EUROPEAN
COMMISSION

Brussels, 24.11.2023
COM(2023) 739 final

2023/0422 (NLE)

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

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Regulation (EC) No 396/2005 establishes, in accordance with the general principles laid down in Regulation (EC) No 178/2002, in particular the need to ensure a high level of consumer protection and harmonised Union provisions relating to maximum levels (MRLs) of pesticide residues in or on food and feed of plant and animal origin. It recognises that, for food and feed produced outside the Union, different agricultural practices as regards the use of plant protection products may be legally applied, sometimes resulting in pesticide residues differing from those resulting from uses legally applied in the Union. Therefore, it provides for the possibility to apply for the setting of MRLs for imported products (i.e., import tolerances) by providing a comprehensive scientific dossier that take these uses and the resulting residues into account, which is evaluated by a Member State and the European Food Safety Authority (EFSA). Also, MRLs set at international level by the Codex Alimentarius Commission are also considered when MRLs are set, taking into account the corresponding good agricultural practices.

For the active substance thiacloprid, the EFSA Conclusions on the peer review[1] identified areas of critical concern in relation to the contamination of groundwater with metabolites of thiacloprid with respect to one or more representative uses that satisfy the approval criteria provided in Article 4 of Regulation (EC) No 1107/2009. As a consequence, the approval of the substance was not renewed by Commission Implementing Regulation (EU) 2020/23[2]. In addition, thiacloprid is classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council as toxic for reproduction category 1B.

Member States had to withdraw authorisations for plant protection products containing thiacloprid as active substance by 3 August 2020. The maximum grace period allowed to be given by a Member State in accordance with Article 46 of Regulation (EC) No 1107/2009 expired on 3 February 2021.

In accordance with Article 14(1)(a) and in conjunction with Article 17 of Regulation (EC) No 396/2005, following the non-renewal of thiacloprid, the Commission drafted a Regulation to lower its MRLs to the limit of quantification (LOQ). Nevertheless, some exceptions are possible for certain import tolerances and Codex MRLs (CXLs), in particular where those were recently reviewed and were found safe by EFSA[3]. Those MRLs were kept according to Article 3(2), point (g) and Article 14 (2), points (a), (c) and (e) of Regulation (EC) No 396/2005.

The Commission proposed a draft Regulation to the Member States, that was thoroughly discussed in the Standing Committee on Plants, Animals, Food and Feed in its meetings on 13-14 February 2023, 10-11 May 2023 and 18-19 September 2023.

• Consistency with existing policy provisions in the policy area

The followed approach is consistent with the provisions of Regulation (EC) No 396/2005.

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1 EFSA Journal (2019). Conclusion on the peer review of the pesticide risk assessment of the active substance thiacloprid. EFSA Journal 2019;17(3):5595. doi: 10.2903/j.efsa.2019.5595.

2 OJ L 8, 14.1.2020, p. 8.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

In line with the favourable Reasoned Opinion adopted by EFSA and based on Article 14(1)(a) and Article 49 (2) of Regulation (EC) No 396/2005, a draft Commission Regulation was prepared and submitted to the SCoPAFF (see chapter 1). According to Article 45(4) of that Regulation the regulatory procedure with scrutiny applies according to Article 5a of Council Decision 1999/468.

• Choice of the instrument

The above mentioned draft Commission Regulation proposing the revision of the MRLs for thiacloprid was submitted to the Standing Committee on Plants, Animals, Food and Feed, on 18-19 September 2023, for an opinion. The Committee did not deliver an opinion on the draft Commission Regulation, as a qualified majority was not reached neither for nor against the proposed measures.

Consequently, pursuant to Article 5a of Council Decision 1999/468/EC in conjunction with Article 45 (4) of Regulation (EC) No 396/2005, the Commission is submitting to the Council and the Parliament a draft Council Regulation relating to the measures to be taken. The Council shall act on the proposed measure by a qualified majority within one month of referral to it. If the Council opposes the measure by a qualified majority, the measure shall not be adopted. If the Council envisages adopting the measure, it shall without delay submit it to the European Parliament. In the absence of an opinion of the Council, the Regulation is sent back to the Commission who shall without delay submit it for scrutiny to the European Parliament. If the Parliament does not oppose the measure, the latter shall be adopted by the Commission. If the Parliament opposes the measure it shall not be adopted by the Commission.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

No ex-post evaluations, stakeholder consultations and impact assessment are foreseen for this implementing Regulation in the context of Regulation (EC) No 396/2005.

4. BUDGETARY IMPLICATIONS

The Regulation has no budgetary impact.

5. OTHER ELEMENTS

• Detailed explanation of the specific provisions of the proposal

This Regulation intends to lower all the existing MRLs for thiacloprid to the LOD following the non-renewal of its approval with the exception of some MRLs based on uses in non- EU countries. The MRLs for thiacloprid in papayas and tea corresponds to import tolerances that were confirmed to be safe for consumers by EFSA in 2023[3]. The MRLs for thiacloprid in in tree nuts, quinces, medlars, loquats/Japanese medlars, apricots, cherries (sweet), plums, strawberries, blackberries, dewberries, other small fruits and berries, kiwis, potatoes,

[3] European Food Safety Authority 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.

