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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**

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 maximum residue levels (MRLs) for that active substance. Among the active substances that need to be reviewed under Article 12(1) of Regulation (EC) No 396/2005, EFSA identified 13 active substances for which a review of MRLs is no longer considered necessary, including 6 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) 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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## Summary

Regulation (EC) No 396/2005 establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. In accordance with Article 12(1) of that Regulation, 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.

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) of Regulation (EC) No 396/2005, EFSA identified 13 active substances for which a review of MRLs is no longer considered necessary, including 6 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) 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 article 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<sup>1</sup> establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. In accordance with Article 12(1) of that Regulation, 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<sup>2</sup> a reasoned opinion on the review of the existing MRLs for that active substance.

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<sup>3</sup>. 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 article 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) of Regulation (EC) No 396/2005, EFSA identified 13 active substances for which a review of MRLs is no longer considered necessary, including 6 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) 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.

The draft statement was circulated to Member States (MSs) for consultation via a written procedure. Comments received by 30 October 2018 were considered during the finalisation of this statement.

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council 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.

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 value and CXLs do not exist

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 substances ***Beauveria brongniartii*** and **potassium permanganate** were not included in Annex I to Council Directive 91/414/EEC in accordance with Commission Decision 2008/768/EC,<sup>4</sup> following voluntarily withdrawal of support by the respective notifiers. An EFSA Conclusion or an EU peer review of the pesticide risk assessment is not available for these substances. The MRLs have been set to the default MRL of 0.01 mg/kg according to Art 18(1)(b) of Regulation (EC) No 396/2005. As no codex maximum residue limits (CXLs) are established by the Codex Alimentarius Commission and no import tolerances are currently in place for *Beauveria brongniartii* and potassium permanganate, the review of MRLs for these substances becomes obsolete. It is noted that, according to the information provided by Germany during the MS consultation, no analytical methods are currently available to enforce residues of *Beauveria brongniartii* and potassium permanganate in food and feed.

The active substance **(Z)-13-hexadecen-11-yn-1-yl acetate** was initially included in Annex I to Council Directive 91/414/EEC by Commission Directive 2008/127/EC<sup>5</sup> following the EFSA peer review of the pesticide risk assessment (EFSA, 2014a). Following the notifier's decision not to submit confirmatory information as set out in Commission Implementing Regulation (EU) No 2015/418<sup>6</sup>, the active substance was withdrawn by Commission Implementing Regulation (EU) No 2016/638<sup>7</sup>. The full toxicological data package for this substance is missing (except for acute toxicity, skin and eye irritation studies) and thus reference values could not be established (EFSA, 2014a); therefore, it is not possible to verify whether criterion three for the inclusion of the active substance into Annex IV of Regulation (EC) No 396/2005, as laid down in the European Commission guidance document (European Commission, 2015) can be met. On this basis, it is recommended to maintain the MRLs as currently set to the default MRL of 0.01 mg/kg according to Art 18(1)(b) of Regulation (EC) No 396/2005, allowing to identify any potential misuse. As no CXLs or import tolerances are in place for (Z)-13-hexadecen-11-yn-1-yl acetate, the review of MRLs for this substance becomes obsolete.

The active substance **(Z,Z,Z,Z)-7,13,16,19-docosatetraen-1-yl isobutyrate** was initially included in Annex I to Council Directive 91/414/EEC by Commission Directive 2008/127/EC following the EFSA peer review of the pesticide risk assessment (EFSA, 2014b). Following the notifier's decision not to submit confirmatory information as set out in Commission Implementing Regulation (EU) No 2015/308<sup>8</sup>, the active substance was withdrawn by Commission Implementing Regulation (EU) No 2016/636<sup>9</sup>. The full toxicological data package for this substance is missing (EFSA, 2014b) and thus

<sup>4</sup> Commission Decision 2008/768/EC: Commission Decision of 30 September 2008 concerning the non-inclusion of *Beauveria brongniartii* and potassium permanganate 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) 5106). OJ L 263, 2.10.2008, p. 12–13.

