# Consultation strategy for the Revision of Regulation (EC) 1831/2003 on additives for use in animal nutrition.

## 1. Background information

Feed additives are products used in animal nutrition to improve the quality of feed and of food of animal origin, to improve the animals' performance and welfare, to reduce environmental impact of livestock production and to satisfy essential nutritional needs (e.g. vitamins). Additives must be safe for animals, for consumers (e.g. there are no residues of the additive in the meat or eggs that may cause health concerns), for workers/users when they manipulate those products and for the environment. Hence, feed additives must undergo a safety assessment and be subject to a centralised authorisation procedure before they can be placed on the EU market.

The European Commission is carrying out an evaluation of the Feed Additives Regulation, which aims at informing the revision of the Feed Additives Regulation announced under the Farm to Fork strategy and contributing to the European Green Deal. The evaluation examines the performance and impacts of the Regulation as a whole and is being conducted according to the Better Regulation guidelines. It will be conducted in parallel with an impact assessment to inform the revision of the legislation.

Preliminary results from an external study commissioned by the European Commission to support the evaluation suggest that, though the Regulation has worked well in general, there are potential areas for improvement, in particular, to address current needs of sustainable animal farming, alleviate barriers to technical and scientific innovation, improve the authorisation process, reduce unnecessary administrative burden, improve the capacity of Member States to control imports in an efficient manner, reduce dependency on imports from third countries for some additives, reduce the restrictions in the circulation of safe feed additives only intended for export, provide greater legal clarity and consistency for few aspects of the Regulation and reduce undue burden for manufacturers due to outdated labelling provisions.

As the evaluation is ongoing, these preliminary findings will be further examined and, if necessary, revised. Additional weaknesses may also be identified as the work progresses. The root causes and drivers for the problems identified will be analysed in more detail and complemented, as necessary.

This consultation strategy intends to complement the evidence already collected by the external study to inform the evaluation process and identify on which topics stakeholders will be consulted.

## 2. Consultation scope and objectives

The evaluation of the Feed additives Regulation has already gathered a great deal of data, and this already provides a sound basis for most aspects of the revision of the Regulation.

As part of the evaluation process, the Commission collected information through an Online Public Consultation (OPC) and a survey targeting eight non–EU National Competent Authorities (NCAs). An external study supporting the evaluation, including two targeted surveys (one addressed to industry stakeholders and one to the NCAs of the EU Member States), has been finalised and will be published at the time of the impact

assessment report. The study also entailed desk research, a literature review, exploratory interviews with the main stakeholder's organisations and case studies.

Furthermore, relevant evidence was collected from several sources including the following:

- *Internal database and publicly available information on feed additives in DG SANTE* and EFSA
- *Report from the Commission to the Council and the European Parliament on the use of coccidiostats and histomonostats as feed additives. (COM/2008/0233 final)*
- *Register of feed additives*
- *Open public consultation*
- *Audits and fact-finding reports carried out in the feed additives sector by DG SANTE*
- *Target consultation to 8 NCAs from non EU countries carried out by DG SANTE*
- *Rapid Alert System on Food and Feed database*
- *Joint Research Centre-EU Reference Laboratory on Feed Additives*
- European Patent Office and EUROSTAT
- World Trade Organisation

The present consultation will help to complement the information already collected by gathering additional evidence, namely on the following issues and topics:

1. Sustainable farming and scientific innovation. Ensure that innovative feed additives fit with the actions they perform, in particular, actions intended to improve animal welfare, to reduce antimicrobial resistance, to reduce impact on climate change, to reduce impact on the environment and to improve sustainability of livestock production.
2. Extension of the authorisation period.
3. Additives not linked to an authorisation holder
4. Claims beyond those effects assessed by EFSA.
5. Circulation and labelling of feed additives only intended for export.
6. Extrapolation from major to minor species.
7. Extrapolation from food to feed.
8. Testing alternatives not using animals.
9. Data sharing to prevent duplication of toxicological tests.
10. Indication of labelling requirements in a physical label.
11. Definition of preparations of feed additives
12. The use of feed additives in drinking water.
13. Identification of feed additives and premixtures at declaration time in international trade.
14. Worker safety provisions for premixtures.
15. Administrative simplification of authorisation procedure.
16. Tolerances for feed additives incorporated in premixtures.
17. Register of feed additives.
18. Environmental assessment of farmed non-food producing animals.

This consultation strategy will also help to prepare the impact assessment supporting the revision of the legislative proposal. The aim is to collect views and additional facts and figures on the questions to be addressed by the impact assessment namely**:**

- How the problems can be defined (i.e. negative consequences, magnitude, dimension and drivers)?
- Why should the EU act?
- What should be achieved?
- What are the various options to achieve the objectives?
- What are their economic, social and environmental impacts and who will be affected?
- What are the likely impacts of the different policy options?

