Pesticide Action Network Europe

PFAS in pesticides

PAN Europe's response to the public consultation on the proposal for a universal restriction of per- and polyfluoroalkyl substances (PFAS)

Pesticide Action Network (PAN) Europe welcomes the proposal for a restriction on per- and polyfluoroalkyl substances (PFAS) submitted to the European Chemical Agency (ECHA) by the authorities of Denmark, Germany, the Netherlands, Norway and Sweden. Considering the widely acknowledged harm to human health and the environment caused by PFAS, a universal REACH restriction is crucial for the EU to meet its commitment to move towards a toxic free environment. Nevertheless, PAN Europe considers that the current proposal for a restriction must be improved "*to ensure that the use of PFAS is phased out in the EU, unless it is proven essential for society*" as pledged in the EU Chemical Strategy for Sustainability. In particular, the time-unlimited derogation granted to active substances approved for use in pesticides under Regulation 1107/2009[1] is not justified according to PAN Europe. This response aims to substantiate this claim and therefore, **calls upon the ECHA scientific Committees (RAC and SEAC) to include active substances used in pesticides in the scope of this PFAS restriction.**

PAN Europe is a non-profit organisation gathering expertise and knowledge on the harms to humans and the environment caused by synthetic pesticides and on the EU regulation of pesticides authorisation and use.

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[1] Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market.

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I. State of the play

i. Regulatory status of PFAS pesticides approved in the EU

Pesticides contain one or more active substances i.e., the component that is declared as acting against the targeted 'harmful' organism (pest). Additionally, various substances are added to enhance the pesticides' toxicity and/or efficiency towards their target. Depending on their role, these substances are called, according to the Regulation 1107/2009, synergists (enhancing the toxicity of the declared active ingredient), safeners (increasing crop tolerance to the declared active substance), co-formulants (any other added substance, e.g., anti-foaming agents, solvents, surfactants), or adjuvants (separate products made up of co-formulants, that are mixed with a pesticide formulation just before use, to enhance its effectiveness or other pesticidal properties). All these compounds are due to be regulated by Regulation 1107/2009 whose aim is to ensure a high level of protection of human health, animal health and the environment. Where these chemicals are also being used for industrial purposes, they must be registered under the REACH Regulation.

According to Regulation 1107/2009, active substances, safeners, synergists, co-formulants and pesticide formulations shall have no harmful effects on human health, including that of vulnerable groups, or animal health and no acceptable effects on the environment. To ensure this high level of protection, active substances, safeners, synergists must undergo an explicit approval system, while co-formulants found harmful must be listed as unacceptable. Following individual assessment of each of these components, pesticide formulations must undergo an authorisation process prior to being put on national markets.

While the PFAS restriction includes chemicals that fall under the remit of other EU Regulations than the REACH 1907/2006 Regulation (Food Contact Materials Regulation, Cosmetics Regulation), active substances used in pesticides whose approval is governed by Regulation 1107/2009, are specifically excluded from the scope of the proposal. Instead, these substances deliberately sprayed on crops in open fields, which thereby contaminate the environment and food, have been granted a time-unlimited derogation on the assumption that they will be properly dealt with under Regulation 1107/2009. On their part, co-formulants used in pesticide products are included under the scope of this restriction proposal but safeners, synergists and adjuvants are not mentioned.

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Regulatory status of PFAS active substances under Regulation 1107/2009

In appendix A.3.17 of the proposal for a restriction, the rapporteurs have listed 46 active substances used in pesticide products meeting the OECD definition of PFAS[2]. According to PAN Europe, the list actually entails 47 active substances with tritosulfuron (EC No 604-291-0/CAS No 142469-14-5) and triflum**u**ron (EC No 264-980-3/CAS No 64628-44-0) standing as two different substances instead of one as indicated in appendix A.3.17[3]. Out of these 47 listed active substances, 38 are still approved for use in pesticides under Regulation 1107/2009 in August 2023 (Table 1), while 9 of them were removed from the EU market between 2017 and 2023, in three cases due to an explicit non-renewal decision by the Commission (Table 2).

