



Council of the
European Union

Brussels, 16 August 2021
(OR. en)

11268/21

AGRILEG 175
PESTICIDE 33

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	11 August 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

No. Cion doc.:	D073965/03
Subject:	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 flupyradifurone and difluoroacetic acid in or on certain products

Delegations will find attached document D073965/03.

Encl.: D073965/03



Brussels, **XXX**
SANTE/11428/2020
(POOL/E4/2020/11428/11428-EN.docx)
D073965/03
[...](2021) **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 flupyradifurone and difluoroacetic acid 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 flupyradifurone and difluoroacetic acid 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/EEC¹, and in particular Article 14(1)(a) and Article 49(2) thereof,

Whereas:

- (1) For flupyradifurone and difluoroacetic acid, maximum residue levels ('MRLs') were set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance flupyradifurone on strawberries, table olives, okra/lady's fingers, cauliflowers, broccoli, Brussels sprouts, head cabbages, kales, kohlrabies, "lettuces and salad plants", "spinaches and similar (leaves)", "herbs and edible flowers", beans, peas, rapeseeds/canola seeds, mustard seeds and olives for oil production, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs for flupyradifurone and its main metabolite difluoroacetic acid.
- (3) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application for import tolerances was submitted for flupyradifurone used in the United States on citrus fruits, prickly pears/cactus fruits, cotton seeds, sweet corn, barley, maize/corn, sorghum and wheat, in the United States and Canada on tree nuts, pome fruits, grapes, blueberries, "root and tuber vegetables", tomatoes, sweet peppers/bell peppers, aubergines/eggplants, melons, celeries, pulses, peanuts, soybeans and hops, in Brazil on coffee beans, and in Ghana and Ivory Coast on cocoa beans. The applicants state that the authorised uses of that substance on such crops in those countries lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 for flupyradifurone and difluoroacetic acid and that higher MRLs are necessary to avoid trade barriers for the import of those crops.

¹ OJ L 70, 16.3.2005, p. 1.

- (4) In the context of these applications, the applicant submitted to the Rapporteur Member State, the Netherlands, the additional rotational crop field studies and livestock feeding studies within the deadline set under Commission Regulation (EU) 2016/486².
- (5) In accordance with Article 8 of Regulation (EC) No 396/2005, those applications were evaluated by the Netherlands, 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 MRLs³. It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.
- (7) As regards flupyradifurone in prickly pear/cactus fruit, melons, tomatoes and hops, the Authority concluded that the submitted data was insufficient to set new MRLs. As regards flupyradifurone in celeries, an acute intake concern could not be excluded. 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.
- (8) Following the assessment of the additional rotational crop field studies and livestock feeding studies, the Authority recommended raising, lowering or keeping the existing MRLs for flupyradifurone and difluoroacetic acid in rotational crops and products of animal origin. In particular, the Authority suggested lowering the MRLs for flupyradifurone in grape leaves and difluoroacetic acid in maize, cocoa beans and swine liver. These MRLs should be set in Annex II to Regulation (EC) No 396/2005 at the existing levels or the levels identified by the Authority.
- (9) Based on the reasoned opinions 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.

² Commission Regulation (EU) 2016/486 of 29 March 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 cyazofamid, cycloxydim, difluoroacetic acid, fenoxycarb, flumetralin, fluopicolide, flupyradifurone, fluxapyroxad, kresoxim-methyl, mandestrobin, mepanipyrim, metalaxyl-M, pendimethalin and tefluthrin in or on certain products (OJ L 90, 6.4.2016, p. 1).

³ EFSA scientific reports available online: <http://www.efsa.europa.eu>:

Reasoned opinion on the setting of import tolerances, modification of existing maximum residue levels and evaluation of confirmatory data following the Article 12 MRL review for flupyradifurone and DFA. EFSA Journal 2020;18(6):6133.

Reasoned opinion on the modification of the existing maximum residue levels for flupyradifurone and DFA in rapeseeds/canola seeds and mustard seeds. EFSA Journal 2020;18(11):6298.

Reasoned opinion on the modification of the existing maximum residue levels for flupyradifurone and DFA in okra/lady's finger. EFSA Journal 2021;19(5):6581.

- (10) 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.
- (11) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (12) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional measure for products which have been produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.
- (13) 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.
- (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 and III to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to flupyradifurone in grape leaves and difluoroacetic acid in maize, cocoa beans and swine liver, for products which were produced in the Union or imported into the Union before [*Office of Publication: please insert date 6 months after entry into force*].

Article 3

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*] as regards the MRLs for flupyradifurone in grape leaves and difluoroacetic acid in maize, cocoa beans and swine liver.

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