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Subject:	COMMISSION REGULATION (EU) …/… of XXX amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine in or on certain products

Delegations will find attached document D068967/04.

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EUROPEAN
COMMISSION

Brussels, XXX
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[…](2020) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for carbon tetrachloride, chlorothalonil, chlorpropham, dimethoate, ethoprophos, fenamidone, methiocarb, omethoate, propiconazole and pymetrozine 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)(a) and Article 18(1)(b) thereof,

Whereas:

(1) For chlorothalonil, chlorpropham, dimethoate, fenamidone, omethoate, propiconazole and pymetrozine maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For carbon tetrachloride, MRLs were set in Annex II and Part B of Annex III to that Regulation. For ethoprophos and methiocarb, MRLs were set in Part A of Annex III to that Regulation.

(2) The approval of the active substance chlorothalonil was not renewed by Commission Implementing Regulation (EU) 2019/677[2]. The approval of the active substance chlorpropham was not renewed by Commission Implementing Regulation (EU) 2019/989[3]. The approval of the active substance dimethoate was not renewed by Commission Implementing Regulation (EU) 2019/1090[4]. The approval of the active

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1 OJ L 70, 16.3.2005, p. 1.

2 Commission Implementing Regulation (EU) 2019/677 of 29 April 2019 concerning the non-renewal of the approval of the active substance chlorothalonil, 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 114, 30.4.2019, p. 15).

3 Commission Implementing Regulation (EU) 2019/989 of 17 June 2019 concerning the non-renewal of approval of the active substance chlorpropham, 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 160, 18.6.2019, p. 11).

4 Commission Implementing Regulation (EU) 2019/1090 of 26 June 2019 concerning the non-renewal of approval of the active substance dimethoate, 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

substance ethoprophos was not renewed by Commission Implementing Regulation (EU) 2019/344[5]. The approval of the active substance fenamidone was not renewed by Commission Implementing Regulation (EU) 2018/1043[6]. The approval of the active substance methiocarb was not renewed by Commission Implementing Regulation (EU) 2019/1606[7]. The approval of the active substance propiconazole was not renewed by Commission Implementing Regulation (EU) 2018/1865[8]. The approval of the active substance pymetrozine was not renewed by Commission Implementing Regulation (EU) 2018/1501[9].

(3) The active substances carbon tetrachloride and omethoate were never approved in the Union for the use in plant protection products. Temporary MRLs were set for carbon tetrachloride in cereals by Regulation (EC) No 149/2008[10] and omethoate in several products by Regulation (EU) 2017/1135[11].

(4) All existing authorisations for plant protection products containing those active substances have been revoked. It is therefore appropriate to delete the 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.

(5) The Commission consulted the European Union reference laboratories as regards the need to adapt certain limits of determination (LODs). Those laboratories concluded

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market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 173, 27.6.2019, p. 39).

5 Commission Implementing Regulation (EU) 2019/344 of 28 February 2019 concerning the non-renewal of approval of the active substance ethoprophos, 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 62, 1.3.2019, p. 7).

6 Commission Implementing Regulation (EU) 2018/1043 of 24 July 2018 concerning the non-renewal of approval of the active substance fenamidone, 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 188, 25.7.2018, p. 9).

7 Commission Implementing Regulation (EU) 2019/1606 of 27 September 2019 concerning the non-renewal of the approval of the active substance methiocarb, 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 250, 30.9.2019, p. 53).

8 Commission Implementing Regulation (EU) 2018/1865 of 28 November 2018 concerning the non-renewal of approval of the active substance propiconazole, 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 304, 29.11.2018, p. 6).

9 Commission Implementing Regulation (EU) 2018/1501 of 9 October 2018 concerning the non-renewal of approval of the active substance pymetrozine, 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 254, 10.10.2018, p. 4).

10 Commission Regulation (EC) No 149/2008 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto (OJ L 58, 1.3.2008, p. 1).

11 Commission Regulation (EU) 2017/1135 of 23 June 2017 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 dimethoate and omethoate in or on certain products (OJ L 164, 27.6.2017, p. 28).

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 LODs, default values should be listed in Annex V in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.

(6) In accordance with Article 6(2) of Regulation (EC) No 396/2005, an application was submitted for modification of the existing MRL for potatoes together with residue trials and monitoring data. The request was made to account for potential contamination of potatoes above the default MRL of 0.01 mg/kg when stored in facilities with a history of chlorpropham use. The applicant claims that, due to the specific properties of chlorpropham, with the current cleaning operations of these storage facilities remaining residues cannot be fully avoided. The submitted monitoring data confirm the presence of residues of chlorpropham in untreated potatoes.

(7) The Netherlands evaluated that application in accordance with Article 8 of Regulation (EC) No 396/2005 and forwarded the evaluation report to the Commission.

(8) The European Food Safety Authority ('the Authority') assessed the application and the evaluation report, examining in particular risks to consumers and, where relevant, to animals and gave a scientific opinion on the proposed MRL[12]. It forwarded that opinion to the applicant, the Commission and the Member States and made it available to the public.

(9) The Authority concluded in its scientific opinion that the MRLs recommended by the Netherlands either at 0.3 mg/kg or at 0.4 mg/kg 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 substance and considered the presence of 3-chloroaniline, which is formed at conditions reflecting oven-baking of potatoes. Neither the lifetime exposure to chlorpropham via consumption of all food products that may contain it, nor the short-term exposure to chlorpropham and its major metabolite 3-chloroaniline, due to high consumption of potatoes, showed that there is a risk that the acceptable daily intake or the acute reference dose is exceeded.

(10) In light of the Authority's conclusions on risk to consumers, and taking into account that the levels should be set as low as reasonably achievable, the MRL for potatoes should be set at a level of 0.4 mg/kg resulting from the Good Laboratory Practice (GLP) trials and corresponding to the 97.5th percentile of all the sample results. Moreover, as the Authority concluded that the current cleaning practices are inadequate, it is appropriate to provide food business operators with sufficient time to develop and introduce a new cleaning methodology.

(11) This temporary MRL will be reviewed based on monitoring data submitted to the Commission by 31 December 2021 and thereafter by 31 December of each subsequent year. It will allow the Commission to regularly re-assess the situation and gradually reduce the MRL, where appropriate, as implementation of better cleaning

[12] EFSA scientific reports available online: http://www.efsa.europa.eu:
Reasoned Opinion on the setting of temporary maximum residue levels for chlorpropham in potatoes. EFSA Journal 2020;18(6):6061.

methodology progresses. A report on the development and implementation of cleaning practices should be submitted to the Commission together with the monitoring data by 31 December 2021, and updates to it in the subsequent years.

(12) 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.

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

(14) 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.

(15) 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 V 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*.

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