Furthermore, and contrary to what seems to be assumed in the proposal for a restriction, most of these 38 approved active substances are not identified as 'more concerning' due to their persistence and toxicity properties, what would imply that they are subject to stricter authorisation requirements[4][5]. Indeed, only 11 out of these 38 substances are approved as candidates for substitution (CfS) in accordance with Article 24 and point 4 of Annex II of Regulation 1107/2009. Of these 11 substances, only 7 were found as meeting two of the PBT criteria during risk assessment (Table 1). Thus, this classification, which in accordance with Article 50(1) of Regulation 1107/2009 requires Member States to substitute them, applies only to one fifth of the identified PFAS active substances used in pesticide products. Furthermore, it must be noted that even for these substances the substitution requirement was implemented in such a very limited number of times since its introduction under Regulation 1107/2009 that the Commission itself acknowledged that "*the expected benefits for human health or the environment from substituting these more hazardous active substances have not materialised.*"[6]. This is confirmed by the fact that, according to the EU Pesticides Database[7], these 11 approved PFAS active substances that are CfS, instead of being substituted with safer alternatives, are authorised in pesticide products in the majority of Member States. However, due to a lack of data on individual substances' sales and uses, it is impossible to estimate the extent of contamination resulting from the approval of these 11 CfS or of any of the 38 PFAS substances.

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[2] Although 48 active substances are announced in the restriction report (Annex XV, p. 72).
[3] Appendix A.3.17 refers to the substance "triflum**o**ron/tritosulfuron" (p. 270). Triflum**o**ron does not exist contrary to triflumuron.
[4] See page 73 of Anne XV of the restriction report.
[5] See point 4 of Annex II of Regulation (EC) No 1107/2009 listing the identification criteria for candidates for substitution.
[6] COM, Report, Evaluation of Regulation (EC) No 1107/2009 and of Regulation (EC) No 396/2005 EUR-Lex - 52020DC0208 - EN - EUR-Lex (europa.eu)
[7] EU Pesticides Database - Active substances (europa.eu)

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Table 1: 38 active substances meeting the OECD PFAS definition approved under Regulation 1107/2009

Active substance	Period of approval	Status (CfS or not)	Reason for being a CfS
Beflubutamid	01/12/2007 - 31/10/2026		
Cyflufenamid	01/04/2010 - 31/03/2024		
Cyflumetofen	01/06/2013 - 31/10/2025		
Diflufenican	01/01/2009 - 31/12/2023	CfS	2 PBT criteria
Flazasulfuron	01/08/2017 - 31/07/2032		
Flonicamid	01/09/2010 - 30/11/2026		
Fluazifop-P	01/01/2012 - 31/12/2023		
Fluazinam	01/03/2009 - 29/02/2024		
Flubendiamide	01/09/2014 - 31/08/2024		
Flufenacet	01/01/2004 - 31/10/2023	CfS	2 PBT criteria
Flumetralin	11/12/2015 - 11/12/2023	CfS	2 PBT criteria
Fluometuron	01/06/2011 - 31/08/2024	CfS	low ADI / ARfD / AOEL
Fluopicolide	01/06/2010 - 31/08/2026		
Fluopyram	01/02/2014 - 31/01/2024		
Flurochloridone	01/06/2011 - 31/03/2026	CfS	toxic for reproduction 1B
Flutianil	14/04/2019 - 14/04/2029		
Flutolanil	01/03/2009 - 29/02/2024		
Gamma-Cyhalothrin	01/04/2015 - 31/03/2025	CfS	low ADI / ARfD / AOEL
Isoxaflutole	01/08/2019 - 31/07/2034		
Lambda-Cyhalothrin	01/01/2002 - 31/03/2024	CfS	2 PBT criteria
Mefentrifluconazole	20/03/2019 - 20/03/2029		
Metaflumizone	01/01/2015 - 31/12/2024		
Oxathiapiprolin	03/03/2017 - 03/03/2027		
Oxyfluorfen	01/01/2012 - 31/12/2024	CfS	2 PBT criteria
Penoxsulam	01/08/2010 - 31/05/2026		
Penthiopyrad	01/05/2014 - 31/05/2025		
Picolinafen	01/11/2016 - 30/06/2031		
Prosulfuron	01/05/2017 - 31/07/2024	CfS	2 PBT criteria

