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COMMISSION REGULATION (EU) .../...

of XXX

**amending Commission Regulation (EU) No 283/2013 as regards the information to be
submitted for active substances**

(Text with EEA relevance)

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amending Commission Regulation (EU) No 283/2013 as regards the information to be submitted for active substances

(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/EEC¹, and in particular Article 78(1), point (b), thereof,

Whereas:

- (1) Commission Regulation (EU) No 283/2013² lays down data requirements for active substances. For active substances that are chemicals, the data requirements are laid down in Part A of the Annex to that Regulation, and for active substances that are micro-organisms, the data requirements are laid down in Part B of that Annex, while the general requirements are set out in the introductory part of that Annex.
- (2) Available methodologies for conducting regulatory studies and risk assessments have evolved. In particular, new approaches for conducting risk assessments and new study protocols that may include alternatives to animal testing have become available while certain others have become obsolete. In addition, new approaches for conducting risk assessments have been developed for active substances of biological origin. In particular, the European Food Safety Authority (EFSA)'s Guidance Documents on conducting risk assessments for birds and mammals³ and bees⁴ were revised referring to different or additional tests. Moreover, EFSA, together with the European Chemicals Agency (ECHA), developed and published a new Guidance Document on the impact of water treatment processes on residues of active substances or their

¹ OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>.

² 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 (OJ L 93, 3.4.2013, p. 1, ELI: <http://data.europa.eu/eli/reg/2013/283/oj>).

³ EFSA (European Food Safety Authority), Aagaard A, Berny P, Chaton PF, Antia AL, McVey E, Arena M, Fait G, Ippolito A, Linguadoca A, Sharp R, Theobald A and Brock T, 2023. Guidance on the risk assessment for Birds and Mammals. EFSA Journal 2023;21(2):7790.

⁴ EFSA (European Food Safety Authority), Adriaanse P, Arce A, Focks A, Ingels B, Jolli D, Lambin S, Rundlof M, Sußenbach D, Del Aguila M, Ercolano V, Ferilli F, Ippolito A, Szentes Cs, Neri FM, Padovani L, Rortais A, Wassenberg J and Auteri D, 2023. Revised guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2023;21(5):7989.

metabolites in water abstracted for the production of drinking water⁵, requiring applicants to perform additional tests.

- (3) It is therefore necessary to update the data requirements laid down in Regulation (EU) No 283/2013, in order to take into account the current scientific and technical knowledge.
- (4) Regarding procedures for the approval or renewal of approval of active substances, in order to leave applicants sufficient time to meet the new requirements introduced by this Regulation, while taking into account that certain applicants may be able to meet these new requirements earlier than others, it is appropriate to lay down a transitional period during which the new requirements introduced by this Regulation will be optional.
- (5) Regarding procedures related to the authorisation of plant protection products, it is also appropriate to lay down transitional measures for data concerning the active substances contained in those plant protection products in order to allow applicants to submit data according to the requirements that applied at the time of the approval or the latest renewal of the approval of the active substances concerned and which hence underpin their approval. However, as certain applicants may be able to meet the new requirements set out in this Regulation, they should be allowed to submit data based on the new requirements.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee, on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) No 283/2013

The Annex to Regulation (EU) No 283/2013 is amended as set out in the Annex to this Regulation.

Article 2

Transitional measures as regards certain procedures concerning active substances

1. For applications submitted before *[Office of Publications, please insert date = 24 months after the date of entry into force of this Regulation]*, applicants may choose to submit the following data in accordance with the Annex to Commission Regulation (EU) No 283/2013 as it stood before being amended by this Regulation:
 - (a) data required pursuant to Article 8(1) of Regulation (EC) No 1107/2009, except the data provided for in point (a) thereof, and pursuant to Article 8(2) of that Regulation;
 - (b) data required pursuant to Article 6(2) of Commission Implementing Regulation (EU) 2020/1740, except the data referred to in point (c) thereof.

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⁵ ECHA and EFSA (European Chemicals Agency and European Food Safety Authority), Hofman-Caris, R., Dingemans, M., Reus, A., Shaikh, S. M., Muñoz Sierra, J., Karges, U., aus der Beek, T., Nogueiro, E., Lythgo, C., Parra Morte, J. M., Bastaki, M., Serafimova, R., Friel, A., Court Marques, D., Uphoff, A., Bielska, L., Putzu, C., Papadaki, P. (2023). Guidance document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water. EFSA Journal, 21(8), 1-108. Available online: <https://doi.org/10.2903/j.efsa.2023.8194>.

2. Applicants that decide to use the possibility provided for in paragraph 1 shall specify that choice in writing when submitting the application concerned. That decision shall be irrevocable for the procedure concerned.

Article 3

Transitional measures as regards certain procedures concerning plant protection products

1. Where, for the latest approval or renewal of the approval of an active substance, data on that active substance was submitted in accordance with the Annex to Regulation (EU) No 283/2013 as it stood before being amended by this Regulation, applicants may choose to submit the data that is required on that active substance in the application for the authorisation of a plant protection product containing that active substance in accordance with the Annex to Regulation (EU) No 283/2013 as it stood before being amended by this Regulation.
2. Applicants that decide to use the possibility provided for in paragraph 1 shall specify that choice in writing when submitting the application concerned. That decision shall be irrevocable for the procedure concerned.

Article 4

Entry into force and application

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,

For the Commission
The President
Ursula VON DER LEYEN