

Framework for Interaction between the European Food Safety Authority and the Stakeholder Discussion Group on Environmental Risk Assessment (Stakeholder DG on ERA)

Environment, Plants & Ecotoxicology
Unit (PLANTS Unit)



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APPLY BY SUBMITTING [THIS NOMINATION FORM](#) BY THE 30TH OF NOVEMBER AT 23 :59 (CEST)

1. BACKGROUND

Environmental risk assessment (ERA) of plant protection products (PPPs) is required by [Regulation \(EC\) No 1107/2009](#), which regulates the placing on the market of these products in the European Union.

In line with EFSA Strategic objectives 2027 on ensuring preparedness for future risk analysis needs, more up-to-date scientific guidance and methodological approaches need to be developed. For regulatory environmental risk assessment (ERA), opportunities identified so far include the integration of several aspects related to the landscape (e.g., landscape structure and ecology) and combining prospective and retrospective assessments. To develop such assessments, fit-for-purpose methodologies need to be developed, and data need to be collected and generated as well. This requires clear and effective tiered approach risk assessment schemes, promoting the uptake of new tools (e.g. mechanistic effect models) and methodologies (e.g. adverse outcome pathways (AOPs), new approach methodologies (NAMs), etc.).

EFSA has established a multiannual plan for 2024-2028 to advance the ERA of PPPs following a systems-based approach. The activities under this multiannual plan aim to consolidate risk assessment methodologies including biodiversity assessment and consideration of indirect effects via trophic interactions and will integrate new tools and scientific knowledge.

For honey bees, a conceptual approach for a systems-based approach to the ERA of multiple stressors was developed by the Scientific Committee¹ supported by the development of an effect model for honey bee colonies (ApisRAM) to be used for the regulatory ERA of PPPs^{2, 3} and the

¹ <https://www.efsa.europa.eu/en/efsajournal/pub/6607>

² <https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2022.EN-7184>

³ [EFSA-Q-2022-00786](#)



collection and sharing of standardised data on pollinator/bee health by stakeholders (EU Bee Partnership)⁴ on a dedicated platform^{5, 6} to become operational as of 2024.

A new project was recently initiated by EFSA to specifically generate data on non-target arthropods⁷ and a series of open calls were recently published, as part of the above-mentioned multiannual plan, to generate other datasets relevant for ERA, in particular:

- to develop environmental scenarios which consider in agricultural areas, landscape structure and the ecology of terrestrial non-target species⁸;
- to develop a harmonised tiered approach for pesticides of low concerns to lean the risk assessment of active substances that have a low toxicity or a low exposure profile⁹;
- to establish a partnership that can support EFSA in addressing various needs to further advance the risk assessment in the area of terrestrial ecotoxicology¹⁰.

These projects will collect and generate data for progressing the integration of species ecology and landscape features in the risk assessment, to gain knowledge on the environmental exposure to PPP with different application scenarios, and to identify novel strategies and tools for assessing potential PPP effects at higher level of biological organisation i.e., at population and community level.

The main focus is on terrestrial ecotoxicology for which drafting or updating guidance have been identified as a priority¹¹, in particular, in light of the revision of the current SANCO Guidance Document on Terrestrial Ecotoxicology (European Commission (2002)¹² on some specific organisms (i.e. non-target arthropods -NTAs, non-target terrestrial plants-NTTPs and in-soil organisms).

Beyond the needs of incorporating the most updated scientific knowledge into risk assessments, EFSA intends to investigate the possibilities to facilitate data collection and sharing among different actors, ultimately supporting data flows between modelling and monitoring approaches.

2. SCOPE OF INTERACTION

In light of both the complexity of the subject and the stakeholder and public interest EFSA has decided to establish the **Stakeholder DG on ERA**.

The scope of this call for expression of interest is to identify representatives of organisations which will broaden the available EUBP expertise to cover a broader remit for this group, i.e., extending from bee/pollinator to ecology, ecotoxicology and environmental risk assessment. Therefore, EFSA will firstly invite members of the EUBP who have particular interest and

⁴ <https://www.efsa.europa.eu/en/supporting/pub/en-1423>

⁵ <https://www.efsa.europa.eu/en/supporting/pub/en-6694>

⁶ EFSA-Q-2022-00788

⁷ <https://etendering.ted.europa.eu/cft/cft-display.html?cftId=8625>

⁸ Services - 48237-2023 - TED Tenders Electronic Daily (europa.eu)

⁹ [GP/EFSA/PLANTS/2023/04: Develop a stepwise approach for a fit for purpose risk assessment, in particular for low-concern active substances and uses](https://www.efsa.europa.eu/en/art36grants/article36/euba-efsa-prev-2023-01-pera-advancing-era-plant-protection-products-towards)

¹⁰ <https://www.efsa.europa.eu/en/art36grants/article36/euba-efsa-prev-2023-01-pera-advancing-era-plant-protection-products-towards>

¹¹ https://food.ec.europa.eu/system/files/2023-06/pesticides_ppp_app-list-guidance_priority-list.pdf

¹² European Commission, 2002. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002-rev. 2 final, 17 October 2002



expertise in ERA to express their interest or to nominate experts from their organisation to join the Stakeholder DG on ERA.

The group, composed of relevant organisations with equal representativeness, will be informed and, where needed, consulted at various stages of the development of the EFSA multiannual plan and activities in the area of ERA.

3. STAKEHOLDER INVOLVEMENT

The Stakeholder DG on ERA will be invited to at least one plenary meeting per year organised by EFSA in order to be updated/consulted on the EFSA activities related to the ERA.

