NEW REPORT

Nov. 2023

EUROPE'S TOXIC HARVEST

UNMASKING PFAS PESTICIDES AUTHORISED IN EUROPE

Pesticide Action Network Europe

générations FUTURES

Executive Summary

Our organisations reveal the presence of eternal pollutants (PFAS) among pesticides. These hazardous substances are exempted from the forthcoming European restriction, all the while their use in agriculture is rising. Immediate action is needed to get them banned.

In recent times, public concern regarding Per- and Polyfluoroalkyl Substances (PFAS) has heightened, primarily because of their widespread pollution and toxic properties. PFAS are hazardous and persistent pollutants that threaten our health and environment. Known as "forever chemicals" once released, they persist for generations.

While PFAS contamination is often attributed to 'accidental' industrial emissions or negligent pollution, our report uncovers an intentional and widespread source of PFAS pollution: **the PFAS pesticides.** Specifically, currently 12% (37) of the synthetic active ingredients authorised for pesticide use in the European Union are PFAS, all containing strong carbon-fluoride bonds, enhancing their persistence in the environment, or of their degradation products (i.e. metabolites). These 37 active substances are deliberately sprayed across EU agricultural fields, contaminating our food, water, and the environment. Europe is giving its consent and the pesticide industry is cashing its profits.

An analysis of the French sales data for these substances raises alarms on the rising popularity of PFAS pesticides. Between 2008 and 2021, their sales in France increased dramatically, tripling in magnitude. This indicates massive spraying of PFAS pesticides in open fields, leading to significant exposure of French citizens and the environment.

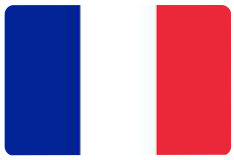
Chemical companies are well aware of the PFAS problem, but the pesticide producers such as Bayer, Syngenta and BASF hide their liability behind a lack of regulation. Despite the European Union's intention to ban all PFAS chemicals through a EU-wide restriction, PFAS pesticides have been excluded, under the assumption that these are regulated under EU Pesticide Regulation. Our report reveals that the current pesticide assessment fails to address the presence of PFAS in pesticide products due to shortcomings in implementation of the EU Regulation. PFAS pesticides are slipping through the cracks of a flawed pesticide assessment system, while regulators are turning a blind eye at the expense of our health and that of our environment.

Pesticides are among the first sources of PFAS exposure for citizens, whether through residues in their food and water, or via direct exposure, especially impacting farmers, farmworkers and bystanders. The use of PFAS in pesticides poses an entirely avoidable threat to the health and environment of not just the current generation but also those to come. At a moment where EU regulators have promised to its citizens under the European Green Deal to drastically decrease pesticide dependency, urgent action is not a choice but a necessity. **PAN Europe and Générations Futures demand an immediate ban on all PFAS pesticides.**

Highlights

37 active substances approved for use in pesticides in Europe are PFAS in 2023

12% of all the approved synthetic active substances in Europe.



30 PFAS active substances are authorised in pesticides in France in 2023

13% of the synthetic active substances authorised in pesticides in France.

French sales of PFAS pesticides have risen from 700 tonnes in 2008 to 2 332 tonnes in 2021. This means a **threefold increase** in 13 years.

PFAS were introduced in pesticides to boost their stability, **making pesticides effective (last) longer**. Known PFAS pesticides producers are Bayer, BASF and Syngenta.

Most PFAS substances and/or their metabolites are persistent. It means they have a very long lifespan into the environment.

Soil, air but also water, including **drinking water** end up contaminated. PFAS residues build up in living organisms including crops, leading to PFAS residues in **food products**.

PFAS pollution due to pesticides is **intentional** and **direct**. This differs from the PFAS pollution deriving from accidental and negligent industrial leakages.

Pesticides are **not essential to protect crops** and the EU has committed to halve its dependency to synthetic pesticides by 2030.

PFAS: falling through the cracks of the Pesticide Regulation

Persistent of pesticides and/or that of their degradation products (metabolites) is not alone considered sufficient for a ban.

Shortcomings in risk assessment

- Other hazardous properties of PFAS substances and their metabolites are not thoroughly assessed, namely their **endocrine disrupting properties**, their **impact on the environment**, biodiversity and ecosystems.
- **Cocktails effects** are not assessed.

Failing risk management

- PFAS pesticide substances are approved and prolonged when regulators have identified **unacceptable risks** or when the risk assessment could not be finalised.
- PFAS active substances approved as "candidates for substitution" are not in fact **never substituted** and are still used.
- The **precautionary principle** is not being applied.

Content

Background

What are PFAS? The forever threat

In the world of modern chemistry, a group of man-made organic chemicals called per- and polyfluoroalkyl substances (PFAS) has quietly entered our lives. Their ubiquitous detection in the environment and living organisms, including humans, is a cause for growing concern. These chemicals, characterised by a stable, unreactive fluoro-carbon segment, have been in use since the 1950s predominantly because of their water-repellent properties.

PFAS have stealthily infiltrated our daily lives, finding their way into consumer products and industrial applications alike. They lurk in non-stick coatings on frying pans, hide in paper food packaging, and even make their way into cosmetics, textiles, paints, and pharmaceuticals. According to the European Environment Agency (EEA), the PFAS group encompasses more than 10 000 chemicals based on the OECD definition, each with its unique properties and potential for harm.

For decades, the scientific community has been sounding the alarm about the potential toxicity of these chemicals. These substances (or their immediate metabolites), which do not break down easily, persist in our environment, our bodies, and the food we consume, accumulating to levels that can cause adverse effects. Their persistence raises questions about the long-term consequences of chronic exposure. PFAS chemicals exhibit a range of concerning properties, from mobility and bioaccumulation to long-range transport potential. Some are suspected carcinogens, others are linked to developmental issues in children, and many show adverse effects even at low concentrations, impacting the liver, immune system, and endocrine systems. Furthermore, these chemicals pose significant threats to aquatic environments as they may persist in water and sediments, resulting in long-term exposure of aquatic organisms. The pervasive presence of PFAS, including in drinking waters across Europe and citizens' bodies, underscores the challenge of reversibility of contamination.

In this report, we shed light on an aspect of PFAS pollution that is less familiar to the public: their presence on our food and our environment through pesticide residues. PFAS can be detected in pesticide products, whether as active ingredients or as co-formulants, often in quantities that remain largely undisclosed, posing the risk of substantial contamination.

Boosting pesticide effectiveness

The presence of PFAS in pesticides results from the deliberate introduction of one or more trifluoromethyl (-CF3) group(s) in their molecular structure to boost the effectiveness of a substance. Namely, the chemical engineering introducing this fluorinated backbone, with strong carbon-fluoride bonds, improves both the hydrophobic (water repellent) and lipophobic (fat/oil repellent) properties of substances, and therefore their stability. This latter property is particularly praised by the pesticide industry as it results in pesticides being effective for longer periods, allegedly diminishing the frequency of crop spraying. However, “stability” is simply the industry's term to depict the persistence of their substances, whose lifespan in the environment and living organisms becomes longer.

