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STATEMENT

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Pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005

European Food Safety Authority (EFSA)

Abstract

Regulation (EC) No 396/2005 establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. According to Article 12(1) of Regulation (EC) No 396/2005, EFSA shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC a reasoned opinion on the review of the existing MRLs for that active substance. Article 12(2) of that Regulation stipulates that EFSA shall provide by 1 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC before 2 September 2008. Among the active substances that need to be reviewed under Article 12(1) or Article 12(2) of Regulation (EC) No 396/2005, EFSA identified 12 active substances for which a review of MRLs is no longer considered necessary, including five active substances that were already included temporarily in Annex IV of Regulation (EC) No 396/2005 by risk managers pending finalisation of their evaluation under Directive 91/414/EEC or Regulation (EC) No 1107/2009 and pending submission of EFSA's reasoned opinion in accordance with Article 12 of Regulation (EC) No 396/2005. EFSA prepared a statement explaining the reasons why a review of MRLs for these substances became obsolete. The relevant question numbers are considered addressed by this statement.

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Keywords: Regulation (EC) No 396/2005, MRLs, peer review, active substance

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Amendment: An editorial correction that clarifies but does not materially affect the contents or outcome of this scientific output was carried out. To avoid confusion, the older version of the output has been removed from the EFSA Journal, but is available on request.

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Summary

Regulation (EC) No 396/2005 establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. According to Article 12(1) of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC a reasoned opinion on the review of the existing MRLs for that active substance. Article 12(2) of that Regulation stipulates that EFSA shall provide by 1 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC before 2 September 2008.

According to the legal provisions, EFSA shall base its reasoned opinion on the relevant assessment report prepared under Directive 91/414/EEC or Regulation (EC) No 1107/2009. The reasoned opinion should cover all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance, including analytical methods and limit of determination (LOD) for enforcement of the proposed MRLs. All proposed MRLs should accommodate uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. Among the active substances that need to be reviewed under Article 12(1) and 12(2) of Regulation (EC) No 396/2005, EFSA identified 12 active substances for which a review of MRLs is no longer considered necessary, including 5 active substances that were already included temporarily in Annex IV of Regulation (EC) No 396/2005 by risk managers pending finalisation of their evaluation under Directive 91/414/EEC or Regulation (EC) No 1107/2009 and pending submission of EFSA's reasoned opinion in accordance with Article 12 of Regulation (EC) No 396/2005. The general principles for the establishment and update of Annex IV are laid down in Article 5 of Regulation (EC) No 396/2005. Nevertheless, as none of the articles in Regulation (EC) No 396/2005 provides for clear decision-making criteria regarding inclusion of active substances in Annex IV, these criteria were defined in a guidance document of the European Commission.

EFSA prepared a statement explaining the reasons why a review of MRLs for these substances became obsolete, including the EFSA view concerning the Annex IV inclusion where relevant. The corresponding question numbers are considered addressed by this statement. Furthermore, for three active substances, the existing uses were assessed in the framework of the renewal (combined assessment). The list of active substances for which the MRL review was addressed during the renewal is also reported as an Annex to this statement.

The statement was circulated to Member States for consultation via a written procedure before finalisation.

Table of contents

1. Introduction

Regulation (EC) No 396/2005[1] establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at the European level. According to Article 12(1) of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC a reasoned opinion on the review of the existing MRLs for that active substance. Article 12(2) of that Regulation stipulates that EFSA shall provide by 1 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[2] before 2 September 2008. According to the legal provisions, EFSA shall base its reasoned opinion on the relevant assessment report prepared under Directive 91/414/EEC or Regulation (EC) No 1107/2009.[3] The reasoned opinion should cover all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance, including analytical methods and limit of determination (LOD) for enforcement of the proposed MRLs. All proposed MRLs should accommodate uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. According to Article 5(1) of Regulation (EC) No 396/2005 active substances of plant protection products evaluated under Directive 91/414/EEC for which no MRLs are required shall be defined and listed in Annex IV to this Regulation, taking into account the uses of those active substances and the matters referred to in points (a), (c) and (d) of Article 14(2). The general principles for the establishment and update of Annex IV are laid down in Article 5 of Regulation (EC) No 396/2005, which requires that for an active substance which shall be included in Annex IV account should be taken of:

- the use of the active substance;
- the scientific and technical knowledge available;
- the results of an assessment of any potential risks to consumers with a high intake and high vulnerability and, where appropriate, to animals;
- the results of any evaluations and decisions to modify the use of plant protection products.

