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

of XXX

amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chitosan, clopyralid, difenoconazole, fat distillation residues, flonicamid, hydrolysed proteins, and lavandulyl senecioate in or on certain products

(Text with EEA relevance)

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amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chitosan, clopyralid, difenoconazole, fat distillation residues, flonicamid, hydrolysed proteins, and lavandulyl senecioate 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 in particular Article 5 and Article 14(1), point (a), thereof,

Whereas:

- (1) For the active substances difenoconazole and flonicamid, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For the active substance clopyralid, MRLs were set in Part A of Annex III to that Regulation. For chitosan, fat distillation residues, hydrolysed proteins, and lavandulyl senecioate no specific MRLs were set, nor were those substances included in Annex IV to that Regulation, so the default value laid down in Article 18(1), point (b), thereof applies.
- (2) As regards clopyralid, an application pursuant to Article 6(1) of Regulation (EC) No 396/2005 requesting a modification of the existing MRL was submitted for honey and other apiculture products. As regards difenoconazole, such an application was submitted for rye and wheat. As regards flonicamid, such an application was submitted for potatoes, lettuces and salad plants, spinaches and similar leaves, beans (without pods), cardoons, celeries, Florence fennels and rhubarbs.
- (3) In accordance with Articles 8 and 9 of Regulation (EC) No 396/2005, those applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission. The Commission forwarded the applications, the evaluation reports, and the supporting dossiers to the European Food Safety Authority (the 'Authority').
- (4) The Authority assessed the applications and the evaluation reports, examining 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.

¹ OJ L 70, 16.3.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/396/oj>.

² EFSA 2024. Modification of the existing maximum residue level for clopyralid in honey. EFSA Journal, 22 (1), e8546. <https://doi.org/10.2903/j.efsa.2024.8546>.

- (5) As regards difenoconazole in wheat and rye, the Authority concluded that further consideration by risk managers was required as the overall chronic exposure was considered provisional pending the submission of confirmatory data on possible preferential metabolism/degradation of the four stereo isomers of difenoconazole in plants and animals and the impact of isomerisation on the toxicity of difenoconazole. Since wheat and rye are minor contributors to the overall chronic exposure, and as the Authority confirmed that exceedances are not to be expected even assuming a possible shift in the ratio of its isomers, it is appropriate to establish the new MRL of 0.1 mg/kg proposed by the Authority for difenoconazole in wheat and rye.
- (6) As regards all the proposed modifications to MRLs for clopyralid, difenoconazole and flonicamid 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 those substances. Neither the lifetime exposure to those substances via consumption of all food products that may contain 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.
- (7) Based on the opinions 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.
- (8) Chitosan is approved as a basic substance by Commission Implementing Regulation (EU) 563/2014³. Fat distillation residues and hydrolysed proteins have been renewed as low-risk active substances by Commission Implementing Regulations (EU) 2023/1755⁴ and 2023/1446⁵, respectively. Lavandulyl senecioate has been approved as low-risk active substance by Commission Implementing Regulation (EU) 2020/646⁶.

EFSA 2023. Modification of the existing maximum residue levels for difenoconazole in wheat and rye. EFSA Journal, 21(8), e08207. <https://doi.org/10.2903/j.efsa.2023.8207>.

EFSA 2023. Modification of the existing maximum residue levels for flonicamid in various crops EFSA Journal, 22(1), e8545. <https://doi.org/10.2903/j.efsa.2024.8545>.

³ Commission Implementing Regulation (EU) No 563/2014 of 23 May 2014 approving the basic substance chitosan hydrochloride 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 Commission Implementing Regulation (EU) No 540/2011 (OJ L 156, 24.5.2014, p. 5)
ELI: http://data.europa.eu/eli/reg_impl/2014/563/oj.

⁴ Commission Implementing Regulation (EU) 2023/1755 of 11 September 2023 renewing the approval of the low-risk active substance fat distillation residues in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L 224, 12.9.2023, p. 18)
ELI: http://data.europa.eu/eli/reg_impl/2023/1755/2023-09-12.

⁵ Commission Implementing Regulation (EU) 2023/1446 of 12 July 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, calcium carbide, cymoxanil, dodemorph, ethylene, extract from tea tree, fat distillation residues, fatty acids C7-C20, flonicamid (IKI-220), gibberellic acid, gibberellins, halosulfuron-methyl, hydrolysed proteins, iron sulphate, magnesium phosphide, maltodextrin, metamitron, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, pyrethrins, sulcotriane, tebuconazole and urea (OJ L 178, 13.7.2023, p. 1)
ELI: http://data.europa.eu/eli/reg_impl/2023/1446/oj.

⁶ Commission Implementing Regulation (EU) 2020/646 of 13 May 2020 approving the active substance Lavandulyl senecioate as a low-risk substance 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

The conditions of use of those substances 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 those substances in Annex IV to Regulation (EC) No 396/2005.

- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) 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, III 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*.

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

market, and amending Commission Implementing Regulation (EU) No 540/2011 (OJ L 151, 14.5.2020, p. 3)
ELI: http://data.europa.eu/eli/reg_impl/2020/646/oj