Review of the existing maximum residue levels for hexythiazox according to Article 12 of Regulation (EC) No 396/2005

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance hexythiazox. To assess the occurrence of hexythiazox residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EC) No 33/2008, the MRLs established by the Codex Alimentarius Commission as well as the import tolerances and European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

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Keywords: hexythiazox, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, acaricide

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Summary

Hexythiazox was included in Annex I to Directive 91/414/EEC on 1 June 2011 by Commission Directive 2011/46/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, The European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked Finland, the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 21 December 2016 and finalised on 3 March 2017. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 9 February 2018.

Based on the conclusions derived by EFSA in the framework of Commission Regulation (EC) No 33/2008, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS and Member States, EFSA prepared in August–September 2018 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 5 October 2018 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The nature of hexythiazox in primary crops was investigated only in fruit crops and leafy crops following foliar and local applications. Therefore, a general residue definition for all plant commodities could not be established. The residue was defined as hexythiazox (any ratio of constituent isomers) for both enforcement and risk assessment purposes for fruit crops and leafy crops, and tentatively for the other commodity groups. Validated analytical methods for the enforcement of this residue definition are available for all major crop groups and in addition for tea and hops.

Significant residues of hexythiazox above 0.01 mg/kg are not expected in rotational crops following the authorised uses.

Hexythiazox was found to be relatively stable under standard hydrolysis conditions, except under conditions mimicking sterilisation, when around 50% degraded to the metabolite PT-1-3. However, based on processing studies and the review of the authorised Good Agricultural Practices (GAPs), the residue definition for both risk assessment and for enforcement purposes in processed commodities is proposed to be the same as for the primary crops, i.e. parent only.

The available residue trials were sufficient to derive MRL proposals and risk assessment values for all commodities under evaluation, except for apricots, cherries and plums where tentative MRLs are derived, and for beans with pods, kiwi, soya beans, cotton seeds and bananas where the available data were insufficient to derive MRLs.

Robust processing factors (fully supported by data) could be derived for processing of citrus fruits (peeling, juice, marmalade, wet and dry pomace), apple (pasteurised juice; purée; canned fruit; wet and dry pomace), grapes (wine; must; pasteurised juice; wet and dry pomace), strawberry (jam, canned fruits) and hops (beer). The metabolite PT-1-3 was below the detection limit in all processed commodities investigated, except in dry pomace, where residues were detected at low levels.

Hexythiazox is authorised for use on several feed items and dietary burdens calculated for cattle, equine and swine were found to exceed the trigger value of 0.1 mg/kg dry matter. Based on metabolism studies on dairy ruminants and laying hens a common residue definition in all livestock commodities can be proposed. The residue definition for enforcement and risk assessment was derived as hexythiazox (any ratio of constituent isomers). Based on studies investigating the behaviour of residues in livestock, further supported by feeding studies, residues are not expected to be significant in commodities of animal origin (below 0.01 mg/kg).

However, as fully validated analytical methods for enforcement are not available, only tentative MRLs could be derived in livestock commodities.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA Pesticides Residues Intake Model (PRIMO). Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for hexythiazox. Additional calculations of the consumer exposure, considering these
CXLs, were therefore carried out. The highest chronic exposure was calculated for the German children, representing 13.2% of the acceptable daily intake (ADI).

As an acute reference dose (ARfD) was not deemed necessary for hexythiazox, calculation of acute consumer exposure was not performed.
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Background

Regulation (EC) No 396/2005\(^1\) (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that 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\(^2\) a reasoned opinion on the review of the existing MRLs for that active substance. As hexythiazox was included in Annex I to Council Directive 91/414/EEC on 1 June 2011 by means of Commission Directive 2011/46/EU\(^3\) and has been deemed to be approved under Regulation (EC) No 1107/2009\(^4\), in accordance with Commission Implementing Regulation (EU) No 540/2011\(^5\), as amended by Commission Implementing Regulation (EU) No 541/2011\(^6\), EFSA initiated the review of all existing MRLs for that active substance.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that, in the framework of Directive 91/414/EEC, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the EU, and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

To gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;
- the analytical methods for enforcement of the proposed MRLs.

Finland, the designated rapporteur Member State (RMS) in the framework of Commission Regulation (EC) No 33/2008\(^7\), was asked to complete the PROFile for hexythiazox and to prepare a supporting evaluation report (Finland, 2012). The PROFile and the supporting evaluation report were submitted to EFSA on 31 August 2012 and made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 21 December 2016 and finalised on 3 March 2017. Additional evaluation reports were submitted by Germany, Hungary, Belgium, Spain, Finland, France, Greece, Italy, Portugal and the European Union Reference Laboratories for Pesticide Residues (Belgium, 2017; EURL, 2017; Finland, 2017a,b; France, 2017; Germany, 2017; Greece, 2017a,b; Hungary, 2017; Italy, 2017; Portugal, 2017; Spain, 2017) and, after having considered all the information provided by the RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 9 February 2018. Further clarifications were sought from Member States via a

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\(^{1}\) 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.

\(^{3}\) Commission Directive 2011/46/EU of 14 April 2011 amending Council Directive 91/414/EEC to include hexythiazox as active substance and amending Commission Decision 2008/934/EC. OJ No L 101, 15.4.2011, p. 20–23.

\(^{4}\) 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.

\(^{5}\) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

\(^{6}\) Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.

\(^{7}\) 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 L15, 18.1.2008, p. 5–12.
written procedure in February–March 2018. Additional evaluation reports were made available by the Netherlands and Italy (Italy, 2018; Netherlands, 2018) and by Finland (Finland, 2018).

Based on the conclusions derived by EFSA in the framework of Commission Regulation (EC) No 33/2008, the MRLs established by the Codex Alimentarius Commission (codex maximum residue limit; CXLs) as well as the additional information provided by Member States and the European Union Reference Laboratories for Pesticide Residues, EFSA prepared in August–September 2018 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 5 October 2018 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Finland, 2012, 2017b, 2018) and the evaluation reports submitted by the Member States Germany, Hungary, Belgium, Spain, Finland, France, Greece, Italy, the Netherlands, Portugal and the European Union Reference Laboratories for Pesticide Residues (Belgium, 2017; EURL, 2017; Finland, 2017a; France, 2017; Germany, 2017; Greece, 2017a,b, Hungary, 2017; Italy, 2017, 2018; Portugal, 2017; Spain, 2017; Netherlands, 2018) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2018a) and the Member States consultation report (EFSA, 2018b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) (excel files) and the PROFile are key supporting documents and made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the report sheet of the PRIMo(EU) and PRIMo (CXL) is presented in Appendix C.

Terms of Reference

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

The active substance and its use pattern

Hexythiazox is the ISO common name for (4RS,5RS)-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide (IUPAC). Hexythiazox is a racemic mixture of enantiomers (4R,5R) and (4S,5S).

Hexythiazox is a non-systemic acaricide and insecticide used in agriculture and horticulture. Hexythiazox acts by contact and stomach action. It has ovicidal, larvicidal and nymphicidal activity. It is not active against adult species, but eggs laid by treated females do not survive.

The chemical structure of the active substance and its main metabolites are reported in Appendix F.

Hexythiazox was evaluated following a resubmission application for inclusion in Annex I to Council Directive 91/414/EEC in the framework of Commission Regulation (EC) No 33/2008, with Finland designated as RMS. The representative uses supported for the peer review process comprised outdoor foliar spray applications against spider mites in apples, grapes and citrus. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2011/46/EU, which entered into force on 1 June 2011. According to Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, hexythiazox is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as an acaricide only. According to the Annex to the approval, the applicant was required to submit to the European Commission further studies in the area of residues, toxicology and ecotoxicology by 31 May 2013. The confirmatory data relevant for the residue area (the potential occurrence of the metabolite PT-1-3 in processed commodities and its toxicological relevance) were assessed by the RMS (Finland, 2014) and considered sufficient by the Standing Committee on the Food Chain and Animal Health without involvement of EFSA (European Commission, 2014).
The EU MRLs for hexythiazox are established in Annex IIIA of Regulation (EC) No 396/2005 and codex maximum residue limits (CXLs) for hexythiazox were also established by the Codex Alimentarius Commission (CAC). An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

**Table 1:** Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

| Procedure | Legal implementation | Remarks |
|-----------|----------------------|---------|
| MRL application (EFSA, 2012) | Commission Regulation (EU) No 592/2012(a) | Application to modify the existing MRL of hexythiazox in tea |
| Implementation of CAC 2010 | Commission Regulation (EU) No 520/2011(b) | Various crops |

MRL: maximum residue level; CAC: Codex Alimentarius Commission.

(a): Commission Regulation (EU) No 592/2012 of 4 July 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenthrin, captan, cyprodinil, fluopicolide, hexythiazox, isoprothiolane, metaldehyde, oxadiazon and phosmet in or on certain products. OJ L 176, 6.7.2012, p. 1–37.

(b): Commission Regulation (EU) No 520/2011 of 25 May 2011 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benalaxyl, boscalid, buprofezin, carbofuran, carbosulfan, cypermethrin, fluopicolide, hexythiazox, indoxacarb, metaflumizone, methoxyfenozide, paraquat, prochloraz, spirotetramat, prothioconazole and zoxamide in or on certain products. OJ L 140, 27.5.2011, p. 2–47.

For the purpose of this MRL review, the critical uses of hexythiazox currently authorised within the EU, as well as uses authorised in third countries that might have a significant impact on international trade, have been collected by the RMS and reported in the PROFile. The additional good agricultural practices (GAPs) reported by Member States during the completeness check were also considered. The details of the authorised GAPs for hexythiazox are given in Appendix A.

**Assessment**

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Finland, 2012), the draft assessment report (DAR) prepared under Council Directive 91/414/EEC (Finland, 2006), the additional report and its addenda prepared under Commission Regulation (EC) No 33/2008 (Finland, 2009, 2010), the confirmatory data (Finland, 2014) preceding the review report on hexythiazox (European Commission, 2014), the conclusion on the peer review of the pesticide risk assessment of the active substance hexythiazox (EFSA, 2010), the Joint Meeting on Pesticide Residues (JMPR) Evaluation report (FAO, 2009b,c, 2011), the previous reasoned opinion on hexythiazox (EFSA, 2012) as well as the evaluation reports submitted during the completeness check and further clarifications (Belgium, 2017; EURL, 2017; Finland, 2017a,b, 2018; France, 2017; Germany, 2017; Greece, 2017a,b; Hungary, 2017; Italy, 2017, 2018; Portugal, 2017; Spain, 2017; Netherlands, 2018). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997–2000, 2009, 2010, 2013).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

1. **Residues in plants**

1.1. **Nature of residues and methods of analysis in plants**

1.1.1. **Nature of residues in primary crops**

The metabolism of hexythiazox in fruit crops (grape, citrus, pear and apple) and in leafy crops (tea) was investigated during the peer review under Commission Regulation (EC) No 33/2008 (EFSA, 2010). The reported studies indicated that the metabolism of hexythiazox in primary crops is limited.

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8 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
In fruit crops, following local treatment of fruits and leaves, hexythiazox was the major component of the residues ranging from 71% in pears (preharvest interval (PHI) 30 days) up to 93% in grapes (PHI 21 days) of the total radioactive residue (TRR) at harvest. Hexythiazox accounted for more than 60% of the TRR even 60 days after application. Other metabolites were detected at very low levels. The only exception was in citrus, where 60 days after fruit treatment degradation occurred; with the metabolite PT-1-8 (trans) detected above 10% of the TRR, yet the parent compound still remained the major component of the residues. However, at the PHI of the critical GAP for citrus fruits (PHI 28 days) the parent compound accounted for 70% of the TRR and the metabolite PT-1-8 (sum of cis and trans) was less than 5% of the TRR.

In leafy crops, similarly to fruit crops, following foliar applications the parent hexythiazox accounted for 84.5% of the TRR after 21 days of treatment.

Although only a single, ^14_C-hexythiazox label on the thiazolidine moiety was used in all of the studies, given the limited degradation of the parent compound, additional labelling was not considered necessary.

In summary, hexythiazox is degraded slowly in both crop groups studied; the parent compound was the major component of the residues. The metabolism studies are considered to be representative of the most critical GAPs assessed in this review in terms of application method for fruit and leafy crops. However, as metabolism studies for cereals and for pulses and oil seeds are not available, some commodities for which existing GAPs were reported are not covered. As a consequence, a data gap is identified regarding the nature of residues in primary crops for pulses and oilseeds and for cereals.

1.1.2. Nature of residues in rotational crops

Among the crops under consideration, fruiting vegetables (such as tomatoes, cucumbers, melons) as well as legume vegetables (beans) and cereals (maize) may be grown in rotation. According to the soil degradation studies performed in the framework of the peer review, the DT_90 values of hexythiazox (up to 248 days) and its metabolites PT-1-2 (up to 877 days) and PT-1-3 (up to 180 days) exceeded 100 days (EFSA, 2010). Therefore, an investigation of residues in rotational crops, following single and multiannual application, is required.

A confined rotational crop study investigating residue uptake in lettuce, turnip and wheat for two different plant-back intervals (PBI) of 30 and 122 days after treatment (DAT) was submitted during the peer review (Finland, 2006). The application rates used in this study were 280 and 560 g a.s./ha on bare soil (1.8–3.5 N the maximum total dose rate considered in this review) which cover the maximum application rates authorised for non-perennial crops within the EU.

At final harvest, total radioactivity was low (< 0.02 mg eq/kg) in lettuce heads, turnips and wheat grains. Significant amounts of the TRRs were only detected in wheat chaff (0.03–0.07 mg eq/kg) and in wheat straw (0.11–0.27 mg eq/kg) for both PBIs. In wheat straw, the major metabolite was PT-1-2, amounting up to 0.04 mg eq/kg (PBI 122 days). This was also the major and predominant metabolite in soil. Other individual component accounting for more than 0.01 mg eq/kg was not detected.

On the basis of the above findings, metabolism in primary and rotational crops was found to be similar.

Given the high persistence of PT-1-2, the potential occurrence of residues following multiannual applications was assessed. In particular, in order to conclude if specific MRLs and/or risk mitigation measures should be recommended for rotational crops, PT-1-2 concentrations measured in the tested soils detailed above were compared with the PT-1-2 concentrations expected in soil following multiannual applications according to the most critical indoor and outdoor EU GAPs.

Considering the maximum application rate of 2 × 0.08 kg a.s./ha (indoor application on courgettes and gherkins) assessed in this review, single first order soil DT_50 of 264 days, a soil bulk density of 1.5 g/cm^3, a soil depth of 20 cm and no crop interception, the soil concentration that would result from the plateau concentration in soil taking into account accumulation over the years were calculated as 0.035 mg PT-1-2/kg soil.

In the confined rotational crop study following application of 560 g a.s./ha, at the time of the planting of the succeeding crop at day 122, PT 1-2 was 0.054 mg hexythiazox eq/kg soil, which (molecular weight relative to hexythiazox: 0.77) equals to 0.04 mg PT-1-2/kg soil (Finland, 2006).

Therefore, the rotated crops in the metabolism study were exposed to a soil concentration of PT-1-2 slightly higher (1.14N) compared to the calculated plateau (0.04 and 0.035 mg/kg soil). Hence, the
rotational crops study covers the multiannual applications of hexythiazox assessed in the present review. Therefore, based on the calculated plateau and the results of the confined rotational crops study, it can be concluded that significant residues of hexythiazox and its persistent soil metabolites are not expected in rotational crops provided that hexythiazox is used according to the GAPs reported in this review.

1.1.3. Nature of residues in processed commodities

The effect of industrial processing on the nature of the residues was investigated in the framework of the peer review (EFSA, 2010). A hydrolysis study showed that hexythiazox is relatively stable under conditions simulating pasteurisation (90°C, pH 4, 20 min), baking, brewing and boiling (100°C, pH 5, 60 min), with up to 20% of hydrolysis occurring (20% and 13% of TRR, respectively). Interestingly, degradation was more distinctive under pasteurisation compared to baking conditions.

In contrast, under sterilisation conditions (120°C, pH 6, 20 min), degradation to the metabolite PT-1-3 accounts for up to 48% of the TRR, roughly the same amount as the non-hydrolysed parent compound. Hydrolyses studies assessing the route and rate of degradation in water (EFSA, 2010) conducted at various pH (pH 5, 7 and 9) and temperatures (22°C, 50°C and 70°C) suggest that the degradation of the parent compound is both pH and temperature dependent. Whereas hexythiazox at 22°C is stable at pH 5–7, and it takes more than 500 days to reach its half-life (DT50) even at pH 9; at 70°C the same degradation level is reached over 300 days, 12 days or within less than 5 h in a buffer solution of pH 5, 7 or 9, respectively.

It can be concluded that the effect of processing on the stability of hexythiazox is most pronounced under sterilisation. The formation of metabolite PT-1-3 is only expected at significant levels under these conditions. Despite that under pasteurisation, roughly 20% degradation of the parent occurred, the formation of metabolite PT-1-3 was not significant (~2% of TRR).

Considering that PT-1-3 is more acutely toxic than the parent, additional toxicological information was required on its toxicological relevance and on its possible transfer and level in processed commodities (EFSA, 2010). Additional toxicological studies were assessed by the RMS and submitted to the European Commission as confirmatory data (Finland, 2014). On the basis of this additional information received, the Standing Committee on the Food Chain and Animal Health agreed that the toxicity of metabolite PT-1-3 was well addressed and its mutagenicity could be ruled out (European Commission, 2014). It has been confirmed by the RMS in the framework of the present review that the conclusion was made according to the principles at the time of the approval, noting that it may be peer reviewed in the framework of the renewal (Finland, 2018).

