Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Text with EEA relevance)

COMMISSION REGULATION (EU) No 283/2013

of 1 March 2013

setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC[(1)], and in particular Article 78(1)(b) thereof,

Whereas:

(1) In accordance with Article 8(4) of Regulation (EC) No 1107/2009, Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances[(2)] was adopted. It contains the requirements for the dossiers to be submitted for the approval of active substances, as set out in Annex II to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[(3)].

(2) It is necessary to modify the data requirements concerning chemical substances in order to take into account current scientific and technical knowledge.

(3) More detailed information for the implementation of the data requirements is laid down in relevant guidance documents.

(4) Regulation (EU) No 544/2011 should therefore be repealed.

(5) A reasonable period should be allowed to elapse before the modified data requirements become applicable in order to permit applicants to prepare themselves to meet those requirements.

(6) In order to permit Member States and the interested parties to prepare themselves to meet the new requirements, it is appropriate to lay down transitional measures concerning data submitted for applications for the approval, renewal of approval or amendment to the conditions of approval of active substances and data submitted

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for applications for authorisation, renewal of authorisation and amendment to the authorisation of plant protection products.

(7) These transitional measures are without prejudice to Article 80 of Regulation (EC) No 1107/2009.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

Article 1

Data requirements for active substances

The data requirements for the active substance provided for in Article 8(1)(b) of Regulation (EC) No 1107/2009 shall be as set out in the Annex to this Regulation.

Article 2

Repeal

Regulation (EU) No 544/2011 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation

Article 3

Transitional measures as regards procedures concerning active substances

With respect to active substances, Regulation (EU) No 544/2011 shall continue to apply as regards the following:

(a) procedures concerning the approval of an active substance or an amendment to the approval of such a substance pursuant to Article 13 of Regulation (EC) No 1107/2009 for which the dossiers provided for in Article 8(1) and (2) thereof have been submitted by 31 December 2013;

(b) procedures concerning the renewal of approval of an active substance pursuant to Article 20 of Regulation (EC) No 1107/2009 for which the supplementary dossiers referred to in Article 9 of Commission Regulation (EU) No 1141/2010[(4)] have been submitted by 31 December 2013.

Article 4

Transitional measures as regards procedures concerning plant protection products

[F1 1 In case of applications for authorisation, as referred to in Article 28 of Regulation (EC) No 1107/2009, which concern plant protection products containing one or more active substances for which the dossiers have been submitted in compliance with Article 3 or for which the approval has not been renewed in accordance with Article 14 of Regulation (EC) No

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1107/2009 and in accordance with Commission Implementing Regulation (EU) No 844/2012[(5)], Regulation (EU) No 544/2011 shall continue to apply to the submission of data concerning this(these) active substance(s).**]**

2 By way of derogation from paragraph 1, from 1 January 2014 applicants may choose to apply the data requirements, as set out in the Annex to this Regulation. This choice shall be made in writing when submitting the application and shall be irrevocable.

Textual Amendments

F1 Substituted by Commission Regulation (EU) No 1136/2014 of 24 October 2014 amending Regulation (EU) No 283/2013 as regards the transitional measures applying to procedures concerning plant protection products (Text with EEA relevance).

Article 5

Entry into force and date of application

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

2 For procedures concerning the renewal of approval of active substances whose approval expires on 1 January 2016 or later, this Regulation shall apply as of entry into force.

As regards all other procedures, it shall apply from 1 January 2014.

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

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ANNEX

INTRODUCTION**Information to be submitted, its generation and its presentation**

1. The information submitted shall meet the following requirements.

1.1. The information shall be sufficient to evaluate the foreseeable risks, whether immediate or delayed, which the active substance may entail for humans, including vulnerable groups, animals and the environment and contain at least the information and results of the studies referred to in this Annex.

1.2. Any information on potentially harmful effects of the active substance, its metabolites and impurities on human and animal health or on groundwater shall be included.

