EFSA Working Group on trifluoroacetic acid (TFA)
9th Working Group meeting on the revision of the toxicological reference values for trifluoroacetic acid

12 December 2025
09:00-17:00
MINUTES - Agreed on 19 December 2025

Location: EFSA - Parma / Webconference

Attendees:

- **Working Group Members**

Adeline Cavelier, Tamara Coja, Andrea Gall, Antonio Hernández-Jerez, Christiane Vleminckx

- **European Commission**

Mark Williams

- **ECHA (CLH)**

Stine Husa

- **Hearing experts**[1]

None

- **EFSA**

PREV Unit: Elodie Bergsma, Marco Binaglia, Mathilde Colas, Juan Parra (Chair)

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Mark Williams and Stine Husa.

II. Adoption of agenda

The agenda was adopted with a change. An additional point was proposed under AOB related to newly available data submitted during or outside of the public consultation.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

[1] As defined in Article 17 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work: http://www.efsa.europa.eu/en/keydocs/docs/expertselection.pdf
[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Update from ECHA/EFSA procedures

ECHA CLH procedure: update was provided via written procedure. No change to the timeline for the ECHA CLH procedure.

EFSA procedure: the legal deadline was extended to 31 July 2026. Hearing experts will be invited to the next WG meeting on 12 January.

V. Overview of the comments on toxicokinetics, mechanistic data and biomonitoring

The WG discussed comments provided during the public consultation submitted on the toxicokinetic section, biomonitoring and epidemiological studies. The outcome of the assessment will be updated accordingly.

VI. BMD modelling: follow-up on the T4 level in F1 offspring

The revised BMD model including additional data was presented and discussed. The updated BMD analyses will be shared and discussed with the EFSA ED WG.

VII. Uncertainty factors for the ARfD an ADI derivation

Uncertainty factors were discussed for different endpoints.

VIII. EOGRTS: selection of the PoD

The WG discussed results from EORTGS on reproductive performance and immunotoxicity.

IX. Draft statement

An amended table of contents of the draft statement was discussed and agreed with the WG.

X. Preparatory meeting

X.1 Preparatory meeting on WG TFA, 20 November 2025
X.1a Antonio HERNÁNDEZ- JEREZ
X.1b Discussed comments related to biomonitoring, mechanistic data and toxicokinetics.

XI. AOB

a. Action points

The planning was discussed, and next steps were agreed. Tasks were allocated among the WG members.

b. Next steps

The 10th WG meeting is scheduled for 12 January 2025 via teleconference.

EFSA Working Group on trifluoroacetic acid (TFA)
8th Working Group meeting on the revision of the toxicological reference values for trifluoroacetic acid

5 November 2025
13:00-17:00
MINUTES - Agreed on 24 November 2025

Location: EFSA - Parma / Webconference

Attendees:

- **Working Group Members**

Adeline Cavelier, Tamara Coja, Andrea Gall, Antonio Hernández-Jerez, Christiane Vleminckx

- **European Commission**

Mark Williams

- **ECHA (CLH)**

Stine Husa

- **Hearing experts**[1]

None

- **EFSA**

PREV Unit: Elodie Bergsma, Marco Binaglia (Chair), Federica Crivellente Mathilde Colas, Juan Parra

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Juan Parra and Mark Williams.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Clinical chemistry

An overview of clinical chemistry and haematology findings across 90-day, 1-year studies and EORTGS was given. The WG specifically discussed the decrease in bilirubin in the repeated-dose toxicity studies.

V. BMD analysis

BMD modelling was presented. Reliability of the modelling was discussed, and the WG advised on the inclusion/exclusion of additional data and revision of the model will be pursued.

VI. Developmental toxicity in rabbits

The developmental toxicity study in rabbits was presented to determine whether it should be considered reliable without restrictions and evaluate its relevance for the risk assessment.

VII. AOB

a. Action points

The planning was discussed, and next steps were agreed. Tasks were allocated among the WG members.

b. Next steps

The 9th WG meeting is scheduled for 12 December 2025 via teleconference.

