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Subject:	COMMISSION REGULATION (EU) …/… of XXX 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 (Z)-13-hexadecen-11-yn-1-yl acetate, (Z,Z,Z,Z)-7,13,16,19-docosatetraen-1-yl isobutyrate, acrinathrin, azimsulfuron, famoxadone, prochloraz and sodium hypochlorite in or on certain products

Delegations will find attached document D087941/4.

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EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

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 (Z)-13-hexadecen-11-yn-1-yl acetate, (Z,Z,Z,Z)-7,13,16,19-docosatetraen-1-yl isobutyrate, acrinathrin, azimsulfuron, famoxadone, prochloraz and sodium hypochlorite in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

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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 (Z)-13-hexadecen-11-yn-1-yl acetate, (Z,Z,Z,Z)-7,13,16,19-docosatetraen-1-yl isobutyrate, acrinathrin, azimsulfuron, famoxadone, prochloraz and sodium hypochlorite 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/EEC[1], and in particular Article 14(1), point (a), Article 18(1), point (b), and 49(2) thereof,

Whereas:

(1) For acrinathrin, azimsulfuron, famoxadone and prochloraz maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For (Z)-13-hexadecen-11-yn-1-yl acetate, (Z,Z,Z,Z)-7,13,16,19-docosatetraen-1-yl isobutyrate and sodium hypochlorite no specific MRLs are set in Regulation (EC) No 396/2005. As these active substances are not included in Annex IV to that Regulation, the default value of 0,01 mg/kg laid down in Article 18(1), point (b), of that Regulation applies.

(2) The approval of the active substances (Z)-13-hexadecen-11-yn-1-yl acetate and (Z,Z,Z,Z)-7,13,16,19-docosatetraen-1-yl isobutyrate expired on 13 May 2016. The Commission withdrew the approval of those active substances by Commission Implementing Regulations (EU) 2016/638[2] and (EU) 2016/636[3] as the applicants did not submit the confirmatory information by the deadline. The approval of the active substance sodium hypochlorite expired on 31 August 2019 as no application for its renewal had been submitted. For those active substances, the default value of

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

[2] Commission Implementing Regulation (EU) 2016/638 of 22 April 2016 withdrawing the approval of the active substance Z-13-hexadecen-11-yn-1-yl acetate, 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 108, 23.4.2016, p. 28).

[3] Commission Implementing Regulation (EU) 2016/636 of 22 April 2016 withdrawing the approval of the active substance Z,Z,Z,Z-7,13,16,19-docosatetraen-1-yl isobutyrate, 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 108, 23.4.2016, p. 22).

0,01 mg/kg laid down in Article 18(1), point (b), of Regulation (EC) No 396/2005 applies. MRLs for all products of those active substances because of the specific analytical methods applicable should be set at the product specific limit of determination ('LOD') in Annex V to that Regulation.

(3) The approval of the active substance acrinathrin expired on 31 December 2021 as the applicant withdrew the application for its renewal. All existing authorisations for plant protection products containing that active substance have been revoked. No MRLs based on Codex maximum residue limits ('CXLs') or import tolerance requests exist for acrinathrin. It is therefore appropriate to delete the MRLs set out for that active substance in Annex II to Regulation (EC) No 396/2005 in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1), point (a), thereof. MRLs for all products should be set at the product specific LOD in Annex V to that Regulation. Additionally, as the MRLs on all products are set at the product specific LODs, there is no longer a need for confirmatory data. Therefore, all footnotes containing requests for confirmatory data should be deleted.

(4) The approval of the active substance azimsulfuron expired on 31 December 2021 as no application for its renewal had been submitted. All existing authorisations for plant protection products containing that active substance have been revoked. No MRLs based on CXLs or import tolerance requests exist for azimsulfuron. It is therefore appropriate to delete the MRLs set out for that active substance in Annex II to Regulation (EC) No 396/2005 in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1), point (a), thereof. MRLs for all products should be set at the product specific LOD in Annex V to that Regulation.

(5) The approval of the active substance famoxadone expired on 9 September 2021 as the Commission did not renew the approval. All existing authorisations for plant protection products containing that active substance have been revoked. No MRLs based on import tolerance requests exist. MRLs based on CXLs exist. The European Food Safety Authority ('the Authority') published on 30 March 2023 a statement on the targeted risk assessment for famoxadone[4]. In the statement, the Authority assessed the CXLs in the light of the lowered toxicological reference values that were established after the non-renewal of approval of the active substance famoxadone by Commission Implementing Regulation (EU) 2021/1379[5]. The Authority recommended lowering the MRL of famoxadone in or on table grapes as it could not be excluded that the acute reference dose would be exceeded. MRLs for wine grapes, potatoes, tomatoes, cucumbers, courgettes, barley, wheat, swine (muscle, fat, liver, kidney, edible offal (other than liver and kidney)), bovine (muscle, fat, liver, kidney, edible offal (other than liver and kidney)), sheep (muscle, fat, liver, kidney, edible offal (other than liver and kidney)), goat (muscle, fat, liver, kidney, edible offal (other than liver and kidney)), equine (muscle, fat, liver, kidney, edible offal (other than liver and kidney)), other farmed terrestrial animals (muscle, fat, liver, kidney, edible offal (other than liver and kidney)), poultry, milk and birds eggs were based on CXLs that the

[4] European Food Safety Authority; Statement on the targeted risk assessment for famoxadone. EFSA Journal 2023;21(3):7932.

[5] Commission Implementing Regulation (EU) 2021/1379 of 19 August 2021 concerning the non-renewal of approval of the active substance famoxadone, 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 297, 20.8.2021, p. 32).

Authority had confirmed are safe for consumers. Those MRLs should be maintained at the existing levels according to Article 3(2), point (g), and Article 14 (2), points (a), (c) and (e), of Regulation (EC) No 396/2005. For aubergines/eggplants, gherkins, melons, broccoli, cauliflowers, leeks, oat, rye and herbal infusions from flowers for which the MRLs were based on uses in the EU are no longer authorized, it is therefore appropriate to lower the existing MRLs set out for famoxadone in Annex II to Regulation (EC) No 396/2005 to the product specific LOD in accordance with Article 17 of that Regulation, in conjunction with Article 14(1), point (a) and (2) thereof. Additionally, for the avoidance of doubt, the footnote indicating lack of information on analytical methods should be deleted.

(6) The approval of the active substance prochloraz expired on 31 December 2021 as no application for its renewal had been submitted. All existing authorisations for plant protection products containing that active substance have been revoked. No MRLs based on import tolerance requests exist. MRLs based on CXLs exist but the residue definition differs from the one established by the Codex Alimentarius and confirmatory data has not been submitted to support those MRLs. In addition, the Authority published on 30 August 2023 a statement on the targeted risk assessment for prochloraz[6]. In the statement, the Authority assessed the CXLs and found that it could not be excluded that the acute reference dose would be exceeded for granate apples/pomegranates and papayas. It is therefore appropriate to delete the MRLs set out for that active substance in Annex II to Regulation (EC) No 396/2005 in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1), point (a), thereof. MRLs for all products should be set at the product specific LOD in Annex V to that Regulation in accordance with Article 18(1), point (b), of that Regulation. Additionally, as the MRLs on all products are set at the product specific LODs, there is no longer a need for confirmatory data. Therefore, all footnotes containing requests for confirmatory data should be deleted.

(7) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LODs. For all the active substances covered by this Regulation those laboratories proposed product specific LODs that are analytically achievable.

(8) Through the World Trade Organisation, the trading partners of the Union were consulted on the modified MRLs and their comments have been taken into account.

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

(10) To allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products which have been produced in the Union or imported into the Union before the modified MRLs become applicable and for which information shows that a high level of consumer protection is maintained. This is the case for all products except for famoxadone in or on table grapes and for prochloraz in or on granate apples/pomegranates and papayas.

(11) 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

[6] European Food Safety Authority Statement on the targeted risk assessment for prochloraz. EFSA Journal 2023;21(8):8231.

operators to adapt themselves to the requirements which result from the modification of the MRLs.

(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 V to Regulation (EC) No 396/2005 are 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 … [*Publications Office, please insert date 6 months after the date of entry into force of this Regulation*], except for famoxadone in or on table grapes and prochloraz in or on granate apples/pomegranates and papayas.

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 … [*Publications Office, 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 Commission
The President
Ursula VON DER LEYEN