Call to EFSA stakeholder organisations for nominating experts to the *ad hoc* EFSA Allergenicity Stakeholder Consultation Group

Deadline for submission of nominations: 15 August 2020

1. Introduction

In 2017, EFSA's Scientific Panel on Genetically Modified Organisms (hereafter the GMO Panel) published a guidance document on the allergenicity assessment of genetically modified (GM) plants[1]. The guidance addresses non-IgE-mediated adverse immune reactions to foods, *in vitro* protein digestibility tests and endogenous allergenicity. In relation to the *in vitro* protein digestibility tests, the GMO Panel considered that additional investigations were needed (interim phase) before any additional recommendations in the form of guidance for applicants could be provided. To support this interim phase, EFSA launched a procurement to test a refined protocol for *in vitro* protein digestion. The final report was recently published[2], opening up new opportunities in this field that is still in its infancy and which has great potential for further improvement. In addition, a dedicated working group will be established to discuss and provide an opinion on the topic considering all available information. The working group will also consider critical gaps in the field of allergenicity assessment and protein safety in general, and future development needs in these areas. Continuity with previous activities related to allergenicity will be ensured by enrolling experts from the former *ad hoc* Allergenicity Working Group.

2. Scope of the mandate

The mandate will address a recurrent question for the GMO Panel and the scientific community on the usefulness of the current *in vitro* protein digestibility test – a pepsin resistance test that is performed for the allergenicity assessment in particular and for protein safety, in general. The question is of major relevance as the pepsin resistance test is mandatory according to Codex Alimentarius[3] and is embedded into the GMO Panel guidance document[4].

This project will also help to fill current gaps in the risk assessment of novel proteins. In particular, it will highlight key aspects that need additional work/discussion to further improve the allergenicity assessment and the protein safety assessment, formulating specific research needs on the topic. In relation to this, protein allergenicity and toxicity have been explicitly highlighted in the Food Safety Regulatory Research needs of 2030, published by EFSA in 2019[5].

---

[1] EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messean A, Nielsen EE, Nogue F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M, Eigenmann P, Epstein M, Hoffmann-Sommergruber K, Koning F, Lovik M, Mills C, Moreno FJ, van Loveren H, Selb R and FernandezDumont A, 2017. Guidance on allergenicity assessment of genetically modified plants. EFSA Journal2017;15(5):4862, 49 pp. https://doi.org/10.2903/j.efsa.2017.4862

[2] Mackie A, Dupont D, Torcello-Gómez A, Jardin J, Deglaire A, 2019. Report on EFSA project OC/EFSA/GMO/2017/01. *In vitro* protein digestibility (Allergestion). EFSA supporting publication 2019:EN-1765. 82 pp. doi:10.2903/sp.efsa.2019.EN-1765

[3] http://www.fao.org/3/a-a1554e.pdf

[4] EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on Guidance for risk assessment of food and feed from genetically modified plants. EFSA Journal 2011; 9(5): 2150. [37 pp.] doi:10.2903/j.efsa.2011.2150. Available online: www.efsa.europa.eu/efsajournal.htm

[5] EFSA (European Food Safety Authority), Bronzwaer S, Kass G, Robinson T, Tarazona J, Verhagen H, Verloo D, Vrbos D and Hugas M, 2019. Editorial on food Safety Regulatory Research Needs 2030. EFSA Journal 2019;17(7):e170622, 8 pp

3. Scientific process and stakeholders' engagement

As explained above, a dedicated working group will be established in accordance with EFSA's rules[6]; continuity with past discussions on GMO Panel guidance document will be ensured by considering relevant panel members and members of the former Allergenicity Working Group. The working group will include experts with competencies in *in vitro* protein digestibility, food allergy and risk assessment. As outlined in the mandate, the GMO Panel will task the working group to produce two deliverables: (1) a statement on the usefulness of *in vitro* protein digestion in risk assessment; and (2) a scientific opinion providing recommendations for future developments, including research needs, in the field of allergenicity assessment, and protein safety in general.

