The Commission is carrying out an early review of the approval of the biocidal active substances iodine, PVP iodine and zineb

Before a biocidal active substance can be approved by the Commission, its safety for human health, animal health and the environment as well as its effectiveness against harmful organisms are evaluated. Based on this evaluation, the Commission may approve the active substance after consultation of Member States. The approval regulation specifies the date of approval, when the approval will expire, and specific conditions or measures for the use of the active substance. Article 15(1) of the Regulation (EU) No 528/2012[1] (the Biocidal Products Regulation, 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 (this means that the conditions set in the BPR to approve an active substance are no longer met). Article 15(1) of the BPR requires that the Commission makes public the information that it carries out such a review.

Article 5(1) of the BPR provides that active substances considered as having endocrine-disrupting (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, unless the conditions for derogation set out in Article 5(2) are met. The scientific criteria for determining the ED properties under the BPR, as specified in Commission Delegated Regulation (EU) No 2017/2100[2], are applicable since 7 June 2018.

The Commission has significant indications that the active substances iodine, PVP iodine and zineb may have ED properties. Consequently, these substances may no longer satisfy the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2).

Therefore, the Commission has decided to review the approval of these substances.

Contact details of responsible service

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Reference documents:

- Information on the Biocidal Products Regulation: https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr.

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

[2] 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).

- Information on endocrine disruptors: https://ec.europa.eu/health/endocrine_disruptors/overview_en.
- Information on active substances for which an application for approval for a specific biocidal product-type has been submitted under the Biocidal Products Directive (Directive 98/8/EC) or the Biocidal Products Regulation (Regulation (EU) No 528/2012): https://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances.
- link to SANTE website on review procedure (https://ec.europa.eu/health/biocides/active_substances/review_approval_en)