EFSA Working Group on trifluoroacetic acid (TFA)
7th Working Group meeting on the revision of the toxicological reference values for trifluoroacetic acid

13 October 2025
09:00-13:00/14:00-17:00
MINUTES - Agreed on 30 October 2025

Location: EFSA - Parma / Webconference

Attendees:

- **Working Group Members**

Adeline Cavelier, Tamara Coja, Andrea Gall, Antonio Hernández-Jerez, Christiane Vleminckx

- **European Commission**

None

- **ECHA (CLH)**

Stine Husa

- **Hearing experts**[1]

None

- **EFSA**

PREV Unit: Mathilde Colas, Rafaela De Jesus, Juan Parra (Chair)

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Overview of the comments submitted during the public consultation (22 July to 22 September)

A total of 177 comments were received from various stakeholders, including Member States, NGOs, industry representatives, academia, and individuals acting in a personal capacity.

As the original study reports were not available, several stakeholders requested additional explanations and conclusions on the studies to ensure a transparent review process. It was noted that a sanitised version of original study reports will be made publicly available on Open EFSA by the end of the procedure.

Additional reports from other EU and Member State agencies concerning TFA assessments were also shared with the Working Group during the public consultation.

The Working Group focused its discussions particularly on comments related to the one-year rat study, multigeneration reproductive toxicity studies, and developmental toxicity studies in rats and rabbits.

V. AOB

a. Action points

The planning was discussed, and next steps were agreed. Tasks were allocated among the WG members.

b. Next steps

The 8th WG meeting is scheduled for 5 November 2025 (1 – 5 pm) via teleconference.

EFSA Working Group on trifluoroacetic acid (TFA)
6th Working Group meeting on the revision of the toxicological reference values for trifluoroacetic acid

4 July 2025
09:00-13:00/14:00-18:00
MINUTES - Agreed on 15 July 2025

Location: EFSA - Parma / Webconference

Attendees:

- **Working Group Members**

Adeline Cavelier, Tamara Coja, Andrea Gall, Antonio Hernández-Jerez, Christiane Vleminckx

- **European Commission**

None

- **ECHA (CLH)**

Stine Husa

- **Hearing experts**[1]

None

- **EFSA**

PREV Unit: Mathilde Colas, Rafaela De Jesus, Annetta Grillo, Jochem Louisse, Juan Parra (Chair)

I. Welcome and apologies for absence

The Chair welcomed the participants.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Analytical methods

The methods of analysis used in the key studies to set health-based guidance values were discussed and the WG agreed that are considered reliable (i.e. fit for purpose).

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[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

V. Draft statement finalisation

Revisions were made directly within the draft statement and Annexes, and changes are reflected in the new version of documents.

VI. Any Other Business

The public consultation will be launched from end of July to end of September 2025.

The 7th WG meeting is scheduled for 13 October 2025 (physical meeting).

EFSA Working Group on trifluoroacetic acid (TFA)
5th Working Group meeting on the revision of the toxicological reference values for trifluoroacetic acid

3-4 June 2025
14:00-18:00/09:00-13:00
MINUTES - Agreed on 18 June 2025

Location: EFSA - Parma / Webconference

Attendees:

- **Working Group Members**

Adeline Cavelier, Tamara Coja, Andrea Gall, Antonio Hernández, Christiane Vleminckx

- **European Commission**

None

- **ECHA (CLH)**

Stine Husa (3 June only).

- **Hearing experts**[1]

None

- **EFSA**

PREV Unit: Rafaela De Jesus, Annetta Grillo, Jochem Louisse, Juan Parra (Chair)

I. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Mathilde Colas.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

IV. Updates on RoB in vivo and in vitro analysis

The status of the RoB analysis was presented. Working group's comments related to *in vivo* and *in vitro* RoB protocols were addressed; the protocols will be amended according to the discussion.

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[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

V. Follow-up discussions

The main topics of discussion were the content of the 2020 CONTAM Panel Opinion on PFAS, the RoB assessment for one of the available biomonitoring studies, and the NOAEL/LOAEL setting of one developmental toxicity study and its acceptability. The Working Group discussed the mechanistic information available on TFA-mediated PPAR activation and its relevance to humans.