PFAS pesticides on the loose in Europe

Because PFAS pesticides became globally popular over the last decades, there were some prior indications that certain active substances approved in the EU might be PFAS, but the exact number remained unknown. It wasn’t until the work undertaken within the framework of the EU Green Deal that national authorities from Germany, Denmark, the Netherlands, Norway and Sweden submitted a PFAS restriction proposal to the European Chemical Agency, shedding light into this issue. The authorities specifically examined which pesticides fell under the OECD definition of PFAS and compiled a list, initially identifying 47 PFAS active substances. Subsequently, our own review revealed that 37 of these active substances were still approved for use in pesticides in the EU (Table 1). The competent authorities concluded that the use of these substances is most probably already restricted to an extent or regulated under the EU pesticide Regulation because of their harmful properties and therefore excluded them from the restriction.

To date, 445 active substances are approved under the Pesticide Regulation (1). Excluding the 139 that are approved as low-risk, basic substances or are microorganisms allowed for organic, leaves 306 synthetic active substances allowed exclusively for conventional farming, according to the EU pesticide database. This means that PFAS active substances represent about 12.1% of the approved synthetic active substances in the EU. This figure suggests that, contrary to the regulators’ assumption, the PFAS pollution due to the use of PFAS pesticides is not marginal. This is confirmed by the data exposed in the next section of this report.

Table 1: PFAS active substances approved for use in Europe

Active substance	Current period of (re)approval
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
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 - 15/06/2025
Flumetralin	11/12/2015 - 11/12/2023
Fluometuron	01/06/2011 - 31/08/2024
Fluopicolide	01/06/2010 - 31/08/2026
Fluopyram	01/02/2014 - 31/01/2024
Flurochloridone	01/06/2011 - 31/03/2026
Flutianil	14/04/2019 - 14/04/2029
Flutolanil	01/03/2009 - 29/02/2024
Gamma-Cyhalothrin	01/04/2015 - 31/03/2025
Isoxaflutole	01/08/2019 - 31/07/2034
Lambda-Cyhalothrin	01/01/2002 - 31/03/2024
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
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
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
Tetraconazole	01/01/2010 - 31/12/2023
Trifloxystrobin	01/08/2018 - 31/07/2033
Tritosulfuron	01/12/2008 - 30/11/2023

Pesticides: an overlooked source of PFAS pollution

Beyond accidental environmental contamination: PFAS pesticides pollution

In the public debate surrounding PFAS contamination, the focus invariably gravitates towards unintentional pollution, often overlooking another critical dimension of serious concern - the deliberate introduction of PFAS into our food and environment.

Generally, pesticides are applied directly on agricultural crops, which leads not only to residues in food but also to direct emission into the environment. These pesticides are persistent and/or toxic themselves or may also be transformed to more toxic and/or persistent substances. In the case of PFAS pesticides, in some cases the trifluoromethyl (-CF3) group(s) can get transformed to the very persistent trifluoroacetic acid (TFA), which contributes to an extent to the overall contamination of this substance into the environment. The few existing data on the environmental levels of TFA 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 (2) and in German (3) tap waters. Furthermore, according to the German Environment Agency (UBA), “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.”(4). Flufenacet, diflufenican and fluazinam are all three approved in the EU. This pollution of the environment due to the spraying of PFAS pesticides leads to a bioconcentration in crops (5) which results in food contamination. A recent study (6) found TFA concentration of 6.1 µg/L in beer as a result of TFA, due to its presence in malt (the maximum allowed pesticide concentration in tap water being 0.1 µg/L).

The case of France

The dramatic rise in the sales of PFAS pesticides

To gain a better understanding of the extent of PFAS pesticide use, we studied a specific Member State, France. French pesticide sales data are readily available and were extracted from the database BNVD for the years 2008 to 2021 for the 47 substances identified as PFAS. The data reveal a very significant increase in sales of PFAS pesticides during this time-period. Sales have risen from 700 tonnes in 2008 to 2,332 tonnes in 2021. This means a threefold increase in 13 years. Here, it is important to note that the fall in sales for 2019 is not due to a reduction in use. It is explained by the announcement at the end of 2018 of an increase in sales taxation of pesticide products: in anticipation of this increase, farmers built up stocks at the end of 2018 and consequently bought less in 2019. This drop, which can be observed for all pesticides, does not therefore reflect a fall in use.

Since the year 2020, more than 2 000 tonnes of these highly problematic substances have been deliberately sprayed in fields in France. There are currently 30 PFAS active substances authorised in France.

Table 2: Total volume of sales (in tonnes) per year

Year	Sales
2008	701
2009	862
2010	944
2011	1146
2012	997
2013	1171
2014	1488
2015	1575
2016	1702
2017	1647
2018	2154
2019	1614
2020	2165
2021	2332

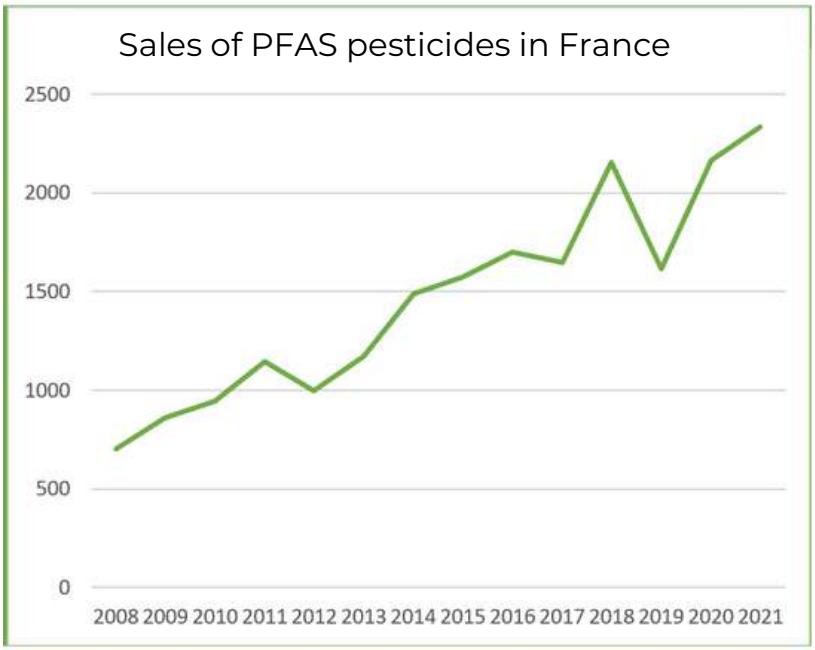


Table 3: Top 10 sold substances in France in 2021 and their respective volume (in tonnes)

