EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Director

Brussels,
SANTE/E4/LF/gb(2018)6773056

Dear Dr Url,

Subject: **Conclusion on endocrine disrupting properties according to the new scientific criteria in pending applications of new active substances under Regulation (EC) No 1107/2009**

Commission Regulation (EU) 2018/605[1] introduced new scientific criteria for the determination of endocrine disrupting properties. Those criteria apply as of 10 November 2018 to applications for approval/renewal of active substances in accordance with Regulation (EC) No 1107/2009, including pending applications.

Pending applications are defined as those submitted before 10 November 2018 and for which, by that date, the SCoPAFF has not voted on a draft Regulation concerning the approval/renewal of that active substance. This includes also applications which are currently either at the level of EFSA or the Rapporteur Member States, but where the data in the dossier were submitted under consideration of the interim criteria, now replaced by the new scientific criteria.

The aim of this letter is to highlight the importance that EFSA carries out the assessment of these pending applications in light of the new scientific criteria. Where EFSA can conclude on the endocrine disrupting properties of the substance based on the data available in the dossier, the EFSA Conclusion should indicate whether the substance is or is not an endocrine disruptor according to Commission Regulation (EU) 2018/605.

[1] Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

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However, application dossiers submitted in the past might not contain all the necessary information to enable EFSA to conclude this assessment in line with the agreed guidance. Applicants therefore need the possibility to submit additional data where required to fill a relevant gap. For applications in support of the renewal of approval of active substances, this has recently been clarified through Regulation (EU) 2018/1659 amending Regulation (EU) No 844/2012.

For new active substances, Regulation (EC) No 1107/2009 sets out directly the relevant provisions governing the approval procedure. In cases, where the general stop of the clock according to Articles 11(3) or 12(3) of Regulation (EC) No 1107/2009 is ongoing or was not yet applied during the assessment procedure, the RMS or EFSA should request any missing information essential to conclude on the endocrine disrupting properties during that stop of the clock. When requesting additional information from the applicants, EFSA should consider that animal testing is to be minimised and tests on vertebrates are to be undertaken only as a last resort, in accordance with Article 62 of Regulation (EC) No 1107/2009. The applicant should further be reminded that he can also submit within the same period of time information to address the derogation possibilities in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009 (negligible exposure) and/or apply for a derogation under Article 4(7) of that Regulation. Even though not legally obliged to provide such data (in the light of Article 12(2) of the Regulation), applicants should have an interest to complete their dossier in order to facilitate decision-making.

In case the stop of the clock, according to Articles 11(3) or 12(3) of Regulation (EC) No 1107/2009, was already applied during the peer review, the assessment should be finalised based on the criteria laid down in Commission Regulation (EU) 2018/605 and based on the data available in the dossier. In case EFSA considers that some information essential to conclude on the endocrine disrupting properties of the substance is missing, this should be detailed in the conclusion, specifying the studies needed to obtain the missing information and an estimated timing for generating such studies. For such cases, in the light of Article 13 (1) of Regulation (EC) No 1107/2009, the Commission will have to present a draft review report to the SCoPAFF within 6 months from the publication of the conclusion for discussion with the Member States.

However, without clarity that the substance does not have endocrine disrupting properties, it will not be possible for the Commission to propose approval. For such cases, the Commission will, therefore, give a mandate to EFSA to request the applicant to submit (on a voluntary basis) the additional information needed and to assess that information in order to conclude on the endocrine disrupting properties of the substance, following a similar approach as set for renewals in Implementing Regulation (EU) 2018/1659. Again, although not legally obliged to respond to such a request, applicants should have an interest to provide the requested information in order to safeguard the possibility to obtain an approval of the active substance.

In light of the resources needed by all involved parties, EFSA should take into account that a detailed assessment as regard endocrine disrupting properties may not be essential from a regulatory point of view, where it finds that an active substance already meets one or several cut-off criteria not related to endocrine disrupting properties (e.g. the substance is classified as mutagen, carcinogen or toxic for reproduction, categories 1A or 1B, or it is identified as a persistent, bioaccumulative and toxic substance).

In those cases, there would already be a clear reason for non-approval of the substance. Similarly, there may be cases where the scientific assessment indicates critical concerns not related to endocrine disrupting properties, which could *per se* point to a non-approval of the substance, irrespective of the conclusion on the endocrine disrupting properties.

Yours sincerely,

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