1.1.4. Methods of analysis in plants

In the framework of the peer review under Commission Regulation (EC) No 33/2008, DFG S19 multi-residue and single residue analytical methods were considered sufficiently validated for the determination of hexythiazox in high water (apples, tomatoes), high acid (oranges, grapes) and high oil (cotton seed) content commodities, using high-performance liquid chromatography with ultraviolet detection (HPLC-UV) or gas chromatography with electron capture detector (GC-ECD) quantification and its independent laboratory validation (ILV) at the limit of quantification (LOQ) of 0.05 mg/kg (Finland, 2009, 2012).

In the framework of confirmatory data assessment following the peer review and in the present review, fully validated Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) methods, including ILV using high performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) for the detection of hexythiazox were provided for high acid, high oil, high water and dry commodities (Finland, 2014, 2017b; Greece, 2017b). The methods were validated in apples, grapes, oranges and their processed commodities as well as in soybean seeds, whole plant and hay at the LOQ of 0.01 mg/kg. Additionally, validated methods are also available in matrices considered difficult to analyse (hops, tea) with a LOQ of 0.01 mg/kg using HPLC–MS/MS (Finland, 2017b). These methods are also suitable and validated for the detection of the hexythiazox metabolite PT-1-3, if deemed necessary (Finland, 2014, 2017b).

Additional information on the availability of analytical methods for the enforcement of hexythiazox during routine laboratory analyses was also provided by the EURLs in the framework of this review. According to the information received, by using a QuEChERS method and HPLC–MS/MS for detection, an LOQ of 0.01 mg/kg is achievable for routine analyses of hexythiazox in high acid, high oil and dry.
commodities (EURL, 2017). For high water content commodities, a LOQ of 0.005 mg/kg is successfully validated (EURL, 2017).

1.1.5. Stability of residues in plants

In the framework of the peer review, storage stability of hexythiazox was demonstrated for a period of 24 months at −20°C in commodities with high water content (apples), high acid content (strawberries) matrices and for 4 months at −30°C in specific matrices (tea) (EFSA, 2010). Additional stability studies evaluated in the framework of the present MRL review showed hexythiazox (analysed as the sum of parent compound and all metabolites containing the PT-1-3 moiety) to be stable for 7 and 8 months in high oil content (almond nutmeat) and dry commodities (stover) stored at −10°C, respectively (Finland, 2017b). Further storage stability studies in mandarin (EFSA, 2010) and sorghum grain (Finland, 2012) conducted for shorter periods are also available.

In addition, as part of the confirmatory data submitted following the peer review, storage stability data for hexythiazox and PT-1-3 in processed commodities were also provided. Storage stability was demonstrated for each substance for 1 year in processed apple (juice, puree, canned fruit, pomace), grapes (wine, juice, raisins and pomace), citrus (juice, marmalade, canned fruit, pomace) stored at −18°C (Finland, 2014).

1.1.6. Proposed residue definitions

Based on the metabolism in primary crops, the residue definition for enforcement and risk assessment was set in leafy crops and fruit crops as parent hexythiazox (EFSA, 2010). This residue definition amended as hexythiazox (any ratio of constituent isomers) is still applicable based on the present review and remains limited to fruit crops and leafy crops only.

In the absence of metabolism studies on cereals and oil seeds, tentatively the same residue definition was used for the relevant authorised uses on these crops. Nonetheless, a data gap is identified and at least one additional metabolism study with a third group is required to confirm the applicability of the residue definition for these crops.

The above residue definition covers also rotational crops considering that residues are not expected in succeeding crops above the LOQ following the authorised uses. It is noted that in case additional uses on non-perennial crops will be granted in the future, the proposed default residue definition may need to be reconsidered.

Based on hydrolyses studies, hexythiazox is relatively stable during processing, except under sterilisation conditions when it was degraded to the metabolite PT-1-3 up to 48%. Therefore, this metabolite should in principle be considered for inclusion in the residue definition for processed commodities. Nevertheless, in the framework of this MRL review, the parent compound only is still considered a sufficient marker for enforcement and risk assessment in processed commodities for the following reasons:

- regarding the toxicity profile of PT-1-3 no concern for mutagenicity was identified and specific reference values were not proposed;
- significant formation of PT-1-3 was not confirmed in the available processing studies (see Section 1.2.3);
- consumer exposure from the existing uses is relatively low (see Section 3), providing a sufficient margin of safety.

Therefore, it is concluded that the same residue definition for enforcement and risk assessment as proposed for primary and rotational crops is also applicable to processed commodities. Nevertheless, if additional uses will be granted in the future, additional processing studies may be required and the residue definition for processed commodities may need to be reconsidered.

Fully validated analytical methods are available to enforce the proposed residue definition in high acid, high water, high oil content, dry and difficult to analyse commodities at the LOQ of 0.01 mg/kg. Moreover, the information provided by the EURLs supports that this LOQ is achievable by routine analyses in all major matrices.

In addition, EFSA emphasises that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of hexythiazox and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance becomes available.
1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of hexythiazox residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Finland, 2012), including residue trials evaluated in the framework of the peer review (Finland, 2006) or in the framework of a previous MRL application (EFSA, 2012) as well as additional data submitted during the completeness check (Finland, 2017b; Greece, 2017b; Italy, 2017). All residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions. Decline of residues during storage of the trial samples is therefore not expected.

It is noted that in residue trials supporting import tolerances on citrus fruits, tree nuts, pome fruits, peaches, plums, grapes, maize grains and hops the analytical method used was based on a common moiety method, which detects in addition to the parent compound all metabolites containing the PT-1-3 moiety. Nonetheless, overestimation of the residues is not expected, as based on the metabolism studies the parent compound is not metabolised significantly at the corresponding PHI.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

Residue trials are not available to support the authorisations on kiwi fruits, bananas, beans with pods, soya beans and cotton seeds. Therefore, MRL or risk assessment values for these crops could not be derived by EFSA and the following data gaps were identified:

- Kiwi fruits: Eight trials compliant with the southern outdoor GAP are required.
- Soya bean: Eight trials compliant with the southern outdoor GAP are required. Furthermore, prior to the trials the metabolism of hexythiazox in pulses and oil seeds needs to be established.
- Cotton seed: Eight trials compliant with the southern outdoor GAP are required. Furthermore, prior to the trials the metabolism of hexythiazox in pulses and oil seeds needs to be established.
- Beans with pods: Eight trials on beans with pods compliant with the southern outdoor GAP and eight trials compliant with the indoor GAP are required. Furthermore, prior to the trials the metabolism of hexythiazox in pulses and oil seeds needs to be established.
- Bananas: Four trials compliant with the southern outdoor GAP are required.

For some crops, the number of residue trials reported is not compliant with the data requirements, only tentative MRL and risk assessment values could be derived by EFSA and the following data gaps were identified:

- Apricots: the import tolerance GAP is supported by extrapolation from nine residue trials on peaches. Considering that the extrapolation guidance allows extrapolation to apricots from ‘peaches and apricots’, provided that a minimum of 50% is with apricots, a minimum of four trials compliant with the import tolerance GAP is required. No trials are available compliant with the southern outdoor GAP. Therefore, eight additional trials supporting the southern outdoor GAP are also required.
- Cherries (sweet): Two additional trials on cherries compliant with the import tolerance GAP are required. No trials are available compliant with the northern outdoor or southern outdoor GAP. Therefore, eight trials compliant with the northern outdoor GAP and four trials compliant with the southern outdoor GAP are also required. In addition, the RMS highlighted that the MRL derived based on the trials is higher compared to the MRL in force in the country of origin (USA, MRL 1 mg/kg). However, risk managers should consider whether it is preferable to align the MRL based on an import tolerance with that of the exporting country.
- Plums: whereas the less critical northern outdoor GAP is fully supported, two additional trials on plums compliant with the import tolerance GAP are required. No trials are available compliant with the southern outdoor GAP. Therefore, eight additional trials supporting the southern outdoor GAP are also required.

For all other crops, the available residue trials are sufficient to derive MRL and risk assessment values, taking note of the following considerations:
- Peaches: no trials are available supporting the southern outdoor GAP. Therefore, eight residue trials compliant with the southern outdoor GAP are still required.
- Sweet peppers/bell peppers: trials supporting the southern outdoor GAP are not available. Therefore, eight residue trials compliant with the southern outdoor GAP are still required.
- Cucumbers, courgettes, gherkins: trials supporting the southern outdoor GAP are not available. Therefore, eight residue trials compliant with the southern outdoor GAP are still required.
- Cane fruits and other small fruits and berries, except cranberries: trials supporting the northern outdoor GAP are not available. However, considering the metabolism studies, the environmental fate studies, the rotational crop studies, trials with other crops and that the foliar application is carried out after harvest followed by a long vegetation period, a no-residue situation is expected. Therefore, two residue trials would be desirable to confirm the no-residue situation. No trials are available compliant with the southern outdoor GAP and the indoor GAPs. Therefore, four residue trials compliant with the southern outdoor GAP and four for the EU indoor GAPs are still required. For rose hips, azaroles and elderberries only northern outdoor GAPs are authorised.
- Cranberries: trials supporting the northern outdoor and the indoor GAPs are not available. However, considering the metabolism studies, the environmental fate studies, the rotational crop studies, trials with other crops and that the foliar application is carried out after harvest followed by a long vegetation period, a no-residue situation is expected for these GAPs. Therefore, two residue trials would be desirable to confirm the no-residue situation.
- Maize/corn grains: the import tolerance GAP was considered to derive the MRL and risk assessment values. In 21 residue trials supporting the GAP, including trials more critical than the GAP for this import tolerance (PHI, dose rate) and using the common moiety method for detection (detects the parent and metabolites containing the PT-1-3 moiety), residues were below the LOQ of 0.02 mg/kg. Therefore, based on this dataset, this GAP was deemed sufficiently supported by data, despite the lack of metabolism studies for cereals. No trials are available compliant with the southern outdoor GAP. Therefore, eight residue trials compliant with the southern outdoor GAP are still required.

1.2.2. Magnitude of residues in rotational crops

Significant residues of hexythiazox and its persistent soil metabolites are not expected in rotational crops (see Section 1.1.2). Nonetheless, for completeness and as supporting information, a rotational crop field trial was submitted for the peer review (Finland, 2006). A field rotational crop study was conducted with leaf lettuce, radish, mustard, grain sorghum and wheat at two sites. Bare soil was treated with 0.21 kg/ha hexythiazox (1.3N) and rotational crops were planted with PBIs of 30, 120 and 240/270 days. The analytical method detecting the PT-1-3 common moiety was used. Residues were all below the detection limit of 0.01 mg/kg, except for radish top and sorghum stover at one of the sites following the 30-day PBI. Residues ranged between 0.03 and 0.05 mg/kg in the radish top, and below or at the LOQ of 0.01 mg/kg in stover samples. These findings, in view of the overdosed bare soil application, also support that significant residues are not expected in succeeding crops.

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed by studies conducted on citrus, apples, grapes, strawberry and hops (Finland, 2006, 2012, 2014; EFSA, 2010; Greece, 2017b). An overview of all available processing studies is available in Appendix B.1.2.3.

Based on the nature of residue studies hexythiazox is relatively stable, except under sterilisation conditions where the formation of metabolite PT-1-3 is expected. Investigation of its possible transfer and level in processed commodities was investigated in pasteurised/sterilised food items. During the peer review and in the confirmatory data assessment, several processing studies including heat treatment were provided on oranges, mandarins, grapes, and apples (Finland, 2006, 2014).

With respect to citrus fruits, the level of hexythiazox was measured following processing of oranges and mandarins (10N; days after last application (DALA) 13–15 days) in peeled fruits, canned fruits (pasteurised), juice, and marmalade (sterilised), as well as in wet and dry pomace. The effect of sterilisation on the formation of PT-1-3 in marmalade was studied in particular in 6 trials. The marmalade was cooked at 55–60°C and sterilised at 120°C for 10 min. Citric acid was added before sterilisation. PT-1-3 was not detected at or above the limit of detection of 0.015 mg/kg in marmalade (Finland, 2006). As confirmatory data additional processing studies were provided and processing...
Factors were calculated for the parent compound in processed commodities of orange (pasteurised juice; marmalade; canned oranges; wet and dry pomace) simulating common industrial practices (Finland, 2014).

For grapes, the effect of processing, including the formation of PT-1-3 was evaluated in pasteurised grape juice, must, red and white wine, dried raisins and wet and dry pomace (Finland, 2006, 2014). PT-1-3 was only detected in dry pomace at or slightly above 0.01 mg/kg in overdosed trials.

For apples, processing studies investigated the levels of the parent and the metabolite PT-1-3 in pasteurised juice, purée, canned fruit as well as in wet and dry pomace (Finland, 2014). PT-1-3 was only detected in dry pomace at or slightly above 0.01 mg/kg in overdosed trials.

Additional processing studies on strawberries (jam following sterilisation) (Finland, 2012), oranges (peeled fruits), grapes (must; white and red wine; wet and dry pomace) (Greece, 2017b) and hops (Finland, 2012) were also submitted in the framework of the present MRL review. Following heat treatment, PT-1-3 was below the detection limit of 0.01 mg/kg in the processed commodities from strawberries and grapes. Processing studies on hops, using the common moiety method detecting the sum of hexythiazox and PT-1-3 containing metabolites indicated that residues are not transferred to beer.

Overall, the processing studies simulated common industrial practices. Residues of hexythiazox decreased compared to the RAC in all processed commodities, except for wet and dry pomace and raisins. The confirmatory studies showed that PT-1-3 was only formed in dry pomace, at low levels.

Robust processing factors could be derived for processing of citrus fruits (peeling, juice, marmalade, wet and dry pomace), apple (pasteurised juice; purée; canned fruit; wet and dry pomace), grapes (raisin; wine; must; pasteurised juice; wet and dry pomace), strawberry (jam, canned fruits) and hops (beer).

On the basis on the information available during the peer review and submitted as confirmatory data, it was concluded that the occurrence of PT-1-3 in processed commodities was expected to be low, if present at all, when considering the representative uses in the peer review (citrus fruits, apples, grapes) but its occurrence and consequences in other commodities, raw or processed, may require attention (European Commission, 2014).

Processing studies investigating the occurrence of PT-1-3 in processed vegetables (tomatoes, aubergines, peppers and cucurbits with edible peel), and other fruits (cherries, apricots, peaches, plums) are not available to support the existing uses. However, considering the relatively low levels of hexythiazox residues in these commodities according to the available trials, in the framework of this review it is confirmed that the occurrence of PT-1-3 in processed commodities is expected to be low. Therefore, taking also into account the results of the consumer risk assessment (see Section 3), additional processing studies are currently not needed. Nevertheless, if additional uses will be granted in the future, additional processing studies may be required.

### 1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for apricots, cherries, plums where tentative MRLs are derived, and for beans with pods, kiwi, soybeans, cotton seeds and bananas where the available data were insufficient to derive tentative MRLs.

### 2. Residues in livestock

Hexythiazox is authorised for use on several crops that might be fed to livestock. The dietary burdens were calculated for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. Dietary burdens calculated for cattle, equine and swine were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in ruminants.

The nature of hexythiazox residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Finland, 2006). Reported metabolism studies include a study in lactating goat and one in laying hens using $^{14}$C hexythiazox labelled in the 5-position of the thiazolidine ring.

A lactating goat was dosed twice daily with an overall of 1.16 mg/kg body weight (bw) per day of hexythiazox for seven consecutive days, corresponding to approximately 227 times the maximum exposure of cattle. The majority of the total radioactive residues was excreted. In the study, the highest residue levels were found in liver, kidney and fat (1.91, 0.41 and 0.42 mg eq/kg, respectively), while in muscle and milk residues accounted for a maximum of 0.11 and 0.15 mg eq/kg each. The...
parent compound and its major metabolites were detected in all tissues investigated, but their levels were varying. Hexythiazox remained the predominant metabolite in fat and milk (61% and 31% of the TRR) while in liver, kidney and muscle it was found at very low levels or even below the LOQ. In these matrices, degradation was more extensive with the isomers of PT-1-10 metabolite found most abundantly (31%, 26% and 16% of the TRR, respectively), followed by the isomers of PT-1-4 (18%, 16% and 28% of the TRR, respectively). G1 metabolites (consisting of several unidentified metabolites) were also identified above 10% of the TRR in liver (12%) and kidney (23%), and were the most abundant metabolites in urine (39%).

Altogether, the residue pattern was similar qualitatively, with the individual levels of parent and metabolites being different in the various tissues. Residues in milk reached a plateau level during the fifth day of dosing.

Although not required (dietary burden did not exceed the trigger value for poultry), the metabolism study in hens is reported for completeness. In this study laying hens were dosed with either 0.35 or 3.5 mg/kg bw per day of hexythiazox for six consecutive days. The study demonstrates that transfer of residues to eggs and tissues is relatively low. Most of the total administered dose was recovered in excreta (~90% of the administered dose) and limited translocation was observed in eggs (up to 1.1% of the dose). Hexythiazox was extensively metabolised, with the total radioactive residues accounted for a maximum of 0.50, 0.14, 0.07, 0.6 and 0.1 mg/kg hexythiazox equivalent in the low dose in eggs, liver, fat, kidney and breast muscle, respectively. Residue levels were proportionately higher in the high residue group, except in eggs where the difference was only fourfold. In fat, hexythiazox constituted 48% of the TRR, whereas PT-1-8 (cis and trans) made up 20% and 26% of the TRR, respectively. In eggs and liver, the parent compound was extensively metabolised; the isomers of PT-1-10 were the highest residues constituting 14% of the TRR in both tissues, all other residue components were below 10% of the TRR. Hexythiazox was gradually accumulating in eggs; a plateau was not detected within the 6-day feeding period.