Nevertheless, as none of the articles in Regulation (EC) No 396/2005 provides for clear decision-making criteria regarding inclusion of active substances in Annex IV, these criteria were defined in a guidance document of the European Commission (2015). According to the decision tree figure 1 outlined in this guidance document, an active substance should comply with one of the following criteria in order to be recommended for inclusion in Annex IV of Regulation (EC) No 396/2005:

- Criterion one: The active substance is approved as a basic substance under Regulation (EC) No 1107/2009
- Criterion two: The compound is listed in Annex I of Regulation (EC) No 396/2005
- Criterion three: The compound has no identified hazardous properties
- Criterion four: Natural exposure is higher than the one linked to the use of plant protection products (PPP)
- Criterion five: No consumer exposure is forecasted linked to the mode of application of the PPP.

Among the active substances that need to be reviewed under Article 12(1) and Article 12(2) of Regulation (EC) No 396/2005, EFSA identified 12 active substances for which a review of MRLs is no longer considered necessary, including 5 active substances that were already included temporarily in Annex IV of Regulation (EC) No 396/2005 by risk managers pending finalisation of their evaluation under Directive 91/414/EEC or Regulation (EC) No 1107/2009 and pending submission of EFSA's reasoned opinion in accordance with Article 12 of Regulation (EC) No 396/2005. EFSA prepared a statement explaining the reasons why a review of MRLs for these substances is no longer considered necessary, including the EFSA view concerning the Annex IV inclusion where relevant. The corresponding question numbers are considered addressed by this statement. Furthermore, for three

[1] 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. OJ L 70, 16.3.2005, p. 1–16.

[2] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

active substances, the existing uses were assessed in the framework of the renewal (combined assessment). The list of active substances for which the MRL review was addressed during the renewal is also reported in an Annex to this statement.

The draft statement was circulated to Member States (MSs) for consultation via a written procedure. Comments received by 10 September 2020 were considered during the finalisation of this statement. The collation of comments received on the draft statement is considered as a background document to this statement and is made publicly available (EFSA, 2020).

2. Assessment

2.1. Substances for which EU-MRLs are established at default values

The MRLs for the following substances are set at the LOD in accordance with Article 18 of Regulation (EC) No 396/2005. For the active substances for which all MRLs are reduced to the relevant LOD, default values are listed in Annex V in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005.

The active substance **aluminium sulphate** is currently authorised according to Commission Implementing Directive (EU) 2011/47/EU.[4] An EFSA conclusion on the peer review of the pesticide risk assessment is available (EFSA, 2010c). No codex maximum residue limits (CXLs) are currently in place for this active substance and all MRLs are currently set at the default value. Therefore, the MRL review for this active substance is considered obsolete.

The active substance **aluminium ammonium sulphate** is currently authorised according to Commission Directive (EU) 2008/127/EC.[5] An EFSA conclusion on the peer review of the pesticide risk assessment is available (EFSA, 2012c). No CXLs are currently in place for this active substance and all MRLs are currently set at the default value. Therefore, the MRL review for this active substance is considered obsolete.

The active substance **diflubenzuron** is currently authorised according to Commission Directive 2008/69/EC.[6] An EFSA conclusion on the peer review of the pesticide risk assessment is available (EFSA, 2012a). Confirmatory data were also assessed by EFSA (2015). Following the peer review of the confirmatory data, diflubenzuron was restricted to uses on non-edible crops by Commission Implementing Regulation (EU) 2017/855,[7] due to the genotoxic potential of its impurity and metabolite 4-chloroaniline (PCA). Following the modification of the condition of approval to non-edible crops, diflubenzuron was included in Annex V of Regulation 396/2005 with MRLs lowered to the relevant LOD by Reg. (EU) 2019/91.[8] Furthermore, the application for the renewal of the approval was withdrawn by the applicant and the approval of diflubenzuron will expire on 31 December 2020. While CXLs are in place for this substance, it is clear from the reasoning that led to restriction to non-edible crops and to the lowering of all MRLs to the LOD, that none of the CXLs are acceptable for reasons of consumer protection. Therefore, the review of MRLs for this substance becomes obsolete.

