# Commission Regulation (EU) No 1138/2013 of 8 November 2013 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bitertanol, chlorfenvinphos, dodine and vinclozolin in or on certain products (Text with EEA relevance)

## COMMISSION REGULATION (EU) No 1138/2013

## of 8 November 2013

## amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bitertanol, chlorfenvinphos, dodine and vinclozolin 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 Articles 14(1)(a) and 18(1)(b) and Article 49(2) thereof,

Whereas:

(1) For bitertanol, chlorfenvinphos and vinclozolin maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For dodine 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 dodine on pome fruits, peaches, apricots, cherries, table olives and olives for oil production an application was made in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.

(3) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was made for dodine on bananas. The applicant claims that the authorised use of dodine on such crops in Northern, Central and South America leads to residues exceeding the MRL authorised under Regulation (EC) No 396/2005 and that a higher MRL is necessary to avoid trade barriers for the importation of bananas.

(4) 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.

(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 these opinions to the Commission and the Member States and made them available to the public.

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(6) The United Kingdom submitted a request to the Authority under Article 43 of Regulation (EC) No 396/2005 to assess the risks the current MRL for bitertanol on bananas may pose, in the light of the acute reference dose (ARfD) for bitertanol, established in October 2010[(3)].

(7) For dodine, the Authority concluded that all requirements with respect to data were met and that the modifications to the MRLs requested by the applicant 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 substance. Neither the lifetime exposure to that substance via consumption of all food products that may contain that substance, nor the short-term exposure due to high consumption of the relevant crops and products showed that there is a risk that the acceptable daily intake (ADI) or the acute reference dose (ARfD) is exceeded.

(8) For bitertanol, the Authority, in its opinion of 21 February 2012, identified an acute health concern for consumers and recommended lowering the MRL for bitertanol on bananas[(4)]. Having identified an acute health concern for consumers as regards bitertanol on bananas, the Authority assessed the safety of the existing MRLs for bitertanol on other crops for which MRLs were set above the limit of determination (LOD). The Authority recommended lowering the MRLs for pome fruit, stone fruit, cucurbits (edible peel) and tomatoes. MRLs for those products should be set at the LOD appropriate for the specific substance/product combination.

(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) All existing authorisations for plant protection products containing the active substances chlorfenvinphos and vinclozolin have been revoked. In accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1)(a) thereof the MRLs set out for those active substances in Annexes II and III should therefore be deleted.

(11) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt the existing LODs for bitertanol, chlorfenvinphos and dodine. Those laboratories concluded that technical development permits the setting of lower LODs for the three substances. In the light of the conclusions of those laboratories, it is appropriate to set lower MRLs.

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

(13) For vinclozolin, the model established by the Authority to assess acute and chronic risk[(5)] shows that a high level of consumer protection is maintained. This Regulation should therefore provide for a transitional arrangement, in order to allow normal marketing, processing and consumption of products which have been lawfully produced before the application of this Regulation.

(14) 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

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to prepare themselves to meet the new requirements which will result from the modification of the MRLs.

(15) 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.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annexes II, III and V to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

*Article 2*

As regards bitertanol in sugar beet (root) of code number 0900010, dodine in cherries of code number 0140020 and vinclozolin in all products, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were lawfully produced before 6 June 2014.

*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 6 June 2014. However, for dodine in table olives of code number 0161030, bananas of code number 0163020 and olives for oil production of code number 0402010, it shall apply from its date of entry into force.

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

Done at Brussels, 8 November 2013.

*For the Commission*

*The President*

José Manuel BARROSO

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ANNEX

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

(1) Annex II is amended as follows:

(a) the column for bitertanol is 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] | **Bitertanol (F)** |
|---|---|---|
| (1) | (2) | (3) |
| 0100000 | 1. **FRUIT FRESH OR FROZEN NUTS** | |
| 0110000 | (i) **Citrus fruit** | **0,01**[b] |
| 0110010 | Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids) | |
| 0110020 | Oranges (Bergamot, bitter orange, chinotto and other hybrids) | |
| 0110030 | Lemons (Citron, lemon, Buddha's hand (*Citrus medica* var. *sarcodactylis*)) | |
| 0110040 | Limes | |
| 0110050 | Mandarins (Clementine, tangerine, mineola and other hybrids tangor (*Citrus reticulata* x *sinensis*)) | |
| 0110990 | Others | |

| | |
|---|---|
| **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 |

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| | | |
|---|---|---|
| 0120000 | (ii) **Tree nuts** | **0,02**[b] |
| 0120010 | Almonds | |
| 0120020 | Brazil nuts | |
| 0120030 | Cashew nuts | |
| 0120040 | Chestnuts | |
| 0120050 | Coconuts | |
| 0120060 | Hazelnuts (Filbert) | |
| 0120070 | Macadamia | |
| 0120080 | Pecans | |
| 0120090 | Pine nuts | |
| 0120100 | Pistachios | |
| 0120110 | Walnuts | |
| 0120990 | Others | |
| 0130000 | (iii) **Pome fruit** | **0,01**[b] |
| 0130010 | Apples (Crab apple) | |
| 0130020 | Pears (Oriental pear) | |
| 0130030 | Quinces | |
| 0130040 | Medlar | [c] |
| 0130050 | Loquat | [c] |
| 0130990 | Others | |
| 0140000 | (iv) **Stone fruit** | **0,01**[b] |
| 0140010 | Apricots | |
| 0140020 | Cherries (Sweet cherries, sour cherries) | |
| 0140030 | Peaches (Nectarines and similar hybrids) | |
| 0140040 | Plums (Damson, greengage, mirabelle, sloe, red date/Chinese date/Chinese jujube (*Ziziphus zizyphus*)) | |

**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