<sup>5</sup> 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.

<sup>6</sup> Commission Implementing Regulation (EU) 2015/418 of 12 March 2015 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance Z-13-hexadecen-11-yn-1-yl acetate. OJ L 68, 13.3.2015, p. 36–38.

<sup>7</sup> Commission Implementing Regulation (EU) 2016/638 of 22 April 2016 withdrawing the approval of the active substance Z-13-hexadecen-11-yn-1-yl acetate, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011. OJ L 108, 23.4.2016, p. 28–29.

<sup>8</sup> Commission Implementing Regulation (EU) 2015/308 of 26 February 2015 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance Z,Z,Z,Z-7,13,16,19-docosatetraen-1-yl isobutyrate. OJ L 56, 27.2.2015, p. 9–11.

<sup>9</sup> Commission Implementing Regulation (EU) 2016/636 of 22 April 2016 withdrawing the approval of the active substance Z,Z,Z,Z-7,13,16,19-docosatetraen-1-yl isobutyrate, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011. OJ L 108, 23.4.2016, p. 22–23.



reference values could not be established; therefore, it is not possible to verify whether criterion three for the inclusion of the active substance into Annex IV of Regulation (EC) No 396/2005, as laid down in the European Commission guidance document (European Commission, 2015) can be met. On this basis, it is recommended to maintain the MRLs as currently set to the default MRL of 0.01 mg/kg according to Art 18(1)(b) of Regulation (EC) No 396/2005, allowing to identify any potential misuse. As no CXLs or import tolerances are in place for (Z,Z,Z,Z)-7,13,16,19-docosatetraen-1-yl isobutyrate, the review of MRLs for this substance becomes obsolete.

The active substance **difenacoum** has been included in Annex I to Council Directive 91/414/EEC by Commission Directive 2009/70/EC,<sup>10</sup> following the EFSA peer review of the pesticide risk assessment (EFSA, 2008). The approval is restricted only to uses as a rodenticide in the form of pre-prepared baits placed in specially constructed, tamper-resistant and secured bait boxes. Thus, residues in food of plant or animal origin are unlikely to occur under the conditions of use and accordingly, no toxicological reference values have been derived. Nevertheless, due to the hazardous properties of difenacoum (acute tox.1, repr.1B, STOT RE 1), it is recommended to maintain the MRLs as currently set to the default MRL of 0.01 mg/kg according to Art 18(1)(b) of Regulation (EC) No 396/2005. As no CXLs or import tolerances are in place for difenacoum, and based on the above considerations, the review of MRLs for this substance becomes obsolete.

The active substance **sodium silver thiosulfate** has been approved by Commission Implementing Regulation (EU) No 1195/2013<sup>11</sup>, following the EFSA peer review of the pesticide risk assessment (EFSA, 2013a). The approval is restricted only to indoor uses in non-edible crops. Thus, residues in food of plant or animal origin are unlikely to occur under the conditions of use and accordingly, no toxicological reference values have been derived. The active substance is not a naturally occurring compound. 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) (EFSA, 2013a). In view of the above considerations, inclusion of sodium silver thiosulfate in Annex IV of Regulation (EC) No 396/2005 may be considered by risk managers. As no CXLs or import tolerances are in place for sodium silver thiosulfate, the review of MRLs for this substance becomes obsolete.

The active substance **sodium hypochlorite** was included in Annex I to Council Directive 91/414/EEC by Commission Directive 2008/127/EC, and deemed to have been approved under Regulation (EC) No 1107/2009, as amended by Commission Implementing Regulation (EU) No 190/2013<sup>12</sup>, following the EFSA peer review of the pesticide risk assessment (EFSA, 2012c). The approval has been restricted only to indoor uses as a disinfectant.

