Modification of the existing maximum residue level for ethephon in kaki/Japanese persimmons

European Food Safety Authority (EFSA),
Alba Brancato, Daniela Brocca, Chloé De Lentdecker, Zoltan Erdos, Lucien Ferreira,
Luna Greco, Samira Jarrah, Dimitra Kardassi, Renata Leuschner,
Christopher Lythgo, Paula Medina, Ileana Miron, Tunde Molnar, Alexandre Nougadere,
Ragnar Pedersen, Hermine Reich, Angela Sacchi, Miguel Santos, Alois Stanek,
Juergen Sturma, Jose Tarazona, Anne Theobald, Benedicte Vagenende, Alessia Verani and
Laura Villamar-Bouza

Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer CropScience submitted a request to the competent national authority in Spain to modify the existing maximum residue level (MRL) for the active substance ethephon in kaki/Japanese persimmons. The data submitted in support of the request are sufficient to derive a MRL proposal for the crop under consideration. An adequate analytical method for enforcement is available to control the residues of ethephon in kaki/Japanese persimmon fruits. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of ethephon according to the reported agricultural practice is unlikely to present a risk to consumer health.

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Keywords: ethephon, kaki/Japanese persimmon, pesticide, MRL, consumer risk assessment

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Correspondence: pesticides.mrl@efsa.europa.eu
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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience submitted an application to the competent national authority in Spain (evaluating Member State, EMS) to modify the existing maximum residue level (MRL) for the active substance ethephon in kaki/Japanese persimmons. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and to the European Food Safety Authority (EFSA). To accommodate for the intended use of ethephon, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) of 0.05 mg/kg to 0.3 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) prepared under Directive 91/414/EEC, the Commission review report on ethephon, the conclusion on the peer review of the pesticide risk assessment of the active substance ethephon, the Joint Meeting on Pesticide Residue (JMPR) evaluation report as well as the conclusions from previous EFSA opinions on ethephon.

The metabolism of ethephon following foliar application was investigated in crops belonging to the groups of cereals and fruits. Ethephon was metabolised with formation of ethylene and the metabolite 2-hydroxyethyl phosphonic acid (HEPA). Parent active substance was the main residue. The only significant metabolite was HEPA, which was present in grain at similar levels as the parent. Studies investigating the effect of processing on the nature of ethephon (hydrolysis studies) demonstrated that the active substance is stable under pasteurisation conditions but mainly degraded to ethylene, a volatile substance, with increase of temperature and pH.

As the proposed use of ethephon is on permanent crops, the assessment of residues in rotational crops is not required.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of metabolites, the residue definition for enforcement and risk assessment in the fruit and cereal crops was proposed as ethephon. For the intended use, EFSA concludes that the metabolism in fruits has been sufficiently addressed and the residue definitions apply.

Sufficiently validated analytical methods are available to quantify residues in kaki/Japanese persimmons according to the enforcement residue definition. The method allows quantification of residues at or above 0.05 mg/kg.

The data submitted in support of the MRL application are sufficient to derive a MRL proposal for the crop under consideration. Specific studies investigating the magnitude of ethephon residues in processed commodities are not required as this fruit is usually eaten raw. Residues of ethephon in commodities of animal origin were not assessed since persimmons are normally not fed to livestock.

The toxicological profile of ethephon was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.03 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.05 mg/kg bw.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). The comprehensive long-term exposure assessment performed in the framework of the MRL review was updated to take into account the MRL modifications since that and to include the STMR derived from the submitted supervised residue trials on kaki/Japanese persimmons. The acute risk assessment was conducted only for persimmon fruits.

No long-term or acute consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total estimated intake accounted for up to 19% of the ADI (WHO Cluster diet B), with a contribution of less than 0.01% of the ADI from expected residues in kaki/Japanese persimmons. The calculated maximum acute exposure for this fruit was 9.6% of the ARfD.

EFSA concluded that the short-term and long-term intake of residues resulting from the use of ethephon according to the reported agricultural practice is unlikely to present a risk to consumer health.

EFSA proposes to amend the existing MRL as reported in the summary table below.