Pyridalyl	01/07/2014 - 30/06/2024		
Pyroxsulam	01/05/2014 - 30/04/2025		
Sulfoxaflor	18/08/2015 - 18/08/2025		
Tau-Fluvalinate	01/06/2011 - 31/08/2024		
Tefluthrin	01/01/2012 - 31/12/2024		
Tembotrione	01/05/2014 - 31/07/2024	CfS	low ADI / ARfD / AOEL
Tetraconazole	01/01/2010 - 31/12/2023		
Trifloxystrobin	01/08/2018 - 31/07/2033		
Triflusulfuron-methyl	01/01/2010 - 31/12/2023		
Tritosulfuron	01/12/2008 - 30/11/2023		

Table 2: 9 active substances meeting the OECD PFAS definition not approved under Regulation 1107/2009 (or previous Council Directive 91/414/ECC)

Active substance	Date of expiration of approval	Reason for no longer being approved
Acrinathrin	31/12/2021	Renewal application withdrawn
Benfluralin	12/02/2023	Non-renewal decision
Bifenthrin	31/07/2019	Renewal application withdrawn
Fipronil	30/09/2017	Renewal application withdrawn
Flufenoxuron	31/12/2011	Non approval decision
Haloxyfop-p	31/12/2020	Renewal application withdrawn
Picoxystrobin	31/08/2017	Non-renewal decision
Triflumizole	30/06/2020	No renewal application
Triflumuron	31/03/2021	No renewal application

a. Pesticide use: an overlooked source of PFAS contamination

Intentional environmental contamination

The presence of PFAS in pesticides results from the deliberate introduction of one or more trifluoromethyl (-CF3) group(s)[8] in their molecular structure to enhance the properties of these

[8] See page 73 of Anne XV of the restriction report.

substances (stability or lipophilicity i.e ability to dissolve in some liquids). The proportion of these fluorinated pesticides has significantly increased over the last two decades. Between 2015 and 2020, they represented nearly 70% of the new pesticides introduced into the global market[9]. This fluorination of pesticide substances has resulted in active substances and/or co-formulants that are PFAS[10]. In addition to this intentional introduction of PFAS, an analysis by the US Environmental Protection Agency[11] highlighted that PFAS chemicals used to coat the insides of shipping containers of pesticides may migrate from the walls to the liquid solutions in the container, i.e. into the pesticide product and thus into the environment. PAN Europe understands that this non-intentional exposure to PFAS is expected to be addressed in the context of the PFAS restriction and will thus not address it any further in this contribution.

As highlighted by the rapporteurs in their restriction proposal, pesticide products "*are usually applied directly on outdoor crops and therefore direct emission to the environment takes place*.". Following their transformation in the environment or in organisms, trifluoromethyl (-CF3) group(s) attached to the pesticide's substance contribute to the emission of trifluoroacetic acid (TFA) to an extent, which remains largely unknown. Yet, the few existing data suggest that further regulatory action is needed to prevent direct harm to the environment caused by PFAS pesticides use. When looked at closely, PFAS pesticides and TFA were found in Swedish freshwaters[12] and in German tap waters[13]. Further, according to the German Environment Agency (UBA)[14], "*Based on the sales figures and including all 28 active ingredients, a maximum of 504 t TFA can be emitted per year in Germany via pesticide applications (excluding flurtamone and flutolanil max. 457 t/a TFA). The three active ingredients, which are the most important sources with regard to TFA, can each emit a maximum of 197 t (flufenacet), 84 t (diflufenican) and 78 t (fluazinam) TFA. Flufenacet is thus the most significant pesticide active ingredient - in terms of Germany-wide emissions of TFA."*. Flufenacet, diflufenican and fluazinam are all three approved in the EU (Table 1).

