PFAS PESTICIDES

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CONTEXT

→at EU level, PFAS are being addressed by ECHA

January 2023: Submission of proposal to ECHA to restrict circa 10 000 PFAS under REACH by 5 national authorities: https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b

→Pesticide active substances can also be PFAS: **EFSA** remit

- June 2023: the European Commission requested to EFSA to ensure that pesticide active substances and metabolites identified as PFAS based on chemical structure are **explicitly mentioned in the EFSA conclusions**, according to the Restriction proposal under REACH.

  →Note on PFAS added in EFSA conclusions: in the first section and in the Appendix D

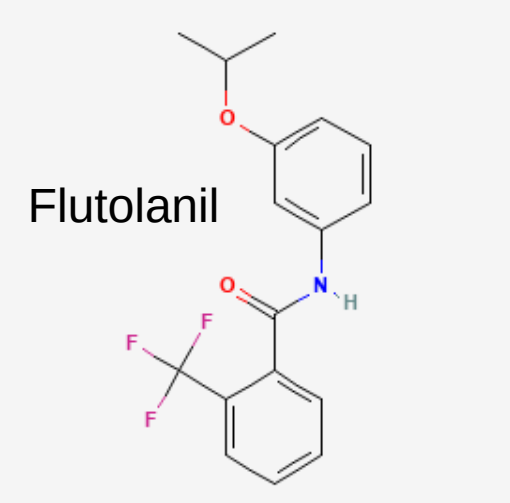
  →First cases: tritosulfuron (EFSA, 2023), flutolanil (EFSA, 2023) and related metabolites

PFAS PESTICIDE ACTIVE SUBSTANCE

How do we define PFAS pesticide active substances and metabolites?
Based on the structure

OECD guidance (2021)[1]

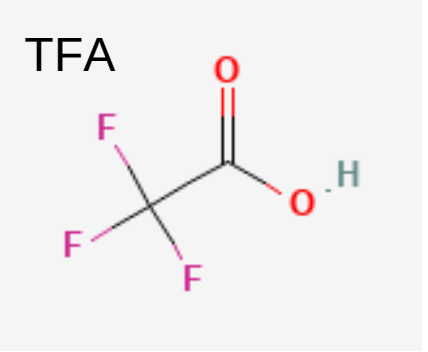
'Fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF3) or a perfluorinated methylene group (–CF2–)'



MSs restriction intention submitted by ECHA (2023)[2]

→ more recent definition used in EFSA peer review

'Any substance that contains at least one fully fluorinated methyl (CF3-) or methylene (-CF2-) carbon atom (without any H/Cl/Br/I attached to it).'



[1] https://one.oecd.org/document/ENV/CBC/MONO(2021)25/En/pdf
[2] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b

PFAS PESTICIDE ACTIVE SUBSTANCE IN THE PEER REVIEW

Concerns raised from PFAS

- **Persistence** in the environment
- **Potential for accumulation** in humans, animals and plants
- Certain PFAS are known to cause **adverse effects**

→All these endpoints addressed in the context of the EFSA Peer Review process

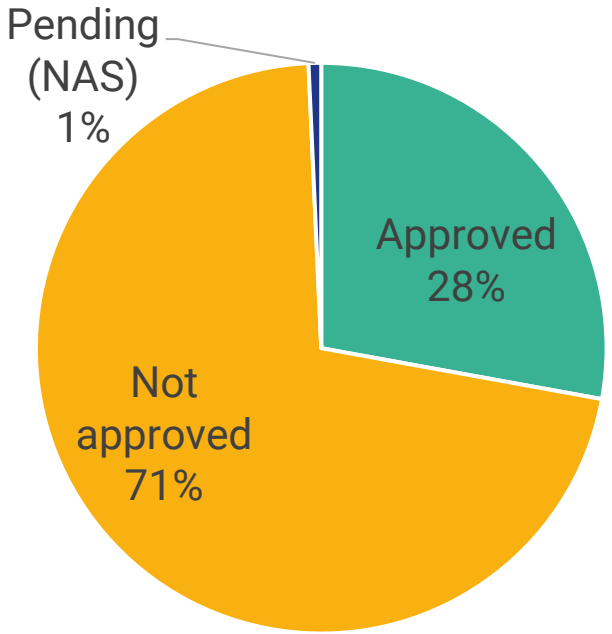
→Outcome reported in the EFSA conclusions independently whether the substance is a PFAS or not