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|------------|-------------------------|-------------------------|------------------------|
| 0161060 | Kaki/Japanese persimmons | 0.05* | 0.3 | The SEU use is sufficiently supported by data. No consumer health concern was identified |

MRL: maximum residue level; SEU: southern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
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Background

Regulation (EC) No 396/2005\(^1\) (hereinafter referred to as 'the MRL regulation') establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the MRL regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC\(^2\), repealed by Regulation (EC) No 1107/2009\(^3\), shall submit an application to a Member State to modify a MRL in accordance with the provisions of Article 7 of the MRL regulation.

The applicant Bayer CropScience\(^4\) submitted an application to the competent national authority in Spain, hereafter referred to as the evaluating Member State (EMS), to modify the existing MRL for the active substance ethephon in kaki/Japanese persimmons. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the MRL regulation.

The EMS assessed the data provided by the applicant in an evaluation report. On 4 May 2016, EFSA received the request to assess the MRL application which was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00333 and the following subject:

*Ethephon: Application to modify MRL in persimmons*

Spain proposed to raise the existing MRL of ethephon in kaki/Japanese persimmons from the limit of quantification of 0.05 mg/kg to 0.3 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

Terms of Reference

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall assess the application and the evaluation report and give a reasoned opinion on the risks to the consumer and where relevant to animals associated with the setting of the requested MRLs. The opinion shall include:

- an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
- the anticipated limit of quantification (LOQ) for the pesticide/product combination;
- an assessment of the risks of the acceptable daily intake (ADI) and acute reference dose (ARfD) being exceeded as a result of the modification of the MRL;
- the contribution to the intake due to the residues in the product for which the MRL was requested;
- any other element relevant to the risk assessment.

In accordance with Article 11 of the MRL regulation, EFSA shall give its reasoned opinion as soon as possible and at the latest within 3 months from the date of receipt of the application.

The evaluation report submitted by the EMS (Spain, 2016) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

The active substance and its use pattern

The detailed description of the intended Southern use of ethephon in kaki/Japanese persimmons, which is the basis for the current MRL application, is reported in Appendix A.

Ethephon is the ISO common name for 2-chloroethyl phosphonic acid (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix D.

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\(^1\) Regulation (EC) No 396/2005 of the 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.

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

\(^4\) Bayer CropScience, C/Charles Robert Darwin, 13, Parque Tecnológico, 46980 Paterna (Valencia), Spain.
Etherephon was evaluated in the framework of Directive 91/414/EEC with the Netherlands designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2006/85/EC which entered into force on 1 August 2007 for use as a plant growth regulator. In accordance with Commission Implementing Regulation (EU) No 540/2011, ethephon is approved under Regulation (EC) No 1107/2009, repealing Directive 91/414/EEC. The representative use assessed in the peer review was a foliar application on wheat and barley. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2008).

The EU MRLs for ethephon are established in Annex II of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2009) and the proposed modifications implemented in the MRL legislation. After completion of the MRL review, EFSA has issued a reasoned opinion on the modification of MRLs for ethephon (EFSA, 2014). The proposals from the reasoned opinion have been considered in recent MRL regulations. A draft regulation (SANTE/11707/2016) taking over some of the Codex MRLs (CXLs) adopted by Codex Committee on Pesticide Residues (CCPR) in 2016 in the EU legislation has been voted at the Standing Committee on Plants, Animals, Food and Feed held on 28-29 November 2016.

Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (Spain, 2016), the DAR prepared under Directive 91/414/EEC (Netherlands, 2004), the European Commission review report on ethephon (European Commission, 2008), the conclusion on the peer review of the pesticide risk assessment of the active substance ethephon (EFSA, 2008), the JMPR Evaluation report (FAO, 2015) as well as the conclusions from previous EFSA opinion and report on ethephon (EFSA, 2009, 2014, 2016).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a-g, 2000, 2010a, b, 2016; OECD, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

A selected list of end points of the studies assessed by EFSA in the framework of the EU pesticide peer review and the MRL review, including the end points of studies submitted in support of the current MRL application, are presented 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 ethephon after foliar application in primary fruit and cereals/grass crop groups was assessed in the framework of the EU pesticides peer review and the MRL review (Netherlands, 2004; EFSA, 2008, 2009). An additional metabolism study on cotton was assessed by the Joint Meeting on Pesticide Residue (JMPR) but has not been peer reviewed at EU level (FAO, 2015).