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[9] Alexandrino, Almeida, Mucha, Carvalho. Revisiting pesticide pollution: The case of fluorinated pesticides. Environ Pollut. 2022;292(Pt A):118315. doi:10.1016/j.envpol.2021.118315

[10] Lasee, McDermett, Kumar, Guelfo, Payton, Yang, Anderson, Targeted analysis and Total Oxidizable Precursor assay of several insecticides for PFAS, Journal of Hazardous Materials Letters, Volume 3, 2022, 100067, ISSN 2666-9110, https://doi.org/10.1016/j.hazl.2022.100067.

[11] EPA PFAS Container Leaching Study 08122022_0.pdf

[12] Björnsdotter et al, Mass Balance of Perfluoroalkyl Acids, Including Trifluoroacetic Acid, in a Freshwater Lake Environmental Science & Technology 2022 56 (1), 251-259. DOI: 10.1021/acs.est.1c04472

[13] Scheurer, Nödler, Freeling, et al. Small, mobile, persistent: Trifluoroacetate in the water cycle - Overlooked sources, pathways, and consequences for drinking water supply. Water Res. 2017;126:460-471. doi:10.1016/j.watres.2017.09.045

[14] Hintergrund 11/2021: Chemikalieneintrag in Gewässer vermindern – Trifluoracetat (TFA) als persistente und mobile Substanz mit vielen Quellen (umweltbundesamt.de)

Food contamination due to crop intake

This pollution of the environment due to the spraying of PFAS pesticides leads to a bioconcentration in crops[15,16] which results in food contamination. A recent study[17] found TFA concentration of 6.1 µg/L in beer as a result of TFA presence in malt. Thus, the use of PFAS in pesticides contributes to the contamination of both water resources and food.

Please refer to the confidential attachment.

II. Shortcomings of Regulation 1107/2009 to address PFAS in pesticide products

The purpose of Regulation 1107/2009 concerning the placing of plant protection products on the market is to ensure "*a high level of protection of both human and animal health and the environment*" (Article 1(3)). Active substances can only be approved in pesticide products if they have no harmful effects on human health, including that of vulnerable groups, or animal health and no unacceptable effects on the environment (Article 4(1) to (3)). Specific approval criteria are listed in Annex II of Regulation 1107/2009. Active substances are individually risk assessed in the light of these criteria prior to a regulatory decision on their approval in accordance with Articles 1 and 4. All the provisions that govern these procedures are underpinned by the precautionary principle (Article 1(4)). Thus under Regulation 1107/2009 the fate of an active substance (approval or non-approval) depends on its individual properties, contrary to the proposal for a PFAS restriction which endorses a group approach based on the chemical structure of PFAS substances (falling under the OECD definition).

Out of the 38 approved active substances meeting the OECD definition of PFAS, 27 are undergoing individual reassessment. According to PAN Europe, these 27 individual reapproval procedures will not lead to 27 PFAS bans because of important gaps in Regulation 1107/2009 to address specifically PFAS as well as due to the lack of a thorough examination of their toxicity potential, which will most likely not stop the approval of new PFAS substances in the next few years. Hence, the need to change the regulatory approach.

