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 the 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 11 active substances for which a review of MRLs is no longer considered necessary, including 7 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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Statement of EFSA for substances that do not require MRL review

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 detection (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 11 active substances for which a review of MRLs is no longer considered necessary, including 7 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.

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

Regulation (EC) No 396/2005\(^1\) 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\(^2\) 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 detection (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 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 11 active substances for which a review of MRLs is no longer considered necessary, including 7 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 EFSA view concerning the Annex IV inclusion where relevant. The corresponding question numbers are considered addressed by this statement. The draft statement was circulated to Member States (MSs) for consultation via a written procedure. Comments received by 12 November \(^{1}\) 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.
2019 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.

2. **Assessment**

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

The MRLs for the following substances are set at the limit of detection (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 linuron was initially included in Annex I to Council Directive 91/414/EEC by Commission Directive 2003/31/EC. Following the EFSA peer review of the pesticide risk assessment (EFSA, 2016), linuron was not renewed by Commission Implementing Regulation (EU) 2017/244. After the decision of non-renewal, the active substance was moved to Annex V of Regulation (EC) No 396/2005 with specific MRLs at limit of quantification (LOQ) by Commission Regulation (EU) 2019/58. Therefore, the review of MRLs for this substance becomes obsolete.

The active substance buprofezin was included in Annex I to Directive 91/414/EEC by Commission Directive 2011/6/EU pending the submission of confirmatory information as regards the processing and conversion factors for consumer risk assessment (EFSA, 2010). Following submission and assessment of the confirmatory data (EFSA, 2015a), the European Commission requested EFSA to deliver its conclusion in view of new data. EFSA (2015b) concluded that the confirmatory information required has not been fully provided and that exposure of consumers to aniline via consumption of processed crops cannot be excluded except by imposing further restrictions. The conditions of approval for buprofezin were therefore amended by Commission Implementing Regulation (EU) 2017/360, restricting the use of buprofezin to non-edible crops only. Thus, residues in food of plant or animal origin are unlikely to occur under the restricted conditions of use. Subsequently, buprofezin was moved to Annex V of Regulation (EC) No 396/2005 with specific MRLs at LOQ by Commission Regulation (EU) 2019/91. Therefore, the review of MRLs for this substance becomes obsolete.

The active substance Bacillus thuringiensis subs. tenebrionis (NB 176 (TM 14 1)) was initially included in Annex I to Council Directive 91/414/EEC by Commission Directive 2008/113/EU. An EFSA conclusion on the peer review of the pesticide risk assessment is available (EFSA, 2013). Since no application for renewal of the approval was submitted on 30 April 2019, Bacillus thuringiensis subs. tenebrionis (NB 176 (TM 14 1)) is currently not approved any longer. 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. Therefore, the review of MRLs for this substance becomes obsolete.

The active substance orthosulfamuron was provisionally included in Annex I to Council Directive 91/414/EEC by Commission Directive 2006/806/EC. Following the EFSA peer review of the pesticide risk assessment (EFSA, 2014), the approval of orthosulfamuron was not confirmed by Commission...
Implementing Regulation (EU) 2017/840. Subsequently, the active substance was moved to Annex V of Regulation (EC) No 396/2005 with specific MRLs at LOQ by Commission Regulation (EU) 2019/1792. Therefore, the review of MRLs for this substance becomes obsolete.

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 view concerning the Annex IV inclusion for these substances is also provided below.

The active substance limestone has been temporarily included in Annex IV of Regulation (EC) No 396/2005 by Commission Regulation (EC) No 839/2008, pending finalisation of its 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) of Regulation (EC) No 396/2005. Limestone was approved by Commission Implementing Regulation (EU) No 127/2008 with expiration of approval on 31 August 2019. Since no application for renewal of the approval was submitted, the substance is considered not approved any longer. No Codex maximum residue limits (CXLs) are established by the Codex Alimentarius Commission for this active substance.

During the peer review, the limited data available indicated that limestone is not acutely toxic by the oral route, and it is irritating to skin and eyes, and to the respiratory system; however, it was not possible to draw a firm conclusion. No relevant data were submitted for short- and long-term toxicity, genotoxicity, carcinogenicity and reproductive toxicity. Nevertheless, based on the representative uses (as protection coating for trees in forestry), it was agreed that there was no need to set an acceptable daily intake (ADI) or an acute reference dose (ARfD). Overall, due to the nature of the substance which is composed of different crystal forms of calcium carbonate and considering the representative use (no residues on food and feed may occur), a consumer risk assessment was not considered required (EFSA, 2011b). Although limestone is no longer approved, due to its nature, any potential misuse is expected to be easily identified. 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.