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 correspond to CXLs that were considered safe for consumers[3].

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THE COUNCIL OF THE EUROPEAN UNION,

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

Whereas:

(1) For thiacloprid, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005.

(2) According to Commission Implementing Regulation (EU) 2020/23[2], the approval of the active substance thiacloprid was not renewed, following the critical concerns identified by the European Food Safety Authority (the 'Authority') in relation to the contamination of groundwater with metabolites of thiacloprid[3]. Additionally, thiacloprid is classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[4] as toxic for reproduction category 1B[5].

(3) All authorisations for plant protection products containing the active substance thiacloprid have been revoked, due to the human health risk emanating from the use of thiacloprid and the contamination of groundwater. It is therefore appropriate to delete the existing MRLs based on the good agricultural practices related to those authorisations set for this substance in Annex II of Regulation (EC) No 396/2005 in

1 OJ L 70, 16.3.2005, p. 1.

2 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).

3 European Food Safety Authority Conclusion on the peer review of the pesticide risk assessment of the active substance thiacloprid. EFSA Journal 2019;17(3):5595.

4 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).

5 Commission Regulation (EU) 2017/776 of 4 May 2017 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 116, 5.5.2017, p. 1).

accordance with Article 17 of that Regulation in conjunction with Article 14(1)(a) thereof.

(4) In accordance with Article 43 of Regulation (EC) No 396/2005, the Commission requested the Authority to provide a reasoned opinion, assessing the risks that the current MRLs based on import tolerances and Codex MRLs (CXLs) for thiacloprid may pose to consumers considering the most recent consumption data available and the presence or absence of the required confirmatory data to address the data gaps identified during the MRL review in accordance to the Article 12 of Regulation (EC) No 396/2005[6].

(5) The Authority concluded that the MRLs set for thiacloprid residues in papayas and tea were derived from import tolerances, which had been supported by data and are considered safe for consumers[7]. These MRLs should therefore be maintained in accordance with Article 3 (2)(g) of Regulation (EC) No 396/2005.

(6) For thiacloprid residues in 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 the existing MRLs correspond to the CXL values and the Authority concluded that are considered safe for consumers[7]; they should therefore also be maintained according to the principles of Article 14(2)(e) of Regulation (EC) No 396/2005.

(7) For raspberries, cucumbers, courgettes, rapeseeds/canola seeds, mustard seeds and cotton seeds, it is appropriate to lower the existing MRLs to the corresponding CXL values, which the Authority concluded are safe for consumers[7]; they should therefore also be lowered. The Authority evaluated the confirmatory data submitted to address the data gaps identified during the MRL review in accordance with Article 12 of Regulation (EC) No 396/2005 and concluded that the data requirements were fulfilled or not longer required[7]. Therefore, and for the avoidance of doubt, the respective footnotes indicating lack of information on residue trials, on crop metabolism with seed treatment and on analytical methods for different commodities should be deleted.

(8) The Authority identified a health risk for consumers concerning the MRLs for peaches and sweet peppers/bell peppers[7]. It is therefore appropriate to lower the MRLs for those products to the product specific LODs.

(9) For thiacloprid residues based on non-longer authorised good agricultural practices in the EU, it is appropriate to lower the respective MRLs set in Annex II to Regulation (EC) No 396/2005 to the product-specific limit of determination ('LOD') in accordance with Article 14(1)(a) of Regulation (EC) No 396/2005, in conjunction with Article 17 of that Regulation.

(10) The Commission consulted the European Union reference laboratories for residues of thiacloprid as regards the need to adapt certain LODs. Those laboratories proposed product specific LODs that are analytically achievable for all products.

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6 Commission Regulation (EU) 2015/1200 of 22 July 2015 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 amidosulfuron, fenhexamid, kresoxim-methyl, thiacloprid and trifloxystrobin in or on certain products (OJ L 195, 23.7.2015, p. 1).

7 European Food Safety Authority 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.

(11) 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. In particular the MRLs for fat from swine, bovine, sheep, goat, equine and other farmed terrestrial animal were aligned to that of muscle, for which the respective CXLs were implemented, to reflect the proportion of muscle and fat in "meat (from mammals other than marine mammals)" .

(12) Regulation (EC) No 396/2005 should therefore be amended accordingly.

(13) To allow for the normal marketing, processing and consumption of products, this Regulation should not apply to any products, which have been produced in the Union or imported into the Union before the new MRLs become applicable and for which a high level of consumer protection is maintained. This is the case for all products, except peaches and sweet peppers/bell peppers.

(14) A reasonable period should be allowed to elapse before the modified MRLs become applicable in order to permit Member States, third countries and food business operators to prepare themselves to meet the new requirements which will result from the modification of the MRLs.

(15) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. The measures provided for in this Regulation should therefore be adopted by the Council.

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 396/2005 is 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 Publications: please insert date 6 months after the date of entry into force of this Regulation*], except for peaches and sweet peppers/bell peppers.

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 Publications: please insert date 6 months after the date of entry into force of this Regulation*].

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

Done at Brussels,

For the Council
The President