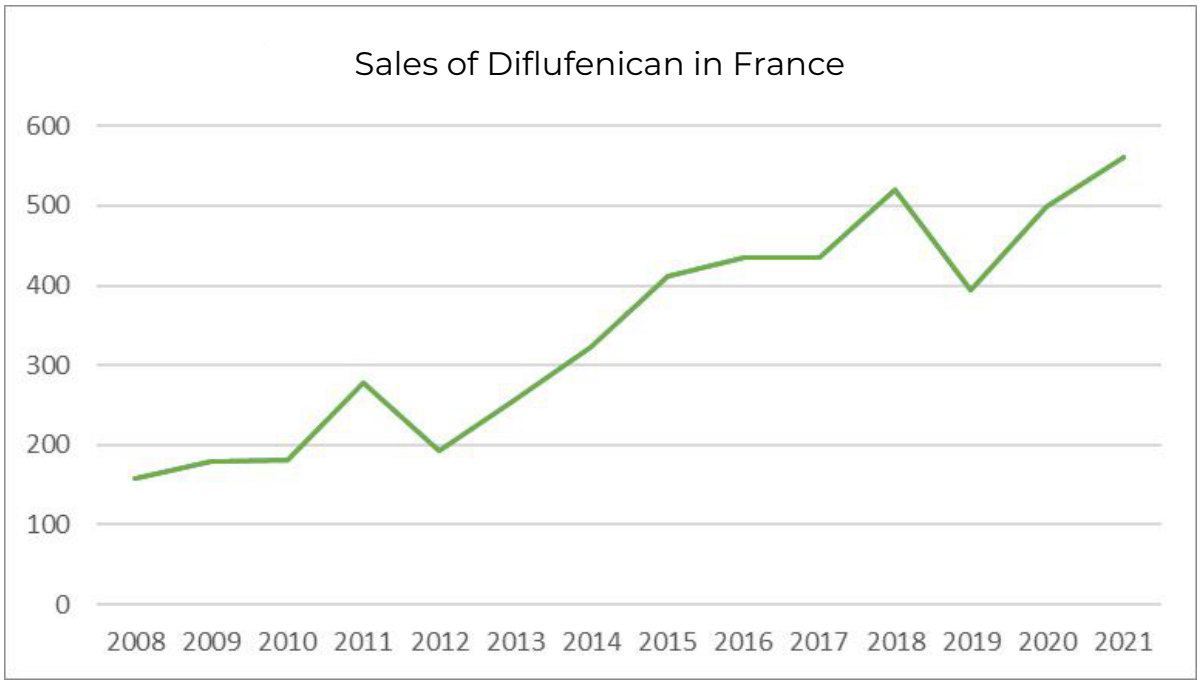
	Substance	Sales in 2021
1	flufenacet	804
2	diflufenican	561
3	fluopyram	137
4	mefentrifluconazole	110
5	trifloxystrobin	94
6	lambda-cyhalothrin	80
7	flurochloridone	70
8	fluopicolide	61
9	fluazinam	61
10	tau-fluvalinate	48

Two PFAS active substances have been sold extensively since 2008. Each year, they stand in first or second place among the best-selling PFAS substances: diflufenican and flufenacet.

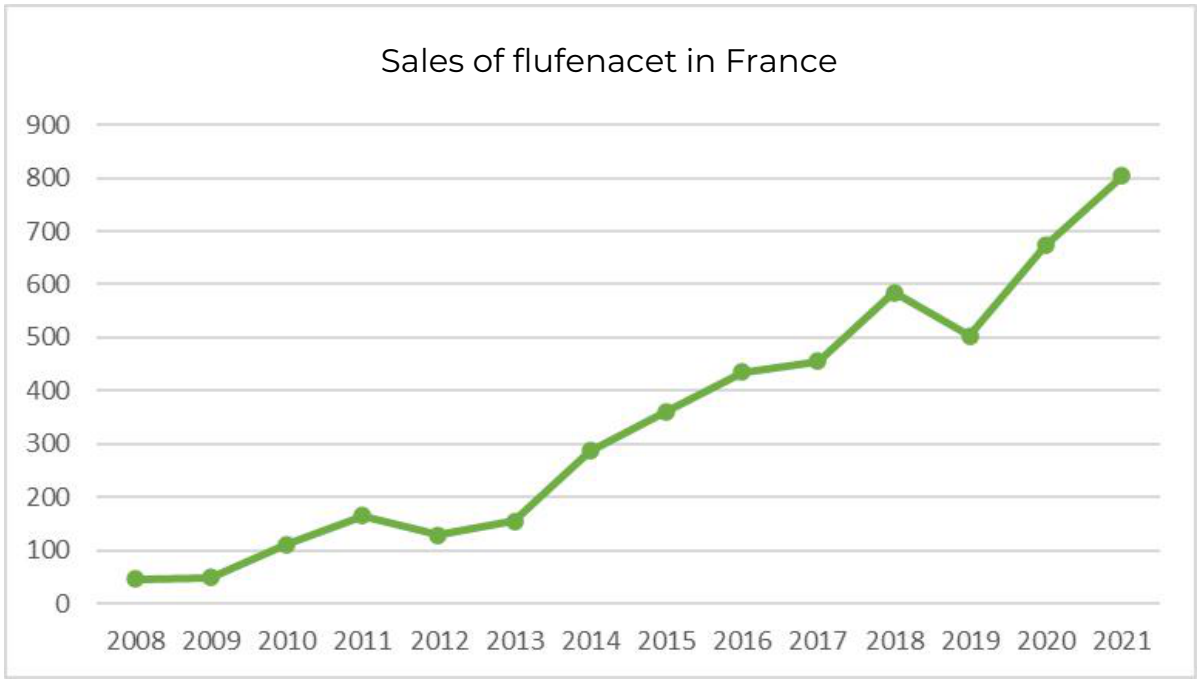
Table 4: Top 3 most sold PFAS substances each year

	Top 1	Top 2	Top 3
2008	diflufenican	trifloxystrobin	fluazinam
2009	diflufenican	trifloxystrobin	fluazinam
2010	diflufenican	flufenacet	flurochloridone
2011	diflufenican	flufenacet	flurochloridone
2012	diflufenican	flufenacet	flurochloridone
2013	diflufenican	flufenacet	flurochloridone
2014	diflufenican	flufenacet	fluazinam
2015	diflufenican	flufenacet	flurochloridone
2016	flufenacet	diflufenican	fluazinam
2017	flufenacet	diflufenican	fluazinam
2018	flufenacet	diflufenican	fluopyram
2019	flufenacet	diflufenican	fluopyram
2020	flufenacet	diflufenican	fluopyram
2021	flufenacet	diflufenican	fluopyram

Diflufenican is a very persistent herbicide. Since 2018, it is considered as a PBT (Persistent, Bioaccumulative and Toxic) substance by the Czech Republic in charge of its risk assessment (Rapporteur Member State) and should therefore have been banned in the EU. However, the sales of diflufenican have increased 4-fold in 13 years. In 2021, sales of diflufenican reached a peak at 561 tonnes.



Flufenacet is an herbicide which has an extremely persistent metabolite, the TFA: more than 10 000 days are needed to break down half of this compound in soil. TFA also contaminates groundwater at levels that surpass the permitted levels and therefore are considered illegal (> 10 µg/L). However, its sales have increased 18-fold since 2008. It is now the most popular PFAS pesticide in France peaking at more than 800 tonnes sold in 2021.



Who benefits from these PFAS pesticides?

Of these 10 most sold substances in France, five (including flufenacet and diflufenican) are on the market following an approval request from Bayer. The companies behind the other five substances include BASF, Syngenta, ISK Bioscience Europe and ADAMA Agan Ltd (Table 5).

Table 5: Pesticide companies behind the authorisations of the Top 10 sold substances in France in 2021

	Substance	Application submitted by
1	flufenacet	Bayer CropScience AG
2	diflufenican	Bayer CropScience AG
3	fluopyram	Bayer CropScience AG
4	mefentrifluconazole	BASF Agro B.V.
5	trifloxystrobin	Bayer CropScience AG
6	lambda-cyhalothrin	Syngenta Task Force (6 companies)
7	flurochloridone	Agan Chemical Manufacturers Ltd (now Adama Agan Ltd)
8	fluopicolide	Bayer CropScience
9	fluazinam	ISK Biosciences Europe NV
10	tau-fluvalinate	Makhteshim Agan ICC

PFAS and European regulation: slipping through the cracks!