According to the peer review, the main metabolic pathway identified in rats was oxidation of the cyclohexane ring to form the major metabolite PT-1-8 (cis). In addition, studies demonstrated that metabolites PT-1-4 and PT-1-8 (cis and trans) were not acutely toxic and did not display mutagenic potential in an in vitro test (EFSA, 2010).

In the metabolism studies on both ruminant and poultry, the presence of several metabolites (in particular metabolites PT-1-10, PT-1-4 and PT-1-8 and their isomers) indicates extensive metabolism involving hydroxylation of the cyclohexyl ring. Based on the results of the available studies, metabolites PT-1-10, PT-1-4 and PT-1-8 and their isomers would in principle be considered in the residue definition. However, according to the above-mentioned metabolism studies, after exposure to the maximum dietary burden (227 N), residue levels are expected to remain well below 0.01 mg/kg in milk, muscle, fat, liver and kidney.

Two livestock feeding studies on ruminants also support this conclusion.

In one study, dairy cows were dosed with hexythiazox for 4 weeks at three levels, 5, 15 and 50 mg/kg feed per day. The analytical method using HPLC-UV detected the parent compound and its metabolites containing the common moiety of PT-1-3 with a LOQ of 0.01 mg/kg. Residues were below the LOQ of 0.01 mg/kg in all tissues analysed and in milk at the feeding level closest to the maximum calculated dietary burden (28N). In the other study, dairy cows were fed with 0.024 or 0.26 mg/kg bw per day (4.7N or 51N) hexythiazox for 14 days and animals were sacrificed 8 days following the last treatment. The analytical method also detected the common moiety of PT-1-3. All tissue and milk samples were below the LOQ of 0.05 mg/kg.

The storage stability of hexythiazox residues in animal products has not been investigated. Nonetheless, considering that on the basis of the metabolism study it was possible to conclude that significant residues are not expected in animal commodities and the feeding studies were only used as supporting information, a storage stability study is not required.

Hence, in the framework of this review, the residue definition for ruminants can be proposed as hexythiazox (any ratio of constituent isomers) for enforcement purposes and for risk assessment.

Analytical methods capable of analysing the parent compound only are not available. Nonetheless, according to the information received from the EURLs, screening validation data indicate that hexythiazox can be enforced in all commodities of animal origin at a screening detection limit of 0.005 mg/kg using the quadrupole time-of-flight LC-MS system (LC-MS-Q-ToF) (EURL, 2017).

A data gap is identified, namely a fully validated analytical method is required for the enforcement of the proposed residue definition. It is concluded that based on the metabolism studies supported by the feeding studies, residues above the LOQ of 0.01 mg/kg are not expected. Tentative MRLs and risk
assessment values for the relevant commodities in cattle, equine and swine can be established at the LOQ, while MRLs for sheep, goat and poultry products are not required because these species are not expected to be exposed to hexythiazox residues.

Although the log P_{ow} of hexythiazox is lower than 3, considering that the parent compound was present in fat at higher levels than in the other tissues, and in a feeding study residues could only be detected in the cream of milk but not in skimmed milk, EFSA concludes that hexythiazox is fat soluble.

It is noted that in case additional uses on crops fed to livestock will be granted in the future, the proposed default residue definitions may need to be reconsidered.

3. Consumer risk assessment

In the framework of this review, only the uses of the active substance reported by the RMS in Appendix A were considered; however, the use of hexythiazox was previously also assessed by the JMPR (FAO, 2009b, 2011). The CXLs, resulting from these assessments by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. To facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs.

3.1. Consumer risk assessment without consideration of the existing CXLs

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009a).

For those commodities where data were insufficient to derive a MRL in Section 1, EFSA considered the existing EU MRL for an indicative calculation, noting that the existing residue definition is equivalent to the proposed residue definition for risk assessment. The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation. All input values included in the exposure calculations are summarised in Appendix D.

Acute exposure calculations were not carried out since an acute reference dose (ARfD) was not deemed necessary for this active substance (EFSA, 2010).

The exposure values calculated were compared with the toxicological reference value for hexythiazox, derived by EFSA (2010) under Commission Regulation (EC) No 33/2008. The highest chronic exposure was calculated for German children, representing 9.7% of the acceptable daily intake (ADI). Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers.

Despite formation of the metabolite PT-1-3 in hydrolysis studies, this metabolite was not detected in processed food commodities. Although not all processed commodities from crops with authorised uses were investigated, considering the maximum amount of residues present in these commodities, and that the overall exposure to hexythiazox is low, EFSA concludes that the occurrence, if any, of this metabolite is unlikely to be of concern for the authorised uses reported in the framework of this review. In case future uses of hexythiazox would lead to much higher consumer exposure, the assessment might need to be revised.

It is noted by EFSA that the above risk assessment was performed disregarding the possible impact of the isomer ratios of hexythiazox to plant or livestock metabolism. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

3.2. Consumer risk assessment with consideration of the existing CXLs

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix E and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. An overview of the input values used for this exposure calculation is also provided in Appendix D.

It is noted that the residue definition for enforcement of the CXLs is hexythiazox for plant commodities, while for risk assessment it is the sum of hexythiazox and all metabolites containing the \textit{trans}-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3), expressed as hexythiazox. Therefore, for risk assessment, the definition is wider compared to the one proposed by EFSA.
However, as outlined earlier, the residue definition can be considered comparable in view of the limited metabolism. Moreover, in many trials supporting the most critical GAPs, the analytical method used were detecting the PT-1-3 common-moiety.

With respect to commodities of animal origin, the residue definition for both enforcement and risk assessment of the CXLs is the sum of hexythiazox and all metabolites containing the trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3), expressed as hexythiazox. This residue definition is more comprehensive compared to the definitions proposed by EFSA, however, as no residues above the LOQ of 0.05 mg/kg were estimated by JMPR, the CXLs based on the wider residue definition will not lead to significant overestimation.

Chronic exposure calculations were also performed using revision 2 of the EFSA PRIMo and the exposure values calculated were compared with the toxicological reference value derived for hexythiazox. The highest chronic exposure was calculated for the German children, representing 13.2% of the ADI.

Based on these calculations, EFSA concludes that the CXLs are not expected to be of concern for European consumers.

Conclusions

The nature of hexythiazox in primary crops was investigated only in fruit crops and leafy crops following foliar and local applications. Therefore, a general residue definition for all plant commodities could not be established. The residue was defined as hexythiazox (any ratio of constituent isomers) for both enforcement and risk assessment purposes for fruit crops and leafy crops, and tentatively for the other commodity groups. Validated analytical methods for the enforcement of this residue definition are available for all major crop groups and in addition for tea and hops.

Significant residues of hexythiazox above 0.01 mg/kg are not expected in rotational crops following the authorised uses.

Hexythiazox was found to be relatively stable under standard hydrolysis conditions, except under conditions mimicking sterilisation, when around 50% degraded to the metabolite PT-1-3. However, based on processing studies and the review of the authorised GAPs, the residue definition for both risk assessment and for enforcement purposes in processed commodities is proposed to be the same as for the primary crops, i.e. parent only.

The available residue trials were sufficient to derive MRL proposals and risk assessment values for all commodities under evaluation, except for apricots, cherries and plums where tentative MRLs are derived, and for beans with pods, kiwi, soya beans, cotton seeds and bananas where the available data were insufficient to derive MRLs.

Robust processing factors (fully supported by data) could be derived for processing of citrus fruits (peeling, juice, marmalade, wet and dry pomace), apple (pasteurised juice; purée; canned fruit; wet and dry pomace), grapes (wine; must; pasteurised juice; wet and dry pomace), strawberry (Jam, canned fruits) and hops (beer). The metabolite PT-1-3 was below the detection limit in all processed commodities investigated, except in dry pomace, where residues were detected at low levels.

Hexythiazox is authorised for use on several feed items and dietary burdens calculated for cattle, equine and swine were found to exceed the trigger value of 0.1 mg/kg DM. Based on metabolism studies on dairy ruminants and laying hens a common residue definition in all livestock commodities can be proposed. The residue definition for enforcement and risk assessment was derived as hexythiazox (any ratio of constituent isomers). Based on studies investigating the behaviour of residues in livestock, further supported by feeding studies, residues are not expected to be significant in commodities of animal origin (below 0.01 mg/kg).

However, as fully validated analytical methods for enforcement are not available, only tentative MRLs could be derived in livestock commodities.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for hexythiazox. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure was calculated for the German children, representing 13.2% of the ADI.

As an ARfD was not deemed necessary for hexythiazox, calculation of acute consumer exposure was not performed.
Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 2 footnotes for details). In particular, some tentative MRLs and existing EU MRLs need to be confirmed by the following data:

- a representative study investigating primary crop metabolism in a third crop group (relevant for the authorised uses on soybeans, beans with pods, cotton seeds);
- additional residue trials on banana, kiwi fruits, soya beans, beans with pods, cotton seeds, apricots, cherries (sweet), plums;
- a fully validated analytical method for the determination of hexythiazox (any ratio of constituent isomers) in animal commodities.

It is highlighted, however, that some of the MRLs derived result from a CXL or from a GAP in one climatic zone only, whereas other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- additional residue trials on peaches, sweet peppers/bell peppers, cucumbers, courgettes, gherkins, cane fruits and small berries (except rose hips, azaroles, cranberries and elderberries).
- additional residue trials supporting the southern outdoor GAP on maize/corn grain and a representative study investigating primary crop metabolism in a third crop group.

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

A minor deficiency was also identified in the assessment but this deficiency is not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data is therefore considered desirable but not essential:

- residue trials compliant with the northern outdoor GAP for cane fruits and other small fruits and berries and the indoor GAP for cranberries confirming the no-residue situation in these crops.

In addition, the rapporteur Member State highlighted that the MRL derived for cherries based on the GAP for import tolerance is higher compared to the MRL in force in the country of origin. Risk managers should consider whether alignment of the MRL in force in the exporting country is required.

Table 2: Summary table

| Code number | Commodity       | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------------|-------------------------|---------------------|-----------------------|---------|
|             |                 | (mg/kg)                 |                     |                       |         |
| **Enforcement residue definition (existing):** | hexythiazox | **Enforcement residue definition (proposed):** | hexythiazox (any ratio of constituent isomers) | (F) | (F) |
| 110010      | Grapefruits     | 1                       | 0.5                 | 0.5                   | Recommended⁶  |
| 110020      | Oranges         | 1                       | 0.5                 | 0.5                   | Recommended⁶  |
| 110030      | Lemons          | 1                       | 0.5                 | 0.5                   | Recommended⁶  |
| 110040      | Limes           | 1                       | 0.5                 | 0.5                   | Recommended⁶  |
| 110050      | Mandarins       | 1                       | 0.5                 | 0.5                   | Recommended⁶  |
| 120010      | Almonds         | 0.5                     | 0.05*               | 0.05                  | Recommended⁶  |
| 120020      | Brazil nuts     | 0.5                     | 0.05*               | 0.05                  | Recommended⁶  |
| 120030      | Cashew nuts     | 0.5                     | 0.05*               | 0.05                  | Recommended⁶  |
| 120040      | Chestnuts       | 0.5                     | 0.05*               | 0.05                  | Recommended⁶  |
| 120050      | Coconuts        | 0.5                     | 0.05*               | 0.05                  | Recommended⁶  |
| 120060      | Hazelnuts/cobnuts | 0.5                 | 0.05*               | 0.05                  | Recommended⁶  |
| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review MRL (mg/kg) | Comment |
|-------------|-----------|------------------------|---------------------|-------------------------------|---------|
| 120070      | Macadamias| 0.5                    | 0.05*               | 0.05                           | Recommended*<sup>(9)</sup> |
| 120080      | Pecans    | 0.5                    | 0.05*               | 0.05                           | Recommended*<sup>(9)</sup> |
| 120090      | Pine nut kernels | 0.5              | 0.05*               | 0.05                           | Recommended*<sup>(9)</sup> |
| 120100      | Pistachios| 0.5                    | 0.05*               | 0.05                           | Recommended*<sup>(9)</sup> |
| 120110      | Walnuts   | 0.5                    | 0.05*               | 0.05                           | Recommended*<sup>(9)</sup> |
| 130010      | Apples    | 1                      | 0.4                 | 0.4                            | Recommended*<sup>(9)</sup> |
| 130020      | Pears     | 1                      | 0.4                 | 0.4                            | Recommended*<sup>(9)</sup> |
| 130030      | Quinces   | 0.5                    | 0.4                 | 0.4                            | Recommended*<sup>(9)</sup> |
| 130040      | Medlars   | 0.5                    | 0.4                 | 0.4                            | Recommended*<sup>(9)</sup> |
| 130050      | Loquats/Japanese medlars | 0.5    | 0.4                 | 0.4                            | Recommended*<sup>(9)</sup> |
| 140010      | Apricots  | 1                      | 0.3                 | 0.7                            | Further consideration needed*<sup>(b)</sup> |
| 140020      | Cherries (sweet) | 1    | 0.3                 | 1.5                            | Further consideration needed*<sup>(b)</sup> |
| 140030      | Peaches   | 1                      | 0.3                 | 0.7                            | Recommended*<sup>(9)</sup> |
| 140040      | Plums     | 0.5                    | 0.3                 | 0.7                            | Further consideration needed*<sup>(b)</sup> |
| 151010      | Table grapes | 1                  | 1                   | 1                              | Recommended*<sup>(9)</sup> |
| 151020      | Wine grapes | 1                   | 1                   | 1                              | Recommended*<sup>(9)</sup> |
| 152000      | Strawberries | 0.5                  | 6                   | 6                              | Recommended*<sup>(9)</sup> |
| 153010      | Blackberries | 0.5                 | –                   | 0.01*                          | Recommended*<sup>(9)</sup> |
| 153020      | Dewberries | 0.5                    | –                   | 0.01*                          | Recommended*<sup>(9)</sup> |
| 153030      | Raspberries (red and yellow) | 0.5 | –                   | 0.01*                          | Recommended*<sup>(9)</sup> |
| 154010      | Blueberries | 0.5                    | –                   | 0.01*                          | Recommended*<sup>(9)</sup> |
| 154020      | Cranberries | 0.5                    | –                   | 0.01*                          | Recommended*<sup>(9)</sup> |
| 154030      | Currants (black, red and white) | 0.5 | –                   | 0.01*                          | Recommended*<sup>(9)</sup> |
| 154040      | Gooseberries (green, red and yellow) | 0.5 | –                   | 0.01*                          | Recommended*<sup>(9)</sup> |
| 154050      | Rose hips | 0.5                    | –                   | 0.01*                          | Recommended*<sup>(9)</sup> |
| 154060      | Mulberries (black and white) | 0.5 | –                   | 0.01*                          | Recommended*<sup>(9)</sup> |
| 154070      | Azaroles/Mediterranean medlars | 0.5 | –                   | 0.01*                          | Recommended*<sup>(9)</sup> |
| 154080      | Elderberries | 0.5                    | –                   | 0.01*                          | Recommended*<sup>(9)</sup> |
| 161010      | Dates     | 2                      | 2                   | 2                              | Recommended*<sup>(9)</sup> |
| 162010      | Kiwi fruits (green, red, yellow) | 1 | –                   | 1                              | Further consideration needed*<sup>(f)</sup> |
| 163020      | Bananas   | 0.5                    | –                   | 0.5                            | Further consideration needed*<sup>(f)</sup> |
| 231010      | Tomatoes  | 0.5                    | 0.1                 | 0.1                            | Recommended*<sup>(9)</sup> |
| 231020      | Sweet peppers/bell peppers | 0.5 | –                   | 0.09                           | Recommended*<sup>(9)</sup> |
| 231030      | Aubergines/eggplants | 0.5 | 0.1                 | 0.1                            | Recommended*<sup>(9)</sup> |
| 232010      | Cucumbers | 0.5                    | 0.05                | 0.05                           | Recommended*<sup>(9)</sup> |
| 232020      | Gherkins  | 0.5                    | 0.05                | 0.05                           | Recommended*<sup>(9)</sup> |
| 232030      | Courgettes | 0.5                    | 0.05                | 0.05                           | Recommended*<sup>(9)</sup> |
| 233010      | Melons    | 0.5                    | 0.05                | 0.07                           | Recommended*<sup>(9)</sup> |
| 233020      | Pumpkins  | 0.5                    | 0.05                | 0.07                           | Recommended*<sup>(9)</sup> |
| 233030      | Watermelons | 0.5                  | –                   | 0.07                           | Recommended*<sup>(9)</sup> |
| 260010      | Beans (with pods) | 0.5    | –                   | 0.5                            | Further consideration needed*<sup>(f)</sup> |
| 401070      | Soya beans | 0.5                    | –                   | 0.5                            | Further consideration needed*<sup>(f)</sup> |
| 401090      | Cotton seeds | 0.5                  | –                   | 0.5                            | Further consideration needed*<sup>(f)</sup> |
| 500030      | Maize/corn grains | 0.5 | –                   | 0.02                           | Recommended*<sup>(9)</sup> |
| 610000      | Teas      | 4                      | 15                  | 15                             | Recommended*<sup>(9)</sup> |
| 700000      | Hops      | 20                     | 3                   | 3                              | Recommended*<sup>(9)</sup> |
| 1011010     | Swine muscle | 0.05                  | 0.05*               | 0.05                           | Further consideration needed*<sup>(9)</sup> |
| Code number | Commodity              | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment                  |
|-------------|------------------------|-------------------------|----------------------|-----------------------|--------------------------|
| 1011020     | Swine fat tissue       | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1011030     | Swine liver            | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1011040     | Swine kidney           | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1012010     | Bovine muscle          | 0.05                    | 0.05*                | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1012020     | Bovine fat tissue      | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1012030     | Bovine liver           | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1012040     | Bovine kidney          | 0.01*                   | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1013010     | Sheep muscle           | 0.05                    | 0.05*                | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1013020     | Sheep fat tissue       | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1013030     | Sheep liver            | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1013040     | Sheep kidney           | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1014010     | Goat muscle            | 0.05                    | 0.05*                | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1014020     | Goat fat tissue        | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1014030     | Goat liver             | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1014040     | Goat kidney            | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1015010     | Equine muscle          | 0.05                    | 0.05*                | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1015020     | Equine fat tissue      | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1015030     | Equine liver           | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1015040     | Equine kidney          | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1016010     | Poultry muscle         | 0.05                    | 0.05*                | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1016020     | Poultry fat tissue     | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1016030     | Poultry liver          | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1020010     | Cattle milk            | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1020020     | Sheep milk             | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1020030     | Goat milk              | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
| 1020040     | Horse milk             | 0.05                    | 0.05                 | 0.05                  | Further consideration needed<sup>(g)</sup> |
|             | Other commodities of   | Reg (EU) No             |                      |                      | Further consideration needed<sup>(i)</sup> |
|             | plant and animal origin| 592/2012                |                      |                      |                          |

MRL: maximum residue level; CXL: codex maximum residue limit.

