Commission Regulation (EU) 2015/400 of 25 February 2015 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 bone oil, carbon monoxide, cyprodinil, dodemorph, iprodione, metaldehyde, metazachlor, paraffin oil (CAS 64742-54-7), petroleum oils (CAS 92062-35-6) and propargite in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2015/400

of 25 February 2015

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(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), Article 18(1)(b) and Article 49(2) thereof,

Whereas:

(1) For iprodione, maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For cyprodinil, metaldehyde, metazachlor and propargite, MRLs were set in Part A of Annex III to Regulation (EC) No 396/2005. For bone oil, carbon monoxide, dodemorph, paraffin oil CAS 64742-54-7 and petroleum oils (CAS 92062-35-6), 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 bone oil the European Food Safety Authority, hereinafter 'the Authority', submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[(2)]. The non-inclusion of bone oil in Annex I to Council Directive 91/414/EEC[(3)] is provided for in Commission Decision 2008/943/EC[(4)]. Considering that the use of bone oil 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 as set out in Article 18(1)(b) of Regulation (EC) No 396/2005.

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(3) For carbon monoxide the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[(5)]. The non-inclusion of carbon monoxide in Annex I to Directive 91/414/EEC is provided for in Commission Decision 2008/967/EC[(6)]. Considering that the use of carbon monoxide 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 as set out in Article 18(1)(b) of Regulation (EC) No 396/2005.

(4) For cyprodinil the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction of Article 12(1) thereof[(7)]. It proposed to change the residue definition for products of animal origin. It recommended lowering the MRLs for medlar, loquat, table and wine grapes, blackberries, raspberries, other small fruits and berries, carrots, horseradish, parsnips, parsley roots, salsify, garlic, shallots, spring onions, beans (without pods), peas (without pods), asparagus, peas (dry) and lupins (dry). It recommended keeping or raising the existing MRLs for certain products. It concluded that concerning the MRLs for almonds, herbal infusions from roots, spices from roots and rhizomes and for all products of animal origin, 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.

(5) For dodemorph the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[(8)]. The inclusion of dodemorph in Annex I to Directive 91/414/EEC is provided for in Commission Directive 2008/125/EC[(9)]. According to Commission Implementing Regulation (EU) No 540/2011[(10)], the use of dodemorph is limited to ornamental plants in glasshouse only. Considering that the use of dodemorph is authorised within the Union only for not edible crops and no authorised uses on edible crops in third countries have been notified, it is appropriate to set the MRLs 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.

(6) For iprodione the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(2) of Regulation (EC) No 396/2005 in conjunction of Article 12(1) thereof[(11)]. It proposed to change residue definition for products of animal origin. It concluded that concerning the MRLs for lemons, almonds, hazelnuts, apples, pears, quinces, medlar, loquat, apricots, cherries, peaches, plums, table and wine grapes, strawberries, blackberries, dewberries, raspberries, blueberries, cranberries, currants, gooseberries, azaroles, kiwi, potatoes, beetroot, carrots, horseradish, parsnips, parsley roots, radishes, garlic, onions, shallots, spring onions, tomatoes, peppers, aubergines, cucumbers, gherkins, courgettes, cucurbits with inedible peel, broccoli, cauliflowers, Brussels sprouts, head cabbages, Chinese cabbages, lambs lettuce, scarole, cress, rocket, lettuce, leaves and sprouts of *Brassica* spp., witloof, herbs, beans (fresh, with pods), beans (fresh, without pods), peas (fresh, with pods), peas (fresh, without pods),

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rhubarb, beans (dry), lentils (dry), peas (dry), linseed, sunflower seeds, wheat, barley, rice, herbal infusions from flowers, herbal infusions from roots, sugar beet and for all products of animal origin, 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. The Authority also concluded that concerning the MRLs for celeriac, swedes, turnips, kale, kohlrabi, land cress, spinach, beet leaves (chard), peas (fresh, without pods), asparagus, celery, fennel, leek, rape seed, herbal infusions from leaves, spices and sugar beets, no information was available and that further consideration by risk managers was required. The MRLs for these products 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.

(7) For metaldehyde the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[(12)]. It recommended lowering the MRLs for strawberries, swedes, asparagus, celery and fennel. It recommended keeping or raising the existing MRLs for certain products. It concluded that concerning the MRLs for potatoes, beetroot, carrots, celeriac, horseradish, Jerusalem artichokes, parsnips, parsley roots, radishes, salsify, turnips, tomatoes, aubergines, flowering, head and leafy *Brassica*, kohlrabi, lettuce and other salad plants, spinach and similar, leeks and globe artichokes, 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. The Authority also concluded that, concerning the MRLs for all products of animal origin, no information was available and that further consideration by risk managers was required. The MRLs for these products 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.

(8) For metazachlor the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[(13)]. It proposed to change the residue definition for risk assessment and enforcement purposes of the products of plant origin, as well as the products of animal origin. It recommended lowering the MRLs for garlic, Brussels sprouts, globe artichokes, leek, linseeds, sunflower seeds, rape seeds, mustard seeds, borage, gold of pleasure and milk. It recommended keeping or raising the existing MRLs for certain products. It concluded that concerning the MRLs for horseradish, radishes, swedes, turnips, flowering brassica, head cabbages, leafy brassica and kohlrabi, 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

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from the publication of this Regulation. The Authority also concluded that concerning the MRLs for oranges, lemons, tree nuts, pome fruits, stone fruits, berries and small fruits, potatoes, rocket and asparagus, no information was available and that further consideration by risk managers was required. The MRLs for these products 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.

(9) For paraffin oil (CAS 64742-54-7) the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[14]. The non-inclusion of paraffin oil (CAS 64742-54-7) in Annex I to Directive 91/414/EEC is provided for in Commission Decision 2009/617/EC[15]. Considering that the use of paraffin oil (CAS 64742-54-7) 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 as set out in Article 18(1)(b) of Regulation (EC) No 396/2005.

(10) For petroleum oils (CAS 92062-35-6) the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[16]. The non-inclusion of petroleum oils (CAS 92062-35-6) in Annex I to Directive 91/414/EEC is provided for in Commission Decision 2009/616/EC[17]. Considering that the use of petroleum oils (CAS 92062-35-6) 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 as set out in Article 18(1)(b) of Regulation (EC) No 396/2005.

(11) For propargite the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[18]. The non-inclusion of propargite in Annex I to Directive 91/414/EEC is provided for in Commission Decision 2008/934/EC[19] and confirmed in Commission Implementing Regulation (EU) No 943/2011[20]. Considering that the use of propargite 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 as set out in Article 18(1)(b) of Regulation (EC) No 396/2005. In accordance with Article 17 of Regulation (EC) No 396/2005 in conjunction with Article 14(1)(a) thereof the MRLs set out for that active substance in Annex III to that Regulation should therefore be deleted.

(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

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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 Plants, Animals, Food and Feed,

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

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 3 October 2015.

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 3 October 2015.

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

Done at Brussels, 25 February 2015.

For the Commission

The President

Jean-Claude JUNCKER