The active substance **fat distillation residues** was initially included in Annex I to Council Directive 91/414/EEC by Commission Directive 2008/127/EC.[5] An EFSA conclusion on the peer review of the pesticide risk assessment related to the first approval is available (EFSA, 2012b). Since the applicant withdrew the support for the renewal of the approval, the approval of fat distillation residues will expire on 31 August 2021. The MRLs are currently set to the default MRL of 0.01 mg/kg according to Art 18(1)(b) of Regulation (EC) No 396/2005 and no CXLs are currently in place for this active substance. Therefore, the review of MRLs for this substance becomes obsolete.

[4] Commission Implementing Directive 2011/47/EU of 15 April 2011 amending Council Directive 91/414/EEC to include aluminium sulphate as active substance and amending Commission Decision 2008/941/EC. OJ L 102, 16.4.2011, p. 24–27.

[5] Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances. OJ L 344, 20.12.2008, p. 89–111.

[6] Commission Directive 2008/69/EC of 1 July 2008 amending Council Directive 91/414/EEC to include clofentezine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen as active substances. OJ L 172, 2.7.2008, p. 9–14.

[7] Commission Implementing Regulation (EU) 2017/855 of 18 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance diflubenzuron. OJ L 128, 19.5.2017, p. 10–13.

[8] Commission Regulation (EU) 2019/91 of 18 January 2019 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 buprofezin, diflubenzuron, ethoxysulfuron, ioxynil, molinate, picoxystrobin and tepraloxydim in or on certain products. OJ L 22, 24.1.2019, p. 74–85.

The active substance **flufenoxuron** was assessed for a possible inclusion in Annex I to Directive 91/414/EEC. Applicant's withdrawal of support for the active substance led to a decision on non-inclusion of flufenoxuron by Commission Decision of 5 December 2008 (2008/934/EC)[9]. Following the decision on non-inclusion of the active substance in Annex I to Council Directive 91/414/EEC the notifier made a resubmission in accordance with the provisions laid down in Articles 14 to 19 of Commission Regulation (EC) No. 33/2008. An EFSA conclusion on the peer review of the pesticide risk assessment prepared in the framework of the resubmission is available (EFSA, 2011a). Due to concerns related to the potential of flufenoxuron to bioaccumulate in mammals, the high risk for aquatic organisms and the outstanding issues with regard to aquatic organisms exposed through the food chain; the proposed definition of flufenoxuron as PBT (persistent bioaccumulating and toxic) and the risk for non-target arthropods (European Commission, 2011) the non-approval of flufenoxuron was implemented by Commission Implementing Regulation (EU) No 942/2011[10]. Following the non-approval, risk managers decided to lower all MRLs to the relevant LOD, except for the MRL in tea, which was already evaluated by EFSA and corresponds to an import tolerance request from Japan (EFSA, 2009) and was implemented by Regulation (EU) 2020/1633[11]. CXLs are in place for this substance but they were never legally implemented in the EU legislation due to a reservation expressed by the EU delegation (FAO, 2015). Based on the above considerations, the review of MRLs for this substance becomes obsolete.

The active substance **imazaquin** was initially included in Annex I to Council Directive 91/414/EEC by Commission Directive 2008/69/EC. Following the peer review by EFSA (2011b) the condition of approval of imazaquin was amended by Commission Implementing Regulation (EU) 1100/2011[12], requiring further confirmatory information and defining the date for expiration of approval at 31 December 2018. Since an application for the renewal of the approval of the active substance was not submitted, imazaquin is currently no longer approved. During the MS consultation on the draft statement on active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005 prepared by EFSA in 2019, a request to keep the MRL for imazaquin at the current LOD of 0.05 mg/kg in soybeans in order to support an existing import tolerance was received (EFSA, 2019). Subsequently, the review of MRLs under Article 12 of Regulation (EC) No 396/2005 was initiated in May 2020. According to the information provided by the EURLs, imazaquin can be monitored in plant and animal commodities with a lower LOD of 0.01 mg/kg (EURLs, 2020). Since no import tolerances were finally reported by MSs and no CXLs were established by the Codex Alimentarius Commission (CAC), the MRL review process was terminated and the review of the MRLs for this substance becomes obsolete.

