REASONED OPINION

Review of the existing maximum residue levels (MRLs) for ethephon[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Article 12(2) of Regulation (EC) No 396/2005 lays down that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for ethephon as this active substance was included in Annex I to Directive 91/414/EEC before 02 September 2008. In order to collect the pesticide residues data supporting the existing MRLs for that active substance, EFSA asked The Netherlands, as the designated rapporteur Member State, to complete the Pesticide Residues Overview File (PROFile). The completed PROFile was submitted to EFSA on 02 September 2008.

According to Article 6(1) of the Regulation, The Netherlands also received an application from the company Bayer CropScience to maintain MRLs of 2 and 0.5 mg/kg for ethephon in wine grapes and pineapples for which EFSA identified potential intake concerns in the framework of a previous reasoned opinion. The subsequent evaluation report drafted by The Netherlands was forwarded to EFSA on 08 July 2009 according to Article 9 of the Regulation.

Based on the information provided in the evaluation report for pineapples and wine grapes, the PROFile and the EFSA conclusion on ethephon prepared in the framework of Directive 91/414/EEC, EFSA issued a first draft reasoned opinion that was circulated to Member State experts for consultation. On 05 October 2009, the RMS submitted an updated version of the PROFile, which took into consideration all Member States' comments, serving as a basis for finalisation of this reasoned opinion. The following conclusions were derived.

Metabolism of ethephon was investigated in two different crop groups following foliar application. Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment in cereals, fruits and fruiting vegetables could be defined as ethephon. A validated analytical method for enforcement of this residue definition with a LOQ of 0.05 mg/kg in all major crop groups is also available. Considering that the use of ethephon is also supported in cotton seed, an additional metabolism study is required in order to confirm the proposed residue definition for oilseeds as well.

Regarding the magnitude of residues in primary crops, a sufficient number of supervised residues trials is available for most of the GAPs reported by the RMS, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive appropriate MRLs.

1 On request of EFSA, Question No EFSA-Q-2008-533 and EFSA-Q-2009-00701, issued on 08 October 2009.
2 Correspondence: praper.mrl@efsa.europa.eu

For citation purposes: European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for ethephon on request of EFSA. EFSA Journal 2009; 7(10):1347. [44 pp.]. doi:10.2903/j.efsa.2009.1347. Available online: www.efsa.europa.eu

For apples and table olives, EFSA was only able to derive provisional MRLs pending the submission and evaluation of confirmatory residues trials.

In processed commodities, levels of ethephon were shown to be stable during pasteurisation whereas during baking, boiling, brewing and sterilisation it is mainly degraded to ethylene. This compound was also observed in plant metabolism and not considered relevant for inclusion in the residue definition, mainly due to its volatility. Studies investigating the magnitude of residues in some processed products are also available but in most cases they only allowed EFSA to derive indicative processing factors. For enforcement purposes, only the following robust processing factors could be derived:

Table grapes, dried (raisins):	9.80
Pineapples, peeled:	0.25
Olives, oil (virgin, crude and refined):	0.02

Occurrence of ethephon residues in rotational crops was already investigated during the peer review of ethephon. It was concluded that metabolic patterns in primary and succeeding crops are similar and that significant residues in rotational crops are not expected. These conclusions also apply to the GAPs of ethephon supported in the framework of this review.

Based on the uses reported by the RMS, significant intakes were calculated for dairy ruminant, meat ruminants and pigs. Metabolism in lactating ruminants was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant residue definition for both enforcement and risk assessment in pigs and ruminants was therefore defined as ethephon. Available studies also demonstrated that residues of ethephon are not expected in significant amounts and MRLs in pigs and ruminants can be set at the LOQ. Pending the submission and evaluation of a validated analytical method for enforcement of residues in foods of animal origin, it is proposed to maintain on a provisional basis the existing LOQ of 0.05 mg/kg. For poultry products no MRLs are required because there is no significant exposure of poultry to ethephon residues.

Both chronic and acute consumer exposure resulting from the MRLs proposed in the framework of this review were calculated and an exceedance of the ARfD was identified for table grapes, representing 196% of the ARfD. Considering the fall-back MRL for table grapes resulting from the Southern European GAP, the highest chronic exposure represented 12.1% of the ADI (German child) and the highest acute exposure amounted to 91.9% of the ARfD (tomatoes).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for ethephon. Additional calculations of the consumer exposure, including these CXLs, were therefore performed and exceedances of the ARfD were identified for the existing CXLs in apples (742%), peppers (302%), tomatoes (197%), melons (191%), cherries (160%) figs (108%) and table grapes (107%). Excluding CXLs for these commodities from the calculation, the highest chronic exposure represented 18.5% of the ADI (Dutch child) and the highest acute exposure amounted to 91.9% of the ARfD (tomatoes).

The MRL recommendations resulting from the above assessment are summarized in the table below. Most of the proposed MRLs are fully supported by data and therefore recommended for inclusion in Annex II to Regulation (EC) No 396/2005. Only the proposed MRLs for apples, table olives, cotton seed and all animal commodities are recommended for inclusion in Annex III to the Regulation because validity of these MRLs still needs to be confirmed by submission of the following data:

- a representative metabolism study for oilseeds;
- 8 additional residues trials complying with the Southern GAP in apples;
- 4 additional residues trials complying with the Southern GAP in table olives;
- a validated analytical method for enforcement of residues in foods of animal origin.

Commodity	Existing EC MRL (mg/kg)	Existing CXL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Residue definition for enforcement: *ethephon*				
Walnuts	0.1	0.5	0.5	Recommendations based on CXLs for which no risk to consumers is identified. These recommendations will also cover the uses evaluated at European level, when applicable (there is no European use for blueberries).
Blueberries	0.05*	20	20	
Pineapples	0.5	2	2	
Barley grain	0.5	1	1	
Rye grain	0.5	1	1	
Wheat grain	0.2	1	1	
Apples	0.5	5	0.6(t)	Recommendations resulting from the uses evaluated at European level that are sufficiently supported by (except for apples where 8 additional trials are required) and for which no risk to consumers is identified. CXLs are higher but a potential risk for European consumers could not be excluded.
Cherries	3	10	3	
Table grapes	0.05*	1	0.7	
Tomatoes	1	2	1	
Hazelnuts	0.1	0.2	0.2	Recommendations resulting from the uses evaluated at European level that are sufficiently supported by data (except for table olives and cotton seed where minor data gaps were identified) and for which no risk to consumers is identified. These recommendations will also cover the existing CXLs, when available.
Pears	0.05*	-	0.05*	
Wine grapes	1	1	2	
Table olives	0.05*	-	5(t)	
Olives for oil production	0.05*	-	10	
Cotton seed	2	2	2(t)	
Meat of ruminants, horses, pigs and poultry	0.05*	0.1*	0.05*(t)	Recommendations based on the existing CXLs, but considering the European LOQ. These recommendations will also cover the uses evaluated at European level.
Fat of ruminants, horses, pigs and poultry	0.05*	-	0.05*(t)	
Edible offals of ruminants, horses, pigs and poultry	0.05*	0.2*	0.05*(t)	
Milk	0.05*	0.05*	0.05*(t)	
Eggs	0.05*	0.2*	0.05*(t)	
Other products of plant and/or animal origin	see App C	see App D	-	No MRLs required according to European authorizations and no safe CXLs are identified/reported. Risk managers to decide whether a specific LOQ needs to be established or whether the default MRL of 0.01 mg/kg can apply.

(*): Indicates that the MRL is set at the limit of analytical quantification.
(t): Indicates that the MRL is recommended for inclusion in Annex III of Regulation (EC) N° 396/2005

KEY WORDS

ethephon, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, ethylene, 2-hydroxyethyl phosphonic acid

TABLE OF CONTENTS

BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting as well as the review of pesticide MRLs at Community level. Article 12(2) of that regulation lays down that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC before 02 September 2008.

According to Article 12(1) of the Regulation, 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 while MRLs set out in Regulation (EC) No 396/2005 should accommodate for all uses authorised within the EC as well as uses authorised in third countries having 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.

In order to have an overview on the pesticide residues data that have been considered for the setting of the MRLs under the former MRL legislation, EFSA developed the Pesticide Residue Overview File (PROFile). The PROFile is an electronic inventory of all pesticide residues data relevant to the risk assessment as well as the 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 processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities and;
- the analytical methods for enforcement of the proposed MRLs.

As ethephon was included in Annex I to Directive 91/414/EEC on 01 August 2007, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-533 was included in the EFSA Register of Question.

The Netherlands, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, were asked to complete the PROFile for ethephon. The completed PROFile was submitted to EFSA on 02 September 2008 and subsequently checked for completeness. On 12 June 2009, after having clarified some issues with the RMS, the PROFile was considered complete for assessment.

