COMMISSION IMPLEMENTING DECISION

of 9.3.2017

on the examination of testing proposals for reproductive toxicity referred by the European Chemicals Agency to the Commission pursuant to Article 51(7) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(Text with EEA relevance)

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THE EUROPEAN COMMISSION,

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


Whereas:

(1) In accordance with Article 10(a)(ix) of Regulation (EC) No 1907/2006, several registrants have submitted to the European Chemicals Agency (‘Agency’), as part of their registration dossier, a testing proposal for a two-generation reproductive toxicity study in the version that was applicable at the point in time when the registrants submitted their registration dossier.

(2) Testing proposals are subject to the requirements of point 8.7.3 of Annex IX to Regulation (EC) No 1907/2006 for substances produced in the lower (100 tonnes and more) and higher tonnage bands (1000 tonnes and more). For the higher tonnage band they further have to fulfil the requirements of point 8.7.3 of Annex X to that Regulation.

(3) In accordance with Article 40 of Regulation (EC) No 1907/2006, the Agency has examined those testing proposals and has drafted decisions, which have been addressed to the registrants for comments. Those draft decisions required the registrants to submit either a two-generation reproductive toxicity study (test method: EU B.35/OECD TG 416) or, alternatively, an extended one-generation reproductive toxicity study (‘EOGRTS’) (test method: EU B. 56/OECD TG 443) with the extension of cohort 1B. The Agency further determined in those draft decisions the conditions for the test method EU B.56/OECD TG 443 to ensure that that test method would generate at least as much information as a two-generation reproductive toxicity study.

Pursuant to Article 51(4) of Regulation (EC) No 1907/2006, the Agency submitted those draft decisions to its Member State Committee, referred to in Article 76(1)(e) of Regulation (EC) No 1907/2006 (‘MSC’), together with the proposals for amendments of the Member States’ competent authorities.

The MSC failed to reach a unanimous agreement on the Agency’s draft decisions, due to the fact that at the time of the submission of the registration dossier by the registrants, the then applicable version of Annexes IX and X to Regulation (EC) No 1907/2006 required the two-generation reproductive toxicity study (test method: EU B.35/OECD 416) for the fulfilment of the standard information requirement.

The Agency referred those draft decisions and all relevant related documentation to the Commission, in accordance with Article 51(7) of Regulation (EC) No 1907/2006.

The Agency has subsequently informed the Commission that the three registrants mentioned in the Annex have ceased manufacturing the substance for which they had submitted a testing proposal to the Agency. Two of these registrants were not submitting in their technical dossier the testing proposal on behalf of any other registrants in accordance with Article 11 of Regulation (EC) No 1907/2006. In one specific case both the lead registrant and the only other member of the joint submission ceased manufacturing.

Pursuant to Article 50(3) of Regulation 1907/2006, the registration is no longer valid and no further information should be requested from the registrants, when they have ceased manufacturing the substance for which they had submitted a testing proposal to the Agency, unless the registrants submit a new registration or report.

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

The procedures to assess the testing proposals to perform a two-generation reproductive toxicity study (EU B.35, OECD TG 416), initiated by the registrants referred to in the Annex, have become without object since the registrants have ceased manufacturing the substance concerned and their registration is no longer valid, unless they submit a new registration to the Agency.

Article 2

This Decision is addressed to the registrants referred to in the Annex.

Done at Brussels, 9.3.2017

For the Commission
Karmenu VELLA
Member of the Commission