Commission Regulation (EU) No 1127/2014 of 20 October 2014 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 amitrole, dinocap, fipronil, flufenacet, pendimethalin, propyzamide, and pyridate in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) No 1127/2014

of 20 October 2014

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 amitrole, dinocap, fipronil, flufenacet, pendimethalin, propyzamide, and pyridate 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 Articles 18(4) and 49(2) thereof,

Whereas:

(1) For amitrole, flufenacet, pendimethalin, propyzamide and pyridate, maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For dinocap and fipronil, MRLs were set in Part A of Annex III to that Regulation.

(2) For amitrole, the European Food Safety Authority, hereinafter '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[(2)]. The Authority concluded that concerning the MRLs in citrus fruits, almonds, hazelnuts, walnuts, pome fruits, stone fruits, table and wine grapes, currants, gooseberries, table olives and olives for oil production some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. Those MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

(3) For dinocap, 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[(3)]. All existing authorisations for plant protection products containing the active substance dinocap have been revoked. It is therefore appropriate

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to set the MRLs at the specific limit of determination or the level of Codex MRLs which are safe for consumers in the Union. It is also appropriate to change the residue definition.

(4) The Authority indicated that the existing MRLs for dinocap in wine grapes and melons may raise concerns of consumer protection. The MRLs for those 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.

(5) For fipronil, 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[(4)]. It recommended lowering the MRLs for flowering and head brassicas, swine, bovine, sheep and goat fat and liver, swine kidney, poultry liver and eggs. For other products it recommended raising or keeping the existing MRLs.

(6) In accordance with Article 53 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[(5)], Germany notified on 10 February 2012 to the Commission the temporary authorisation of plant protection products containing the active substance fipronil, due to an outbreak of *Elateridae* species, a danger that could not be contained effectively by any other reasonable means. Consequently, Germany also notified the other Member States, the Commission and the Authority in accordance with Article 18(4) of Regulation (EC) No 396/2005 of its request for an increase of the MRL in poultry fat, as potatoes containing fipronil residues compliant with the existing MRL in potatoes may be fed to chicken, leading to residues above the existing MRL in poultry fat.

(7) Germany submitted to the Commission an appropriate consumer risk assessment and proposed temporary MRLs on that basis.

(8) The Authority assessed the data provided and issued a reasoned opinion on the safety of the proposed temporary MRLs in accordance with Article 18(4) of Regulation (EC) No 396/2005[(6)]. It concluded that a potential long-term consumer health risk could not be excluded.

(9) As exposure to residues from different products contributed to the potential long-term consumer health risk, the authorisations for the uses on head cabbage and kale were withdrawn at the request of the authorisation holder.

(10) Commission Regulation (EU) No 212/2013[(7)] entered into force on 1 April 2013, thereby amending Annex I to Regulation (EC) No 396/2005.

(11) The European Commission requested the Authority to recalculate the expected residue levels of fipronil in commodities of animal origin and the consumer exposure resulting from those residue levels, taking into account the withdrawal of authorisations for uses on head cabbage and kale and the amendment of Annex I to Regulation (EC) No 396/2005. The Authority submitted a reasoned opinion on the modification of MRLs following the withdrawal of uses on head cabbage and kale in accordance with Article 43 of Regulation (EC) No 396/2005[(8)]. It concluded that the proposed MRLs are adequately supported by data and no risk for consumers was identified.

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(12) For flufenacet, 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[9]. It recommended lowering the MRLs for swine, bovine, sheep, goat and poultry liver. For other products it recommended raising or keeping the existing MRLs. The Authority concluded that concerning the MRLs in strawberries, blueberries, cranberries, currants and gooseberries some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. Those MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

(13) For pendimethalin, 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[10]. It recommended lowering the MRLs for carrots, legume vegetables (fresh), pulses (dry), peanuts, sunflower seed, soya bean, cotton seed, swine, bovine, sheep, goat and poultry meat and fat, milk and birds' eggs. Taking into account additional information on the good agricultural practice provided by Germany and the Netherlands and as there is no risk for consumers, the MRL for carrots should be set in Annex II to Regulation (EC) No 396/2005 at the existing level. That MRL will be reviewed; the review will take into account the information available within two years from the publication of this Regulation. For other products the Authority recommended raising or keeping the existing MRLs.

