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

**of **XXX****

**amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clothianidin and thiamethoxam in or on certain products**

(Text with EEA relevance)

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

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## **amending Annexes II and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clothianidin and thiamethoxam in or on certain products**

(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 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC<sup>1</sup>, and in particular Article 14(1)(a), Article 18(1)(b) and Article 49(2) thereof,

Whereas:

- (1) For clothianidin and thiamethoxam maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. The European Food Safety Authority (the ‘Authority’) reviewed these MRLs in accordance with Article 12 of Regulation (EC) 396/2005<sup>2</sup> and recommended MRLs which it found safe for consumers. Commission Regulation (EU) 2016/156<sup>3</sup> included these MRLs in Annex II to Regulation (EC) No 396/2005. Some of these MRLs were based on Codex maximum residue limits (CXLs) and had already been included in Annex II to Regulation (EC) No 396/2005 through earlier amendments<sup>4</sup>.
- (2) On 11 July 2015<sup>5</sup> the Codex Alimentarius Commission (CAC) adopted a new set CXLs for clothianidin and thiamethoxam. As they were found to be safe for

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<sup>1</sup> OJ L 70, 16.3.2005, p. 1.

<sup>2</sup> EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for clothianidin and thiamethoxam according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(12):3918, 120 pp. doi:10.2903/j.efsa.2014.3918

<sup>3</sup> Commission Regulation (EU) 2016/156 of 18 January 2016 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for boscalid, clothianidin, thiamethoxam, folpet and tolclofos-methyl in or on certain products, OJ L 31, 6.2.2016, p. 1.

<sup>4</sup> Commission Regulation (EU) No 441/2012 of 24 May 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenthrin, boscalid, cadusafos, chlorantraniliprole, chlorothalonil, clothianidin, cyproconazole, deltamethrin, dicamba, difenoconazole, dinocap, etoxazole, fenpyroximate, flubendiamide, fludioxonil, glyphosate, metalaxyl-M, meptyldinocap, novaluron, thiamethoxam, and triazophos in or on certain products, OJ L 135, 25.5.2012, p. 4

<sup>5</sup> [ftp://ftp.fao.org/codex/reports/reports\\_2015/REP15\\_PRe.pdf](ftp://ftp.fao.org/codex/reports/reports_2015/REP15_PRe.pdf). Joint FAO/WHO food standards programme Codex Alimentarius Commission. Appendices III and IV. Thirty-Eight Session. Geneva, Switzerland, 6-11 July 2015.

consumers in the Union<sup>6</sup> by the Authority, Commission Regulation (EU) No 2017/671<sup>7</sup> included them in Regulation (EC) No 396/2005.

- (3) Clothianidin and thiamethoxam were included in Annex I to Directive 91/414/EEC on 1 August 2006 and 1 February 2007, respectively, and, therefore, before the entry into force of Regulation (EU) No 1107/2009. The most recent risk assessments<sup>8,9</sup> for bees from the exposure to these substances conducted by the Authority under Regulation (EC) No 1107/2009 found that, due to their intrinsic properties, the exposure from outdoor use of clothianidin and thiamethoxam leads to unacceptable risks for bees, or such risks could not be excluded based on the available data. Therefore, Commission Implementing Regulations (EU) 2018/784<sup>10</sup> and 2018/785<sup>11</sup> restricted, the approval of clothianidin and thiamethoxam, respectively, to uses in permanent greenhouses only and required that the resulting crops stayed within a permanent greenhouse during their entire life cycle.
- (4) Following the adoption of these restrictions, all applications for the renewal of the approval of the active substances clothianidin and thiamethoxam were withdrawn. Therefore, the approval of clothianidin expired on 31 January 2019 and the approval of thiamethoxam expired on 30 April 2019.
- (5) In the light of the Authority's risk assessment for bees and of all the available pertinent information, there is currently no evidence that would allow any outdoor uses for clothianidin and thiamethoxam to be considered as safe for bees. Producers of the substances can however, at any time, submit additional information, as provided in Articles 7 of Regulation (EC) No 1107/2009, demonstrating the safety for bees of outdoor uses of clothianidin and thiamethoxam. That information, if submitted, would be reviewed within the time period provided for in that Regulation. To date, no such information has been submitted.
- (6) Adverse effects of clothianidin and thiamethoxam on bees are directly linked to the intrinsic properties of those substances. Therefore, the risks for bees from outdoor uses of these substances are unlikely to be limited to the Union.
- (7) There is a substantial body of evidence showing that active substances which are neonicotinoids, such as clothianidin and thiamethoxam, play an important role in the decline of bees and other pollinators worldwide. The Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services on pollinators, pollination

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<sup>6</sup> Scientific support for preparing an EU position in the 47th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2015;13(7):4208 [178 pp.].

<sup>7</sup> Commission Regulation (EU) 2017/671 of 7 April 2017 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clothianidin and thiamethoxam in or on certain products (OJ L 97, 8.4.2017, p. 9).