With regard to the extended one-generation reproductive toxicity study, the Working group agreed on the setting of parental, reproductive and offspring NOAELs/LOAELs on the basis of the effects observed.

The WG discussed and agreed on uncertainty factors to be used for reference values derivation.

VI. Draft statement

The WG addressed the comments received on the draft statement and updated the text. The WG defined the criteria for including information on differently scored studies in the main statement and/or Appendixes. The WG agreed to include the information of the RoB analysis results into three appendixes, one for *in vitro,* one for *in vivo* and one for human studies.

VII. Any Other Business

The next meeting will be held on the 4th of July via web conference.

EFSA Working Group on trifluoroacetic acid (TFA)
4th Working Group meeting on the revision of the toxicological reference values for trifluoroacetic acid

5 May 2025
09:00-18:00
MINUTES - Agreed on 14 May 2025

Location: EFSA - Parma / Webconference

Attendees:

- **Working Group Members**

Adeline Cavelier, Tamara Coja, Andrea Gall, Antonio Hernández, Christiane Vleminckx

- **European Commission**

Mark Williams

- **ECHA (CLH)**

Stine Husa, Silvia Lapenna

- **Germany**

Daniel Stalter, Christina August

- **Hearing experts**[1]

None

- **EFSA**

PREV Unit: Mathilde Colas, Rafaela De Jesus, Annetta Grillo, Juan Parra (Chair)

I. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Mark Williams, Daniel Stalter and Christina August.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Biomonitoring analysis

An overview of the three human biomonitoring studies identified within the available data submitted was provided. The results of the risk of bias analysis conducted were presented to the Working Group.

V. Analysis on level of adversity

The effects observed in clinical chemistry (glucose, cholesterol and triglycerides) and immunophenotypic parameters were examined for possible adversity. To illustrate the mechanism of action of peroxisome proliferators, the cases of fenoxaprop-P and fenoxaprop were presented.

Although effects were consistent in some cases, there was no clear dose-response pattern or histopathological correlates. Differences between species (rats, rabbits), sex and type of effect (increase, decrease) were noted. Differences in the potential mechanism of action of TFA between species and relevance to humans were also discussed. The Working group agreed that other changes accompanying the observed effects should be further studied.

VI. Proposal for NOAEL setting and toxicological reference values

With regard to the extended one-generation toxicity study, the Working group agreed on the setting of parental, reproductive and offspring NOAELs on the basis of the effects observed.

Revised toxicological reference values (ADI and ARfD) were proposed by the Working group based on the most robust data package.

VII. Other scientific discussion

a. Risk of Bias analysis

EFSA has completed the assessment analysis of the in vivo and in vitro studies. A preparatory meeting will be organised to discuss the Working group's comments and harmonise the interpretation of the risk of bias criteria in the protocol.

b. Advice from the EFSA ED Working Group

A dose-range finding and an extended one generation toxicity study (EOGRT, with no inclusion of a second generation) were made available to the EFSA ED WG. At the 27th WG on Endocrine Disruptors on 8-9 April 2025, specific questions were raised to the ED Working group notably the possible adversity of thyroid hormone effects and the NOAEL / LOAEL setting.

The Working group agreed with the advice from the ED Working group.

VIII. Draft statement

The WG reviewed the draft statement and assigned sections for further drafting.

IX. Any Other Business

The next meeting will be held on 3 and 4 June 2025 in Parma and via web conference (hybrid meeting).

EFSA Working Group on trifluoroacetic acid (TFA)
3rd Working Group meeting on the revision of the toxicological reference values for trifluoroacetic acid

08-09 April 2025
14:00-18:00 / 09:00-13:00
MINUTES - Agreed on 29 April 2025

Location: EFSA – Web conference

Attendees:

- **Working Group Members**

Adeline Cavelier, Tamara Coja, Andrea Gall, Christiane Vleminckx, Antonio Hernandez

- **European Commission**

Mark Williams

- **ECHA**

Stine Husa, Silvia Lapenna

- **Hearing experts**[1]
  - RIVM: Wieneke Bil
  - TFA Task Force: Maura Karina Ferreira Emiliano, Anja Hueser, Degroot Antoinette

- **EFSA**

PREV Unit : Mathilde Colas, Rafaela De Jesus, Juan Parra (Chair)

I. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received by Mark Williams, and Antonio Hernandez.

