EFSA RISK ASSESSMENTS OF TFA

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PREV mammalian toxicity

EUROPEAN FOOD SAFETY AUTHORITY

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
- 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

BACKGROUND

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.

ADI = 0.05 mg/kg bw per day (expressed as sodium trifluoroacetate) based on a 90-day rat study – UF 200 (extrapolation from subchronic to chronic exposure).
No ARfD needed based on the available toxicological studies

BACKGROUND

August 2023:

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

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**

EUROPEAN COMMISSION MANDATE

Ref. Ares(2024)5440452 - 26/07/2024

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food Safety, Sustainability, and Innovation
Pesticides and Biocides

Brussels
SANTE.E.4/MW/et(2024)6060727

[redacted]

Subject: Request for a review of the toxicological reference values for trifluoroacetic acid (TFA)

Trifluoroacetic acid (TFA) is a persistent metabolite formed from the breakdown of some active substances used in plant protection [1] and biocidal products as well as from the breakdown of other PFAS chemicals. It is also used as a pre-cursor in the manufacture of chemicals and occurs naturally in the environment.

TFA thus originates from multiple sources and may also form in soil from the breakdown of certain active substances. It may then leach into groundwater or may be present as a residue in crops, in particular crops grown in rotation with those treated with substances that breakdown into TFA.

Request from the Commission to issue an EFSA statement

26 July 2024

- **To derive HBGVs** (ADI and ARfD) for TFA to be used in risk assessments.
- **Proposed values in the draft statement**:

ADI = 0.03 mg/kg bw per day (expressed as sodium trifluoroacetate)	ARfD of 0.6 mg/kg bw (expressed as sodium trifluoroacetate)

- **60-day public consultation** – from 22 July to 22 September 2025

→**Substantial number of comments collected: 177 comments from a wide range of stakeholders:**

NEXT STEPS

Extended legal deadline: 31 July 2026

NEW MANDATE TO CONSIDER THE FATE AND BEHAVIOUR OF TFA IN SOIL AND WATER

- Why is TFA a concern?
  - Concerns about the presence of TFA in the environment and human exposure (in particular through drinking water) have increased over the years.
  - For persistent active substances, the formation of TFA may occur over extended periods.
  - The standard **OECD 307 soil degradation study,** when only following the option of a **120-day incubation**, may not adequately capture the long-term formation of TFA.

A **new joint mandate** has been received by **EFSA and ECHA,** currently under acceptance phase.

MAIN OBJECTIVES OF THE NEW MANDATE

- Compile list of approved substances with TFA formation potential
- Indicate factors and conditions influencing TFA formation in soil/ surface water systems.
- Assess suitability of OECD Study Guidelines
- Explore Alternative Prediction Methods

- **Deadline**: within 18 mo from acceptance (to accommodate consultation with Biocidal Product C.ttee (BPC) in ECHA

Thanks for your attention

WORKSHOP ON LATEST ADVANCEMENTS OF PFASs RISK ASSESSMENT

EFSA online event

17 November 2025, 14.00-18.00

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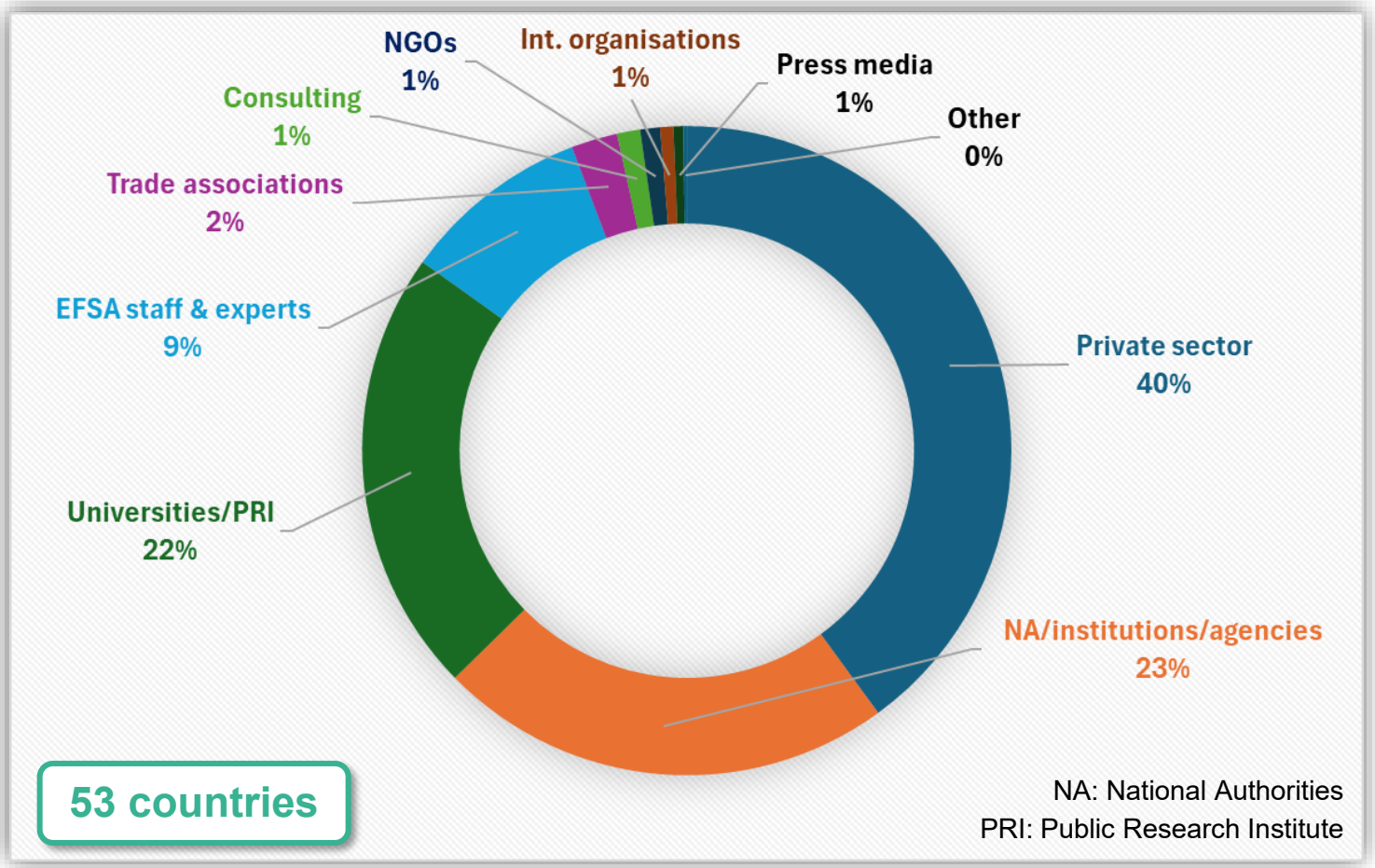
PARTICIPANTS