- Can regulatory costs be reduced without affecting the achievement of the objectives?
- What are the aspects of the Feed Additives Regulation that can be simplified or modified to reduce administrative burden?

## 3. Mapping of stakeholders

Building on the wide consultations already carried out to support the evaluation, the Commission will consult in particular the stakeholders listed in the table below.
All stakeholders will be consulted on the topics and on general questions listed above. The consultation will be conducted in a way and with tools adapted to their profiles, specificities and specific interest.

Table: Stakeholders

| | STAKEHOLDERS | SPECIFIC ASPECTS OF THE CONSULTATION |
|---|---|---|
| 1 | Manufacturers of feed additives and feed premixtures | |
| 2 | Traders of feed additives (importers/exporters/distributors) | |
| 3 | Applicants for feed additive authorisations and professional consultancy for feed additives applications | |
| 4 | Compound feed and pet food producers | |
| 5 | Users of feed additives: workers | |
| 6 | Farmers | This group will be divided in the consultation activities in different subgroups according to the type of production (meat, milk and eggs) and farm type. |
| 7 | Business and professional associations representing segments/interest groups of direct relevance to feed additives, mainly EU umbrella organisations: farmers, feed additives, compound feed, pet food, feed materials veterinary medicinal products. | This group will be divided in different subgroups in the consultation activities:<br>– Farmers;<br>– feed additives;<br>– compound feed;<br>– pet food;<br>– feed materials;<br>– veterinary medicinal products. |
| 8 | Non-governmental organisations or other organisations representing segments/interest groups of relevance to feed additives, mainly EU umbrella animal welfare organisations. | |
| 9 | Non-governmental organisations or other organisations representing segments/interest groups of relevance to feed additives, mainly EU umbrella pet owners' organisations. | |
| 10 | Non-governmental organisations or other organisations representing segments/interest groups of relevance to feed additives, mainly EU umbrella environmental organisations. | |
| 11 | Non-governmental organisations or other organisations representing segments/interest groups of relevance to feed additives, mainly EU umbrella trade unions' organisations: | |
| 12 | Organisations representing consumers at EU level | |
| 13 | Other (e.g. relevant academia and research ) | |
| 14 | National competent authorities (relevant national public authorities or agencies) responsible for all aspects related to feed additives. | |

## 4. Selection of consultation activities & their accessibility

Some of the actions indicated in the table below will be performed by an external contractor in charge of a study supporting the impact assessment.

| ACTION | ACCESSIBILITY | INDICATIVE PLANNING | LINGUISTIC REGIME |
|---|---|---|---|
| **Consultation on combined evaluation roadmap/inception impact assessment**.<br>Performed by the Commission<br>Addressed to all stakeholders.<br>Objective: gather information and understand views and opinions on the proposed roadmap<br>Feedback period: 6 weeks. | *Commission's 'Have your say' page and SANTE page.* | 14/12/2020 start consultation<br>25/01/2021 finish consultation | EN |
| **Online Public Consultation (OPC).**<br>Performed by the Commission<br>Addressed to all stakeholders<br>Objective: easier and more general questions to be answered by the general public with a view to collect data, gather expertise and information, and understand views and opinions of a broad range of stakeholders.<br>Feedback period: 12 weeks | *Commission's 'Have your say' page and SANTE page.* | 20/01/2021 start consultation - 17/03/2021 finish consultation | All EU official languages |
| **Targeted consultation (questionnaire)**<br>Performed by the contractor<br>Addressed to national competent authorities (NCAs) of Member States and EFTA countries.<br>Objective: detailed questions with a view to collect data, gather expertise and information and understand views and opinions.<br>Feedback period: 4 weeks. | *Commission's 'Have your say' page and SANTE page.* | May 2021-Junel 2021[1] | English |
| **Targeted consultation (questionnaire)**<br>Performed by the contractor<br>Addressed to stakeholders having direct impact on feed additives (stakeholders listed in rows 1 to 7 of the table above).<br>Objective: detailed questions with a view to collect data, gather expertise and information and understand views and opinions.<br>Feedback period: 4 weeks | *Commission's 'Have your say' page and SANTE page.* | May 2021-June 2021[1] | English |
| **Workshop (1 day)**<br>Organised by the contractor in collaboration with the Commission.<br>Addressed to all stakeholders<br>Objective: validation of the analysis, gather information, understand views and opinions and validate information | The contractor and the Commission will alert competent authorities and stakeholders. *SANTE page* | May 2021-June 2021[1] | English |
| **Case studies**<br>Performed by the contractor<br>Addressed to four Member states<br>Objective: shall help to refine the assessment on | The contractor and the Commission will alert MS | May 2021-June 2021[1] | English |