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5 Commission Directive 2006/85/EC of 23 October 2006 amending Council Directive 91/414/EEC to include fenamiphos and ethephon as active substances. OJ L 293, 24.10.2006, p. 3–5.
6 Commission Regulation (EU) No 559/2011 of 7 June 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 captan, carbendazim, cyromazine, ethephon, fenamiphos, thiophanate-methyl, triasulfuron and triclopyr in or on certain products. OJ L 152, 11.6.2011, p. 1–21.
7 Commission Regulation (EU) 2015/399 of 25 February 2015 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 1,4-dimethylnaphthalene, benfuracar, carbofuran, carbosulfan, ethephon, fenamidone, fenvalerate, fenhexamid, furathiocarb, imazaquin, mephalan, picoxystrobin, spiroxamine, tepraloxydim and trifloxystrobin in or on certain products. OJ L 71, 14.3.2015, p. 1–55.
8 Commission Regulation (EU) 2015/846 of 28 May 2015 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 acetamiprid, ametocarb, amisulbrom, bupirimine, fipronil, ethephon, ethylene, fludioxonil, flupyradifurone, furlong, pirimicarb, pyrazolcarboxamide, teburafon, tebufenpyrad and toxaphene in or on certain products. OJ L 140, 5.6.2015, p. 1–49.
9 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
10 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.
Metabolism of ethephon mainly proceeded via conversion to 2-hydroxyethyl phosphonic acid (HEPA) and via decomposition to ethylene, which was released in the atmosphere, and phosphate which was taken up in the natural phosphate cycle of the plant (EFSA, 2008). Ethephon was the main compound in residues. The only significant metabolite was HEPA, which in grain was present at similar levels as the parent. Considering that HEPA was of lower toxicity than the parent, its inclusion in the residue definition for risk assessment was concluded as unnecessary and the residue definition for enforcement and risk assessment is set as ethephon only (EFSA, 2009).

For the intended use, the metabolic behaviour in primary fruit crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

The proposed use of ethephon is on a permanent crop. Therefore, the assessment of residues in rotational crops is not required in the framework of this MRL application.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of ethephon was investigated in the framework of the EU pesticides peer review and the MRL review (Netherlands, 2004; EFSA, 2008, 2009). These studies showed that ethephon is hydrolytically stable during pasteurisation, whereas it is mainly degraded to ethylene during baking, boiling, brewing and sterilisation. This compound was also observed in plant metabolism and it was not considered relevant for inclusion in the residue definition, due to its volatility.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of ethephon residues were assessed during the EU pesticides peer review and the MRL review and in the framework of a previous MRL application (EFSA, 2008, 2009, 2014). The methods were based on high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) and found sufficiently validated for plant commodities, including high water content commodities, at the LOQ of 0.05 mg/kg.

For the intended use, analytical methods are sufficiently validated for the enforcement of residues of ethephon. The methods allow quantifying residues of ethephon at or above the LOQ of 0.05 mg/kg.

1.1.5. Stability of residues in plants

The storage stability of ethephon in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (Netherlands, 2004; EFSA, 2008). It was demonstrated that in matrices with water content, to which the crop under assessment belongs, residues were stable for 24 months when stored at ≤ –20°C.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and/or degradation products, the capabilities of enforcement analytical methods, the following residue definitions were proposed:

- residue for risk assessment: ethephon
- residue definition for enforcement: ethephon

The residue definitions are limited to cereals and fruit crops and are applicable to processed products as well (EFSA, 2009).

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition.

EFSA concluded that these residue definitions are appropriate for the intended use on kaki/Japanese persimmons and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Four GAP-compliant residue trials on kaki/Japanese persimmons were provided. The trials were conducted in Spain over a single season (2012) instead of at least two as required (European
Commission, 1997b). Considering that the kaki/Japanese persimmon is a minor crop and the various agroclimatic conditions of the different locations, the deviation is accepted and no additional data is required. The number and quality of the trials is sufficient to derive a MRL proposal of 0.3 mg/kg.