→Part of the approval criteria under Article 4 of PPP Regulation

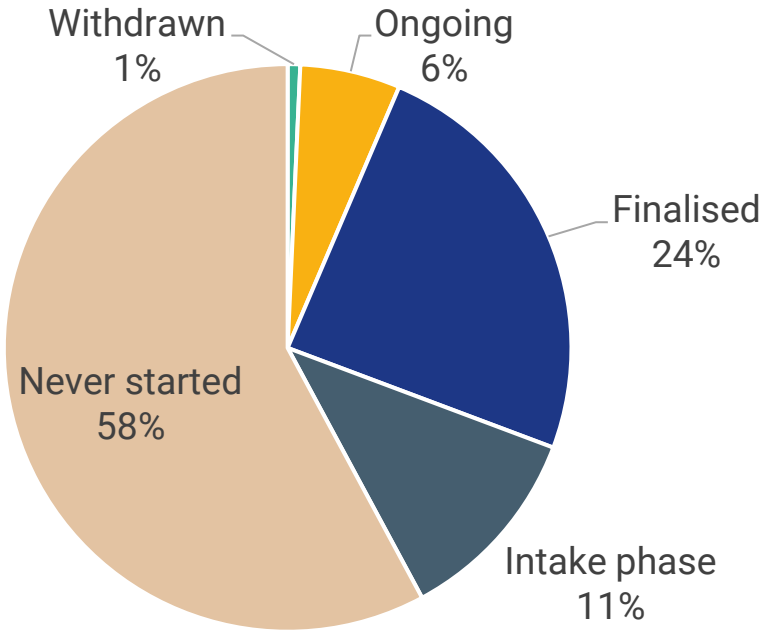
Persistence in the environment	• Data requirement in 283/2013 • Cut off criteria: POP, PBT, vPvB
Toxic for reproduction / developmental toxicity	• Data requirement in 283/2013 • Cut off criteria: toxic to reproduction 1A/1B
Carcinogenicity	• Data requirement in 283/2013 • Cut off criteria: carcinogen 1A/1B
Endocrine disruptors	• Data requirement in 283/2013 • Cut off criteria: ED

PFAS PESTICIDE ACTIVE SUBSTANCE IN THE PEER REVIEW

→**140 PFAS pesticide active substances** identified as PFAS based on structure so far – <u>non exhaustive list</u>



Status under Regulation (EC) 1107/2009



Status of the EFSA peer review process

OUTCOME OF THE PEER REVIEW

59 PFAS active substances peer reviewed or under PR process

- Approved: 66% - Not approved: 32% - Pending (NAS): 2%

Example of some recent EFSA conclusions:

PFAS active substance	Outcome of the peer review	Status under Reg 1107/2009
Tritosulfuron EFSA conclusion, 2023	No CAOC but several INF set including linked to **data gaps on metabolite TFA**	Currently approved but application withdrawn by the applicant in May 2024
Flutolanil EFSA, conclusion 2023	No CAOC but several INF set including linked to **data gaps on metabolite TFA**	Approved until June 2025; renewal under discussion
Triflusulfuron-methyl EFSA conclusion, 2022	Several CAOC and INF set including concerns raised on **ED criteria met.**	Not approved since Nov 2023
Benfluralin EFSA conclusion, 2019	Several CAOC and INF set, including concerns raised on **PBT criteria may be met**.	Not approved since Feb 2023

TRIFLUOROACETIC ACID (TFA)

- Persistent metabolite
- Originates from multiple sources:
  - Formed from the breakdown of PFAS chemicals including some active substances used in PPPs and biocidal products
  - *Pre-cursor in the manufacture of chemicals and occurs naturally in the environment (?).*
- It may leach into groundwater or may be present as a residue in crops

Among 59 cases, **12 PFAS active substances** shown to produce TFA in residues, soil and/or groundwater

For the **7 ongoing peer review processes,** actions from EFSA:

- Public consultation: comments to clarify whether TFA is formed in residues, soil, groundwater – importance of radiolabelling
- Data requested if needed (data requirements)
- Experts' consultation set

CASE OF TRIFLUOROACETIC ACID (TFA) - 1

Before 2017

TFA formed by several pesticide active substance: evaluation performed in different peer review processes

2017

Most robust toxicological data package in the case of flurtamone**:** **toxicological reference values** derived.

January 2021

Article 56 notification from Bayer / REACH registrant to EFSA, the EC and all MSs: information on **adverse developmental effects in rabbits** after TFA exposure

November 2022

REACh dossier evaluation by ECHA, updated, including the new developmental toxicity study.

August 2023

Updated assessment in the context of tritosulfuron: **data gap on aneugenicity** based on EFSA SC Guidance doc on genotoxicity (2021)

CASE OF TRIFLUOROACETIC ACID (TFA) - 2

November 2023

CLH proposal from DE in the registry of CLH intentions on TFA

May 2024

Update to Article 56 notification from TFA task force: submission of all remaining studies to EFSA, the EC and all MSs

June 2024

Submission of CLH dossiers by DE on TFA and TFA salt:

→ Proposal classification for **reproductive toxicity 1B, vPvM, PMT**

July 2024

EC **mandate** to EFSA for a review of the toxicological reference values for

trifluoroacetic acid (TFA)

31 October 2025

Deadline for the EFSA **statement** on toxicological reference values for TFA

Thanks for your attention

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