II. Adoption of agenda

The agenda was adopted without changes.

III. Declarations of Interest of Working Groups members

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Scientific discussions

a. Mapping of potential adversity

The Working Group discussed most relevant effects observed across studies for possible adversity (i.e. thyroid hormones, liver, biochemistry, haematology and immunophenotyping). Differences between sexes and species and the dose-response relationship were questioned.

b. Re-evaluation of in vivo regulatory studies

Following re-assessment of in vivo regulatory studies by the Working group, the NOAELs set by previous peer review were not challenged.

c. Discussion related to EFSA CONTAM Panel (2020)

The Working Group exchanged on the scientific evaluation on the risks to human health related to the presence of PFAS in food, notably the critical adverse effects observed and tolerable weekly intake set by the EFSA CONTAM Panel.

V. Hearing experts

The hearing experts had one hour to present their replies and ask any follow-up questions from the Working Group.

a. Hearing experts from TFA task force

The experts Maura Karina, Ferreira Emiliano, Anja Hueser, Degroot Antoinette from TFA task force participated as hearing experts to give expert advice, where needed, on some of endpoints examined in the extended One-Generation study in rats, i.e. whether changes in thyroid hormones and effects on the immunophenotyping should be considered treatment-related and adverse

b. Hearing expert from RIVM

The expert Wieneke Bil from RIVM participated as hearing expert to expert advice, on whether the effects on the immunophenotyping should be considered treatment-related and adverse in the extended One-Generation study in rats

VI. Any Other Business

The tasks were assigned among WG members.
Possible adversity of the thyroid hormones in the EORGT study will be discussed on 9 April afternoon at the 27th WG meeting on Endocrine Disruptors (ED).

VII. Next meeting

The next meeting will be held on 5 May 2025 via web conference.

EFSA Working Group on trifluoroacetic acid (TFA)

2nd Working Group meeting on the revision of the toxicological reference values for trifluoroacetic acid

04 - 05 February 2025
MINUTES – Agreed on 21 February 2024

Location: EFSA - Parma / Web-conference

Attendees:

- **Working Group Members**
  - Cavelier Adeline
  - Coja Tamara
  - Gall Andrea
  - Vleminckx Christiane
- **European Commission**
  - Williams Mark
- **Hearing experts**[1]
  - None
- **ECHA**
  - Husa Stine, Lapenna Silvia
- **EFSA**
  - PREV Unit : Parra Juan (Chair), Colas Mathilde, De Jesus Rafaela, Mangas Iris (5th February)

I. Welcome and Apologies for absence

The Chair welcomed the participants. Apologies were received from Iris Mangas for the session on the 4th of February. Apologies were received from Daniel Stalter and Christina August.

II. Adoption of the agenda

The agenda was adopted without changes.

III. Declarations of interest

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

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[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Assessment of genotoxicity and new regulatory in vivo toxicity studies

The WG discussed the reliability assessment of in vitro genotoxicity studies against the Klimisch score. The available data confirmed that all endpoints (mutagenicity, aneugenicity and clastogenicity) are covered.

The reliability of regulatory in vivo studies was also assessed, with particular focus on the effects observed in the extended one generation reproductive toxicity study in rats and the new developmental toxicity study in rabbits. While the WG agreed with the reliability assessment, adversity and treatment-related effects will require further discussion.

V. Data extraction of *in vitro* and non-regulatory *in vivo* studies/ Risk of bias protocol.

EFSA provided an overview of the non-regulatory in vivo oral studies and in vitro mechanistic studies to the WG. The WG will conduct a risk-of-bias appraisal.

VI. Assessment of existing regulatory studies

The WG agreed to re-evaluate the previously peer-reviewed studies conducted under EFSA procedures.

