



# EFSA Technical Group on the Tools related to the application of the Transparency Regulation (TG TOOLS)

## Terms of Reference (ToR)

### 1. Background

Following the conclusion of the main implementation phase leading up to the entry into application of the Transparency Regulation, EFSA is continuing its stakeholder engagement on the Transparency Regulation through the fora foreseen by the Stakeholder Engagement Approach (SEA).

In order to prepare for the implementation of the Transparency Regulation, EFSA created several fora to foster the technical dialogue on dedicated tools (e.g., Notification of Studies Technical Group (TG), IUCLID TG, IUCLID HYPERCARE support). The activities of these TGs and Hypercare support came to an end in Q2 2022, with the final meeting of the Notification of Studies TG in June 2022. In parallel, EFSA established a new forum for discussion (Pesticide Steering Network sub-group IUCLID<sup>1</sup>) to continue the dialogue with Member States and stakeholders on the use of IUCLID for Pesticides submissions.

Following on this stakeholder engagement, EFSA is establishing a dedicated forum for technical exchanges on the use of tools<sup>2</sup> related to the application of the Transparency Regulation.

### 2. Objectives

The goal of the EFSA TG on TOOLS is to engage with relevant users of the EFSA tools related to the application of the Transparency Regulation.

The **main objectives** of the EFSA TG TOOLS are:

- to enhance interaction among users and providers;
- to gather feedback from users on the usability of the tools and the corresponding available manuals and/or training materials;
- to collect suggestions for improvement, adjustment, simplification, harmonisation, clarifications;
- to present to users the latest improvements before their implementation, where considered relevant by EFSA (e.g., in case of major tool changes).

The **tools included** in the scope of this Technical Group are:

- CONNECT.EFSA within the following business applications: account registration, notification of studies, pre-submission advice, public consultation, AskAQuestion;

<sup>1</sup> <https://www.efsa.europa.eu/sites/default/files/2021-08/tems-of-reference-iuclid-psn-subgroup.pdf>

<sup>2</sup> CONNECT.EFSA within the following business applications: account registration, notification of studies, pre-submission advice, public consultation, AskAQuestion; OPEN.EFSA and public dossier; confidentiality request and Submission Builder.

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The **tools excluded** from the scope of this Technical Group are:

- E-Submission Food Chain Platform (ESFC, under the responsibility of the European Commission);
- IUCLID (under Pesticide Steering Network sub-group IUCLID);
- Trainings on how to use the tools.

### 3. Terms of Reference

Members of the EFSA TG TOOLS are expected to:

- Inform and nominate additional experts from their Member States and/or organisations to participate to *ad-hoc* tele-meeting on specific topics, nominate back-up;
- Attend meetings (tele-meetings), collect and share experience from their members;
- Contribute to the specific agenda point, allowing to clarify points of misunderstanding and discuss issues encountered. Issues must be discussed without referring to confidential information to facilitate sharing of knowledge on common issues;
- Contribute to the general agenda point, which will be opened with a presentation/demo by EFSA followed by a Q&A session;
- Provide feedback on the usability and functionalities of the tools within the scope of this Technical Group;
- Share knowledge and expertise with other stakeholders, members;
- Participate to surveys/presentations to report back on their experience with the tools;
- Share experience with “on the job practice” to contribute to the further development of common working procedures;
- Provide input for further improvement of training materials and/or manuals on the tools.

The Technical Group will not handle the organisation of trainings, nor be used for limited communication on new releases of the tools, as those are relevant for all stakeholders and are therefore announced on the respective EFSA’s communication channels<sup>3</sup>.

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<sup>3</sup> <https://www.efsa.europa.eu/en/applications/toolkit#see-also>

#### 4. Composition of the Technical group

The composition of the EFSA TG TOOLS will be decided by EFSA, as follows:

- Representatives from EFSA Registered Stakeholders, category Business and food industry, selected via a call for expression of interest (max 15)<sup>4</sup>;
- Representatives from other categories of EFSA Registered Stakeholders, selected via a call for expression of interest (max 6)<sup>5</sup>;
- Representatives from Member States, nominated via a call for expression of interest through the Advisory Forum (max 8)<sup>6</sup>;
- Representatives from laboratories/facilities<sup>7</sup>, selected via a call for expression of interest via the JRC-Network (max 2)<sup>8</sup>;
- Representatives of the European Commission are invited to attend meetings of the Technical Group as observers. Representatives of other agencies, bodies or Institutions of the European Union, third countries or international organisations may be invited to attend meetings of the Technical Group as observers.

EFSA will decide on the final composition of the Technical Group to ensure a fair representativeness across Business and food industry domain, across business operators' size (small, big), and across Member States having an active role in the risk assessment process per areas.

#### 5- Working method

The EFSA TC Group on TOOLS shall meet virtually twice a year to provide feedback on the usability of the tools in place to support the application of the Transparency Regulation. The working language of the Technical Group is English. In between the meetings, written consultation and/or testing of upcoming changes in the tools may take place. The Technical Group will use the following means of collaboration: dedicated Microsoft Teams channels and space in SharePoint. The meetings will be chaired by EFSA.

#### 6- Deliverables and Outcome

Each meeting (tele-meeting, physical meeting) of the Technical Group will be announced publicly and the following documents will be made available on the EFSA website<sup>9</sup>: agenda, participants list, presentations and a summary of the main issues discussed and action list.

EFSA will ensure that the feedback received by the TG members is shared with the respective EFSA tool responsible and considered in the update of training materials/manuals to enhance understanding and use of the various tools in place to support the implementation of the Transparency Regulation.

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<sup>4</sup> All 9 expressions of interest received were accepted.

<sup>5</sup> All 2 expressions of interest received were accepted.

<sup>6</sup> All 2 expressions of interest received were accepted.

<sup>7</sup> Laboratories/facilities involved as actor in the Notification of Studies.

<sup>8</sup> The expression of interest received was accepted.

<sup>9</sup> <https://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation>

## 7- Timeline

The EFSA TG TOOLS will be active from October 2022 to October 2024. The Terms of Reference will be reviewed after 2 years, taking into account members feedback and EFSA's needs.

The Technical Group meeting planning is as follows:

- October 2022: creation of the EFSA Technical Group on TOOLS;
- November 2022: 1<sup>st</sup> meeting (kick-off meeting);
- March 2023: 2<sup>nd</sup> meeting;
- October 2023: 3<sup>rd</sup> meeting;
- March 2024: 4<sup>th</sup> meeting;
- October 2024: 5<sup>th</sup> meeting (closure meeting).