For sodium hypochlorite the review of MRLs under Art 12 of Regulation (EC) No 396/2005 has been started in March 2018 by initiation of the collection of Good Agricultural Practice (GAP) data. No authorisations as pesticides have been reported by MSs during the GAP collection, nor import tolerances were notified. It is noted however that in the United Kingdom a commodity substance approval has been granted for this active substance, which allows the substance to be used as a bactericide or viricidal seed treatment on mushrooms and tomato seeds.<sup>13</sup> Nevertheless, no MRLs were required to be established for the active substance under those conditions of use.

It is noted that consumers may be exposed to residues of sodium hypochlorite or other active substances releasing the same residues, in particular from biocidal uses. Most importantly, from drinking water disinfection and food and feed area disinfectants. Sodium hypochlorite and several other active substances releasing 'active chlorine' are approved, or are under review, in the framework of Regulation (EU) 528/2012<sup>14</sup> (e.g. active chlorine released from sodium hypochlorite; active chlorine released from calcium hypochlorite; active chlorine generated from sodium chloride by electrolysis; active chlorine released from chlorine). Based on the biocidal assessments, **chlorate** is considered the

<sup>10</sup> Commission Directive 2009/70/EC of 25 June 2009 amending Council Directive 91/414/EEC to include difenacoum, didecyldimethylammonium chloride and sulphur as active substances. OJ L 164, 26.6.2009, p. 59–63.

<sup>11</sup> Commission Implementing Regulation (EU) No 1195/2013 of 22 November 2013 approving the active substance sodium silver thiosulfate, 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 315, 26.11.2013, p. 27–31.

<sup>12</sup> Commission Implementing Regulation (EU) No 190/2013 of 5 March 2013 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance sodium hypochlorite. OJ L 62, 6.3.2013, p. 19–21.

<sup>13</sup> See <http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/commodity-substances/commodity-substance-sodium-hypochlorite.htm>

<sup>14</sup> Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products. OJ L 167, 27.6.2012, p. 1–123.

key metabolite with respect to dietary intake. Currently, at EU level, the presence of chlorates is being discussed in the context of different legislative developments, namely in the setting of (i) a threshold level for chlorate in drinking water, (ii) MRLs for chlorate in food, and (iii) MRLs for chlorate in foods for infants and young children.

No CXLs are established by the Codex Alimentarius Commission for sodium hypochlorite. Currently, a default MRL of 0.01 mg/kg according to Art 18(1)(b) of Regulation (EC) No 396/2005 is in force for sodium hypochlorite. It is noted that, due to the use and nature of the compound, the need for methods of analysis for monitoring residues of this compound in food and feed of plant and animal origin has been waived. According to the rapporteur Member State (RMS) (IE) in the framework of the Art 12 MRL review, an ISO method exists for the determination of the residues in water expressed as the amount of total available chlorine (Ireland, 2018) (methods for sodium hypochlorite itself is technically not feasible).

Based on the above considerations, in particular on the fact that residues from other sources may occur, mainly from disinfectant by-products, and other metabolites like chlorates, it is proposed to discontinue the standard assessment under Art 12 of Regulation (EC) No 396/2005 and maintain all MRLs at the default limit of quantification (LOQ). However, if the need to establish specific MRLs for sodium hypochlorite is identified by risk managers, a specific mandate may be required noting that this should cover all possible source of exposure.

## 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) of Regulation (EC) No 396/2005. The EFSA view concerning the Annex IV inclusion for these substances is also provided below.