As explained in this report, the intentional contamination of the environment by PFAS pesticide active substances is far from anecdotal. Yet, the EU has taken no specific measure to limit the use of these substances in pesticides.

EU's incomplete move toward a PFAS-free future

In 2020, the phasing out of PFAS in the EU, stood as a key commitment of the EU Chemical Strategy for Sustainability to achieve a toxic free environment. To implement this promise, a proposal for a universal restriction (7) of PFAS was submitted to the European Chemical Agency (ECHA) in early 2023. This regulatory action aims to significantly restrict the use of these persistent pollutants.

To address PFAS contamination in a comprehensive way, regulators decided to have a straightforward approach: banning the entire group of PFAS chemicals due to their global concerning properties, rather than individually targeting each PFAS substance. Therefore, the restriction proposal aims to cover a wide range of uses and sectors and therefore promote PFAS-free processes and products, although some time-limited derogations for some uses are included. While the restriction includes PFAS co-formulants used in pesticide products, the 37 PFAS active substances used in pesticides across the EU are completely excluded from the scope of the restriction.

However, this exclusion of PFAS pesticide active substances from the PFAS restriction is based on several unsupported presumptions by the national authorities who drafted the report, as we show here.

The first underlying rationale for this proposed exception raised by the authors is that the presence of pesticide substances on the market results from an explicit approval procedure under the Pesticide Regulation, which would already flag them as concerning substances for toxicity reasons and minimise or phase out their use. Indeed, the authorities assume that PFAS active substances are mostly approved as candidates for substitution (CfS), which would mean that they are being put on the market for a relatively short period (7 years) and only when their substitution by less toxic alternatives cannot occur.

This assumption is in fact incorrect. Out of the 37 PFAS pesticide substances, only 11 are approved as candidates for substitution and seven of them because they were found to meet two of the three PBT criteria during risk assessment. Therefore, this classification, which requires Member States to substitute them, applies to less than a third of the PFAS pesticides. The rest are treated as any other pesticide. Furthermore, it must be noted that even for the 11 substances that have been identified as CfS, the substitution requirement is implemented in such a minimal number of times by Member States since its introduction (8) 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." Therefore, most of the 11 PFAS active substances approved as CfS, instead of being substituted with safer alternatives, are authorised in pesticide products in Member States (according to the EU Pesticides Database).

Table 6: PFAS substances approved as candidates for substitution in the EU

Candidates for substitution	Criteria of Annex II point 4	National authorisations
Diflufenican	2 PBT criteria	AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,FR,HR,HU,IE,IT,LT,LU,LV,MT,NL,NO,PL,PT,RO,SE,SI,SK
Flufenacet	2 PBT criteria	AT,BE,BG,CY,CZ,DE,EE,EL,ES,FR,HR,HU,IE,IT,LT,LU,LV,MT,NL,PL,PT,RO,SE,SI,SK
Flumetralin	2 PBT criteria	no information
Fluometuron	low ADI / ARfD / AOEL	EL,ES
Flurochloridone	toxic for reproduction 1B	CZ,EL,FR,HR,HU,PL,RO,SK
Gamma-Cyhalothrin	low ADI / ARfD / AOEL	AT,BE,BG,CZ,DE,DK,EE,FI,HU,IE,LT,LV,PL,RO,SE,SK
Lambda-Cyhalothrin	2 PBT criteria	AT,BE,BG,CY,CZ,DE,DK,EE,EL,ES,FI,FR,HR,HU,IE,IT,LT,LU,LV,MT,NL,NO,PL,PT,RO,SI,SK
Oxyfluorfen	2 PBT criteria	BG,CY,EL,ES,HR,IT,MT,PL,PT,RO
Prosulfuron	2 PBT criteria	AT,BE,BG,CZ,DE,EL,ES,FR,HR,HU,IT,LU,MT,NL,PL,PT,RO,SI,SK
Tetraconazole	low ADI / ARfD / AOEL	AT,BE,BG,CY,CZ,DE,EL,ES,FR,HR,HU,IT,MT,PL,PT,RO,SI,SK

Secondly, the proposal includes a simplified assumption that a ban on all PFAS pesticide active substances would increase pest resistance to pesticides in Europe because of a decreased chemical diversity. This statement is untrue (9). Multiple chemical-based strategies, promoted by the pesticide sector (10) have been applied for more than 40 years by farmers and have only led to more resistance for all pest organisms (insects, fungi, plants). It is counterproductive (11)and traps farmers in the pesticide treadmill. According to scientists, the most efficient strategy to manage pest control and pest resistance is the implementation of integrated pest management (IPM) methods, according to which farmers should consider chemical solutions only as a last resort, after other non-chemical methods have been applied and failed (12) . Therefore, not banning PFAS substances will not help farmers to better protect their crops and maintain their yields.

Moreover, the authors of the restriction proposal assume that pesticides do not constitute a significant source of PFAS pollution in Europe. However, this claim was evidently not sufficiently investigated. The existing data put forward in this report suggests that PFAS pesticide pollution is strongly underestimated. Indeed, sales data in France in 2021 (2297 tonnes) amounts for half of the EU-wide sales estimate that was made in the restriction proposal (5479 tonnes).

Finally, the exclusion of pesticide substances from the restriction proposal is based on a fear of double regulating these substances. In the following sections of the report, we show that the revealed presence of approved PFAS pesticide substances reflects important blind spots of the Pesticide Regulation, and shortcomings in its implementation. We conclude that further regulatory action is needed to get them banned.

PFAS hazardous properties: a blind spot of the Pesticide Regulation?

This section shows how the Pesticide Regulation is failing to ensure the needed comprehensive approach to phase out PFAS substances in pesticides.

The primary objective of the Pesticide Regulation, which governs the approval and marketing of pesticides, is to ensure "a high level of protection for both human and animal health and the environment" (13) . To achieve this purpose, pesticide products can only contain active substances that demonstrate no adverse effects on human health, especially for vulnerable populations, and no unacceptable effects on the environment (14) . Detailed approval criteria are outlined in Annex II of the Pesticide Regulation. Prior to regulatory decisions on their approval, active substances undergo individual risk assessments. These procedures must be deeply rooted in the precautionary principle, according to EU law. And yet, substances as harmful as PFAS end up getting authorised and are sprayed into European fields. We analysed in detail the most recent evaluation dossier of the 10 most sold PFAS substances in France and point out several gaps of the Pesticide Regulation which we highlight below.

Weaknesses in the regulation of persistent pesticides

A common characteristic of PFAS chemicals is their (high) persistence (of parent compound or metabolites). Persistence alone is considered by the authors of the PFAS restriction proposal as the main issue of these substances and this common property is considered sufficient to justify a grouping approach for the restriction. However, under the Pesticide Regulation, persistence properties of an active substance or of its metabolites, alone, do not automatically preclude its approval contrary to other hazardous properties (15) . In other words, the hazard-based approach does not apply to persistence alone and persistent or very persistent substances still have to go through a full risk assessment to identify whether they have a potential to cause harm to human and animal health or unacceptable effects to the environment. Unfortunately, it seems very common that PFAS active substances pass through this assessment procedure and are granted approval.

