Pesticide Action Network Europe

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

Brussels, 15 March 2024

Subject: EU Standing committee on Plants, Animals, Food and Feed - 20-21 March - position of Pesticide Action Network (PAN) Europe

Dear members of the PAFF committee,

On 20 and 21 March, 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 approval of captan
2. Proposal for non-renewal of the approval of dimethomorph
3. Proposal for non-renewal of the approval of mepanipyrim
4. Proposal to extend the approval of 20 substances including four PFAS
5. Proposal for renewal of the approval of metrafenone
6. Proposal for renewal of the approval of metconazole as a candidate for substitution
7. Proposal to withdraw the approval of acibenzolar-S-methyl
8. EFSA conclusions
9. Draft renewal reports
10. Confirmatory information: pendimethalin
11. Guidance on emergency authorisations according to Article 53 of Regulation (EC) No 1107/2009
12. PFAS

Pesticide Action Network Europe

1. **Proposal for renewal of 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 previously mentioned, 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 non-renewal of the approval of dimethomorph (B. 02)**

PAN Europe strongly supports the long-awaited Commission's proposal for the non-renewal of the approval of dimethomorph. Since September 2019, dimethomorph has been classified as damaging fertility (toxic for reproduction category 1B) under Regulation (EC) 1272/2008. Based on EFSA's

conclusions published in May 2023, it is now also considered to have endocrine disrupting effects on both humans and wild mammals as non-target organisms. In accordance with points 3.6.4, 3.6.5 and 3.8.2 of Annex II of Regulation (EC) 1107/2009, such a harmful substance cannot be approved unless exposure to humans and non-target organisms is found negligible. From EFSA's conclusions, it is clear that both dietary exposure (food intake and drinking water) and non-dietary exposure (operators and residents) are not negligible for the representative uses, which cannot be deemed to be addressed by any risk mitigation measures. As a result, it is clear that dimethomorph does not meet the approval criteria 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 of the Commission and Member States to ensure a high level of protection of human, animal health and the environment as specified by Regulation (EC) 1107/2009.

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

3. Proposal for non-renewal of the approval of mepanipyrim (B.03)

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

which must preclude its renewal in accordance with Regulation (EC) 1107/2009. Yet, the approval period of mepanipyrim has been repeatedly extended over the last decade and is now due to expire in March 2025 (initially expiring in October 2014). In accordance with Regulation (EC) 1107/2009 and Article 14(2) of Commission Implementing Regulation 844/2012, the Commission proposal for a non-renewal of the approval of this substance should take effect as soon as possible.

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

4. Proposal to extend the approval of 20 substances including four PFAS substances (B.04)

PAN Europe is highly critical of the systematic practice of the Commission and Member States of extending substances' approval periods because the (re)approval procedure has not been completed within the legal timeframe. This practice is unacceptable, particularly when prolongations concern substances for which there is evidence indicating that their use may cause harm to humans and/or the environment. The extension of their authorisation period clearly contravenes the requirement of Articles 1(3) and 4(1) to (3) of Regulation (EC) 1107/2009 and its legal provisions of ensuring a high level of protection of human and animal health and the environment from harmful pesticides.

In 2020, the EU pledged to phase out PFAS in Europe as they pose an unacceptable risk for human health and the environment. The present proposal includes four active substances meeting the PFAS OECD definition and included in the EU list of PFAS active substances of the proposal for a PFAS restriction. Three of these four PFAS substances are approved as candidates for substitution under Regulation (EC) 1107/2009. In accordance with Article 24 of the Regulation, the approval of candidates for substances shall not exceed seven years.

- Fluometuron was initially approved until May 2021. It was included in the list of candidates for substitution by Commission Implementing Regulation (EU) 2015/408 in light of its low Acceptable Daily Intake (ADI).
- Prosulfuron was renewed as a candidate for substitution in May 2017 given its persistent (P) and toxic (T) properties for aquatic organisms. This approval period shall expire in April 2024 in line with Article 24 of Regulation (EC) 1107/2009.
- Tau-fluvalinate was initially approved until May 2021. It is classified as particularly toxic for aquatic organisms with long term effects (Aquatic acute category 1; Aquatic chronic category 1) under Regulation (EC) 1272/2008.
- Tembotrione was approved until July 2024 and included in the list of candidates for substitution by Commission Implementation Regulation (EU) 2020/1295 because of its low acceptable ADI and acceptable operator exposure level (AOEL). According to Regulation (EC) 1272/2008, it is

also classified as suspected of being toxic for reproduction (category 2) and as particularly toxic for aquatic organisms with long term effects (Aquatic acute category 1; Aquatic chronic category 1).

