European Parliament
2019-2024

Plenary sitting

B9-0057/2024

11.1.2024

MOTION FOR A RESOLUTION

pursuant to Rule 112(2) and (3) and (4)(c) of the Rules of Procedure

on the proposal for a Council regulation amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for thiacloprid in or on certain products
(COM(2023)0739 – 2023/3005(RPS))

Committee on the Environment, Public Health and Food Safety

Members responsible: Anja Hazekamp, Maria Arena, Michal Wiezik, Jutta Paulus

B9-0057/2024

European Parliament resolution on the proposal for a Council regulation amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for thiacloprid in or on certain products (COM(2023)0739 – 2023/3005(RPS))

The European Parliament,

– having regard to the proposal for a Council regulation amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for thiacloprid in or on certain products (COM(2023)0739),

– 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[1], and in particular Article 14(1), point (a), and Article 49(2) thereof,

– 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[2], and in particular Article 4(1) and Article 4(2), first subparagraph, point (a), and point 3.6.4 of Annex II,

– having regard to 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[3], and in particular Article 5(1) thereof,

– having regard to Articles 11, 13, 168 and 191 of the Treaty of the Functioning of the European Union,

– having regard to the reasoned opinion adopted by the European Food Safety Authority (EFSA) on 9 February 2023, and published on 15 March 2023[4],

– having regard to the conclusion on pesticides peer review approved by EFSA on 17 January 2019, and published on 14 March 2019[5],

– having regard to the opinion adopted by the Committee for Risk Assessment (RAC) of the European Chemical Agency (ECHA) on 12 March 2015[6],

---

1 OJ L 70, 16.3.2005, p. 1.
2 OJ L 309, 24.11.2009, p. 1.
3 OJ L 31, 1.2.2002, p. 1.
4 EFSA statement on the short-term (acute) dietary risk assessment and evaluation of confirmatory data for certain maximum residue levels (MRLs) for thiacloprid, EFSA Journal 2023;21(3):7888, https://doi.org/10.2903/j.efsa.2023.7888.
5 EFSA conclusion on the peer review of the pesticide risk assessment of the active substance thiacloprid, EFSA Journal 2019;17(3):5595, https://doi.org/10.2903/j.efsa.2019.5595.
6 RAC opinion proposing harmonised classification and labelling at EU level of Thiacloprid

– having regard to Article 5a(4), point (e), and Article 5a(5) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[7],

– having regard to Rule 112(2) and (3), and (4)(c) of its Rules of Procedure,

– having regard to the motion for a resolution by the Committee on the Environment, Public Health and Food Safety,

A. whereas thiacloprid is an active ingredient in insecticides mainly used on cotton, pome fruit, vegetables, and potatoes;

B. whereas the approval of the active substance thiacloprid expired on 3 February 2020, and was not renewed according to Commission Implementing Regulation (EU) 2020/23[8]; whereas the grace period for plant protection products containing thiacloprid expired on 3 February 2021;

C. whereas the approval of the active substance thiacloprid was not renewed as it could not be established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 were satisfied; whereas, in particular, EFSA identified two critical areas of concern; whereas the first critical area of concern related to the indication of the contamination of groundwater with several relevant metabolites of thiacloprid whose carcinogenic potential could not be excluded (M30, M34 and M46) above the parametric drinking water limit of 0,1 µg/L for all the representative uses[9]; whereas the second critical area of concern related to the harmonised classification by ECHA of thiacloprid as presumed to damage fertility and the unborn child (toxic for reproduction category 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[10] making thiacloprid a 'cut-off substance' in accordance with Article 4(1) of Regulation (EC) No 1107/2009;

D. whereas EFSA also concluded that the assessment of the risks to bees and non-target terrestrial plants could not be finalised;

E. whereas thiacloprid is also classified in accordance with Regulation (EC) No 1272/2008 as suspected of causing cancer (carcinogenic category 2), very toxic for aquatic life

---

(ISO); {(2Z)-3-[(6-chloropyridin-3-yl)methyl]-1,3-thiaz olidin-2-ylidene}cyanamide, https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e180638ff8.

7 OJ L 184, 17.7.1999, p. 23.

8 Commission Implementing Regulation (EU) 2020/23 of 13 January 2020 concerning the non-renewal of the approval of the active substance thiacloprid, 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 8, 14.1.2020, p. 8).