According to the assessment of the EMS, the methods used to analyse the samples collected from the residue trials were sufficiently validated and fit for purpose. Since the samples from the trials were stored for less than 4 months at ~18°C prior to analysis, results are valid regarding storage stability.

1.2.2. Magnitude of residues in rotational crops

The proposed use of ethephon is on a permanent crop; therefore, no information on the magnitude of residues in rotational crops is required.

1.2.3. Magnitude of residues in processed commodities

Since kaki/Japanese persimmons are usually eaten raw, no information on the magnitude of residues in processed products is required.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal as well as risk assessment values for kaki/Japanese persimmons (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on this fruit resulting from the intended southern Europe (SEU) use are likely to pose a consumer health risk.

2. Residues in livestock

The nature and magnitude of residues of ethephon in commodities of animal origin were not assessed since this fruit is normally not fed to livestock.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for ethephon used in the risk assessment (ADI and ARfD values) were derived under the EU pesticides peer review (European Commission, 2008).

3.1. Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for the fruit assessed in this application only in accordance with the internationally agreed methodology (FAO, 2016). The calculations were based on the highest residue (HR) derived from supervised field trials and the input value can be found in Appendix C.2.

The short-term exposure did not exceed the ARfD for kaki/Japanese persimmons (see Appendix B.3).

3.2. Long-term (chronic) dietary risk assessment

In the framework of the MRL review a comprehensive long-term exposure assessment was performed taking into account the existing uses at EU level and available Codex maximum residue limits (CXLs) (EFSA, 2009). EFSA has revised this calculation including the median residue (STMR) levels for table grape and table olives derived in an EFSA opinion published after the MRL review (EFSA, 2014). The calculation is now further updated with the STMR value derived from the residue trials submitted in support of this MRL application on kaki/Japanese persimmons and the STMR values from the CXLs taken over in the EU MRL legislation (FAO, 2015). The input values used in the exposure calculations are summarised in Appendix C.2.

The estimated long-term dietary intake was in the range of 0–19% of the ADI. The contribution of residues expected in kaki/Japanese persimmons to the overall long-term exposure is presented in more detail in Appendix B.3.
EFSA concluded that the long-term intake of residues of ethephon resulting from the authorised and the intended SEU use on kaki/Japanese persimmons is unlikely to present a risk to consumer health.

**Conclusions and recommendations**

The data submitted in support of this application were found to be sufficient to derive an MRL proposal for kaki/Japanese persimmons.

Adequate analytical methods for enforcement are available to control the residues of ethephon in the commodity under consideration.

Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of ethephon according to the reported agricultural practice is unlikely to present a risk to consumer health.

The MRL recommendation is summarised in Appendix B.4.

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**Abbreviations**

a.s. active substance  
ADI acceptable daily intake  
ARID acute reference dose  
BBCH growth stages of mono- and dicotyledonous plants  
bw body weight  
CAS Chemical Abstract Service  
CCPR Codex Committee on Pesticide Residues (CCPR)  
CF conversion factor for enforcement to risk assessment residue definition  
CXL Codex maximum residue limit  
DAR draft assessment report  
DAT days after treatment  
EMS evaluating Member State  
FAO Food and Agriculture Organization of the United Nations  
GAP Good Agricultural Practice  
HEPA 2-hydroxyethyl phosphonic acid  
HPLC–MS/MS high-performance liquid chromatography with tandem mass spectrometry  
HR highest residue  
IEDI international estimated daily intake  
IESTI international estimated short-term intake  
ISO International Organisation for Standardisation  
IUPAC International Union of Pure and Applied Chemistry  
JMPR Joint FAO/WHO Meeting on Pesticide Residues  
LOQ limit of quantification  
MRL maximum residue level  
OECD Organisation for Economic Co-operation and Development  
PBI plant back interval  
PF processing factor  
PHI preharvest interval  
PRIMo (EFSA) Pesticide Residues Intake Model  
RMS rapporteur Member State  
SANCO Directorate-General for Health and Consumers  
SEU southern Europe  
SL soluble concentrate  
STMR supervised trials median residue  
WHO World Health Organization
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|------------|-----------------------------------|-------------|-------------|-------------------------------|--------------|---------|
| Kaki/Japanese persimmons | SEU Spain | F | Fruit ripening | SL | Concentrate | 480 g/L | Foliar spraying | BBCH 81-85 | 1 | – | 3.4-4.5 | 1500-2000 | 67 | 10 | – |

NEU: northern European Union; SEU: southern European Union; MS: Member State; SL: soluble concentrate; a.s.: active substance.