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[15] Lasee, Subbiah, Thompson, Karnjanapiboonwong, Jordan, Payton. and Anderson, (2019), Plant Uptake of Per- and Polyfluoroalkyl Acids under a Maximum Bioavailability Scenario. Environ Toxicol Chem, 38: 2497-2502. https://doi.org/10.1002/etc.4571

[16] EU Reference Laboratories for Residues of Pesticides, 2017,

[17] Scheurer, Nödler, Ultrashort-chain perfluoroalkyl substance trifluoroacetate (TFA) in beer and tea – An unintended aqueous extraction, Food Chemistry, 351, 129304, 2021, 2021/07/30/, 0308-8146, https://doi.org/10.1016/j.foodchem.2021.129304

i. Weaknesses in the persistence regulation

As highlighted in the restriction dossier, the common property to all chemicals that belong to the PFAS groups is their high persistence or that of their degradation products. However, persistence (P) or very persistent (vP) properties of an active substance, alone, do not preclude its approval under Regulation 1107/2009. Regulation 1107/2009 requires indeed the persistence in soil and water of active substances to be assessed and Regulation 283/2013 specifies the data required from the applicant[18]. However, while Regulation 1107/2009 requires no unacceptable effects on the environment, demonstrating persistence of an active substance alone is insufficient to stop its approval. According to Annex II of Regulation 1107/2009, persistence (P) or very persistence (vP) must always be accompanied by other properties of concern to prevent approval of a substance. Only PFAS active substances classified as Persistent Organic Pollutants (POP)[19], meeting the criteria for Persistence, Bioaccumulation and Toxicity (PBT)[20], or which are very Persistent and very Bioaccumulative (vPvB)[21] cannot be approved. Contrary to vPvB, very Persistent and very Mobile (vPvM) properties are not regulated by Regulation 1107/2009.

Thus, only persistent substances with specific additional properties are banned under Regulation 1107/2009, but substances which are solely very persistent can be approved or reapproved for use in the EU. For instance, the substance fluopicolide was approved in 2010, while data in its assessment report highlighted its persistence in soil (DT50 up to 132 days, DT 90 up to 434-1184 days), in water (DT50 up to 263 days). Another example is pydiflumetofen, whose approval is pending. According to EFSA's conclusions[22], the DT50 of the substance is 8540 days, which makes it a highly persistent substance. Yet, to our surprise no 'critical area of concern' was identified by EFSA. This suggests that the representative formulation of Pydiflumetofen assessed was found as meeting the approval requirements of Regulation 1107/2009 for at least one of its uses. To PAN Europe, it is incomprehensible how a pesticide substance with such a long lifetime in the environment could be approved considering it has certain toxic properties to exert its pesticidal action.

[18] Point 7.1 of Chapter 7 of Regulation (EU) No 283/2013.
[19] Point 3.7.1 of Annex II of Regulation (EC) No 1107/2009.
[20] Point 3.7.2 of Annex II of Regulation (EC) No 1107/2009.
[21] Point 3.7.3 of Annex II of Regulation (EC) No 1107/2009.
[22] EFSA's peer review regarding Pydiflumerofen, URL link.

ii. Environment not sufficiently protected

Pesticides are designed to have a toxic action to 'target' organisms considered pests in conventional agriculture, and are inevitably also toxic to non-target organisms, such as plants, insects, fish, amphibians and mammals. Although the Regulation 1107/2009 aims to ensure that pesticides placed in the market have no unacceptable effects on the environment, taking into account their impact on ecosystems and biodiversity, so far there is no clear definition of what an "unacceptable" effect is, which has led unfortunately to poor environmental risk assessment and management decisions. For instance, despite the provisions of the EU law there are currently 105 approved pesticide active substances, which are "very toxic to aquatic life with long lasting effects" (Chronic aquatic toxicity, Category 1). For several of them, the only requirement is that Member States shall "pay particular attention" when using such substances close to water resources, building "where appropriate" on risk mitigation measures, the implementation of which is entirely up to Member States and rarely monitored. In fact, recent studies indicate that pesticides continue to be detected in water resources even in nature protection areas, where their use should be kept at the minimum, at concentrations that are putting aquatic life at risk[23]. There is a clear need to improve the environmental risk assessment and management, under Regulation 1107/2009 to ensure that ecosystem and biodiversity are truly protected. Therefore, expecting that PFAS pesticides would be sufficiently regulated is a misconception as the provisions of the Regulation 1107/2009 to ensure a high level of protection of the environment, are poorly implemented.