* Indicates that the MRL is set at the limit of quantification.

(a): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix E).

(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix E).

(c): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix E).

(d): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).

(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E).

(f): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL; no CXL is available (combination C-I in Appendix E).

(g): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix E).

(h): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).

(i): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
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Abbreviations

a.i. active ingredient
a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAC Codex Alimentarius Commission

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| Acronym | Description |
|---------|-------------|
| CAS     | Chemical Abstract Service |
| CXL     | codex maximum residue limit |
| DALA    | days after last application |
| DAR     | draft assessment report |
| DAT     | days after treatment |
| DB      | dietary burden |
| DM      | dry matter |
| DT<sub>90</sub> | period required for 90% dissipation (define method of estimation) |
| EC      | emulsifiable concentrate |
| EMS     | evaluating Member State |
| eq      | residue expressed as a.s. equivalent |
| EURLs   | European Union Reference Laboratories for Pesticide Residues (former CRLs) |
| FAO     | Food and Agriculture Organization of the United Nations |
| GAP     | Good Agricultural Practice |
| GC-ECD  | gas chromatography with electron capture detector |
| HPLC-Ms/MS | high performance liquid chromatography with tandem mass spectrometry |
| HPLC-UV | high-performance liquid chromatography with ultraviolet detector |
| HR      | highest residue |
| IEDI    | international estimated daily intake |
| ILV     | independent laboratory validation |
| InChiKey| International Chemical Identifier Key |
| ISO     | International Organisation for Standardization |
| IUPAC   | International Union of Pure and Applied Chemistry |
| JMPR    | Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues) |
| LC      | liquid chromatography |
| LOQ     | limit of quantification |
| Mo      | Monitoring |
| MRL     | maximum residue level |
| MS      | Member States |
| MS      | mass spectrometry detector |
| NEU     | northern European Union |
| OECD    | Organisation for Economic Co-operation and Development |
| PBI     | plant-back interval |
| PF      | processing factor |
| PHI     | preharvest interval |
| P<sub>ow</sub>| partition coefficient between n-octanol and water |
| PRIMo   | (EFSA) Pesticide Residues Intake Model |
| PROFile | (EFSA) Pesticide Residues Overview File |
| Q-ToF   | quadrupole time-of-flight |
| QuEChERS| Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RA      | risk assessment |
| RAC     | raw agricultural commodity |
| RD      | residue definition |
| RMS     | rapporteur Member State |
| SANCO   | Directorate-General for Health and Consumers |
| SC      | suspension concentrate |
| SDL     | screening detection limit |
| SEU     | southern European Union |
| SMILES  | simplified molecular-input line-entry system |
| STMR    | supervised trials median residue |
| TTR     | total radioactive residue |
| UV      | ultraviolet (detector) |
| WHO     | World Health Organization |
| WP      | wettable powder |
## Appendix A – Summary of authorised uses considered for the review of MRLs

### A.1. Authorised outdoor uses in northern EU

| Crop and/or situation | MS or country | F G or Y(1) | Pests or group of pests controlled | Preparation | Method kind | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|------------|-----------------------------------|-------------|------------|------------|---------------------------------|---------------|---------|
| **Apples**            | FR, DE, CZ, FI, SE | F | Spider mites | WP 100 g/kg | Foliar treatment – spraying | 85 1 | – – | 0.1 kg a.i./ha | 28 | Also authorised with SC-formulation (250 g a.s./L) |
| **Pears**             | FR, DE, CZ, FI | F | Spider mites | WP 100 g/kg | Foliar treatment – spraying | 85 1 | – – | 0.1 kg a.i./ha | 28 | See apples |
| **Quinces**           | FR | F | Spider mites | WP 100 g/kg | Foliar treatment – spraying | 85 1 | – – | 0.1 kg a.i./ha | 28 | See apples |
| **Medlars**           | FR | F | Spider mites | WP 100 g/kg | Foliar treatment – spraying | 85 1 | – – | 0.1 kg a.i./ha | 28 | See apples |
| **Loquats**           | FR | F | Spider mites | WP 100 g/kg | Foliar treatment – spraying | 85 1 | – – | 0.1 kg a.i./ha | 28 | See apples |
| **Cherries**          | FI | F | Spider mites | WP 100 g/kg | Foliar treatment – spraying | 85 1–1 | – – | 0.1 kg a.i./ha | 28 | PHI: 30 days |
| **Plums**             | FI | F | Spider mites | WP 100 g/kg | Foliar treatment – spraying | 85 1–1 | – – | 0.1 kg a.i./ha | 28 | PHI: 30 days |
| **Table grapes**      | DE, CZ, SE, BE | F | Spider mites | WP 100 g/kg | Foliar treatment – spraying | 15 onwards 2 | 30 | 0.08 kg a.i./ha | 21 | Also authorised with SC-formulation (250 g a.s./L) |
| **Wine grapes**       | DE, CZ, SE, BE | F | Spider mites | WP 100 g/kg | Foliar treatment – spraying | 15 onwards 2 | 30 | 0.08 kg a.i./ha | 21 | Also authorised with SC-formulation (250 g a.s./L) |
| **Strawberries**      | DE, CZ, SE, BE | F | Spider mites | WP 100 g/kg | Foliar treatment – spraying | 97 1 | – – | 0.1 kg a.i./ha | 3 | Also authorised with SC-formulation (250 g a.s./L) |
| **Blackberries**      | BE | F | Spider mites | SC 250 g/kg | Foliar treatment – spraying | 91–99 3 | – – | 0.1 kg a.i./ha | n.a | Application on shrubs, after last harvest |

(1) Y indicates a new Member State in the EU for the plant protection product concerned.
| Crop and/or situation | MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|------------------------------------|-------------|-------------|--------------------------------|------------|---------|
|                       |               |                                    | Type(b)     | Conc. a.s.  | Method kind                     |            |         |
| Dewberries            | BE F          | Spider mites                       | SC          | 250 g/kg    | Foliar treatment – spraying     | 91–99      | 3       | 0.1 kg a.i./ha n.a. See blackberries |
| Raspberries           | BE F          | Spider mites                       | SC          | 250 g/kg    | Foliar treatment – spraying     | 91–99      | 3       | 0.1 kg a.i./ha n.a. See blackberries |
| Blueberries           | BE F          | Spider mites                       | SC          | 250 g/kg    | Foliar treatment – spraying     | 91–99      | 3       | 0.1 kg a.i./ha n.a. See blackberries |
| Cranberries           | BE F          | Spider mites                       | SC          | 250 g/kg    | Foliar treatment – spraying     | 91–99      | 3       | 0.1 kg a.i./ha n.a. See blackberries |
| Currants              | BE F          | Spider mites                       | SC          | 250 g/kg    | Foliar treatment – spraying     | 91–99      | 3       | 0.1 kg a.i./ha n.a. See blackberries |
| Gooseberries          | BE F          | Spider mites                       | SC          | 250 g/kg    | Foliar treatment – spraying     | 91–99      | 3       | 0.1 kg a.i./ha n.a. See blackberries |
| Rose hips             | DE, HU F      | Spider mites                       | WP          | 100 g/kg    | Foliar treatment – spraying     | 91–99      | 3       | 0.1 kg a.i./ha n.a. See blackberries |
| Mulberries            | DE F          | Spider mites                       | WP          | 100 g/kg    | Foliar treatment – spraying     | 91–99      | 3       | 0.1 kg a.i./ha n.a. See blackberries |
| Azaroles              | DE F          | Spider mites                       | WP          | 100 g/kg    | Foliar treatment – spraying     | 91–99      | 3       | 0.1 kg a.i./ha n.a. See blackberries |
| Elderberries          | DE, HU F      | Spider mites                       | WP          | 100 g/kg    | Foliar treatment – spraying     | 91–99      | 3       | 0.1 kg a.i./ha n.a. See blackberries |
| Gherkins              | HU F          | Spider mites                       | WP          | 100 g/kg    | Foliar treatment – spraying     | 89         | 7       | 0.03 kg a.i./ha 3 Also authorised with SC-formulation (250 g a.s./L) |
| Hops                  | DE, CZ, HU, BE F | Spider mites                       | WP          | 100 g/kg    | Foliar treatment – spraying     | 1          | 1       | 0.15 kg a.i./ha 28 Also authorised with SC-formulation (250 g a.s./L) |

MRL: active substance; MS: Member State; a.s.: active substance; WP: wettable powder; a.i.: active ingredient; SC: suspension concentrate.  
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).  
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.  
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.  
(d): PHI: minimum preharvest interval.
| Crop and/or situation | MS or country | F G or T | Pests or group of pests controlled | Preparation Type(b) Conc. a.s. | Application Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | Application rate per treatment a.s./hL min–max | Water L/ha min–max | PHI (days)(d) | Remarks |
|-----------------------|---------------|----------|-----------------------------------|--------------------------------|-------------------------|-----------------------------|---------------|-----------------------------------|-----------------------------------------------|------------------|-----------|---------|
| Grapefruits           | FR, IT        | F        | Spider mites                      | WP 100 g/kg                   | Foliar treatment – spraying | 68-83                       | 3                          | –                                  | –                              | –          | 0.08 kg a.i./ha | 14 Also authorised with SC-formulation (250 g a.s./L) |
| Oranges               | FR, IT        | F        | Spider mites                      | WP 100 g/kg                   | Foliar treatment – spraying | 68-83                       | 3                          | –                                  | –                              | –          | 0.08 kg a.i./ha | 14 See grapefruits |
| Lemons                | FR, IT        | F        | Spider mites                      | WP 100 g/kg                   | Foliar treatment – spraying | 68-83                       | 3                          | –                                  | –                              | –          | 0.08 kg a.i./ha | 14 See grapefruits |
| Limes                 | FR, IT        | F        | Spider mites                      | WP 100 g/kg                   | Foliar treatment – spraying | 68-83                       | 3                          | –                                  | –                              | –          | 0.08 kg a.i./ha | 14 See grapefruits |
| Mandarins             | FR, IT        | F        | Spider mites                      | WP 100 g/kg                   | Foliar treatment – spraying | 68-83                       | 3                          | –                                  | –                              | –          | 0.08 kg a.i./ha | 14 See grapefruits |
| Apples                | FR, PT        | F        | Spider mites                      | WP 100 g/kg                   | Foliar treatment – spraying | 85                         | 1                          | –                                  | –                              | 0.1 kg a.i./ha | 28 Also authorised with SC-formulation (250 g a.s./L) |
| Pears                 | FR, PT        | F        | Spider mites                      | WP 100 g/kg                   | Foliar treatment – spraying | 85                         | 1                          | –                                  | –                              | 0.1 kg a.i./ha | 28 Also authorised with SC-formulation (250 g a.s./L) |
| Quinces               | FR            | F        | Spider mites                      | WP 100 g/kg                   | Foliar treatment – spraying | 85                         | 1                          | –                                  | –                              | 0.1 kg a.i./ha | 28 Also authorised with SC-formulation (250 g a.s./L) |
| Medlars               | FR            | F        | Spider mites                      | WP 100 g/kg                   | Foliar treatment – spraying | 85                         | 1                          | –                                  | –                              | 0.1 kg a.i./ha | 28 Also authorised with SC-formulation (250 g a.s./L) |
| Loquats               | FR            | F        | Spider mites                      | WP 100 g/kg                   | Foliar treatment – spraying | 85                         | 1                          | –                                  | –                              | 0.1 kg a.i./ha | 28 Also authorised with SC-formulation (250 g a.s./L) |
| Apricots              | ES            | F        | Spider mites                      | WP 100 g/kg                   | Foliar treatment – spraying | 1                           | –                          | –                                  | –                              | 0.075 kg a.i./ha | 14 0.0075 kg a.s./hL (1,000 L/ha assumed) |
| Crop and/or situation | MS or country | F | G or T<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages & season<sup>(c)</sup> | Number min-max | Interval between application (min) | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|---------------|---|---------------------|-----------------------------------|-------------|-------------|-----------|-------------|-------------------------------|----------------|-----------------------------|-------------------------------|-----------------|---------|
| Cherries              | ES            | F | Spider mites        | WP                                | 100 g/kg    | Foliar treatment – spraying | 1         |             | 0.075 kg a.i./ha (1,000 L/ha assumed) | 14              | 0.0075 kg a.i./ha              |
| Peaches               | ES            | F | Spider mites        | WP                                | 100 g/kg    | Foliar treatment – spraying | 1         |             | 0.075 kg a.i./ha (1,000 L/ha assumed) | 14              | 0.0075 kg a.i./ha              |
| Plums                 | ES            | F | Spider mites        | WP                                | 100 g/kg    | Foliar treatment – spraying | 1         |             | 0.075 kg a.i./ha (1,000 L/ha assumed) | 14              | 0.0075 kg a.i./ha              |
| Table grapes          | ES            | F | Spider mites        | WP                                | 100 g/kg    | Foliar treatment – spraying | 1         |             | 0.075 kg a.i./ha (1,000 L/ha assumed) | 14              | 0.0075 kg a.i./ha              |
| Wine grapes           | ES            | F | Spider mites        | WP                                | 100 g/kg    | Foliar treatment – spraying | 1         |             | 0.075 kg a.i./ha (1,000 L/ha assumed) | 14              | 0.0075 kg a.i./ha              |
| Strawberries          | PT            | F | Spider mites        | WP                                | 100 g/kg    | Foliar treatment – spraying | 97        | 1           | 0.1 kg a.i./ha | 3                           |
| Blackberries          | IT            | F | Tetranychus urticae | SC                                | 259 g/kg    | Foliar treatment – spraying | 1         |             | 0.05 kg a.i./ha | 7                           |
| Dewberries            | IT            | F | Tetranychus urticae | SC                                | 259 g/kg    | Foliar treatment – spraying | 1         |             | 0.05 kg a.i./ha | 7                           |
| Raspberries           | ES            | F | Spider mites        | WP                                | 100 g/kg    | Foliar treatment – spraying |             |             | 0.075 kg a.i./ha (1,000 L/ha assumed) | 7              | 0.0075 kg a.s./hL              |
| Blueberries           | IT            | F | Tetranychus urticae | SC                                | 259 g/kg    | Foliar treatment – spraying | 1         |             | 0.05 kg a.i./ha | 7                           |
| Currants              | IT            | F | Tetranychus urticae | SC                                | 259 g/kg    | Foliar treatment – spraying | 1         |             | 0.05 kg a.i./ha | 7                           |
| Gooseberries          | IT            | F | Tetranychus urticae | SC                                | 259 g/kg    | Foliar treatment – spraying | 1         |             | 0.05 kg a.i./ha | 7                           |

<sup>(a)</sup> Crop and/or situation, MS or country, F G or T, Pests or group of pests controlled.

<sup>(b)</sup> Preparation, Type, Conc. a.s., Method kind, Range of growth stages & season, Number min-max, Interval between application (min).

<sup>(c)</sup> Application rate per treatment, Water L/ha min-max, Rate and unit.

<sup>(d)</sup> PHI (days), Remarks.