In the meantime, The Netherlands also received an application from the company Bayer CropScience B.V.[3] to modify the existing MRLs for the ethephon in grapes and pineapples. This application was notified to the European Commission and EFSA and subsequently evaluated by the RMS in accordance with Article 8 of the Regulation. After completion, the evaluation report of the RMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 08 July 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00701.

Based on the PROFile and the evaluation report submitted, EFSA prepared a draft reasoned opinion which was circulated to Member States (MS) for commenting on 29 July 2009. All comments received by 19 August 2009 were considered for finalisation of the reasoned opinion. In addition, The

[3] Bayer CropScience B.V., Energieweg 1, 3640 AE Mijndrecht, The Netherlands

RMS submitted on 05 October 2009 an updated version of the PROFile, which took into consideration all Member States' comments. This updated PROFile served as a basis for finalisation of the reasoned opinion.

TERMS OF REFERENCE

According to Article 12(1) 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.

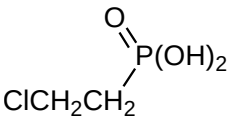
According to Article 12(2) of that Regulation, the reasoned opinion shall be provided within 12 months of the entry into force of this regulation. As the Regulation entered into force on 02 September 2008, the deadline for providing the reasoned opinion was 01 September 2009.

ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank the rapporteur Member State The Netherlands for the good collaboration as well as the completion of the PROFile.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Ethephon is the ISO common name for 2-chloroethyl phosphonic acid (IUPAC).



Ethephon is an ethylene generating plant growth regulator. It is a systemic compound which penetrates the plant tissues and decomposes to ethylene, hereby affecting the growth of the plant. It is mainly used to enhance the ripening of fruits and to prevent lodging of cereal crops.

Ethephon was evaluated in the framework of Directive 91/414/EEC in stage 2 with The Netherlands being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process included outdoor treatment of wheat and barley at a rate of 0.48 kg a.s./ha both in Northern and Southern Europe. Following the peer review a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was taken and published in Directive 2006/85/EC. The Annex I inclusion entered into force on 01 August 2007 and Member States are now required to review their national authorizations by 31 July 2011 in accordance with the uniform principles of Annex VI.

EC MRLs for ethephon in products of plant and animal origin have been set for the first time in 1994 by means of Directive 1994/29/EC and Directive 1994/30/EC. These MRLs have been modified on several occasions and transferred to Annex II of Regulation (EC) No 396/2005 without further amendments. Additional MRLs for commodities that were not covered by the former European MRL legislation are established in Annex III B of the Regulation. These temporary MRLs were derived from the MRLs that have been set at national level before the Regulation entered into force. All existing EC MRLs for ethephon are summarized in Appendix C to this document. On 15 September 2008, EFSA provided a reasoned opinion on certain MRLs of concern for ethephon and on 12 June 2009 a regulation amending the existing MRLs for ethephon was voted by the Standing Committee on the Food Chain and Animal Healtn. This regulation is, however, still pending publication. CXLs for ethephon have been established by the Codex Alimentarius Commission and are reported in Appendix D to this reasoned opinion.

For the purpose of this MRL review, the critical uses of ethephon currently authorized within the EC as well as uses authorised in third countries that might have a significant impact on international trade, have been reported by the RMS. In addition, the GAPs supported in the framework of the MRL application for grapes and pineapples were considered. A detailed overview of all critical GAPs is available in Appendix A to this document. For Northern and Southern Europe, several outdoor treatments in fruit crops, tomatoes, cotton seed and cereals are authorised. For tomatoes, the indoor use is also authorised. As Member States are still required to review their national approvals by 31 July 2011, modification of these GAPs might occur in the near future. Additionally, several outdoor treatments performed outside the EC, in particular in the US and in Brazil, were reported for some nuts, pineapples and cereals.

ASSESSMENT

1. Methods of analysis

1.1. Methods for enforcement of residues in food of plant origin

During the peer review under Directive 91/414/EC, an analytical method based on HPLC-MS/MS was evaluated and sufficiently validated for commodities with high water content (tomato), commodities with high acid content (oranges), commodities with high oil content (olives) and dry commodities (wheat grain), all with a LOQ of 0.05 mg/kg (EFSA, 2008a). The described method was also reported by the RMS in the PROFile.

Additionally, the 1999 JMPR reported the availability of a GC-FPD method for determining ethephon in various plant commodities with high water or high acid content (WHO/FAO, 2000). The LOQ of this method is generally about 0.02 mg/kg.

Hence it is concluded that ethephon residues can be enforced in food of plant origin with a LOQ of at least 0.05 mg/kg.

1.2. Methods for enforcement of residues in food of animal origin

During the peer review under Directive 91/414/EC, an analytical method for enforcement was not considered because no MRLs were proposed for commodities of animal origin (EFSA, 2008a). In the framework of this review, however, MRLs for food of animal origin are recommended and analytical methods for enforcement of residues in food of animal origin are required.

In the DAR on ethephon, prepared in the framework of Directive 91/414/EEC, a GC-MS/MS method is reported which was considered appropriate for enforcement of residues in milk and meat with LOQs of 0.01 and 0.05 mg/kg respectively (The Netherlands, 2004). Additional validation of the method in other foods of animal origin as well as an independent laboratory validation are still required.

The 1994 JMPR reported the availability of a GC-FPD method for determining ethephon in various commodities of plant and animal origin (WHO/FAO, 1995). The LOQs derived for milk, meat and other commodities of animal origin amounted to 0.05, 0.1 and 0.2 mg/kg, respectively. This method involves derivatisation of ethephon to dimethyl ethephon with diazomethane, which is a hazardous substance not to be used for routine enforcement methods. A revised method avoiding the use of this substance was therefore validated in plant commodities (WHO/FAO, 2000) but it is not clear whether this revised method is also valid for foods of animal origin.

Hence an appropriate method for enforcement of ethephon in food of animal origin is currently not available.

2. Mammalian toxicology

The toxicological assessment of ethephon was peer reviewed under Directive 91/414/EEC and toxicological reference values were published by EFSA (2008a). These toxicological reference values are summarized in Table 2-1.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
ADI	EFSA	2008	0.03	1 yr oral dog study, supported by human data	1000*
ARfD	EFSA	2008	0.05	28 days oral dog study (AChE inhibition), lowered to get a 10 fold MoS to the NOAEL from human data	100

* An additional conversion factor of 10 was considered since ChE activity was not measured in the study.

Regarding the toxicity of the plant and rat metabolite 2-hydroxyethyl phosphonic acid (HEPA), only few information was peer reviewed under Directive 91/414/EEC. It was therefore concluded, as a precautionary assumption, that ethephon and HEPA have similar toxicities and that the toxicological reference values for ethephon could also apply to HEPA. During the peer review, an addendum to the DAR addressing this issue was prepared by the Netherlands but it was submitted too late for consideration in the peer review (EFSA, 2008a). It has therefore been decided to further consider the addendum in the framework of this MRL review, which demonstrates that ethephon and HEPA do not share the same mechanism of toxicity and that toxicological effects for HEPA are expected to occur at higher doses than the parent compound (The Netherlands, 2008).

The mechanism for ethephon inhibition of cholinesterase (mainly butyrylcholinesterase - BChE) starts with the slow dissociation of chloride and the phosphorylation of BChE with liberation of ethylene. In HEPA, the chloride is substituted by a hydroxyl group. Experimental in vitro assay confirmed that HEPA does not have the ability of phosphorylating the active site of ChE, whereas ethephon showed inhibition levels of up to 89% by 90 minutes.

The acute oral LD_{50} of HEPA is > 2000 mg/kg bw; it is not genotoxic in *S. typhimurium* tester strains TA 98 TA 100 TA 1535 TA 1537 TA 102, in a TK assay in mouse lymphoma cells and in a chromosome aberration test with CHO Chinese hamster ovary cells.

Comparison of toxicological studies performed with ethephon and HEPA (for both compounds gavage studies were considered to eliminate any possible influences due to toxicokinetics), shows that HEPA is less toxic than ethephon: at 150 mg/kg bw/day, ethephon caused the inhibition of ChE activity in erythrocytes; at 600 mg/kg bw/day mortalities occurred, together with poor condition, abnormal respiratory sound/abnormal breathing, reduced body weight gain, inhibition of ChE activity in erythrocytes. The relevant NOAEL for ethephon is 75 mg/kg bw/day. In a 4-week study with HEPA, clinical signs (including mortalities) were mainly noted during the first week of treatment at 1000 mg/kg bw/day (hence the dose was reduced at 700 mg/kg bw/day, resulting in a significant improvement of health). The relevant NOAEL for HEPA is 350 mg/kg bw/day, however no adverse effects are expected at a dose level of 700 mg/kg bw/day.