The EU has committed to phase out PFAS pollution in Europe and there is already available evidence about the harmful effects of these four specific PFAS active substances or their metabolites on human health, animal health and/or the environment. Taking this into consideration together with the fact that other potential adverse effects such as impact on the immune system or the nervous system have been poorly investigated or not investigated at all, these four PFAS substances must be swiftly banned.

We call on Member States **to reject this Commission's proposal and proceed to immediate non-approvals of above-mentioned substances, in line with Regulation (EC) 1107/2009 and the EU commitment to phase out PFAS in Europe.**

5. Proposal for renewal of the approval of metrafenone (C. 01)

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

The results of the XETA test showed positive and statistically significant effects (ANOVA) at the lowest tested concentration but discrepancies of 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 at the need for "*Additional information to fully investigate the endocrine activity through the T-modality for non-target organisms (i.e. a valid and reliable XETA). If the XETA is positive, a mode of action (MoA) should be postulated and further data would be needed to further investigate adversity (i.e. a Larval Amphibian Growth and Development Assay (LAGDA))*" In view of this clear consensus, and given that endocrine disruption posed by active substances 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.**

6. Proposal for renewal of the approval of metconazole as a candidate for substitution (C. 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 claims it could not finalise the consumer risk assessment of metconazole and triazole metabolites is of high concern and should not allow 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 towards 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 is not meeting the endocrine disrupting criteria set out in Commission Regulation (EU) 2018/605. Yet, the primary mode of action of the substance is the blocking of ergosterol biosynthesis through inhibition of cytochrome P450 sterol 14-demethylase (CYP51). For this reason, and considering the fact that the substance is approved as a growth regulator on oilseed rape, these conclusions are very disconcerting. Especially as some articles from scientific literature support the opinion of an A-mediated endocrine effect.
3) Increasing prevalence of azole-resistant strains in *A. fumigatus*: there is growing evidence that azole-resistant *Aspergillus spp.* is diminishing the effectiveness of medicinal azole treatments, leading to harmful consequences for patients. The use of azole fungicides stands as a significant source of the increasing incidence of environmental resistance to *Aspergillus spp* (Zhang J et al, 2021; Danish GW on resistance, Snelders et al, 2012 etc). We note that the EFSA has 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.

7. Proposal to withdraw the approval of acibenzolar-S-methyl (C. 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 fetuses linked to exposure to acibenzolar-S-methyl and to examine whether these changes may be produced via an endocrine mode of action. In addition, the applicant was requested to submit further data by 2019 to carry out its endocrine disrupting assessment in light of Regulation (UE) 2018/605. In 2020, EFSA and the Rapporteur Member States (France) considered the confirmatory data were incomplete and could not conclude on the endocrine disrupting properties of the substance. As a result, the Commission requested EFSA to carry out a peer review to further assess the endocrine disrupting properties of acibenzolar-S-methyl. Conclusions, published in June 2021, show that based on the extraordinarily incomplete data set provided by the applicant compared to what is asked in EFSA/ECHA 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**

8. EFSA conclusions (A. 04)

a) Tritosulfuron

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

In recent years, the persistence of PFAS has led to dangerous levels of pollution of our environment and living organisms, which the EU has recognised as an unacceptable risk and has taken action to address this under the REACH restriction. Similarly, **we ask you to invite the Commission to propose the non-renewal of approval of tritosulfuron** to protect human health and the environment from this deliberate and direct source of PFAS pollution.