Of the 10 best-selling substances in France, the data in their dossiers show that 9 of these substances and/or their metabolites are persistent or very persistent according to the PBT and vPvB (very Persistent very Bioaccumulative) criteria set out in the Pesticide Regulation (16) . For the tenth substance (Lambda cyhalothrin), the data provided by the applicant showed significant variations in rate of degradation and some results exceeded the threshold for persistence. This means that persistent properties of the active substance cannot be totally ruled out.

Table 7: Examples of PFAS active substances or metabolites meeting the Persistent (P) or very Persistent (vP) criteria (based on France's top 10 sales)

Substance name	Substance classification (PBT/vPvB criteria)	Metabolites (PBT/vPvB criteria)
Diflufenican	Very persistent (vP)	/
Flufenacet	/	TFA: very persistent (vP)
Fluopicolide	Very persistent (vP)	M-01: very persistent (vP)
Fluazinam	/	HYPA: very persistent (vP)
Fluopyram	Very persistent (vP)	/
Flurochloridone	/	R42819 : very persistent (vP)
Mefentrifluconazole	Very persistent (vP)	1,2,4 triazole: persistent (P)
Tau-fluvalinate	/	Haloaniline : persistent (P)
Trifloxystrobin	/	CGA 321113: very persistent (vP)

Shortcomings in the implementation of the Pesticide Regulation

In addition to these general blind spots on persistence, we have identified several highly problematic gaps in the assessment of substances as it was illustrated from the evaluation of the "dossiers" (Renewal or Draft assessment reports) for the 10 most sold PFAS substances in France in 2021. These gaps demonstrate that the toxicity of PFAS substances is poorly assessed and/or does not lead to protective ban decisions by the European Commission and Member States. The gaps in the risk assessment of PFAS substances are unfortunately common practice and are not limited to PFAS pesticides.

Gaps in risk assessment

Metabolites

As mentioned before, the very persistence of PFAS substances in pesticides can also result from the properties of their degradation products (metabolites). However, the Pesticide Regulation, in the way it is currently implemented, not only fails to fully address the toxicity of pesticide metabolites but may also fail to regulate them in case they are found to be toxic.

For pesticides, metabolites are classified as 'relevant' or 'non-relevant', from a toxicological point of view, focusing, however, only on human health. This classification determines the permitted levels in the environment as well as in water for human consumption. It means that an active substance can still be approved if its metabolites meet one of the so-called "cut off criteria" such as being classified as damaging fertility (toxic for reproduction category 1B), while it would be banned if the active substance itself presented this classification (17) . Instead, these metabolites classified as hazardous will be considered as "relevant" by regulators, and the substance will be approved as long as its concentration in groundwater is not expected to exceed 0.1 µg/L. This risk assessment practice goes against the hazard-based approach of the Pesticide Regulation, and a risk-based approach applies to pesticide residues. In addition, the methodology to identify relevant metabolites has strong limitations as hazardous properties, such as persistency and endocrine disruption, are not one of the criteria needed to identify metabolites as relevant, whereas other hazardous properties such as toxicity to reproduction and carcinogenicity are not always assessed if the parent compound is not considered toxic (18).

The consequence of this poor assessment is that the majority of metabolites are being classified as non-relevant and are allowed in groundwater up to 10 µg/L, i.e. a hundred-fold higher than for relevant ones. For example, TFA, a major metabolite of certain PFAS pesticides has not been identified as relevant, even though its half-life is more than 10,000 days and may spread to different environmental compartments resulting in the chronic exposure of a wide range of environmental species. Furthermore, emerging evidence points that TFA's toxicity in pesticide risk assessment has been largely underestimated.

Therefore, despite being identified as extremely persistent, pesticide companies do not carry out a thorough long-term risk assessment for non-relevant metabolites. These limitations have led to the authorisation of substances whose metabolites are harmful resulting in the contamination of European drinking waters at concerning levels for consumers and spread throughout the environment leading to chronic exposure of the ecosystems (19) .

Table 8: PFAS active substances approved despite problematic metabolites (based on France's top 10 sales)

Flufenacet	Pour toutes les utilisations, le métabolite très persistant TFA est prévu dans les eaux souterraines à des niveaux supérieurs à la limite légale de 10 µg/L pour les métabolites non pertinents.
Fluopicolide	Risque potentiel de contamination des eaux souterraines au-delà de la limite réglementaire de 0,1 µg/L. L'évaluation des eaux souterraines du métabolite lysimétrique M15 doit être finalisée (trouvé à des concentrations moyennes annuelles allant jusqu'à 0,095 µg/L).
Mefentriconazole	Métabolite 1,2,4 triazole : toxique pour la reproduction catégorie 1B.

Endocrine disrupting properties

Another concern shared by the scientific community and regulators regarding PFAS is that some of the chemicals interfere with the endocrine system of humans and other living organisms. According to the Pesticide Regulation, pesticide active substances, safeners or synergists, cannot be approved if it is shown that they have endocrine disrupting properties that may cause adverse effects to humans or non-target species.

However, the criteria to identify endocrine disrupting (ED) pesticides are only applicable since 2018 and therefore all application dossiers submitted in the framework of the approval of active substances before that date did not include sensitive tests to assess whether a substance is an endocrine disruptor. This has created enormous data gaps in the assessment of ED pesticides, where conclusions could not be drawn because the companies on one hand had submitted long-term toxicity studies without the ED-sensitive endpoints and on the other, had failed to provide all ED-specific tests hiding behind the lack of a guidance document. Therefore, until 2018 the ED properties of PFAS were poorly assessed.

This unfortunately resulted in PFAS with ED properties getting approved. Further, the assessment of endocrine disruptors conducted since 2018 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.

Table 9: PFAS substances whose ED assessment is not finalised (based on France's top 10 sales)

Fluopyram	The ED assessment for birds and fish was not finalised.
Lambda-cyhalothrin	The ED assessment for non-target organisms, the consumer risk assessment and the risk assessment for aquatic organisms for a metabolite were not finalised
Mefentrifluconazole	The ED assessment for fish was not finalised.

Absence of assessment of cocktail effects

Another concern, also raised in the PFAS restriction proposal, is that EU citizens and the environment are generally exposed to different PFAS and several harmful chemicals at the same time. Such a combined exposure can multiply the harmful effect of individual substances and generate new toxic effects. The inevitable cocktail effects of these mixtures to humans and the environment should lead to a reconsideration of the level of exposure deemed safe. Although the Pesticide and the Maximum Residue Levels (MRL) Regulations (20) require the cumulative and synergistic effects of pesticides to be assessed and taken into account for decision making since 2005, the European Food Safety Authority (EFSA) has not developed any guidance to carry out this cumulative and synergetic assessment and therefore it is not established yet that the exposure levels to pesticides are truly safe. In the meantime, no mixtures safety factor has been imposed to compensate for this weakness in the risk assessment.

This lack of assessment of cocktail effects and of chronic toxicity of the pesticide formulation has concrete and severe consequences

Namely, it leads to the marketing of pesticide products containing several active substances, including several PFAS active substances. For instance, the two PFAS active substances approved as candidates for substitution diflufenican and flufenacet are generally mixed in one herbicide product (21) , sometimes together with a third active substance (22) and potentially harmful co-formulants. As a refresher, flufenacet and diflufenican are two most sold PFAS substances in France. The risk of exposure to these substances is therefore extremely high both for the environment and humans.