Consequently, it is concluded that HEPA and ethephon have a different mechanism of toxicity and that for HEPA adverse effects are expected to occur at exposure levels 5-10 times higher than for ethephon. Specific ADI of ARfD values for HEPA were not derived.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of ethephon was investigated in cereals (wheat) and in fruits and fruiting vegetables (tomato and pineapples) (EFSA, 2008a). Additional information on the fate of ethephon was also available after application to squash, cucumber, apple and cherry trees. These studies indicate that metabolism of ethephon in plants mainly proceeds via conversion to 2-hydroxyethyl phosphonic acid (HEPA) and via decomposition via ethylene, which is released in the atmosphere, and phosphate, which is incorporated in the natural phosphate cycle of the plant. The wheat metabolism study shows that in the edible part (grain) of cereals treated at normal field rates, the metabolite HEPA and ethephon are present at similar levels. In tomatoes, HEPA was found to increase over time but 12 days after treatment, which corresponds to the supported PHI for most fruiting crops, the metabolite was still present at levels four times lower than ethephon (The Netherlands, 2004). Moreover, residues trials on grapes where levels of both ethephon and HEPA were measured were reported by the Netherlands (2009). After a PHI of 28 days, all trials demonstrated that HEPA was present at levels lower or similar to the parent compound. Considering that HEPA was shown to be of different toxicity than the parent compound (see also section 2), there is no need to include HEPA in the residue definition for risk assessment together with the parent compound but the question could be raised whether a separate risk assessment for HEPA would be necessary. EFSA concludes that a separate risk assessment for HEPA will not be more critical than the risk assessment for ethephon because HEPA is not expected to be present in higher amounts than the parent compound and adverse effects for HEPA are expected to occur at exposure levels 5-10 times higher than for ethephon (see also section 2). A separate residue definition for risk assessment of HEPA is therefore not required.

Consequently, the residue definition for enforcement and risk assessment in cereals, fruits and fruiting vegetables is defined as ethephon only. Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.1). These conclusions reflect the views of the RMS (The Netherlands, 2008) and are also in line with the findings of the 1994 JMPR (WHO/FAO, 1995). During the peer review of ethephon (EFSA, 2008a), it was decided to include HEPA in the residue definition for risk assessment but this conclusion is no longer relevant as additional information on the toxicity of HEPA has been considered in the meantime.

It is noted that ethephon is also authorised for use on cotton seed, for which no representative metabolism study is available. In order to extend the proposed residue definition to oilseeds, a representative metabolism study for this crop group should be submitted. Awaiting such information to be submitted and evaluated, it is proposed on a provisional basis to define the residue for enforcement and risk assessment in cotton seeds as ethephon.

3.1.1.2. Magnitude of residues

The use of ethephon is reported on a large number of crops by the RMS (Appendix A). With regard to pineapples and wine grapes, EFSA relied upon the supervised residues field trials provided by the RMS in the framework of the MRL application (The Netherlands, 2009). For the remaining crops under consideration, EFSA relied upon the supervised residues field trials that were reported by the RMS in the PROFile. The combined results for all available residues trials are summarized in Table 3-1.

Table 3-1. Overview of the available residues trials data

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement (ethephon)	Risk assessment (ethephon)					
Hazelnuts	Import (USA)	Outdoor	0.1; 0.03; 0.04; 0.06	0.1; 0.03; 0.04; 0.06	0.05	0.1	0.2	1.0	Trials in compliance with the GAP (PROFile). Rmax = 0.22 Rber = 0.14
Walnuts	Import (USA)	Outdoor	0.06; 0.04; 0.27; 0.03; 0.05; 0.02; 0.02	0.06; 0.04; 0.27; 0.03; 0.05; 0.02; 0.02	0.04	0.27	0.4	1.0	Trials in compliance with the GAP (PROFile). Rmax = 0.37 Rber = 0.11
Apples	NEU	Outdoor	0.26; 0.08; 0.40; 0.27; 0.40; 0.13; 0.14; 0.06; 0.08	0.26; 0.08; 0.40; 0.27; 0.40; 0.13; 0.14; 0.06; 0.08	**0.14**	**0.4**	**0.6(t)**	**1.0**	Trials with one application instead of two. Considered acceptable because the last application has the most impact on the final residue (PROFile). Rmax = 0.61 Rber = 0.54
	SEU	Outdoor	-	-	-	-	-	-	8 residues trials complying with the GAP are required. Awaiting the submission and evaluation of these trials, provisional MRL and risk assessment values are derived from the Northern data (PROFile).
Pears	NEU	Outdoor	5 x <0.015	5 x <0.015	0.02	0.02	0.05*	1.0	Trials in compliance with the GAP (PROFile).

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement (ethephon)	Risk assessment (ethephon)					
Cherries	NEU	Outdoor	0.42; 0.14; 0.52; 0.33	0.42; 0.14; 0.52; 0.33	0.38	0.52	1	1.0	Trials in compliance with the GAP (PROFile). Rmax = 1.18 Rber = 0.89
	SEU	Outdoor	0.48; 0.59; 0.17; 2.7; 1.6; 0.67; 2.0; 0.64; 0.37	0.48; 0.59; 0.17; 2.7; 1.6; 0.67; 2.0; 0.64; 0.37	**0.64**	**2.70**	**3**	**1.0**	Trials in compliance with the GAP (PROFile). Rmax = 3.65 Rber = 3.20
Table grapes Wine grapes	NEU	Outdoor	1 application: 0.52; 0.21 2 applications: 1.5; 0.31; 0.39; 0.19; 0.16	1 application: 0.52; 0.21 2 applications: 1.5; 0.31; 0.39; 0.19; 0.16	**0.31**	**1.50**	**2**	**1.0**	Combined dataset with 1 application (2 trials) and 2 applications (5 trials). Considered acceptable because the last application has the most impact on the final residue (The Netherlands, 2009). Rmax = 2.07 Rber = 0.91
	SEU	Outdoor	1 application: 0.37; 0.25; 0.18; 0.05 2 applications: 0.07; 0.46; <0.05; <0.05; 0.15	1 application: 0.37; 0.25; 0.18; 0.05 2 applications: 0.07; 0.46; <0.05; <0.05; 0.15	0.15	0.46	0.7	1.0	Combined dataset with 1 application (4 trials) and 2 applications (5 trials). Considered acceptable because the last application has the most impact on the final residue (The Netherlands, 2009). Rmax = 0.64 Rber = 0.50

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement (ethephon)	Risk assessment (ethephon)					
Table olives	SEU	Outdoor	0.51; 1.9; 1.2; 1.8	0.51; 1.9; 1.2; 1.8	1.5	1.9	5 (t)	1.0	Trials in compliance with the GAP (PROFile). 4 additional trials are required for table olives (major crop in SEU). Rmax = 4.65 Rber = 3.65
Pineapples	Import (CR)	Outdoor	0.2; <0.05; 0.15; 0.11; 0.19	0.2; <0.05; 0.15; 0.11; 0.19	0.15	0.20	0.4	1.0	Trials in compliance with the GAP (The Netherlands, 2009). Rmax = 0.40 Rber = 0.38
Tomatoes	SEU	Outdoor	0.78; 0.62; 0.24; 0.78; 0.45; 0.68; 0.50; 0.46; 0.40	0.78; 0.62; 0.24; 0.78; 0.45; 0.68; 0.50; 0.46; 0.40	**0.50**	**0.78**	**1**	**1.0**	Trials in compliance with the GAP (PROFile). Rmax = 1.10 Rber = 1.36
	NEU/ SEU	Indoor	0.51; 0.68; 0.79; 0.45; 0.28; 0.27; 0.68; 0.66; 0.52; 0.31; 0.36	0.51; 0.68; 0.79; 0.45; 0.28; 0.27; 0.68; 0.66; 0.52; 0.31; 0.36	0.51	0.79	1	1.0	Trials in compliance with the GAP (PROFile). Rmax = 1.02 Rber = 1.34
Olives for oil production	SEU	Outdoor	3.5; 5.2; 1.7; 1.3	3.5; 5.2; 1.7; 1.3	2.60	5.20	10	1.0	Trials in compliance with the GAP (PROFile). Rmax = 12.15 Rber = 9.55
Cotton seed	SEU	Outdoor	<0.1; 0.58; 0.30; 1.1; <0.1; <0.1; 0.35; 0.19	<0.1; 0.58; 0.30; 1.1; <0.1; <0.1; 0.35; 0.19	0.25	1.10	2 (t)	1.0	Trials in compliance with the GAP (PROFile). Rmax = 1.45 Rber = 0.82

