EUROPEAN
COMMISSION

Brussels, 7.9.2015
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COMMISSION IMPLEMENTING DECISION

of 7.9.2015

on the evaluation of the substance polyhaloalkene pursuant to Article 46(1) 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)

[ONLY THE ENGLISH TEXT IS AUTHENTIC]

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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 51(7) thereof,

Whereas:

(1) Pursuant to Article 45 of Regulation (EC) No 1907/2006, the European Chemicals Agency (ECHA) is responsible for coordinating the substance evaluation process of substances specified in the Community Rolling Action Plan, provided for in Article 44 of Regulation (EC) No 1907/2006, whereby it shall rely on the competent authorities of Member States to conduct such evaluation.

(2) Because of concerns about hazardous degradation products, consumer exposure, high tonnage, wide dispersive use and high environmental exposure, the substance polyhaloalkene was included in February 2012 in the Community Rolling Action Plan for a substance evaluation process.

(3) In 2012, the competent authority of Germany has, on the basis of the registration dossier submitted by the registrants and in accordance with Article 45(4) of Regulation (EC) No 1907/2006, conducted the evaluation of the substance polyhaloalkene and has prepared, in accordance with Article 46(1) of Regulation (EC) No 1907/2006, a draft decision that has been presented to the Member State Committee of the ECHA on 6 February 2014.

[redacted] That draft decision required the registrants to submit further information on the potential mutagenicity of the substance [redacted]

[1] OJ L 396, 30.12.2006.

[redacted]

(5) That draft decision and the comments received from [redacted] and [redacted] have been discussed by the Member State Committee of ECHA. Since no unanimous agreement was reached, ECHA has, pursuant to Article 51(7) of Regulation (EC) No 1907/2006, forwarded the draft decision and all relevant documentation to the Commission on 17 March 2014.

(6) The Commission has examined the draft decision, the documentation, the registration dossier for the substance polyhaloalkene (which has been updated in May and September 2014), and the available relevant supporting information. Based on that examination, the Commission follows the conclusion of the evaluating Member State Competent Authority ('MSCA') that one of the observed concerns (mutagenicity *in vitro*, lack of valid negative test to disprove these results *in vivo*) and its relevance to humans have not been dismissed during the substance evaluation process. The Commission furthermore observes that a carcinogenicity study is not available and that further clarification is needed regarding the mutagenic potential of polyhaloalkene, both *per se* and in order to determine whether a carcinogenicity study should be carried out for this substance.

(7) The Transgenic rodent somatic and germ cells mutations assay ('TGR') and the *in vivo* mammalian Comet Assay ('Comet Assay') are both suitable methods to investigate the mutagenicity concern in somatic cells, but only the TGR has been officially validated for the assessment of DNA damage in germ cells. Moreover, sampling and storage of germ cells during the TGR would enable subsequent analysis of germ cells for mutation frequency without further use of animals.

(8) When choosing the test method to be carried out, due weight should be given to animal welfare considerations. The most appropriate testing strategy should be based on a thorough review of the data available on polyhaloalkene and should be the one that is expected to use the least number of experimental animals to clarify the mutagenicity concern. It should be taken into account that the results of the chosen test method may trigger the need for further testing.

(9) The registrants had followed up from a positive Ames result by performing an in vivo Unscheduled DNA-synthesis assay ('UDS'). The UDS is not a suitable test method to dismiss the mutagenicity concern because it is not appropriate for target tissues other than the liver and because it does not cover all potentially relevant DNA repair processes. Furthermore, in the UDS conducted by the registrants, methodological issues related to sample collection have invalidated the results.

(10) The draft Commission decision has been notified to the registrants concerned, who have been informed of their right to comment. The Commission has duly taken into account the comments of those registrants when preparing this decision.

(11) 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 registrants of polyhaloalkene, registered pursuant to Regulation (EC) No 1907/2006 (EC No 468-710-7, CAS No 754-12-1) and referred to in Article 5 (registrants), shall carry out one of the tests set out in the Annex to further investigate the mutagenicity concern posed by the substance, as provided by Article 2.

Article 2

1. The registrants shall review all available information on polyhaloalkene including information on toxicokinetics and any effects observed on germ cells.

2. The registrants shall carry out the Transgenic Rodent Somatic and Germ Cell Mutation Assay (TGR) if the review referred to in paragraph 1 indicates that there is a likelihood that polyhaloalkene causes mutagenicity in germ cells. The germ cells shall be sampled and stored for further analysis in case of positive test results in somatic cells.

3. The registrants may choose to carry out the Comet Assay instead of the TGR if they conclude that polyhaloalkene has a low likelihood of causing mutagenicity in mammalian germ cells.

Article 3

The registrants shall, in accordance with Article 53 of Regulation (EC) No. 1907/2006, make every effort to reach an agreement as to who is to conduct the testing in accordance with Article 2.

Within 90 days from the receipt of this Decision, they shall inform ECHA of the name of the registrant conducting the test, of the test method chosen and of the reasons that led to such choice in accordance with Article 2.

Article 4

The registrants shall update their registration with the results of the test carried out in accordance with Article 2 within the following time limits after the date of receipt of this Decision:

(a) 36 months where the TGR is chosen;

(b) 24 months where the Comet Assay is chosen.

Article 5

This Decision is addressed to the following registrants:

[redacted]

Done at Brussels, 7.9.2015

For the Commission
Karmenu VELLA
Member of the Commission

[redacted]