

Call to EFSA stakeholder organisations and EU Member States for nominating stakeholder experts to the *ad hoc* EFSA Discussion Group on the FEEDAP Panel Guidance on the assessment of the efficacy of feed additives

Deadline for submission of nominations: 18 April 2017

1. Introduction

Regulation (EC) No 1831/2003 establishes the rules governing the Community authorisation of additives for use in animal nutrition. Moreover, Regulation (EC) No 429/2008 provides detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives.

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) has adopted a series of guidance documents which aim at complementing Regulation (EC) No 429/2008 to help the applicants in the preparation and submission of technical dossiers for the authorisation of additives for use in animal nutrition according to Regulation (EC) No 1831/2003. Some of these guidance documents have been updated after their first adoption, while others have never been reviewed or updated. Among them, the guidance on the assessment of the efficacy of feed additives was considered one with the highest priority.

Since the publication of this guidance document, the FEEDAP Panel has identified areas in which an update is needed to provide further clarification or to include modification considering recent scientific developments and the Panel's experience gained during the last years while working under the provisions of Regulation (EC) No 429/2008, under the framework of the provisions laid down in Regulation (EC) No 1831.

The FEEDAP Panel considered it fundamental to involve stakeholder representatives and experts from the Member States risk assessment bodies in the early stages of the guidance revision. In the framework of the new approach on Transparency in Risk Assessment (TERA project) and the Stakeholder Engagement Approach (SEA), EFSA aims at exploring ways to enhance the participation of stakeholders in the development of guidance documents. EFSA is launching a Discussion Group on the Guidance the assessment of the efficacy of feed additives, currently under revision in the EFSA FEEDAP Panel. European Commission representatives will also participate actively in this Discussion Group.

2. Scope of the Guidance Document

The Guidance Document is intended to assist the applicant in the preparation and the presentation of its application, as foreseen in Article 7.6 of Regulation (EC) No 1831/2003. This document does not substitute for the obligation of an applicant to comply with the requirements of Regulation (EC) No 1831/2003 and its implementing rules.

In particular, the Guidance Document is intended to provide the information necessary to properly assess the efficacy of feed additives as required in Section 4 of Annex II and the relevant sections of Annex III of Regulation (EC) No 429/2008.

3. Drafting process and stakeholders' involvement

The drafting will be carried out by an *ad hoc* working group of the EFSA FEEDAP Panel. The draft Guidance Document will be subject to a public consultation. This process ensures the opportunity for the public (including all relevant stakeholders) to comment on and contribute to the development of this Guidance.

In order to facilitate the drafting process before the public consultation, an *ad hoc* EFSA FEEDAP Panel Discussion Group will be created as an EFSA stakeholder discussion group of the EFSA SEA. The Discussion Group is a consultative body; the drafting of the Guidance Document remains a responsibility of the working group of the EFSA FEEDAP Panel.

4. Role and composition of the *ad hoc* EFSA FEEDAP Panel Discussion Group on the Guidance on the assessment of the efficacy of feed additives

The Discussion Group is coordinated by the FEED Unit. The drafting working group of the FEEDAP Panel will consult the Discussion Group on initial versions of (parts of) the draft Guidance Document. The Discussion Group will be active during the preparation of the draft guidance prior to and after the public consultation. The group is expected to:

- Attend specific meetings (e.g. teleconferences) of the FEEDAP Panel WG on the Guidance revision (e.g. as hearing experts, for targeted consultation) before and after public consultation;
- Comment on the draft guidance document on efficacy before its endorsement for public consultation by the EFSA FEEDAP Panel (over the time span of the Discussion Group) comment during the public on-line consultation of the draft guidance document;
- Participation in events that might be organised during the discussion and after the adoption of the document.
- Prepare a shared document to provide EFSA with feedback on the experience of the Discussion Group right after the end of the project. Members of the Discussion Group shall define together how to finalise such report (linked to the adoption of the revised guidance documents).

The main actors specific for this DG on assessment of the efficacy of feed additives are expected to be the companies' associations, farmers and primary producer's organisations, associations of Practitioners, relevant non-governmental organisations (NGOs), consumers' associations, academia and the Member States (MS). The discussion Group will be composed of a maximum of 6 representatives from the companies' associations and farmers and primary producer's organisations, a maximum of 6 representatives from the MS (identified via the Advisory Forum representatives) and a maximum of 3 representatives from associations of Practitioners, relevant NGOs, consumers' associations and academia. Upon specific needs of topics identified during the discussion, the nominated representatives are entitled to nominate substitutes to cover the identified subject (this could also be done through the invitation of hearing experts).