The active substance pepper dust extraction residue (PDER) has been temporarily included in Annex IV of Regulation (EC) No 396/2005 by Commission Regulation (EC) No 839/2008, pending finalisation of its 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) of Regulation (EC) No 396/2005. PDER was initially approved by Commission Implementing Regulation (EU) No 127/2008 with expiration of approval on 31 August 2019. Since no application for renewal of the approval was submitted, the substance is considered not approved any longer and the extension of the approval period to 31 August 2020 indicated by Commission Implementing Regulation (EU) 2019/324. No CXLs are established by the Codex Alimentarius Commission for this active substance.

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12 Commission Implementing Regulation (EU) 2017/840 of 17 May 2017 concerning the non-approval of the active substance orthosulfamuron, 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 125, 18.5.2017, p. 10–11.

13 Commission Regulation (EU) 2019/1792 of 17 October 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 amitrole, fipronil, flupyradiflor-methyl, imazosulfuron, isoproturon, orthosulfuron and triasulfuron in or on certain products. OJ L 277, 29.10.2019, p. 66–88.

14 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.

15 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.

16 Commission Implementing Regulation (EU) 2017/195 of 3 February 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of several active substances listed in Part B of the Annex to Implementing Regulation (EU) No 686/2012 (AIR IV renewal programme). OJ L 31, 4.2.2017, p. 21–24.

17 Commission Implementing Regulation (EU) 2019/324 of 25 February 2019 amending Implementing Regulation (EU) No 540/2011 as regards the approval periods of the active substances bifenthrin, carboxin, FEN 560 (also called fenugreek or fenugreek seed powder), pepper dust extraction residue and sodium aluminium silicate. OJ L 57, 26.2.2019, p. 1–3.
For PDER, EFSA issued a conclusion on the peer-review of the pesticide risk assessment (EFSA, 2011b). In that framework, no suitable data were available to set reference values. However, PDER is the material remaining after steam distillation to remove pepper oil from food grade black pepper and therefore contains a lower amount of piperine, alkaloids and terpenoids than present in food grade black pepper. A quantitative risk assessment was also performed by the rapporteur Member State (RMS) comparing the exposure to piperine derived from the use of PDER as a plant protection product (considering 0.4% content of piperine) to the estimates derived from the dietary exposure to black pepper (considering 4% piperine) (United Kingdom, 2008). Consequently it was concluded that consumer exposure of piperine, alkaloids and terpenoids from the use of PDER as an animal repellent are unlikely to be significant compared to the intake by the daily culinary use of food grade black pepper and no risks to human health are expected from the use of piperine and related compounds present in PDER. Therefore, data waivers for specific toxicological studies with PDER were supported during the peer review. Moreover, it was highlighted that an excessive use of PDER with direct application on edible crops, without removing any potential remainder by washing or peeling the crop before consumption, would probably render the food less palatable and thus limit the intake of large amounts of PDER by the consumer. No areas of concern or data gaps were identified during the peer review and, already in that framework, it was concluded that PDER could be considered a candidate for Annex IV of Commission Regulation (EC) No 396/2005 (EFSA, 2011b). Although PDER is not any longer approved, the above considerations are still valid. 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.

The active substance ammonium acetate has been temporarily included in Annex IV of Regulation (EC) No 396/2005 by Commission Regulation (EC) No 839/2008, pending finalisation of its 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) of Regulation (EC) No 396/2005. Ammonium acetate was initially approved by Commission Implementing Regulation (EU) No 127/2008 with expiration of approval on 31 August 2019. Since no application for renewal of the approval was submitted, the substance is considered not approved any longer. No CXLs are established by the Codex Alimentarius Commission for this active substance. During the peer review, no toxicological reference values were derived considering the intended uses (placed inside traps, never coming into direct contact with the crops, (EFSA, 2012c)). No full toxicological data package is available. Ammonium acetate showed neurotoxic properties. However, EFSA noted that neurotoxic properties were observed at very high dose levels by the oral route (20% in diet) and at lower doses by the intraperitoneal route. Consequently, Annex IV inclusion based on criterion three for this active substance is not supported by EFSA. Nevertheless, it is noted that ammonium acetate is expected to dissociate to acetic acid and ammonia. Therefore, based on this additional information, risk managers may consider to maintain this active substance in Annex IV. The review of MRLs under Article 12 of Regulation (EC) No 396/2005 is considered obsolete.