[1] The consultation will start within this range period

| | | | |
|---|---|---|---|
| different topics. | | | |
| **Case studies**<br>Performed by the contractor<br>Addressed to six feed additives producers of which three are SMEs (not as a part of a big company) and two produce also premixtures.<br>Objective: shall help to refine the assessment on different topics. | The contractor will alert stakehokders | May 2021- June 2021[1] | English |
| **Targeted interviews**<br>Performed by the contractor<br>Addressed to most representative environmental, consumer and animal welfare organisations, academia and research institutions feed additives organisation, pet food organisation, compound feed organisation, animal health organisation and farmer organisation.<br>Objective: to collect data, collect information, validate analysis and understand views and opinions. Environmental, consumer and animal welfare organisations will require additional efforts to inform them objectively in a pedagogic manner about the role of feed additives for consumers, environment, animal welfare, and human health. | The contractor and the Commission will alert competent authorities and stakeholders | May 2021-Junel 2021[1] | English |
| **Focus groups meetings**<br>Performed by the contractor<br>Objective: to discuss the study and to gather opinions about specific issues, which requires deep examination after the surveys are concluded. Depending on the topic to discuss will be addressed to one or other stakeholders | The contractor and the Commission will alert stakeholders | The contractor and the Commission will alert the organisations | English |

## 5. Summary /overview on consultation activities by stakeholder groups and indicative timing

The following table summarises the planned consultation activities

| **CONSULTATION ACTIVITY INDICATIVE PLANNING** | **ROADMAP** | **OPC** | **TARGETED CONSULTATION** | **FOCUS GROUP MEETINGS** | **WORKSHOP** | **CASE STUDIES** | **TARGETED INTERVIEWS** |
|---|---|---|---|---|---|---|---|
| | **14/12/2020-25/01/2021** | **20/01/2021-17/03/2021** | **May 2021-June 2021[2]** | | **May 2021-June 2021[2]** | **May 2021-June 2021[2]** | **May 2021-June 2021[2]** |
| Manufacturers of feed additives and premixtures of feed additives | **X** | **X** | **X** | **X** | **X** | **X** | |
| Traders of feed additives (importers/exporters/dis | **X** | **X** | **X** | **X** | **X** | | |

[2] The consultation will start within this range period

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| tributors) | | | | | | | |
| Applicants for feed additive authorisations and professional consultancy for feed additives applications | **X** | **X** | **X** | **X** | **X** | **X** | |
| Compound feed and pet food producers | **X** | **X** | **X** | **X** | **X** | | |
| Users of feed additives : workers | **X** | **X** | **X** | **X** | **X** | | |
| Farmers | **X** | **X** | **X** | **X** | **X** | | **X** |
| Business and professional associations representing segments/interest groups of direct relevance to feed additives, mainly EU umbrella organisations: farmers, pet food, feed additives, compound feed, feed materials veterinary medicinal products or animal health. | **X** | **X** | **X** | **X** | **X** | | X |
| Non-governmental organisations or other organisations representing segments/interest groups of relevance to feed additives, mainly EU umbrella organisations: animal welfare/pet owners, human health, environment and trade unions. | **X** | **X** | | | **X** | | **X**[3] |
| Organisations representing consumers at EU level | **X** | **X** | | | **X** | | **X** |
| Other (e.g. relevant academia and research) | **X** | **X** | | | **X** | | **X** |
| National competent authorities (relevant national public authorities or agencies) responsible for all aspects related to feed additives | **X** | **X** | **X** | | **X** | **X** | |

## 6. Consultation webpage & communication activities

**Ways to publicise the consultation**

[3] This apply to organisations related to animal welfare and environment

The public in general and stakeholders are invited to contribute to the different consultations. For the roadmap, the open public consultation and the targeted consultations all the information on how to participate in the consultation will be available in *Commission's 'Have your say' page and SANTE page.*

Member States' authorities as well as European organisations will be invited to inform and promote the Commission web surveys among their members. The open public consultation will be publicised also through Member states' Permanent Representations, European Economic and Social Committee and Committee of Regions

For the participation in the Workshop, the information will be available in SANTE page so the interested stakeholders and competent authorities can apply. The Commission will seek actively the participation by directly informing applicants of feed additives and the main stakeholder organisations. Due to limitations in the number of participants, criteria will be established to have a representative sample of the stakeholders and to ensure transparency and fair participation of all interested parties. Those criteria will be published on the SANTE webpage. Member States' authorities as well as European organisations will be invited to inform and promote the workshop among their members.

Press releases will announce the launch of the consultation on the roadmap, the open public consultation and the targeted consultations.

**Ways to publicise the results of the consultation activities**

The output of all consultation activities will be summarised in a synopsis report and reported in the Impact Assessment report as well as being published on the relevant Commission webpage.