(14) The Authority concluded that concerning the MRLs for pendimethalin in strawberries, garlic, onions, shallots, tomatoes, peppers, aubergines, cucurbits with edible and inedible peel, globe artichokes, leek, swine, bovine, sheep and goat liver and kidney, and poultry liver some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. Those MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

(15) The Authority concluded that concerning the MRLs for pendimethalin in witloof, rape seed, herbal infusions (dried, flowers) and spices (fruits and berries) no information was available and that further consideration by risk managers was required. The MRLs for those 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.

(16) The Authority concluded that concerning the MRLs for pendimethalin in horseradish, parsnips and parsley root no information was available and that further consideration by risk managers was required. Taking into account additional information on the good agricultural practices provided by Germany, Latvia and the Netherlands and as there is no risk for consumers, the MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level. Those MRLs will be reviewed;

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

(17) As regards pendimethalin in salsify, herbal infusions (dried, roots), spices (seeds) and caraway, the Authority submitted an opinion concerning MRLs for those products[(11)].

(18) For propyzamide, 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[(12)]. It proposed to change the residue definition. It recommended lowering the MRLs for table and wine grapes, strawberries, cane fruits, blueberries, cranberries, currants, gooseberries, elderberries, salsify, witloof, rhubarb, sunflower seed, rape seed, soya bean, sugar beet (root) and chicory roots. For other products it recommended keeping the existing MRLs.

(19) The Authority concluded that concerning the MRLs for propyzamide in lamb's lettuce, lettuce, escarole, cress, rocket (rucola), leaves and sprouts of brassica, herbs, beans (dry), lentils, peas (dry), swine, bovine, sheep and goat meat, fat, liver and kidney, and ruminant milk some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. Those MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

(20) The Authority concluded that concerning the MRLs for propyzamide in leek and hops no information was available and that further consideration by risk managers was required. The MRLs for those 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.

(21) As regards propyzamide in herbal infusions (dried), the Authority submitted an opinion concerning MRLs for those products[(13)].

(22) For pyridate, 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[(14)]. The Authority concluded that concerning the MRLs in salsify, garlic, onions, shallots, spring onions, sweet corn, flowering brassica, Brussels sprouts, head cabbage, kale, kohlrabi, chives, asparagus, leek, lupins, poppy seed, rape seed, maize, herbal infusions (dried, flowers), herbal infusions (dried, leaves), herbal infusions (dried, roots), spices (seeds), spices (fruits and berries), swine, bovine, sheep and goat meat, fat, liver and kidney, poultry meat, fat and liver, ruminant milk and birds' eggs some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, MRLs for those products should be set in Annex II to Regulation (EC) No 396/2005 at the existing level or the level identified by the Authority. Those MRLs will be reviewed; the review will take into account the information available within two years from the publication of this Regulation.

(23) The Authority concluded that concerning the MRLs for pyridate in globe artichokes, barley, rice and wheat no information was available and that further consideration by

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risk managers was required. The MRLs for those products should be set at the specific limit of or at the default MRL as set out in Article 18(1)(b) of Regulation (EC) No 396/2005.

(24) As regards pyridate in celery leaves (dill leaves), the Authority submitted an opinion concerning the MRL for that product[15].

(25) As regards products for which neither relevant authorisations or import tolerances were reported at Union level nor Codex MRLs were available, the Authority concluded that further consideration by risk managers was required. Taking into account the current scientific and technical knowledge, MRLs for those 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.

(26) 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 Articles 14(2) and 18(4) of Regulation (EC) No 396/2005.

(27) 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.

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

(29) 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.

(30) 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.

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

Article 2

As regards the active substances in and on products, as set out in the following list, 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 13 May 2015:

(1) amitrole: all products;

(2) dinocap: all products except wine grapes and melons;

(3) fipronil, flufenacet, pendimethalin, propyzamide and pyridate: all products.