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement (ethephon)	Risk assessment (ethephon)					
Barley grain Rye grain Wheat grain	NEU	Outdoor	Wheat: 0.01; 4 x <0.05; 2 x 0.06 Barley: 0.005; 0.01; 0.03; 3 x <0.05; 2 x 0.05; 0.06	Wheat: 0.01; 4 x <0.05; 2 x 0.06 Barley: 0.005; 0.01; 0.03; 3 x <0.05; 2 x 0.05; 0.06	0.05	0.06	0.1	1.0	Combined dataset on wheat (7) and barley (9) complying with the Northern GAP in cereals (PROFile). Trials with lower application rate were also considered as residues were higher. Rmax = 0.09 Rber = 0.10
	SEU	Outdoor	Wheat: 0.004; 10 x <0.05 Barley: 2 x 0.01; 0.02; 0.04; 5 x <0.05; 0.05; 3 x 0.06	Wheat: 0.004; 10 x <0.05 Barley: 2 x 0.01; 0.02; 0.04; 5 x <0.05; 0.05; 3 x 0.06	**0.05**	**0.06**	**0.1**	**1.0**	Combined dataset on wheat (11) and barley (13) complying with the Southern GAP in cereals (PROFile). Trials with lower application rate were also considered as residues were higher. Rmax = 0.08 Rber = 0.10
	Import (US)	Outdoor	-	-	-	-	-	-	No representative trials compliant with the GAP.
Barley straw Rye straw Wheat straw	NEU	Outdoor	Wheat: 0.27; 0.08; 0.22; 0.14; 0.13; 0.51; 0.38 Barley: 0.2; 0.07; 0.16;0.04; 0.005; 0.06; 0.21; 1.1; 0.33	Wheat: 0.27; 0.08; 0.22; 0.14; 0.13; 0.51; 0.38 Barley: 0.2; 0.07; 0.16;0.04; 0.005; 0.06; 0.21; 1.1; 0.33	0.18	1.10	2	1.0	Combined dataset on wheat (7) and barley (9) complying with the Northern GAP in cereals (PROFile). Trials with lower application rate were also considered as residues were higher. Rmax = 0.09 Rber = 0.10

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement (ethephon)	Risk assessment (ethephon)					
	SEU	Outdoor	Wheat: 0.36; 0.33; 0.22; 0.075; 0.15; 0.15; 0.56; 0.45; 1.3; 0.46; 0.12 Barley: 0.19; 0.01; 0.04; 0.20; 0.13; 0.25; 0.43; 0.08; 0.63; <0.05; 0.09; 0.36; <0.05	Wheat: 0.36; 0.33; 0.22; 0.075; 0.15; 0.15; 0.56; 0.45; 1.3; 0.46; 0.12 Barley: 0.19; 0.01; 0.04; 0.20; 0.13; 0.25; 0.43; 0.08; 0.63; <0.05; 0.09; 0.36; <0.05	**0.20**	**1.30**	**2**	**1.0**	Combined dataset on wheat (11) and barley (13) complying with the Southern GAP in cereals (PROFile). Trials with lower application rate were also considered as residues were higher. Rmax = 0.08 Rber = 0.10
	Import (US)	Outdoor	-	-	-	-	-	-	No representative trials compliant with the GAP.

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial. The individual conversion factor for each trial is defined as the ratio of the trial result according to the risk assessment residue definition and the result according to the enforcement residue definition.
(t): Indicates that a provisional MRL is proposed awaiting submission and evaluation of additional studies/data.

A sufficient number of trials complying with the GAP was reported by the RMS for all crops under assessment, except in the following cases:

- For the use of ethephon on apples in Southern Europe, no trials are available and 8 trials complying with the GAP are therefore required. Awaiting the submission and evaluation of these trials, provisional MRL and risk assessment values are derived from the Northern data.
- For pears, a data requirement of 8 residues trials normally applies while only 5 trials are available. Considering however that all results are below the LOQ, indicating that it concerns a no residues situation, further residues trials are not required.
- Regarding the use of ethephon on wine grapes in Northern Europe, the data requirement of 8 residues trials also applies while only 7 trials are available. Considering the overall availability of residues trials in Northern and Southern Europe, further trials are neither required in this case.
- For table olives, only 4 residues trials are available, although it is a major crop in Southern Europe. 4 additional trials complying with the GAP are therefore required. Awaiting these trials to be submitted and evaluated, provisional MRL and risk assessment values can be derived.
- Regarding olives for oil production, only 4 trials are available while 8 trials are normally required. Nevertheless, the number of trials is considered acceptable in this case because residues in the oil were demonstrated to be below the LOQ (see also section 3.1.1.3).
- No trials are available to support the use of ethephon on cereals in the US but residues trials complying with the European GAP are sufficient to derive MRL and risk assessment values in these crops. If the proposed MRL does not accommodate for the use of ethephon in the US, 8 representative residues trials would have to be submitted.

Storage stability of ethephon was demonstrated for a period of 24 months at -20 °C in commodities with high water, high acid and high oil content as well as dry commodities (EFSA, 2008a). According to the RMS, all the residues trial samples were stored in accordance with these conditions, except for walnuts and olives (oil production) where storage conditions of the residues trials samples were not reported to the RMS. Considering however that storage stability of ethephon was demonstrated for a long period in a broad range of crops, degradation of residues during storage of the trial samples is not expected.

Consequently, the available residues data are considered acceptable to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for apples and table olives where a provisional MRL is calculated awaiting additional trials to be submitted and evaluated (see also Table 3-1). Tentative MRLs were derived for cereal straws in view of the future need to set MRLs in feed items. In cases where several uses are supported for one commodity, the final MRL proposal was derived from the most critical use and indicated in bold in the table. In order to better reflect the real residue levels, the MRL proposals were also calculated without consideration of the conventional MRL classes that are usually applied in legislation.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of residues was investigated in the framework of the peer review and ethephon levels appear to be stable during pasteurisation whereas during baking, boiling, brewing and sterilisation it is mainly degraded to ethylene (EFSA, 2008a). This compound was also observed in plant metabolism and not considered relevant for inclusion in the residue definition, mainly due to its volatility.

Processing studies investigating the magnitude of residues in processed commodities have been reported in different sources. An overview of all available processing studies is available in Table 3-2. Robust processing factors for enforcement and risk assessment purposes could only be derived for raisins, peeled pineapples and olive oil. The processing factors reported for the remaining commodities should be considered indicative as they are not sufficiently supported by studies; a minimum of 3 processing studies is normally required.

With regard to the risk assessment, further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if there would be the intention to derive more robust processing factors, in particular for enforcement purposes, additional processing studies would be required.

Table 3-2. Overview of the available processing studies

Processed commodity	Number of studies	Median PF (a)	Median CF (b)	Comments
Processing factors recommended for enforcement and risk assessment (sufficiently supported by data)				
Table grapes, dried (raisins)	4	9.80	1.00	Processing studies performed on raisin waste (The Netherlands, 2004).
Pineapples, peeled	16	0.25	1.0	4 trials where residues were measured in peeled and unpeeled fruits at 4 different PHIs (The Netherlands, 2009). As the PHI didn't seem to affect the processing factor, all data were pooled to obtain 16 values.
Olives, virgin oil	4	0.02	1.00	A worst-case median processing factor was calculated because residues in oil were below the LOQ (PROFile).
Olives, crude oil	4	0.02	1.00	
Olives, refined oil	4	0.02	1.00	
Indicative processing factors (limited data sets)				
Apples, juice	1	1.60	1.00	For juice, the processing factor was derived from the clarified juice being the most critical (The Netherlands, 2004).
Apples, dry pomace	1	1.00	1.00	
Apples, wet pomace	1	0.60	1.00	
Wine grapes, juice	2	2.10	1.00	No indication whether the red wine was heated or not (The Netherlands, 2004).
Wine grapes, dry pomace	2	2.00	1.00	
Wine grapes, must	2	0.80	1.00	
Wine grapes, red wine	2	1.80	1.00	
Wine grapes, white wine	2	1.20	1.00	
Tomatoes, sauce/puree	1	0.60	1.00	The processing factor for juice is derived from juice that was reconstituted from concentrate being the most critical (The Netherlands, 2004).
Tomatoes, paste	1	0.80	1.00	
Tomatoes, juice	1	0.40	1.00	
Cotton seed, crude oil	1	0.01	1.00	Worst-case median processing factors were calculated because residues in oil were below the LOQ (The Netherlands, 2004).
Cotton seed, refined oil	1	0.01	1.00	
Cotton seed, meal/press cake	1	0.03	1.00	

Processed commodity	Number of studies	Median PF (a)	Median CF (b)	Comments
Wheat and rye, white flour	1	0.3	1.0	For the flour, a worst-case median processing factor was calculated because residues in flour were below the LOQ (EFSA, 2008a).
Wheat and rye, bran	1	1.4	1.0	

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

3.1.2. Rotational crops

The use of ethephon in permanent crops (apples, pears, cherries, grapes and olives) or in third countries is not considered relevant with regard to the potential occurrence of residues in rotational crops. Within Europe, however, ethephon is also authorised for use in cereal crops, cotton seed and tomatoes, which requires further consideration of ethephon residues in rotational crops.