305 participants (out of 608 registrants) & 180 questions received



PROGRAMME (1/2)

SESSION 1 | Scientific assessments of PFASs Chair: Guilhem de Seze, EFSA (IT)		
14:00-14:10	Welcome and introduction to the event	Guilhem de Sèze, EFSA
14:10-14:20	WHO initiatives to evaluate PFAS (Phase 1)	Virunya Bhat, WHO, Switzerland
14:20-14:30	EFSA risk assessments on PFASs	Chantra Eskes, EFSA, Italy Ron Hoogenboom, EFSA SC; WUR, Netherlands Marco Binaglia, EFSA, Italy
14:30-14:40	EU Member States Initiative Group on PFAS	Matthieu Schuller, ANSES, France & Jorge Numata, BfR, Germany
14:40-14:50	BfR international conference on PFASs	Jorge Numata, BfR, Germany
14:50-15:00	ECHA activities on PFASs	Peter van der Zandt, ECHA, Finland
15:00 – 15:10	EEA reports on PFASs	Nadia Cerioli, EEA, Denmark
15:10 – 15:20	PARC activities on PFASs	Lutz Ahrens, University of Agricultural Sciences, Uppsala, Sweden Thorhallur Thalldorsson, EFSA SC; Statens Serum Institute, Denmark; University of Iceland, Reykjavík
15:20 – 15:50	Questions and answers	Chair, Speakers, Participants
15:50 – 16:10	Coffee break	

PROGRAMME (2/2)

SESSION 2 | Stakeholders perspectives on scientific assessment of PFASs **Chair: Mary Gilsenan, EFSA (IT)**		
16:10-16:15	**The European Consumers Organisation: BEUC**	Lauri ten Grotenhuis, Netherlands
16:15-16:20	**EU Agrocooperative & EU Farmers: Copa and Cogeca**	Henrik Bang Jensen, Denmark
16:20-16:25	**Pesticides Action Network Europe: PAN-Europe**	Angeliki Lyssimachou, Belgium
16:25-16:30	**CropLife Europe**	Emma Brown, Belgium
16:30 – 17:00	**Questions and answers**	Chair, Speakers, Participants
SESSION 3 | General discussion **Moderator: Carlos das Neves, EFSA (IT)**		
17:00-17:45	**General discussions**	Chair, Speakers, Participants
17:45-18:00	**Concluding remarks**	Carlos das Neves, EFSA

MAIN TAKE-HOME MESSAGES

- **PFAS is a large family of compounds which require large scale testing**
- **Need for harmonisation, sharing, alignment and team-up**

  Coordination & prioritization across scientific, academic and regulatory domains
- **Need for integrated solutions**

  Environmental, animal and human health data needed to strengthen risk assessment
- **Persistence and collaboration in risk assessment, risk communication, and in closing scientific knowledge gaps**
  - Foster dialogue, engagement & collaboration
  - Joint strategy to prioritise knowledge gaps and generate missing data
  - Support, training and capacity building
  - Coordinated & clear communication

NEXT STEPS

- Publication of **presentations & workshop report**
- Reflection on **how to build further bridges for co-ordination and communication across all actors** involved

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