



**COUNCIL OF
THE EUROPEAN UNION**

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COVER NOTE

from: the European Commission
date of receipt: 26 June 2012
to: Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

No Cion doc.: C(2012) 4302 final

Subject: Commission Regulation (EU) No.../... of 26.6.2012 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for spinosad in or on raspberries

Delegations will find attached Commission document C(2012) 4302 final.

Encl.: C(2012) 4302 final



EUROPEAN COMMISSION

Brussels, 26.6.2012
C(2012) 4302 final

COMMISSION REGULATION (EU) No .../..

of 26.6.2012

amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for spinosad in or on raspberries

(Text with EEA relevance)

COMMISSION REGULATION (EU) No .../..

of 26.6.2012

amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for spinosad in or on raspberries

(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 18(4) thereof,

Whereas:

- (1) For spinosad maximum residue levels (MRLs) are set in Part A of Annex III to Regulation (EC) No 396/2005.
- (2) In accordance with Article 53 of 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/EEC², France notified on 11 May 2012 to the Commission the temporary authorisation of plant protection products containing the active substance spinosad, due to an unexpected outbreak of *Drosophila suzukii*, a danger that was unforeseeable and could not be contained by any other reasonable means. Consequently, France has also notified to the other Member States, the Commission and The European Food Safety Authority, hereinafter "the Authority", in accordance with Article 18(4) of Regulation (EC) No 396/2005 that it has authorised the placing on the market in its territory of raspberries containing pesticide residues exceeding the relevant MRL. Currently, that MRL is set at 0.3.
- (3) France submitted to the Commission an appropriate consumer risk assessment and proposed a temporary MRL on that basis.

¹ OJ L 70, 16.3.2005, p. 1.

² OJ L 309, 24.11.2009, p. 1.

- (4) The Authority assessed the data provided and issued a statement³ on the safety of the proposed temporary MRL.
- (5) The Authority concluded that the use of spinosad on raspberries, as authorised in France, is not likely to result in a consumer exposure exceeding the toxicological reference value and therefore is not expected to pose a public health concern.
- (6) Based on the statement of the Authority and taking into account the factors relevant to the matter under consideration, the appropriate modification to the MRL fulfil the requirements of Article 18(4) of Regulation (EC) No 396/2005.
- (7) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (8) Given that the emergency uses of plant protection products containing spinosad are already authorized by France and the resulting urgent need to ensure a high level of consumer protection, it is appropriate to provide for the MRL by applying the procedure referred to in Article 45(5) of Regulation (EC) No 396/2005.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 396/2005 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the next 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, 26.6.2012

For the Commission
The President
José Manuel BARROSO

³ European Food Safety Authority; Statement on the modification of the existing MRL for spinosad in raspberries. EFSA Journal 2012;10(5):2751 [26 pp.] doi:10.2903/j.efsa.2012.2751 Available online: <http://www.efsa.europa.eu/efsajournal.htm>

ANNEX

In Part A of Annex III to Regulation (EC) No 396/2005, the column for spinosad is replaced by the following:

[For Official Journal: insert table Annex IIIA existing].