iii. Gaps in the assessment of pesticide metabolites in groundwater

As for other chemicals, the very persistence of PFAS substances in pesticides does not always result from the properties of the (parent) substance but also from their degradation products, including from their metabolites in the case of pesticides' substances. However, Regulation 1107/2009, in the way it is currently implemented, fails to fully address the toxicology of pesticide metabolites. The requirements applicable to metabolites depend indeed on whether these metabolites are considered "*relevant*" by regulators. According to Article 3(32) of Regulation 1107/2009, "*a metabolite is deemed relevant if there is reason to assume that it has comparable intrinsic properties as the active substance in terms of its biological target activity, or that it poses a higher or comparable risk to organisms than the parent substance or that it has certain toxicological properties that are considered unacceptable. Such a metabolite is relevant for the overall approval decision or for the definition of risk mitigation measures".*

[23] Wolfram et al. Pesticide occurrence in protected surface waters in nature conservation areas of Germany. Sci Total Environ. 2023 Feb 1;858(Pt 3):160074. doi: 10.1016/j.scitotenv.2022.160074

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Point 9.2.4 in Part A of Regulation No 284/2013 provides that metabolites which occur in concentration levels above 0.1 µg/L in groundwater must be assessed. In line with Drinking Water and Groundwater Directives, the concentration of metabolites deemed relevant in drinking water and groundwater must not exceed 0.1 µg/L. As a result, when metabolites are found "relevant" during risk assessment, the active substance under assessment can only be approved at EU level if the parametric drinking water value in the groundwater is not expected to exceed 0.1 µg/L.

The method to identify relevant metabolites during risk assessment is developed in the Guidance document Sanco/221/2000 – rev.11[24]. According to this latter, metabolites are deemed relevant when they meet at least one of the following conditions:

- The biological activity of the metabolite is above 50% of the activity of the parent substance,
- The metabolite is found genotoxic or classified as toxic to reproduction (1A,1B, 2) or as carcinogen (1A,1B, 2) under Regulation 1272/2008,
- The parent substance is classified as carcinogen (1A,1B, 2) or due to its acute or chronic toxicity (Acute Tox. 1, 2, 3, STOT SE1 or STOT RE1)

While 3 genotoxicity studies are required, the rest of the data are requested on a case-by-case approach depending on the classification of the parent substance under Regulation 1272/2008. When the parent substance has none of the above listed classifications, no data are required on metabolites. As a result, most of the possible hazardous properties associated with PFAS, namely persistence, bioaccumulation or endocrine disruption, are not criteria to identify relevant metabolites for groundwater.

Out of the 38 approved PFAS substances, 14 have no relevant classification[25] in accordance with Regulation 1272/2008 and are not subject to any CLH intention. Therefore, the classification of their metabolites, including TFA, will depend on the screening of their biological activity and of the three controversial genotoxicity studies[26] required without consideration for their -PFAS associated- other properties. There is thus a reasonable risk that the metabolites of PFAS substances are not regarded as relevant, and thus that PFAS contamination of groundwater above 0.1 µg/L is allowed. Moreover, classified substances identified as PFAS whose metabolites would be found relevant can still enter on the EU market if groundwater contamination level is not expected to exceed 0.1 µg/L.

[24] pesticides_ppp_app-proc_guide_fate_metabolites-groundwtr-rev11.pdf (europa.eu)
[25] Carcinogen 1A,1B, 2, Acute Tox. 1, 2, 3, STOT SE1, STOT RE1.
The 14 active substances are Beflubutamid; Cyflufenamid; Flonicamid; Fluazifop-P; Flubendiamide; Flufenacet; Flumetralin; Fluometuron; Fluopicolide; Gamma-Cyhalothrin; Lambda-Cyhalothrin; Oxyfluorfen; Penoxsulam; Tau-Fluvalinate.
[26] Sensitivity questioned.

