



Brussels, **XXX**  
SANTE/11196/2018 Rev. 1  
[...](2018) **XXX** draft

**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 azoxystrobin, bicyclopyrone, chlormequat, cyprodinil, difenoconazole, fenpropimorph, fenpyroximate, fluopyram, fosetyl, isoprothiolane, isopyrazam, oxamyl, prothioconazole, spinetoram, trifloxystrobin and triflumezopyrim 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 azoxystrobin, bicyclopyrone, chlormequat, cyprodinil, difenoconazole, fenpropimorph, fenpyroximate, fluopyram, fosetyl, isoprothiolane, isopyrazam, oxamyl, prothioconazole, spinetoram, trifloxystrobin and triflumezopyrim 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)(a) thereof,

Whereas:

- (1) On 6 July 2018, the Codex Alimentarius Commission adopted new Codex maximum residue limits (CXLs) for azoxystrobin, bicyclopyrone, chlormequat, cyprodinil, difenoconazole, fenazaquin, fenpropimorph, fenpyroximate, flonicamid, fluopyram, flupyradifurone, quinclorac, fosetyl, imazamox, imazapyr, isoprothiolane, isopyrazam, oxamyl, picoxystrobin, prothioconazole, quinclorac, saflufenacil, spinetoram, tebuconazole, trifloxystrobin and triflumezopyrim<sup>2</sup>.
- (2) Maximum residue levels (MRLs) had been set for those substances in Annexes II and III to Regulation (EC) No 396/2005, except for bicyclopyrone and triflumezopyrim for which no specific MRLs were set nor were those substances included in Annex IV to that Regulation, so the default value of 0.01 mg/kg laid down in Article 18(1)(b) thereof applies.
- (3) In accordance with Article 5(3) of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>3</sup>, where international standards exist or their completion is imminent, they are to be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level

---

<sup>1</sup> OJ L 70, 16.3.2005, p. 1.

<sup>2</sup> [http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-41%252FReport%252FFINAL%252FREP18\\_CACe.pdf](http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-701-41%252FReport%252FFINAL%252FREP18_CACe.pdf).

Joint FAO/WHO food standards programme Codex Alimentarius Commission. Appendix II. Forty-first Session. Rome, Italy, 2-6 July 2018.

<sup>3</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).

of protection from the one determined as appropriate in the Union. Moreover, in accordance with point (e) of Article 13 of that Regulation, the Union is to promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in the Union is not reduced.

- (4) The Union presented a reservation<sup>4</sup> to the Codex Committee on Pesticides Residues on the CXLs proposed for the following pesticide/product combinations: bicyclopyrone (mammalian edible offal); difenoconazole (pome fruit; rice); fenazaquin (all products); fenpropimorph (banana); fenpyroximate (pears; cucumbers; melons; peppers; coffee beans; citrus fruits; animal products); flonicamid (all products); fluopyram (milk; rice; dry peas); flupyradifurone (all products); imazamox (all products); imazapyr (all products); oxamyl (cucumber; summer squash); picoxystrobin (all products); quinclorac (all products); saflufenacil (all products); spinetoram (avocado; animal products); tebuconazole (all products); trifloxystrobin (head cabbages).
- (5) The CXLs for azoxystrobin, bicyclopyrone, chlormequat, cyprodinil, difenoconazole, fenpropimorph, fenpyroximate, fluopyram, fosetyl, isoprothiolane, isopyrazam, oxamyl, prothioconazole, spinetoram, trifloxystrobin and triflumezopyrim, which are not listed in recital 4, should therefore be included in Regulation (EC) No 396/2005 as MRLs except where they relate to products which are not referred to in Annex I to that Regulation or where they are at a lower level than the current MRLs. Those CXLs are safe for consumers in the Union<sup>5</sup>.
- (6) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance potassium phosphonates on blackberries, raspberries, blueberries, currants, gooseberries and elderberries, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs for fosetyl.
- (7) In accordance with Article 8 of Regulation (EC) No 396/2005, that application was evaluated by the Member State concerned and the evaluation report was forwarded to the Commission.
- (8) The European Food Safety Authority ('the Authority') assessed the application and the evaluation report, examining in particular the risks to the consumer and, where relevant, to animals and gave a reasoned opinion on the proposed MRLs<sup>6</sup>. It forwarded that opinion to the applicant, the Commission and the Member State and made it available to the public.
- (9) The Authority concluded that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicant 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 substance. Neither the lifetime exposure to this substance via consumption of all food products that may contain it, 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.

---

<sup>4</sup> European Union comments on Codex Circular Letter CL 2018/39-PR : [https://ec.europa.eu/food/sites/food/files/safety/docs/codex\\_cac\\_41\\_cl\\_2018-39-pr.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/codex_cac_41_cl_2018-39-pr.pdf).

<sup>5</sup> Scientific support for preparing an EU position in the 50th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2018;16(7):5306.

<sup>6</sup> EFSA scientific reports available online: <http://www.efsa.europa.eu>: Reasoned opinion on the modification of the existing maximum residue levels for potassium phosphonates in certain berries and small fruits. EFSA Journal 2018;16(9):5411.

- (10) Based on the reasoned opinion of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (11) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (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 III 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*  
*Jean-Claude JUNCKER*