On an ad hoc basis, the group can be consulted to collect input/feedback on a particular topic of high public interest. For this purpose, dedicated virtual meetings may be organised.

The outcome of any stakeholder engagement activity that will be organised during the period 2024-2028 as part of the stakeholder engagement programme will be made publicly available on the EFSA website.

4. PROCESS FOR NOMINATION

EFSA's stakeholders are representative organisations that have an interest in the Authority's work or in the wider food and feed sector. EFSA divides stakeholders into seven major groups; all groups with interest in the area are invited to nominate members for the Stakeholder DG on ERA. Additional information on EFSA's stakeholder engagement principles and involvement is available at this [link](#).

Organisations already part of the [EFSA Registered Stakeholders](#) community can proceed directly with the nomination of the proposed members for the Stakeholder DG on ERA.

Other organisations interested in nominating a member for the Stakeholder DG on ERA are encouraged to send first a request to be registered as an EFSA registered stakeholder; information and the link for submitting the request are available at [this link](#).

Organisations that are not eligible to become EFSA Registered Stakeholder, are still invited to submit their expression of interest to the Stakeholder DG on ERA. As stipulated in Article 4 of the Decision of the Management Board of EFSA on the criteria for establishing a list of stakeholders and the establishment of the Stakeholder Forum and Stakeholder Bureau, a non-registered stakeholder may be invited to the meetings of EFSA topic-driven engagement initiatives based on the need for specific expertise or technical knowledge. Such engagement will be assessed on a case-by-case basis. Any involvement of non-registered stakeholders will be made public in a transparent and timely manner.

Organisations may submit nominations for up to three stakeholder experts, however, no more than one stakeholder expert per organisation will be selected by EFSA. The representativeness of the category will be also considered to ensure the right balance i.e. EFSA will ensure that there will be a balance in the stakeholders selected so that no one group is over-represented.



Nominations of members should be sent by filling in [this Nomination form](#).

The deadline for submission of the nominations is on the 30th of November 2023 at 23:59 (CEST). Any application reaching EFSA after the set deadline will be deemed invalid.

5. COMPOSITION AND SELECTION OF MEMBERS

EFSA will select a **maximum of 14 stakeholder expert representatives** from the nominations received through this call.

The selection will follow the principles established in EFSA's Stakeholder Engagement Approach and the Decision of the Management Board of EFSA on the criteria for establishing a list of stakeholders and the establishment of the Stakeholder Forum and Stakeholder Bureau; in particular those applicable to targeted engagement platforms as described in <https://www.efsa.europa.eu/sites/default/files/Document18992.pdf>.

For the selection, EFSA will consider the following principles:

- Knowledge and expertise of the nominated stakeholder expert, considering the need for the Stakeholder Discussion Group to cover a range of technical and scientific areas in the environmental risk assessment, particularly on terrestrial ecotoxicology, including agronomy and landscape ecology.
- Interest in the field and expected benefits from the participation of the organisation as expressed in its application;
- Role and remit of the organisation at the EU level;
- Achieving a balanced representation of stakeholder interests and categories;

After the selection, EFSA will inform all nominating organisations of the selected stakeholder experts, inviting non-selected organisations to contact those selected within their group and to contribute to the process through the selected organisations.

In the event that the Stakeholder Group does not reach its maximum capacity of 14 members through the initial selection process, EFSA reserves the right to consider expressions of interest and invite additional stakeholder groups to join the Stakeholder Group on an ad-hoc basis, in accordance with the established criteria and procedures for stakeholder engagement. The inclusion of new Members will be made public in a transparent and timely manner.

6. ROLES AND RESPONSIBILITIES

The selected stakeholder experts may be invited to comment on documents related to the EFSA activities on the ERA.

The members should follow the indications received regarding the confidentiality of personal information and documents marked as restricted or confidential. Personal information should be treated as confidential and will not be distributed; restricted documents can be shared within the organisation if needed for preparing the comments but may not be further distributed or published.



The names of the stakeholder experts and nominating organisations will be made publicly available.

8. TRANSPARENCY REQUIREMENT

Openness and transparency are fundamental aspects of EFSA and are enshrined as concepts in EFSA's regulatory framework (art. 38 of EFSA's Founding Regulation (EC) No 178/2002) and in the Decision of the Management Board establishing the Stakeholder Forum and Stakeholder Bureau.

The transparency of the work of the Stakeholder DG on ERA will be made available through the timely announcement of EFSA's upcoming activities on Environmental Risk Assessment as well as through the publication of agendas, participant' lists and the outcome of each of the meetings of this group on the EFSA website.

Any written comments received from the Stakeholder Discussion Group following a specific consultation will be compiled and published with the indication of the member organisation that submitted the comment. When submitting comments, the members may claim that personal data, documents covered by copyrights, or the parts of the comments containing confidential information are restricted to the EFSA work and may not be included in the public version. EFSA will check the claims according to the applicable legal provisions.

9. MONITORING AND REVIEW

A review of the effectiveness of EFSA's stakeholder engagement, including activities related with the Stakeholder DG on ERA, shall be carried out every three years, as of the entry into force of the Decision of the Management Board of the European Food Safety Authority on the criteria for establishing a list of stakeholders and the establishment of the Stakeholder Forum and Stakeholder Bureau and, at any time, upon request of the Management Board, Article 10.

10. CONTACT

Please do not hesitate to contact EFSA at PLANTS@efsa.europa.eu for any questions or clarifications with regards to this initiative and process to follow.