Review of the existing MRLs for hexythiazox.
| Crop and/or situation | MS or country | F (G or I) | Pests or group of pests controlled | Preparation | Conc. a.s. | Type(b) | Method kind | PHI (days)(d) | Remarks |
|-----------------------|--------------|-----------|-----------------------------------|-------------|-----------|---------|-------------|-------------|---------|
| Mulberries ES F Spider mites WP 100 g/kg | Foliar treatment – spraying | 7 | – | – | 0.075 kg a.i./ha (1,000 L/ha assumed) | |
| Kiwi fruits IT F Tetranychus urticae WP 100 g/kg | Foliar treatment – spraying | 14 | Also authorised with SC-formulation (250 g a.s./L). | 0.0075 kg a.s./hl (1,000 L/ha assumed) | |
| Bananas ES F Spider mites WP 100 g/kg | Foliar treatment – spraying | 14 | 0.075 kg a.i./ha | |
| Tomatoes PT, IT F Spider mites WP 100 g/kg | Foliar treatment – spraying | 3 | Also authorised with SC-formulation (250 g a.s./L) | 0.1 kg a.i./ha | |
| Sweet peppers IT F Tetranychus urticae WP 100 g/kg | Foliar treatment – spraying | 7 | Also authorised with SC-formulation (250 g a.s./L). | 0.05 kg a.i./ha | |
| Aubergines PT, IT F Spider mites WP 100 g/kg | Foliar treatment – spraying | 3 | Also authorised with SC-formulation (250 g a.s./L) | 0.1 kg a.i./ha | |
| Cucumbers EL F Tetranychus urticae WP 100 g/kg | Foliar treatment – spraying | 3 | Also authorised with SC-formulation (250 g a.s./L) | 0.08 kg a.i./ha | |
| Gherkins EL F Tetranychus urticae WP 100 g/kg | Foliar treatment – spraying | 3 | Also authorised with SC-formulation (250 g a.s./L) | 0.08 kg a.i./ha | |
| Courgettes EL F Tetranychus urticae WP 100 g/kg | Foliar treatment – spraying | 3 | Also authorised with SC-formulation (250 g a.s./L) | 0.08 kg a.i./ha | |
| Melons PT, FR F Spider mites WP 100 g/kg | Foliar treatment – spraying | 3 | Also authorised with SC-formulation (250 g a.s./L) | 0.08 kg a.i./ha | |
| Crop and/or situation | MS or country | F or G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|--------------|----------------|----------------------------------|-------------|----------------|-------------------------------|--------------|---------|
|                       |              |                |                                  | Type(b) Conc. a.s. Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit |                     |
| Pumpkins              | PT, FR       | F              | Spider mites                     | WP 100 g/kg Foliar treatment – spraying | 89 | 1 | – | – | 0.08 kg a.i./ha | 3 | Also authorised with SC-formulation (250 g a.s./L) |
| Watermelons           | PT, FR       | F              | Spider mites                     | WP 100 g/kg Foliar treatment – spraying | 89 | 1 | – | – | 0.08 kg a.i./ha | 3 | Also authorised with SC-formulation (250 g a.s./L) |
| Beans (with pods)     | IT           | F              | Tetranychus urticae              | WP 100 g/kg Foliar treatment – spraying | 1 | – | – | – | 0.05 kg a.i./ha | 3 | Also authorised with SC-formulation (250 g a.s./L) |
| Soyabeans             | IT           | F              | Tetranychus urticae              | WP 100 g/kg Foliar treatment – spraying | 1 | – | – | 0.05 kg a.i./ha | 35 | PHI: 34. Also authorised with SC-formulation (250 g a.s./L) |
| Cotton seeds          | ES           | F              | Tetranychus urticae              | WP 100 g/kg Foliar treatment – spraying | 1 | – | – | – | 0.075 kg a.i./ha | 14 | 0.0075 kg a.s/hL (1,000 L/ha assumed) |
| Maize                 | ES           | F              | Tetranychus urticae              | WP 100 g/kg Foliar treatment – spraying | 1 | – | – | 0.075 kg a.i./ha | 14 |                     |

MRL: active substance; MS: Member State; a.s.: active substance; WP: wettable powder; a.i.: active ingredient; SC: suspension concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
### A.3. Authorised indoor uses in EU

| Crop and/or situation | MS or country | F G or I | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|----------|-------------------------------------|-------------|-------------|---------------------------------|------------|---------|
| Strawberries          | PT, DE, CZ, BE| I        | Spider mites                        | WP          | Foliar treatment – spraying | 100 g/kg | 97 1 | 0.1 kg a.i./ha | 3 Also authorised with SC-formulation (250 g a.s./L). |
| Blackberries          | IT I Tetranychus urticae | SC 259 g/kg | Foliar treatment – spraying | 1 | – – | 0.05 kg a.i./ha | 7 |
| Dewberries            | IT I Tetranychus urticae | SC 259 g/kg | Foliar treatment – spraying | 1 | – – | 0.05 kg a.i./ha | 7 |
| Raspberries           | ES I Spider mites | WP 100 g/kg | Foliar treatment – spraying | – – | 0.075 kg a.i./ha | 7 0.0075 kg a.s./hL (1,000 L/ha assumed) |
| Blueberries           | IT I Tetranychus urticae | SC 259 g/kg | Foliar treatment – spraying | 1 | – – | 0.05 kg a.i./ha | 7 |
| Cranberries           | BE I Spider mites | SC 250 g/kg | Foliar treatment – spraying | 91-99 3 | – – | 0.1 kg a.i./ha | n.a. Application on shrubs, after last harvest |
| Currants              | IT I Tetranychus urticae | SC 259 g/kg | Foliar treatment – spraying | 1 | – – | 0.05 kg a.i./ha | 7 |
| Gooseberries          | IT I Tetranychus urticae | SC 259 g/kg | Foliar treatment – spraying | 1 | – – | 0.05 kg a.i./ha | 7 |
| Mulberries            | ES I Spider mites | WP 100 g/kg | Foliar treatment – spraying | – – | 0.075 kg a.i./ha | 7 0.0075 kg a.s./hL (1,000 L/ha assumed) |
| Tomatoes              | DE, PT, CZ, HU, BE I Spider mites | WP 100 g/kg | Foliar treatment – spraying | 89 1 | – – | 0.1 kg a.i./ha | 3 Also authorised with SC-formulation (250 g a.s./L) |
| Sweet peppers         | DE, HU I Spider mites | WP 100 g/kg | Foliar treatment – spraying | 89 1 | – – | 0.1 kg a.i./ha | 3 Also authorised with SC-formulation (250 g a.s./L) |
### Crop and/or situation | MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks
--- | --- | --- | --- | --- | --- | --- | ---
Aubergines | DE, HU | I Spider mites | WP 100 g/ kg | Foliar treatment – spraying | 89 1 | – – | 0.1 kg a.i./ha 3 Also authorised with SC-formulation (250 g a.s./L)
Cucumbers | DE | I Spider mites | SC 250 g/ kg | Foliar treatment – spraying | 89 1 | – – | 0.1 kg a.i./ha 3
Gherkins | NL | I Spider mites | SC 250 g/ kg | Foliar treatment – spraying | 89 2 7 | – – | 0.08 kg a.i./ha 3
Courgettes | NL | I Spider mites | SC 250 g/ kg | Foliar treatment – spraying | 89 2 7 | – – | 0.08 kg a.i./ha 3
Melons | DE | I Spider mites | SC 250 g/ kg | Foliar treatment – spraying | 89 1 | – – | 0.1 kg a.i./ha 3
Pumpkins | DE | I Spider mites | SC 250 g/ kg | Foliar treatment – spraying | 89 1 | – – | 0.1 kg a.i./ha 3
Watermelons | DE | I Spider mites | SC 250 g/ kg | Foliar treatment – spraying | 89 1 | – – | 0.1 kg a.i./ha 3
Beans (with pods) | IT | I Tetranychus urticae | WP 100 g/ kg | Foliar treatment – spraying | 1 | – – | 0.05 kg a.i./ha 3 Also authorised with SC-formulation (250 g a.s./L)

**MRL**: active substance; **MS**: Member State; **a.s.**: active substance; **WP**: wettable powder; **a.i.**: active ingredient; **SC**: suspension concentrate.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
### A.4. Import tolerance

| Crop and/or situation | MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|---------------|------------------------------------|-------------|-------------|-------------------------------|-------------------------|---------|
|                       |               |                                    | Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages & season<sup>(c)</sup> | Number min-max | Interval between application (min) | A.s./L/ha | Water L/ha | Rate and unit |         |
| Grapefruits | USA | F Spider mites | WP 500 g/kg | Foliar treatment – spraying | 1 | – | 0.219 kg a.i./ha | 28 | Also authorised with EC-formulation (118 g a.s./L) |
| Oranges | USA | F Spider mites | WP 500 g/kg | Foliar treatment – spraying | 1 | – | 0.219 kg a.i./ha | 28 | See grapefruits |
| Lemons | USA | F Spider mites | WP 500 g/kg | Foliar treatment – spraying | 1 | – | 0.219 kg a.i./ha | 28 | See grapefruits |
| Limes | USA | F Spider mites | WP 500 g/kg | Foliar treatment – spraying | 1 | – | 0.219 kg a.i./ha | 28 | See grapefruits |
| Mandarins | USA | F Spider mites | WP 500 g/kg | Foliar treatment – spraying | 1 | – | 0.219 kg a.i./ha | 28 | See grapefruits |
| Almonds | USA | F Spider mites | WP 500 g/kg | Foliar treatment – spraying | 1 | – | 0.219 kg a.i./ha | 28 | |
| Brazil nuts | USA | F Spider mites | WP 500 g/kg | Foliar treatment – spraying | 1 | – | 0.219 kg a.i./ha | 28 | |
| Cashew nuts | USA | F Spider mites | WP 500 g/kg | Foliar treatment – spraying | 1 | – | 0.219 kg a.i./ha | 28 | |
| Chestnuts | USA | F Spider mites | WP 500 g/kg | Foliar treatment – spraying | 1 | – | 0.219 kg a.i./ha | 28 | |
| Coconuts | USA | F Spider mites | WP 500 g/kg | Foliar treatment – spraying | 1 | – | 0.219 kg a.i./ha | 28 | |
## Table

| Crop and/or situation | MS or country | F or G or I<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|---------------|-----------------------------|-----------------------------------|-------------|-----------------------------|--------------------------|---------|
| Horse chestnut        | USA           | F                           | Spider mites                      | WP          | 500 g/kg                    | Foliar treatment – spraying | 1       | –       | 0.219 kg a.i./ha | 28 |
| Hazelnuts             | USA           | F                           | Spider mites                      | WP          | 500 g/kg                    | Foliar treatment – spraying | 1       | –       | 0.219 kg a.i./ha | 28 |
| Macadamias            | USA           | F                           | Spider mites                      | WP          | 500 g/kg                    | Foliar treatment – spraying | 1       | –       | 0.219 kg a.i./ha | 28 |
| Pecans                | USA           | F                           | Spider mites                      | WP          | 500 g/kg                    | Foliar treatment – spraying | 1       | –       | 0.219 kg a.i./ha | 28 |
| Pine nut kernels      | USA           | F                           | Spider mites                      | WP          | 500 g/kg                    | Foliar treatment – spraying | 1       | –       | 0.219 kg a.i./ha | 28 |
| Pistachios            | USA           | F                           | Spider mites                      | WP          | 500 g/kg                    | Foliar treatment – spraying | 1       | –       | 0.219 kg a.i./ha | 28 |
| Walnuts               | USA           | F                           | Spider mites                      | WP          | 500 g/kg                    | Foliar treatment – spraying | 1       | –       | 0.219 kg a.i./ha | 28 |
| Apples                | USA           | F                           | Spider mites                      | EC          | 118 g/L                     | Foliar treatment – spraying | 1       | –       | 0.207 kg a.i./ha | 28 |
| Pears                 | USA           | F                           | Spider mites                      | EC          | 118 g/L                     | Foliar treatment – spraying | 1       | –       | 0.207 kg a.i./ha | 28 |
| Quinces               | USA           | F                           | Spider mites                      | EC          | 118 g/L                     | Foliar treatment – spraying | 1       | –       | 0.207 kg a.i./ha | 28 |
| Medlars               | USA           | F                           | Spider mites                      | EC          | 118 g/L                     | Foliar treatment – spraying | 1       | –       | 0.207 kg a.i./ha | 28 |
| Loquats               | USA           | F                           | Spider mites                      | EC          | 118 g/L                     | Foliar treatment – spraying | 1       | –       | 0.207 kg a.i./ha | 28 |

<sup>(a)</sup> Crop group (FAO classification);

<sup>(b)</sup> Type of preparation;

<sup>(c)</sup> Range of growth stages & season;

<sup>(d)</sup> PHI (days) = Preharvest interval.
| Crop and/or situation | MS or country | Pests or group of pests controlled | Preparation | Application | Range of growth stages & season | Number min-max | Interval between application (min) | Application rate per treatment A.s./hL min-max | Water L/ha min-max | Rate and unit | PHI (days) | Remarks |
|-----------------------|---------------|------------------------------------|-------------|-------------|--------------------------------|----------------|-----------------------------|-----------------------------------------------|-------------------|-------------|-----------|---------|
| Apricots              | USA           | F Spider mites                     | EC 118 g/L  | Foliar treatment – spraying | 1                | --                          | 0.207 kg a.i./ha | 7 |
| Cherries              | USA           | F Spider mites                     | EC 118 g/L  | Foliar treatment – spraying | 1                | --                          | 0.207 kg a.i./ha | 7 |
| Peaches               | USA           | F Spider mites                     | EC 118 g/L  | Foliar treatment – spraying | 1                | --                          | 0.207 kg a.i./ha | 7 |
| Plums                 | USA           | F Spider mites                     | EC 118 g/L  | Foliar treatment – spraying | 1                | --                          | 0.207 kg a.i./ha | 7 |
| Table grapes          | USA           | F Spider mites                     | WP 500 g/kg | Foliar treatment – spraying | 1                | --                          | 0.219 kg a.i./ha | 28 Also authorised with EC-formulation (118 g/L) |
| Wine grapes           | USA           | F Spider mites                     | WP 500 g/kg | Foliar treatment – spraying | 1                | --                          | 0.219 kg a.i./ha | 28 Also authorised with EC-formulation (118 g/L) |
| Maize                 | USA           | F Spider mites                     | EC 118 g/L  | Foliar treatment – spraying | 1                | --                          | 0.207 kg a.i./ha | 45 |
| Teas                  | India         | F Spider mites                     | EC 5.45 g/kg| Foliar treatment – spraying | 2                | --                          | 0.027 kg a.i./ha | 5 |

MRL: active substance; MS: Member State; a.s.: active substance; WP: wettable powder; a.i.: active ingredient; EC: emulsifiable concentrate.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI – minimum pre-harvest interval.
## Appendix B – List of end points

### B.1. Residues in plants

#### B.1.1. Nature of residues and methods of analysis in plants

#### B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) |
|-----------------------------------|-------------|---------|----------------|----------------|
| Fruit crops                       | Grapes      | Local application corresponding to 210 g a.s./ha | Fruits: 0, 14, 21, 41, Leaves: 0, 14, 28 and 56 |
|                                  | Grapes      | Local application corresponding to 2 x 100 g a.s./ha | 21 |
|                                  | Citrus      | Local leaves and fruit: 5.3 g a.s./L | 0, 7, 14, 30, 60 and 91 |
|                                  | Pears       | Local application on leaves and fruit: 5 g a.s./L | 0, 5, 10, 20, 30 and 60 |
|                                  | Apple       | Local application on leaves and fruit: 5 g a.s./L | 10, 20, 30 and 50 |
| Leafy crops                      | Tea         | Foliar, 200 g a.s./ha | 0, 7, 14, 21 |
| Cereals                           | Data gap    | Label: thiazolidine-5-14C hexythiazox. Due to limited metabolism study, additional label was not considered necessary Source: Finland (2006, 2009) |
| Pulses and oil seeds             | Data gap    | |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) |
|-------------------------------------|-------------|---------|----------------|-----------|
| Root/tuber crops                    | Turnip      | Bare soil, 280 g a.s./ha or 560 g a.s./ha | 30 or 122 |
| Leafy crops                         | Lettuce     | Bare soil, 280 g a.s./ha or 560 g a.s./ha | 30 or 122 |
| Cereal (small grain)                | Wheat       | Bare soil, 280 g a.s./ha or 560 g a.s./ha | 30 or 122 |
|                                    | Label: thiazolidine-5-14C hexythiazox Source: Finland (2006) |

| Processed commodities (hydrolysis study) | Conditions | Investigated? |
|------------------------------------------|------------|---------------|
|                                        | Pasteurisation (20 min, 90°C, pH 4) | Yes |
|                                        | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes |
|                                        | Sterilisation (20 min, 120°C, pH 6) | Yes |
|                                        | Source: EFSA (2010) | |
Can a general residue definition be proposed for primary crops? No

Rotational crop and primary crop metabolism similar? Yes

Residue pattern in processed commodities similar to residue pattern in raw commodities? No, under sterilisation (120°C, pH 6, 20 min) hexythiazox is degraded to PT-1-3 (48% TRR)
However, considering that for PT-1-3 no concern for mutagenicity was identified and that the occurrence of this metabolite in processed commodities is expected to be low based on the available processing studies, the same residue definitions as for primary and rotational crops are proposed for processed commodities in the current review.
If additional uses will be granted in the future, the residue definition for processed commodities may need to be reconsidered.

Plant residue definition for monitoring (RD-Mo) Fruits and leafy crops: hexythiazox (any ratio of constituent isomers)

Plant residue definition for risk assessment (RD-RA) Fruits and leafy crops: hexythiazox (any ratio of constituent isomers)

Conversion factor (monitoring to risk assessment) Not applicable

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) High acid, high water, high oil content, dry and difficult to analyse matrices (tea, hops):
- QuEChERS, HPLC–MS/MS;
- LOQ: 0.01 mg/kg (Finland, 2014, 2017b; Greece, 2017b);
- ILV available (Finland, 2017b);
- QuEChERS (HPLC–MS/MS) for enforcement in routine analysis, LOQ 0.01 mg/kg in high acid, high oil and dry commodities; LOQ 0.005 mg/kg for high water content commodities (EURL, 2017).