b) Mecoprop-P

In October 2023, EFSA published its updated peer review on mecoprop-p following its endocrine disruption assessment. Overall, EFSA concluded that the endocrine disrupting criteria of points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) 1107/2009 were not met for the EATS-modalities for humans and non-target organisms. Regardless of these conclusions, mecoprop-p cannot be considered to meet the approval criteria of Regulation (EC) 1107/2009 with regard to the critical area of concern identified by EFSA in 2023. The predicted exposure to residents is above the AOEL for children entering treated areas (75th percentile), even by applying a buffer strip of 10 m and a drift reduction during application. This critical area of concern, which indicates that the conditions set out in Article 4 of Regulation (EC) 1107/2009 are not met, particularly regarding the provisions of the Regulation aiming to ensure that products placed on the market and their residues *"shall not have any harmful effects on human health, including that of vulnerable groups*" (Recital 24; Article 4(2) & (3)). Moreover, mecoprop-p is classified

as very toxic to aquatic life (Aquatic Acute 1) and very toxic to aquatic life with long lasting effects (Aquatic Chronic 1) as well as harmful if swallowed and causing serious eye damage under Regulation (EC) 1272/2007. Therefore, it cannot be concluded that the use of the substance does not cause any harm to human health or does not have any unacceptable effects on the environment. Nevertheless, the approval of mecoprop-p has been repeatedly extended for a total of 9 years and a half. It is high time that citizens, including agricultural workers, and the environment stop being exposed to this hazardous substance.

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

9. Draft Renewal report (A.05)

a) 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 applies 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.

b) Folpet

While we note that EFSA did not list any critical area of concern and unfinalised issues, we consider that the neurotoxic potential of flopet as well as its carcinogenicity were insufficiently investigated and its toxicity is therefore underestimated. In a recent study by Paul, K.C. et al, folpet was classified as a Parkinson-relevant pesticide. This finding echoes those of previous research (Fitzmaurice AG et al, 2014). Pesticide-related neurological diseases are rising in the EU and specialists have called policymakers to action to address what they describe as an upcoming “Parkinson's epidemic”. Moreover, folpet is

classified as suspected of causing cancer (carcinogen category 2) because although intestinal tumours were observed in mice, it was assumed that a safe dose can be established. However, there is no scientific consensus that a safe dose for carcinogens can be established. Moreover, according to an independent analysis of the industry studies submitted in the course of the carcinogenicity assessment, folpet's cancer action is not limited to the intestine of mice. Exposure to folpet induced tumour incidences also in rats and therefore it should have been classified as a presumed to be carcinogen (category 1B) according to Regulation (EC) No 1272/2008. According to Regulation (EC) 1107/2009, substances falling under this category shall not be approved. Last but not least, folpet has also been classified as very toxic to aquatic life .

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

c) Metribuzin

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

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

Moreover, metribuzin is classified as acutely toxic when ingested (category 4, H302) particularly toxic for aquatic organisms with long term effects (Aquatic acute category 1; Aquatic chronic category 1) under Regulation (EC) 1272/2008. To ensure a high level of protection of human health, animal health and the environment, and line with the approval criteria set out in Article 4(1) to (3), metribuzin cannot be renewed. Considering its approval period was initially due to expire in September 2017 and has been continuously extended (now until February 2025), a non-renewal decision should occur in the shortest delay.

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

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10. Confirmatory information: pendimethalin (A. 06)

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

11. Guidance on emergency authorisations according to Article 53 (A. 07)

PAN Europe welcomes that the Commission has undertaken work to amend the guidance document on emergency authorisations. This amendment must bring the guidance document into line with the judgement of the EU Court of Justice on the scope of Article 53(1).

Namely, the amended guidance document must clarify that:

- The Court ruling applies to all pesticides that have been banned or restricted to protect human and animal health, and the environment, as acknowledged by the European Commission during the hearing in the ENVI committee of the European Parliament on 6 March 2023. Therefore, no derogation under Article 53 can be provided to EU-banned or EU-restricted pesticides. PAN Europe considers that this judgement also applies to pesticides whose applications for approval have been rejected for failing to meet the approval criteria (e.g. 1,3-dichloropropene);
- Furthermore, no derogation under Article 53 can be provided to treat seeds with an EU-banned pesticide, no matter where the treated seeds will be marketed (e.g. for EU export);
- Member States must thoroughly evaluate if the requests to provide an emergency authorisation are truly needed, in the light of Integrated Pest Management (IPM) and Sustainable Use of pesticides Directive 2009/128/EC. Namely, Member States must carry out a full agronomic assessment, with scientific evidence, including a list of non-chemical and chemical alternatives that have been considered etc. This information must be provided in their notifications to the Commission.