Last but not least, PAN Europe observes that there is currently no procedure to ensure harmonised assessment of the toxicological profile of common metabolites such as TFA to different active substances. As explained earlier, this assessment highly depends on the properties of the parent substances, including on whether it has a harmonised classification according to CLP Regulation 1272/2008. As a result, while the parametric drinking water value in the groundwater for a metabolite of a parent substance "A" might be set above 0.1 µg/L, this tolerable value might not be exceeded when this same metabolite is emitted by a parent substance "B". This conflicting and inconsistent treatment of common metabolites in the context of Regulation 1107/2009 fails to prevent groundwater contamination by PFAS used in pesticides.

iv. Absence of assessment of cumulative and synergistic effects

One reason put forward by the rapporteurs to support the relevance of this restriction proposal is that EU citizens and the environment are generally exposed to several PFAS at the same time. Although required by Article 4(3) of Regulation 1107/2009 and Article 14 of Regulation 396/2005 on the setting of Maximum Residues Limits (MRLs), no assessment of cumulative and synergetic effects of pesticide products and their residues is carried out during individual risk assessment of a pesticide substance or when setting MRLs. EFSA has started developing a methodology but its scope is limited to dietary exposure and won't be finalised before 2030 at the earliest[27]. In the meantime, the toxicity of mixtures of substances is highly underestimated during risk assessment. For instance, herbicide formulations mixing the PFAS substances flufenacet and diflufenican are currently authorised in several EU Member States[28]. Not only the combined toxicity of these two substances is not assessed but these types of products are sprayed in an environment, which is likely to be exposed to other pesticide products and additional pollutants.

v. Gaps in the assessment of pesticide formulations

Chronic toxicity for humans

While Regulation 1107/2009 and a case law[29] oblige Member States to assess the long-term toxicity of pesticide formulations relevant for humans before authorising them, this assessment

[27] PAN Europe, How to best address cocktail effects in the Pesticide legislation? Towards the implementation of a MAF.
[28] Examples in Belgium: Recherche de produits phytopharmaceutiques | Phytoweb (belgium.be); in France: 220186046 | ephy (anses.fr) and in Germany: Data sheet PSM - Chrome (bund.de)
[29] Case C-616/17, EUR-Lex - 62017CJ0616 - EN - EUR-Lex (europa.eu)

is still not carried out to date[30]. This contributes to the marketing of products whose toxicity for humans and the environment potential is significantly underestimated.

Data gaps on co-formulants used only in pesticide products

While Regulation 1107/2009 requires the same level of protection from co-formulants included in pesticides as for active substances (i.e. no harmful effects on human health and animal health, no unacceptable effects on the environment), no regulatory action was taken until very recently to ensure the implementation of this obligation. This is only in 2021 that a first series of co-formulants on the market was listed as unacceptable and in 2023 that harmonised criteria to identify further unacceptable co-formulants were adopted. Yet, there are no data requirements applicable to co-formulants under Regulation 1107/2009 to ensure a toxicity assessment similar to the one of active substances, and only those also used for industrial purposes are due to be registered under the REACH Regulation[31], which requires toxicity data which are not equivalent to those required for active substances[32]. Against this background, PAN Europe welcomes the inclusion of co-formulants in the scope of the PFAS restriction. This will contribute to a more thorough assessment and regulation of these compounds.

vi. Can't PFAS substances be banned due to their other properties?

Although PFAS's common denominator is their very persistence in the environment and other organisms, most of the chemicals in this group combine this persistence with other hazardous properties. The most commonly observed of these properties are mobility, bioaccumulation, long range transport potential (LRTP), high toxicity for the environment, endocrine disruption, negative impacts on early-life development (i.e. in children) and carcinogenicity. Because some of these properties[33] have a stronger regulatory weight than persistence alone under Regulation 1107/2009, if identified they might prevent the (re)approval of certain PFAS substances but this is not systematic[34].

[30] Home - Secrets Toxiques

[31] See article 15(1) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

[32] Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances in accordance with Regulation (EC) No 1107/2009.

