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

Deadline for submission of nominations: 21 May 2019

1. Introduction

In March 2019, the European Commission (EC) mandated EFSA to revise its 2013 guidance document¹ on the risk assessment of plant protection products and bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA, 2013), which was republished in 2014 following feedback from MSs collected during a workshop organised by the EC.

So far, there has been insufficient support by Member States represented in the Standing Committee on Plants, Animals, Food and Feed to implement the guidance for regular renewal and approval assessments. Many Member States, before considering its full implementation, have expressed their preference for a revision of several aspects of the guidance document. In addition, new evidence has become available since the original guidance was published. As a follow-up, in March 2019, the EC mandated EFSA to review its 2013 guidance document.

2. Scope of the mandate

The scope of the mandate is to revise several areas of the current guidance document as indicated in the feedback from stakeholders and Member States and by considering new scientific evidence that has become available since its publication in 2013. In particular, the EC requested EFSA to review: the evidence on bee background mortality, by considering bee keeping management and natural background mortality; the different exposure routes, in particular considering spray application and seed treatment or granular application; the list of bee-attractive crops, in particular considering the presence of bees, guttation and agricultural practices; and the methodology with regard to higher tier testing.

The risk assessment methodologies for bees currently applicable in the regulatory context (i.e. European Commission $(2002)^2$ and EPPO $(2010)^3$) are not fully adequate to address the approval criteria for bees introduced by Regulation (EC) No 1107/2009 and in the light of more recent scientific evidence. Therefore, the implementation of an updated guidance will improve the risk assessment delivered by EFSA; will increase the harmonisation between Member States and will result in a more fit-for-purpose EU risk assessment for bees, in line with the current requirements of the legal framework. In

¹ Mandate to EFSA to revise the Guidance on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus spp.* and solitary bees), Ref. Ares (2019) 1608315 - 11/03/2019

² European Commission, 2002. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002-rev. 2 final, 17 October 2002

³ European and Mediterranean Plant Protection Organization, Environmental risk assessment scheme for Plant Protection Products — chapter 10: honey bees (EPPO/OEPP, 2010) revised in September 2010 with ICPBR recommendations

addition, it will address better the continuously increasing public concerns regarding bees and pesticides.

3. Scientific process and stakeholder engagement

An EFSA scientific working group composed of experts with specific scientific competence in bee risk assessment and bee biology will be set up in accordance with EFSA's rules for setting up working groups⁴. The deliverables of the work as outlined in the mandate received by the Commission will be the responsibility of EFSA and its working group. The Commission has asked EFSA to ensure stakeholder engagement and consultation of risk managers throughout the process and in an iterative way⁵. An outline of the process for the revision of the 2013 Guidance, that includes consultation of relevant stakeholders, Members States and risk managers at various stages of the scientific process during the 24 months mandate deadline, is under preparation by EFSA and will be agreed with the Commission by June 2019.

EFSA has considered both the complexity of the subject and the stakeholder and public interest of the subject in question, and has decided to establish an ad-hoc stakeholder consultation group composed of relevant organisations that will be consulted at various stages of development of the work to provide input to the EFSA scientific working group. This call for expression of interests to stakeholder organisations is organised through the list of registered stakeholder organisations⁶ and is published on EFSA's website to allow other, non-registered organisation to indicate their interest to participate as stakeholder representatives. The selection process will be organised by EFSA, similarly to previous initiatives such as the development of guidance for the implementation of the criteria to identify endocrine disruptors, emerging risks and data collection.

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

In accordance with the mandate received and agreed with the Commission, EFSA will be consulting the *ad hoc* stakeholder consultation group at key stages of the development of the work, and in particular, at the initial stage of the work, by providing input to the EFSA scientific working group on the 2013 Bee Guidance Document (estimated timeframe June-July 2019); secondly, at the stage of a revised guidance document that will be also submitted to public consultation (estimated time frame September 2020).

The outcome of any stakeholder engagement activity that will be organised during 2019-2020 as part of the stakeholder engagement programme will be made publicly available on the EFSA website.

Written comments from the Consultation Group members will be considered by the EFSA scientific working group. Considering the time constraints, no responses to the individual comments will be made. No physical meetings of the EFSA Stakeholder Consultation Group will be organised. Virtual meetings may be organised on an *ad hoc* basis.

2

⁴ Establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups

⁵ Acceptance of the Mandate to revise the Guidance on the risk assessment of plant protection products on bees, Ref. BU/GdS/MT/CS/mc (2019)-out-21369335

⁶ List of Registered stakeholders

For transparency purposes, the comments received from the Stakeholder Consultation Group will be compiled and published with the indication of the member organisation that submitted the comment. When submitting comments, the members may claim that personal data, documents covered by copyrights, or the parts of the comments containing confidential information are restricted to the EFSA scientific working group and Consultation group and may not be included in the public version. EFSA will check the claims according to the applicable legal provisions.

5. Process for nomination of EFSA stakeholder organisations for the *ad hoc* EFSA Bee Guidance Consultation Group

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

Nominations of members should be sent by email to pras.secretariat@efsa.europa.eu indicating in the Subject box: "Nomination for the Bee Guidance Stakeholder Consultation Group" and submitting in attachment a completed Nomination form.

Organisations may submit nominations for up to three stakeholder experts, however, no more than one stakeholder expert per organisation will be selected by EFSA.

The deadline for submission of the nominations is 21 May 2019.

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

EFSA will select a **maximum of 14 stakeholder expert representatives** from the nominations received through this call. Up to two representatives from each of the seven stakeholder categories may be selected.

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 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 Stakeholder Consultation Group to cover a range of technical and scientific areas, including (environmental risk assessment, bee biology, agronomy bee health)

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.

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

The selected stakeholder experts will be invited to comment on the 2013 Guidance Document as well as on initial versions of/parts of the draft Guidance Document.

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 stakeholder experts and nominating 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 pras.secretariat@efsa.europa.eu for any questions or clarifications with regards to this initiative and process to follow.

Please take note of the deadline for receiving the expressions of interest to contribute as a member/expert of the EFSA *ad hoc* stakeholder consultation group – 21 May 2019 at midnight. Any application reaching EFSA after the set deadline will be deemed invalid.