The active substance **oxadiazon** was initially included in Annex I to Council Directive 91/414/EEC by Commission Directive 2008/69/EC. An EFSA conclusion on the peer review of the pesticide risk assessment related to the first approval is available (EFSA, 2010a). Since the applicant withdrew the support for the renewal of the approval, oxadiazon is currently not any longer approved. No CXLs are established by the CAC. Following the non-approval, risk managers decided to lower all MRLs to the relevant LOD by Regulation (EU) 2020/1633[12]. Therefore, the review of MRLs for this substance becomes obsolete.

[9] Commission Decision of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances (notified under document number C(2008) 7637). OJ L 333, 11.12.2008, p. 11–14.

[10] Commission Implementing Regulation (EU) No 942/2011 of 22 September 2011 concerning the non-approval of the active substance flufenoxuron, 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, and amending Commission Decision 2008/934/EC. OJ L 246, 23.9.2011, p. 13–15.

[11] Commission Regulation (EU) 2020/1633 of 27 October 2020 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 azinphos-methyl, bentazone, dimethomorph, fludioxonil, flufenoxuron, oxadiazon, phosalone, pyraclostrobin, repellants: tall oil and teflubenzuron in or on certain products. OJ L 367, 5.11.2020, p. 1–38.

[12] Commission Implementing Regulation (EU) No 1100/2011 of 31 October 2011 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances dicamba, difenoconazole, and imazaquin. OJ L 285, 1.11.2011, p. 10–14.

2.2. Substances which are temporarily included in Annex IV of Regulation (EC) No 396/2005 and for which CXLs do not exist

The following active substances have been included temporarily in Annex IV of Regulation (EC) No 396/2005 by risk managers pending finalisation of their evaluation under Directive 91/414/EEC or Regulation (EC) No 1107/2009 and pending submission of EFSA's reasoned opinion in accordance with Article 12(1) and 12(2) of Regulation (EC) No 396/2005. The EFSA's view concerning the Annex IV inclusion for these substances is also provided below.

The active substance **acetic acid** has been temporarily included in Annex IV of Regulation (EC) No 396/2005 by Commission Regulation (EC) No 839/2008.[13] Acetic acid was initially approved by Commission Directive 2008/127/EC[5] with expiration of approval on 31 August 2019. An application for renewal of the approval was submitted and it was deemed necessary to extend the approval with expiration on 31 August 2022. No CXLs are established by the CAC for this active substance.

In the framework of the first approval, EFSA issued a conclusion on the peer review of the pesticide risk assessment of acetic acid (EFSA, 2013a). In the sections on mammalian toxicology and residues, no data gap and no critical area of concern were identified. Acetic acid was assessed for its representative uses as an herbicide on pome fruit, stone fruit, paths and roads, ornamental trees and shrubs, turf, and lawns. Since it is sprayed only at the base of the fruit trees, there is no direct application to the fruits. Therefore, no significant residues of acetic acid are expected to be present in edible crops. Based on the widespread presence of acetic acid in human foods, together with the fact that it is a normally occurring metabolite in humans and animals, it was concluded that the establishment of an acceptable daily intake (ADI) and acute reference dose (ARfD) for oral intake of acetic acid by consumers was not necessary. During the peer review, it was concluded that acetic could be considered a candidate for Annex IV of Commission Regulation (EC) No 396/2005. For acetic acid, the review of MRLs under Article 12 of Regulation (EC) No 396/2005 has been started by initiation of the collection of Good Agricultural Practices (GAPs) in September 2019. According to the uses reported by MSs during the GAP collection, acetic acid is not applied directly on the crops and the conclusions laid down during the peer review are also valid for the existing uses. Consequently, it is proposed to retain the substance in Annex IV of Regulation (EC) No 396/2005 and the review of MRLs under Art 12 of Regulation (EC) No 396/2005 becomes obsolete.

