EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11309/2016 Rev. 1
[…](2016) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, azoxystrobin, cyantraniliprole, cyflufenamid, cyproconazole, diethofencarb, dithiocarbamates, fluazifop-P, fluopyram, haloxyfop, isofetamid, metalaxyl, prohexadione, propaquizafop, pyrimethanil, *Trichoderma atroviride* strain SC1 and zoxamide in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, azoxystrobin, cyantraniliprole, cyflufenamid, cyproconazole, diethofencarb, dithiocarbamates, fluazifop-P, fluopyram, haloxyfop, isofetamid, metalaxyl, prohexadione, propaquizafop, pyrimethanil, *Trichoderma atroviride* strain SC1 and zoxamide 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) thereof,

Whereas:

(1) For azoxystrobin, diethofencarb, fluazifop-P, haloxyfop and pyrimethanil, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For dithiocarbamates, metalaxyl, prohexadione and zoxamide MRLs were set in Annex II and Part B of Annex III to that Regulation. For aminopyralid, cyantraniliprole, cyflufenamid, cyproconazole, fluopyram and propaquizafop, MRLs were set in Part A of Annex III to that Regulation. For isofetamid and *Trichoderma atroviride* strain SC1, no specific MRLs were set nor were those substance 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.

(2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance aminopyralid on maize, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRL.

(3) As regards azoxystrobin, such an application was submitted for rhubarb, linseeds, safflower seeds and borage seeds. As regards cyantraniliprole, such an application was submitted for table grapes, strawberries, beans (without pods), peas (without pods), globe artichokes, herbal infusions from roots, root and rhizome spices. As regards cyflufenamid, such an application was submitted for stone fruits and globe artichokes. As regards cyproconazole, such an application was submitted for pulses, barley and oat. As regards dithiocarbamates, such an application was submitted for persimmons following the use of mancozeb on that product. As regards fluazifop-P, such an application was submitted for pumpkin seeds. As regards fluopyram, such an

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

application was submitted for apricots, peppers, "spinaches and similar leaves", witloof, "herbs and edible flowers", peas (with pods), lentils, other legume vegetables of code 0260990, sesame seeds, sunflower seeds, pumpkin seeds, safflower seeds, borage seeds, hemp seeds, castor beans, barley, buckwheat, oat and sugar beet. As regards metalaxyl, such an application was submitted for grapefruits, oranges, strawberries, Brussels sprouts and "spinaches and similar leaves". As regards prohexadione, such an application was submitted for strawberries. As regards propaquizafop, such an application was submitted for celeriacs, parsnips, parsley roots, radishes, cauliflowers, head cabbages, "lettuces and salad plants", poppy seeds, soyabeans, mustard seeds. As regards pyrimethanil, such an application was submitted for leek. As regards zoxamide, such an application was submitted for "lettuces and salad plants", "spinaches and similar leaves" and "herbs and edible flowers" .

(4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for diethofencarb used on bananas and haloxyfop-P on soyabeans. The applicants claim that the authorised uses of those substances on such crops in South and Central America lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops.

(5) 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.

(6) The European Food Safety Authority, hereinafter '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 those opinions to the Commission and the Member States and made them available to the public.

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

Reasoned opinion on the modification of the existing maximum residue level for aminopyralid in maize. EFSA Journal 2016;14(6):4497 [16 pp.].

Reasoned opinion on the modification of the existing maximum residue levels for azoxystrobin in various crops. EFSA Journal 2016;14(5):4459 [17 pp.].

Reasoned opinion on the modification of the existing maximum residue level for cyantraniliprole in table grapes. EFSA Journal 2016;14(7):4553 [14 pp.].

Reasoned opinion on the modification of the existing maximum residue levels for cyantraniliprole in various crops. EFSA Journal 2015;13(10):4263 [25 pp.].

Reasoned opinion on the modification of the existing maximum residue levels for cyflufenamid in stone fruits and globe artichokes. EFSA Journal 2016;14(6):4519 [14 pp.].

Reasoned opinion on the modification of the existing maximum residue levels for cyproconazole in pulses, barley and oat. EFSA Journal 2016;14(6):4526 [18 pp.].

Reasoned opinion on the setting of import tolerance for diethofencarb in bananas. EFSA Journal 2016;14(8):xxxx [xx pp.].