The active substance **fatty alcohols** is currently temporarily included in Annex IV of Regulation (EC) No 396/2005 by Commission Regulation (EC) No 839/2008<sup>15</sup>, 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). Fatty alcohols are not included in Annex I to Council Directive 91/414/EEC in accordance with Commission Decision 2008/941/EC,<sup>16</sup> following voluntarily withdrawal of support by the notifier. No CXLs are established by the Codex Alimentarius Commission for fatty alcohols and no import tolerances are currently in place. Based on the available toxicological data (Italy, 2007), fatty alcohols (1-decanol, octanol, dodecanol, hexanol) do not have hazardous properties according to the criteria as described in European Commission (2015); it is noted that although octanol is irritant to the eyes and skin, this property is not listed within the criteria as described in the above mentioned guidance document. In addition, in some of the toxicity studies adverse effects are observed at the limit doses; however, these adverse effects are potentially linked to irritating properties. Overall, there is no need to establish consumer reference values because of the toxicological profile of the fatty alcohols. On this basis, inclusion of fatty alcohols (1-decanol, octanol, dodecanol, hexanol) into Annex IV of Regulation (EC) No 396/2005 may be confirmed. Furthermore, according to the information provided by Germany during the MS consultation, some fatty alcohols are present at natural background levels. Nevertheless, it is noted for completeness, that an EU peer review of the pesticide risk assessment was not conducted for this group of substances and no data are currently available to EFSA on the levels of fatty alcohols occurring naturally. Based on all the above considerations, the review of MRLs for this substance becomes obsolete.

The active substances **tall oil crude** and **tall oil pitch** are currently temporarily included in Annex IV of Regulation (EC) No 396/2005 by Commission Regulation (EC) No 839/2008, 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). Both substances were initially included in Annex I to Council Directive 91/414/EEC by Commission Directive 2008/127/EC as amended by

<sup>15</sup> 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.

<sup>16</sup> Commission Decision 2008/941/EC: Commission Decision of 8 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. OJ L 335, 13.12.2008, p. 91–93.



Commission Implementing Regulation (EU) No 637/2012<sup>17</sup>, following the EFSA peer review of the pesticide risk assessment (EFSA, 2012a,b). The approval was restricted only for uses as repellents. Thus, residues in food of plant or animal origin were considered unlikely to occur under the conditions of use as a protection coating for trees in forestry. Nonetheless, following the evaluation of the requested confirmatory information (EFSA, 2015), the approval of these substances were withdrawn by Commission Implementing Regulations (EU) No 2017/1186<sup>18</sup> (tall oil crude) and 2017/1125<sup>19</sup> (tall oil pitch). No CXLs or import tolerances are currently in place for these substances. The data available for both substances are incomplete and not sufficient to conclude on their toxicological profile, including the setting of reference values, nor to adequately assess the hazard properties of these substances (EFSA, 2012a,b). Consequently, it is not possible to verify whether criterion three for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005, as laid down in the European Commission guidance document (European Commission, 2015) can be met. On this basis, Annex IV inclusion based on criterion three for these substances is not supported by EFSA. Nevertheless, it is noted that, according to the information provided by Germany during the MS consultation, tall oil crude and tall oil pitch are a mixture of mostly naturally occurring substances and setting MRLs at the LOQ might not be feasible for these specific substances. Therefore, based on this additional information, risk managers may consider to maintain these active substances in Annex IV. EFSA notes for completeness that in case the substances would remain in Annex IV, there will be no possibility to identify any potential misuses. Based on the above considerations the review of MRLs for these substances is considered obsolete.

The active substance **potassium thiocyanate** 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). For potassium thiocyanate, EFSA issued a conclusion on the peer review of the pesticide risk assessment (EFSA, 2013b) listing several data gaps that would have required further contributions from the applicant. Subsequently the applicant withdrew its application for the approval of potassium thiocyanate and therefore the substance was not approved (cf. Commission Implementing Regulation (EU) No 108/2014<sup>20</sup>). No CXLs are established by the Codex Alimentarius Commission for this active substance and no import tolerances are currently in place. The toxicological and residues data package for this substance is limited (e.g. no investigation has been made to define the residue and the actual biologically active substance was unknown for the peer review; no data were available for acute inhalation toxicity, skin and eye irritation, skin sensitisation; no valid studies were available for carcinogenicity, reproductive and developmental toxicity and thus, it was not possible to derive reference values) (EFSA, 2013b). Consequently, it is not possible to verify whether criterion three for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005, as laid down in the European Commission guidance document (European Commission, 2015) can be met. On this basis, Annex IV inclusion based on criterion three is not supported by EFSA. Nevertheless, it is noted that, according to the information available during the peer review, thiocyanate ion is naturally occurring in food (Netherlands, 2007). Overall, considering that thiocyanate is a ubiquitous compound detected in various foodstuffs (e.g. Weuffen et al., 1992) and that setting MRLs at the LOQ might not be feasible for this specific substance, risk managers may consider to maintain potassium thiocyanate in Annex IV. Based on all the above considerations the review of MRLs under Art 12 of Regulation (EC) No 396/2005 is considered obsolete.