The active substance **gliocladium catenulatum strain J1446** has been temporarily included in Annex IV of Regulation (EC) No 396/2005 by Commission Regulation (EC) No 839/2008[13]. Following the peer review for the renewal (EFSA, 2017), the active substance was permanently included in Annex IV of Regulation (EC) No 396/2005 by Commission Regulation (EC) No 2019/977[14]. Consequently, the review of MRLs under Art 12 of Regulation (EC) No 396/2005 becomes obsolete.

The active substance **lime sulphur** has been temporarily included in Annex IV by Commission Regulation (EU) 2015/1608[15] of 24 September 2015. EFSA issued a conclusion on the peer review of the pesticide risk assessment of lime sulphur (EFSA, 2010b). In the peer review, a data gap was identified in the area of residues regarding the uncertainty whether there is presence of remainders of polysulfides on the crop surface and whether this may become an issue for consumer safety, and therefore dietary risk assessment was not finalised. For lime sulphur, the review of MRLs under Article 12 of Regulation (EC) No 396/2005 has been started by initiation of the collection of GAPs in February 2019. During the procedure, additional data addressing the data gap identified in the framework of the peer-review regarding the potential presence of polysulfide residues were submitted by the RMS (Czech Republic, 2019). Furthermore, no Codex MRLs have been set for lime sulphur. Therefore, it is proposed to retain the substance in Annex IV of Regulation (EC) No 396/2005. Consequently, the review of MRLs under Art 12 of Regulation (EC) No 396/2005 becomes obsolete.

[13] Commission Regulation (EC) No 839/2008 of 31 July 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Annexes II, III and IV on maximum residue levels of pesticides in or on certain products. OJ L 234, 30.8.2008, p. 1–216.

[14] Commission Regulation (EU) 2019/977 of 13 June 2019 amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aclonifen, Beauveria bassiana strain PPRI 5339, Clonostachys rosea strain J1446, fenpyrazamine, mefentrifluconazole and penconazole in or on certain products. OJ L 159, 17.6.2019, p. 1–25.

[15] Commission Regulation (EU) 2015/1608 of 24 September 2015 amending Annex IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for capric acid, paraffin oil (CAS 64742-46-7), paraffin oil (CAS 72623-86-0), paraffin oil (CAS 8042-47-5), paraffin oil (CAS 97862-82-3), lime sulphur and urea in or on certain products. OJ L 249, 25.9.2015, p. 14–16.

The active substance **maltodextrin** has been temporarily included in Annex IV of Regulation (EC) No 396/2005 by Commission Regulation (EC) No 839/2008[13]. Maltodextrin has been approved by Commission Implementing Regulation (EU) No 355/2013[16], following the EFSA peer review of the pesticide risk assessment (EFSA, 2013b). No CXLs are established by the CAC for this active substance.

Maltodextrin is a naturally occurring compound (sugar by-product of starch hydrolysis) and based on the available toxicological information it has no hazardous properties. Nevertheless, during the peer review, EFSA recommended to further investigate whether the application of a polysaccharide to the surface of fruit and vegetables could increase the growth of fungi which are known to produce mycotoxins (e.g. patulin in apples and pears) (EFSA, 2013b). In order to collect additional data addressing this open point, EFSA started the procedure for the MRL review in December 2018. During the data collection, additional information on the possible presence of fungi which are known to produce mycotoxins on the surface of treated fruits was made available. This additional information was evaluated by the RMS that concluded that the application of maltodextrin does not lead to increased fungal growth (Ireland, 2019). This information was shared for consultation with the MS in the draft statement on active substances that do not require a review of the existing MRLs under Article 12 of Regulation (EC) No 396/2005 prepared by EFSA in 2019. During the MS consultation, the UK raised a point on the RMS conclusion, asking EFSA an evaluation of the data as considered by the RMS in its evaluation report (EFSA, 2019). Consequently, this point was further discussed by Member States during the SCoPAFF meeting and it was clarified that according to the specific provisions for the approval[16] of maltodextrin as active substance in accordance with Regulation (EC) No 1107/2009, '*Member States shall pay particular attention to the potential increased growth of fungi and possible presence of mycotoxins on the surface of treated fruits*' implementing proper mitigation measures, where appropriate.

