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#### COVER NOTE

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From:	European Commission
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To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

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No. Cion doc.:	D033914/02
Subject:	COMMISSION REGULATION (EU) No .../. of XXX amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for anthraquinone, benfluralin, bentazone, bromoxynil, chlorothalonil, famoxadone, imazamox, methyl bromide, propanil and sulphuric acid in or on certain products (Text with EEA relevance)

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Delegations will find attached document D033914/02.

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Brussels, **XXX**  
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D033914/02  
[...](2014) **XXX** draft

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

**of **XXX****

**amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for anthraquinone, benfluralin, bentazone, bromoxynil, chlorothalonil, famoxadone, imazamox, methyl bromide, propanil and sulphuric acid in or on certain products**

(Text with EEA relevance)

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

of **XXX**

**amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for anthraquinone, benfluralin, bentazone, bromoxynil, chlorothalonil, famoxadone, imazamox, methyl bromide, propanil and sulphuric acid 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<sup>1</sup>, and in particular Article 5(1), Article 14(1)(a), Article 18(1)(b) and Article 49(2) thereof,

Whereas:

- (1) For bentazone, bromoxynil, chlorothalonil, famoxadone and imazamox, maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For benfluralin and propanil, MRLs were set in Part A of Annex III to that Regulation. For anthraquinone, methyl bromide and sulphuric acid no MRLs are set in Regulation (EC) No 396/2005, and as those active substances are not included in Annex IV to that Regulation, the default value of 0.01 mg/kg laid down in Article 18(1)(b) of that Regulation applies.
- (2) For anthraquinone, the European Food Safety Authority, hereinafter "the Authority", submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) thereof<sup>2</sup>. The non-inclusion of anthraquinone in Annex I to Directive 91/414/EEC is provided for in Commission Decision 2008/986/EC<sup>3</sup>. Considering that the use of anthraquinone is no longer authorised within the Union and no authorised uses in third countries have been notified, it is appropriate to set the MRLs at the specific limit of determination or at the default MRL in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.

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<sup>1</sup> OJ L 070, 16.3.2005, p. 1.

<sup>2</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for anthraquinone according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(6):2761. [6 pp.].

<sup>3</sup> Commission Decision 2008/986/EC of 15 December 2008 concerning the non-inclusion of anthraquinone in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (OJ L 352, 31.12.2008, p. 48).

- (3) For benfluralin, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005<sup>4</sup>. It recommended lowering the MRLs for lettuce, scarole, rocket, witloof, beans (fresh, with pods), beans (fresh, without pods), peas (fresh, with pods), peas (fresh, without pods), lentils, beans (dry), peas (dry), sunflower seeds, rape seeds, barley grain, wheat grain and chicory roots. It recommended keeping the existing MRLs for certain products. It concluded that concerning the MRLs for garlic, tomatoes, cucumbers, melons and peanuts no information was available and that further consideration by risk managers was required. The MRLs for these commodities should be set at the specific limit of determination or at the default MRL as set out in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (4) For bentazone, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof<sup>5</sup>. It proposed to change the residue definition. It recommended lowering the MRLs for garlic, shallots, herbs, beans (fresh, without pods), peas (fresh, with pods), peas (fresh, without pods), peanuts, millet, poultry (meat, fat and liver) and birds' eggs. It recommended keeping the existing MRLs for certain products. It concluded that concerning the MRLs for potatoes, leek, herbal infusions (dried, leaves), swine (meat, fat, liver and kidney), bovine (meat, fat, liver and kidney), sheep (meat, fat, liver and kidney), goat (meat, fat, liver and kidney) and milk (from cattle, sheep and goat), some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for these products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation. It also concluded that concerning the MRLs for spring onions, cucumbers, poppy seeds and soya beans no information was available and that further consideration by risk managers was required. The MRLs for these commodities should be set at the specific limit of determination or at the default MRL as set out in Article 18(1)(b) of Regulation (EC) No 396/2005.
- (5) For bromoxynil, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof<sup>6</sup>. It proposed to change the residue definition. It recommended lowering the MRLs for garlic, onions, shallots, sweet corn, asparagus, leek and linseeds. It recommended keeping the existing MRLs for certain products. It concluded that concerning the MRL for hops some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRL for that product should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. This MRL

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<sup>4</sup> European Food Safety Authority, 2013. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for benfluralin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(6):3278. [33 pp.].

<sup>5</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for bentazone according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(7):2822. [65 pp.].

<sup>6</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for bromoxynil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(8):2861. [41 pp.].

