EFSA's risk assessments on PFASs

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17 November 2025

EUROPEAN FOOD SAFETY AUTHORITY

OUTLINE

1. EFSA’s activities on PFASs
2. PFASs as contaminants in the food chain
3. Pesticides

OVERVIEW OF EFSA's ACTIVITIES ON PFASs

✓ Risk assessment activities

- Contaminants in the food chain
- Pesticides peer-review
- Food contact materials

✓ Monitoring data collection

Collection of monitoring data following the European Commission recommendation to monitor the presence of PFAS in food from 2022 to 2025 (EC recommendation 2022/1431, 2022).

✓ Collaborations / exchanges

- 2024-2025 EFSA Focal Point Tailor Made activity on Member States Initiative Group on PFASs
- Interactions with PARC
- Exchanges with ECHA, EEA, EMA and observer to WHO

✓ 2024 study on the use of NAMs to explore immunotoxicity of PFASs

PFAS WORKSHOP EFSA 2025

EFSA'S 2020 RISK ASSESSMENT

Ron Hoogenboom

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2020 EFSA CONTAM RISK ASSESSMENT

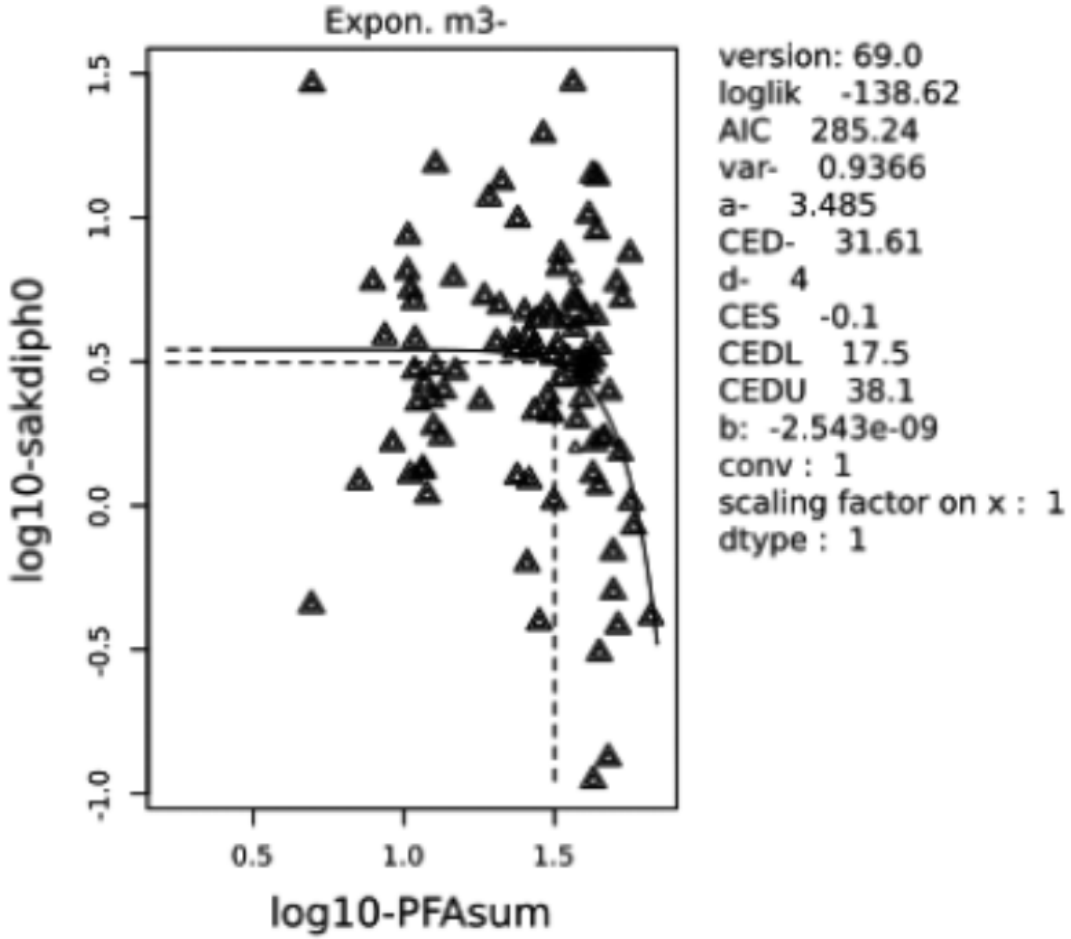
- Opinion on PFOS and PFOA 2018
  - Separate TWIs based on elevated cholesterol levels in humans
- Update 2020
  - Inclusion of other PFASs and application of mixture approach
  - Too much uncertainty on cholesterol increase
- Effects on immune system selected as critical endpoint
  - Observed in several animal and human studies