Ethephon was found to decline rapidly in soil and DT_{90} values ranging between 22 and 66 days were derived from field degradation studies (EFSA, 2008a). Moreover, a rotational crops study was reported by the Netherlands (2004) where a bare soil was treated with 2.36 kg a.s./ha of ^{14}C-labelled ethephon and residues in succeeding radishes, collards and wheat were characterized. This study shows that radioactivity in mature plants samples paralleled or decreased at even faster rate compared to the soil levels. In plant extracts no radioactive peaks greater than 0.01 mg/kg were detected. Only very low levels of ethephon and HEPA were detected in certain samples of the crops examined and radioactivity found in plant matrices was mainly attributed to incorporation of residues into all categories of plant biomolecules (EFSA, 2008a).

Consequently, following application of ethephon according to the GAPs on cereals, cotton seed and tomatoes no residues are expected in follow-up crops.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

The use of ethephon results in significant residues levels in cereal straw, apples and cotton seed, which might be fed to livestock. The median and maximum dietary burdens were therefore calculated for the different types of livestock using to the agreed European methodology (European Commission, 1996). The input values for all relevant commodities have been selected according to the latest recommendations of the 2004 JMPR (WHO/FAO, 2005) and are summarized in the table below. For apple pomace (wet), cereal bran and cotton seed meal the indicative processing factors derived under section 3.1.1.3 have been included in the calculation.

The results of the calculations are reported in Table 3-4, indicating a significant intake for ruminants and pigs. No significant intake was identified for poultry.

Table 3-3. Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Apples pomace	0.08	STMR x PF	0.08	STMR x PF
Cereal grain	0.05	STMR	0.05	STMR
Cereal bran	0.07	STMR x PF	0.07	STMR x PF
Cereal straw	0.20	STMR	1.30	HR
Cotton seed	0.25	STMR	0.25	STMR
Cotton seed meal	0.008	STMR x PF	0.008	STMR x PF

Table 3-4. Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded ?
Dairy ruminants	0.016	0.007	Cotton seed	0.45	Yes
Meat ruminants	0.039	0.012	Apple pomace	0.92	Yes
Poultry	0.004	0.004	Wheat grain	0.07	No
Pigs	0.004	0.004	Cotton seed	0.10	Yes

3.2.2. Nature of residues

Considering that the dietary burden of ruminants and pigs is triggered, investigation on the fate of residues in these animals is necessary. During the peer review of ethephon, a metabolism study was assessed where lactating goats were dosed with 0.37 and 0.46 mg/kg bw/d of ^{14}C-ethephon, corresponding to the 7N and 8N exposure of meat ruminants (The Netherlands, 2004). This study demonstrates that the parent compound is hydrolysed to lose its chlorine and phosphate groups and that the carbon units are taken up into the tricarboxylic acid cycle to yield natural products like fat, protein, carbohydrate and CO_2. Ethephon and HEPA are expected to be the only toxicologically relevant compounds and the highest radioactive residue level was found in liver (1 mg/kg) of which 0.15% was considered ethephon and/or HEPA (max. 0.0015 mg/kg). Since metabolism in rats and ruminants was demonstrated to be similar, the findings in ruminants can also be extrapolated to pigs. Based on these data and the fact that residues in all ruminant commodities were expected to be very low, no residue definition was proposed in the framework of the peer review (EFSA, 2008a). In the framework of this review, however, additional crops contribute to the dietary burden of livestock resulting in a higher exposure of livestock to ethephon residues and the necessity to establish a residue definition in pigs and ruminants. Also in contrast to the peer review, data are now available indicating that HEPA is expected to result in adverse effects at much higher exposure levels than ethephon (see also section 2). Therefore, the relevant residue in pigs and ruminants is now defined as ethephon, both for enforcement and risk assessment purposes.

For poultry there is in principle no necessity to establish a residue definition because the calculated dietary burden of poultry to ethephon residues amounted to less than 0.1 mg/kg DM. Nevertheless, a metabolism study with laying hens is reported in the DAR on ethephon. This study demonstrates that metabolic pathways of ethephon in ruminants and poultry are very similar (The Netherlands, 2004). It is therefore concluded that the relevant residue in poultry could also be defined as ethephon, provided that the use of ethephon is supported on additional crops resulting in a higher exposure of poultry to ethephon residues. In the meantime, a residue definition for poultry products is not required.

3.2.3. Magnitude of residues

According to the above mentioned metabolism study in lactating goats, highest residues of ethephon and/or HEPA were found in liver (0.0015 mg/kg) at a 8N dosing rate. These finding are also confirmed by a 28 days livestock feeding study with cows. In this study, after dosing the cows with 43 mg/kg feed (*ca.* 30N), ethephon residues accounted for <0.01, <0.01, 0.64 and 0.095 mg/kg in milk, muscle, liver and kidneys, respectively (the Netherlands, 2004).

It is therefore concluded that significant residues in edible matrices of ruminants and pigs are not expected and that MRLs for these commodities can be established at the LOQ. It is noted, however, that a validated analytical method for enforcement of ethephon in foods of animal origin is currently not available. Awaiting such method to be submitted and evaluated, the LOQ of 0.05 mg/kg, currently established in European legislation, could be applied.

MRLs for poultry products are not required because they are not exposed to significant levels of ethephon.

4. Consumer risk assessment

In this review, only the GAPs reported by the RMS were considered but, previously, the use of ethephon has also been assessed by the 1994 JMPR (WHO/FAO, 1995) and by the 1999 JMPR (WHO/FAO, 2000). The CXLs, resulting from these JMPR assessments and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. In order to facilitate the consideration of CXLs by risk managers, the consumer exposure was calculated both with and without inclusion of the existing CXLs (see Appendix D).

4.1. Consumer risk assessment without the CXLs

Chronic and acute intake calculations considering the MRLs proposed in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). The input values for the proposed MRLs are summarized in Table 4-1. The STMR and HR values selected for chronic and acute intake calculations are based on the residue levels in the raw agricultural commodities. As pineapples are commonly peeled before consumption, the relevant processing factor reported in Table 3-2 was considered as well. Similarly, a processing factor was also applied to the olives for oil production. The contributions of other commodities, for which no MRL was derived in the framework of this review, were not included in the calculation.

The detailed results of the chronic and acute intake calculations are reported in Appendix B.1 to this document. The highest chronic exposure was calculated for the German children, representing 12.8% of the ADI. With regard to the acute exposure, however, an exceedance of the ARfD was identified for table grapes, representing 196% of the ARfD. A second intake calculation was therefore performed, considering a fall-back MRL of 0.7 mg/kg for table grapes based on the use of ethephon in Southern Europe (see Table 3-1). According to the results of this second intake calculation (see Appendix B.2), the chronic exposure decreased to 12.1 % of the ADI and the highest acute exposure is then calculated for tomatoes, representing 91.9% of the ARfD.

Consequently, uses of ethephon reported in the framework of this review, except for the Northern European use on table grapes, (see Appendix A) are acceptable with regard to consumer exposure and MRLs resulting from these uses can be recommended for MRL setting (see also Table 3-1 and section 3.2.3).

Table 4-1. Input values for the consumer risk assessment without CXLs

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Hazelnuts	0.05	STMR	0.10	HR
Walnuts	0.04	STMR	0.27	HR
Apples	0.14	STMR	0.40	HR
Pears	0.02	STMR	0.02	HR
Cherries	0.64	STMR	2.70	HR
Table grapes	0.31	STMR	1.50	HR
Wine grapes	0.31	STMR	1.50	HR
Table olives	1.50	STMR	1.90	HR
Pineapples	0.04	STMR x PF	0.05	HR x PF
Tomatoes	0.51	STMR	0.79	HR
Cotton seed	0.25	STMR	1.10	HR
Olives for oil production	0.05	STMR x PF	0.10	HR x PF
Barley grain	0.05	STMR	0.06	HR
Rye grain	0.05	STMR	0.06	HR
Wheat grain	0.05	STMR	0.06	HR
Swine meat, fat, liver and kidneys	0.05	MRL (=LOQ)	0.05	MRL (=LOQ)
Ruminant meat, fat, liver and kidneys	0.05	MRL (=LOQ)	0.05	MRL (=LOQ)
Milk	0.05	MRL (=LOQ)	0.05	MRL (=LOQ)

4.2. Consumer risk assessment including the CXLs

In order to include the CXLs in the calculations of the consumer exposure, all data relevant to the consumer risk assessment of the CXLs have been collected (PSD, 2009), the outcome of this data collection being reported in Appendix D to this document.

The MRLs proposed in the framework of this review and for which no consumer intake concerns were identified (see section 4.2), were then compared with the existing CXLs for ethephon. For each commodity, the highest value was selected and corresponding input values for risk assessment are summarized in Table 4-2. For the acute exposure assessment in blueberry juice the STMR was used instead of the HR assuming that blueberry lots are bulked before processing. For the peeling of pineapples, no processing factor could be derived from the JMPR data. Hence the peeling factor derived under section 3.1.1.3 is applied. For products of animal origin, it is noted that LOQs derived by the JMPR are higher compared to the LOQ currently in place at EU level. Nevertheless, the

livestock dietary burden calculated by the 1994 JMPR (PSD, 2009) is within the same order of magnitude as the European dietary burden calculated under section 3.2.1. Therefore, the European LOQ of 0.05 mg/kg in all commodities of animal origin is expected to accommodate for the established CXLs.

