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

of XXX

amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, azoxystrobin, flonicamid, isofetamid, mefentrifluconazole, metazachlor, pyrimethanil, quartz sand, and sodium silver thiosulphate in or on certain products

(Text with EEA relevance)

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amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acibenzolar-S-methyl, azoxystrobin, flonicamid, isofetamid, mefentrifluconazole, metazachlor, pyrimethanil, quartz sand, and sodium silver thiosulphate 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/EEC¹, and Article 5 and Article 5 and Article 14(1), point (a), thereof,

Whereas:

- (1) For the active substances acibenzolar-S-methyl, azoxystrobin, flonicamid, isofetamid, mefentrifluconazole, metazachlor, and pyrimethanil, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. Quartz sand is included temporarily in Annex IV to that Regulation. For sodium silver thiosulphate no specific MRLs were set, nor were this substance included in Annex IV to that Regulation, so the default value laid down in Article 18(1), point (b), thereof applies.
- (2) As regards acibenzolar-S-methyl, an application requesting a modification of the existing MRL for 'grapes' was submitted pursuant to Article 6(1) of Regulation (EC) No 396/2005. As regards azoxystrobin, such an application was submitted for hops. As regards flonicamid, such an application was submitted for Chinese cabbages/pet-tsai, kales, and kohlrabies. As regards isofetamid, such an application was submitted for 'lettuces and salad plants' (except lettuces). As regards mefentrifluconazole, such an application was submitted for 'citrus fruits', hazelnuts/cobnuts, pistachios, strawberries, 'other small fruits and berries', table olives, kaki/Japanese persimmons, 'other root and tuber vegetables except sugar beets', tomatoes, sweet peppers/bell peppers, aubergines/eggplants, 'cucurbits with edible peel', 'cucurbits with inedible peel', 'flowering brassica', Brussel sprouts, head cabbages, Roman rocket/rucola, baby leaf crops, spinaches, 'herbs and edible flowers', beans (without pods), peas (without pods), cardoons, celeries, Florence fennels, globe artichokes, rhubarbs, 'pulses', linseeds, poppy seeds, soyabeans, mustard seeds, gold of pleasure seeds, olives for oil production, hops, swine liver, and 'swine, others'. As regards metazachlor, such an application was submitted for leeks and honey. As regards pyrimethanil, such an application was submitted for table grapes, garlic, and honey.

¹ OJ L 70, 16.3.2005, p. 1.

- (3) In accordance with Articles 8 and 9 of Regulation (EC) No 396/2005, the applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission.
- (4) The European Food Safety Authority ('the Authority') assessed the applications and the evaluation reports. It examined in particular the risks to consumers and, where relevant, to animals, and gave reasoned opinions on the proposed MRLs². It forwarded its reasoned opinions to the applicants, the Commission and the Member States and made them available to the public.
- (5) As regards flonicamid in 'leafy brassica, others', as it is appropriate to extrapolate from the residue trials on kales to 'leafy brassica, others', as confirmed by the Technical Guidelines on extrapolation of MRLs³, it is unnecessary to request the Authority to provide a reasoned opinion on those crops specifically. It is therefore appropriate to set the MRL for flonicamid in 'leafy brassica, others' at 0,5 mg/kg on the basis of the residue trials performed on kales.
- (6) As regards mefentrifluconazole in lentils, lupins/lupini beans, and 'pulses, other' the Authority concluded that further consideration by risk managers was required concerning whether to establish the new MRL at the level of 0,2 mg/kg, as derived by the Authority based on the assessment of the residue trials on dry peas, or at the MRL of 0,15 mg/kg, as derived by the Authority based on the combined assessment of the residue trials on dry beans and dry peas. As the Authority concluded that both limits would be safe for consumers, and in order to ensure that the proposed MRL covers reliably the uses in accordance with Good Agricultural Practices for peas, it is appropriate to set the MRLs for mefentrifluconazole in lentils, lupins/lupini beans, and 'pulses, other' at the level of 0,2 mg/kg.
- (7) In its reasoned opinion, the Authority concluded that the data submitted by the applicant concerning mefentrifluconazole in hazelnuts, beans and soyabeans were insufficient to set new MRLs. As all the other modifications to MRLs for acibenzolar-S-methyl, azoxystrobin, flonicamid, isofetamid, mefentrifluconazole, metazachlor, and pyrimethanil requested by the applicants, the Authority concluded that all data requirements had been met and that such modifications were acceptable with regard to consumer safety on the basis 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 these substances. Neither the lifetime exposure to those substances via consumption of all food products that may contain