Gaps in the assessment of pesticide formulations

The Pesticide Regulation and EU case law (23) oblige Member to assess the human relevant long-term toxicity of pesticide formulations (products) before authorising them. Long term toxicity studies, however, are still not carried out on the formulations to date, even when there are indications that the whole product is more toxic than the active substance itself. This contributes to the marketing of products whose toxicity potential for humans and the environment is significantly underestimated.

Furthermore, while the Pesticide Regulation requires the same level of protection from the co-formulants added in pesticide formulations and for active substances (i.e. no harmful effects on human health and animal health, no unacceptable effects on the environment), no concrete regulatory action was taken until very recently to ensure the implementation of this obligation. It was only in 2023 that harmonised criteria to identify further unacceptable co-formulants were adopted. Yet, despite these criteria, there are no data requirements applicable to co-formulants, meaning that Member States do not receive the toxicological data they need to carry out a risk assessment to take a decision to ban certain co-formulants. Some very limited data are available from other pieces of legislation but for substances that are used exclusively as co-formulants in pesticide products, no data exist. As a result, their toxicity remains totally unknown. Therefore, we welcome that PFAS co-formulants, unlike active substances, are currently included in the PFAS restriction proposal.

Un-protective risk management decisions

"Cut-off" substances

To ensure a high level of protection of human health, animal health and the environment, the Pesticide Regulation foresees that when active substances are found to have some hazardous properties (CMRs Cat 1A/B, POP, PBT, vPvB) [24] , they must promptly be banned without further need for risk (exposure) assessment. These properties stand as "cut off criteria". Earlier we explained that neither 'persistent' nor 'very persistent' alone were regarded as cut-off criteria to prevent the approval of persistent substances such as PFAS.

However, risk managers do not entirely comply with this cut-off approach, and PFAS substances that fulfil the cut-off criteria and should have been banned are actually approved in the EU. Moreover their authorisation period has been repeatedly prolonged.

Table 10: PFAS active substances meeting a cut off criteria (based on France's top 10 sales)

Diflufenican	PBT criteria (2018)
Flurochloridone	Toxic for reproduction category 1B (2018)

While flurochloridone's approval initially expired in 2020, it has been prolonged until 2026 giving thereby a 6-year reprieve to this substance before it gets banned (or receives another prolongation). In the case of diflufenican, the Member State in charge of its assessment, concluded that the substance meets the PBT criteria, yet its bioaccumulation properties are not acknowledged in EFSA's peer review conclusion. The substance's EU market approval has already been prolonged for 5 extra years due to delays in the regulatory process.

Substances with 'Critical Areas of Concern'

When EFSA cannot conclude that there is at least one safe use of the substance for human health and the environment in all exposure scenarios, it highlights "critical areas of concern" in its conclusion. This should be understood as a red light by the Commission and Member States as it means that the concerned substance does not meet the approval requirements of the Pesticide Regulation and therefore must be banned. However, in practice, the risk managers often overlook this scientific conclusion and approve active substances including PFAS for which critical areas of concern have been identified by EFSA. Most critical areas of concern deal with the risk of groundwater/drinking water contamination above safety levels or with the unacceptable effects of these substances on the environment.

Table 11: PFAS active substances approved while no safe use could be demonstrated (based on France's top 10 sales)

Fluopicolide	Fluopicolide has potential for long range transport through the atmosphere when applied by spraying as for the representative uses evaluated. Potential risk of groundwater contamination above the regulatory limit of 0.1 µg/L.
Fluopyram	A high long-term risk to insectivorous birds for strawberries and tomatoes used in 2013. The two uses were prohibited only in 2019.
Flurochloridone	A high risk to algae was identified for the representative uses. It was demonstrated that the test material used in the ecotoxicity studies is representative of the technical specification.
Lambda cyhalothrin	A high acute and chronic risk to aquatic organisms was indicated for all representative uses. It could not be fully demonstrated that the batches used in the toxicological and ecotoxicological studies are compliant to the proposed technical specification, as it appears that some impurities have not been tested (or not at an appropriate level) in the toxicological studies.
Tau-fluvalinate	A high risk is identified for the aquatic environment. A high risk is identified for non-target arthropods. A severe impact on non-target arthropods is to be expected in the in-field and off-field area.

Substances for which the assessment is not finalised

In all the dossiers we analysed, we found that EFSA has identified "issues that could not be finalised" or "data gaps". The most frequently encountered aspects that could not be finalised were the risk to consumers and the assessment of endocrine disrupting properties, even though the latter would result in a ban. In some cases, additional data is deemed necessary by EFSA to determine whether the substance meets the regulatory authorisation criteria. However, the Commission has prolonged the authorisation of these substances without requesting any additional data, despite EFSA's opinion that the assessment is incomplete.

Table 12: PFAS active substances approved while the assessment is not finalised and essential data are missing (based on France's top 10 sales)

Fluopyram	Approved for the first time in 2014 even though the assessment of the potential endocrine disruptor effects on birds and fish could not be finalised. This assessment still can't be finalised after submission of confirmatory data.
Mefentrifluconazole	The ED assessment for fish is not finalised. Further information was deemed necessary by EFSA but the Commission approved the substance without requesting any additional data

No substitution

Based on the information presented earlier, there is no doubt that PFAS active substances are harmful and underregulated, despite the provisions of the Pesticide Regulation, which state that pesticides and their metabolites should not harm human health and the environment. On top of not being banned, PFAS active substances are not all flagged as "candidates for substitution", contrary to the claim made in the proposal for a PFAS restriction.

Out of the top 10 sold PFAS pesticide active substances in France, only 4 are approved as candidates for substitution, while the rest remain off the radar and are treated as any other pesticide. The fact that they are massively sold in France, despite the many available alternatives, further shows the lack of implementation of the substitution principle

Table 13: PFAS substances approved as candidates for substitution (based on France's top 10)

Diflufenican	2 PBT criteria
Flufenacet	2 PBT criteria
Flurochloridone	toxic for reproduction 1B
Lambda-Cyhalothrin	2 PBT criteria

Are new PFAS pesticide substances safer?

Overall, new pesticide active substances approved in recent years are regarded by regulators as safer than those approved many years ago. We fact-checked this assumption. The example of flutianil, approved for the first time in 2019, shows that the most recent substances are just as problematic as the older ones.

