

SETTING HEALTH THRESHOLDS FOR TFA

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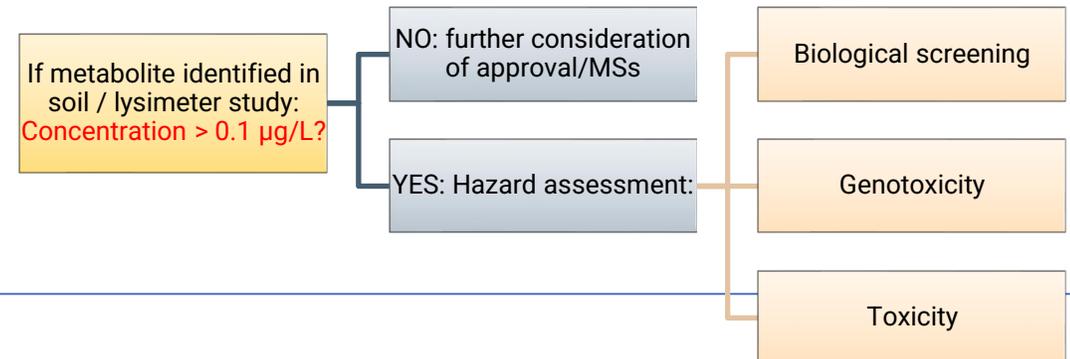
HOW ARE PESTICIDE METABOLITES ASSESSED?

■ In plants/farm animals

- a **consumer risk assessment** is triggered:
 - Consumer exposure can be then compared to consumer health-based guidance values (HBGV) ADI and ARfD to estimate the risk
 - HBGV are protective of human health hazards (e.g. reproductive toxicity) if exposure is below these values.

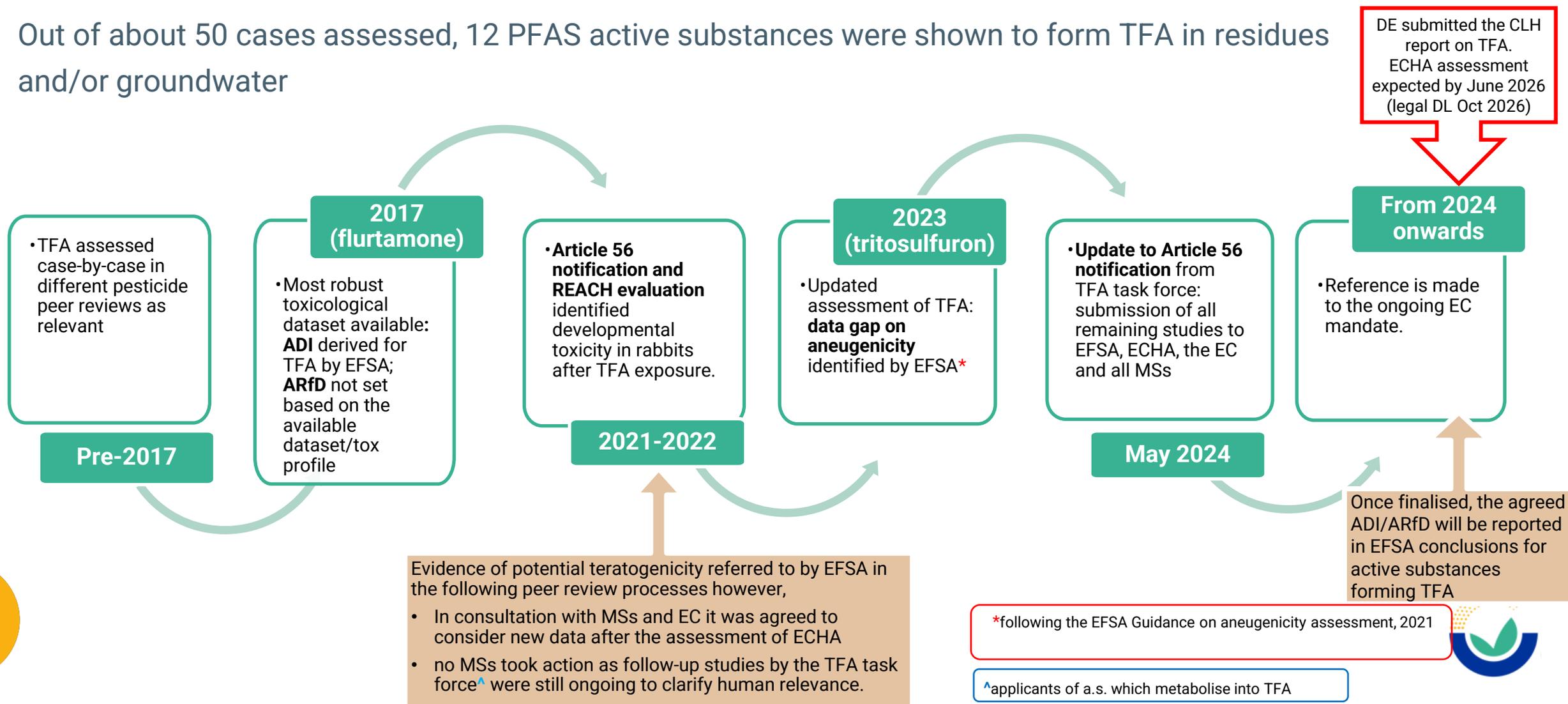
■ In groundwater

- Metabolites are assessed according to the Commission Guidance on groundwater metabolites ([SANCO/221/2000 rev.11, 2021](#)), using a decision-tree approach to determine relevance.
 - if it is found above 0.1 ug/L: a hazard-based criteria are first applied before conducting a **consumer risk assessment**:
 - qualified as relevant in groundwater if ECHA agreed on classification and labelling as CMR (human health) and/or based on the assessment by EFSA.



