Commission Implementing Decision (EU) 2019/1194 of 5 July 2019 on the identification of 4-tert-butylphenol (PTBP) 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 (notified under document C(2019) 4987) (Only the English text is authentic) (Text with EEA relevance)

COMMISSION IMPLEMENTING DECISION (EU) 2019/1194

of 5 July 2019

on the identification of 4-tert-butylphenol (PTBP) 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

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(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 30 August 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 4-tert-butylphenol [(PTBP) (EC No 202-679-0, CAS No 98-54-4) 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 15 December 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 PTBP 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. Two members expressed doubts about the reliability of the key scientific study[(3)] and were of the opinion that the available evidence does not allow to conclude that there

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2019/1194. (See end of Document for details)*

is 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. A third member, while supporting the identification of PTBP as a substance of very high concern, also expressed doubts about the reliability of the key study. The Commission disagrees with the doubts expressed about the reliability of the key scientific study.

(3) On 17 January 2017, 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 PTBP on the basis of Article 57(f) of that Regulation.

(4) The Commission concurs with the MSC opinion expressing its unanimous agreement on that there is scientific evidence of adverse effects in fish linked to an estrogen mode of action of PTBP, which demonstrates that the substance meets the World Health Organization/International Programme on Chemical Safety (WHO/IPCS)[(4)] definition of an endocrine disruptor. Exposure to PTBP leads to serious and irreversible adverse effects on sexual development of fish, namely a complete and irreversible sex reversal of affected fish populations resulting in all-female populations. The conclusion that PTBP exerts endocrine disruptive properties is further supported by read-across from other substances[(5)] belonging to the same chemical class of alkylphenols as PTBP. For these reasons, the Commission concludes that for PTBP there is scientific evidence of probable serious effects to the environment.

(5) The Commission considers that the adverse effects are 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. Effects observed in fish are irreversible and may be relevant for wildlife populations. The majority of the MSC was of the opinion that, on the basis of the available information, it appears difficult to derive a safe level of exposure to adequately assess the risks although it may exist. The Commission concurs with that assessment. The Commission therefore 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 the sexual development of fish were observed in the key study at low concentration levels (lowest observed effect concentration: 1 µg/l) further strengthens the concern.

(6) PTBP should be identified pursuant to Article 57(f) of Regulation (EC) No 1907/2006 as a substance of very high concern due to its endocrine disrupting properties with 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).

(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 4-tert-butylphenol (PTBP) (EC No 202-679-0, CAS No 98-54-4) is identified as a substance of very high concern pursuant to Article 57(f) of Regulation (EC) No 1907/2006 due