



Council of the  
European Union

Brussels, 30 July 2021  
(OR. en)

11127/21

AGRILEG 163  
PESTICIDE 26

#### COVER NOTE

---

From:	European Commission
date of receipt:	28 July 2021
To:	General Secretariat of the Council

---

No. Cion doc.:	D073921/03
Subject:	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 acibenzolar-S-methyl, aqueous extract from the germinated seeds of sweet <i>Lupinus albus</i> , azoxystrobin, clopyralid, cyflufenamid, fludioxonil, fluopyram, fosetyl, metazachlor, oxathiapiprolin, tebufenozide and thiabendazole in or on certain products

---

Delegations will find attached document D073921/03.

---

Encl.: D073921/03



Brussels, **XXX**  
SANTE/10518/2021  
(POOL/E4/2021/10518/10518-EN.docx)  
D073921/03  
[...] (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 acibenzolar-S-methyl, aqueous extract from the germinated seeds of sweet *Lupinus albus*, azoxystrobin, clopyralid, cyflufenamid, fludioxonil, fluopyram, fosetyl, metazachlor, oxathiapiprolin, tebufenozide and thiabendazole 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 acibenzolar-S-methyl, aqueous extract from the germinated seeds of sweet *Lupinus albus*, azoxystrobin, clopyralid, cyflufenamid, fludioxonil, fluopyram, fosetyl, metazachlor, oxathiapiprolin, tebufenozide and thiabendazole 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 acibenzolar-S-methyl, azoxystrobin, cyflufenamid, fludioxonil, fluopyram, metazachlor, oxathiapiprolin, tebufenozide and thiabendazole, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For clopyralid and fosetyl, MRLs were set in Part A of Annex III to that Regulation. For aqueous extract from the germinated seeds of sweet *Lupinus albus*, no specific MRLs were set in Regulation (EC) No 396/2005 nor was that 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 acibenzolar-S-methyl on hazelnuts/cobnuts, beans and peas (with pods), 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 clopyralid, such an application was submitted for wheat, oat and products of animal origin, following uses of clopyralid on cereals, pastures and grasslands. As regards fludioxonil, such an application was submitted for blueberries, cranberries, currants and gooseberries. As regards fosetyl, such an application was submitted for almonds, chestnuts, hazelnuts/cobnuts, pistachios, walnuts, granate apples/pomegranates, herbs and edible flowers, blueberries, gooseberries, currants, garlic, shallots, wine grapes, avocados, table olives, olives for oil production, potatoes, horseradishes, flowering brassica, Chinese cabbages, kales, spinaches, wheat and products of animal origin following uses of potassium phosphonates. As regards metazachlor, such an application was submitted for horseradishes, swedes, turnips and bovine liver. As regards oxathiapiprolin, such an application was submitted for hops.

---

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

As regards tebufenozide, such an application was submitted for apricots and peaches. As regards thiabendazole, such an application was submitted for citrus fruits and witloofs/Belgian endives.

- (4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 applications for import tolerances were submitted for azoxystrobin used in the United States on sugar beet roots, cyflufenamid used in the United States on hops, fluopyram used in the United States on soyabeans, oxathiapiprolin used in China on grapes and in Canada and the United States on citrus fruits, blackberries, dewberries, raspberries, Chinese cabbage, basil and edible flowers, asparagus, potatoes, sweet potatoes, bulb vegetables, “Solanaceae and Malvaceae”, cucurbits, flowering brassica, Brussels sprouts, head cabbages, “lettuces and salad plants”, “spinaches and similar leaves”, peas (with and without pods), leeks and ginseng, and thiabendazole used in the United States on sweet potatoes and in Guatemala, Belize, Honduras, Panama, Dominican Republic, Nicaragua and Costa Rica on mangoes. The applicants state that the authorised uses of those substances on such crops in those countries 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 ('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<sup>2</sup>. It forwarded

---

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

Reasoned opinion on the modification of the existing maximum residue level for acibenzolar- S-methyl in hazelnuts. EFSA Journal 2019;17(6):5705.

Reasoned opinion on the modification of the existing maximum residue levels for acibenzolar- S-methyl in beans with pods and peas with pods. EFSA Journal 2021;19(2):6430.

Reasoned opinion on the setting of import tolerance for azoxystrobin in sugar beet roots. EFSA Journal 2021;19(2):6401.

Reasoned opinion on the modification of the existing maximum residue levels for clopyralid in various commodities. EFSA Journal 2021;19(1):6389.

Reasoned opinion on the setting of import tolerance for cyflufenamid in hops. EFSA Journal 2021;19(3):6492.

Reasoned opinion on the modification of the existing maximum residue levels for fludioxonil in certain small fruits and berries. EFSA Journal 2021;19(3):6477.

Reasoned opinion on the review of the existing maximum residue levels for fluopyram according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(4):6059.

Reasoned opinion on the modification of the existing maximum residue level for fosetyl/phosphonic acid for potatoes and wheat. EFSA Journal 2019;17(5):5703.

Reasoned opinion on the modification of the existing maximum residue levels for fosetyl/phosphonic acid in various crops. EFSA Journal 2020;18(1):5964.

Reasoned opinion on the modification of the existing maximum residue levels for potassium phosphonates in flowering brassica, Chinese cabbages, kales and spinaches. EFSA Journal 2020;18(5):6122.

Reasoned opinion on the modification of the existing maximum residue levels for potassium phosphonates in various crops. EFSA Journal 2020;18(9):6240.

Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for metazachlor in various commodities. EFSA Journal 2019;17(10):5819.

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

- (7) As regards oxathiapiprolin, the Authority concluded that for dewberries, potatoes, sweet potatoes, Brussels sprouts and peas (without pods), the submitted data was insufficient to set new MRLs. 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. The Authority 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.
- (8) As regards fluopyram, several MRLs were modified by Commission Regulation (EU) 2021/618<sup>3</sup>. That Regulation lowered the MRL for soyabeans as of 6 November 2021. In the interest of legal certainty, it is appropriate for the MRL provided for by this Regulation to apply from the same date.
- (9) In the context of the approval of the active substance aqueous extract from the germinated seeds of sweet *Lupinus albus*, 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>4</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<sup>5</sup>, where it recommended the inclusion of aqueous extract from the germinated seeds of sweet *Lupinus albus* in Annex IV to Regulation (EC) No 396/2005.
- (10) Based on the reasoned opinions and the conclusion 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.
- (11) Regulation (EC) No 396/2005 should therefore be amended accordingly.

---

Reasoned opinion on the modification of the existing maximum residue levels and setting of import tolerances for oxathiapiprolin in various commodities. EFSA Journal 2019;17(7):5759.

Reasoned opinion on the setting of import tolerances for oxathiapiprolin in various crops. EFSA Journal 2020;18(6):6155.

Reasoned opinion on the modification of the existing maximum residue levels for tebufenozide in apricots and peaches. EFSA Journal 2021;19(1):6400.

Reasoned opinion on the modification of the existing maximum residue levels and setting of import tolerances for thiabendazole in various crops. EFSA Journal 2021;19(5):6586.

<sup>3</sup> Commission Regulation (EU) 2021/618 of 15 April 2021 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 diclofop, fluopyram, ipconazole and terbuthylazine in or on certain products (OJ L 131, 16.4.2021, p. 55).

<sup>4</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>5</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance aqueous extract from the germinated seeds of sweet *Lupinus albus*. EFSA Journal 2020;18(7):6190.

(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, 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 apply from 6 November 2021 as regards the MRL for fluopyram in soyabeans.

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*