# Commission Regulation (EU) 2016/1003 of 17 June 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 abamectin, acequinocyl, acetamiprid, benzovindiflupyr, bromoxynil, fludioxonil, fluopicolide, fosetyl, mepiquat, proquinazid, propamocarb, prohexadione and tebuconazole in or on certain products (Text with EEA relevance)

## COMMISSION REGULATION (EU) 2016/1003

## of 17 June 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 abamectin, acequinocyl, acetamiprid, benzovindiflupyr, bromoxynil, fludioxonil, fluopicolide, fosetyl, mepiquat, proquinazid, propamocarb, prohexadione and tebuconazole 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) and Article 16(1)(a) thereof,

Whereas:

(1) For abamectin, acetamiprid, bromoxynil, fludioxonil, propamocarb, prohexadione and tebuconazole, maximum residue levels (MRLs) were set in Annex II to Regulation (EC) No 396/2005. For acequinocyl, fluopicolide, fosetyl, mepiquat and proquinazid, MRLs were set in Part A of Annex III to that Regulation. For benzovindiflupyr, no specific MRLs were set nor was that substance 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 abamectin on pome fruits, cucurbits with edible peel, Chinese cabbage, ‘lettuces and salad plants’ of code 0251000, spinaches, beans and peas with pods and celery, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs.

(3) As regards acequinocyl, such an application was submitted for cherries and plums. As regards acetamiprid, such an application was submitted for leafy brassica. As regards bromoxynil, such an application was submitted for chives. As regards fluopicolide, such an application was submitted for blackberries, spinaches and purslanes. As regards fosetyl, such an application was submitted for blackberries, celeriacs and Florence fennels. As regards mepiquat, such an application was submitted for cultivated

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fungi. As regards propamocarb, such an application was submitted for celeriacs, purslanes, chards, celery leaves and Florence fennels. As regards proquinazid, such an application was submitted for currants and gooseberries. As regards tebuconazole, such an application was submitted for rye and wheat.

(4) In accordance with Article 6(2) and (4) of Regulation (EC) No 396/2005 an application was submitted for fludioxonil used on pineapples and prohexadione used on cherries. The applicant claims that the authorised uses of those substances on such crops in the United States lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops.

(5) 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.

(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[(2)]. It forwarded those opinions to the Commission and the Member States and made them available to the public.

(7) The Authority concluded in its reasoned opinion that, as regards the use of abamectin on 'lettuces and salad plants' and spinaches, the submitted data were not sufficient to set new MRLs. The existing MRLs should therefore be kept.

(8) As regards fosetyl on blackberries, the Authority recommended setting an MRL value of 100 mg/kg. In accordance with the existing Union guidelines on extrapolation of MRLs, it is appropriate to set that MRL also for raspberries.

(9) As regards mepiquat, recent monitoring data show that residues occur on untreated cultivated fungi at a level higher than the limit of determination. Such residues result from a cross-contamination with straw lawfully treated with mepiquat. The Authority proposed three different MRLs for those products, to be considered by the risk managers, which were based on the approaches recommended by the Food and Agriculture Organisation of the United Nations (FAO) respectively for the setting of MRLs in spices and of extraneous MRLs[(3)]. As there is no risk to consumers, the MRL for those products should be set in Annex III to Regulation (EC) No 396/2005 at the level corresponding to the 99th percentile of all the sample results. This MRL is set as temporary valid until 31 December 2018. After this date the MRL will be 0,02* mg/kg unless further modified by a Regulation in light of new information provided by 30 April 2018 at the latest.

(10) 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

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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.

(11) For benzovindiflupyr, the Authority submitted a conclusion on the peer review of the pesticide risk assessment of the active substance[4]. In that framework, it recommended to set MRLs covering both the representative uses according to GAPs in the Union and import tolerance requests from Brazil. The Commission consulted the European Union reference laboratories on the appropriate limits of determination.

(12) Based on the reasoned opinions and the conclusion 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.

(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 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, 17 June 2016.

*For the Commission*

*The President*

Jean-Claude JUNCKER

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ANNEX

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

(1) Annex II is amended as follows:

(a) the columns for abamectin, acetamiprid, bromoxynil, fludioxonil, prohexadione, propamocarb and tebuconazole 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[c]** | **Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a) (F) (R)** | **Acetamiprid (R)** | **Bromoxynil and its salts, expressed as bromoxynil** | **Fludioxonil (F) (R)** | **Prohexadione (prohexadione (acid) and its salts expressed as prohexadione-calcium)** | **Propamocarb (Sum of propamocarb and its salts, expressed as propamocarb) (R)** | **Tebuconazole (R)** |
|---|---|---|---|---|---|---|---|---|
| (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8) | (9) |
| 0100000 | **FRUITS, FRESH or FROZEN; TREE NUTS** | | | 0,01[a] | | | 0,01[a] | |
| 0110000 | **Citrus fruits** | 0,0,5 (+) | 0,9 | | 10 | 0,01[a] | | |
| 0110010 | Grapefruits | | | | | | | 5 |
| 0110020 | Oranges | | | | | | | 0,9 |
| 0110030 | Lemons | | | | | | | 5 |
| 0110040 | Limes | | | | | | | 5 |
| 0110050 | Mandarins | | | | | | | 5 |
| 0110990 | Others | | | | | | | 5 |
| 0120000 | **Tree nuts** | | 0,07 | | | 0,01[a] | | 0,05 |

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| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 0120010 | Almonds | 0,02 (+) | | | 0,01[a] | | | |
| 0120020 | Brazil nuts | 0,01[a] | | | 0,01[a] | | | |
| 0120030 | Cashew nuts | 0,01[a] | | | 0,01[a] | | | |
| 0120040 | Chestnuts | 0,01[a] | | | 0,01[a] | | | |
| 0120050 | Coconuts | 0,01[a] | | | 0,01[a] | | | |
| 0120060 | Hazelnuts/ cobnuts | 0,02 (+) | | | 0,01[a] | | | |
| 0120070 | Macadamias | 0,01[a] | | | 0,01[a] | | | |
| 0120080 | Pecans | 0,01[a] | | | 0,01[a] | | | |
| 0120090 | Pine nut kernels | 0,01[a] | | | 0,01[a] | | | |
| 0120100 | Pistachios | 0,01[a] | | | 0,2 | | | |
| 0120110 | Walnuts | 0,02 (+) | | | 0,01[a] | | | |
| 0120990 | Others | 0,01[a] | | | 0,01[a] | | | |
| 0130000 | **Pome fruits** | 0,03 (+) | 0,8 | | 5 | 0,1 | | |
| 0130010 | Apples | | | | | | | 0,3 |
| 0130020 | Pears | | | | | | | 0,3 |
| 0130030 | Quinces | | | | | | | 0,5 |
| 0130040 | Medlars | | | | | [b] | | 0,5 |
| 0130050 | Loquats/ Japanese medlars | | | | | [b] | | 0,5 |
| 0130990 | Others | | | | | | | 0,5 |
| 0140000 | **Stone fruits** | | | | | | | |
| 0140010 | Apricots | 0,02 (+) | 0,8 | | 5 | 0,01[a] | | 0,6 |
| 0140020 | Cherries (sweet) | 0,01[a] | 1,5 | | 5 | **0,4** | | 1 (+) |
| 0140030 | Peaches | 0,02 (+) | 0,8 | | 10 | 0,01[a] | | 0,6 |
| 0140040 | Plums | 0,01[a] (+) | 0,03 | | 5 | 0,01[a] | | 1 |