EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Director

Brussels,
SANTE/E4/MN/skd(2021)3585388

Dear Mr Hansen,

Subject: Request to ECHA for opinions pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012 related to the review of approval of the active substances iodine, polyvinylpyrrolidone iodine and zineb

Article 15(1) of Regulation (EU) No 528/2012 on Biocidal Products[1] (the BPR) provides that the Commission may review the approval of a biocidal active substance for one or more product-types at any time where there are significant indications that the conditions laid down in Article 4(1) of this Regulation are no longer met.

The active substances iodine, polyvinylpyrrolidone iodine[2] and zineb[3] have been identified as possible endocrine disruptors in the screening study performed for the preparation of the impact assessment accompanying the proposal that led to Commission Delegated Regulation (EU) 2017/2100 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012[4]. 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.

In accordance with Article 15(1) of the BPR, and in light of the significant indications that the substance may have ED properties, the Commission started a review of these active substances. In February 2020, the Commission informed the applicants for the

[1] OJ L 167, 27.6.2012, p.1

[2] Iodine (CAS no 7553-56-2) and polyvinylpyrrolidone iodine (CAS no 25655-41-8), approved for product-types 1, 3, 4 and 22 in Commission Implementing Regulation (EU) No 94/2014 of 31 January 2014 (OJ L 32, 1.2.2014, p. 23: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1566312454497&uri=CELEX:32014R0094

[3] Zineb (zinc ethylenebis(dithiocarbamate) (polymeric); CAS No: 12122-67-7), approved for product-type 21 in Commission Implementing Regulation (EU) No 92/2014 of 31 January 2014 (OJ L 32, 1.2.2014, p. 16: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0092&from=EN.

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

Mr Bjorn Hansen
Executive Director
European Chemicals Agency
Telakkakatu, 6
FI-00150 Helsinki, Finland

approval of these active substances that it is carrying out a review of these substances and provided the opportunity to submit comments. The Commission also made publicly available the information that it is carrying out this review on the website of the Directorate-General Health and Food Safety and published the comments received from the applicants[5].

Pursuant to Article 15(2) of Regulation (EU) No 528/2012, ECHA is requested to collect all relevant information within 90 days of receiving this request and to formulate opinions addressing for each of these active substances the elements set out in the attached mandate within 270 days thereafter.

Yours sincerely,

[e-signed]
Sabine Jülicher

Enclosure: Mandate

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