Commission Regulation (EU) 2016/71 of 26 January 2016 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 1-methylcyclopropene, flonicamid, flutriafol, indolylacetic acid, indolylbutyric acid, pethoxamid, pirimicarb, prothioconazole and teflubenzuron in or on certain products (Text with EEA relevance)

COMMISSION REGULATION (EU) 2016/71

of 26 January 2016

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 1-methylcyclopropene, flonicamid, flutriafol, indolylacetic acid, indolylbutyric acid, pethoxamid, pirimicarb, prothioconazole and teflubenzuron 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), Article 18(1)(b) and Article 49(2) thereof,

Whereas:

(1) For 1-methylcyclopropene and pethoxamid maximum residue levels (MRLs) were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005. For flonicamid, flutriafol, pirimicarb, prothioconazole and teflubenzuron MRLs were set in Part A of Annex III to that Regulation. For indolylacetic acid and indolylbutyric 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 1-methylcyclopropene 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)]. It recommended keeping the existing MRLs.

(3) For flonicamid the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[(3)]. It recommended lowering the MRLs for potatoes, swine muscle and birds' eggs. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for citrus fruits, cherries, plums, tomatoes, aubergines, courgettes, cucurbits with inedible peel, rye, wheat and hops some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, MRLs

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) 2016/71. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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. The Authority concluded that concerning the MRLs for apricots, barley and oats 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.

(4) For flutriafol the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[4]. It recommended lowering the MRLs for cherries, witloof, peanuts, barley grain, rye grain, wheat grain, sugar beet (root). For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for pome fruits, wine grapes, strawberry, beetroot, tomatoes, melons, watermelons, rice grain, swine liver, bovine liver, sheep liver and goat 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. The Authority concluded that concerning the MRLs for sweetcorn, beet leaves (chard), peas (fresh, without pods), lentils (fresh), asparagus, pulses (dry), maize grain and oats grain 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.

(5) For indolylacetic acid the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005. The non-inclusion of indolylacetic acid in Annex I to Council Directive 91/414/EEC[5] is provided for in Commission Decision 2008/941/EC[6]. Considering that the use of indolylacetic acid is no longer authorised within the Union and no authorised uses in third countries have been notified, taking into account the natural levels of indolylacetic acid in plants, it is appropriate to set the MRLs at a level that is not exceeded by natural levels but is still safe for the consumer.

(6) For indolylbutyric acid the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005. Considering that the use of indolylbutyric acid is authorised only for use in non-consumable crops within the Union and no authorised uses in third countries have been notified, taking into account the natural levels of indolylbutyric acid in plants, it is appropriate to set the MRLs at a level that is not exceeded by natural levels but is still safe for the consumer.

(7) For pethoxamid 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[7]. It recommended keeping the existing MRLs.

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) 2016/71. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(8) For pirimicarb 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[8]. It proposed to change the residue definition for plant products, poultry and birds' eggs. It recommended lowering the MRLs for almonds, chestnuts, hazelnuts, walnuts, medlar, loquat, strawberries, elderberries, potatoes, cassava, sweet potatoes, yams, arrowroot, beetroot, carrots, celeriac, horseradish, Jerusalem artichokes, parsnips, parsley root, radishes, salsify, swedes, turnips, garlic, onions, tomatoes, peppers, aubergines, okra, sweetcorn, head cabbage, lettuce, spinach, chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil, bay leaves (laurel), tarragon, peas (fresh, without pods), asparagus, fennel, beans (dry), lentils (dry), peas (dry), lupins (dry), poppy seed, sunflower seed, gold of pleasure, barley grain, buckwheat grain, maize grain, millet grain, oats grain, rye grain, sorghum grain, wheat grain, sugar beet (root), chicory roots, poultry (meat, fat and liver) and birds' eggs. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for apples, pears, quinces, cherries, peaches, blackberries, dewberries, raspberries, melons, watermelons, Brussels sprouts, kale, scarole, beet leaves (chard), witloof, beans (fresh, with pods), peas (fresh, with pods), cardoons, celery, linseed, rape seed, mustard seed, borage, herbal infusions (dry, from flowers, leaves and roots) and for all products of animal origin, except poultry products 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. The Authority indicated that concerning the MRLs for table and wine grapes and spice from fruits and berries no sufficient information was available to derive MRLs, no CXLs are 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. The Authority indicated that also for the MRLs of kohlrabi, beans (fresh, without pods), lentils (fresh) and spice (from seeds) not sufficient information was available to derive MRLs. However, Codex maximum residues limits (CXLs) are available and they do not represent any risk to consumers. In these cases, MRLs should be set at the CXLs. The Authority also indicated that the existing MRLs for cauliflower, broccoli, Chinese cabbage, kale and leek may raise concerns of consumer protection. The MRLs for those products should be set at the level identified by the Authority, which is derived from the existing Codex maximum residues limits (CXLs) and for which no risk to consumers is identified, or at the default MRL as set out in Article 18(1)(b) of Regulation (EC) No 396/2005.

