



Brussels, **XXX**  
SANTE/12766/2020 Rev. 1  
[...](2021) **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 24-epibrassinolide, *Allium cepa* L. bulb extract, cyflumetofen, fludioxonil, fluroxypyr, sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate 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 24-epibrassinolide, *Allium cepa* L. bulb extract, cyflumetofen, fludioxonil, fluroxypyr, sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate 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 5(1) and Article 14(1)(a) thereof,

Whereas:

- (1) For fludioxonil, fluroxypyr, sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For cyflumetofen, MRLs were set in Part A of Annex III to that Regulation. For 24-epibrassinolide and *Allium cepa* L. bulb extract, no specific MRLs were set in Regulation (EC) No 396/2005 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.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance cyflumetofen on citrus fruits, apricots, peaches, tomatoes, aubergines/eggplants, cucumbers and hops, 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 fludioxonil, such an application was submitted for elderberries. As regards fluroxypyr, such an application was submitted for chives, celery leaves, parsley, thyme, basil and edible flowers. As regards sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate, such an application was submitted for table olives and olives for oil production.
- (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

---

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

relevant, to animals, and gave reasoned opinions on the proposed MRLs<sup>2</sup>. It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.

- (6) As regards all 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.
- (7) In the context of the approval of the active substance 24-epibrassinolide, an MRL application was included in the summary dossier in accordance with Article 8(1)(g) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council<sup>3</sup>. That application was evaluated by the Member State concerned in accordance with Article 11(2) of that Regulation. The Authority assessed the application and delivered a conclusion on the peer review of the pesticide risk assessment of the active substance, where it recommended the inclusion of 24-epibrassinolide in Annex IV to Regulation (EC) No 396/2005<sup>4</sup>.
- (8) *Allium cepa* L. bulb extract has been approved as a basic substance by Commission Implementing Regulation (EU) 2021/81<sup>5</sup>. The conditions of use of the substance are not expected to lead to the presence of residues in food or feed commodities that may pose a risk to the consumer. It is therefore appropriate to include *Allium cepa* L. bulb extract in Annex IV to Regulation (EC) No 396/2005.
- (9) Based on the reasoned opinions and the conclusions of the Authority and taking into account the factors relevant to the matter under consideration, the respective modifications to the MRLs fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.

---

<sup>2</sup> EFSA scientific reports available online: <http://www.efsa.europa.eu>:

Reasoned opinion on the modification of the existing maximum residue levels for cyflumetofen in various crops. EFSA Journal 2021;19(1):6373.

Reasoned opinion on the modification of the existing maximum residue levels for fludioxonil in elderberries. EFSA Journal 2020;18(7):6175.

Reasoned opinion on the modification of the existing maximum residue levels for fluroxypyr in chives, celery leaves, parsley, thyme and basil and edible flowers. EFSA Journal 2020;18(10):6273.

Reasoned opinion on the modification of the existing maximum residue levels for sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate (sodium nitrocompounds) in table olives and olives for oil production. EFSA Journal 2020;18(11):6313.

<sup>3</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

<sup>4</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance 24-epibrassinolide. EFSA Journal 2020;18(6):6132.

<sup>5</sup> Commission Implementing Regulation (EU) 2021/81 of 27 January 2021 approving the basic substance *Allium cepa* L. bulb extract 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 29, 28.1.2021, p. 12).

- (10) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (11) 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*.

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*