Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, 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 284/2013

of 1 March 2013

setting out the data requirements for plant protection products, 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 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products[(2)] was adopted. It contains the data requirements for the authorisation of plant protection products, as set out in Annex III to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant products on the market[(3)].

(2) It is necessary to modify the data requirements concerning chemical preparations 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(4) Regulation (EU) No 545/2011 should therefore be repealed.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 and amendment to the conditions of approval of active substances and for applications

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for authorisation, renewal of authorisation and amendment to 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 plant protection products

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

Article 2

Repeal

Regulation (EU) No 545/2011 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 545/2011 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

1 Regulation (EU) No 545/2011 shall continue to apply as regards procedures concerning the authorisation of a plant protection product, as referred to in Article 28 of Regulation (EC) No 1107/2009, provided that the respective application has been submitted by

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31 December 2015 and that the plant protection product contains at least one active substance for which the dossiers or supplementary dossiers have been submitted in compliance with Article 3.

[[F1]Regulation (EU) No 545/2011 shall continue to apply as regards procedures concerning the renewal of authorisations of plant protection product pursuant to Article 43(2) of Regulation (EC) No 1107/2009, following the renewal of an active substance carried out pursuant to Regulation (EU) No 1141/2010.**]**

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 Inserted by Commission Regulation (EU) 2015/1475 of 27 August 2015 amending Regulation (EU) No 284/2013 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 efficacy and the foreseeable risks, whether immediate or delayed, which the plant protection product 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 plant protection product on human and animal health or on groundwater shall be included as well as known and expected cumulative and synergistic effects.

1.3. Any information on potentially unacceptable effects of the plant protection product on the environment, on plants and plant products shall be included as well as known and expected cumulative and synergistic effects.

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. 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.

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

1.8. Where relevant, the information shall be generated in accordance with Directive 2010/63/EU of the European Parliament and of the Council[(5)].

1.9. The information shall include a list of endpoints for the plant protection product.

1.10. The information shall include the proposed classification and labelling of the plant protection product in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(6)], where relevant.

1.11. Information as provided for in Commission Regulation (EU) No 283/2013[(7)] may be required by the competent authorities on co-formulants. Before requiring additional studies to be performed, the competent authorities shall assess all available information provided in accordance with other Union legislation.

1.12. The information provided for the plant protection product and that provided for the active substance, shall be sufficient to:

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(a) decide whether, or not, the plant protection product is to be authorised;

(b) specify conditions or restrictions to be associated with any authorisation;

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

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

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

(f) permit an estimation of acute and chronic exposure to operators, workers, residents and bystanders including, where relevant, the cumulative exposure to more than one active substance;

(g) permit an evaluation to be made as to the nature and extent of the risks for humans, animals (species normally fed and kept by humans or food producing animals) and of the risks for other non-target vertebrate species;

(h) predict the distribution, fate, and behaviour in the environment, as well as the time courses involved;

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

(j) permit an assessment of the impact of the plant protection product on non target species;

(k) identify measures necessary to minimise contamination of the environment and impact on non-target species;

(l) classify the plant protection product as to hazard in accordance with Regulation (EC) No 1272/2008.

1.13. Where relevant, tests shall be designed and data analysed using appropriate statistical methods.

1.14. Exposure calculations shall refer to scientific methods accepted by the European Food Safety Authority (the Authority), when available. Additional methods, when used, shall be justified.

2. The requirements set out in this Regulation shall represent the minimum data to be submitted. Additional requirements at national level may be necessary in specific circumstances, that is to say specific scenarios, patterns of use other than those taken into account for approval. Careful attention shall be given to environmental, climatic and agronomic conditions when tests are set up and approved by the competent authorities.

3. **Good laboratory practice (GLP)**

3.1. Tests and analyses shall be conducted in accordance with the principles laid down in Directive 2004/10/EC of the European Parliament and of the Council[8] where testing is done to obtain data on the properties or safety with respect to human or animal health or the environment.