(9) For prothioconazole 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 proposed to change the residue definition for both plant products and for products of animal origin. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for beetroot,

Changes to legislation: *There are outstanding changes not yet made to Commission Regulation (EU) 2016/71. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

carrots, horseradish, parsnips, parsley root, salsify, swedes, turnips, onions, broccoli, cauliflower, Brussels sprouts, head cabbage, leek, beans (dry), lentils (dry), peas (dry), lupins (dry), linseed, peanuts, poppy seed, rape seed, mustard seed, gold of pleasure, barley grain, oats grain, rye grain, wheat grain 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, 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. The Authority also indicated that the existing MRLs for prothioconazole in sugar beet may raise concerns of consumer protection. The MRLs for this product 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. In the context of a procedure for the authorisation of the use of prothioconazole on shallots, an application was submitted in accordance with Article 6(1) of Regulation (EC) No 396/2005 for modification of the existing MRLs. The Authority assessed the application and the evaluation report and recommended raising the existing MRL in its reasoned opinion[10]. On 11 July 2015 the Codex Alimentarius Commission (CAC), adopted a new Codex maximum residue limit (CXL) for cranberry, maize, potato, soya bean (dry) and sweetcorn[11]. These CXLs should therefore be included in Regulation (EC) No 396/2005 as MRLs. These CXLs are safe for consumers in the Union[12].

(10) For teflubenzuron the Authority submitted a reasoned opinion on the existing MRLs in accordance with Article 12(1) of Regulation (EC) No 396/2005[13]. It recommended lowering the MRLs for plums and potatoes. For other products it recommended raising or keeping the existing MRLs. It concluded that concerning the MRLs for apples, tomatoes, Brussels sprouts, head cabbages 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, 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. The Authority concluded that concerning the MRLs for head cabbage some information was not available and that further consideration by risk managers was required. As there is no risk for consumers, MRL for this product should be set in Annex II to Regulation (EC) No 396/2005 at the level of the CXL, which is safe for consumers in the Union.

(11) As regards products of plant and animal origin for which no authorisations, import tolerances or CXLs exist, MRLs should be set at the specific limit of determination or at the default MRL in accordance with Article 18(1)(b) of 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. Based on the reasoned opinions of the Authority and taking into account the factors relevant to

***Changes to legislation:** There are outstanding changes not yet made to Commission Regulation (EU) 2016/71. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

the matter under consideration, the appropriate modifications to the MRLs fulfil the requirements of Articles 14(2) of Regulation (EC) No 396/2005.

(13) 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.

(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 and interested parties to prepare themselves to meet the new requirements which will result from the modification of the MRLs.

(17) 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

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 16 August 2016:

(1) 1-methylcyclopropene, flonicamid, flutriafol, indolylacetic acid, indolylbutyric acid, pethoxamid and teflubenzuron: all products;

(2) pirimicarb: all products, except cauliflower, broccoli, Chinese cabbage, kale and leek;

(3) prothioconazole: all products, except sugar beet.

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 16 August 2016.

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