will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

- (6) For chlorothalonil, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof<sup>7</sup>. It concluded that concerning the MRLs for apples, pears, quinces, medlars, loquat, apricots, peaches, table and wine grapes, strawberries, gooseberries, bananas, papayas, potatoes, carrots, celeriac, horseradish, parsnips, parsley root, salsify, turnips, garlic, onions, shallots, spring onions, tomatoes, aubergines, cucumbers, gherkins, courgettes, melons, pumpkins, watermelons, cauliflowers, Brussels sprouts, head cabbages, celery leaves, parsley, beans (fresh, with pods), beans (fresh, without pods), peas (fresh, with pods), peas (fresh, without pods), lentils (fresh), asparagus, celery, leek, cultivated fungi, beans (dry), lentils (dry), peas (dry), lupins (dry), peanuts, barley grain, oat grain, wheat grain, rye grain, hops, swine (meat, fat, liver and kidney), bovine (meat, fat, liver and kidney), sheep (meat, fat, liver and kidney), goat (meat, fat, liver and kidney), poultry (meat, fat and liver), milk (from cattle, sheep and goat) and birds' eggs, some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for these products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (7) For famoxadone, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof<sup>8</sup>. It recommended lowering the MRL for oat grain. It recommended keeping the existing MRLs for certain products. It concluded that concerning the MRLs for rape seeds, swine (meat, fat, liver and kidney), bovine (meat, fat, liver and kidney), sheep (meat, fat, liver and kidney), goat (meat, fat, liver and kidney), poultry (meat, fat and liver), milk (from cattle, sheep and goat) and birds' eggs, some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for these products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.
- (8) For imazamox, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof<sup>9</sup>. It concluded that concerning the MRLs for beans (fresh, with pods), peas (fresh, without pods), beans (dry), lentils (dry), peas (dry) sunflower seeds, rape seeds, soya beans, maize, rice swine (meat, fat, liver and kidney), bovine (meat,

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<sup>7</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for chlorothalonil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(10):2940. [87 pp.].

<sup>8</sup> European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for famoxadone according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(7):2835. [53 pp.].

<sup>9</sup> European Food Safety Authority, 2013. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for imazamox according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(6):3282. [34 pp.].

fat, liver and kidney), sheep (meat, fat, liver and kidney), goat (meat, fat, liver and kidney) and milk (from cattle, sheep and goat), some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, the MRLs for these products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. These MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

- (9) For methyl bromide, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) thereof<sup>10</sup>. The non-inclusion of methyl bromide in Annex I to Directive 91/414/EEC is provided for in Commission Decision 2008/753/EC<sup>11</sup> and confirmed in Commission Decision 2011/120/EU<sup>12</sup>. No authorised uses in third countries have been notified. For methyl bromide the default MRLs cannot be quantified by control laboratories and it is therefore not appropriate to set any MRLs for this substance. However, methyl bromide is naturally transformed into bromide ion, for which MRLs quantifiable by control laboratories are already established.
- (10) For propanil, the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction with Article 12(1) thereof<sup>13</sup>. The non-inclusion of propanil in Annex I to Directive 91/414/EEC is provided for in Commission Decision 2008/769/EC<sup>14</sup> and confirmed in Commission Regulation (EU) No 2011/1078/EU<sup>15</sup>. Considering that the use of propanil is no longer authorised within the Union and no authorised uses in third countries have been notified, it is appropriate to set the MRLs at the limit of determination or at the default MRL in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005. The MRLs set out for propanil in Annex III should therefore be deleted in accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1)(a) thereof.
- (11) For sulphuric acid, the Authority submitted a reasoned opinion in accordance with Article 12(1) thereof<sup>16</sup>. The non-inclusion of sulphuric acid in Annex I to

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<sup>10</sup> European Food Safety Authority, 2013. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for methyl bromide according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(7):3339. [29 pp.].

<sup>11</sup> Commission Decision 2008/753/EC of 18 September 2008 concerning the non-inclusion of methyl bromide in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (OJ L 258, 26.9.2008, p. 68).

<sup>12</sup> Commission Decision 2011/120/EU of 21 February 2011 concerning the non-inclusion of methyl bromide in Annex I to Council Directive 91/414/EEC (OJ L 47, 22.2.2011, p. 19).

<sup>13</sup> European Food Safety Authority, 2013. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for propanil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(6):3280. [22 pp.].

<sup>14</sup> Commission Decision 2008/769/EC of 30 September 2008 concerning the non-inclusion of propanil in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (OJ L 263, 2.10.2008, p. 14).

<sup>15</sup> Commission Implementing Regulation (EU) No 1078/2011 of 25 October 2011 concerning the non-approval of the active substance propanil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 279, 26.10.2011, p. 1).

<sup>16</sup> European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for sulphuric acid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(1):2556. [9 pp.].

Directive 91/414/EEC is provided for in Commission Decision 2008/937/EC<sup>17</sup>. Considering the low toxicity of sulphuric acid the Authority recommended not setting any MRLs. It is therefore appropriate to include sulphuric acid in Annex IV to Regulation (EC) No 396/2005.

- (12) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain limits of determination. As regards several substances, those laboratories concluded that for certain commodities technical development requires the setting of specific limits of determination.
- (13) 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.
- (14) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (15) In order to allow for the normal marketing, processing and consumption of products, this Regulation should provide for a transitional arrangement for products which have been lawfully produced before the modification of the MRLs and for which information shows that a high level of consumer protection is maintained.
- (16) 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 to prepare themselves to meet the new requirements which will result from the modification of the MRLs.
- (17) 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.
- (18) 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, IV and V to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

#### *Article 2*

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 [*Office of Publications please insert date of application of this Regulation*].

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<sup>17</sup> Commission Decision 2008/937/EC of 5 December 2008 concerning the non-inclusion of sulphuric acid in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (OJ L 334, 12.12.2008, p. 88).

*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, however, apply from [*Office of Publication: please insert date 6 months after entry into force*].

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

Done at Brussels,

*For the Commission*  
*The President*  
*José Manuel BARROSO*