The active substance **1-decanol** 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

<sup>17</sup> Commission Implementing Regulation (EU) No 637/2012 of 13 July 2012 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances iron sulphate, repellents by smell of animal or plant origin/tall oil crude and repellents by smell of animal or plant origin/tall oil pitch. OJ L 186, 14.7.2012, p. 20–24.

<sup>18</sup> Commission Implementing Regulation (EU) 2017/1186 of 3 July 2017 withdrawing the approval of the active substance repellents by smell of animal or plant origin/tall oil crude, 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 Implementing Regulation. OJ L 171, 4.7.2017, p. 131–133.

<sup>19</sup> Commission Implementing Regulation (EU) 2017/1125 of 22 June 2017 withdrawing the approval of the active substance repellents by smell of animal or plant origin/tall oil pitch, 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 Implementing Regulation (EU) No 540/2011. OJ L 163, 24.6.2017, p. 10–12.

<sup>20</sup> Commission Implementing Regulation (EU) No 108/2014 of 5 February 2014 concerning the non-approval of the active substance potassium thiocyanate, 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 36, 6.2.2014, p. 9–10.

Directive 91/414/EEC or Regulation (EC) No 1107/2009 and pending submission of EFSA's reasoned opinion in accordance with Article 12(1). 1-Decanol was initially not included in Annex I to Directive 91/414/EEC by Commission Decision 2008/941<sup>21</sup> following voluntarily withdrawal of support by the notifier. Following resubmission application according to Regulation 33/2008<sup>22</sup>, and the subsequent peer review by EFSA (2010), the substance was included in Annex I to Directive 91/414/EEC by Commission Directive 2011/33/EU<sup>23</sup> and deemed to have been approved under Regulation (EC) No 1107/2009, as amended by Commission Implementing Regulation (EU) 2018/1266<sup>24</sup>. No CXLs are established by the Codex Alimentarius Commission for this active substance. Sufficient information is available to conclude on the toxicological profile of the substance. Based on the available information, 1-decanol has no hazardous properties and there is no need to establish toxicological reference values because of the toxicological profile of the substance (EFSA, 2010). The toxicokinetic and metabolism properties of the linear aliphatic alcohols are reasonably well understood. 1-Decanol is expected to be rapidly and readily absorbed from the gastrointestinal tract and extensively metabolised to the corresponding fatty acid, which may occur naturally in humans. 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 **S-abscisic acid** has been temporarily included in Annex IV of Regulation (EC) No 396/2005 by Commission Regulation (EC) No 588/2014<sup>25</sup>, 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). S-Absciscic acid has been approved by Commission Implementing Regulation (EU) No 151/2014<sup>26</sup> following the EFSA peer review of the pesticide risk assessment (EFSA, 2013c). No CXLs are established by the Codex Alimentarius Commission for this active substance. S-abscisic acid is a naturally occurring compound and based on the available toxicological information it has no hazardous properties (EFSA, 2013c). On the basis of the above considerations, as well as due to its natural occurrence, 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).

<sup>21</sup> Commission Decision 2008/941/EC: Commission Decision of 8 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) 7803). OJ L 335, 13.12.2008, p. 91–93.

<sup>22</sup> Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.

<sup>23</sup> Commission Directive 2011/33/EU of 8 March 2011 amending Council Directive 91/414/EEC to include 1-decanol as active substance and amending Commission Decision 2008/941/EC. OJ L 62, 9.3.2011, p. 23–26.