Any emergency authorisation which does not comply with the above elements of the judgement of the Court will be cancelled by the Commission. This should start with a cancellation of the Romanian emergency authorisations granted to imidacloprid and thiamethoxam to treat sunflower and maize seeds from January to May 2024, as we wrote to the Commission.

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12. PFAS (A. 12)

As the Commission and the Member States will soon decide on whether to renew the approval of the PFAS active substances tritosulfuron and flutolanil, PAN Europe would like to bring to your attention the concerning findings of its report about PFAS pesticides in EU food 'Toxic Harvest: the rise of forever pesticides in fruit and vegetables in Europe'. The report examined the presence of PFAS pesticides in fruit and vegetables grown in the EU and imported over the decade 2011 to 2021. Alarmingly, this investigation, which is based on official data from the EU Member State monitoring programmes for pesticide residues in food, reveals an increasing exposure of European consumers to PFAS pesticides.

Key findings of the study include:

- Residues of 31 different approved PFAS pesticides were detected in fruit and vegetables in the EU between 2011 and 2021;
- The number of fruit and vegetables containing residues of at least one PFAS pesticide in the EU has tripled in 10 years;
- In 2021, European-grown fruits such as strawberries (37%), peaches (35%) and apricots (31%) were particularly contaminated, often containing cocktails of three to four different PFAS in a single fruit;
- The Netherlands, Belgium, Austria, Spain, Portugal and Greece are the leader producers of PFAS-contaminated food within the EU, while countries such as Costa Rica, India and South Africa are for the EU the main exporters of high-PFAS laden food.

The findings raise serious environmental and human health concerns. PFAS pesticides are deliberately sprayed on crops making food consumption a direct and systematic route of exposure to PFAS for EU consumers.

The EU Pesticides Regulation (EC) 1107/2009 aims to ensure that active substances (or products and their residues) placed on the market do not adversely affect human or animal health or the environment. Yet, 37 active substances that are PFAS are currently approved in the EU, according to the official list provided in the PFAS restriction proposal. These account for 16% of the synthetic active substances approved for use in conventional farming within the EU, representing a significant proportion.

An earlier report by PAN Europe and Générations Futures demonstrated that PFAS pesticide substances are in fact not adequately regulated by the Pesticides Regulation. This is because of poor implementation of the Law's provisions and lack of regulation of "persistence" of active substances and that of their metabolites. It was concluded that, unless urgent additional action is undertaken, the current pesticide risk assessment procedure will not lead to the phase-out of PFAS pesticides in line with the EU pledge to ban all unnecessary PFAS in the framework of the EU Chemical Strategy for Sustainability. Our current report confirms these previous findings. By zooming in on the top 10 most detected PFAS substances in fruit

and vegetables, there is evidence of their persistence or that of their metabolites (incl. TFA), along with their known or potential toxicity to human health.

Starting with tritosulfuron and flutolanil as well as pydiflumetofen, we urge you to take immediate action to protect Europeans and the environment from the harmful effects of PFAS contamination by banning PFAS active substances in pesticides by:

- Considering persistence of an active substance or that of its metabolites as an unacceptable effect for the environment, in light of the intrinsic toxic properties of synthetic active substances and the cumulative nature of the PFAS pollution.
- Revising Annex II of the Pesticide Regulation to ban Persistent, Mobile and Toxic (PMT) and very Persistent and very Mobile (vPvM) active substances.
- Improving the implementation of the EU Pesticide Regulation to ensure a high level of protection for humans, animals, and the environment.
- Banning the manufacture (and in turn export) as well as the import of PFAS pesticides by ensuring active substances are included in the scope of the proposal for a PFAS restriction

You may find more information following the links to our technical report and our policy briefing, together with an analysis of the top 10 PFAS pesticides and our policy demands.

More detailed analyses are available for Austria, Belgium, France, Germany, the Netherlands and Spain.

From beforehand, thank you for your consideration.

Sincerely yours,

On behalf of PAN Europe

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