TFA ASSESSMENT IN EFSA PEER REVIEW PROCESS

Out of about 50 cases assessed, 12 PFAS active substances were shown to form TFA in residues and/or groundwater



EUROPEAN COMMISSION MANDATE

26 July 2024: Request from the Commission to issue an EFSA output and to review the consumer HBGVs for TFA (ADI and ARfD)

- **1: to collect evidence** in addition to data on TFA already available from EFSA peer review processes, including data generated by the TFA Task Force, data used by DE for the CLH proposals and data submitted to MSs as part of the process for PPP authorisation
- **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 assessment.

→ Consultation with Member States, EFSA's Panels/WGs, ECHA CLH, NGOs, Task force

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



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Food Safety, Sustainability, and Innovation
Pesticides and Biocides

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

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

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.



1 - CALL FOR DATA

Call for data (toxicological and metabolism data on TFA)

From 6 August to 7 October 2024

1) **Member States:**

- Data from the PPP authorisation dossiers.

2) **Competent Authority Germany**, responsible for the CLH proposal under the ECHA procedure:

- Studies and list of references (**including literature search**) 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.**



2 - ASSESS EVIDENCE

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, 11 WG meetings organised

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 (including EFSA Panels members) : <https://open.efsa.europa.eu/working-group/300000059894772>



DRAFT STATEMENT –ADI AND ARFD

Acceptable daily intake (ADI): 0.03 mg/kg bw per day (expressed as sodium trifluoroacetate)

NOAEL = 8.65 mg/kg bw per day

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

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

Uncertainty factor (UF): $100 \times 3 = 300$

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

Reference values under discussion –based on the feedback received during the public consultation

Acute Reference Dose (ARfD): 0.6 mg/kg bw (expressed as sodium trifluoroacetate)

NOAEL = 60 mg/kg bw

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

Uncertainty factor (UF): 100



OUTCOME OF THE PUBLIC CONSULTATION ON THE **DRAFT STATEMENT**

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

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

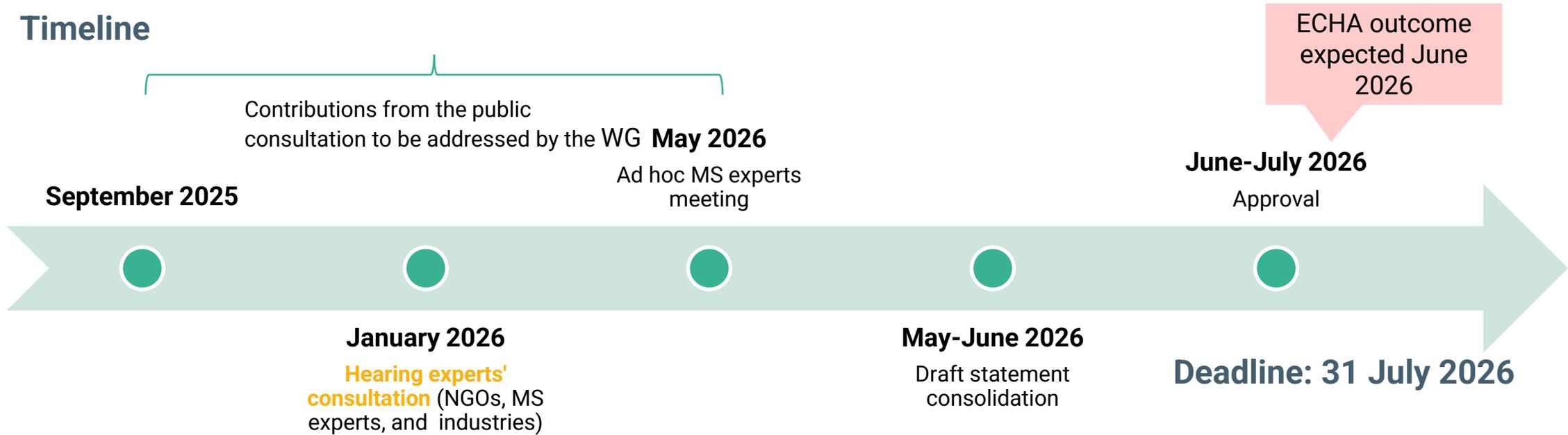
→ 173 comments from a wide range of stakeholders:

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



FOLLOW UP ACTIVITIES

Timeline



New mandate to consider the fate and behaviour of TFA in soil and water

Main objective 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: 1 June 2027

<https://open.efsa.europa.eu/question/EFSA-Q-2025-00693>



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