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method); HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity          | T (°C) | Stability (months) |
|-----------------------------------|----------|--------------------|--------|-------------------|
| High water content                | Apple<sup>(a)</sup> | –20                | 24     |
| High acid content                 | Strawberry<sup>(a)</sup> | –20                | 24     |
| High oil content                  | Almond nutmeat<sup>(b)</sup> | –10               | 7<sup>(c)</sup> |
| Dry                               | Stover<sup>(b)</sup> | –10               | 8<sup>(c)</sup> |
| Specific matrices                 | Tea (dry)<sup>(a)</sup> | –30               | 4      |

(a): Study evaluated during the peer review (EFSA, 2010).
(b): Study evaluated in the framework of this review (Finland, 2017b).
(c): Common moiety method used, which is not compliant with the residue definition for enforcement. For these commodities storage stability data is supporting trials using common moiety method only.
## B.1.2. Magnitude of residues in plants

### B.1.2.1. Summary of residues data from the supervised residue trials

| Crop | Region/indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR<sup>(b)</sup> (mg/kg)<sup>(b)</sup> | STMR<sup>(c)</sup> (mg/kg)<sup>(c)</sup> |
|------|-----------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|-------------------------------|-------------------------------|
| Citrus fruits | SEU | Orange (whole fruit): 7 × < 0.05, 2 × 0.07, 0.08 Mandarin (whole fruit): 5 × < 0.05, 0.07, 0.08, 0.09 | Trials on oranges and mandarins compliant with GAP (Finland, 2012). Extrapolation to other citrus fruits possible MRL<sub>OECD</sub> = 0.12 | 0.15 | 0.09 | 0.05 |
| | Import (USA) | Orange: < 0.05, 0.06, 0.08, 0.09, 0.12, 0.16 Grapefruit: 2 × < 0.05, 2 × 0.05, 0.11, 0.15 Lemon: 0.06, 0.08, 0.15, 0.16, 0.23 | Trials on oranges, grapefruits and lemons compliant with GAP. Extrapolation to other citrus fruits possible MRL<sub>OECD</sub> = 0.31 | 0.4 | 0.23 | 0.08 |
| Tree nuts | Import (USA) | 7 × < 0.02 | GAP-compliant trials on almonds and overdosed trials on pecans (Finland, 2012). Extrapolation to other tree nuts is applicable MRL<sub>OECD</sub> = 0.02 | 0.02 | 0.02 | 0.02 |
| Pome fruits | NEU | Apples: 6 × < 0.05; 0.06; 0.08; Pears: < 0.01; < 0.05 | Trials on apples and pears compliant with GAP (Finland, 2006, 2009; EFSA, 2010). Extrapolation to other pome fruits is possible MRL<sub>OECD</sub> = 0.12 | 0.15 | 0.08 | 0.05 |
| | SEU | Apples: < 0.01; 6 × < 0.05; 0.08; Pears: 2 × < 0.01; | Trials on apples and pears compliant with GAP (Finland, 2006, 2009; EFSA, 2010). Extrapolation to other pome fruits is possible MRL<sub>OECD</sub> = 0.13 | 0.15 | 0.08 | 0.05 |
| | Import (USA) | Apples: 0.04; 0.05; 3 × 0.07; 0.08; 2 × 0.09; 2 × 0.10; 0.14; 0.15; Pears: 0.05; 0.06; 2 × 0.10; 0.12; 0.14 | Trials on apples and pears compliant with GAP (Finland, 2006, 2009; EFSA, 2010). Extrapolation to other pome fruits is possible MRL<sub>OECD</sub> = 0.27 | 0.3 | 0.15 | 0.09 |
| Crop | Region/indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR (mg/kg)(b) | STMR (mg/kg)(c) |
|------|------------------|------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|-------------|-------------|
| Cherries (sweet) | NEU | -- | No residue trials available | -- | -- | -- |
| | SEU | -- | No residue trials available | -- | -- | -- |
| | Import (USA) | 0.34; 0.39; 0.48; 0.55; 0.60; 0.71 | Trials on cherries compliant with GAP (Finland, 2012). In the country of origin, the existing MRL is 1 mg/kg MRL\text{OECD} = 1.53 | 1.5 (tentative)(d) | 0.71 | 0.52 |
| Peaches, apricots | SEU | -- | No residue trials available | -- | -- | -- |
| | Import (USA) | 0.06; 0.07; 0.09; 0.11; 0.14; 0.18; 0.21; 0.26; 0.48 | Trials on peaches compliant with GAP (Finland, 2012). Extrapolation to apricots performed on a tentative basis (not foreseen by the current guidance) MRL\text{OECD} = 0.7 | 0.7 (tentative for apricots)(d) | 0.48 | 0.14 |
| Plums | NEU | 11 \times < 0.05; | Trials on plums are overdosed compared to the GAP (Finland, 2012). No additional trial required since all residues are below the LOQ MRL\text{OECD} = 0.05 | 0.05 | 0.05 | 0.05 |
| | SEU | -- | No residue trials available | -- | -- | -- |
| | Import (USA) | 2 \times 0.03; 2 \times 0.07; 0.08; 0.36 | Trials on plums compliant with GAP (Finland, 2012) MRL\text{OECD} = 0.61 | 0.7 (tentative)(d) | 0.36 | 0.07 |
| Table and wine grapes | NEU | 2 \times 0.06; 0.09; 0.12; 0.13; 0.16; 0.18; 0.19 | Trials on grapes compliant with GAP (Finland 2006, 2009; EFSA, 2010) MRL\text{OECD} = 0.37 | 0.4 | 0.19 | 0.13 |
| | SEU | 3 \times 0.02; 2 \times < 0.05; 2 \times 0.05; 0.06; 3 \times 0.09; 0.10; 0.12; 0.13; 0.14 | Trials on grapes compliant with GAP (Finland 2006, 2009; EFSA, 2010; Greece, 2017a,b; Italy, 2018) MRL\text{OECD} = 0.23 | 0.3 | 0.14 | 0.09 |
| | Import (USA) | 2 \times 0.03; 2 \times 0.04; 0.09; 0.13; 2 \times 0.14; 0.15; 0.17; 0.19; 0.20; 2 \times 0.30; 0.41 | Trials on grapes compliant with GAP (Finland, 2012) MRL\text{OECD} = 0.61 | 0.7 | 0.41 | 0.15 |
## Crop Options

| Crop                                      | Region/ indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)                                                                 | Recommendations/comments (OECD calculations)                                                                 | MRL proposals (mg/kg) | HR (mg/kg)<sup>(b)</sup> | STMR (mg/kg)<sup>(c)</sup> |
|-------------------------------------------|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|-----------------------|------------------------|--------------------------|
| Strawberries                              | NEU                         | 9 × < 0.05; 0.07; 2 × 0.08                                                                                                                                  | Trials on strawberries compliant with GAP (Finland, 2012)  
MRL<sub>OECD</sub> = 0.11                                                                                      | 0.15                  | 0.08                   | 0.05                     |
|                                           | SEU                         | 7 × < 0.05; 0.07                                                                                                                                             | Trials on strawberries compliant with GAP (Finland, 2012)  
MRL<sub>OECD</sub> = 0.08                                                                                      | 0.08                  | 0.07                   | 0.05                     |
|                                           | EU                          | 2 × < 0.05; 0.06; 0.07; 0.11; 0.13; 0.16; 0.19                                                                                                               | Trials on strawberries compliant with GAP (Finland, 2012)  
MRL<sub>OECD</sub> = 0.32                                                                                      | 0.4                   | 0.19                   | 0.09                     |
| Cane fruits and other small fruits and berries, except cranberries | NEU                         | –                                                                                                                                                    | No residue trials available. No residue is expected based on the use pattern (foliar application after harvest), the nature of residue studies (non-systemic, translocation to fruits) and trials on other crops (PHI is driving factor) | 0.01*                | 0.01                   | 0.01                     |
|                                           | SEU                         | –                                                                                                                                                    | No residue trials available. Not authorised for outdoor use on rose hips, azaroles and elderberries in SEU | –                    | –                      | –                        |
|                                           | EU                          | –                                                                                                                                                    | No residue trials available. Not authorised for indoor use on rose hips, azaroles and elderberries | –                    | –                      | –                        |
| Cranberries                               | NEU                         | –                                                                                                                                                    | No residue trials available. No residue is expected based on the use pattern (foliar application after harvest), the nature of residue studies (non-systemic, translocation to fruits) and trials on other crops (PHI is driving factor) | 0.01*                | 0.01                   | 0.01                     |
|                                           | EU                          | –                                                                                                                                                    | No residue trials available. No residue is expected based on the use pattern (foliar application after harvest), the nature of residue studies (non-systemic, translocation to fruits) and trials on other crops (PHI is driving factor) | 0.01*                | 0.01                   | 0.01                     |
| Crop                              | Region/indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations)                          | MRL proposals (mg/kg) | HR (mg/kg)(b) | STMR (mg/kg)(c) |
|----------------------------------|------------------|-----------------------------------------------------------------------------------------------|------------------------------------------------------------------------|----------------------|----------------|----------------|
| Kiwi fruits (green, red, yellow) | SEU              | —                                                                                              | No residue trials available                                            | —                    | —              | —              |
| Bananas                          | SEU              | —                                                                                              | No residue trials available                                            | —                    | —              | —              |
| Tomatoes, aubergines/eggplants   | SEU              | 7 × < 0.05; 0.06; 2 × 0.07                                                                      | Trials on tomatoes compliant with GAP (Finland, 2012). Extrapolation to aubergines possible MRL\(_{OECD}\) = 0.09 | 0.09                 | 0.07           | 0.05           |
|                                  | EU               | 6 × < 0.05; 2 × 0.05                                                                            | Trials on tomatoes compliant with GAP (Finland, 2012). Extrapolation to aubergines possible MRL\(_{OECD}\) = 0.08 | 0.08                 | 0.05           | 0.05           |
| Sweet peppers/bell peppers       | SEU              | —                                                                                              | No residue trials available                                            | —                    | —              | —              |
|                                  | EU               | 6 × < 0.05; 2 × 0.065                                                                           | Trials compliant with GAP (Finland, 2012) MRL\(_{OECD}\) = 0.08         | 0.09                 | 0.07           | 0.05           |
| Cucumbers                        | SEU              | —                                                                                              | No residue trials available                                            | —                    | —              | —              |
|                                  | EU               | 2 × < 0.01; 6 × < 0.05                                                                          | Trials on cucumber with dose rate within 25% deviation (Finland, 2012) MRL\(_{OECD}\) = 0.05 | 0.05                 | 0.05           | 0.05           |
| Courgettes                       | SEU              | —                                                                                              | No residue trials available                                            | —                    | —              | —              |
|                                  | EU               | 2 × < 0.01; 6 × < 0.05                                                                          | Trials on cucumber performed with 1 × 0.08 kg a.s./ha instead of 2 × 0.08 is deemed acceptable, as no residues are expected before the last treatment (Finland, 2012). Extrapolation to courgettes possible MRL\(_{OECD}\) = 0.05 | 0.05                 | 0.05           | 0.05           |
| Gherkins                         | NEU              | 6 × < 0.02; 2 × < 0.025                                                                          | Trials on gherkins compliant with GAP (Finland, 2012) MRL\(_{OECD}\) = 0.02 | 0.03                 | 0.03           | 0.02           |
|                                  | SEU              | —                                                                                              | No residue trials available                                            | —                    | —              | —              |
|                                  | EU               | 2 × < 0.01; 6 × < 0.05                                                                          | Trials on cucumber performed with 1 × 0.08 kg a.s./ha instead of 2 × 0.08 is deemed acceptable, as no residues are expected before the last treatment (Finland, 2012). Extrapolation to gherkins possible | 0.05                 | 0.05           | 0.05           |
| Crop                              | Region/indoor<sup>a</sup> | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations)                                                                                                                                                                                                                     | MRL proposals (mg/kg) | HR (mg/kg)<sup>b</sup> | STMR (mg/kg)<sup>c</sup> |
|----------------------------------|---------------------------|-----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|------------------------|------------------------|
| Melons, watermelons, pumpkins    | SEU                       | 7 × < 0.05; 0.06                                                                               | Trials performed on melons compliant with GAP (Finland, 2012). Extrapolation to watermelons and pumpkins possible MRL<sub>OECD</sub> = 0.07                                                                                                                   | 0.07                  | 0.06                   | 0.05                   |
|                                  | EU                        | 8 × < 0.05                                                                                   | Trials performed on melons compliant with GAP (Finland, 2012). Extrapolation to watermelons and pumpkins possible MRL<sub>OECD</sub> = 0.05                                                                                                                   | 0.05                  | 0.05                   | 0.05                   |
| Beans (with pods)                | SEU                       | --                                                                                           | No residue trials available                                                                                                                                                                                                                                    | --                    | --                     | --                     |
|                                  | EU                        | --                                                                                           | No residue trials available                                                                                                                                                                                                                                    | --                    | --                     | --                     |
| Soybeans                         | SEU                       | --                                                                                           | No residue trials available                                                                                                                                                                                                                                    | --                    | --                     | --                     |
| Cotton seeds                    | SEU                       | --                                                                                           | No residue trials available.                                                                                                                                                                                                                                     | --                    | --                     | --                     |
| Maize/corn grains                | SEU                       | --                                                                                           | No residue trials available.                                                                                                                                                                                                                                     | --                    | --                     | --                     |
|                                  | Import (USA)              | 21 × < 0.02                                                                                   | Trials performed on maize are overdosed compared to the GAP (Finland, 2012)                                                                                                                                                                                                | 0.02                  | 0.02                   | 0.02                   |
| Teas                             | Import (IND)              | 0.78; 0.89; 1.22; 1.27; 1.28; 1.31; 1.54; 1.80                                                                 | Trials on green tea compliant with application rate, but shorter PHI (EFSA, 2012) MRL<sub>OECD</sub> = 3.78                                                                                                                                                    | 4                     | 1.80                   | 1.28                   |
| Hops                             | NEU                       | 0.614; 0.792; 0.792; 1.310; 1.530                                                            | Trials compliant with GAP with dose rate within 25% deviation (Finland, 2012) MRL<sub>OECD</sub> = 3.02                                                                                                                                                            | 3                     | 1.53                   | 0.79                   |
| Maize/corn stover                | SEU                       | --                                                                                           | No residue trials available                                                                                                                                                                                                                                     | --                    | --                     | --                     |
|                                  | Import (USA)              | --                                                                                           | Not relevant for import tolerance                                                                                                                                                                                                                               | --                    | --                     | --                     |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; PHI: preharvest interval.

<sup>a</sup>: Indicates that the MRL is proposed at the limit of quantification.

<sup>b</sup>: NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

<sup>c</sup>: Highest residue.

<sup>d</sup>: Supervised trials median residue.

<sup>e</sup>: MRL proposal is tentative because additional trials are required.
B.1.2.2. Residues in succeeding crops

| Study Type                              | Description                                                                                                                                  |
|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| Confinned rotational crop study        | Residues are not expected at significant levels in succeeding crops, provided that hexythiazox is used according to the GAPs considered in this review. |
| Field rotational crop study            | A field rotational study following bare soil applications (1.3N compared to the most critical GAP) also supports that significant residues are not expected in succeeding crops. |

GAP: Good Agricultural Practice.

B.1.2.3. Processing factors

| Processed commodity                             | Number of studies (a) | Individual values | Median PF |
|-------------------------------------------------|-----------------------|-------------------|-----------|
| Oranges, grapefruits, lemons, lime, mandarins, peeled | 4(b)                  | 0.04; 0.07; 0.15; 0.33 | 0.1       |
| Oranges, grapefruits, lemons, lime, mandarins, juice | g(b)                  | 0.09; 0.13; 0.21; 2 × 0.22; 0.26; 0.3; 0.43; 0.64 | 0.2       |
| Oranges, grapefruits, lemons, lime, mandarins, dry pomace | 5                    | 2.9; 4.9; 7.1; 7.3; 11.1 | 7.1       |
| Oranges, grapefruits, lemons, lime, mandarins, wet pomace | 5                    | 0.6; 3 × 1.5; 2.8 | 1.5       |
| Oranges, marmalade                            | g(b)                  | 0.1; 0.09; 0.14; 0.15; 0.20; 0.26; 0.27; 0.71; 0.91 | 0.2       |
| Table grapes, dried (raisins)                | 7                    | 0.52, 1.10, 1.20, 1.40, 1.70, 2.40, 3.30 | 1.4       |
| Wine grapes, juice                            | 10                   | 0.02, 0.02, 0.05, 0.07, 0.08, 0.08, 0.09, 0.14, 0.18, 0.70 | 0.08      |
| Wine grapes, dry pomace                       | 12                   | 5.00, 6.83, 9.33, 9.80, 15.10, 15.17, 16.50, 17.70, 17.80, 23.20, 23.80, 42.20 | 15.8      |
| Wine grapes, wet pomace                       | 12                   | 0.83, 1.00, 1.67, 2.67, 3.40, 3.80, 4.40, 6.20, 6.60, 6.90, 8.50, 16.60 | 4.1       |
| Wine grapes, must                             | 6                    | 0.10, 0.33, 0.40, 0.50, 0.67, 0.67 | 0.45      |
| Apples, juice                                 | 3                    | 0.2; 0.2; 0.3 | 0.2       |
| Apples, dry pomace(c)                         | 6                    | 5.4; 4.7; 12.8; 10.8; 21.1; 35.2 | 11.8      |
| Apples, wet pomace(c)                         | 6                    | 1.5; 1.2; 1.8; 2.8; 4.0; 3.9 | 2.3       |
| Apples, purée                                 | 3                    | 1; 0.2; 0.3 | 0.3       |
| Apples, canned                                | 3                    | 0.1; 2 × < 0.03(d) | < 0.03    |
| Strawberries, jam                             | 4                    | 0.5; 0.54; 0.79; 1.07 | 0.66      |
| Strawberries, canned                          | 4                    | 0.36; 0.4; 0.52; 0.99 | 0.46      |
| Hops, beer                                    | 4                    | 3 × < 0.1(d); 0.1 | < 0.10    |

n.a. not analysed individually, common moiety method used.

Source: Finland (2006, 2012, 2014); Greece (2017a,b).

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

(b): Studies with residues in processed commodity below the LOQ were disregarded.

(c): Processing factors for pomace derived from juice or puree.