² EFSA, 2023. Modification of the existing maximum residue levels for acibenzolar-S-methyl in grapes. EFSA Journal, 21(8), 1–26. <https://doi.org/10.2903/j.efsa.2023.8208>
 EFSA, 2023. Modification of the existing maximum residue level for azoxystrobin in hops. EFSA Journal, 21(8), 1–25. <https://doi.org/10.2903/j.efsa.2023.8124>
 EFSA, 2023. Modification of the existing maximum residue levels for flonicamid in kales, Chinese cabbages and kohlrabies. EFSA Journal, 21(8), 1–31. <https://doi.org/10.2903/j.efsa.2023.8202>
 EFSA, 2023. Modification of the existing maximum residue levels for isofetamid in certain salad plants. EFSA Journal, 21(8), 1–27. <https://doi.org/10.2903/j.efsa.2023.8206>
 EFSA, 2023. Modification of the existing maximum residue levels for mefentrifluconazole in various commodities. EFSA Journal, 21(9), 1–139. <https://doi.org/10.2903/j.efsa.2023.8237>
 EFSA, 2023. Modification of the existing maximum residue levels for metazachlor in leeks and honey. EFSA Journal, 21(8), 1–27. <https://doi.org/10.2903/j.efsa.2023.8220>
 EFSA, 2023. Modification of the existing maximum residue levels for pyrimethanil in table grapes, garlic and honey. EFSA Journal, 21(8), 1–30. <https://doi.org/10.2903/j.efsa.2023.8195>

³ Technical guidelines on data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin (SANTE/2019/12752 – 10 May 2023).

them nor the short-term exposure due to high consumption of the relevant products show a risk that the acceptable daily intake or the acute reference dose is exceeded.

- (8) Based on the reasoned opinion of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, it is concluded that the proposed modifications to the MRLs are acceptable.
- (9) Quartz sand was temporarily included in Annex IV to Regulation (EC) No 396/2005 pending the finalisation of its evaluation either under Council Directive 91/414/EEC⁴ or under Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁵, and pending the review of MRLs on that active substance in accordance with Article 12 of Regulation (EU) No 396/2005. In the context of application for renewal of the approval of this active substance under Regulation (EC) No 1107/2009, the Authority issued a conclusion on the peer review of the pesticide risk assessment of quartz sand⁶. Based on that conclusion, no MRLs are required for quartz sand. Therefore, it is appropriate for this substance to remain permanently in Annex IV to Regulation (EC) No 396/2005.
- (10) Sodium silver thiosulphate has been approved by Commission Implementing Regulation (EU) 1195/2013⁷, which provides that only indoor uses in non-edible crops shall be authorised for substance. The conditions of use of this substance are not expected to lead to the presence of residues in food or feed commodities that may pose a risk to the consumer and, therefore, no MRLs are required. It is therefore appropriate to include sodium silver thiosulphate in Annex IV to Regulation (EC) No 396/2005.
- (11) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (12) 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

Annexes II and IV 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*.

⁴ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁵ 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 (OJ L 309, 24.11.2009, p. 1).

⁶ Conclusion on the peer review of the pesticide risk assessment of the active substance quartz sand. EFSA Journal 2022;20(9):7552.

⁷ Commission Implementing Regulation (EU) No 1195/2013 of 22 November 2013 approving the active substance sodium silver thiosulfate, 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 315, 26.11.2013, p. 27).

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

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