Flutianil was approved for the first time in 2019 even though:

- The substance is persistent and its metabolite OC 53635 is very persistent based on the PBT or vPvB criteria.
- A potential risk for toddlers and infants due to the consumption of contaminated drinking water was identified by EFSA and a refinement of the assessment was not possible. No additional data has been requested by the Commission even though a data gap has clearly been identified by EFSA
- The consumer risk assessment was not finalised
- The endocrine disruption assessment for non-target organisms other than wild mammals was not finalised

Manufacture of PFAS pesticide products for exports

While the proposed restriction intends to completely phase out PFAS in Europe, including their manufacture and export to third countries, the pesticide regulation is not fit to address this aspect of PFAS pollution. Indeed, 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”, but it does not cover the manufacture of pesticide products, contrary to the REACH Regulation. This means that pesticides products which are not or no longer authorised in the EU because they are regarded as too toxic for human health and the environment, can still be produced, stored and transported in the EU if they are exported for use in a third country. This results in the export of tonnes of hazardous active substances and pesticide products for use in agriculture in non-EU countries. The EU will not lead by example the fight for a global PFAS phasing out if it keeps allowing the export of PFAS (authorised and banned) pesticides from European pesticide factories to third countries, in particular to low and middle-income countries. Furthermore, it must be noted that the manufacture, storage and transport of PFAS substances and PFAS pesticide products are likely to lead to PFAS contamination in the EU.

overview table of the toxicity of the ten best-selling substances in France

Active Substance (a.s.)	Classification CLP	Active substance Persistency[1)]	Metabolite persistency	Identified risk of groundwater contamination by a.s. and/or metabolite above 0.1µg/L?	Candidate for substitution ?	"Critical area of concern" identified by EFSA?	"Issue that could not be finalised" identified by EFSA?
Based on top 10 sales in France							
flufenacet	Very toxic to aquatic life with long lasting effects. May cause damage to organs through prolonged or repeated exposure. Harmful if swallowed. May cause an allergic skin reaction.	Not persistent	TFA : Very persistent	Yes	Yes	No EFSA peer review available	No EFSA peer review available
diflufenican	Very toxic to aquatic life with long lasting effects.	Very persistent	/	Yes	Yes	No recent EFSA peer review available RMS estimates diflufenican is PBT	No recent EFSA peer review available. Issue that could not be finalised identified by the RMS in the RAR
fluopyram	Toxic to aquatic life with long lasting effects.	Very persistent	/	No	No	No	Yes
méfentrifluconazole	Very toxic to aquatic life with long lasting effects. May cause an allergic skin reaction.	Very persistent	1,2,4-triazole: Persistent	No	No	No	Yes
trifloxystrobin	Very toxic to aquatic life with long lasting effects. May cause harm to breast-fed children. May cause an allergic skin reaction.	Not persistent	CGA 321113 : Very persistent	Yes	No	Yes	Yes
lambda cyhalothrin	Very toxic to aquatic life with long lasting effects. Toxic if swallowed, Harmful in contact with skin Fatal if inhaled.	Not persistent	/	No	Yes	Yes	Yes
flurochloridone	Very toxic to aquatic life with long lasting effects. May damage fertility. May damage the unborn child. Harmful if swallowed. May cause an allergic skin reaction.	Not persistent	R42819 : Very persistent	Yes	Yes	Yes	Yes
fluopicolide	Suspected of damaging the unborn child	Very persistent	M-01: Very persistent	Yes	Yes	Yes	Yes
fluazinam	Very toxic to aquatic life with long lasting effects. Suspected of damaging the unborn child Harmful if inhaled. Causes serious eye damage. May cause an allergic skin reaction.	Not persistent	HYPA : Very persistent	No	No	No recent EFSA peer review available. Critical area of concern identified by the RMS in the RAR	No recent EFSA peer review available. Issue that could not be finalised identified by the RMS in the RAR
tau-fluvalinate	Very toxic to aquatic life with long lasting effects. Harmful if swallowed Causes skin irritation	Not persistent	Haloaniline : persistent	No	No	Yes	Yes
Most recently approved new PFAS active substance							
flutianil	Very toxic to aquatic life with long lasting effects.	Persistent	OC 56635: Very persistent	Yes	No	No	Yes

Conclusion

A dramatic contamination

The report shows that pesticide use is contributing to the dramatic contamination of our planet with PFAS, and that this contamination is deliberate and direct. Pesticides are sprayed in open fields and released directly on our food and into the environment, contaminating soil as well as water, and living organisms. Sales data from France suggest that the substances have become increasingly popular over the years with a new record of tonnes sold each year. Therefore, the extent of this deliberate contamination may be greater than regulators believe.

An analysis of the 10 best-selling substances in France raises alarming concerns. These PFAS substances are persistent and toxic, and yet they fall through the cracks of the regulatory process carried under the Pesticide Regulation, revealing shortcomings in the EU law implementation (summary table Annex 1).

Ban PFAS pesticides

Synthetic pesticides are not essential for crop protection and, in the frame of the EU Green Deal, the EU is committed to significantly reducing its reliance on synthetic pesticides over the next few years. It is therefore unacceptable that, while the EU has decided to ban PFAS chemicals in Europe, it has not taken specific measures to reduce pollution from PFAS-based pesticides. We call for an urgent ban on this easily avoidable source of PFAS pollution.

Policy Demands

Long-term solution: including PFAS pesticide substances in the **universal PFAS restriction**

The inclusion of PFAS used as active substances in pesticides within the scope of the currently discussed REACH PFAS restriction is the most appropriate policy means to ensure a comprehensive phasing out of all PFAS chemicals, including pesticides. This results both from the group approach undertaken in this restriction and from the scope of the REACH Regulation which includes the manufacture and the import of PFAS on top of their placing on the European market. Therefore, we ask regulators to delete the current exemption for pesticide substances foreseen in the present restriction proposal.

Intermediate action: improving the implementation of the **Pesticide Regulation**

The PFAS restriction will only come into effect around 2030 following several years of regulatory discussions and an 18-month transition period. This period is far too long for pesticides, considering that their use in open fields results in deliberate PFAS environmental pollution and PFAS residues in our food. In the meantime and in line with the European Green Deal, the EU has set the objective to move away from pesticide dependency in agriculture and cut by 50% the use and risk of chemical pesticides and of more hazardous ones by 2030. Therefore, **the European Commission and Member States must use the latitude they have under the Pesticides Regulation to already ban PFAS active substances**.

This is of particular relevance as 27 PFAS active substances out of 37 are currently being reassessed for renewal of their approval. For the remaining 11 active substances, the Commission and Member States are empowered to review their current approval, in the light of new scientific and technical knowledge (25) .

1 Consider persistence as unacceptable effect on the environment

To date, persistence alone is not considered to constitute an unacceptable effect of pesticides and their residues on the environment by decision makers implementing the Pesticide Regulation. Therefore, persistent substances can still be approved. This approach is now clashing with that undertaken under the proposed PFAS restriction proposal. Indeed, the legal basis for this later regulatory action is that the persistence of PFAS chemicals poses an unacceptable risk to health and the environment. Considering the EU's ambition to bring consistency between its different chemical framework and the latitude risk managers have in the definition of what is unacceptable under the Pesticide Regulation and REACH, there is a clear need for risk managers to align across the different regulations on chemicals.

Pesticides pose a unique threat due to their inherent toxicity and widespread use in food production. Specifically designed to be biologically active and eliminate organisms that are considered pests, these substances are also harmful to non-target species. Their application in open agricultural fields results in the intentional introduction of these toxic chemicals into the different environmental compartments. This practice contaminates not only the environment but also our food and water supply, potentially endangering human health and ecosystems. Therefore, if the active substance or their metabolites are found to be persistent, immediate action is necessary for their strict regulation. **In other words, the European Commission and Member States must start considering persistence data on active substances or their metabolites as an unacceptable effect and ban substances on this sole ground.**

2 Strictly comply with the approval requirements of the Pesticide Regulation

As demonstrated in the report, some PFAS active substances do not meet the approval requirements to be approved, either because they meet one of the cut-off criteria, or because of other health or environmental concerns, particularly in cases where EFSA has identified critical areas of concern warning that no safe use exists. In case of any uncertainty identified in the assessment the risk managers must evoke the precautionary principle, in line with the provisions of the EU Pesticides Regulation.