(d): Residues in processed commodity below LOQ.
### B.2. Residues in livestock

| Relevant groups   | Dietary burden expressed in mg/kg bw per day | Most critical diet(\(a\)) | Most critical commodity(\(a\)) | Trigger exceeded (Y/N) |
|------------------|---------------------------------------------|-----------------------------|---------------------------------|------------------------|
|                  | Med. | Max. | Med. | Max.                                   |                           |                       |                   |
| Cattle (all diets) | 0.0051 | 0.0051 | 0.13 | 0.13 | Cattle (dairy) | Grapefruits, dried pulp | Yes |
| Cattle (dairy only) | 0.0051 | 0.0051 | 0.13 | 0.13 | Cattle (dairy) | Grapefruits, dried pulp | Yes |
| Sheep (all diets)  | 0.0025 | 0.0025 | 0.06 | 0.06 | Sheep (lamb) | Apple, pomace, wet | No |
| Sheep (ewe only)   | 0.0020 | 0.0020 | 0.06 | 0.06 | Sheep (ram/ewe) | Apple, pomace, wet | No |
| Swine (all diets)  | 0.0025 | 0.0025 | 0.11 | 0.11 | Swine (breeding) | Grapefruits, dried pulp | Yes |
| Poultry (all diets) | 0.0030 | 0.0030 | 0.04 | 0.04 | Poultry (layer) | Corn, field, hominy meal | No |
| Poultry (layer only) | 0.0030 | 0.0030 | 0.04 | 0.04 | Poultry (layer) | Corn, field, hominy meal | No |

bw: body weight; DM: dry matter.
(\(a\)): Calculated for the maximum dietary burden.

### B.2.1. Nature of residues and methods of analysis in livestock

#### B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Livestock (available studies) | Animal | Dose (mg/kg bw per day) | Duration (days) | N rate/comment |
|-------------------------------|--------|-------------------------|----------------|----------------|
| Laying hen                    |        | 0.35 or 3.5             | 6              | 116 or 1,160 N/compared to maximum dietary burden of laying hen |
| Lactating goat                |        | 1.16                    | 7              | 227 N/compared to maximum dietary burden of dairy cattle |

\(^{14}\)C hexythiazox labelled in the 5-position of the thiazolidine ring
Source: Finland (2006)

| Time needed to reach a plateau concentration in milk and eggs (days) | Milk: 5 days, eggs: plateau not reached (more than 6 days) |
|-----------------------------------------------------------------------|-------------------------------------------------------------|
| Metabolism in rat and ruminant similar (Yes/No)                       | Yes                                                        |
| Animal residue definition for monitoring (RD-Mo)                      | Hexythiazox (any ratio of constituent isomers) |
| Animal residue definition for risk assessment (RD-RA)                 | Hexythiazox (any ratio of constituent isomers) |
| Conversion factor (monitoring to risk assessment)                     | Not relevant                                               |
| Fat soluble residues (Yes/No)                                        | Yes                                                       |
| Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) | Data gap: fully validated method not available Screening data generated by EURLs indicate that hexythiazox can be enforced with a screening detection limit (SDL) of 0.005 mg/kg using LC-MS-Q-ToF in honey, muscle, eggs and milk (EURL, 2017) |

bw: body weight; LC-MS: liquid chromatography; Q-ToF: quadrupole time-of-flight.

### B.2.1.2. Stability of residues in livestock

Storage stability data are not available and are not required.
### B.2.2. Magnitude of residues in livestock

#### B.2.2.1. Summary of the residue data from livestock feeding studies

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N (mg/kg) | MRL proposal (mg/kg) |
|------------------|-----------------------------------------------|-------------------------------|----------------------|
|                  | Mean | Highest | STMR | HR  |                  |
| Cattle (all diets) |      |         |      |     |                  |
| Muscle           | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* (b) (tentative) |
| Fat              | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* (b) (tentative) |
| Liver            | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* (b) (tentative) |
| Kidney           | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* (b) (tentative) |
| Cattle (dairy only) |      |         |      |     |                  |
| Milk             | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* (b) (tentative) |
| Swine (c)        |      |         |      |     |                  |
| Muscle           | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* (b) (tentative) |
| Fat              | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* (b) (tentative) |
| Liver            | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* (b) (tentative) |
| Kidney           | < 0.01 | < 0.01 | < 0.01 | < 0.01 | 0.01* (b) (tentative) |
| Sheep (all diets) |      |         |      |     |                  |
| Based on the dietary burden calculation no residue is expected. Therefore there is no need to set MRLs in sheep tissues or milk |

| Poultry (all diets) |      |         |      |     |                  |
| Based on the dietary burden calculation no residue is expected. Therefore there is no need to set MRLs in poultry tissues or eggs |

bw: body weight; DM: dry matter; MRL: maximum residue level; STMR: supervised trials median residue; HR: highest residue. 
*: Indicates that the MRL is proposed at the limit of quantification.
(a): Closest feeding level and N dose rate related to the maximum dietary burden.
(b): MRL proposal is tentative because a data gap was identified (fully validated analytical method for enforcement).
(c): Since extrapolation from cattle to swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in swine.

### B.3. Consumer risk assessment

#### B.3.1. Consumer risk assessment without consideration of the existing CXLs

| ADI | 0.03 mg/kg bw per day (EFSA, 2010) |
|-----|-----------------------------------|
| Highest IEDI, according to EFSA PRIMo | 9.7% ADI (DE, child) |

Assumptions made for the calculations

The calculation is based on the median residue levels in the raw agricultural commodities, except for citrus fruits, where the relevant peeling factor was applied. For those commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation. The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation.

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; GAP: Good Agricultural Practice.

No acute reference dose was allocated during the peer review and therefore an acute risk assessment is not necessary.
B.3.2. Consumer risk assessment with consideration of the existing CXLs

|ADI| 0.03 mg/kg bw per day (EFSA, 2010) |
|---|---|
|Highest IEDI, according to EFSA PRIMo| 13.2% ADI (DE, child) |

Assumptions made for the calculations
For those commodities having a CXL higher than the EU MRL proposal, median residue levels applied in the EU scenario were replaced by the median residue levels derived by JMPR.
Considering that CXLs for meat were expressed on a fat basis, EFSA recalculated the corresponding median residue levels for meat.

No acute reference dose was allocated during the peer review and therefore an acute risk assessment is not necessary.

B.4. Proposed MRLs

|Code number| Commodity| Existing EU MRL (mg/kg)| Existing CXL (mg/kg)| Outcome of the review | Comment |
|---|---|---|---|---|---|
|110010| Grapefruits| 1| 0.5| 0.5| Recommended(a) |
|110020| Oranges| 1| 0.5| 0.5| Recommended(a) |
|110030| Lemons| 1| 0.5| 0.5| Recommended(a) |
|110040| Limes| 1| 0.5| 0.5| Recommended(a) |
|110050| Mandarins| 1| 0.5| 0.5| Recommended(a) |
|120010| Almonds| 0.5| 0.05*| 0.05| Recommended(a) |
|120020| Brazil nuts| 0.5| 0.05*| 0.05| Recommended(a) |
|120030| Cashew nuts| 0.5| 0.05*| 0.05| Recommended(a) |
|120040| Chestnuts| 0.5| 0.05*| 0.05| Recommended(a) |
|120050| Coconuts| 0.5| 0.05*| 0.05| Recommended(a) |
|120060| Hazelnuts/cobnuts| 0.5| 0.05*| 0.05| Recommended(a) |
|120070| Macadamias| 0.5| 0.05*| 0.05| Recommended(a) |
|120080| Pecans| 0.5| 0.05*| 0.05| Recommended(a) |
|120090| Pine nut kernels| 0.5| 0.05*| 0.05| Recommended(a) |
|120100| Pistachios| 0.5| 0.05*| 0.05| Recommended(a) |
|120110| Walnuts| 0.5| 0.05*| 0.05| Recommended(a) |
|130010| Apples| 1| 0.4| 0.4| Recommended(a) |
|130020| Pears| 1| 0.4| 0.4| Recommended(a) |
|130030| Quinces| 0.5| 0.4| 0.4| Recommended(a) |
|130040| Medlars| 0.5| 0.4| 0.4| Recommended(a) |
|130050| Loquats/Japanese medlars| 0.5| 0.4| 0.4| Recommended(a) |
|140010| Apricots| 1| 0.3| 0.7| Further consideration needed(b) |
|140020| Cherries (sweet)| 1| 0.3| 1.5| Further consideration needed(b) |
|140030| Peaches| 1| 0.3| 0.7| Recommended(c) |
|140040| Plums| 0.5| 0.3| 0.7| Further consideration needed(b) |
|151010| Table grapes| 1| 1| 1| Recommended(d) |
|151020| Wine grapes| 1| 1| 1| Recommended(d) |
|152000| Strawberries| 0.5| 6| 6| Recommended(d) |
|153010| Blackberries| 0.5| –| 0.01*| Recommended(d) |
|153020| Dewberries| 0.5| –| 0.01*| Recommended(d) |
|153030| Raspberries (red and yellow)| 0.5| –| 0.01*| Recommended(d) |
| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review MRL (mg/kg) | Comment |
|-------------|-----------|------------------------|---------------------|----------------------------------|---------|
| 154010 | Blueberries | 0.5 | – | 0.01* | Recommended (d) |
| 154020 | Cranberries | 0.5 | – | 0.01* | Recommended (d) |
| 154030 | Currants (black, red and white) | 0.5 | – | 0.01* | Recommended (d) |
| 154040 | Gooseberries (green, red and yellow) | 0.5 | – | 0.01* | Recommended (d) |
| 154050 | Rose hips | 0.5 | – | 0.01* | Recommended (d) |
| 154060 | Mulberries (black and white) | 0.5 | – | 0.01* | Recommended (d) |
| 154070 | Azaroles/Mediterranean medlars | 0.5 | – | 0.01* | Recommended (d) |
| 154080 | Elderberries | 0.5 | – | 0.01* | Recommended (d) |
| 161010 | Dates | 2 | 2 | 2 | Recommended (e) |
| 162010 | Kiwi fruits (green, red, yellow) | 1 | – | 1 | Further consideration needed (f) |
| 163020 | Bananas | 0.5 | – | 0.5 | Further consideration needed (f) |
| 231010 | Tomatoes | 0.5 | 0.1 | 0.1 | Recommended (a) |
| 231020 | Sweet peppers/bell peppers | 0.5 | – | 0.09 | Recommended (d) |
| 231030 | Aubergines/eggplants | 0.5 | 0.1 | 0.1 | Recommended (a) |
| 232010 | Cucumbers | 0.5 | 0.05 | 0.05 | Recommended (d) |
| 232020 | Gherkins | 0.5 | 0.05 | 0.05 | Recommended (d) |
| 232030 | Courgettes | 0.5 | 0.05 | 0.05 | Recommended (d) |
| 233010 | Melons | 0.5 | 0.05 | 0.07 | Recommended (d) |
| 233020 | Pumpkins | 0.5 | 0.05 | 0.07 | Recommended (d) |
| 233030 | Watermelons | 0.5 | – | 0.07 | Recommended (d) |
| 260010 | Beans (with pods) | 0.5 | – | 0.5 | Further consideration needed (f) |
| 401070 | Soybeans | 0.5 | – | 0.5 | Further consideration needed (d) |
| 401090 | Cotton seeds | 0.5 | – | 0.5 | Further consideration needed (d) |
| 500030 | Maize/corn grains | 0.5 | – | 0.02 | Recommended (d) |
| 610000 | Teas | 4 | 15 | 15 | Recommended (a) |
| 700000 | Hops | 20 | 3 | 3 | Recommended (d) |
| 1011010 | Swine muscle | 0.05 | 0.05* | 0.05 | Further consideration needed (h) |
| 1011020 | Swine fat tissue | 0.05 | 0.05 | 0.05 | Further consideration needed (h) |
| 1011030 | Swine liver | 0.05 | 0.05 | 0.05 | Further consideration needed (h) |
| 1011040 | Swine kidney | 0.05 | 0.05 | 0.05 | Further consideration needed (h) |
| 1012010 | Bovine muscle | 0.05 | 0.05* | 0.05 | Further consideration needed (h) |
| 1012020 | Bovine fat tissue | 0.05 | 0.05 | 0.05 | Further consideration needed (h) |
| 1012030 | Bovine liver | 0.05 | 0.05 | 0.05 | Further consideration needed (h) |
| 1012040 | Bovine kidney | 0.01* | 0.05 | 0.05 | Further consideration needed (h) |
| 1013010 | Sheep muscle | 0.05 | 0.05* | 0.05 | Further consideration needed (h) |
| 1013020 | Sheep fat tissue | 0.05 | 0.05 | 0.05 | Further consideration needed (h) |
| 1013030 | Sheep liver | 0.05 | 0.05 | 0.05 | Further consideration needed (h) |
| 1013040 | Sheep kidney | 0.05 | 0.05 | 0.05 | Further consideration needed (h) |
| 1014010 | Goat muscle | 0.05 | 0.05* | 0.05 | Further consideration needed (h) |
| 1014020 | Goat fat tissue | 0.05 | 0.05 | 0.05 | Further consideration needed (h) |
| 1014030 | Goat liver | 0.05 | 0.05 | 0.05 | Further consideration needed (h) |
| 1014040 | Goat kidney | 0.05 | 0.05 | 0.05 | Further consideration needed (h) |
| Code number | Commodity                  | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review MRL (mg/kg) | Comment                           |
|-------------|----------------------------|-------------------------|----------------------|----------------------------------|-----------------------------------|
| 1015010     | Equine muscle              | 0.05                    | 0.05                 | 0.05                             | Further consideration needed (g)  |
| 1015020     | Equine fat tissue          | 0.05                    | 0.05                 | 0.05                             | Further consideration needed (g)  |
| 1015030     | Equine liver               | 0.05                    | 0.05                 | 0.05                             | Further consideration needed (g)  |
| 1015040     | Equine kidney              | 0.05                    | 0.05                 | 0.05                             | Further consideration needed (g)  |
| 1016010     | Poultry muscle             | 0.05                    | 0.05                 | 0.05                             | Further consideration needed (h)  |
| 1016020     | Poultry fat tissue         | 0.05                    | 0.05                 | 0.05                             | Further consideration needed (h)  |
| 1016030     | Poultry liver              | 0.05                    | 0.05                 | 0.05                             | Further consideration needed (h)  |
| 1020010     | Cattle milk                | 0.05                    | 0.05                 | 0.05                             | Further consideration needed (g)  |
| 1020020     | Sheep milk                 | 0.05                    | 0.05                 | 0.05                             | Further consideration needed (h)  |
| 1020030     | Goat milk                  | 0.05                    | 0.05                 | 0.05                             | Further consideration needed (h)  |
| 1020040     | Horse milk                 | 0.05                    | 0.05                 | 0.05                             | Further consideration needed (h)  |
| –           | Other commodities of plant and animal origin | Reg. (EU) No 592/2012 | –                    | –                                | Further consideration needed (g)  |

MRL: maximum residue level; CXL: codex maximum residue limit.

*(F):* The residue definition is fat soluble.

*: Indicates that the MRL is set at the limit of quantification.

(a): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix E).

(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix E).

(c): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix E).

(d): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix E).

(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix E).

(f): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU; no CXL is available (combination C-I in Appendix E).

(g): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix E).

(h): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).

(i): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
Appendix C – Pesticide Residue Intake Model (PRIMO)

Hexythiazox

- Status of the active substance: Code no.
- ADI (mg/kg bw): 0.03
- Proposed LOQ: n.n.
- ADI (mg/kg bw per day): 0.03
- ARfD (mg/kg bw): n.n.
- Source of ADI: EFSA
- Source of ARfD: n.n.
- Year of evaluation: 2010
- Year of evaluation: 2010
- No of diets exceeding ADI: ---

| Commodity/group of commodities | Minimum – maximum TMDI (% of ADI) |
|--------------------------------|-----------------------------------|
| Kiwi                          | 0.9                               |
| Apples                        | 0.8                               |
| Beans (with pods)             | 0.8                               |
| Wine grapes                   | 0.6                               |
| Kiwi                          | 0.5                               |
| Apples                        | 0.4                               |
| Tea (dried leaves and stalks) | 0.4                               |
| Beans (with pods)             | 0.3                               |
| Soya bean                     | 0.3                               |
| Table grapes                  | 0.3                               |
| Wine grapes                   | 0.2                               |
| Bananas                       | 0.2                               |
| Apples                        | 0.2                               |
| Tomatoes                      | 0.2                               |
| Apples                        | 0.2                               |
| Bananas                       | 0.2                               |
| Apples                        | 0.2                               |
| Bananas                       | 0.2                               |
| Table grapes                  | 0.1                               |
| Apples (with pods)            | 0.1                               |
| Bananas                       | 0.1                               |

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | 3rd contributor to MS diet in % of ADI | 2nd contributor to MS diet in % of ADI | 1st contributor to MS diet in % of ADI | TMDI (range) in % of ADI |
|--------------------------------|--------------------------------------|---------------------------------------|---------------------------------------|-------------------------|
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Bananas                        | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples (with pods)             | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Kiwi                           | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Apples                         | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Beans (with pods)              | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |
| Wine grapes                    | 0.2                                  | 0.2                                   | 0.2                                   | 9.7                     |

### Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs at LOQ, were below the ADI. A long-term intake of residues of hexythiazox is unlikely to present a public health concern.
Acute risk assessment is not necessary.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

**Note:** The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**pTMRL:** provisional temporary MRL.

**Conclusion:**
As no ARfD was considered necessary, it is concluded that the short-term intake of Hexythiazox residues is unlikely to present a public health concern.
### Hexythiazox

**Status of the active substance:** Code no. LOQ (mg/kg bw)

| LOQ (mg/kg bw) | Proposed LOQ |
|---------------|--------------|
| 0.03          | R.R.         |

**Toxicological end points**

| ADI (mg/kg bw per day) | EFSA | Source of ARfD |
|------------------------|------|----------------|
| 0.03                   |      | Source of ARfD |

**Year of evaluation:**

| EFSA | Year of evaluation |
|------|--------------------|
| 2010 |                    |

**No of diets exceeding ADI:**

| Highest calculated TMDI values in % of ADI | MS Diet | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities | Commodity / group of commodities | Commodity / group of commodities | Commodity / group of commodities |
|---------------------------------------------|---------|----------------------------------|------------------------------------------|----------------------------------|------------------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| 13.2                                        | DE child| Apples                           | 3.0                                      | Apples                           | 1.3                                      | Milk and cream                     |                                |                                  |                                  |
| 10.8                                        | NL child| Milk and cream                    | 3.8                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 8.7                                         | FR toddler| Bananas                         | 2.9                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 8.6                                         | FR toddler| Bananas                         | 2.8                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 7.1                                         | WHO Cluster diet E | Bananas               | 2.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 6.4                                         | UK infant| Bananas                         | 2.4                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 6.0                                         | FR infant| Bananas                         | 2.4                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 5.6                                         | SE general population 90th percentile | Bananas                 | 2.0                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 5.2                                         | WHO cluster diet E | Bananas                 | 1.9                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 5.1                                         | UK Toddler| Bananas                        | 1.8                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 4.7                                         | DK child| Bananas                         | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 4.6                                         | ES child| Bananas                         | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 4.6                                         | FR all population| Bananas           | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 4.2                                         | PT General population| Bananas            | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 4.0                                         | WHO Cluster diet F | Bananas             | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 3.8                                         | WHO regional European diet | Bananas         | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 3.7                                         | NL general| Bananas                       | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 3.2                                         | ES adult| Bananas                         | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 3.2                                         | FR cluster diet D | Bananas               | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 3.1                                         | UK vegetarian| Bananas          | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 3.0                                         | UK adult| Bananas                         | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 2.9                                         | IT children| Bananas                  | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 2.8                                         | DK adult| Bananas                         | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 2.7                                         | IT adult| Bananas                         | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 2.1                                         | FI adult| Bananas                         | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |
| 1.9                                         | PL general population| Bananas           | 1.7                                      | Apples                           | 1.0                                      | Milk and cream                     |                                |                                  |                                  |

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of hexythiazox is unlikely to present a public health concern.
Acute risk assessment is not necessary.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

pTMRL: provisional temporary MRL.

**pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:
As no ARfD was considered necessary, it is concluded that the short-term intake of hexythiazox residues is unlikely to present a public health concern.

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### Acute risk assessment/children – refined calculations

| Commodity | pTMRL/Threshold MRL | pTMRL/Threshold MRL | pTMRL/Threshold MRL | pTMRL/Threshold MRL |
|-----------|---------------------|---------------------|---------------------|---------------------|
| Processed commodities | (mg/kg) | (mg/kg) | (mg/kg) | (mg/kg) |
| Unprocessed commodities | (mg/kg) | (mg/kg) | (mg/kg) | (mg/kg) |

### Acute risk assessment/adults/general population – refined calculations

| Commodity | pTMRL/Threshold MRL | pTMRL/Threshold MRL | pTMRL/Threshold MRL | pTMRL/Threshold MRL |
|-----------|---------------------|---------------------|---------------------|---------------------|
| Processed commodities | (mg/kg) | (mg/kg) | (mg/kg) | (mg/kg) |
| Unprocessed commodities | (mg/kg) | (mg/kg) | (mg/kg) | (mg/kg) |
Appendix D – Input values for the exposure calculations

D.1. Livestock dieetary burden calculations

| Feed commodity                        | Median dietary burden | Maximum dietary burden |
|---------------------------------------|-----------------------|------------------------|
|                                       | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment                |
| Hexythiazox (any ratio of constituent isomers) |                       |                        |                       |                        |
| Grapefruits, dried pulp               | 0.57                  | STMR × PF (7.1)        | 0.57                  | STMR × PF (7.1)        |
| Oranges, dried pulp                   | 0.57                  | STMR × PF (7.1)        | 0.57                  | STMR × PF (7.1)        |
| Lemons, dried pulp                    | 0.57                  | STMR × PF (7.1)        | 0.57                  | STMR × PF (7.1)        |
| Limes, dried pulp                     | 0.57                  | STMR × PF (7.1)        | 0.57                  | STMR × PF (7.1)        |
| Mandarins, dried pulp                 | 0.57                  | STMR × PF (7.1)        | 0.57                  | STMR × PF (7.1)        |
| Coconut, meal                         | 0.03                  | STMR × default PF (1.5)| 0.03                  | STMR × default PF (1.5)|
| Apple, pomace, wet                    | 0.21                  | STMR × PF (2.3)        | 0.21                  | STMR × PF (2.3)        |
| Corn, field (Maize), grain            | 0.02                  | STMR                   | 0.02                  | STMR                   |
| Corn, pop, grain                      | 0.02                  | STMR                   | 0.02                  | STMR                   |
| Corn, field, milled-by-pdts           | 0.02                  | STMR × default PF (1)  | 0.02                  | STMR × default PF (1)  |
| Corn, field, hominy meal              | 0.12                  | STMR × default PF (6)  | 0.12                  | STMR × default PF (6)  |
| Corn, field, distiller's grain (dry)  | 0.07                  | STMR × default PF (3.3)| 0.07                  | STMR × default PF (3.3)|
| Corn, field, gluten feed              | 0.05                  | STMR × default PF (2.5)| 0.05                  | STMR × default PF (2.5)|
| Corn, field, gluten, meal             | 0.02                  | STMR × default PF (1)  | 0.02                  | STMR × default PF (1)  |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

D.2. Consumer risk assessment without consideration of the existing CXLs

| Commodity                               | Chronic risk assessment |
|-----------------------------------------|-------------------------|
|                                        | Input value (mg/kg)     | Comment               |
| Citrus fruits                           | 0.01                    | STMR × PF (0.1)       |
| Tree nuts                               | 0.02                    | STMR                   |
| Pome fruits                             | 0.09                    | STMR                   |
| Apricots                                | 0.14                    | STMR (tentative)      |
| Cherries (sweet)                        | 0.52                    | STMR (tentative)      |
| Peaches                                 | 0.14                    | STMR                   |
| Plums                                   | 0.07                    | STMR (tentative)      |
| Table and wine grapes                   | 0.15                    | STMR                   |
| Strawberries                            | 0.09                    | STMR                   |
| Cane fruits and other small fruits and berries | 0.01*                 | STMR                   |
| Kiwi fruits, green, red, yellow         | 1.00                    | EU MRL                |
| Bananas                                 | 0.50                    | EU MRL                |
| Tomatoes, aubergines, sweet peppers/bell peppers | 0.05                  | STMR                   |
| Cucurbits with edible peel              | 0.05                    | STMR                   |
| Cucurbits with inedible peel            | 0.05                    | STMR                   |
| Beans (with pods)                       | 0.50                    | EU MRL                |
| Soybeans                                | 0.50                    | EU MRL                |
| Cotton seeds                            | 0.50                    | EU MRL                |
| Maize/corn grains                       | 0.02                    | STMR                   |
| Teas                                    | 1.28                    | STMR                   |
| Hops                                    | 0.79                    | STMR                   |
### Commodity

| Commodity                                      | Chronic risk assessment                                                                 |
|------------------------------------------------|----------------------------------------------------------------------------------------|
|                                                | **Input value (mg/kg)** | **Comment** |
| Swine-, bovine-, equine- meat                  | 0.01*                     |             |
| Swine-, bovine-, equine- fat tissue, liver, kidney, cattle-, horse- milk | 0.01*                     |             |

**STMR:** supervised trials median residue; **PF:** processing factor; **MRL:** maximum residue level.  
*: Indicates that the input value is proposed at the limit of quantification.

### D.3. Consumer risk assessment with consideration of the existing CXLs

| Commodity                                      | Chronic risk assessment                                                                 |
|------------------------------------------------|----------------------------------------------------------------------------------------|
|                                                | **Input value (mg/kg)** | **Comment** |
| Risk assessment residue definition hexythiazox (any ratio of constituent isomers) |                                      |             |
| Citrus fruits                                  | 0.08                      | STMR × PF (CXL)            |
| Tree nuts                                      | 0.02                      | STMR (CXL)                |
| Pome fruits                                    | 0.11                      | STMR (CXL)                |
| Apricots                                       | 0.14                      | STMR (tentative)          |
| Cherries (sweet)                               | 0.52                      | STMR (tentative)          |
| Peaches                                        | 0.14                      | STMR                      |
| Plums                                          | 0.07                      | STMR (tentative)          |
| Table and wine grapes                          | 0.20                      | STMR (CXL)                |
| Strawberries                                   | 0.54                      | STMR (CXL)                |
| Cane fruits and other small fruits and berries | 0.01*                     | STMR                      |
| Kiwi fruits (green, red, yellow)               | 1.00                      | EU MRL                   |
| Bananas                                        | 0.50                      | EU MRL                   |
| Tomatoes, aubergines/eggplants                 | 0.05                      | STMR (CXL)                |
| Sweet peppers/bell peppers                    | 0.05                      | STMR                      |
| Cucurbits with edible peel (Cucumbers, gherkins, courgettes) | 0.05                      | STMR                      |
| Cucurbits with inedible peel (Melons, pumpkins, watermelons) | 0.05                      | STMR                      |
| Beans (with pods)                              | 0.50                      | EU MRL                   |
| Soybeans                                       | 0.50                      | EU MRL                   |
| Cotton seeds                                   | 0.50                      | EU MRL                   |
| Maize/corn grains                              | 0.02                      | STMR                      |
| Teas                                           | 4.55                      | STMR (CXL)                |
| Hops                                           | 0.79                      | STMR                      |
| Dates                                          | 0.26                      | STMR (CXL)                |
| Swine-, bovine-, equine-, sheep-, goat- meat   | 0.01*                     | 0.8 × STMR muscle + 0.2 × STMR fat (CXL, tentative) |
| Swine-, bovine-, equine-, sheep-, goat- fat tissue, liver, kidney | 0.01                      | STMR (CXL, tentative)    |
| Poultry meat                                   | 0.01*                     | 0.9 × STMR muscle + 0.1 × STMR fat (CXL, tentative) |
| Poultry fat tissue                             | 0.01                      | STMR (CXL, tentative)    |
| Poultry liver                                  | 0.01                      | STMR (CXL, tentative)    |
| Cattle-, horse- milk                           | 0.01                      | STMR (CXL, tentative)    |

**STMR:** supervised trials median residue; **PF:** processing factor; **CXL:** codex maximum residue limit; **MRL:** maximum residue level.  
*: Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

- **A**: Specific LOQ or default MRL?
- **B**: Specific LOQ or default MRL?
- **C**: Maintain current EU MRL?
- **D**: Specific LOQ or default MRL?
- **E**: Establish tentative EU MRL?
- **F**: Specific LOQ or default MRL?
- **G**: MRL is recommended.

Consumer risk assessment for GAPs evaluated at EU level – EU scenarios

- **Not considered for the RA.**
- **Current EU MRL is included in the RA.**
- **Tentative median/highest values are included in the RA.**
- **Median/highest values are included in the RA.**

Recommendations resulting from EU authorisations and import tolerances

- Comparison with CXLs
Comparison of the EU recommendation with the existing CXL

- **(I)** Maintain EU recommendation indicating that no CXL is available.
- **(II)** Maintain EU recommendation indicating CXL is not compatible.
- **(III)** Maintain EU recommendation indicating that CXL is covered.
- **(IV)** Maintain EU recommendation; higher CXL is not safe for consumer.
- **(V)** Maintain current CXL or EU recommendation.
- **(VI)** Maintain EU recommendation; higher CXL is not safe for consumer.
- **(VII)** CXL is recommended; EU recommendation is covered as well.

Consumer risk assessment with consideration of the existing CXL

- Input values for the RA remain unchanged.
- CXL included in the RA.
- Risk identified?

Recommendations with consideration of the existing CXL

- Maintain EU recommendation indicating that no CXL is available.
- Maintain EU recommendation indicating CXL is not compatible.
- Maintain EU recommendation indicating that CXL is covered.
- Maintain EU recommendation; higher CXL is not safe for consumer.
- Maintain current CXL or EU recommendation.
- Maintain EU recommendation; higher CXL is not safe for consumer.
- CXL is recommended; EU recommendation is covered as well.
### Appendix F – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChIKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|-------------------------------------------------|---------------------------------|
| hexythiazox                     | (4RS,5RS)-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide | ![Structural formula](image1) |
|                                 | Clc1ccc(cc1)[C@H]1SC(-O)N[C@H]1CNC2CCCCC2[C@H]1C.Clc1ccc(cc1)[C@H]1SC(-O)N([C@H]1C)C(-O)NC1CCCCC1 | ![Structural formula](image2) |
|                                 | KYOUEHWYDNYHAL-IOORBXIBSA-N                     | ![Structural formula](image3) |
| PT-1-2                          | (4R,5R)-5-(4-chlorophenyl)-4-methyl-2-oxo-1,3-thiazolidine-3-carboxamide | ![Structural formula](image4) |
|                                 | NC(-O)N1C(-O)S[C@H]1(c2ccc(Cl)cc2)[C@H]1C | ![Structural formula](image5) |
|                                 | OWQVQVJSIKLFDY-MUWHJKNJS-A-N                     | ![Structural formula](image6) |
|                                 | (4S,5S)-5-(4-chlorophenyl)-4-methyl-2-oxo-1,3-thiazolidine-3-carboxamide | ![Structural formula](image7) |
|                                 | NC(-O)N1C(-O)S[C@H]1(c2ccc(Cl)cc2)[C@H]1C | ![Structural formula](image8) |
|                                 | OWQVQVJSIKLFDY-IMTBSYHQA-N                      | ![Structural formula](image9) |
| PT-1-3                          | (4R,5R)-5-(4-chlorophenyl)-4-methyl-1,3-thiazolidin-2-one | ![Structural formula](image10) |
|                                 | Clc1ccc(cc1)[C@H]1SC(-O)N[C@H]1C | ![Structural formula](image11) |
|                                 | IPCDQNZFHKSICGG-MUWHJKNJS-A-N                    | ![Structural formula](image12) |
|                                 | (4S,5S)-5-(4-chlorophenyl)-4-methyl-1,3-thiazolidin-2-one | ![Structural formula](image13) |
|                                 | Clc1ccc(cc1)[C@H]1SC(-O)N[C@H]1C | ![Structural formula](image14) |
|                                 | OADRWHHLSTWEEOO-DBLGBMPJSA-N                    | ![Structural formula](image15) |
| PT-1-8-cis                      | (4R,5R)-5-(4-chlorophenyl)-N-(cis-4-hydroxycyclohexyl)-4-methyl-2-oxo-1,3-thiazolidine-3-carboxamide | ![Structural formula](image16) |
|                                 | O[C@H]1CC[C@H1][CC1]NC(-O)N1C(-O)S[C@H]1(C2ccc(Cl)cc2)[C@H]1C | ![Structural formula](image17) |
|                                 | PKHGZSCHOESPFGS-RBLLNBGSA-N                     | ![Structural formula](image18) |
|                                 | (4S,5S)-5-(4-chlorophenyl)-N-(cis-4-hydroxycyclohexyl)-4-methyl-2-oxo-1,3-thiazolidine-3-carboxamide | ![Structural formula](image19) |
|                                 | O[C@H]1CC[C@H1][CC1]NC(-O)N1C(-O)S[C@H]1(C2ccc(Cl)cc2)[C@H]1C | ![Structural formula](image20) |
|                                 | PKHGZSCHOESPFGS-BSLXNSKLS-A-N                   | ![Structural formula](image21) |
| Code/trivial name\(^{(a)}\) | IUPAC name/SMILES notation/InChiKey\(^{(b)}\) | Structural formula\(^{(c)}\) |
|-----------------------------|-------------------------------------------------|------------------|
| **PT-1-8-trans**            | \((4R,5R)-5-(4\text{-}chlorophenyl)\text{-}N(\text{trans}\text{-}4\text{-}hydroxycyclohexyl)\text{-}4\text{-}methyl\text{-}2\text{-}oxo\text{-}1,3\text{-}thiazolidine\text{-}3\text{-}carboxamide\) Sentences... | ![Structural formula](attachment:structure.png) |
| **PT-1-4**                  | \((4R,5R)-5-(4\text{-}chlorophenyl)\text{-}N\text{-}\{(1R,3RS)\text{-}3\text{-}hydroxycyclohexyl\}\text{-}4\text{-}methyl\text{-}2\text{-}oxo\text{-}1,3\text{-}thiazolidine\text{-}3\text{-}carboxamide\) Sentences... | ![Structural formula](attachment:structure2.png) |
| **PT 1-10**                 | \((4R,5R)-5-(4\text{-}chlorophenyl)\text{-}N\text{-}\{(1R,3RS,4RS;1R,3RS,4SR)\text{-}3,4\text{-}dihydroxycyclohexyl\}\text{-}4\text{-}methyl\text{-}2\text{-}oxo\text{-}1,3\text{-}thiazolidine\text{-}3\text{-}carboxamide\) Sentences... | ![Structural formula](attachment:structure3.png) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

\(^{(a)}\): The metabolite name in bold is the name used in the conclusion.

\(^{(b)}\): ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 6 September 2017).

\(^{(c)}\): ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).