Representatives of business and feed industry, farmers and primary producer's organisations: The discussion group shall be composed, as far as possible, of representative of organisations covering the whole feed chain, from primary production to retail. The experts shall be selected on the basis of their expertise in the area of efficacy of feed additives (mainly on animal production, animal nutrition, veterinary medicine) and their strong motivation. Representatives of organisations can express their interest in taking part in the Discussion group through one of the industry association or directly by contacting EFSA. Members of these associations are invited to decide among them which organisations are best placed to take part in the group and propose candidates by sending the name, contact details and Curriculum Vitae of the candidates to DIG-FEED-GuidanceUpdate@efsa.europa.eu and copy Stakeholders@efsa.europa.eu and submitting in attachment a Nomination form filled in (<http://www.efsa.europa.eu/sites/default/files/170331stakeholdersnominationcall-feed-efficacy-form.doc>).

Representatives of the Member States: The experts from the Member States shall be selected on the basis of the relevance of their professional and scientific background on efficacy of feed additives as well as their motivation. In particular, experts shall be selected according to their expertise in the following areas: animal production, animal nutrition, veterinary medicine, as well as in risk assessment. Members States are invited to propose candidates by sending the names and contact details of the candidates to DIG-FEED-GuidanceUpdate@efsa.europa.eu and copy afsecretariat@efsa.europa.eu and submitting in attachment a Nomination form filled in (<http://www.efsa.europa.eu/sites/default/files/170331stakeholdersnominationcall-feed-efficacy-form.doc>). The call for candidates will be processed via the EFSA Advisory Forum

Representatives of consumers' associations and NGOs, associations of practitioners and academia:
The experts shall be selected on the basis of their expertise in the area of efficacy of feed additives (mainly on animal production, animal nutrition, veterinary medicine) and their strong motivation. Representatives of organisations can express their interest in taking part in the Discussion Group through one of these associations or directly by contacting EFSA. Members of these associations are invited to decide among them which organisations are best placed to take part in the group and propose candidates by sending the name, contact details and Curriculum Vitae of the candidates to DIG-FEED-GuidanceUpdate@efsa.europa.eu and copy to Stakeholders@efsa.europa.eu and submitting in attachment a Nomination form filled in (<http://www.efsa.europa.eu/sites/default/files/170331stakeholdersnominationcall-feed-efficacy-form.doc>).

5. Process for nomination of EFSA stakeholder organisations for the *ad hoc* EFSA FEEDAP Panel Discussion Group on the Guidance on the assessment of the efficacy of feed additives

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 Consultation Group. Additional information on EFSA's stakeholder engagement principles and involvement is available at: <https://www.efsa.europa.eu/en/partnersnetworks/stakeholder>.

Organisations already registered as EFSA stakeholders (<https://www.efsa.europa.eu/sites/default/files/stakeholders-registered-list.pdf>) can proceed directly with the nomination of the proposed member for the Consultation Group. Other organisations interested in nominating a member for the Consultation Group should send first a request to be registered as a EFSA stakeholder; information and the link for submitting the request are available at <https://www.efsa.europa.eu/en/engage/stakeholders>.

As stipulated in Article 3 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 (mb160316-a3), non-registered stakeholder may be invited to the meetings of EFSA Discussion Group based on the need for specific expertise or technical knowledge. Such engagement will be assessed on case-by-case basis. Any involvement of non-registered stakeholders will be made public in transparent and timely manner.

Nominations of members for the Discussion Group should be sent by email to DIG-FEED-GuidanceUpdate@efsa.europa.eu and submitting in attachment a Nomination form filled in (<http://www.efsa.europa.eu/sites/default/files/170331stakeholdersnominationcall-feed-efficacy-form.doc>).

The deadline for submission of the nominations is **18 April 2017**. Organisations may submit nominations for up to three stakeholder experts; however, as indicated below no more than one stakeholder expert per organisation will be selected by EFSA.

6. Process and criteria for the selection of EFSA stakeholder representatives in the *ad hoc* EFSA FEEDAP Panel Discussion Group on the Guidance on the assessment of the efficacy of feed additives; follow up

EFSA will select a maximum of 18 stakeholder expert representatives from the nominations received through this call, distributed according to the following groups (as defined at <https://www.efsa.europa.eu/en/partnersnetworks/stakeholder>):

- Up to 6 experts nominated by stakeholders representing the business and feed industry, distributors, and farmers and primary producers organisations;
- Up to 6 experts nominated by MS;

- Up to 3 experts nominated by stakeholders representing consumer organisations, academia, associations of practitioners and NGOs;

The selection will be made only from the pool of stakeholder experts nominated by stakeholder organisations registered as EFSA stakeholders or with ongoing requests. It 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:

- 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;
- Knowledge and expertise of the nominated stakeholder expert, considering the need for the Consultation Group to cover a range of technical and scientific areas, including animal nutrition, animal production and feed technology, and the different methodologies and scientific disciplines.

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.

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

Members of the Consultation Group from stakeholders representing business and feed industry, farmers and primary producer's organisations, associations of practitioners, relevant NGOs and consumers' associations, academia and MS will be invited to submit a Declaration of Interests according to the EFSA template; submitted Declarations of Interests will be published by EFSA. These stakeholder experts are responsible for ensuring that their comments represent the views of the organisation, considering, as appropriate, the views of other non-selected organisations within the same main stakeholder groups.