(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.

Modifications of existing MRL for ethephon in persimmons
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 | Crops | Applications | Sampling (DAT) |
|----------------------------------|-------------|-------|--------------|----------------|
| Fruit crops                      | Tomato      | Foliar, 1.44 kg/ha | 0, 5, 12 |
| Cereals/grass                    | Wheat       | Foliar, 0.36 kg/ha and 3.6 kg/ha BBCH 39 | 0, 14, 34 |

Additional supporting information on pineapple
Reference: Netherlands (2004)
Metabolism study on cotton (foliar, 1.4 kg/ha, 7 DAT) assessed by JMPR (FAO, 2015), but not peer reviewed at EU level

| Rotational crops | Processed commodities (hydrolysis study) | Conditions | Investigated? |
|------------------|-----------------------------------------|------------|---------------|
|                  | Waxy corn, potatoes, pasta              | 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 |

Ethephon was hydrolytically stable during pasteurisation, but degraded mainly to ethylene during baking, boiling, brewing and sterilisation
Reference: Netherlands (2004)

DAT, days after treatment.

Can a general residue definition be proposed for primary crops?
No

Rotational crop and primary crop metabolism similar?
Not relevant for the crop under consideration

Residue pattern in processed commodities similar to residue pattern in raw commodities?
Yes

Plant residue definition for monitoring (RD-Mo)
Ethephon (fruit and cereal group)

Plant residue definition for risk assessment (RD-RA)
Ethephon (fruit and cereal group)

Conversion factor (monitoring to risk assessment)
Not applicable

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)
HPLC-MS/MS, LOQ 0.05 mg/kg, high water content (tomatoes), high oil content (olives), high acid content (oranges, grapes) and dry matrices (wheat grain)
Reference: EFSA (2008, 2009, 2014)
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category              | Commodity              | T (°C) | Stability (months) |
|-----------------------------------|------------------------|------------------------|--------|-------------------|
| High water content                | Tomato, apple          | –20                    | 24     |
| High oil content                  | Cotton seed            | –20                    | 24     |
| Dry/high starch                    | Wheat grain             | –20                    | 24     |
| High acid content                 | Grape, blackberry       | –20                    | 24     |
| Other                             | Wheat straw             | –20                    | 24     |
| Reference: Netherlands (2004)     |                        |                        |        |

Reference: Netherlands (2004)
B.1.2. Magnitude of residues in plants

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

| Crop                      | Region/indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments (OECD calculations) | MRL proposal (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) | CF\(^{(d)}\) |
|---------------------------|--------------------------|---------------------------------------------------------------|-----------------------------|---------------------|---------------------|-------------------|-------------|
| Kaki/Japanese persimmons  | SEU                       | 0.05; 0.07; 0.11; 0.12                                          | Underlined, sample with higher residues at longer PHI of 14 days MRL\(_{OECD} = 0.26/0.3\) | 0.3                 | 0.12                | 0.09              | 1           |

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

\(^{(a)}\): SEU: Outdoor trials conducted in southern Europe.

\(^{(b)}\): Highest residue according to the residue definition for monitoring.

\(^{(c)}\): Supervised trials median residue according to the residue definition for monitoring.

\(^{(d)}\): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Residues in succeeding crops

Confined rotational crop study (quantitative aspect) Not required
Field rotational crop study Not required

B.1.2.3. Processing factors

Not required.

B.2. Residues in livestock

Not required (product is not a feed item in the EU).