STUDY WITH INFANTS (ABRAHAM ET AL., 2020)

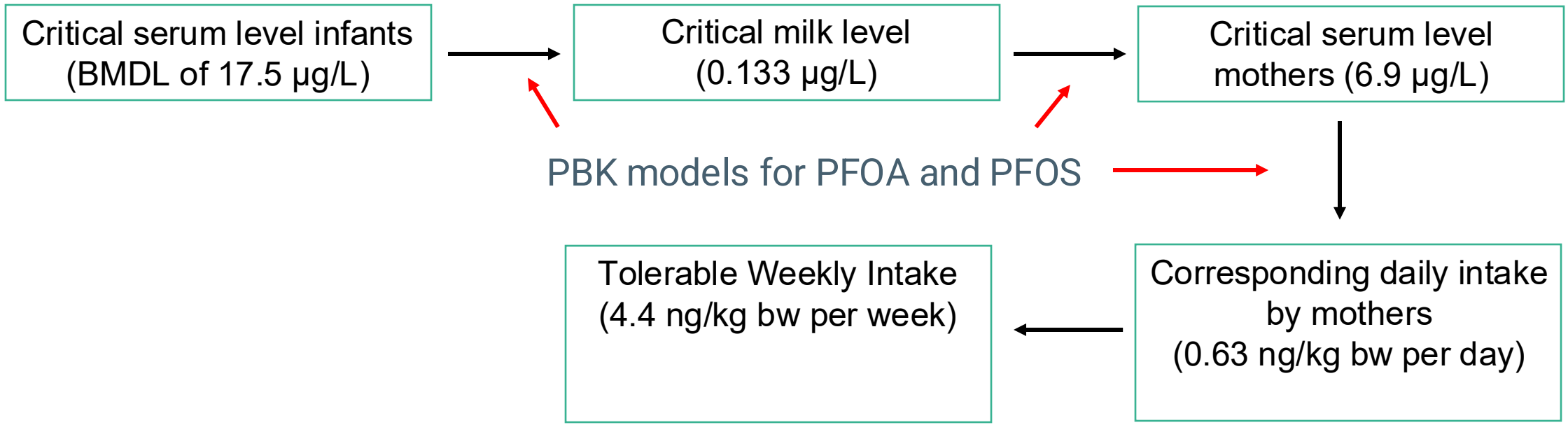
- Carried out end of nineties, focus on OCPs and dioxins
- Reverse association between PFOA serum levels and antibody titers against Hib, tetanus and diphtheria
  - NOAECs of 12.2, 16.9 and 16.2 ng/mL for PFOA
- No significant association for PFOS, PFNA and PFHxS
- Data on Sum of 4 PFASs provided to EFSA

BMD MODELLING DIPHTHERIA FOR SUM OF 4 PFASs

- NOAEC of 31.9 ng/mL for the sum of 4 PFASs
- Data modelled with PROAST software
- $BMDL_{10}$ of 17.5 ng/mL for the sum of 4 PFASs
- Used as Reference Point (RP) to derive Tolerable Weekly Intake (TWI)



DERIVATION OF THE TWI BASED ON BMDL IN SERUM INFANTS



TWI (TOLERABLE WEEKLY INTAKE)

- Translated to intake by infants via milk, and mothers using toxicokinetic model
- TWI of 4.4 ng/kg bw per week
  - For the sum of PFOA, PFNA, PFHxS and PFOS
  - Only PFASs detected in blood of the infants
- Similar potencies assumed for 4 PFASs (default when lack of data)
- Effects may also occur with other PFASs, but no data
  - Only for other effects occurring at higher doses; would suggest lower toxicity
  - TWI applies for PFASs accumulating in mothers and are transferred to infants

CONCLUSIONS

- New TWI of 4.4 ng/kg bw per week
  - for sum of 4 PFASs
- Lack of data on:
  - mode of action behind decreased vaccination response
  - on immunotoxicity other PFASs
  - and to derive relative potency factors based on this endpoint
- TWI exceeded by the European population, implying a health concern
  - Supported by biomonitoring data