In light of successful past collaboration between EFSA and stakeholders and the great interest in this subject, EFSA has decided to re-establish an *ad hoc* stakeholder consultation group. The group will be asked to provide input to the working group at various stages of the process.

EFSA is therefore calling for expressions of interest from stakeholder organisations that are on the EFSA list of registered stakeholder organisations[7]. This call for interest is also published on EFSA's website to reach non-registered organisations and to invite them to express their interest in participating in the group. Registering as an EFSA stakeholder is a pre-requisite for being eligible to join the stakeholder consultation group. The selection process will be organised by EFSA, as with the previous initiative on this topic.

4. Role and composition of the *ad hoc* EFSA Allergenicity Stakeholder Consultation Group

EFSA will consult the ad hoc stakeholder consultation group at key stages of the development of the deliverables and on specific issues such as the role of the *in vitro* protein digestion test in the safety assessment of proteins, and development needs in allergenicity assessment.

The consultation group will be invited to online meetings of the Allergenicity WG (physical meetings are suspended due to the Coronavirus situation) and to a workshop that is scheduled to take place in spring 2021. The aim of the workshop will be to collect views and suggestions to feed the discussions of the working group and to propose recommendations for further developments and research in the field.

In the interest of transparency, EFSA will make all the activities/events of the stakeholder consultation group publicly available on its website.

All comments received from the group will be published with a clear affiliation. When submitting comments, members of the group may ask for personal data, documents covered by copyright, or the parts of the comments containing confidential information to be restricted to the EFSA scientific working group and stakeholder consultation group. EFSA will check the requests according to the applicable legal provisions.

[6] Establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups
[7] List of Registered stakeholders

5. Process for nomination of EFSA stakeholder organisations for the *ad hoc* EFSA Allergenicity Stakeholder Consultation Group

EFSA's stakeholders are representative organisations that have an interest in EFSA's work or more widely in the food and feed sector. EFSA divides stakeholders into seven major categories; all groups with an interest in the area of allergenicity 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 members for the consultation croup. Other organisations interested in nominating a member should send first a request to be registered as an EFSA stakeholder; information and the link for submitting the request are available at https://www.efsa.europa.eu/en/engage/stakeholders.

Nominations of members should be sent by email to GMOManagement@efsa.europa.eu indicating in the Subject box: "Nomination for the Allergenicity Stakeholder Consultation Group" and submitting in attachment a filled in Nomination form.

Organisations may submit up to two nominations (one principal and one back-up, if available); however, no more than one expert per organisation may be selected.

The deadline for submission of nominations is 15 August 2020.

6. Process and criteria for the selection of EFSA stakeholder representatives in the *ad hoc* EFSA Allergenicity Stakeholder Consultation Group

The consultation group will consist of a **maximum of 12 experts**; up to five representatives from EU Member States, up to five representatives from the different stakeholder categories and two experts representing international organisations and third-country counterparts.

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:

- interest in the field of allergenicity assessment and expected benefits from the participation of the organisation as expressed in their application;
- role and remit of the organisation at EU level;
- achieving a balanced representation of stakeholder interests; and
- knowledge and expertise of the nominated stakeholder expert, considering the need for the stakeholder consultation group to cover a range of technical and scientific areas, including allergenicity risk assessment, *in vitro* protein digestibility and food allergy.

After the selection process, EFSA will inform all stakeholder organisations of the selected expert(s).

7. Roles and responsibilities of the stakeholder experts selected as members of the *ad hoc* EFSA Allergenicity Consultation Group

The selected experts from stakeholder organisations will be invited to comment on the deliverables.

The members should follow the indications received regarding the confidentially 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 selected experts and their associated organisations will be made publicly available.

8. Further information on the initiative, call for expression of interest or any other related matters

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

Deadline for submitting an expression of interest to contribute to EFSA ad hoc stakeholder consultation group is 15 August 2020 at midnight. Any application reaching EFSA after the set deadline will be deemed invalid.