The active substance **orange oil** has been temporarily included in Annex IV by Commission Regulation (EU) 588/2014[17] of 2 June 2014. EFSA issued a conclusion on the peer review of the pesticide risk assessment of orange oil (EFSA, 2013c). In the peer review, a conclusion on the dietary risk for consumers was not possible since the nature of the pertinent residue on the treated crops was not confirmed as D-limonene. In order to collect additional data addressing this open point, EFSA started the procedure for the MRL review in July 2019. Information provided by the RMS in the evaluation report (France, 2020) allowed to conclude that there is a high volatilisation of D-limonene (main component of orange oil) after 21 h at room temperature when applied as dilute formulation of 1% v/v. No supervised residue trials were conducted for D-limonene. However, based on the high volatility of the compound, it seems that no residues are expected on and/or into the raw agricultural commodities. Therefore, when orange oil is used as a plant protection product, residues are expected to be lower than background levels and/or use as flavouring agent. The translocation in the plant is not expected for this compound that is a pure contact product with no systemic activity (France, 2012; EFSA, 2013c). No Codex MRLs have been set for orange oil. On the basis of the above considerations, it is proposed to retain the substance in Annex IV of Regulation (EC) No 396/2005. The review of MRLs under Art 12 of Regulation (EC) No 396/2005 is considered obsolete. Based on the above explanation in Sections 2.1 and 2.2, the following question numbers are considered addressed (Table 1).

[16] Commission Implementing Regulation (EU) No 355/2013 of 18 April 2013 approving the active substance maltodextrin, 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 109, 19.4.2013, p. 14–17.

[17] Commission Regulation (EU) No 588/2014 of 2 June 2014 amending Annexes III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for orange oil, Phlebiopsis gigantea, gibberellic acid, Paecilomyces fumosoroseus strain FE 9901, Spodoptera littoralis nucleopolyhedrovirus, Spodoptera exigua nuclear polyhedrosis virus, Bacillus firmus I-1582, s-abscisic acid, L-ascorbic acid and Helicoverpa armigera nucleopolyhedrovirus in or on certain products. OJ L 164, 3.6.2014, p. 16–17.

Table 1: List of active substances that do not require MRL review

No	Question number (MRL review)	Active substance	RMS	Status under Reg (EU) No 1107/2009	Assessment made by EFSA	MRL Regulation	Outcome
1.	EFSA-Q-2009-00084	Aluminium sulphate	NL	Approved	EFSA (2010c)	Default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg. 396/2005	MRLs at default value
2.	EFSA-Q-2009-00150	Aluminium ammonium sulphate	IE	Approved	EFSA (2012c)	Default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg. 396/2005	MRLs at default value
3.	EFSA-Q-2009-00104	Diflubenzuron	EL	Approved	EFSA (2012a)	Reg. (EU) 2019/91	MRLs at default value
4.	EFSA-Q-2009-00164	Fat distillation residues	CZ	Approved	EFSA (2012b)	Default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg. 396/2005	MRLs at default value
5.	EFSA-Q-2009-00053	Flufenoxuron	FR	Not approved	EFSA (2009) EFSA (2011a)	Reg. (EU) 2020/1633	MRLs at default value except for tea
6.	EFSA-Q-2009-00108	Imazaquin	BE	Not approved	EFSA (2011b)	Reg. (EC) No 149/2008	MRLs at default value
7.	EFSA-Q-2009-00111	Oxadiazon	IT	Not approved	EFSA (2010a)	Reg. (EU) 2020/1633	MRLs at default value
8.	EFSA-Q-2009-00149	Acetic acid	AT	Approved	EFSA (2013a)	Reg. (EC) No 839/2008	Inclusion in Annex IV confirmed
9.	EFSA-Q-2008-559	*Gliocladium catenulatum* strain J1446	HU	Approved	EFSA (2017)	Reg. (EU) 2019/977	Inclusion in Annex IV confirmed
10.	EFSA-Q-2009-00092	Lime sulphur	CZ	Approved	EFSA (2010b)	Reg. (EU) 2015/1608	Inclusion in Annex IV confirmed
11.	EFSA-Q-2013-00521	Maltodextrin	IE	Approved	EFSA (2013b)	Reg. (EC) No 839/2008	Inclusion in Annex IV confirmed
12.	EFSA-Q-2013-00914	Orange oil	FR	Approved	EFSA (2013c)	Reg. (EU) No 588/2014	Inclusion in Annex IV confirmed