<sup>8</sup> European Food Safety Authority; Peer review of the pesticide risk assessment for bees for the active substance clothianidin considering the uses as seed treatments and granules. EFSA Journal 2018;16(2):5177.

<sup>9</sup> European Food Safety Authority; Peer review of the pesticide risk assessment for bees for the active substance thiamethoxam considering the uses as seed treatments and granules. EFSA Journal 2018;16(2):5179.

<sup>10</sup> Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin (OJ L 132, 30.5.2018, p. 35).

<sup>11</sup> Commission Implementing Regulation (EU) 2018/785 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance thiamethoxam (OJ L 132, 30.5.2018, p. 40).

and food production concluded in its 2016 assessment report<sup>12</sup> that neonicotinoids (such as clothianidin and thiamethoxam) have adverse effects on bees and other pollinators. The impact of neonicotinoids on wildlife has been assessed by the International Union for Conservation of Nature (IUCN) Task Force on Systemic Pesticides since 2012. The Worldwide Integrated Assessment of the Impact of Systemic Pesticides on Biodiversity and Ecosystems (WIA) has examined 1,121 scientific studies and results indicate that pollinator populations are highly vulnerable to the existing levels of pollution with neonicotinoids and are likely to have large-scale and wide ranging negative biological and ecological impacts<sup>13</sup>. A recent review of the existing scientific knowledge corroborated this conclusion indicating that neonicotinoid use is driving the decline of pollinator population in different world regions<sup>14</sup>.

- (8) Since the ban on outdoor uses of clothianidin and thiamethoxam in the Union, several countries outside the Union have also restricted the use of clothianidin and thiamethoxam to protect pollinators, including bees<sup>15,16,17</sup>. Other countries are currently re-evaluating their approval of these active substances<sup>18,19,20</sup>.
- (9) Regulation (EC) No 396/2005 establishes in accordance with the general principles laid down in Regulation (EC) No 178/2002<sup>21</sup> provisions related to maximum residue levels of pesticides residues in or on food and feed of plant and animal origin. In accordance with Article 5(1) of the latter Regulation, food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking

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<sup>12</sup> IPBES (2016). The assessment report of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services on pollinators, pollination and food production. S.G. Potts, V. L. Imperatriz-Fonseca, and H. T. Ngo (eds). Secretariat of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services, Bonn, Germany. 552 pages. <https://doi.org/10.5281/zenodo.3402856>.

<sup>13</sup> IUCN SSC CEM Task Force on Systemic Pesticides. Worldwide Integrated Assessment. Peer reviewed scientific journal articles compiled in Environmental Science and Pollution Research" volume 22, issue 1, January 2015

<sup>14</sup> Neonic Insecticides and Invertebrate Species Endangerment, Pierre Mineau. Module in Earth Systems and Environmental Sciences. 2021. <https://www.sciencedirect.com/science/article/pii/B9780128211397001264>.

<sup>15</sup> Health Canada's Pest Management Regulatory Agency. Re-evaluation Decision RVD2019-05, Clothianidin and Its Associated End-use Products: Pollinator Re-evaluation. Pest Management Regulatory Agency 11 April 2019 ISSN: 1925-0886.

<sup>16</sup> Re-evaluation Decision RVD2019-04, Thiamethoxam and Its Associated End-use Products: Pollinator Re-evaluation. Pest Management Regulatory Agency 11 April 2019 ISSN: 1925-0886.

<sup>17</sup> Ministerio de Ganadería, Agricultura y Pesca de Paraguay. Resolución N° 503/019 DGSA Modificación de etiquetas para los Productos Fitosanitarios a base de los ingredientes activos Clotianidina, Imidacloprid, Tiametoxan y Clorpirifos. December 2019.

<sup>18</sup> Australian Pesticides and Veterinary Medicines Authority. Reconsideration of Neonicotinoid Approvals and Registrations. Commonwealth of Australia Gazette No. APVMA 23, November 2019.

<sup>19</sup> New Zealand Environmental Protection Authority. Application to decide whether there are grounds for reassessment of the neonicotinoids clothianidin, thiamethoxam, imidacloprid, thiacloprid, and acetamiprid (APP203949). December 2019.

<sup>20</sup> United States Environmental Protection Agency. Proposed Interim Registration Review Decision Case Numbers 7620 and 7614. Docket Numbers EPA-HQ-OPP-2011-0865 and EPA-HQ-OPP-2011-0581. January 2020.

<sup>21</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1.

into account, where appropriate, the protection of animal health and welfare, plant health and the environment.