VII. First proposal for setting reference values

The WG discussed the potential revision of previously established reference values (EFSA, 2017):

- An ADI of 0.05 mg/kg bw per day (expressed as sodium trifluoroacetate) was derived based on the 90-day study in rats.
    - NOAEL = 9.9 (males) and 12.2 (females) based on changes in haematological and clinical parameters, organ weights and histopathological liver findings
- An ARfD was deemed unnecessary.

The WG deliberated on whether the ADI and ARfD require updating based on the latest data.

VIII. Distribution of the tasks

The tasks were assigned among WG members.

IX. AOB

The next WG meeting is scheduled for 8 and 9 April 2025 via web conference.

The WG agreed to invite hearing expert(s) in immunotoxicity and consult the WG on Endocrine Disruptors or alternative inviting a hearing expert(s).

EFSA Working Group on trifluoroacetic acid (TFA)

1st Working Group meeting on the revision of the toxicological reference values for trifluoroacetic acid.

12 - 13 November 2024

MINUTES – Agreed on 21 November 2024

Location: EFSA - Parma (Meeting Room 00/M02) / Web-conference

Attendees:

- **Working Group Members**
  - Cavelier Adeline
  - Coja Tamara
  - Gall Andrea
  - Vlemickx Christiane
- **European Commission**
  - Williams Mark
- **Hearing experts**[1]
  - None
- **EFSA**
  - PREV Unit : Parra Juan (Chair), Colas Mathilde, De Jesus Rafaela, Mangas Iris

I. Welcome and Apologies for absence

The Chair welcomed the participants. Apologies were received from Iris Mangas for the session on the 12th of November.

II. Adoption of the agenda

The agenda was adopted without changes.

III. Declarations of interest

In accordance with EFSA's Policy on Independence[2] and the Decision of the Executive Director on Competing Interest Management[3], EFSA screened the Annual Declarations of Interest filled out by the Working Group members invited to the present meeting. No Conflicts of Interest related to the issues discussed in this meeting have been identified during the screening process, and no interests were declared orally by the members at the beginning of this meeting.

Tamara Coja indicated that her DOI is under assessment for another commitment.

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[2] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

[3] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

IV. Mandate and call for data

The European Commission's mandate to EFSA was introduced to the Working Group, outlining the current state-of-the-art regarding PFAS pesticide active substances forming TFA as a metabolite. The approach adopted during EFSA's peer review process was also explained. It was highlighted that new data on TFA had been submitted by the TFA Task Force under the Article 56 notification of Regulation (EC) 1107/2009. Additionally, Germany's Competent Authority (DE) proposed a harmonised classification for TFA as a reproductive toxicant (category 1B), a very persistent and very mobile substance (vPvM), and a persistent, mobile, and toxic substance (PMT) to ECHA. In response to the recent data on TFA and classification proposals, the European Commission requested EFSA to re-assess toxicological reference values (ADI and ARfD) of TFA.

V. Planning

The timeline for the Working Group's activities was presented. The first step involves a targeted call for toxicological hazard data on TFA and its salts, which was opened from August to October 2024. This call engaged the TFA Task Force, all Member State Competent Authorities, and Germany (related to the drafting of the CLH dossiers). The EFSA Working Group on TFA will evaluate the submitted data and discuss the revision of the toxicological reference values with Member State Competent Authorities during a dedicated ad hoc experts' discussion scheduled for Q2-Q3 2025. ECHA RAC and Germany's Competent Authority will also be invited in view of ECHA-EFSA alignment on the assessment and data package.

The outcome of this process will be an EFSA statement, to be finalised by 31 October 2025. An Appendix to the statement will include a protocol notably detailing the scope of the targeted call for data, criteria for inclusion and exclusion of studies, and assessment questions.

VI. List of Studies: first screening

The studies collected through the targeted call for data were presented. These studies were categorised by endpoints and data submitters, with duplicates removed.

VII. Protocol / Appraisal

The Working Group discussed the methodology for assessing the reliability of the studies and data reporting. Regulatory studies will be analysed first, followed by literature-based studies. The use of Klimisch scoring and risk-of-bias methodologies was proposed for evaluating the study reliability, respectively.

VIII. Distribution of the tasks

The tasks were allocated among Working Group members.

IX. AOB

The next WG meeting will be held on 4 and 5 February 2025 via web conference.