EFSA RISK ASSESSMENTS OF TFA

PREV mammalian toxicity - Marco Binaglia

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 and to review the recommended consumer HBGVs for trifluoroacetic acid (ADI and ARfD)

26 July 2024

- Term of reference (ToR) 1: **to collect evidence** in addition to data on TFA already available from EFSA peer review processes, including:
  - (i) additional data on TFA and TFA Na generated by the TFA Task Force
  - (ii) data used by Germany for the CLH dossier on TFA and TFA Na
  - (iii) data submitted to Member States as part of the process for PPP authorisation
- Term of Reference (ToR) 2: **to assess the available evidence** in relation to the toxicological properties of the metabolite TFA and TFA Na and, **if possible, to derive HBGVs** (ADI and ARfD) for TFA to be used in risk assessments.

→ Consultation with Member States, EFSA's Panels/WGs, ECHA RAC

Reference: https://open.efsa.europa.eu/question/EFSA-Q-2024-00502

TERM OF REFERENCE 1 – TARGETED CALL FOR DATA

Call for toxicological and metabolism data on TFA and sodium trifluoroacetate.

From 6 August to 7 October 2024

1) **Member States:**
   - Data from the PPP authorisation dossiers from pesticide active substances identified as PFAS that either form or potentially form TFA, according to the outcome of EFSA peer review procedures.
   - Available data related to the toxicological hazard properties of TFA or TFA Na covering the endpoints of Section 5 – Subsections 5.1. to 5.9.7 in Commission Regulation (EU) No 283/2013.
2) **Competent Authority Germany**, responsible for the CLH proposal under the ECHA procedure:
   - Studies and list of references used in the context of the CLH report
   - The confidential version of the CLH report (OSOA concept)
3) **TFA Task force:**
   - Original study reports or position papers generated by the TFA task force
4) **EFSA**
   - Data from the dossiers submitted within the EFSA peer review processes.

In total,
170 studies and position papers
collected.

TERM OF REFERENCE 2 – EFSA WORKING GROUP ON TFA

Establishment of a dedicated EFSA Working group on TFA

Assessment questions:

1) Based on the results of the target call for data, do the available data raise a concern for genotoxicity?
2) Based on the results of the target call for data, what is the most suitable basis (leading adverse outcome; critical adverse effect) for setting the ADI?
3) Based on the results of the target call for data, is there a need for setting an ARfD? If so, what is the most suitable basis (leading adverse outcome; critical adverse effect)?

Since November 2024, 8 WG meetings organised – consultation of EFSA ED Working group, hearing experts (MSs experts, TFA task force)

To go further:

- Meeting minutes : https://www.efsa.europa.eu/sites/default/files/2024-11/minutes-wg-trifluoroacetic-acid-tfa.pdf
- Composition of the WG: https://open.efsa.europa.eu/working-group/300000059894772

PUBLIC CONSULTATION ON THE DRAFT STATEMENT AND ANNEXES

Objective: to collect views from stakeholders, identify missing information, requests for clarifications

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

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

- Member states (77)
- NGOs (31)
- Industries (10)
- individuals in personal capacity / others (6)
- EFSA panels and EFSA Scientific Committee (49)

Link: https://connect.efsa.europa.eu/RM/s/consultations/publicconsultation2/a0lTk000004sz0z/pc1508

DRAFT STATEMENT – PROPOSED ADI AND ARFD

Proposed Acceptable daily intake (ADI)

NOAEL = 8.65 mg/kg bw per day

Based on adverse effects at 44.3 mg/kg bw per day in the EORGTS in rats:

- changes in thyroid hormones (decreased T4 levels)
- decreased body weight gain
- minor histopathological findings in the stomach (glandular dilatation)

Uncertainty factor (UF): 100 x 3 = 300

Uncertainties related to the absence of a long-term toxicity/carcinogenicity study and the absence of TDAR assay on TFA.

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

Proposed reference values under discussion – subject to possible revision based on the feedback received during the public consultation

Proposed Acute Reference Dose (ARfD)

NOAEL = 60 mg/kg bw per day

Based on developmental toxicity in rabbits (different eye malformations) at 250 mg/kg bw per day

Uncertainty factor (UF): 100

ARfD of 0.6 mg/kg bw (expressed as sodium trifluoroacetate)

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 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

Thanks for your attention

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