

# Framework for interaction between the European Food Safety Authority and the Stakeholder Discussion Group on Aquaculture Environmental Risk Assessment (StaDG-ERAQUA)

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# CONTENTS

<b>1. BACKGROUND .....</b>	<b>3</b>
<b>2. SCOPE OF INTERACTION.....</b>	<b>3</b>
<b>3. GENERAL OBJECTIVES .....</b>	<b>4</b>
<b>4. WORKING METHODOLOGY .....</b>	<b>4</b>
4.1 COMPOSITION .....	4
4.2 ROLES AND RESPONSIBILITIES .....	4
4.3 OPERATING MODEL.....	5
4.4 EXPECTED DELIVERABLES.....	5
<b>4 TRANSPARENCY REQUIREMENTS .....</b>	<b>5</b>
<b>5 MONITORING AND REVIEW.....</b>	<b>6</b>



# FRAMEWORK FOR INTERACTION BETWEEN THE EUROPEAN FOOD SAFETY AUTHORITY AND THE STAKEHOLDER DISCUSSION GROUP ON AQUACULTURE ENVIRONMENTAL RISK ASSESSMENT (STADG-ERAQUA)

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## 1. BACKGROUND

The team FEED of the Feed & Contaminants (FEEDCO) Unit, is currently engaged in activities related with the environmental risk assessment (ERA) of feed additives intended for marine aquaculture, namely:

- A Framework contract (FWC) for the development of a model to predict environmental concentrations of chemical substances in marine sediment when the substance is applied via feed in marine aquaculture (sea cages) (EFSA/FEEDCO/2023/01; Lot 1: EPA02.02.03), started on 28 June 2024. The closure of the FWC will be at the latest the 28 June 2028.
- A European Commission generic mandate for EFSA to perform an ERA of 7 trace elements used as nutritional additives in feed (cobalt, copper, iodine, manganese, molybdenum, selenium, and zinc) (M-2024-00092), received on 8 July 2024. The assessment should consider the maximum authorised levels and the target species for which they are authorised and should be based on available and/or new data. In this frame, a call for data and a literature review (especially in relation to natural occurrence of these trace elements in marine sediments for which available data is particularly scarce) were completed. The adoption of the scientific opinion is expected for May 2026.

Both activities have in common the ERA of feed additives in marine sediments, the environment compartment considered for marine aquaculture. Currently, the communication with stakeholders has been performed ad hoc in a scattered manner. The creation of a discussion group would expand the discussions ongoing on the subject with professionals with demonstrable expertise.

## 2. SCOPE OF INTERACTION

The aim of this group is to facilitate ongoing discussions in the field of ERA of feed additives for aquaculture and with a focus in marine sediments, allowing for exchanges on the scientific evidence, scientific studies, published outcomes of projects and peer discussions on the subject.



As consultative platform, this group would gather experts in the field of ERA of marine sediments, feed additives and aquaculture, EFSA staff, as well as EU Agencies representatives, feed and veterinary products industry and NGOs representatives.

### 3. GENERAL OBJECTIVES

The experts from this group could be consulted on (inter alia):

1. published deliverables submitted by the contractor working on the FWC for the development of a model to predict environmental concentrations of chemical substances in marine sediments.
2. methodology for sampling of marine sediments.
3. identification of challenges for feed additives ERA and the prioritisation of knowledge gaps.
4. best practices on how to integrate feed additives risk assessment and EU environmental initiatives related with aquaculture.
5. data, methods, technology, collaboration, outreach needs

Different members might have different involvement in the process and in various phases of the group existence.

### 4. WORKING METHODOLOGY

#### 4.1 COMPOSITION

The composition of the group consists of 15 members selected based on their expertise, contributions and relevance to the ERA of marine sediments, including representatives from academia, public authority, industry, consultancy, and private research.

Selected Experts/Stakeholders from the call for expression of interest (15 members out of 28 applications):

- Academia/Research (8 members): These are experts specialised in marine ERA.
- EU/Public Authority (3 members): Representing organisations European Commission's Directorate-General for Maritime Affairs and Fisheries (DG-MARE), European Environment Agency (EEA), and Norwegian Medical Products Agency (NOMA).
- Industry (2 members): Focused on aquafeeds and veterinary products.
- Consultancy/NGO (1 member): Specialised in regulatory affairs of feed additives.
- Private Research (1 member): Involved in ISO/OECD/GLP-related research.

Countries represented: Croatia, Portugal, Ireland, Norway, Italy, France, Denmark, Belgium, Germany, Slovenia.

#### 4.2 ROLES AND RESPONSIBILITIES

The StaDG-ERAQUA is composed by a group of people who share interest and expertise on ERA of marine sediments. The members of the Discussion Group work together for their mutual benefit and in compliance with EFSA's interests.



The role of the members is to facilitate the access to and sharing of specialised knowledge in the field of ERA of feed additives for aquaculture and identify possible challenges and knowledge gaps in the domain.

The success of this Discussion Group relies on the commitment of its members to contribute to relevant discussions, activities, and outputs.

EFSA may monitor the active participation and contributions from the group members as part of its review of whether the Discussion Group fulfils adequately its role. EFSA reserves the right to resign non-contributing members from the Discussion Group.

The EFSA team FEED of the Feed & Contaminants (FEEDCO) Unit will coordinate the Discussion Group activities. Other EFSA staff of the concerned scientific units may take part to the meetings of the Discussion Group and report on activities related to ERA of marine sediments, ensuring efficient collaboration and exchange of information.

### 4.3 OPERATING MODEL

The minimum required effort foreseen for each member taking part to this community is approximately as follows:

- Participation to online meetings 3 to 5 times per year (about 2 hours duration each)
- Consultation on some selected scientific work on the matter upon necessity
- One physical meeting per year upon necessity

Sharing of documents and group exchanges will happen in a corporate EFSA Team channel. The establishment of this community has an initial duration of 1 year, which can be subject to amendments according to new and different needs.

### 4.4 EXPECTED DELIVERABLES

- Meeting minutes summarising the issues discussed and the agreed follow-up actions.
- Reports on issues identified by the StaDG-ERAQUA related to ERA of feed additives in marine sediments for aquaculture (if required)

In case of need, other additional output could be developed by the group. The EFSA coordinator of the Discussion group will also be the chair of the meeting and be responsible for drafting the meetings' minutes and reporting updates.

## 4 TRANSPARENCY REQUIREMENTS

EFSA is fully committed to openness and transparency in line with the EFSA's Regulatory Framework (art. 38 of EFSA's Founding Regulation (EC) No 178/2002) and the Decision of the Management Board of the European Food Safety Authority on the criteria to register stakeholders and the mechanisms to engage with stakeholders. In line with these principles, details of the meetings of the StaDG-ERAQUA will be made available through the publication of agendas, participant lists and the outcome of each of the meetings on the EFSA website.



## 5 MONITORING AND REVIEW

A review of the effectiveness of EFSA's stakeholder engagement, including activities related to the StaDG-ERAQUA, shall be carried out any time during the lifespan of its existence. The establishment of this community can be subject to amendments and/or cancellation according to arising new and different needs.