EUROPEAN FOOD SAFETY AUTHORITY

Call for new scientific information as regards the risk to bees from the use of the three neonicotinoid pesticide active substances clothianidin, imidacloprid and thiamethoxam applied as seed treatments and granules in the EU

Published: 22 May 2015
Deadline: 30 September 2015

Background

Commission Implementing Regulation (EU) No 485/2013 amended the conditions for approvals of the active substances **clothianidin, imidacloprid** and **thiamethoxam** for use in plant protection products, all belonging to the group of neonicotinoids. The specific provisions of the approval were amended to restrict the uses of clothianidin, thiamethoxam and imidacloprid, to provide for specific risk mitigation measures for the protection of bees and to limit the use of the plant protection products containing these active substances to professional users. In particular, the uses as seed treatment, soil treatment and pre-flowering applications of plant protection products containing clothianidin, thiamethoxam and imidacloprid have been prohibited for crops attractive to bees and for cereals, except for uses in greenhouses, for winter cereals and post-flowering applications.

The measures were taken following the previous EFSA assessments of the risk to bees from these substances (EFSA Journal 2013;11(1):3066, 3067, 3068).

In accordance with recital 16 of Regulation (EU) No 485/2013, within two years from the date of entry into force of that Regulation, the European Commission foresees to initiate without undue delay a review of the new scientific information it has received.

For this purpose, on 12 February 2015 EFSA has been requested by the European Commission to organise an open call for data for new scientific information as regards the risk to bees from the three neonicotinoids clothianidin, thiamethoxam and imidacloprid by 25 May 2015 in accordance with Article 21 of Regulation (EC) No 1107/2009 and in the context of Article 31 of Regulation (EC) No 178/2002. As a second step, upon receipt of a follow up mandate from the European Commission, EFSA will undertake a review of the data resulted from the open call and will provide conclusions concerning an updated risk assessment for bees.

Overall objective

The purpose of this open call for data is to offer interested parties and/or stakeholders the opportunity to submit documented information (new, published or unpublished) relevant

to the evaluation of the risk to bees from the uses of the **neonicotinoid pesticides clothianidin, imidacloprid and thiamethoxam.**
With this call for data, the focus will be put on the information related to the uses of the above three substances applied **as seed treatments and granules**.

Target audience
All interested parties, such as national competent authorities in the area of pesticides, interested organizations, research institutions, industry and other interested parties etc.

Information sought
All information on bees (honeybees, bumble bees and solitary bees) related to the above three substances and relevant for the uses **as seed treatments and granules,** which may include the followings:

- literature data, including grey literature and any other data from research activities relevant for the risk assessment for bees (honeybees, bumble bees and solitary bees) for the uses of the three substances applied as seed treatments and granules;

- study reports (e.g. acute laboratory studies, chronic toxicity studies, residues data, field studies etc) conducted specifically to assess the risk to bees (honeybees, bumble bees and solitary bees) from the three substances applied as seed treatments and granules, and not yet considered under the previous EFSA assessments (EFSA Journal 2013;11(1):3066, 3067, 3068);

- national evaluations and/or monitoring data relevant for the risk assessment of bees (honeybees, bumble bees and solitary bees) for the three substances applied as seed treatments and granules that are available at the competent authorities of Member States and not yet considered under the previous EFSA assessments (EFSA Journal 2013;11(1):3066, 3067, 3068);

NOTE
- data already provided and considered relevant in the published systematic literature review report (EFSA supporting publication 2015:EN-756, refer to **Appendix E, I and J**) should not be submitted with the current call;

- data considered as not relevant in the published systematic literature review report (EFSA supporting publication 2015:EN-756, refer to **Appendix F and G**) may be submitted, however a scientific rationale is required to justify that they are relevant for the risk assessment of the uses of the three substances under consideration.

Process of the call for data

In order to allow subsequent processing of the data in a harmonized way, the provider is requested to download and fill in the below **excel template** for each data set or study provided and submit it together with the relevant data.

Neonic_opencall_TEMPLATE

In their submission, the provider is also asked to confirm that it holds all the necessary **rights** to grant EFSA permission to use and, where appropriate, to disclose the submitted information, data, document, paper or study for the purposes defined in the present call (see above § Background and Overall objective; and below) and that the terms and conditions asserted by any copyright holder(s) are fully satisfied. In case the provider does not enjoy the necessary rights for these data or studies, the contact details of the respective owner(s) of data and/or of the relevant copyright holder(s) should also be provided, so that EFSA may seek their approval directly.

EFSA is interested to receive the original study reports whenever possible. In case the data (e.g. paper, report etc.) are publicly available, it may be sufficient to provide EFSA with the information needed to retrieve these data (e.g. the relevant reference / web link to the concerned document etc.).

In addition, data submitters are invited to provide to EFSA a '**brief, non-confidential summary**' for each submitted dataset or study, using the above template.

For transparency reasons, a listing of the submitted information, including the summary information, as reported in the submitted overview table ('Neonic_opencall_TEMPLATE'), will be made publicly available after the call in the form of a Technical Report of EFSA. The complete datasets and the studies received by EFSA during the open call will be evaluated in a follow up risk assessment leading to the production of **EFSA Conclusions**, which will be performed in a second step, upon receipt of a separate mandate from the European Commission.

Interested parties are invited to contact EFSA for further clarifications, if required.

Confidentiality and unpublished data

The provider is requested to specify clearly any information that should remain confidential (i.e. not to be disclosed to the public) and submit appropriate verifiable justification for this claim pursuant to **Article 63 of Regulation (EC) No 1107/2009**. The submitted data, which may include unpublished confidential studies or studies containing raw data or data subject to ongoing research activities, will be used by EFSA **solely for the purpose of the evaluation in the context of the pesticide risk assessment peer review process** that will be undertaken upon receipt of the specific follow up mandate

from the European Commission, in the framework of Regulation (EC) No 1107/2009. In this context the full data set will be shared only with Member State competent authorities during the evaluation process. Should EFSA agree with the confidentiality claim submitted by the provider, it will publish or disclose only summarised information. Without prejudice to Article 63 of Regulation (EC) No 1107/2009, requests for confidential treatment will be considered on a case-by-case basis upon the evaluation of the verifiable justification shared by the submitter outlining the reasons those particulars should not be disclosed.

Interested parties are invited to submit the information ('Neonic_opencall_TEMPLATE' filled in and original reports whenever possible) electronically to EFSA, preferably via email, or alternatively on a physical medium (e.g. CD, memory stick, etc.), clearly indicating the substance name in the subject line, to which the submission refers. All available information should be submitted by **30 September 2015** at the latest.

The provider is also requested to clearly indicate the **contact details** (name of contact person, name of company, email address) of the person responsible for the data submission.

Contact details
It is recommended that submissions are sent electronically to the following email address:

Neonic.Opencall@efsa.europa.eu

Alternatively, submissions on a physical medium (e.g. CD, DVD, memory stick, etc.) may be sent to the following address:

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Via Carlo Magno 1/a
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