[33] See in particular points 3.6.3 to 3.6.5 and 3.8.2 of Annex II of Regulation (EC) 1107/2009.

[34]The PFAS substance flutolanil is likely to be proposed for reapproval as no critical area of concern was identified by EFSA.

This is for instance the case of endocrine disrupting properties[35]. However, the assessment of endocrine disruptors focuses only on a limited number of endocrine pathways (estrogens, androgens, thyroid and steroidogenic, i.e. 'EATS'), and therefore PFAS substances that act *via* other pathways (e.g. lipid regulation) will not be identified. Moreover, long-term toxicity tests including all endocrine disruption endpoints are rarely provided by the applicants, leaving a big gap in their toxicity assessment[36].

There are several cases where substances with toxic properties have been kept in the market, and their toxicity has been revealed only due to concerns raised based on studies from peer-reviewed scientific literature rather than those from the applicant's dossier (e.g. chlorpyrifos). However, peer reviewed studies are carried out only when these substances have been used for several years and therefore for new substances the information is limited. The difference of treatment and truly reliable studies in the assessment from one substance to another indicates that it is difficult to ensure the comprehensive approach needed to phase out PFAS substances.

vii. Manufacture of PFAS pesticide products

Regulation 1107/2009 regulates "*the authorisation of plant protection products in commercial form and […] their placing on the market, use and control within the Community*"[37], but it does not cover the manufacture of pesticide products, contrary to the REACH Regulation[38]. This means that pesticides products which are not authorised in EU can be produced, stored and transported in the EU if they are intended for use in a third country[39]. This results in the export of tonnes of hazardous active substances and pesticide products for use in agriculture of non-EU countries[40]. The EU cannot claim leading by example the fight for a global PFAS phase out if it keeps allowing the export of PFAS pesticides from European pesticide factories to third countries, in particular to low and middle-income countries.

[35] The PFAS triflusulfulron-methyl is currently proposed for non-renewal by the European Commission due to its endocrine disrupting properties to humans and wild mammals. See item C.10 of the Agenda meeting: sc_phyto_20230711_ppl_agenda_0.pdf (europa.eu)
[36] The PFAS triflusulfulron-methyl is currently proposed for non-renewal by the European Commission due to its endocrine disrupting properties to humans and wild mammals. See item C.10 of the Agenda meeting: sc_phyto_20230711_ppl_agenda_0.pdf (europa.eu)
[37] See Article 1(1) of Regulation (EC) No 1107/2009.
[38] See article 1 of Regulation (EC) No 1907/2006
[39] See Article 28(c) and (d) of Regulation (EC) No 1107/2009.
[40] Banned in Europe: How the EU exports pesticides too dangerous for use in Europe (publiceye.ch)

viii. Pesticide use cannot be regarded as essential

Lastly, PAN Europe stresses that the use of pesticides in EU agriculture cannot be regarded as essential for "pests" control and resistance management. On the contrary, the use of synthetic pesticides can lead to an ever-growing pest resistance, which is not resolved by alternating the application of pesticides with different modes of action. There are agronomic, mechanical, physical and biological alternatives to synthetic pesticides, that do not create pest resistance[41]. Their use is acknowledged among scientists as the most effective strategy to manage pests and maintain yields, which is also a requirement of the Directive 2009/128/EC that so far has been poorly implemented across Member States. Furthermore, the EU Farm to Fork Strategy intends to reduce by 50% the use of hazardous pesticides by 2030 to diminish the chemical dependency in EU agriculture and ensure a more sustainable model for food production and consumption in the EU. In this overall context, no derogation to active substances should be granted on the ground of an "essential use" in the context of this restriction.

Conclusion

While PAN Europe welcomes the inclusion of co-formulants used in pesticides products in the proposal for a PFAS restriction, **we ask ECHA scientific committees to expand the scope of the restriction to include active substances approved under Regulation 1107/2009.**

[41] Farmer's Toolbox for Integrated Pest Management (europa.eu)