<sup>24</sup> Commission Implementing Regulation (EU) 2018/1266 of 20 September 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-decanol, 6-benzyladenine, aluminium sulfate, azadirachtin, bupirimate, carboxin, clethodim, cycloxydim, dazomet, diclofop, dithianon, dodine, fenazaquin, fluometuron, flutriafol, hexythiazox, hymexazol, indolylbutyric acid, isoxaben, lime sulphur, metaldehyde, paclobutrazol, penicuron, sintofen, tau-fluvalinate and tebufenozide. OJ L 238, 21.9.2018, p. 81–83.

<sup>25</sup> 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.

<sup>26</sup> Commission Implementing Regulation (EU) No 151/2014 of 18 February 2014 approving the active substance S-abscisic acid, 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 48, 19.2.2014, p. 1–5.

**Table 1:** List of active substances that do not require MRL review including, where relevant, EFSA's considerations as regards their inclusion in Annex IV of Regulation (EC) No 396/2005

No	Question number (MRL review)	Active substance	RMS	Status under Reg (EC) No 1107/2009	Assessment made by EFSA	MRL Regulation	Outcome
1	EFSA-Q-2009-00017	<i>Beauveria brongniartii</i>	DE	Not approved	Not available	Regulation (EC) No 396/2005	MRLs at default value
2	EFSA-Q-2009-00019	Potassium permanganate	ES	Not approved	Not available	Regulation (EC) No 396/2005	MRLs at default value
3	EFSA-Q-2009-00080	1-Decanol	PL (previously UK)	Approved	EFSA (2010)	Regulation (EC) No 839/2008	Annex IV inclusion confirmed
4	EFSA-Q-2009-00089	Fatty alcohols	IT	Not approved	Not available	Regulation (EC) No 839/2008	Annex IV inclusion confirmed
5	EFSA-Q-2009-00145	(Z)-13-Hexadecen-11-yn-1-yl acetate	AT	Not approved	EFSA (2014a)	Regulation (EC) No 396/2005	MRLs at default value
6	EFSA-Q-2009-00146	(Z,Z,Z,Z)-7,13,16,19-Docosatetraen-1-yl isobutyrate	AT	Not approved	EFSA (2014b)	Regulation (EC) No 396/2005	MRLs at default value
7	EFSA-Q-2009-00186	Repellents: Tall oil crude	CZ (previously EL)	Not approved	EFSA (2012a, 2015)	Regulation (EC) No 839/2008	Maintaining the substance in Annex IV is for further consideration by risk managers
8	EFSA-Q-2009-00187	Repellents: Tall oil pitch	CZ (previously EL)	Not approved	EFSA (2012b)	Regulation (EC) No 839/2008	Maintaining the substance in Annex IV is for further consideration by risk managers
9	EFSA-Q-2009-00190	Sodium hypochlorite	IE	Approved	EFSA (2012c)	Regulation (EC) No 396/2005	MRLs at default value
10	EFSA-Q-2010-00186	Difenacoum	IT (previously FI)	Approved	EFSA (2008)	Regulation (EC) No 396/2005	MRLs at default value
11	EFSA-Q-2013-00964	Sodium silver thiosulfate	NL	Approved	EFSA (2013a)	Regulation (EC) No 396/2005	Annex IV inclusion supported
12	EFSA-Q-2014-00122	Potassium thiocyanate	NL	Not approved	EFSA (2013b)	Regulation (EC) No 839/2008	Maintaining the substance in Annex IV is for further consideration by risk managers
13	EFSA-Q-2014-00210	S-Absciscic acid	NL	Approved	EFSA (2013c)	Commission Regulation (EC) No 588/2014	Annex IV inclusion confirmed

MRL: maximum residue level.

### 3. Conclusions

Among the active substances that need to be reviewed under Article 12 of Regulation (EC) No 396/2005, EFSA identified 13 active substances for which a review of MRLs is not needed, including 6 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) 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, including the EFSA view concerning the Annex IV inclusion where relevant. 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

CXL	codex maximum residue limit
DAR	draft assessment report
GAP	Good Agricultural Practice
ISO	International Organisation for Standardization
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
PPP	plant protection product
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers