EUROPEAN
COMMISSION

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COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azinphos-methyl, bentazone, dimethomorph, fludioxonil, flufenoxuron, oxadiazon, phosalone, pyraclostrobin, repellants: tall oil and teflubenzuron in or on certain products

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(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)(a), Article 18(1)(b) and Article 49(2) thereof,

Whereas:

(1) For bentazone, dimethomorph, fludioxonil, pyraclostrobin and teflubenzuron, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For azinphos-methyl, MRLs were set in Annex II and Part B of Annex III to that Regulation. For flufenoxuron, oxadiazon and phosalone, MRLs were set in Part A of Annex III to that Regulation. Repellants: tall oil was included in Annex IV to that Regulation.

(2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance bentazone on potatoes, leeks, herbal infusions from leaves and herbs, poppy seeds and soyabeans, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.

(3) As regards dimethomorph, such an application was submitted for blackberries and raspberries. As regards fludioxonil, such an application was submitted for strawberries and rhubarbs. As regards pyraclostrobin, such an application was submitted for table grapes, sweet corn and coffee beans. As regards teflubenzuron, such an application was submitted for apples, Brussels sprouts and head cabbages.

(4) In accordance with Article 8 of Regulation (EC) No 396/2005, those applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission.

(5) The European Food Safety Authority ('the Authority') assessed the applications and the evaluation reports, examining in particular the risks to the consumer and, where relevant, to animals and gave reasoned opinions on the proposed MRLs[2]. It forwarded

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

[2] EFSA scientific reports available online: http://www.efsa.europa.eu:

Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for bentazone. EFSA Journal 2019;17(5):5704.

those opinions to the applicants, the Commission and the Member States and made them available to the public.

(6) As regards bentazone, the applicant submitted information previously unavailable during the review conducted in accordance with Article 12 of Regulation (EC) No 396/2005. That information concerns residue trials, analytical methods, storage stability and a feeding study. Based on the new information, the Authority recommended lowering the MRLs for potatoes and products of animal origin and increasing the MRL for herbal infusions from leaves and herbs. For leeks, the missing information on residue trials was not submitted. It is therefore appropriate to delete the MRL set out for leeks in Annex II to Regulation (EC) No 396/2005.

(7) As regards dimethomorph, the applicant submitted such previously unavailable information on residue trials. Based on the new information, the Authority recommended lowering the MRLs for blackberries and raspberries to the relevant limit of determination (LOD).

(8) As regards fludioxonil, the applicant submitted such previously unavailable information on residue trials and a feeding study. Based on the new information, the Authority recommended lowering the MRLs for products of animal origin to the relevant LOD.

(9) As regards pyraclostrobin, the applicant submitted such previously unavailable information on residue trials and analytical methods. Based on the new information, the Authority identified an intake concern in relation to the current use of that active substance on table grapes. Member States were consulted to report potential fall-back Good Agricultural Practices (GAPs) that would not lead to an unacceptable risk for consumers. Member States identified a fall-back GAP for table grapes for which the MRL should be set at 0.3 mg/kg.

(10) As regards teflubenzuron, the applicant submitted such previously unavailable information on hydrolysis, metabolism and analytical methods. Based on the new information, the Authority recommended lowering the MRLs for products of animal origin to the relevant LOD.

(11) As regards all other applications, the Authority concluded that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicants were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. It took into account the most recent information on the toxicological properties of the substances. Neither

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Reasoned opinion on the modification of the existing maximum residue levels for bentazone in soyabeans and poppy seeds. EFSA Journal 2019;17(7):5798.

Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for dimethomorph. EFSA Journal 2018;16(10):5433.

Reasoned opinion on the modification of the existing maximum residue levels for fludioxonil in rhubarbs. EFSA Journal 2019;17(9):5815.

Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for fludioxonil. EFSA Journal 2019;17(9):5812.

Reasoned opinion on the modification of the existing maximum residue level for pyraclostrobin in sweet corn. EFSA Journal 2019;17(10):5841.

Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for pyraclostrobin. EFSA Journal 2018;16(11):5472.

Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for teflubenzuron. EFSA Journal 2018;16(10):5427.

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 showed that there is a risk that the acceptable daily intake or the acute reference dose is exceeded.

(12) The approval of the active substance azinphos-methyl expired on 1 January 2007[3]. The active substance flufenoxuron was non-approved by Commission Implementing Regulation (EU) No 942/2011[4]. The approval of the active substance oxadiazon expired on 31 December 2018[5]. The active substance phosalone was non-approved by the Commission Decision of 22 December 2006[6]. The approval of the active substance tall oil pitch was withdrawn by Commission Implementing Regulation (EU) 2017/1125[7]. The approval of the active substance tall oil crude was withdrawn by Commission Implementing Regulation (EU) 2017/1186[8].

(13) All existing authorisations for plant protection products containing those active substances have been revoked. It is therefore appropriate to delete the existing MRLs set out for those substances in Annexes II and III of Regulation (EC) No 396/2005 in accordance with Article 17 of that Regulation in conjunction with Article 14(1)(a) thereof, except for the MRL for flufenoxuron in tea, which is safe to consumers[9] and corresponds to an import tolerance request from Japan, and the MRLs for azinphos-methyl and phosalone in spices which correspond to Codex limits established on the basis of monitoring data and whose dietary exposure is extremely low[10]. For repellants: tall oil, it is appropriate to remove the entry in Annex IV to Regulation (EC) No 396/2005 and list default values for that substance in Annex V in accordance with Article 18(1)(b) of that Regulation.

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3 Commission Regulation (EC) No 1335/2005 of 12 August 2005 amending Regulation (EC) No 2076/2002 and Decisions 2002/928/EC, 2004/129/EC, 2004/140/EC, 2004/247/EC and 2005/303/EC as regards the time period referred to in Article 8(2) of Council Directive 91/414/EEC and the continued use of certain substances not included in its Annex I (OJ L 211, 13.8.2005, p. 6).

4 Commission Implementing Regulation (EU) No 942/2011 of 22 September 2011 concerning the non-approval of the active substance flufenoxuron, 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 Decision 2008/934/EC (OJ L 246, 23.9.2011, p. 13)

5 Commission Directive 2008/69/EC of 1 July 2008 amending Council Directive 91/414/EEC to include clofentezine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen as active substances (OJ L 172, 2.7.2008, p. 9).

6 Commission Decision of 22 December 2006 concerning the non-inclusion of phosalone in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (OJ L 379, 28.12.2006, p. 127).

7 Commission Implementing Regulation (EU) 2017/1125 of 22 June 2017 withdrawing the approval of the active substance repellents by smell of animal or plant origin/tall oil pitch, 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 163, 24.6.2017, p. 10).

8 Commission Implementing Regulation (EU) 2017/1186 of 3 July 2017 withdrawing the approval of the active substance repellents by smell of animal or plant origin/tall oil crude, 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 171, 4.7.2017, p. 131).

9 Reasoned opinion on the modification of the existing MRL for flufenoxuron in tea (dried leaves and stalks, fermented of Camellia sinensis). EFSA Scientific Report (2009); 267.

10 http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-718-51%252FREPORT%252FFinal%252520Report%252FREP19_PRe.pdf.
Report of the 51st session of the Codex Committee on Pesticide Residues. Appendix III. Macao SAR, P.R. China, 8-13April 2019.

(14) The Commission consulted the European Union reference laboratories as regards the need to adapt certain LODs. Those laboratories concluded that for certain products technical development permits the setting of lower LODs. For the active substances for which all MRLs should be reduced to the relevant LOD, default values should be listed in Annex V in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.

(15) 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.

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

(17) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional measure for products which have been produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.

(18) 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 will result from the modification of the MRLs.

(19) 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, IV 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 [*Office of Publication: please insert date 6 months after entry into force*], except for table grapes treated with pyraclostrobin.

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 Publication: please insert date 6 months after entry into force*].

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