9 EFSA conclusion of 17 January 2019.

10 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(aquatic acute 1), and very toxic for aquatic life with long lasting effect (aquatic chronic 1);

F. whereas the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) has not delivered an opinion on the proposal for a Council regulation; whereas, during the PAFF Committee meeting held on 18-19 September 2023, '[e]ight Member States did not support the draft Regulation. Six of them mentioned first and foremost their concerns with maintaining CXLs and import tolerances for a non-approved substance which meets on[e] of the cut-off criteria under Regulation (EC) No 1107/2009 (toxic for reproduction). In addition, one Member State that did not support the draft Regulation had concerns that EFSA had indicated exceedances of the acute reference dose for some products in certain non-standard circumstances, another one mentioned the discrimination of EU farmers that may no longer use plant protection products containing this active substance, while farmers in third countries could still do so, thus leading to unfair competition'[11];

G. whereas Germany requested the following declaration to be included in the summary report of the PAFF Committee meeting held on 18-19 September 2023: 'Thiacloprid is a cut-off active substance according to Regulation (EC) No 1107/2009. During the re-approval procedure of the active substance, it was determined that it meets the cut-off criteria as it has a classification as toxic to reproduction 1B. Accordingly, the active substance was not re-approved. Germany does in general not support the setting of [maximum residue limits (MRLs)] for active substances that are not approved in the EU due to health concerns. The decisive factor here is that the cut-off criteria have been established within the framework of the (re-)approval procedure of an active substance pursuant to Regulation (EC) No 1107/2009'[12];

H. whereas it is therefore appropriate to delete the existing MRLs set for thiacloprid in Annex II to Regulation (EC) No 396/2005 in accordance with Article 17 of that Regulation in conjunction with Article 14(1), point (a), thereof;

I. whereas, in the proposal for a Council regulation, the Commission is however proposing to maintain the MRLs for thiacloprid above the limit of determination for use on more than 30 products for import purposes based on EFSA's reasoned opinion[13];

J. whereas the uses for which MRLs above the limit of determination are considered safe include uses of thiacloprid on papayas, tea, tree nuts, quinces, medlars, loquats/Japanese medlars, apricots, cherries (sweet), plums, strawberries, blackberries, dewberries, other small fruits and berries, kiwis, potatoes, tomatoes, aubergines/eggplants, melons, watermelons, rice, wheat, animal (swine, bovine, sheep, horse, poultry, and other farm animals) products from tissues (muscle, liver, kidney and edible offal), milk and eggs, raspberries, cucumbers, courgettes, rapeseeds/canola seeds, mustard seeds and cotton seeds; whereas the MRLs proposed for those uses range from twice the limit of determination up to a thousand time the limit of determination (for use on teas);

---

11 Summary report of PAFF Committee meeting of 18-19 September 2023, https://ec.europa.eu/transparency/comitology-register/screen/documents/092486/1/consult?lang=en.

12 Ibid.

13 EFSA reasoned opinion of 9 February 2023.

K. whereas, by contrast, the request for import tolerances were refused only for two uses (on peaches and sweet peppers) since an exceedance of the acute reference dose cannot be excluded and the Commission therefore proposed to lower the MRLs for thiacloprid to the limit of determination only for those uses;

L. whereas recital (5) of Regulation (EC) No 396/2005 provides that residues should not be present at levels presenting an unacceptable risk to humans and, where relevant, to animals;

M. whereas Article 4(2), point (a), of Regulation (EC) No 1107/2009 provides that residues of plant protection products shall not have any harmful effect on human heath, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects; whereas point 3.6.4 of Annex II to that Regulation provides that an active substance classified, in accordance with Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B, shall not be approved unless 'residues of the active substance [...] concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005'; whereas Article 18(1), point (b), of Regulation (EC) No 396/2005 sets a default value of 0,01 mg/kg;

N. whereas Article 3(2), point (g), of Regulation (EC) No 396/2005 provides that import tolerance is an MRL set for imported products when 'the use of the active substance in a plant protection product on a given product is not authorised in the Community for reasons other than public health reasons for the specific product and specific use'; whereas thiacloprid does not meet those criteria as it has been banned for health reasons, since it is classified as toxic to reproduction category 1B;

O. whereas Article 5(1) of Regulation (EC) No 178/2002 provides that food law is to 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 into account, where appropriate, the protection of animal health and welfare, plant health and the environment;

P. whereas the present pollinator crisis is one of the main threats to biodiversity and global and local food security; whereas that crisis can worsen the problems of hidden hunger, erodes ecosystem resilience, and can destabilise ecosystems that form our life support system[14];

Q. whereas the Commission announced in its communication of 20 May 2020 on 'A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system'[15] that '[t]he EU will support the global transition to sustainable agri-food systems, in line with the objectives of this strategy and the SDGs', and that '[t]he EU can play a key role in setting global standards with this strategy'; whereas the Commission explicitly stated in the strategy that "[a] more sustainable EU food system also requires increasingly sustainable practices by our trading partners. In order to promote a gradual move towards the use of safer plant protection products, the EU will consider, in compliance with WTO rules and

---

14 van der Sluijs, J.P., Vaage, N.S., 'Pollinators and Global Food Security: the Need for Holistic Global Stewardship', Food ethics 1, 75–91 (2016), https://doi.org/10.1007/s41055-016-0003-z.

