EFSA Stakeholder Consultative Platform pilot *focus group* on a Guidance Document on Allergenicity[1]

Terms of Reference (ToR) - Version 2 (updated JAN 2016)

1. Background

According to chapter A.1.3 of the Definitions of EFSA Scientific Outputs and Supporting Publications[2] "Guidance of the Scientific Committee or Scientific Panel" are documents which explain the principles behind EFSA's procedures and approaches to scientific risk assessments to risk assessors (including the Scientific Committee or Scientific Panels), risk managers and/or applicants of dossiers submitted for evaluation. Guidance documents may also specify the information and data which industry must provide when submitting applications to EFSA for evaluation prior to their authorisation by risk managers.

As recommended in the 2012 External Evaluation of EFSA and consequent recommendations by EFSA's Management Board, the Authority is committed to duly informing and engaging with all those affected by EFSA's work while safeguarding the independence of its scientific advice.

In the framework of the new Open Risk Assessment project, EFSA aims at exploring ways to enhance the participation of stakeholders in the development of guidance documents (GDs).

In October 2014, various aspects of the interaction between EFSA and applicants during the life-cycle of applications were discussed with representatives of the European Commission and stakeholders. Discussions included the development of specific guidance documents in the regulated product areas and the benefits of constructive and transparent cooperation between risk managers, risk assessors and stakeholders during such processes.

Engagement with stakeholders in these areas has been addressed on various occasions by the EFSA Stakeholder Consultative Platform, a group composed of EU-wide stakeholder organisations working in areas related to the food chain, regularly interacting with EFSA. The Platform is responsible, among other, to advise EFSA's Executive Director on EFSA's work and provide feedback on the effectiveness of EFSA's policies in response to stakeholders' concerns[3].

To explore best ways to enhance such engagement, EFSA is suggesting to launch a pilot project and establish a stakeholder *focus group* in the area of regulated products. It is

[1] EFSA-Q-2014-00547
[2] http://www.efsa.europa.eu/en/riskassessment/scdocdefinitions.htm
[3] http://www.efsa.europa.eu/en/partnersnetworks/stakeholder

proposed that the *focus group* will be composed of representatives of the Member States and of EFSA's Stakeholder Consultative Platform and will take the form of a Discussion Group of the Platform. The **pilot *focus group*** is asked to contribute to the development of **a guidance document on allergenicity** (EFSA-Q-2014-00547), which is currently being developed by the GMO Panel but has relevance for the allergenicity risk assessment of proteins in general.

The objectives of the pilot *focus group* are to i) foster the engagement of stakeholders; ii) enhance the quality, clarity and usability of the guidance document thanks to the contribution of a wider spectrum of stakeholders; and iii) draw lessons for future engagement with stakeholders.

2. Terms of Reference

Members of the pilot *focus group* shall:

- provide timely feedback on the scientific and technical content of the Guidance Document based on their expertise, at different stages of guidance development;
- attend specific meetings (dedicated stakeholder workshop; meeting of the GMO Panel WG on allergenicity GD development);
- provide feedback on the experience to allow EFSA to draw lessons.

The pilot *focus group* is a consultative body, the members are not expected to contribute to the drafting of the guidance document which remains a responsibility of the working group of the GMO Panel.

Composition of the pilot *focus group*:

The pilot *focus group* will be created as an EFSA stakeholder discussion group of the EFSA Stakeholder Platform.

It will be composed of a maximum of four representatives from the EFSA Stakeholder Consultative Platform (identified via EFSA stakeholder platform) and a maximum of four representatives from the Member States (identified via the EFSA GMO risk assessment network).

Representatives of the Stakeholder Consultative Platform: The group shall be composed, as far as possible, of representative of organisations covering the whole food chain, from primary production to retail. The experts shall be selected on the basis of their expertise and their strong motivation. In particular, experts shall be selected according to their expertise in the following areas: molecular allergology, protein chemistry, plant science, clinical allergy, gastroenterology, food chemistry, as well as in risk assessment. Representatives of organisations who are not members of the Platform can express their interest in taking part in the group through one of the member of the Platform. Members of the Platform 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 SHPlatformsecretariat@efsa.europa.eu.

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 the topic of the guidance document in question as well as their motivation. In particular, experts shall be selected according to their expertise in the following areas: molecular allergology, protein chemistry, plant science, clinical allergy, gastroenterology, food chemistry, as well as in risk assessment. Members of the EFSA GMO risk assessment

network are invited to propose candidates by sending the names and contact details of the candidates to afsecretariat@efsa.europa.eu.

3. Roles and responsibilities

The pilot *focus group* is coordinated by the GMO unit with the support of the Application Desk Unit. Relations and feedback to the Stakeholder Consultative Platform will be assured through the participation of the Secretariat of the Platform in the group and its activities.

Responsibilities of the *focus group* members are described in section 2 and 4.

4. Expected deliverables and timelines

The pilot *focus group* will be running from May 2015 until December 2017, end of the work on the guidance document.

The group is expected to:

- Comment on the briefing notes ahead of the dedicated stakeholder workshop EFSA is organising in Brussels on 17 June 2015[4] (June 2015);
- Attend and participate in specific meetings: a) dedicated stakeholder workshop on 17th June 2015 in Brussels, b) a meeting of the GMO Panel WG on allergenicity guidance document development (foreseen September/October 2016), c) dedicated Info Session on Guidance Document (foreseen Autumn 2016);
- Comment on the draft guidance document before its endorsement for public consultation by the EFSA GMO Panel (March/April 2016);
- Comment during the public on-line consultation of the draft guidance document (July 2016);
- Prepare a shared document to provide EFSA with feedback on the experience of the pilot *focus group* right after the end of the pilot focus group project. Members of the *focus group* shall define together how to finalise such report (spring 2017, linked to the adoption of the scientific opinion).

Document history	
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[4] http://www.efsa.europa.eu/en/press/news/150414a.htm