**The Commission is carrying out an early review of the approval of the biocidal active substance tolylfluanid**

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 in biocidal products.

Article 15(1) of the Regulation (EU) No 528/20121 (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 the request of a member State if there are indications that the use of the active substance in biocidal products or treated articles raises significant concerns about the safety of such biocidal products or treated articles. Article 15(1) of the BPR requires that the Commission makes public the information that it carries out such a review.

According to data provided by one Member State, one of the metabolites of tolylfluanid has been found in some drinking water supplies. If drinking water is ozonated in water treatment plants, this metabolite can turn into N-nitrosodimethylamine (NDMA), which is classified as a category 1B carcinogen – presumed to cause cancer in humans.

The Commission has received significant indications that the use of this active substance in biocidal products of product-type 7 “film preservatives” raises significant concerns for the protection of human health. Consequently, a review of the approval of that substance has been found necessary.

**Contact details of responsible service**

European Commission Directorate General for Health and Food Safety Directorate E – Food and feed safety innovation

Unit E4- Pesticides and biocides

E-mail address: SANTE-BIOCIDES@ec.europa.eu

**Reference documents:**

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

- 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