15 COM(2020)0381.

following a risk assessment, to review import tolerances for substances meeting the "cut-off criteria" and presenting a high level of risk for human health';

R. whereas, in 2022, the Commission lowered[16] the MRLs for two neonicotinoids that pose a high risk to pollinators to the lowest level that can be measured with the latest technologies, whereby imported products can no longer contain residues of clothianidin and thiamethoxam;

S. whereas in that regard the Commission argued that '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 of the Treaty of the Functioning of the European Union, requiring that "environmental protection requirements must be integrated into the definition and implementation of the Union's policies and activities, in particular with a view to promoting sustainable development", 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)'[17];

T. whereas in the PAFF Committee held on 10-11 May 2023, '[t]he Commission recalled that thiacloprid belongs to the group of neonicotinoids actives substances [but that] since it has different properties than clothianidin and thiamethoxam, it is currently not envisaged to follow the same approach as for clothianidin and thiamethoxam implementing the Farm to Fork Strategy by lowering all MRLs to the LOQ'[18];

U. whereas the fact that thiacloprid would have different properties than other neonicotinoids is disputed in the scientific literature, with results showing that 'the image of thiacloprid as a relatively benign neonicotinoid should now be questioned'[19];

V. whereas, in particular, colonies of bumblebees exposed to thiacloprid have been found to be more likely to die prematurely, and those that survived to suffer from sublethal effects[20]; whereas thiacloprid has also been found to affect the behaviour and immune system of honey bees similarly to imidacloprid, clothianidin and thiamethoxam[21,22];

---

16 Commission Regulation (EU) 2023/334 of 2 February 2023 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 (OJ L 47, 15.2.2023, p. 29).

17 Ibid.

18 Summary report of PAFF Committee meeting of 10-11 May 2023, https://ec.europa.eu/transparency/comitology-register/screen/documents/090500/1/consult?lang=en.

19 Ellis, C., Park, K.J., Whitehorn, P., David, A., Goulson, D., 'The Neonicotinoid Insecticide Thiacloprid Impacts upon Bumblebee Colony Development under Field Conditions', Environmental Science & Technology 2017, 51, 3, 1727–1732, https://pubs.acs.org/doi/10.1021/acs.est.6b04791.

20 Ibid.

21 Brandt, A., Gorenflo, A., Siede, R., Meixner, M., Büchler, R., 'The neonicotinoids thiacloprid, imidacloprid, and clothianidin affect the immunocompetence of honey bees (*Apis mellifera* L.)', Journal of Insect Physiology, Volume 86, March 2016, Pages 40-47, https://www.sciencedirect.com/science/article/pii/S0022191016300014.

22 Tison, L., Hahn, M.-L., Holtz, S., Rößner A., Greggers, U., Bischoff, G., and Menzel, R.,

W. whereas there is increasing evidence that the use of thiacloprid has a devastating impact on biodiversity and especially bees and other pollinators[23];

X. whereas, in its non-renewal report of 22 October 2019[24], EFSA concluded that 'the information available is insufficient to satisfy the requirements set out in Article 4(1) to (3) of Regulation (EC) No 1107/2009', and in particular that '[t]he risk assessment for bees could not be finalised';

Y. whereas thiacloprid should therefore be subject to the same reasoning and rules that were applied to clothianidin and thiamethoxam;

Z. whereas the Commission must protect the environment and Union citizens on the basis of the available scientific information, using the obligations and legal possibilities that Regulations (EC) No 396/2005 and (EC) No 178/2002 provide for to ensure a high level of protection of human and animal health and the environment;

AA. whereas the proposed MRLs do not protect the health of citizens in the Union and do not secure a high level of protection for bees and other pollinators, and they are thereby contrary to Regulations (EC) No 396/2005 and (EC) No 178/2002;

AB. whereas MRLs should not be set for active substances that are not approved in the Union due to health concerns; whereas therefore no import tolerances should be set for thiacloprid as it is classified as toxic for reproduction category 1B; whereas further the classification of thiacloprid as toxic for reproduction category 1B should have been reason enough for the Commission to refuse the requests for import tolerances with reference to the risks for the health of citizens in third countries;

1. Opposes adoption of the proposal for a Council regulation;

2. Considers that the proposal for a Council regulation is not compatible with the aim and content of Regulations (EC) No 396/2005 and (EC) No 178/2002, as well as with Regulation (EC) No 1107/2009, including point 3.6.4 of its Annex II;

3. Calls on the Commission to withdraw the proposal for a regulation;

4. Calls on the Commission to submit a new draft to the committee lowering all MRLs for thiacloprid to the limit of determination for all uses and to refuse any requests for import tolerances;

5. Instructs its President to forward this resolution to the Council and the Commission, and

---

'Honey Bees' Behavior Is Impaired by Chronic Exposure to the Neonicotinoid Thiacloprid in the Field', Environmental Science & Technology 2016, 50, 13, 7218–7227, https://pubs.acs.org/doi/full/10.1021/acs.est.6b02658.

23 Pisa, L., Goulson, D., Yang, E.C., et al., 'An update of the Worldwide Integrated Assessment (WIA) on systemic insecticides. Part 2: impacts on organisms and ecosystems', Environmental Science and Pollution Research 28, 11749–11797 (2021), https://doi.org/10.1007/s11356-017-0341-3.

24 https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances/details/841.

to the governments and parliaments of the Member States.