B.3. Consumer risk assessment

ARfD
0.05 mg/kg bw (European Commission, 2008)

Highest IESTI, according to EFSA PRIMo
Kaki/Japanese persimmons: 9.6% of ARfD (German child)

Assumptions made for the calculations
The calculation is based on the highest residue level expected in the raw agricultural commodity

ADI
0.03 mg/kg bw per day (European Commission, 2008)

Highest IEDI, according to EFSA PRIMo
19% ADI (WHO Cluster diet B)

Contribution of crop assessed:
Kaki/Japanese persimmons: 0.008% of ADI

Assumptions made for the calculations
The calculation is based on the median residue levels derived for raw agricultural commodities
For pineapples, a peeling factor (0.29), and for olives for oil production, a processing (0.02) and a yield (0.2) factor were used to refine the calculation
Commodities for which no EU use was reported in the framework of the MRL review and in the flowing reasoned opinion or no CXLs was recommended for implementation in the EU legislation, were excluded from the calculation

B.4. Recommended MRLs

| Code(a) | Commodity                  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|----------------------------|-------------------------|-------------------------|-----------------------|
| 0161060 | Kaki/Japanese persimmons   | 0.05*                   | 0.3                     | The SEU use is sufficiently supported by data. No consumer health concern was identified |

MRL: maximum residue level; SEU: southern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
# Appendix C – Input values for the exposure calculations

## C.1. Livestock dietary burden calculations

Not relevant.

## C.2. Consumer risk assessment

| Commodity | Chronic risk assessment | Acute risk assessment |
|-----------|-------------------------|-----------------------|
| Kaki/Japanese persimmons | 0.09 STMR | 0.12 HR |
| Hazelnuts | 0.05 STMR (EFSA, 2009) | |
| Walnuts | 0.04 STMR (EFSA, 2009) | |
| Apples | 0.15 STMR (FAO, 2015) | |
| Pears | 0.02 STMR (EFSA, 2009) | |
| Cherries | 0.65 STMR (FAO, 2015) | |
| Table grape | 0.22 STMR (EFSA, 2014) | |
| Wine grape | 0.31 STMR (EFSA, 2009) | |
| Blueberries | 5.3 STMR (EFSA, 2009) | |
| Figs | 0.73 STMR (FAO, 2015) | |
| Table olives | 1.19 STMR (EFSA, 2014) | |
| Pineapples | 0.04 STMR × PeeF (FAO, 2015) | |
| Tomatoes | 0.52 STMR (FAO, 2015) | |
| Cotton seeds | 0.55 STMR (FAO, 2015) | |
| Olives for oil production | 0.01 STMR × PF (EFSA, 2009) × YF(a) | |
| Barley grain | 0.05 STMR (EFSA, 2009) | |
| Rye grain | 0.13 STMR (EFSA, 2009) | |
| Wheat grain | 0.30 STMR (EFSA, 2009) | |
| Swine, bovine, sheep, goat, equine, other farmed animals, muscle & fat | 0.05 MRL (EFSA, 2009) | |
| Swine, bovine, sheep, goat, equine, other farmed animals, liver | 0.13 STMR (FAO, 2015) | |
| Swine, bovine, sheep, goat, equine, other farmed animals, kidney | 0.06 STMR (FAO, 2015) | |
| Swine, bovine, sheep, goat, equine, other farmed animals, edible offal | 0.4 MRL (SANTE/11707/2016) | |
| Poultry, meat & fat | 0.05 MRL (EFSA, 2009) | |
| Poultry, liver | 0.04 STMR (FAO, 2015) | |
| Poultry, kidney | 0.04 STMR (FAO, 2015) | |
| Poultry, edible offal | 0.08 MRL (FAO, 2015) | |
| Milk | 0.05 MRL (EFSA, 2009) | |
| Bird’s eggs | 0.05 MRL (EFSA, 2009) | |

STMR: supervised trials median residue; HR: highest residue; PeeF: peeling factor; PF: processing factor; YF: yield factor. (a): Consumption figures in the PRIMO model are expressed for the raw commodity. A yield factor (YF) of 0.2 is considered to estimate the consumption figure for the processed olive oil.
## Appendix D – Used compound codes

| Code/trivial name | Chemical name | Structural formula |
|-------------------|---------------|--------------------|
| Etaphon           | 2-Chloroethylphosphonic acid ClCCP(=O)(O)O | ![Ethephon structural formula](image) |
| HEPA              | 2-Hydroxyethylphosphonic acid OCCP(=O)(O)O | ![HEPA structural formula](image) |
| Ethylene          | Ethylene C= C | ![Ethylene structural formula](image) |