Chronic and acute intake calculations considering the input values of Table 4-2 were performed using revision 2 of the EFSA PRIMo (EFSA, 2007) and results are reported in Appendix B.3. In this case, the highest chronic exposure was calculated for the German children, representing 52.2% of the ADI. With regard to the acute exposure, however, exceedances of the ARfD were identified for apples (742%), peppers (302%), tomatoes (197%), melons (191%), cherries (160%) figs (108%) and table grapes (107%). Excluding the CXLs for these commodities from the calculations (see Appendix B.4), the chronic exposure decreases to 18.5% of the ADI. The highest acute exposure is then calculated for tomatoes, representing 91.9% of the ARfD. It is therefore concluded that the existing CXLs for ethephon may be recommended for inclusion in European legislation, except for apples, peppers, tomatoes, melons, cherries, figs and table grapes as for these CXLs a potential risk for European consumers could not be excluded.

It is noted that in a previous reasoned opinion on MRLs of concern for ethephon, EFSA identified an acute risk for the CXL of 2 mg/kg in pineapples (EFSA, 2008b). This conclusion was mainly related to the possible occurrence of the HEPA metabolite in pineapples. In the meantime, data have been provided suggesting that this metabolite should not be included in the residue definition for risk assessment (see section 3.1.1.1), resulting in an acceptable exposure for the CXL of ethephon in pineapples.

Table 4-2. Input values for the consumer risk assessment including CXLs

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Hazelnuts	0.05	STMR	0.10	HR
Walnuts	0.04	STMR (PSD, 2009)	0.27	HR (PSD, 2009)
Apples	0.95	STMR (PSD, 2009)	3.79	HR (PSD, 2009)
Pears	0.02	STMR	0.02	HR
Cherries	2.50	STMR (PSD, 2009)	6.57	HR (PSD, 2009)
Table grapes	0.31	STMR (PSD, 2009)	0.82	HR (PSD, 2009)
Wine grapes	0.31	STMR	1.50	HR
Blueberries	5.30	STMR (PSD, 2009)	11.0	HR (PSD, 2009)
Figs	0.90	STMR (PSD, 2009)	2.73	HR (PSD, 2009)
Table olives	1.50	STMR	1.90	HR
Pineapples	0.03	STMR (PSD, 2009) x PF	0.24	HR (PSD, 2009) x PF
Tomatoes	0.41	STMR (PSD, 2009)	1.70	HR (PSD, 2009)
Peppers	0.98	STMR (PSD, 2009)	2.40	HR (PSD, 2009)
Melons	0.24	STMR (PSD, 2009)	0.63	HR (PSD, 2009)
Cotton seed	0.25	STMR	1.10	HR
Olives for oil production	0.05	STMR x PF	0.10	HR x PF

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Barley grain	0.05	STMR (PSD, 2009)	0.50	HR (PSD, 2009)
Rye grain	0.13	STMR (PSD, 2009)	0.24	HR (PSD, 2009)
Wheat grain	0.30	STMR (PSD, 2009)	0.68	HR (PSD, 2009)
Meat, fat, liver, kidneys and edible offals (except other farm animals)	0.05	CXL (=LOQ)	0.05	CXL (=LOQ)
Milk	0.05	CXL (=LOQ)	0.05	CXL (=LOQ)
Eggs	0.05	CXL (=LOQ)	0.05	CXL (=LOQ)

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Metabolism of ethephon was investigated in two different crop groups following foliar application. Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment in cereals, fruits and fruiting vegetables could be defined as ethephon. A validated analytical method for enforcement of this residue definition with a LOQ of 0.05 mg/kg in all major crop groups is also available. Considering that the use of ethephon is also supported in cotton seed, an additional metabolism study is required in order to confirm the proposed residue definition for oilseeds as well.

Regarding the magnitude of residues in primary crops, a sufficient number of supervised residues trials is available for most of the GAPs reported by the RMS, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive appropriate MRLs. For apples and table olives, EFSA was only able to derive provisional MRLs pending the submission and evaluation of confirmatory residues trials.

In processed commodities, levels of ethephon were shown to be stable during pasteurisation whereas during baking, boiling, brewing and sterilisation it is mainly degraded to ethylene. This compound was also observed in plant metabolism and not considered relevant for inclusion in the residue definition, mainly due to its volatility. Studies investigating the magnitude of residues in some processed products are also available but in most cases they only allowed EFSA to derive indicative processing factors. For enforcement purposes, only the following robust processing factors could be derived:

Table grapes, dried (raisins):	9.80
Pineapples, peeled:	0.25
Olives, oil (virgin, crude and refined):	0.02

Occurrence of ethephon residues in rotational crops was already investigated during the peer review of ethephon. It was concluded that metabolic patterns in primary and succeeding crops are similar and that significant residues in rotational crops are not expected. These conclusions also apply to the GAPs of ethephon supported in the framework of this review.

Based on the uses reported by the RMS, significant intakes were calculated for dairy ruminant, meat ruminants and pigs. Metabolism in lactating ruminants was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant residue definition for both enforcement and risk assessment in pigs and ruminants was therefore defined as ethephon. Available studies also

demonstrated that residues of ethephon are not expected in significant amounts and MRLs in pigs and ruminants can be set at the LOQ. Pending the submission and evaluation of a validated analytical method for enforcement of residues in foods of animal origin, it is proposed to maintain on a provisional basis the existing LOQ of 0.05 mg/kg. For poultry products no MRLs are required because there is no significant exposure of poultry to ethephon residues.

Both chronic and acute consumer exposure resulting from the MRLs proposed in the framework of this review were calculated and an exceedance of the ARfD was identified for table grapes, representing 196% of the ARfD. Considering the fall-back MRL for table grapes resulting from the Southern European GAP, the highest chronic exposure represented 12.1% of the ADI (German child) and the highest acute exposure amounted to 91.9% of the ARfD (tomatoes).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for ethephon. Additional calculations of the consumer exposure, including these CXLs, were therefore performed and exceedances of the ARfD were identified for the existing CXLs in apples (742%), peppers (302%), tomatoes (197%), melons (191%), cherries (160%) figs (108%) and table grapes (107%). Excluding CXLs for these commodities from the calculation, the highest chronic exposure represented 18.5% of the ADI (Dutch child) and the highest acute exposure amounted to 91.9% of the ARfD (tomatoes).

The MRL recommendations resulting from the above assessment are summarized in the table below. Most of the proposed MRLs are fully supported by data and therefore recommended for inclusion in Annex II to Regulation (EC) No 396/2005. Only the proposed MRLs for apples, table olives, cotton seed and all animal commodities are recommended for inclusion in Annex III to the Regulation because validity of these MRLs still need to be confirmed by submission of the following data:

- a representative metabolism study for oilseeds;
- 8 additional residues trials complying with the Southern GAP in apples;
- 4 additional residues trials complying with the Southern GAP in table olives;
- a validated analytical method for enforcement of residues in foods of animal origin.

RECOMMENDATIONS

Commodity	Existing EC MRL (mg/kg)	Existing CXL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Residue definition for enforcement: *ethephon*				
Walnuts	0.1	0.5	0.5	Recommendations based on CXLs for which no risk to consumers is identified. These recommendations will also cover the uses evaluated at European level, when applicable (there is no European use for blueberries).
Blueberries	0.05*	20	20	
Pineapples	0.5	2	2	
Barley grain	0.5	1	1	
Rye grain	0.5	1	1	
Wheat grain	0.2	1	1	
Apples	0.5	5	0.6(t)	Recommendations resulting from the uses evaluated at European level that are sufficiently supported by (except for apples where 8 additional trials are
Cherries	3	10	3	
Table grapes	0.05*	1	0.7	

Commodity	Existing EC MRL (mg/kg)	Existing CXL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Tomatoes	1	2	1	required) and for which no risk to consumers is identified. CXLs are higher but a potential risk for European consumers could not be excluded.
Hazelnuts	0.1	0.2	0.2	Recommendations resulting from the uses evaluated at European level that are sufficiently supported by data (except for table olives and cotton seed where minor data gaps were identified) and for which no risk to consumers is identified. These recommendations will also cover the existing CXLs, when available.
Pears	0.05*	-	0.05*	
Wine grapes	1	1	2	
Table olives	0.05*	-	5(t)	
Olives for oil production	0.05*	-	10	
Cotton seed	2	2	2(t)	
Meat of ruminants, horses, pigs and poultry	0.05*	0.1*	0.05*(t)	Recommendations based on the existing CXLs, but considering the European LOQ. These recommendations will also cover the uses evaluated at European level.
Fat of ruminants, horses, pigs and poultry	0.05*	-	0.05*(t)	
Edible offals of ruminants, horses, pigs and poultry	0.05*	0.2*	0.05*(t)	
Milk	0.05*	0.05*	0.05*(t)	
Eggs	0.05*	0.2*	0.05*(t)	
Other products of plant and/or animal origin	see App C	see App D	-	No MRLs required according to European authorizations and no safe CXLs are identified/reported. Risk managers to decide whether a specific LOQ needs to be established or whether the default MRL of 0.01 mg/kg can apply.

(*): Indicates that the MRL is set at the limit of analytical quantification.
(t): Indicates that the MRL is recommended for inclusion in Annex III of Regulation (EC) N° 396/2005

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on ethephon prepared by the rapporteur Member State The Netherlands. Submitted to EFSA on 02 September 2008. Updated on 05 October 2009 following the Member State consultation.

REFERENCES

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs according to Regulation (EC) No 396/2005 on Maximum Residue Levels of Pesticides in Food and Feed of Plant and Animal Origin. 15 March 2007. http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620776373.htm

EFSA (European Food Safety Authority), 2008a. Conclusion on the peer review of the pesticide risk assessment of the active substance ethephon. *EFSA Scientific Report* (2008) 174, 1-65.

EFSA (European Food Safety Authority), 2008b. Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on MRLs of concern for the active substance ethephon. *EFSA Scientific Report* (2008) 159, 1-31.

European Commission, 1996. Appendix G – Livestock Feeding Studies. 7031/VI/95 rev.4, 22 July 1996.

PSD (Pesticide Safety Directorate), 2009. Final report on the collection of Codex Maximum Residue Limits and related information for active substances to be evaluated under Article 12(2) of Regulation (EC) No 396/2005. EFSA Agreement Number EFSA/PRAPeR/2008/01. 13 February 2009.

The Netherlands, 2004. Draft Assessment Report (DAR) on the active substance ethephon prepared by the rapporteur Member State The Netherlands in the framework of Directive 91/414/EEC, April 2004.

The Netherlands, 2008. Final addendum to the Draft Assessment Report on ethephon, compiled by EFSA, September 2008.

The Netherlands, 2009. Evaluation report on the modification of MRLs for ethephon in pineapple and wine grapes prepared by the evaluating Member State The Netherlands under Article 8 of Regulation (EC) No 396/2005, 03 June 2009.

WHO/FAO, 1995. Pesticide residues in food – 1994. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 127, 1995.

WHO/FAO, 2000. Pesticide residues in food – 1999. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 153, 2000.

WHO/FAO, 2005. Pesticide residues in food – 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 178, 2005.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or waiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Apples	*Malus domesticus*	NEU	Outdoor	FR	fruit thinning and ripening	EW	480.0	g/L	Foliar treatment - spraying	69	81	1	2			0.36	0.36	kg a.i./ha	10	
Pears	*Pyrus communis*	NEU	Outdoor	all	fruit thinning	EW	480.0	g/L	Foliar treatment - spraying	69	69	1	1			0.29	0.29	kg a.i./ha		PHI determined by grwoth stage at application
Cherries	*Prunus cerasus, Prunus avium*	NEU	Outdoor	all	fruit ripening	EW	480.0	g/L	Foliar treatment - spraying	81	81	1	1			0.72	0.72	kg a.i./ha	7	
Table grapes	*Vitis euvitis*	NEU	Outdoor	all	fruit thinning and ripening	EW	480.0	g/L	Foliar treatment - spraying	69	81	1	1			0.45	0.45	kg a.i./ha	28	
Wine grapes	*Vitis euvitis*	NEU	Outdoor	all	fruit thinning and ripening	EW	480.0	g/L	Foliar treatment - spraying	69	81	1	1			0.45	0.45	kg a.i./ha	28	
Barley	*Hordeum spp.*	NEU	Outdoor	FR	inhibition of stem elongation	EW	480.0	g/L	Foliar treatment - spraying	41	45	1	1			0.72	0.72	kg a.i./ha		PHI determined by grwoth stage at application
Rye	*Secale cereale*	NEU	Outdoor	FR	inhibition of stem elongation	EW	480.0	g/L	Foliar treatment - spraying	41	45	1	1			0.72	0.72	kg a.i./ha		PHI determined by grwoth stage at application
Wheat	*Triticum aestivum*	NEU	Outdoor	FR	inhibition of stem elongation	EW	480.0	g/L	Foliar treatment - spraying	41	45	1	1			0.72	0.72	kg a.i./ha		PHI determined by grwoth stage at application

n.a.: not applicable

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or waiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Apples	*Malus domesticus*	SEU	Outdoor	FR	fruit thinning and ripening	EW	480.0	g/L	Foliar treatment - spraying	69	81	1	2			0.36	0.36	kg a.i./ha	10	
Cherries	*Prunus cerasus, Prunus avium*	SEU	Outdoor	all	fruit ripening	EW	480.0	g/L	Foliar treatment - spraying	81	81	1	1			0.36	0.36	kg a.i./ha	10	
Table grapes	*Vitis euvitis*	SEU	Outdoor	all	fruit thinning and ripening	EW	480.0	g/L	Foliar treatment - spraying	69	81	1	1			0.45	0.45	kg a.i./ha	28	
Wine grapes	*Vitis euvitis*	SEU	Outdoor	all	fruit thinning and ripening	EW	480.0	g/L	Foliar treatment - spraying	69	81	1	1			0.45	0.45	kg a.i./ha	28	
Table olives	*Olea europaea*	SEU	Outdoor	all	fruit ripening	EW	480.0	g/L	Foliar treatment - spraying	81	81	1	2			36.00	48.00	g a.i./hL	6	
Tomatoes	*Lycopersicum esculentum*	SEU	Outdoor	all	fruit ripening	EW	480.0	g/L	Foliar treatment - spraying	81	81	1	1			1.68	1.68	kg a.i./ha	7	
Cotton seed	*Gossypium spp.*	SEU	Outdoor	all	fruit ripening	EW	480.0	g/L	Foliar treatment - spraying	81	81	1	1			1.44	1.44	kg a.i./ha	7	
Olives for oil production	*Olea europaea*	SEU	Outdoor	ES	fruit ripening	EW	480.0	g/L	Foliar treatment - spraying	81	81	1	1			36.00	48.00	g a.i./hL	11	
Barley	*Hordeum spp.*	SEU	Outdoor	FR	fruit ripening	EW	480.0	g/L	Foliar treatment - spraying	37	45	1	1			0.72	0.72	kg a.i./ha		PHI determined by grwoth stage at application
Rye	*Secale cereale*	SEU	Outdoor	FR	fruit ripening	EW	480.0	g/L	Foliar treatment - spraying	37	45	1	1			0.72	0.72	kg a.i./ha		PHI determined by grwoth stage at application
Wheat	*Triticum aestivum*	SEU	Outdoor	FR	fruit ripening	EW	480.0	g/L	Foliar treatment - spraying	37	45	1	1			0.72	0.72	kg a.i./ha		PHI determined by grwoth stage at application

n.a.: not applicable

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or waiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Tomatoes	*Lycopersicum esculentum*	NEU/SEU	Indoor	all	fruit ripening	EW	480.0	g/L	Foliar treatment - spraying	81	81	1	1			1.44	1.44	kg a.i./ha	7	

n.a.: not applicable

Critical GAPs for Import Tolerances (non-European indoor, outdoor or post-harvest treatments)																			
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application						Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit	
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.				
Hazelnuts	*Corylus avellana*	non-EU	Outdoor	US	fruit ripening	EW	480.0	g/L	Foliar treatment - spraying	81	81	1	1			3.51	5.85	kg a.i./ha	10	
Walnuts	*Juglans regia*	non-EU	Outdoor	US	fruit ripening	EW	480.0	g/L	Foliar treatment - spraying	81	81	1	1			0.76	1.27	kg a.i./ha	5	
Pineapples	*Ananas comosus*	non-EU	Outdoor	BR	fruit ripening	EW	480.0	g/L	Foliar treatment - spraying	81	81	1	1			0.96	0.96	kg a.i./ha	14	
Barley	*Hordeum spp.*	non-EU	Outdoor	US	inhibition of stem elongation	EW	480.0	g/L	Foliar treatment - spraying	37	39	1	1			0.48	0.48	kg a.i./ha		PHI determined by grwoth stage at application
Rye	*Secale cereale*	non-EU	Outdoor	US	inhibition of stem elongation	EW	480.0	g/L	Foliar treatment - spraying	37	39	1	1			0.48	0.48	kg a.i./ha		PHI determined by grwoth stage at application
Wheat	*Triticum aestivum*	non-EU	Outdoor	US	inhibition of stem elongation	EW	480.0	g/L	Foliar treatment - spraying	37	39	1	1			0.48	0.48	kg a.i./ha		PHI determined by grwoth stage at application

n.a.: not applicable

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Appendix B.1 – PRIMo including all EC MRL proposals resulting from the GAPs reported by the RMS

