COMMISSION IMPLEMENTING DECISION (EU) 2018/2013

of 14 December 2018

on the identification of 1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one (3-benzylidene camphor) as a substance of very high concern pursuant to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council

(Only the English text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC [1], and in particular Article 59(9) thereof,

Whereas:

(1) On 25 February 2016, Germany submitted to the European Chemicals Agency ('the Agency'), in accordance with Article 59(3) of Regulation (EC) No 1907/2006, a dossier prepared in accordance with Annex XV to that Regulation ('Annex XV dossier') for the identification of 1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one (3-benzylidene camphor) (EC No 239-139-9, CAS No 15087-24-8) as a substance of very high concern according to Article 57(f) of that Regulation due to its endocrine disrupting properties, for which there is scientific evidence of probable serious effects to the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of Regulation (EC) No 1907/2006.

(2) On 8 June 2016, the Member State Committee of the Agency (MSC) adopted its opinion [2] on the Annex XV dossier. While a majority of the MSC members considered that 3-benzylidene camphor should be identified as a substance of very high concern pursuant to Article 57(f) of Regulation (EC) No 1907/2006, the MSC did not reach unanimous agreement. Three members abstained and two members were of the opinion that there is not sufficient scientific evidence of probable serious effects to the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of Regulation (EC) No 1907/2006. Those two members expressed doubts about the reliability of a key scientific study and stated that there is not sufficient evidence to demonstrate that 3-benzylidene camphor poses an equivalent level of concern.

(3) On 22 June 2016, pursuant to Article 59(9) of Regulation (EC) No 1907/2006, the Agency referred the MSC opinion to the Commission for a decision on the identification of 3-benzylidene camphor on the basis of Article 57(f) of that Regulation.

(4) The Commission notes, in line with the majority opinion of the MSC, that multiple data, presented and discussed in the Annex XV dossier, including the key scientific study referred to in the minority MSC opinion, show that 3-benzylidene camphor alters the function of the endocrine system and hence has an endocrine mode of action. The Commission further notes that the minority opinion agrees that there are strong indications that 3-benzylidene camphor interacts with the endocrine system in fish. Furthermore, the key study demonstrates a serious and irreversible effect on fish fecundity relevant for wildlife populations while the available evidence indicates that the adverse effect is a result of the endocrine mode of action. Hence, the Commission considers, in line with the majority opinion of the MSC, that 3-benzylidene camphor fulfils the World Health Organization/International Programme on Chemical Safety (WHO/IPCS) [3] definition of an endocrine disruptor.

(5) The Commission notes that the adverse effect is of a severity similar to those of other substances which have been identified as substances of very high concern pursuant to Article 57(f) of Regulation (EC) No 1907/2006 due to their endocrine disrupting properties with probable serious effects to the environment and that 3-benzylidene camphor induces irreversible and long lasting effects on wild life populations. The Commission

[1] OJ L 396, 30.12.2006, p. 1.
[2] http://echa.europa.eu/role-of-the-member-state-committee-in-the-authorisation-process/svhc-opinions-of-the-member-state-committee
[3] WHO/IPCS, 2002. Global Assessment of the State-of-the-science of Endocrine Disruptors. WHO/IPCS/EDC/02.2, publicly available at http://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en/

considers that the level of concern of the adverse effects is equivalent to those of substances referred to in points (a) to (e) of Article 57 of Regulation (EC) No 1907/2006. The fact that the adverse effects on fish fecundity were observed in the key study at low concentration levels further strengthens the concern.

(6) 3-benzylidene camphor should be identified as a substance of very high concern pursuant to Article 57(f) of Regulation (EC) No 1907/2006 due to its endocrine disrupting properties with probable serious effects to the environment.

(7) The measures provided for in this Decision are in accordance with the opinion of the Committee established pursuant to Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

1. 1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one (3-benzylidene camphor) (EC No 239-139-9, CAS No 15087-24-8) is identified as a substance of very high concern pursuant to Article 57(f) of Regulation (EC) No 1907/2006 due to its endocrine disrupting properties with probable serious effects to the environment.

2. The substance referred to in paragraph 1 shall be included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006 with the following indication under 'Reason for inclusion': 'Endocrine disrupting properties (Article 57(f) - environment)'.

Article 2

This Decision is addressed to the European Chemicals Agency.

Done at Brussels, 14 December 2018.

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission