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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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Subject:	COMMISSION REGULATION (EU) .../... of XXX 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 fosetyl, potassium phosphonates and disodium phosphonate in or on certain products

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Delegations will find attached document D094704/03.

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

**of **XXX****

**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 fosetyl, potassium phosphonates and disodium phosphonate in or on certain products**

(Text with EEA relevance)

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

of **XXX**

## **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 fosetyl, potassium phosphonates and disodium phosphonate 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<sup>1</sup>, and in particular Article 14(1), point (a), thereof,

Whereas:

- (1) For fosetyl, potassium phosphonates and disodium phosphonate, maximum residue levels ('MRLs') were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) The Commission requested the European Food Safety Authority ('the Authority') to conduct a review of all the existing MRLs for fosetyl, potassium phosphonates and disodium phosphonate in accordance with Article 12(1) of Regulation (EC) No 396/2005. As these three active substances degrade to phosphonic acid, it was appropriate to jointly assess their residues.
- (3) Besides their use as active substances in plant protection products, potassium phosphonates are also ingredients in other products of agricultural relevance (e.g., fertilisers, plant strengtheners, manure, soil amendments). Therefore, the authorised treatment of plants with such products may lead to the detection of phosphonic acid residues in pertinent agricultural products, and it is appropriate to consider the contribution of such other uses than for plant protection when setting the relevant MRLs. The Commission therefore requested the Authority to deliver, in accordance with Article 43 of Regulation (EC) No 396/2005, a reasoned opinion on the joint review of MRLs for fosetyl, potassium phosphonates and disodium phosphonate, taking into account also residues from sources other than the use of plant protection products.
- (4) The Authority submitted a reasoned opinion on the joint review of MRLs for fosetyl, disodium phosphonate and potassium phosphonates in accordance with Article 12(1) and Article 43 of Regulation (EC) No 396/2005<sup>2</sup>. In its opinion, it proposed to change the residue definition for enforcement purposes for the three active substances from

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

<sup>2</sup> Reasoned opinion on the joint review of maximum residue levels (MRLs) for fosetyl, disodium phosphonate and potassium phosphonates according to Articles 12 and 43 of Regulation (EC) No 396/2005. EFSA Journal 2021;19(8):6782.

'Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)' to 'phosphonic acid and its salts, expressed as phosphonic acid', and proposed new MRLs based on that residue definition. The Commission considers it appropriate to establish this new residue definition and to set the MRLs at the level identified by the Authority accordingly.

- (5) The Commission was informed by representatives of official laboratories and food business operators that residues of the parent substance 'fosetyl' may be found in some crops in certain circumstances and that if 'fosetyl' was to be deleted from the residue definition for enforcement purposes for the three active substances, this would have the unintended consequence that the default MRL of 0.01 mg/kg would apply to those residues.
- (6) Therefore, findings of fosetyl should not be considered and the default value of 0.01 mg/kg according to Article 18(1)(b) of Regulation (EC) no 396/2005 does not apply. The MRL for its metabolite phosphonic acid applies.
- (7) The European Union Reference Laboratories noted that the following limits of determination ('LOD') are technically achievable: 0,1 mg/kg in high water and acidic plant origin matrices, 0,2 mg/kg in high fat and dry/high starch content plant origin matrices, 0,05 mg/kg in milk, 0,2 mg/kg in fat and 0,5 mg/kg in liver, kidney and muscle. Nevertheless, in view of the persistence of the residues of these substances, and of the potential multitude of residue sources, it was considered appropriate to maintain the existing lowest MRL at 2 mg/kg, adjusted to a level of 1,5 mg/kg as to take into account the revised residue definition. For teas, coffee, herbal infusions, cocoa and carobs, a lowest MRL of 20 mg/kg is appropriate to take into account the occurrence of phosphonic acid from such other sources.
- (8) The Authority concluded that concerning the MRLs for oranges, grapefruits, apples, pears, pineapples, cucurbits with inedible peel and dry peas, some information concerning residue trials was not available and that therefore further consideration by risk managers was required whether or not those MRLs could be set. As there is no risk for consumers, those MRLs should be set. The MRLs for those products will therefore be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (9) The Authority concluded that concerning the MRLs for dates, figs, kumquats, carambolas, jambuls/jambolans, litchis/lychee, passionfruits/maracujas, prickly pears/cactus fruits, star apples/cainitos, America persimmons/Virginia kaki, papayas, cherimoyas, guavas, breadfruits, durians, soursops/guanabanas, cassava roots/manioc, yams, arrowroots, Jerusalem artichokes, parsnips, parsley roots/Hamburg roots parsley, salsifies, swedes/rutabagas, turnips, okra/lady's fingers, grape leaves and similar species, watercress, fresh beans (without pods), fresh lentils, cardoons, celery, fennel, bamboo shoots, palm hearts, mosses and lichens, algae and prokaryotes organisms, dry lentils, dry peas, dry lupins, oilseeds, oil palms kernel, oil palms fruits, kapok, barley, maize/corn, common millet/proso millet, oat, sorghum, coffee beans, herbal infusions (from flowers, roots), cocoa beans, carobs, spices (bark, roots and rhizome, buds, flower pistil, aril), sugar beet roots and sugar canes, some information concerning monitoring data was not available and that therefore further consideration by risk managers was required whether or not those MRLs could be set. As there is no risk for consumers, those MRLs should be set. The MRLs for those products will be reviewed; the review will take into account the information available within five years from the publication of this Regulation.

- (10) The Authority concluded that concerning the MRL for potatoes, some information concerning processing studies on process waste and dried pulp was not available and that therefore further consideration by risk managers was required whether or not this MRL could be set. As there is no risk for consumers, this MRL should be set. The MRL for potatoes will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (11) In its reasoned opinion, the Authority did not recommend specific MRLs for the categories 'others' of the various groups of plant and animal products. In view of the persistence of the residues of these substances, and of the potential multitude of residue sources, it is therefore appropriate to set those MRLs to the lowest MRL applicable to one of the products within that same product group.
- (12) As regards the MRL for 'Solanaceae and Malvaceae, others', one Member State informed the Commission that an authorisation for fosetyl for the group of fruiting vegetables of Solanaceae exists in its national territory. Therefore, it is therefore appropriate to set that MRL at 70 mg/kg accordingly.
- (13) As regards the MRL for 'lettuces and salad plants, others' one Member State informed the Commission that an authorisation for those substances for the group of lettuces and salad plants exists in its national territory. Therefore, it is therefore appropriate to set that MRL at 150 mg/kg accordingly.
- (14) In its reasoned opinion, the Authority did not recommend specific MRLs for the categories 'edible offals (other than liver and kidney)' of the various groups of animal products. To ensure that those MRLs are established at a realistic level, it is appropriate to set them to the highest MRL applicable to one of the products within that same product group.
- (15) In its reasoned opinion, the Authority did not recommend specific MRLs for the group 'other farmed terrestrial animals'. Since those MRLs are usually set at the same values as for the group 'bovine', it is therefore appropriate to set those MRLs accordingly.
- (16) As no risk for consumers was identified, the MRLs for fosetyl, potassium phosphonates and disodium phosphonate should be set in Annex II to Regulation (EC) No 396/2005.
- (17) While the assessment of fosetyl, disodium phosphonate and potassium phosphonates according to Article 12(1) and Article 43 of Regulation (EC) No 396/2005 was ongoing, and before the proposed new enforcement residue definition was legally established, several applications pursuant to Article 6(1) of Regulation (EC) No 396/2005 requesting modifications of the existing MRLs for fosetyl, potassium phosphonates and disodium phosphonate were submitted for citrus fruits, apricots, cherries, plums, chards/beet leaves, herbal infusions from leaves and herbs, and honey.
- (18) In accordance with Articles 8 and 9 of Regulation (EC) No 396/2005, the Member States concerned evaluated all those applications and forwarded the evaluation reports to the Commission.
- (19) 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 MRLs<sup>3</sup>. It forwarded its reasoned opinions to the applicants, the Commission and the Member States and made it available to the public.

- (20) In its reasoned opinions, the Authority concluded that the data submitted by the applicant concerning those active substances in apricots was insufficient to set a new MRL. As regards the other products, the Authority concluded that risk management considerations were required to establish the appropriate MRLs in view of the residue definition for enforcement that was established. As the Authority proposed to change the residue definition for enforcement purposes for the three active substances from ‘Fosetyl-Al (sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl)’ to ‘phosphonic acid and its salts, expressed as phosphonic acid’, it is appropriate to set the new MRLs based on that residue definition.
- (21) In addition, as the assessments were performed in parallel and were based on different Good Agricultural Practices and datasets, in certain of its reasoned opinions the Authority proposed diverging MRL values for the same product. Therefore, the Commission required additional guidance from the Authority on the appropriate MRLs to be considered for fosetyl, potassium phosphonates and disodium phosphonate for cases when different values were derived in separate reasoned opinions, and considering the new residue definition for enforcement ‘phosphonic acid and its salts, expressed as phosphonic acid’ proposed by the Authority. The Authority was also requested to re-assess the MRL for fosetyl in kiwi fruits (green, red, yellow), that was recently established by Commission Regulation (EU) 2022/1324<sup>4</sup> in view of the proposed new residue definition.
- (22) The Authority submitted a scientific statement<sup>5</sup> on the MRLs for fosetyl, disodium phosphonate and potassium phosphonates in accordance with Article 31 of Regulation (EC) No 178/2002<sup>6</sup>, for all the products that were covered by the relevant reasoned opinions, with the exception of apricots for which the Authority previously concluded that the provided data was insufficient to set a new MRL.
- (23) In its statement, the Authority concluded that for all modifications to the MRLs for those substances, requested by the applicants for citrus fruits, cherries, plums,

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<sup>3</sup> Reasoned Opinion on the modification of the existing MRLs for potassium phosphonates in lemons, limes and mandarins and in herbal infusions from leaves and herbs. EFSA Journal 2021;19(6):6673.

Reasoned Opinion on the modification of the existing maximum residue levels for fosetyl/phosphonic acid in citrus fruits resulting from the use of potassium phosphonates. EFSA Journal 2021;19(11):6926.

Reasoned Opinion on the modification of the existing maximum residue levels for fosetyl/phosphonic acid in chards/beet leaves and honey resulting from the use of potassium phosphonates. EFSA Journal 2022;20(1):6992.

Reasoned Opinion on the modification of the existing maximum residue levels for fosetyl/phosphonic acid in apricots, cherries and plums resulting from the use of potassium phosphonates. EFSA Journal 2022;20(1):7106.

<sup>4</sup> Commission Regulation (EU) 2022/1324 of 28 July 2022 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 benzovindiflupyr, boscalid, fenazaquin, fluazifop-P, flupyradifurone, fluxapyroxad, fosetyl-Al, isofetamid, metaflumizone, pyraclostrobin, spirotetramat, thiabendazole and tolclofos-methyl in or on certain products (OJ L 200, 29.7.2022, p. 68, ELI: <http://data.europa.eu/eli/reg/2022/1324/oj>).

<sup>5</sup> Scientific statement on the maximum residue levels for potassium phosphonates. EFSA Journal 2022;20(7):7400.

<sup>6</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>).

chards/beet leaves, herbal infusions from leaves and herbs, and honey, 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 the substances. Neither the lifetime exposure to these 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 are exceeded.

- (24) Subsequently, another application pursuant to Article 6(1) of Regulation (EC) No 396/2005 requesting modifications of the existing MRLs for those active substances was submitted for leeks and spring onions/green onions/Welsh onions.
- (25) In accordance with Articles 8 and 9 of Regulation (EC) No 396/2005, the Member State concerned evaluated this application and forwarded the evaluation report to the Commission.
- (26) The Authority assessed the application and the evaluation report. It examined in particular the risks to consumers and, where relevant, to animals, and gave a reasoned opinion on the proposed MRLs<sup>7</sup>. It forwarded its reasoned opinion to the applicant, the Commission and the Member States and made it available to the public.
- (27) In its reasoned opinion, the Authority concluded that for all modifications to the MRLs for those substances requested by the applicant 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 the substances. Neither the lifetime exposure to these 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 are exceeded.
- (28) Based on the reasoned opinions and the statement 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.
- (29) 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.
- (30) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (31) For all active substances covered by this Regulation, in order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been placed on the market in the Union before the modification of the MRLs and for which a high level of consumer protection is maintained.
- (32) 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 result from the amendments.

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<sup>7</sup> Reasoned Opinion on the modification of the existing maximum residue levels in leeks and spring onions/green onions/Welsh onions resulting from the use of potassium phosphonates. EFSA Journal 2023;21(5):8033.

(33) 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 III 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 placed on the market in the Union before ... [*Office of Publications, please insert date 6 months after date of entry into force of this Regulation*].

*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 Office, please insert date 6 months after 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*