EUROPEAN
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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

on applications for authorisation under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) for uses in low quantities

(Text with EEA relevance)

DISCLAIMER: subject to potential further changes

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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 132 thereof,

Whereas:

(1) Article 56(1) of Regulation (EC) No 1907/2006 sets out an authorisation requirement for the placing on the market and/or use of substances of very high concern listed in Annex XIV to that Regulation. The implementation of that requirement so far has shown that in certain cases it can constitute a significant administrative burden for undertakings. In its Communication of 18 June 2014 "Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook"[2] the Commission announced its intention to reflect on specific areas of Regulation (EC) No 1907/2006 where rules could be simplified and burdens reduced, and in particular to improve the authorisation process by, amongst others, simplifying that process for some specific low-risk cases, while maintaining the REACH goals and objectives. This was confirmed in the Communication "Better regulation for better results - An EU agenda"[3].

(2) The cost of preparing a standard application for authorisation for the placing on the market for a use and/or the use of a substance listed in Annex XIV to Regulation (EC) No 1907/2006 in low quantities may be very high for an applicant, (in particular when the applicant is a small and medium sized enterprise - SME) compared to the likely

[1] OJ L 396, 30.12.2006, p. 1.
[2] COM(2014) 368 final.
[3] COM(2015) 215 final.

risks for human health and the environment from the use of the substance in low quantities.

(3) It is therefore appropriate to provide undertakings with the possibility of making a simplified application for authorisation for the placing on the market for a use and/or the use of a substance listed in Annex XIV to Regulation (EC) No 1907/2006 where it is used in low quantities. This needs to be done in such a way as to achieve a high level of protection of health and of the environment and encourage the substitution of the substances of very high concern, while at the same time maintaining the competitiveness and innovation of European industry, as well as the good functioning of the internal market.

(4) The authorisation requirement applies to substances of very high concern listed in Annex XIV to REACH regardless the quantities in which they are placed on the market or used. It is therefore appropriate to set the maximum quantity limit for simplified applications at a level which is significantly lower than that which is considered to be a low volume substance for the purpose of the registration requirement in Regulation (EC) No 1907/2006.

(5) It should be ensured that the maximum quantity limit applies to the total amount of the substance an undertaking uses in accordance with one or more authorisations granted following (an) application(s) for low quantities.

(6) In line with Article 62(4)(d) of Regulation (EC) No 1907/2006, applications for authorisation must contain a chemical safety report including exposure scenario(s) developed for the use applied for and the subsequent life-cycle steps. In order to ensure a high level of protection of health for the general public it is appropriate to exclude from the simplified approach for low quantities uses of substances which may result in exposure to the general public from the use of articles or mixtures.

(7) In order to fulfil the conditions for granting the authorisation, risks to human health and/or the environment resulting from the use of a substance in low quantities should be adequately controlled or, alternatively, should there be no suitable alternative substances or technologies, reduced to such a level that they are outweighed by the socio-economic benefits resulting from that use. The extent of the information to be submitted within the chemical safety report format should be clarified for applications for authorisation for uses in low quantities on the basis of the existing guidance on chemical safety assessment, in order to reflect the lower level of detail necessary in such cases while ensuring that the risk management measures in place are appropriate and effective in adequately controlling or limiting the risks related to the use applied for and the subsequent life-cycle steps.

(8) Based on the experience so far, the analysis of alternatives referred to in Article 62(4)(e) of Regulation (EC) No 1907/2006 and, when necessary, the socio-economic analysis referred to in Article 62(5) of that Regulation appear to represent a high share of the total costs of preparing an application for authorisation. At the same time, since the risks arising from the use of a substance in low quantities are likely to be limited, it is appropriate and proportionate to clarify the level of detail of the information deemed necessary in the analysis of alternatives and, to be submitted as a minimum in the socio-economic analysis. However the information provided should still allow the Committee for Risk Assessment and the Committee for Socio-economic Analysis of the Agency to assess the application in the light of the elements referred to in Article 64(4) of Regulation (EC) No 1907/2006.

(9) The time-limited review period referred to in Article 60(8) of Regulation (EC) No 1907/2006 is to a great extent determined by the analysis of alternatives and the socio-economic analysis justifying the authorisation, as well as by the information provided in the chemical safety report. Since the assessment of potential alternatives and of socio-economic aspects will be more limited in applications for authorisation for use in low quantities than in standard applications, it is appropriate to set a default duration of the review period for authorisations granted in those cases. In order to provide for predictability and legal certainty to business, whilst also encouraging substitution, it is appropriate to set that default review period at seven years. However, it should be possible to set a longer or shorter duration where that is justified by the relevant information submitted in the application and/or by third parties.