Putrescine (1,4-diaminobutane) has been temporarily included in Annex IV of Regulation (EC) No 396/2005 by Commission Regulation (EC) No 839/2008, pending finalisation of its 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) of Regulation (EC) No 396/2005. Putrescine (1,4-diaminobutane) was initially approved by Commission Implementing Regulation (EU) No 127/2008 with expiration of approval on 31 August 2019. Following the peer review by EFSA (EFSA, 2012d) the condition of approval of putrescine (1,4-diaminobutane) were amended by Commission Implementing Regulation (EU) 571/2012.18 Since no application for renewal of the approval was submitted, the substance is considered not approved any longer. No CXLs are established by the Codex Alimentarius Commission for this active substance. For putrescine (1,4-diaminobutane), the review of MRLs under Article 12 of Regulation (EC) No 396/2005 has been started by initiation of the collection of Good Agricultural Practice (GAP) data in March 2019 and no EU uses as pesticide have been reported during the GAP collection.

During the peer review, no toxicological reference values were derived considering the intended uses (placed inside traps, never coming into direct contact with the crops, EFSA, 2012d). No full toxicological data package is available, putrescine (1,4-diaminobutane) showed corrosive properties. It

18 Commission Implementing Regulation (EU) No 571/2012 of 28 June 2012 amending Implementing Regulation (EU) No 540/ 2011 as regards the conditions of approval of the active substances aluminium silicate, hydrolysed proteins and 1,4- dinaminobutane (putrescine). OJ L 169, 29.6.2012, p. 46-49.
is noted that additional adverse effects (i.e. decreased food consumption, decreased body weight and increased organ weights) in toxicological studies were observed below the test guideline limit doses as defined in the guidance document of the European Commission on the criteria for Annex IV inclusion (2015). On this basis, Annex IV inclusion based on criterion three for this active substance is not supported by EFSA. Nevertheless, it is noted that putrescine (1,4-diaminobutane) is an organic chemical compound related to cadaverine and is produced by the breakdown of amino acids in living and dead organisms. The two compounds are largely responsible for the foul odour of putrefying flesh, therefore direct application on edible crops would probably render the food less palatable and thus limit the intake of large amounts of putrescine (1,4-diaminobutane) by the consumer. Based on this additional information and also considering the nature of the compound, risk managers may consider to maintain this active substance in Annex IV. The review of MRLs under Article 12 of Regulation (EC) No 396/2005 is considered obsolete.

**Trimethylamine hydrochloride** has been temporarily included in Annex IV of Regulation (EC) No 396/2005 by Commission Regulation (EC) No 839/2008, pending finalisation of its 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) of Regulation (EC) No 396/2005. Trimethylamine hydrochloride was initially approved by Commission Implementing Regulation (EU) No 127/2008 with expiration of approval on 31 August 2019. Since no application for renewal of the approval was submitted, the substance is considered not approved any longer. No CXLs are established by the Codex Alimentarius Commission for this active substance. For trimethylamine hydrochloride the review of MRLs under Article 12 of Regulation (EC) No 396/2005 has been started by initiation of the collection of GAP data in May 2019. Authorisations as attractant in traps have been reported by FR during the GAP collection, while no import tolerances were notified.

During the peer review, no toxicological reference values were derived considering the intended uses (placed inside traps, never coming into direct contact with the crops, EFSA, 2012b). Although a complete toxicological data set is not available for this substance, no hazardous properties were identified based on the available toxicological data (not acutely toxic, not a skin sensitiser, not genotoxic, no reproductive or developmental toxicity effects). Moreover, the active substance is a synthetic replica of the naturally occurring substance trimethylamine resulting from the decomposition of animal and plant material under normal environmental conditions. 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.

The active substance **sodium aluminium silicate** has been temporarily included in Annex IV of Regulation (EC) No 396/2005 by Commission Regulation (EC) No 839/2008, pending finalisation of its 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) of Regulation (EC) No 396/2005. Sodium aluminium silicate was initially approved by Commission Implementing Regulation (EU) No 127/2008 with expiration of approval on 31 August 2019. Since no application for renewal of the approval was submitted, the substance is considered not approved any longer. No CXLs are established by the Codex Alimentarius Commission for this active substance.

