# Commission Regulation (EU) No 459/2010 of 27 May 2010 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 certain pesticides in or on certain products (Text with EEA relevance)

## COMMISSION REGULATION (EU) No 459/2010

## of 27 May 2010

## 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 certain pesticides 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 5(1) and Article 14(1) thereof,

Whereas:

(1) For azoxystrobin, cypermethrin, indoxacarb, isoxaflutole, ethephon fenitrothion, lambda-cyhalothrin, methomyl, profenofos, pyraclostrobin, thiacloprid, triadimefon, triadimenol and trifloxystrobin maximum residue levels (MRLs) were set in Annex II and part B of Annex III to Regulation (EC) No 396/2005. For aminopyralid, boscalid, buprofezin, chlorantraniliprole, cyprodinil, difenoconazole, flusilazole, fosetyl, imidacloprid, mandipropamid, metazachlor, prothioconazole, spinetoram, spirotetramat, sulphur and tebuconazole MRLs were set in part A of Annex III to Regulation (EC) No 396/2005.

(2) In the context of a procedure, in accordance with Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[(2)], for the authorisation of the use of a plant protection product containing the active substance azoxystrobin on swedes an application was made under Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRL.

(3) As regards aminopyralid, such an application was made for the use on pastures. In view of that application, it is necessary to modify the existing MRL for bovine kidney because through grazing the pesticide is ingested by cattle. As regards boscalid, such an application was made for the use on gherkins and courgettes. As regards cyprodinil, such an application was made for the use on celeriac. As regards difenoconazole, such an application was made for the use on fennel, parsley, celery leaves and chervil. As regards indoxacarb, such an application was made for the use on cherries and sugar beets. As regards isoxaflutole, such an application was made to change the residue

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definition. As regards fosetyl, such an application was made for the use on radishes. As regards lambda-cyhalothrin, such an application was made for the use on globe artichokes and currants. As regards metazachlor, such an application was made for the use on rapeseed, kale, cabbage, swedes, turnips, and cereals. In view of that application, it is necessary to modify the existing MRLs for liver from bovines, sheep and goats, since rapeseed, kale, cabbage, swedes, turnips, and cereals are used as feed, and residues may end up on forage for these animals. In addition, it is necessary to modify the residue definition on animal products. As regards pyraclostrobin, such an application was made for the use on beetroot, gherkin and courgettes. As regards spirotetramat, such an application was made for the use on plums and cherries. As regards tebuconazole, such an application was made for the use on swedes and turnips. As regards thiacloprid, such an application was made for the use on lambs lettuce, celery and fennel. As regards trifloxystrobin, such an application was made for the use on parsnips, parsley root, salsify, swedes and turnips.

(4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 applications were made for spinetoram on peaches (including nectarines) and apricots. The authorised use of spinetoram on peaches, nectarines and apricots in South Africa, Argentina, Chile, New Zealand and Israel lead to higher residues than the MRL in Annex III to Regulation (EC) No 396/2005. To avoid trade barriers for the importation of peaches, nectarines and apricots, a higher MRL is necessary.

(5) In accordance with Article 8 of Regulation (EC) No 396/2005, these applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission.

(6) 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[(3)]. It forwarded these opinions to the Commission and the Member States and made them available to the public.

(7) The Authority concluded in its reasoned opinions that all requirements with respect to data were met and that the modifications to the MRLs needed 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 these substances, nor the short term exposure due to extreme consumption of the relevant crops showed that there is a risk that the acceptable daily intake (ADI) or the acute reference dose (ARfD) is exceeded. In some cases the Authority considered that a higher MRL was necessary than the MRL proposed by the evaluating Member State. In those cases it is appropriate to allow the higher MRL, as proposed by the Authority, provided that the Authority considered this MRL safe. In other cases the Authority considered that a lower MRL than the MRL proposed by the evaluating Member State was sufficient. In those cases it is appropriate to set the lower MRL.

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(8) In accordance with Article 12(2) of Regulation (EC) No 396/2005 the Authority evaluated the safety of existing MRLs for ethephon[(4)] and concluded that the MRLs for 12 crops could be set higher to take account of existing CXLs.