1.3. Any information on potentially unacceptable effects of the active substance, its metabolites and impurities on the environment, on plants and plant products shall be included.

1.4. The information shall include all relevant data from the scientific peer reviewed open literature on the active substance, metabolites and breakdown or reaction products and plant protection products containing the active substance and dealing with side-effects on health, the environment and non-target species. A summary of this data shall be provided.

1.5. The information shall include a full and unbiased report of the studies conducted as well as a full description of them. Such information shall not be required, where one of the following conditions is fulfilled:

(a) it is not necessary owing to the nature of the product or its proposed uses, or it is not scientifically necessary;

(b) it is technically not possible to supply.

In such a case a justification shall be provided.

1.6. The simultaneous use of the active substance as a biocide or in veterinary medicine shall be reported.

If the applicant for the active substance in the plant protection product is identical to the one responsible for the notification of the active substance as a biocide or as a veterinary medicine, a summary of all relevant data submitted for approval of the biocide or the veterinary medicine, shall be submitted. This summary shall include toxicological reference values and MRL proposals, taking into account any possible cumulative exposure due to different uses of the same substance based on scientific methods accepted by the European competent authorities, together with a summary of the residues and toxicology data and information on the use of the product.

If the applicant for the active substance in the plant protection product is not identical to the one responsible for the notification of the active substance as a biocide or in veterinary medicine, a summary of all available data shall be submitted.

1.7. Where relevant, the information shall be generated using test methods, which are included in the list referred to in point 6. In the absence of suitable internationally or nationally validated test guidelines, test guidelines accepted by the European competent authority shall be used. Any deviations shall be described and justified.

1.8. The information shall include a full description of the test methods used.

1.9. The information shall include a list of endpoints for the active substance.

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1.10. Where relevant, the information shall be generated in accordance with Directive 2010/63/EU of the European Parliament and of the Council[(6)].

1.11. The information on the active substance, taken together with the information concerning one or more plant protection products containing the active substance and together, if appropriate, with the information concerning safeners and synergists and other components of the plant protection product, shall be sufficient to:

(a) permit an assessment of the risks for humans, associated with handling and use of plant protection products containing the active substance;

(b) permit an assessment of the risks for human and animal health, arising from residues of the active substance and its metabolites, impurities, breakdown and reaction products remaining in water, air, food and feed;

(c) predict the distribution, fate and behaviour in the environment of the active substance and metabolites, breakdown and reaction products, where they are of toxicological or environmental significance, as well as the time courses involved;

(d) permit an assessment of the impact on non-target species (flora and fauna), including the impact on their behaviour, which are likely to be exposed to the active substance, its metabolites, breakdown and reaction products, where they are of toxicological or environmental significance. Impact can result from single, prolonged or repeated exposure and can be direct or indirect, reversible or irreversible;

(e) evaluate the impact on biodiversity and the ecosystem;

(f) identify non-target species and populations for which hazards arise because of potential exposure;

(g) permit an evaluation of short and long-term risks for non-target species, populations, communities and processes;

(h) classify the active substance as to hazard in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(7)];

(i) specify the pictograms, the signal words, and relevant hazard and precautionary statements for the protection of man, non-target species and the environment, which are to be used for labelling purposes;

(j) establish, where relevant, an acceptable daily intake (ADI) level for humans;

(k) establish acceptable operator exposure levels (AOEL);

(l) establish, where relevant, an acute reference dose, (ARfD) for humans;

(m) identify relevant first aid measures as well as appropriate diagnostic and therapeutic measures to be followed in the event of poisoning in humans;

(n) establish the isomeric composition and the possible metabolic conversion of the isomers, when relevant;

(o) establish residues definitions appropriate for risk assessment;

(p) establish residues definitions appropriate for monitoring and enforcement purposes;

(q) permit a risk assessment of consumer exposure, including, where relevant, a cumulative risk assessment deriving from exposure to more than one active substance;