The Commission must put an end to its patterns of prolonging the current approval of these substances years after years and proceed with the ban of all active substances for which it has not been clearly demonstrated that they meet all the approval criteria of the Pesticide Regulation.

3 Move towards a pesticide-free agriculture

The significant reduction of EU dependency to synthetic pesticides including PFAS is urgent and essential to protect farmers', farmworkers' and citizens' health, tackle the biodiversity crisis, the pollution of aquatic and other ecosystems, and support the much-needed transition towards resilient food systems. The need to significantly reduce pesticide use has been stressed by the scientific community, and repeatedly called for by EU citizens.

A recent IPSOS citizens poll showed again a high level of concern about risks of pesticides to food, health and the environment, and a preference for a precautionary approach to the regulation and use of pesticides. As many as 82% of Europeans expressed concerns about the environmental impact of pesticides and 76% were concerned about the impact on their health. A ban on PFAS pesticides will meet citizens' expectations and encourage the use of nature-based alternatives.

Annex : Overview of toxicity issues regarding the 10 most popular PFAS pesticide substances sold in France

Our analysis of the pesticide regulation is based on the dossiers for the 10 most sold PFAS substances in France in 2021, which we analysed in detail. Below, we report on all the shortcomings found in each of these dossiers. These are evidence of the lack of safety of these substances.

Flufenacet

Initially approved from 2004 to 2013, the authorisation has been prolonged 8 times for almost 10 years (until 31/10/2023) without any EFSA peer review being published. This will result in a total of 19 years of authorisation period.

However, flufenacet is a candidate for substitution (maximum authorisation period should be 7 years) and according to the RAR, there is a concern regarding the contamination of groundwater by flufenacet metabolites (the persistent metabolite TFA is predicted to reach groundwater at levels above 0.75 µg/L for all representatives uses in all FOCUS scenarios and in some scenarios above 10 µg/L for all uses)

Diflufenican

Approval of diflufenican expired in 2018 but was prolonged for 5 years even though:

- It is a candidate for substitution (P and T criteria met)
- The Rapporteur Member State (RMS) estimated in 2018 that diflufenican complies with all PBT criteria, as it has a bioconcentration factor higher than 2000, therefore meeting the B criterion as well. This issue remains to be resolved.

Fluopyram

Fluopyram was approved for the first time in 2014 even though the assessment of the potential endocrine disrupting effects in birds and fish could not be finalised. This assessment still cannot be finalised even after submission of confirmatory data by the companies.

Field uses of fluopyram on strawberries and tomatoes were authorised for 5 years from 2014 to 2019 even though a high long-term risk to insectivorous birds was identified by EFSA for these uses.

Mefentrifluconazole

Mefentrifluconazole was approved for the first time in 2019 even though:

- the consumer risk assessment was not finalised
- No final conclusion could be drawn with regard to endocrine disruption in fish. The European Commission authorised the substance without requesting any additional data, going against EFSA's opinion, which considered that further information (e.g. a test according to OECD 229) was necessary in order to draw a final conclusion regarding endocrine disruption in fish.

Trifloxystrobine

Trifloxystrobin was approved in 2018 for the second time for 15 years even though:

- The consumer risk assessment was not finalised
- According to the opinion of EFSA and 2 Member States (France and Germany) trifloxystrobin should be classified as reprotoxic of category 2, which would deem the metabolites relevant and would have led to a ban of the substance due to contamination of groundwater above the legal limit. However, ECHA did not classify it as reprotoxic (and the metabolites are thus considered non relevant) on the basis of confidential data provided by Bayer during the public consultation phase.

Lambda-cyhalothrine

Lambda-cyhalothrin was approved for the second time in 2016 for 7 years and the approval was prolonged of one year until 31/03/2024 even though:

- It is a candidate for substitution because it is bioaccumulative (B) and toxic (T), therefore fulfilling two out of the three PBT criteria and because ADI and AOEL values are very low;
- Lambda-cyhalothrin is neurotoxic with a risk identified for bystanders if they remain between 3 to 10 metres from the spray application;
- Two critical areas of concern were identified by EFSA in 2014, including a high risk for aquatic organisms for all representative uses. However, the commission considered that the risk is acceptable thus going against the EFSA opinion, which clearly concludes that there is a high risk;
- The ED assessment for non target organisms was not finalised;
- The consumer risk assessment was not finalised;
- The risk assessment for aquatic organisms of metabolites of lambda-cyhalothrin was not finalised;
- Many data gaps (34) were identified;

Flurochloridone

Flurochloridone was approved for the first time in 2011 even though:

- A high risk for algae for all representative uses was identified and considered as a critical area of concern by EFSA in 2010
- It has not been demonstrated that the test material used in the ecotoxicity studies is representative of the technical specification. This has been identified as a critical area of concern after the submission of confirmatory data in 2013. The Commission did not follow the opinion of EFSA on this issue

Despite ECHA classifying it as as reprotoxic category 1B in 2018, approval of flurochloridone has been prolonged 3 times (in 2021, 2022 and 2023) until 15/03/2026, resulting in a total of 5 years of prolongation.

Fluopicolide

Approval of fluopicolide would have been expired in 2020 but has been prolonged for more than 6 years until 31/08/2026 even though:

- It is a candidate for substitution (P and T criteria met)
- It has the potential for long-range transport through the atmosphere when applied by spraying

- Metabolite M15, which has to be considered as relevant since fluopicolide is classified as reprotoxic category 2, is expected in groundwater at concentrations above the legal limit for relevant metabolite, according to EFSA. The Commission did not follow the opinion of EFSA on this issue.

Fluazinam

Approval of fluazinam expired in 2019 but was prolonged for 5 years until 29/02/2024 even though:

- No EFSA peer review is available since 2008
- The RMS identified in 2019 in the RAR a high long-term risk to mammals for all representative uses (this is a critical area of concern) and therefore considered that it could not be shown that fluazinam complies with Article 4 of Regulation (EC) No 1107/2009 for at least one of the representative uses.

Tau-fluvalinate

Tau-fluvalinate was approved for the first time in 2011 for 10 years but its approval was prolonged for 3 years until 31/08/2024 even though 3 critical areas of concern were identified by EFSA, including high risk for the aquatic environment and the non-target arthropods.

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16. See points 3.7.2.1 and 3.7.3.1 of Annex II of Regulation (EC) 1107/2009.
17. See the example of triazole active substances: the 1,2,4 triazole metabolite is classified damaging fertility (toxic for reproduction category 1B) but several of its parent active substances are still authorised for use in the EU including the two PFAS substances mefentrifluconazole and tetraconazole.
18. For details, please refer to Groundwater Guidance Document SANCO/221/2000 rev.11 (21/10/2021).
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22. Mixed with pendimethalin, another active substance approved as a candidate for substitution due to its toxic and persistent properties and its bioaccumulative potential.
23. Case C-616/17.
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25. According to Article 21 of Regulation (EC) 1107/2009.

UNMASKING PFAS PESTICIDES AUTHORISED IN EUROPE

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