3. Conclusions

Among the active substances that need to be reviewed under Article 12 of Regulation (EC) No 396/2005, EFSA identified 12 active substances for which a review of MRLs is not needed, including 5 active substances that were already included temporarily in Annex IV of Regulation (EC) No 396/2005 by risk managers pending finalisation of their evaluation under Directive 91/414/EEC or Regulation (EC) No 1107/2009 and pending submission of EFSA's reasoned opinion in accordance with Article 12(1) or Article 12(2) of Regulation (EC) No 396/2005. EFSA therefore prepared a statement explaining the reasons why a review of MRLs is no longer necessary for these active substances. The corresponding question numbers are considered addressed by this statement.

References

Czech Republic, 2019. Evaluation report prepared under Article 2.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for lime sulphur, October 2019. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2009. Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRL for flufenoxuron in tea (dried leaves and stalks, fermented or otherwise of *Camellia sinensis*). EFSA Journal 2009;7(4):267r, 24 pp. https://doi.org/10.2903/j.efsa.2009.267r

EFSA (European Food Safety Authority), 2010a. Conclusion on the peer review of the pesticide risk assessment of the active substance oxadiazon on request of EFSA. EFSA Journal 2010;8(2):1389, 92 pp. https://doi.org/10.2903/j.efsa.2010.1389

EFSA (European Food Safety Authority), 2010b. Conclusion on the peer review of the pesticide risk assessment of the active substance lime sulfur. EFSA Journal 2010;8(11):1890, 45 pp. https://doi.org/10.2903/j.efsa.2010.1890

EFSA (European Food Safety Authority), 2010c. Conclusion on the peer review of the pesticide risk assessment of the active substance aluminium sulfate. EFSA Journal 2010;8(11):1889, 32 pp. https://doi.org/10.2903/j.efsa.2010.1889

EFSA (European Food Safety Authority), 2011a. Conclusion on the peer review of the pesticide risk assessment of the active substance flufenoxuron. EFSA Journal 2011;9(3):2088, 71 pp. https://doi.org/10.2903/j.efsa.2011.2088

EFSA (European Food Safety Authority), 2011b. Conclusion on the peer review of the pesticide risk assessment of the active substance imazaquin. EFSA Journal 2011;9(1):1968, 57 pp. https://doi.org/10.2903/j.efsa.2011.1968

EFSA (European Food Safety Authority), 2012a. Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance diflubenzuron. EFSA Journal 2012;10(9):2870, 26 pp. https://doi.org/10.2903/j.efsa.2012.2870

EFSA (European Food Safety Authority), 2012b. Conclusion on the peer review of the pesticide risk assessment of the active substance fat distillation residues. EFSA Journal 2012;10(2):2519, 43 pp. https://doi.org/10.2903/j.efsa.2012.2519

EFSA (European Food Safety Authority), 2012c. Conclusion on the peer review of the pesticide risk assessment of the active substance aluminium ammonium sulfate. EFSA Journal 2012;10(3):2491, 46 pp. https://doi.org/10.2903/j.efsa.2012.2491

EFSA (European Food Safety Authority), 2013a. Conclusion on the peer review of the pesticide risk assessment of the active substance acetic acid. EFSA Journal 2013;11(1):3060, 57 pp. https://doi.org/10.2903/j.efsa.2013.3060

