Commission Regulation (EU) 2016/1017 of 23 June 2016 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards inorganic ammonium salts (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/1017

of 23 June 2016

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards inorganic ammonium salts

(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 68(1) thereof,

Whereas:

(1) On 14 August 2013, in accordance with the safeguard clause in Article 129(1) of Regulation (EC) No 1907/2006, the French Republic informed the Commission, the European Chemicals Agency ('the Agency') and the other Member States that it had adopted a provisional measure on 21 June 2013[(2)] to protect the public from exposure to ammonia released from cellulose wadding insulation materials with ammonium salts used in buildings.

(2) The provisional measure was authorised until 14 October 2016 by Commission Implementing Decision 2013/505/EU[(3)], adopted under Article 129(2) of Regulation (EC) No 1907/2006.

(3) In accordance with Article 129(3) of Regulation (EC) No 1907/2006, the French Republic initiated the restriction procedure by submitting to the Agency an Annex XV dossier on 18 June 2014.

(4) The Annex XV dossier[(4)] proposed a restriction on inorganic ammonium salts, which are added to cellulose insulation as flame retardants, since they lead to the emission of ammonia gas under certain conditions. The dossier proposed 3 ppm as a limit for the emission of ammonia from cellulose insulation treated with inorganic ammonium salts, rather than setting a limit for the content of ammonium salts in the cellulose insulation. The dossier demonstrated that action on a Union-wide basis is necessary.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EU) 2016/1017. (See end of Document for details)*

(5) On 3 March 2015, the Agency's Committee for Risk Assessment ('RAC') adopted an opinion on the restriction proposed in the Annex XV dossier, concluding that there is a risk to human health due to the release of ammonia from cellulose insulation mixtures and articles that needs to be addressed. RAC further stated that the proposed restriction, as modified by RAC, is the most appropriate Union-wide measure to address the identified risks in terms of the effectiveness in reducing those risks.

(6) RAC proposed that the restriction cover the placing on the market of cellulose insulation containing inorganic ammonium salts, in both mixture and article form. RAC recommended that the restriction oblige suppliers of cellulose insulation mixtures to communicate down the supply chain and ultimately to end users (professional users and consumers) the maximum permissible loading rate[(5)] of the cellulose insulation mixture used in the test done prior to marketing to demonstrate compliance, for example through documentation accompanying the mixtures or through labelling. The restriction should also require that the maximum permissible loading rate, communicated by the supplier, is not exceeded when the cellulose insulation mixtures are used by downstream users, so that ammonia emissions will not exceed the level determined in the pre-market test. RAC also recommended that by way of derogation, cellulose insulation mixtures which are only used for the production of cellulose insulation articles do not have to comply with the limit set for the emission of ammonia, as the resulting article must itself comply with the emission limit when it is placed on the market or used.

(7) On 10 June 2015, the Agency's Committee for Socio-Economic Analysis ('SEAC') adopted an opinion on the restriction proposed in the Annex XV dossier, indicating that the proposed restriction, as modified by SEAC, is the most appropriate Union-wide measure to address the identified risks in terms of the proportionality of its socioeconomic benefits to its socioeconomic costs.

(8) SEAC concluded that two years, rather than the one year proposed in the Annex XV dossier, should be given to economic operators to allow them sufficient time to ensure that emissions of ammonia from cellulose insulation containing inorganic ammonium salts are below the specified emission limit.

(9) RAC and SEAC agreed with the French Republic that an exemption for cellulose insulation treated with inorganic ammonium salts for outdoor use should not be granted.

(10) The Agency's Forum for Exchange of Information on Enforcement was consulted during the restriction process and its recommendations were taken into account.

(11) On 25 June 2015 the Agency submitted the opinions of RAC and SEAC[(6)] to the Commission. Based on those opinions, the Commission concluded that an unacceptable risk to human health arises from cellulose insulation treated with inorganic ammonium salts where the emission of ammonia reaches or exceeds a concentration of 3 ppm under the specified test conditions.

(12) No specific method for the measurement of the emission of ammonia from cellulose insulation treated with inorganic ammonium salts is presently available. Therefore, an existing test method, Technical Specification CEN/TS 16516, should be adapted for

use in determining compliance with the restriction on inorganic ammonium salts until a dedicated method is developed.

(13) Stakeholders should be allowed sufficient time to take appropriate measures to ensure that, if inorganic ammonium salts are used in cellulose insulation, ammonia emissions do not exceed the specified limit. The application of the restriction on inorganic ammonium salts should therefore be deferred. However, in the interests of continuity and legal certainty, the restriction should apply immediately on entry into force of this Regulation in a Member State which already has in place national measures restricting ammonium salts in cellulose insulation that have been authorised by the Commission in the context of the REACH safeguard procedure.

(14) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

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

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 23 June 2016.

For the Commission

The President

Jean-Claude JUNCKER