(10) 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 REGULATION:

Article 1
Subject matter

1. This Regulation lays down provisions on applications for authorisation submitted in accordance with Article 62 of Regulation (EC) No 1907/2006 for the placing on the market for a use and/or the use of substances listed in Annex XIV to that Regulation in low quantities.

2. This Regulation shall be reviewed by [*5 years after the date of entry into force*] with the purpose of evaluating its effectiveness.

Article 2
Criteria for applications for authorisation for uses in low quantities

1. An application for authorisation pursuant to Article 62 of Regulation (EC) No 1907/2006 for the placing on the market for a use and/or the use of a substance in low quantities may be made in accordance with the provisions of this Regulation for the placing on the market for a use and/or use of one substance in a total maximum quantity of 100 kg annually per legal entity.

2. Paragraph 1 shall not apply to:

   (a) substances referred to in Article 57(d), (e) and (f) of Regulation (EC) No 1907/2006 which are used in mixtures for supply to the general public above a concentration limit of 0.1% weight by weight, and

   (b) applications for authorisation for the incorporation of the substance in an article for supply to the general public.

Article 3
Information for applications for authorisation for uses in low quantities

1. The chemical safety report referred to in Article 62(4)(d) of Regulation (EC) No 1907/2006 shall contain the information required by Annex I to that Regulation, subject to the following specifications:

   (a) the risk characterisation shall be calculated on the basis of the Derived No-Effect Level (DNEL), the Predicted No-Effect Concentration (PNEC)

or the dose-response relationship, as appropriate, if published by the Agency as reference values for the purpose of assessing applications for authorisation for the substance;

(b) for substances meeting the criteria in Article 57(a), (b), (c) of Regulation (EC) No 1907/2006 or identified under Article 57(f) of that Regulation only because of hazards to human health, an exposure assessment and a risk characterisation for the indirect exposure of humans via the environment need not be included.

2. The information in the analysis of alternatives referred to in Article 62(4)(e) of Regulation (EC) No 1907/2006 shall be satisfied by including the following elements:

(a) a description and analysis of the function of the substance and justification of the need of the substance in the use(s) applied for;

(b) the maximum annual quantity of the substance used for (each of) the use(s) applied for;

(c) identification and description of the potential alternative substances or technologies to the substance for the use(s) applied for;

(d) a succinct justification why each of the potential alternatives referred to in subparagraph (c) is not technically or economically feasible for the applicant and/or his downstream users within a given time period.

3. For applications for authorisation justified on the basis of Article 60(4) of Regulation (EC) No 1907/2006, the socio-economic analysis referred to in Articles 60(4)(b) and 62(5)(a) of that Regulation shall consist, as a minimum, of a description of the impact of the use applied for on human health and/or the environment and of the socio-economic impacts of a refused authorisation and a conclusion based on the comparison between those impacts. The socio-economic analysis shall include the following information:

(a) a succinct description of the human health or environmental impacts (risk associated with use(s) applied for and related to the intrinsic properties indicated in Annex XIV for the substance) in accordance with the CSR submitted;

(b) a succinct description of the economic and social impacts of a refused authorisation (benefit of the use(s) applied for), supported if available by an estimate of the additional costs and other impacts that would be incurred, and

(c) a conclusion based on a succinct comparison of the risks and benefits of the uses applied for (as described under subparagraphs (a) and (b)).

4. ECHA shall make available specific formats for the chemical safety report, the analysis of alternatives and the socio-economic analysis for applications for authorisation for uses in low quantities, reflecting the elements referred to in paragraphs 1, 2 and 3.

5. The information submitted in accordance with this Article, together with any third party contributions on possible alternatives submitted under Article 64(2) of Regulation (EC) No 1907/2006, shall suffice for the purpose of assessing the socio-

economic factors and the suitability of the alternatives associated with the use(s) of the substance as described in the application.

Article 4

Review period pursuant to Article 60(8) of Regulation (EC) No 1907/2006

Decisions granting an authorisation with regard to applications submitted in accordance with this Regulation shall specify a review period of seven years as from the sunset date referred to in Annex XIV to Regulation (EC) No 1907/2006 for that substance, unless otherwise justified on the basis of the elements referred to in Article 60(8) of that Regulation.

Article 5

A manufacturer, importer or downstream user using a substance in accordance with one or more authorisations granted following (an) application(s) made under this Regulation shall not use that substance above a total quantity of 100 kg per year.

Article 6

This Regulation shall enter into force on the third 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,

For the Commission
The President
Jean-Claude JUNCKER