Reasoned opinion on the modification of the existing maximum residue level for mancozeb (expressed as carbon disulfide) in persimmons. EFSA Journal 2016;14(5):4495 [13 pp.].

Reasoned opinion on the modification of the existing maximum residue levels for fluazifop-P in pumpkin seeds. EFSA Journal 2016;14(5):4486 [14 pp.].

Reasoned opinion on the modification of the existing maximum residue levels for fluopyram in various crops. EFSA Journal 2016;14(6):4520 [27 pp.].

(7) The Authority concluded in its reasoned opinion that, as regards the use of azoxystrobin on rhubarb, the use of fluopyram on sugar beet and the use of propaquizafop on "lettuces and salad plants", the submitted data were not sufficient to set new MRLs. The existing MRLs should therefore be kept.

(8) 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 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.

(9) As regards fluazifop-P, several MRLs were modified by Commission Regulation (EU) 2016/1015[3]. That Regulation lowered the MRL for pumpkin seeds to the relevant limit of determination as of 19 January 2017. In the interest of legal certainty, it is appropriate for the MRL provided for by this Regulation, to apply from the same date.

(10) For cyantraniliprole and isofetamid, the Authority submitted conclusions on the peer review of the pesticide risk assessment of those active substances[4]. In that framework, it recommended to set MRLs covering the representative uses according to good agricultural practices in the Union. The Commission consulted the European Union reference laboratories on the appropriate limits of determination.

(11) The low-risk active substance *Trichoderma atroviride* strain SC1 was approved by Commission Implementing Regulation (EU) 2016/951[5]. The Authority concluded[6] that

---

Reasoned opinion on the setting of import tolerance for haloxyfop-P in soya beans. EFSA Journal 2016;14(7):4551 [15 pp.].

Reasoned opinion on the modification of the existing maximum residue levels for metalaxyl in various crops. EFSA Journal 2016;14(7):4521.

Reasoned opinion on the modification of the existing maximum residue level for prohexadione-calcium in strawberries. EFSA Journal 2016;14(7):4528 [13 pp.].

Reasoned opinion on the modification of the existing maximum residue levels for propaquizafop in various crops. EFSA Journal 2016;14(2):4402 [31 pp.].

Reasoned opinion on the modification of the existing maximum residue level for pyrimethanil in leek. EFSA Journal 2016;14(6):4514 [13 pp.].

Reasoned opinion on the modification of the existing maximum residue levels for zoxamide in various leafy crops. EFSA Journal 2016;14(7):4527 [13 pp.].

[3] Commission Regulation (EU) 2016/1015 of 17 June 2016 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 1-naphthylacetamide, 1-naphthylacetic acid, chloridazon, fluazifop-P, fuberidazole, mepiquat and tralkoxydim in or on certain products (OJ L 172, 29.6.2016, p. 1).

[4] Conclusion on the peer review of the pesticide risk assessment of the active substance cyantraniliprole. EFSA Journal 2014;12(9):3814 [249 pp.].
Conclusion on the peer review of the pesticide risk assessment of the active substance isofetamid. EFSA Journal 2015;13(10):4265 [130 pp.].

[5] Commission Implementing Regulation (EU) 2016/951 of 15 June 2016 approving the low-risk active substance Trichoderma atroviride strain SC1, 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 159, 16.6.2016, p. 6).

as regards the dietary risk assessment for consumers some information was not available and further consideration by risk managers was required. The Standing Committee on Plants, Animals, Food and Feed agreed at its meeting on 19 May 2016 that the substance does not produce relevant metabolites of significant toxicity or at levels leading to an exposure higher than negligible[7]. It is therefore appropriate to include that substance in Annex IV to Regulation (EC) No 396/2005.

(12) Based on the reasoned opinions and the conclusions 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.

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

(14) 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 IV 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 however apply from 19 January 2017 as regards the MRL for fluazifop-P in pumpkin seeds.

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

[6] Conclusion on the peer review of the pesticide risk assessment of the active substance Trichoderma atroviride strain SC1. EFSA Journal 2015;13(4):4092 [33 pp.].

[7] Review report for the active substance *Trichoderma atroviride strain SC1* (SANTE/10389/2016 rev. 1).