- (10) There is growing worldwide concern that the decline of pollinators is a serious threat to global biodiversity, the environment and sustainable development, as well as to maintaining agricultural productivity and food security. According to the Convention on Biological Diversity's International Initiative for the Conservation and Sustainable Use of Pollinators<sup>22</sup>, pollination is one of the most important mechanisms in the maintenance and promotion of biodiversity and, in general, life on earth. Many ecosystems, including agro-ecosystems and two thirds of major food crops depend on pollinators for quality or yield. The Food and Agriculture Organization of the United Nations (FAO) calls for actions to address the drivers of pollinator decline for the sake of sustainable global food production<sup>23</sup>. Highly dependent on pollination, foods such as fruits, vegetables, nuts and seeds are the main dietary contributors of micronutrients necessary to prevent the risk of some non-communicable diseases in humans<sup>24,25</sup>. Therefore, pollinators are important to ensure diversity in diet and to reduce the threat to biodiversity in the global environment.
- (11) As the decline in pollinators is an issue of international concern, Union measures need to be adopted to protect pollinator populations worldwide, including bees, from the risks of active substances, such as the neonicotinoids clothianidin and thiamethoxam. Preserving the pollinator population within the Union only would be insufficient to reverse the worldwide decline of pollinator populations and its effects on biodiversity, agricultural production and food security, also in the Union.
- (12) In accordance with Article 3(d) of Regulation (EC) No 396/2005, MRLs for clothianidin and thiamethoxam were based on Good Agricultural Practices (GAPs) as defined in Article 3(a) of that Regulation, which took into account, in particular, considerations of efficiency to combat plant pests, and protection of the environment and public health in the context of the authorisation of the use of plant protection products containing those substances. The MRLs resulting from these GAPs were subsequently considered and found safe for consumers in the Union. It is now appropriate to complement the regulatory response to date by better integrating within it environmental considerations taking into account in particular whether the GAPs used in the past as a basis for setting MRLs ensure a sufficient protection of the environment, based on current knowledge. GAPs involving outdoor uses of clothianidin and thiamethoxam are not acceptable, in light of current scientific and technical knowledge, due to their effects on bees. Given the global nature of pollinator decline, there is a need to ensure that also commodities imported into the Union do not contain residues resulting from GAPs based on outdoor uses of clothianidin and/or thiamethoxam, in order to avoid the transfer of adverse effects on bees from food production in the Union to production of food in other parts of the world that is then

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<sup>22</sup> <https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-06-en.pdf>.

<sup>23</sup> FAO. 2019. The State of the World's Biodiversity for Food and Agriculture, J. Bélanger & D. Pilling (eds.). FAO Commission on Genetic Resources for Food and Agriculture Assessments. Rome. 572 pp.

<sup>24</sup> Effects of decreases of animal pollinators on human nutrition and global health: a modelling analysis. MR Smith, GM Singh, D Mozaffarian, SS Myers. The Lancet 386, Issue 10007; 2015.

<sup>25</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Europe's Beating Cancer Plan. COM (2021) 44.

imported into the Union.<sup>26</sup> This is appropriate to ensure that all products produced or consumed in the Union are free from clothianidin and thiamethoxam and the production is not associated with pollinator mortality. In view of this, CXLs based on GAPs that do not achieve the appropriate level of protection of the Union should no longer be provided for as MRLs pursuant to Regulation (EC) No 396/2005.

- (13) Furthermore, all authorisations for plant protection products containing clothianidin and/or thiamethoxam in the Union have been revoked. It is therefore appropriate to delete the corresponding MRLs set out in Annex II of Regulation (EC) No 396/2005, in accordance with Article 17 of that Regulation in conjunction with Article 14(1)(a).
- (14) Therefore, taking into account all the factors relevant to the matter under consideration in accordance with Article 14(2), read in the light of Article 11 TFEU, all the current MRLs for clothianidin and/or thiamethoxam as set out by Regulation (EC) No 396/2005 should be lowered to the Limit of Determination (LODs).
- (15) The Commission consulted the European Union reference laboratories on analytically achievable LODs specific to each product. Those LODs should be listed in Annex V in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.
- (16) Through the World Trade Organisation, the trading partners of the Union were consulted on the new MRLs and their comments have been taken into account.
- (17) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (18) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been produced in or imported into the Union before the modification of the MRLs and for which information shows that for such products complying with the existing MRLs a high level of consumer protection is maintained.
- (19) A reasonable period should be allowed to elapse before the modified MRLs become applicable in order to permit operators in third countries, especially in least developed and developing countries, and food business operators to prepare themselves to meet the new requirements which will result from the modification of the MRLs. Such adaptation of agricultural practices can be reasonably expected to be achieved after two growing seasons.
- (20) In order to meet the needs of international trade, applications for import tolerances for clothianidin or thiamethoxam may be submitted pursuant to Article 7 of Regulation (EC) No 396/2005 and should provide relevant information to demonstrate that the GAPs applying for the specific uses of the active substances are safe for pollinators. That information, if submitted, would be assessed on a case by case basis within the time period provided for in that Regulation. In the context of the assessment of a request for an import tolerance, if an applicant provides scientific evidence that the use of these neonicotinoids does not adversely impact pollinators, if all requirements are met, an import tolerance could be set by the Commission
- (21) 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:

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<sup>26</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system. COM (2020) 381.

*Article 1*

Annexes II and V to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

*Article 2*

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products, which were produced in the Union or imported into the Union before [*Office of Publication: please insert date [36 months] after entry into force*].

*Article 3*

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

It shall apply from [*Office of Publication: please insert date [36 months] after entry into force*].

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*