(9) As regards fenitrothion, the validity of MRLs for cereals expired on 1 June 2009. For the sake of clarity it is appropriate to indicate the lowest limit of analytical determination (LOD) for that pesticide on cereals in Regulation (EC) No 396/2005.

(10) As regards sulphur, the Authority recommended in its conclusion[(5)] not to continue to set MRLs for that pesticide because of its low toxicity. In view of that conclusion it is appropriate to delete the existing MRLs for that pesticide and to include it in Annex IV to Regulation (EC) No 396/2005.

(11) 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 5(1) and Article 14(2) of Regulation (EC) No 396/2005.

(12) On 4 July 2009 the Codex Alimentarius Commission (CAC) adopted CXLs for azoxystrobin, buprofezin, chlorantraniliprole, cypermethrin, flusilazole, imidacloprid, lambda-cyhalothrin, mandipropamid, methomyl, profenofos, prothioconazole, spinetoram, spirotetramate, tebuconazole, triadimefon and triadimenol. These CXLs should be included in Regulation (EC) No 396/2005 as MRLs, with the exception of those CXLs which are not safe for a European consumer group and for which the Union presented a reservation to the CAC.

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

(14) 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*

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 day following that of its publication in the *Official Journal of the European Union*.

The MRLs for ethephon shall apply from 8 June 2010.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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Done at Brussels, 27 May 2010.

*For the Commission*

*The President*

José Manuel BARROSO

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ANNEX

Annexes II, III and IV to Regulation (EC) No 396/2005 are amended as follows:

1. In Annex II the heading ‘Isoxaflutole (sum of isoxaflutole, RPA 202248 and RPA 203328, expressed as isoxaflutole)’ is changed by removing ‘and RPA 203328’; the columns for azoxystrobin, cypermethrin, indoxacarb, ethephon, fenitrothion, lambda-cyhalothrin, methomyl, profenofos, pyraclostrobin, thiacloprid, triadimefon, triadimenol and trifloxystrobin are replaced by the following:

PESTICIDE RESIDUES AND MAXIMUM RESIDUE LEVELS (MG/KG)

| **Code number** | **Groups and examples of individual products to which the MRLs apply[a]** | | **Azoxystrobin** | **Cypermethrin (cypermethrin including other mixtures of constituent isomers (sum of isomers)) (F)** | **Ethephon** | **Fenitrothion (sum of isomers)** | **Indoxacarb as sum of the isomers S and R (F)** | **Lambda-Cyhalothrin (F) (R)** | **Methomyl and Thiodicarb (sum of methomyl and thiodicarb expressed as methomyl)** | **Profenofos (F)** | **Pyraclostrobin (F)** | **Thiacloprid (F)** | **Triadimefon and triadimenol (sum of triadimefon and triadimenol) (F)** | **Trifloxystrobin** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8) | (9) | (10) | (11) | (12) | (13) | (14) | |
| 0100000 | 1. **FRESH OR FROZEN; NUTS** | **FRUIT** | | | | | | | | | | | | |
| 0110000 | (i) **fruit** | **15** | **Citrus** | 2 | 0,05[b] | 0,01[b] | 0,02[b] | **0,2** | 0,02[b] | 0,05[b] | 1 | 0,02[b] | 0,1[b] | 0,3 |
| 0110010 | Grapefruit | | | | | | | | | | | | | |
| 0110020 | Oranges | | | | | | | | | | | | | |
| 0110030 | Lemons | | | | | | | | | | | | | |

**a** For the complete list of products of plant and animal origin to which MRLs apply, reference should be made to Annex I.

**b** Indicates lower limit of analytical determination.

**c** Pesticide-code combination for which the MRL as set in Annex III Part B applies.

(F) = Fat soluble
(R) = The residue definition differs for the following combinations pesticide-code number:
Lambda-Cyhalothrin — code 1000000: Lambda-cyhalothrin, including other mixed isomeric consituents (sum of isomers)
Ethephon 0161030 (+) MRL will be valid until 1 July 2011 pending submission and evaluation of additional residue trials
Ethephon 0401090 (+) MRL will be valid until 1 July 2011 pending submission and evaluation of an additional metabolism study.