Council of the
European Union

Brussels, 17 January 2017
(OR. en)

5073/17

AGRILEG 10

COVER NOTE

From:	European Commission
date of receipt:	17 January 2017
To:	General Secretariat of the Council
No. Cion doc.:	D48302/02
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 acequinocyl, amitraz, coumaphos, diflufenican, flumequine, metribuzin, permethrin, pyraclostrobin and streptomycin in or on certain products

Delegations will find attached document D48302/02.

Encl.: D48302/02

EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11769/2016
(POOL/E4/2016/11769/11769-EN.doc)
D048302/02
[…](2016) 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 acequinocyl, amitraz, coumaphos, diflufenican, flumequine, metribuzin, permethrin, pyraclostrobin and streptomycin 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 acequinocyl, amitraz, coumaphos, diflufenican, flumequine, metribuzin, permethrin, pyraclostrobin and streptomycin 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 diflufenican and pyraclostrobin, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For amitraz and permethrin, MRLs were set in Annex II and Part B of Annex III to that Regulation. For acequinocyl and metribuzin, MRLs were set in Part A of Annex III to that Regulation. For coumaphos, flumequine and streptomycin, 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.

(2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance acequinocyl on gherkins, 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 diflufenican and metribuzin, such an application was submitted for olives for oil production. As regards pyraclostrobin, such an application was submitted for chards.

(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.

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

(5) 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 applicants, the Commission and the Member States and made them available to the public.

(6) As regards all those 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) Amitraz, flumequine, permethrin and streptomycin are pharmacologically active substances in veterinary medicine. As regards products of animal origin, MRLs should be set in Regulation (EC) No 396/2005 at the same levels as provided for in Commission Regulation (EU) No 37/2010[3] because exposure from use in veterinary medicinal products is expected to be higher than from use in plant protection products. Those MRLs are safe for consumers in the Union[4].

(8) As regards coumaphos, the Authority identified concerns in relation to the chronic risk assessment, which need to be addressed by means of a risk management decision. Taking into account that Regulation (EU) No 37/2010 sets an MRL for coumaphos only in honey and considering the low contribution of that product to the chronic consumer exposure, it is appropriate to set the MRL for honey and other apiculture products in Regulation (EC) No 396/2005 at the same level.

(9) Based on the reasoned opinions 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.

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

---

2 EFSA scientific reports available online: http://www.efsa.europa.eu:
Reasoned opinion on the modification of the existing maximum residue level for acequinocyl in gherkins. EFSA Journal 2016;14(8):4568 [13 pp.].
Reasoned opinion on the modification of the existing maximum residue level for diflufenican in olives for oil production. EFSA Journal 2016;14(10):4585 [15 pp.].
Reasoned opinion on the modification of the existing maximum residue level for metribuzin in olives for oil production. EFSA Journal 2016;14(10):4591 [13 pp.].
Reasoned opinion on the modification of the existing maximum residue level for pyraclostrobin in beet leaves (chards). EFSA Journal 2016;14(8):4552 [14 pp.].

3 Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

4 Reasoned opinion on the setting of maximum residue levels for amitraz, coumaphos, flumequine, oxytetracycline, permethrin and streptomycin in certain products of animal origin. EFSA Journal 2016;14(8):4570 [39 pp.].

(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 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