. This is contrary to OECD TG 350 which recommends keeping the TOC at the lowest possible level as it can affect the chemical bioavailability. Yet, because the applicant carried out further unsolicited studies for four other species which underscored BCF values below 2000 L/kg, the Commission decided to mandate EFSA and ECHA to give guidance to define BCF for regulatory purposes when data from more than one species are available. To date, no guidance was provided and pendimethalin is still approved despite convincing evidence that it meets the PBT criteria and therefore pose unacceptable effects on the environment as set out in point 3.7.2.3 of Annex II to Regulation (EC) 1107/2009.

PAN Europe strongly condemns these sluggish developments which undermine the hazard-based approach and precautionary principle underpinning Regulation (EC) 1107/2009. BCF studies for *Lepomis macrochirus* are frequently used as the only species to decide on the B classification of active substances and, in the presence of several BCF values, the highest valid BCF value should be considered according to ECHA 2017 Guidance on REACH Chemical Safety Assessment. Therefore, based on the existing evidence provided as part of the confirmatory information procedure and in line with the requirements of Regulation (EC) 1107/2009 including the precautionary principle, pendimethalin should be regarded as meeting the PBT criteria. Its approval should be withdrawn in accordance with Article 4 (1) to (3), Article 21 and point 3.7.2 of Annex II Regulation (EC) 1107/2009 in the shortest delay.

We call on you to invite the **Commission to propose a withdrawal of the approval of pendimethalin**.

9. PFAS (A. 12)

In 2020, the EU pledged "*to ensure that the use of PFAS is phased out in the EU, unless it is proven essential for society"* as one of the key commitments of EU Chemical Strategy for Sustainability to achieve a toxic free environment. In early 2023, a proposal for a universal restriction on per- and polyfluoroalkyl substances (PFAS) was submitted to the European Chemical Agency (ECHA). This proposal listed 47 active substances meeting the OECD definition of PFAS, including 38 active substances still approved to date.

A time-unlimited derogation to the restriction is proposed for the 38 active substances approved for use in pesticide products in accordance with Regulation (EC) 1107/2009. While PAN Europe welcomed this regulatory initiative to address PFAS pollution and the inclusion of co-formulants in its scope, we have replied to ECHA public consultation to highlight that the derogation granted to PFAS active substances is unjustified. The approval of PFAS active substances is a stark demonstration of the regulatory blindspots in the implementation of Regulation (EC) 1107/2009 to address their harmful presence. As pesticide products containing PFAS deliberately and directly contaminate the environment, they constitute an unacceptable source of PFAS contamination which require strong regulatory action to phase them out now.

We call for a **phasing out of the PFAS active substances** approved for use in pesticide products in the EU.

10. Working groups (A. 16)

a) 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.

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.

b) 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.

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From beforehand, thank you for your consideration.

Sincerely yours,

Angeliki Lysimachou
Head of Science and Policy
Pesticide Action Network Europe