COMMISSION IMPLEMENTING DECISION (EU) 2018/594

of 13 April 2018

on the identification of benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitic anhydride) (TMA) as a substance of very high concern according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council

(notified under document C(2018) 2112)

(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) In accordance with Article 59(3) of Regulation (EC) No 1907/2006, on 8 August 2016, the Netherlands submitted to the European Chemicals Agency ('the Agency'), a dossier prepared in accordance with Annex XV to that Regulation ('Annex XV dossier') for the identification of benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitic anhydride) (TMA) (EC No 209-008-0, CAS No 552-30-7) as a substance of very high concern because it fulfils the criterion set out in Article 57(f) of Regulation (EC) No 1907/2006. According to the Annex XV dossier, there is scientific evidence of probable serious effects to human health due to the respiratory sensitising properties of TMA, 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 TMA meets the conditions for identification as a substance of very high concern in accordance with Article 57(f) of Regulation (EC) No 1907/2006, the MSC did not reach a unanimous agreement. Three members abstained. Three members were of the opinion that there is not sufficient scientific evidence of TMA's probable serious effects to human health 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 three members expressed doubts about the type, severity, irreversibility, delay of health effects of TMA, the social concerns linked to its effects and the impossibility to derive a safe level of exposure to TMA.

(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 TMA on the basis of Article 57 (f) of that Regulation.

(4) The Commission notes, in line with the majority opinion of the MSC, that the data presented and discussed in the Annex XV dossier show that TMA causes serious and permanent impairment of lung functions, if the exposure is prolonged and no intervention takes place. The cases of adverse effects reported vary from occupational rhinoconjunctivitis and asthma to severe diseases, such as pulmonary disease-anaemia syndrome, allergic laryngitis and allergic alveolitis. Some of the effects have been so severe that subjects were forced to leave their jobs. The most severe effects can require long medical treatment.

(5) The Commission notes that, while certain effects of TMA are reversible upon cessation of exposure, the first stage of sensitisation (induction) is irreversible. In addition, from the available data on humans, it is not possible to derive a concentration level of TMA below which sensitisation does not happen. Furthermore, it seems that

[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

severe effects have some latency time. The possibility of irreversible effects occurring before a health problem is identified has been recognised in the identification of other substances ([1]) of very high concern in accordance with Article 57(f) of Regulation (EC) No 1907/2006 because of their respiratory sensitising properties, and confirmed by European case-law ([2]).

(6) The Commission notes that workers that have been sensitised previously can only be relocated to tasks with zero exposure to TMA, to avoid the recurrence of the severe adverse effects, causing societal concerns and effects on quality of life of sensitised workers.

(7) The Commission therefore considers, in line with the majority opinion of the MSC, that the level of concern posed by TMA is equivalent to that of substances referred to in points (a) to (e) of Article 57 of Regulation (EC) No 1907/2006 and, hence, that TMA should be identified as a substance of very high concern according to Article 57(f) of that Regulation due to its respiratory sensitising properties.

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

HAS ADOPTED THIS DECISION:

Article 1

1. Benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitic anhydride) (TMA) (EC No 209-008-0, CAS No 552-30-7) is identified as a substance of very high concern according to Article 57(f) of Regulation (EC) No 1907/2006 due to its respiratory sensitising properties.

2. The substance specified 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': 'Respiratory sensitising properties (Article 57(f)) – human health'.

Article 2

This Decision is addressed to the European Chemicals Agency.

Done at Brussels, 13 April 2018.

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

([1]) Agreement of the Member States Committee on the identification of Diazene-1,2-dicarboxamide [C,C-azodi(formamide)] as a substance of very high concern https://echa.europa.eu/documents/10162/5b3971ca-7683-414b-b7df-085744c5b327;
Agreement of the Member States Committee on the identification of Hexahydromethylphthalic anhydride, Hexahydro-4-methylphthalic anhydride, Hexahydro-1-methylphthalic anhydride, Hexahydro-3-methylphthalic anhydride as substances of very high concern https://echa.europa.eu/documents/10162/ab858db8-5467-429c-a94d-2e563f523d01;
Agreement of the Member States Committee on the identification of cyclohexane-1,2-dicarboxylic anhydride, cis-cyclohexane-1,2-dicarboxylic anhydride, transcyclohexane-1,2-dicarboxylic anhydride as substances of very high concern https://echa.europa.eu/documents/10162/8a707077-bf1c-462d-bf25-dd58ffa14cf8.

([2]) Judgment of the General Court of 30 April 2015, *Polynt and Sitre* v *ECHA*, T-134/13, ECLI:EU:T:2015:254, and Judgment of the General Court of 30 April 2015, *Hitachi Chemical Europe and others* v *ECHA*, T-135/13, ECLI:EU:T:2015:253.