EFSA (European Food Safety Authority), 2013b. Conclusion on the peer review of the pesticide risk assessment of the active substance maltodextrin. EFSA Journal 2013;11(1):3007, 35 pp. https://doi.org/10.2903/j.efsa.2013.3007

EFSA (European Food Safety Authority), 2013c. Conclusion on the peer review of the pesticide risk assessment of the active substance orange oil. EFSA Journal 2013;11(2):3090, 55 pp. https://doi.org/10.2903/j.efsa.2013.3090

EFSA (European Food Safety Authority), 2015. Conclusion on the peer review on the review of the approval of the active substance diflubenzuron regarding the metabolite PCA. EFSA Journal 2015;13(12):4222, 30 pp. https://doi.org/10.2903/j.efsa.2015.4222

EFSA (European Food Safety Authority), 2019. Member States consultation report on the statement on active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005 prepared by EFSA, 28 November 2019. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2020. Member States consultation report on the active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005 prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 12 November 2020. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), Arena M, Auteri D, Barmaz S, Bellisai G, Brancato A, Brocca D, Bura L, Byers H, Chiusolo A, Court Marques D, Crivellente F, De Lentdecker C, De Maglie M, Egsmose M, Erdos Z, Fait G, Ferreira L, Goumenou M, Greco L, Ippolito A, Istace F, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Magrans JO, Medina P, Miron I, Molnar T, Nougadere A, Padovani L, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Seramova R, Sharp R, Stanek A, Streissl F, Sturma J, Szentes C, Tarazona J, Terron A, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance *Clonostachys rosea* strain J1446 (approved in Regulation (EU) No 540/2011 as Gliocladium catenulatum strain J1446). EFSA Journal 2017;15(7):4905, 22 pp. https://doi.org/10.2903/j.efsa.2017.4905

EURLs (European Union Reference Laboratories for Pesticide Residues), 2020. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Analytical methods validated by the EURLs and overall capability of official laboratories to be considered for the review of the existing MRLs for imazaquin. September 2020.

European Commission, 2011. Review report for the active substance flufenoxuron finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 July 2011 in view of the non-approval of flufenoxuron as active substances in accordance with Regulation (EC) No 1107/2009. SANCO/11597/2011 - rev 2, 15 July 2011.

European Commission, 2015. Guidance document on criteria for the inclusion of active substances into Annex IV of regulation (EC) No 396/2005. SANCO/11188/2013, rev. 2, 14 September 2015.

FAO (Food and Agriculture Organization of the United Nations), 2015. Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission 38th Session Geneva, Switzerland, 6 – 11 July 2015. Report of the 47th Session of the Codex Committee on Pesticide Residues Beijing, China, 13 - 18 April 2015.
France, 2012. Draft Assessment Report (DAR) on the active substance orange oil prepared by the rapporteur Member State France in the framework of Directive 91/414/EEC, revised February 2012.
France, 2020. Evaluation report prepared under Article 2.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for orange oil, February 2020. Available online: www.efsa.europa.eu
Ireland, 2019. Evaluation report prepared under Article 2.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for Maltodextrin, April 2019. Available online: www.efsa.europa.eu

Abbreviations

ADI	acceptable daily intake
ARfD	acute reference dose
CAC	Codex Alimentarius Commission
CXL	codex maximum residue limit
DAR	draft assessment report
EMS	evaluating Member State
GAP	Good Agricultural Practice
ISO	International Organization for Standardization
LOD	limit of determination
MRL	maximum residue level
MS	Member State
PPP	plant protection product
PBT	persistent bioaccumulating and toxic
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers

Annex A – Active substances for which the Article 12 review was addressed in the framework of the peer review for the renewal

Q-number	Active substance	RMS	Adoption date	Link to EFSA conclusions
EFSA-Q-2009-00154	Blood meal	AT	23/1/2020	http://www.efsa.europa.eu/en/efsajournal/pub/6006
EFSA-Q-2009-00171	Kieselgur (aka diatomaceous earth)	AT	22/6/2020	http://www.efsa.europa.eu/en/efsajournal/pub/2797
EFSA-Q-2009-00166	Garlic extract	IE	16/4/2020	http://www.efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2020.6116