During the peer review no toxicological reference values were derived considering the intended uses as game repellent (EFSA, 2012e), applied as a protective coating to the outside of tree trunks. Although a complete toxicological data set is not available for this substance, no hazardous properties were identified based on the available toxicological data (not acutely toxic, not a skin sensitiser, not genotoxic, no reproductive or developmental toxicity effects). However adverse effects on the urogenital track are described in available toxicological studies below the test guideline limit doses as defined in the guidance document of the European Commission on the criteria for Annex IV inclusion (2015). On this basis, Annex IV inclusion based on criterion three for this active substance is not supported by EFSA.

The active substance **sea-algae extract** has been temporarily included in Annex IV of Regulation (EC) No 396/2005 by Commission Regulation (EC) No 839/2008, pending finalisation of its 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) of Regulation (EC) No 396/2005. Sea-algae extract was initially approved by Commission Implementing Regulation (EU) No 127/2008 with expiration of approval on 31 August 2019. Since no application for renewal of the approval was submitted, the substance is considered not approved any longer. No CXLs are established by the Codex Alimentarius Commission for this active substance.
During the peer review, it was concluded that sea-algae extracts do not have a toxic mode of action and do not present a toxicological concern by themselves. Already in that framework, it was concluded that sea-algae could be considered a candidate for Annex IV of Commission Regulation (EC) No 396/2005 (EFSA, 2012a). Although sea-algae extract is not any longer authorised, the above consideration is still considered valid. 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.

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-2008-575              | Linuron          | IT  | Not approved                      | EFSA (2016)             | Reg. (EU) 2019/58 | MRLs at default value                            |
| 2.   | EFSA-Q-2009-00147            | Putrescine (1,4-Diaminobutane) | ES  | Not approved                      | EFSA (2012d)            | Reg. (EC) No 839/2008 Temporarily included in Annex IV | Maintaining the substance in Annex IV is for further consideration by risk managers |
| 3.   | EFSA-Q-2009-00018            | Buprofezin       | IT  | Approved, restriction of uses on non-edible crops | EFSA (2015a, b) | Reg. (EU) 2019/91 | MRLs at default value                            |
| 4.   | EFSA-Q-2009-00189            | Sodium aluminium silicate | HU  | Not approved                      | EFSA (2012e)            | Reg. (EC) No 839/2008 Temporarily included in Annex IV | Maintaining the substance in Annex IV is for further consideration by risk managers |
| 5.   | EFSA-Q-2009-00124            | Bacillus thuringiensis subsp. tenebrionis (NB 176 (TM 14 1)) | IT  | Not approved                      | EFSA (2013)             | Default MRL of 0.01 mg/kg according to Art 18(1)(b) Reg 396/2005 | MRLs at default value                            |
| 6.   | EFSA-Q-2009-00153            | Ammonium acetate | PT  | Not approved                      | EFSA (2012c)            | Reg. (EC) No 839/2008 Temporarily included in Annex IV | Maintaining the substance in Annex IV is for further consideration by risk managers |
| 7.   | EFSA-Q-2009-00172            | Limestone        | CZ  | Not approved                      | EFSA (2011a)            | Reg. (EC) No 839/2008 Temporarily included in Annex IV | Annex IV inclusion confirmed                     |
| 8.   | EFSA-Q-2009-00176            | Pepper dust extraction residue (PDER) | BE  | Not approved                      | EFSA (2011b)            | Reg. (EC) No 839/2008 Temporarily included in Annex IV | Annex IV inclusion confirmed                     |
| 9.   | EFSA-Q-2009-00188            | Sea-algae extract | BE  | Not approved                      | EFSA (2012a)            | Reg. (EC) No 839/2008 Temporarily included in Annex IV | Annex IV inclusion confirmed                     |
3. Conclusions

Among the active substances that need to be reviewed under Article 12 of Regulation (EC) No 396/2005, EFSA identified 11 active substances for which a review of MRLs is not needed, including 7 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.

Other statements addressing additional active substances that do not require a review of MRLs (e.g. in view of inclusion in Annex IV of Regulation (EC) No 396/2005) may be issued by EFSA if needed.

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**Abbreviations**

| Abbreviation | Description                        |
|--------------|------------------------------------|
| ADI          | acceptable daily intake            |
| ARfD         | acute reference dose               |
| CXL          | codex maximum residue limit        |
| DAR          | draft assessment report            |
| EMS          | evaluating Member State            |
| GAP          | Good Agricultural Practice         |
| LOD          | limit of detection                 |
| LOQ          | limit of quantification            |
| MRL          | maximum residue level              |
| MS           | Member States                      |
| PDER         | pepper dust extraction residue     |
| RMS          | rapporteur Member State            |
| SANCO        | Directorate-General for Health and Consumers |