EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and Feed safety, innovation
Pesticides and Biocides

Mandate requesting ECHA opinions

pursuant to Article 15(2) of Regulation (EU) No 528/2012 on the review of approval of the active substances iodine, polyvinylpyrrolidone iodine and zineb

1. Background

(1) Commission Delegated Regulation (EU) No 2017/2100[1] specifies the scientific criteria for determining the endocrine-disrupting properties (ED criteria) under the BPR. The criteria are applicable as of 7 June 2018. Article 5(1) of the BPR provides that, subject to paragraph 2 of this Article, active substances that are considered as having ED properties that may cause adverse effects in humans or which are identified in accordance with Articles 57(f) and 59(l) of Regulation (EC) No 1907/2006 as having ED properties, shall not be approved.

(2) Iodine, polyvinylpyrrolidone iodine and zineb have been identified as possible endocrine disruptors in the screening study performed during the impact assessment accompanying the proposal that led to Commission Delegated Regulation (EU) 2017/2100[2]. The information collected for this screening study provides significant indications that these active substances may have endocrine-disrupting (ED) properties and therefore may no longer satisfy the conditions laid down in Article 4(1) of the BPR.

(3) In accordance with Article 15(1) of the BPR, and in light of these significant indications that the active substances iodine, polyvinylpyrrolidone iodine and zineb may have ED properties, the Commission started the review of their approval. In February 2020, the Commission informed the applicants for the approval of these active substances about this review, and provided them the opportunity to submit comments. The Commission made publicly available this information on the website of the Directorate-General Health and Food Safety and published the comments received from the applicants[3].

2. The questions to be addressed by the ECHA opinions

(4) ECHA is requested to collect the relevant information within 90 days of receiving this request and to provide opinions for each of the active substances on whether they are considered to have ED properties with respect to humans and/or non-target organisms within 270 days thereafter.

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[1] Commission Delegated Regulation (EU) 2017/2100 was published on 17 November 2017 (see link for all official languages in official journal: http://eur-lex.europa.eu/eli/reg_del/2017/2100/oj) and will be applicable as of 7 June 2018.

[2] https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/2016_impact_assessment_en.pdf

[5] https://ec.europa.eu/health/biocides/active_substances/review_approval_en

(5) ECHA should provide applicants an opportunity to submit comments on the draft opinion.

(6) Certain key data may be lacking in order for ECHA to conclude on the ED properties of the substances within the time frame of delivering on this mandate, and ECHA may therefore not be able to specify in its opinion whether the active substance is considered to have ED properties or not. In that case, the opinion should point out whether evidence and information exists that indicates that the substance may have ED properties, the strength of the evidence that the substance may have ED properties and the relevant studies that are lacking in order to conclude in accordance with the ECHA and EFSA Guidance for the identification of EDs[4].

3. Elements to be considered by ECHA when addressing those questions

(7) Commission Delegated Regulation (EU) 2017/2100 provides the scientific criteria for the determination of ED properties. The ECHA and EFSA Guidance for the identification of EDs provides guidance to applicants and assessors of competent regulatory authorities on how to identify EDs in accordance with the ED criteria.

(8) In particular, ECHA should consider the following:

(a) The information available from the biocidal assessment report(s) available on the active substances and the data submitted in the original applications for approval;

(b) The data underlying the conclusions in the in the screening study performed during the impact assessment accompanying the proposal that led to Commission Delegated Regulation (EU) 2017/2100.

(c) The information submitted by applicants to the Commission within the scope of the review of the approval of the substances;

(d) The information submitted by applicants within the scope of this request and the timeline specified by ECHA as appropriate;

(e) Any further information available to ECHA which may be relevant to assess the ED criteria[5].

4. Deadline for the ECHA opinion

(9) The ECHA opinion should be submitted to the Commission within 270 days of the finalisation of the data collection referred to in paragraph 4 above.

[4] https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5311

[5] For certain active substances information may be available on the authorisation/ approval under other legal frameworks (for example, plant protection products, human medicinal products, veterinary medicinal products, REACH, food additives)