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2023/0306 (NLE)

Proposal for a

COUNCIL REGULATION

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 tricyclazole 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). The Commission can set the MRL applied for, provided that safety for European Consumers has been demonstrated using the same criteria as for domestic products.

In accordance with Article 6 of Regulation (EC) No 396/2005, Italy received an application to set an import tolerance for the active substance tricyclazole in rice.

On 26 April 2018, Italy sent a report with its evaluation of that application to EFSA.

On 18 January 2023, EFSA adopted a favourable Reasoned Opinion on the evaluation of the safety of the proposed modified MRL for tricyclazole in rice[1]. The Commission therefore proposed a draft Regulation to the Member States in the Standing Committee for Plants, Animals, Food and Feed (SCoPAFF) to modify the relevant Union MRL accordingly.

• Consistency with existing policy provisions in the policy area

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

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) 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 modification of the MRL for tricyclazole in rice was submitted to the Standing Committee on Plants, Animals, Food and Feed, on 11 May 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.

[1] EFSA 2023. Reasoned Opinion on the setting of import tolerance for tricyclazole in rice. EFSA Journal 2023;21(1):7757. https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2023.7757

Consequently, pursuant to Article 5a of Council Decision 1999/468/EC, 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 two months 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 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 provides for a modification of the existing MRL for tricyclazole in rice, raising it from the limit of determination established at 0.01 mg/kg to a level of 0.09 mg/kg, based on a scientific opinion by EFSA. In doing so, the MRLs for tricyclazole, which are currently established in Annex V of Regulation (EC) No 396/2005, will be moved to Annex II of that same Regulation.

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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), point (a), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with a special legislative procedure,

Whereas:

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

(2) An application for import tolerances pursuant to Article 6(2) and (4) of Regulation (EC) No 396/2005 for tricyclazole used in Brazil on rice was submitted. The applicant states that the authorised uses of that substance on such crop in Brazil lead to residues exceeding the MRL provided for in Regulation (EC) No 396/2005 and that a higher MRL is necessary to avoid trade barriers for the importation of that crop.

(3) In accordance with Article 8 of Regulation (EC) No 396/2005, this application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.

(4) The European Food Safety Authority ('the Authority') assessed the application and the evaluation report, examining in particular the risks to consumers and, where relevant, to animals, and gave a reasoned opinion on the proposed MRL[2]. It forwarded that opinion to the applicant, the Commission and the Member States and made it available to the public.

(5) The Authority concluded that, for the product concerned, all requirements with respect to completeness of data submission were met and that the modification to the MRL requested by the applicant was acceptable with regard to consumer safety on the basis

[1] OJ L 70, 16.3.2005, p. 1.

[2] Reasoned opinion on the setting of import tolerance for tricyclazole in rice. EFSA Journal 2023;21(1):7757.

of a consumer exposure assessment for 27 specific European consumer groups. The Authority took into account the most recent information on the toxicological properties of the substance, which was not previously available and was only provided with the application concerned. Neither the lifetime exposure to this substance via consumption of all food products that may contain it, nor the short-term exposure due to high consumption of the relevant products showed that there is a risk that the acceptable daily intake or the acute reference dose is exceeded.

(6) Based on the reasoned opinion of the Authority and taking into account the factors listed in Article 14(2) of Regulation (EC) No 396/2005, it is appropriate to conclude that the proposed modification to the MRL fulfils the requirements of that Article.

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

(8) 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

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

Article 2

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 Council
The President