Appendix B.2 – PRIMo including safe EC MRL proposals resulting from the GAPs reported by the RMS

Appendix B.3 – PRIMo including safe EC MRL proposals and all CXLs

Appendix B.4 – PRIMo including safe EC MRL proposals and safe CXLs

APPENDIX B.1 – PRIMO INCLUDING ALL EC MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

Ethephon			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0.05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.03**	ARfD (mg/kg bw):	**0.05**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
2 13

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	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	pTMRLs at LOQ (in % of ADI)
12.8	DE child	5.6	Apples	2.4	Milk and milk products: Cattle	1.6	Tomatoes	3.4
11.3	WHO Cluster diet B	5.2	Tomatoes	1.9	Wine grapes	1.4	Wheat	2.7
11.3	NL child	4.9	Milk and milk products: Cattle	3.0	Apples	1.1	Tomatoes	6.3
6.5	FR all population	4.1	Wine grapes	0.7	Tomatoes	0.5	Wheat	1.2
6.1	ES child	2.1	Milk and milk products: Cattle	1.7	Tomatoes	0.7	Wheat	3.5
6.1	FR infant	4.3	Milk and milk products: Cattle	1.2	Apples	0.3	Tomatoes	4.6
6.0	PT General population	2.6	Wine grapes	1.5	Tomatoes	0.7	Wheat	0.7
5.0	WHO cluster diet D	1.7	Tomatoes	1.1	Wheat	0.8	Milk and milk products: Cattle	2.2
5.0	WHO cluster diet E	1.7	Wine grapes	0.9	Tomatoes	0.7	Wheat	1.7
4.8	WHO regional European diet	1.9	Tomatoes	0.8	Milk and milk products: Cattle	0.5	Wheat	1.9
4.7	SE general population 90th percentile	2.1	Milk and milk products: Cattle	1.3	Tomatoes	0.5	Wheat	2.7
4.4	IE adult	1.3	Wine grapes	0.7	Tomatoes	0.5	Milk and milk products: Cattle	1.4
4.3	IT kids/toddler	2.4	Tomatoes	1.1	Wheat	0.4	Apples	1.1
4.2	ES adult	1.3	Tomatoes	0.8	Milk and milk products: Cattle	0.4	Wine grapes	1.7
4.2	WHO Cluster diet F	1.2	Tomatoes	0.7	Milk and milk products: Cattle	0.6	Wine grapes	1.9
4.1	NL general	1.1	Milk and milk products: Cattle	0.7	Tomatoes	0.7	Wine grapes	1.8
3.9	DK child	1.1	Apples	0.9	Wheat	0.9	Tomatoes	1.7
3.6	FR toddler	1.3	Tomatoes	1.2	Apples	0.4	Wheat	0.7
3.4	IT adult	2.0	Tomatoes	0.7	Wheat	0.4	Apples	0.7
3.3	LT adult	1.1	Tomatoes	0.9	Apples	0.7	Milk and milk products: Cattle	1.3
3.2	DK adult	1.4	Wine grapes	0.7	Tomatoes	0.4	Apples	0.6
3.0	PL general population	1.5	Tomatoes	1.0	Apples	0.3	Table grapes	0.0
2.8	UK Toddler	1.0	Tomatoes	0.8	Apples	0.7	Wheat	0.7
2.7	UK vegetarian	1.1	Tomatoes	0.8	Wine grapes	0.3	Wheat	0.4
2.4	UK Adult	1.1	Wine grapes	0.7	Tomatoes	0.3	Wheat	0.3
2.0	UK Infant	0.7	Apples	0.6	Tomatoes	0.4	Wheat	0.5
1.6	FI adult	0.7	Tomatoes	0.3	Wine grapes	0.2	Apples	0.3

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Ethephon is unlikely to present a public health concern.

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

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 variabilty factor of 3.

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		**1**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**1**	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		**---**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**---**
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
196.4	Table grapes	1.5 / 0.76	196.4	Table grapes	1.5 / 0.76	95.2	Table grapes	1.5 / -	95.2	Table grapes	1.5 / -
91.9	Tomatoes	0.79 / -	66.6	Tomatoes	0.79 / -	71.2	Wine grapes	1.5 / -	71.2	Wine grapes	1.5 / -
78.4	Apples	0.4 / -	66.0	Cherries	2.7 / -	24.1	Tomatoes	0.79 / -	22.9	Cherries	2.7 / -
66.0	Cherries	2.7 / -	57.8	Apples	0.4 / -	22.9	Cherries	2.7 / -	19.4	Tomatoes	0.79 / -
23.3	Wine grapes	1.5 / -	23.3	Wine grapes	1.5 / -	18.0	Apples	0.4 / -	14.9	Apples	0.4 / -
No of critical MRLs (IESTI 1)		1				**No of critical MRLs (IESTI 2)**		1			

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		**---**				**No of commodities for which ARfD/ADI is exceeded:**		**---**			
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
98.7	Grape juice	1.5 / -				11.6	Wine	1.5 / -			
40.8	Apple juice	0.4 / -				5.3	Apple juice	0.4 / -			
27.5	Tomato juice	0.79 / -				3.0	Tomato (preserved-	0.79 / -			
1.4	Wine	1.5 / -				1.2	Raisins	1.5 / -			
1.4	Wheat flour	0.06 / -				0.5	Bread/pizza	0.06 / -			

*) 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:

For Ethephon IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 1 commodities.

Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.

For processed commodities, no exceedance of the ARfD/ADI was identified.

APPENDIX B.2 – PRIMO INCLUDING SAFE EC MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

Ethephon			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0.05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.03**	ARfD (mg/kg bw):	**0.05**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
2 12

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	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	pTMRLs at LOQ (in % of ADI)
12.1	DE child	5.6	Apples	2.4	Milk and milk products: Cattle	1.6	Tomatoes	3.4
11.1	WHO Cluster diet B	5.2	Tomatoes	1.9	Wine grapes	1.4	Wheat	2.7
10.9	NL child	4.9	Milk and milk products: Cattle	3.0	Apples	1.1	Tomatoes	6.3
6.5	FR all population	4.1	Wine grapes	0.7	Tomatoes	0.5	Wheat	1.2
6.1	ES child	2.1	Milk and milk products: Cattle	1.7	Tomatoes	0.7	Wheat	3.5
6.1	FR infant	4.3	Milk and milk products: Cattle	1.2	Apples	0.3	Tomatoes	4.6
5.8	PT General population	2.6	Wine grapes	1.5	Tomatoes	0.7	Wheat	0.7
4.9	WHO cluster diet D	1.7	Tomatoes	1.1	Wheat	0.8	Milk and milk products: Cattle	2.2
4.9	WHO cluster diet E	1.7	Wine grapes	0.9	Tomatoes	0.7	Wheat	1.7
4.7	SE general population 90th percentile	2.1	Milk and milk products: Cattle	1.3	Tomatoes	0.5	Wheat	2.7
4.7	WHO regional European diet	1.9	Tomatoes	0.8	Milk and milk products: Cattle	0.5	Wheat	1.9
4.3	IT kids/toddler	2.4	Tomatoes	1.1	Wheat	0.4	Apples	1.1
4.2	IE adult	1.3	Wine grapes	0.7	Tomatoes	0.5	Milk and milk products: Cattle	1.4
4.1	ES adult	1.3	Tomatoes	0.8	Milk and milk products: Cattle	0.4	Wine grapes	1.7
4.1	WHO Cluster diet F	1.2	Tomatoes	0.7	Milk and milk products: Cattle	0.6	Wine grapes	1.9
4.0	NL general	1.1	Milk and milk products: Cattle	0.7	Tomatoes	0.7	Wine grapes	1.8
3.8	DK child	1.1	Apples	0.9	Wheat	0.9	Tomatoes	1.7
3.5	FR toddler	1.3	Tomatoes	1.2	Apples	0.4	Wheat	0.7
3.3	IT adult	2.0	Tomatoes	0.7	Wheat	0.4	Apples	0.7
3.3	LT adult	1.1	Tomatoes	0.9	Apples	0.7	Milk and milk products: Cattle	1.3
3.1	DK adult	1.4	Wine grapes	0.7	Tomatoes	0.4	Apples	0.6
2.8	PL general population	1.5	Tomatoes	1.0	Apples	0.2	Cherries	0.0
2.7	UK Toddler	1.0	Tomatoes	0.8	Apples	0.7	Wheat	0.7
2.6	UK vegetarian	1.1	Tomatoes	0.8	Wine grapes	0.3	Wheat	0.4
2.4	UK Adult	1.1	Wine grapes	0.7	Tomatoes	0.3	Wheat	0.3
2.0	UK Infant	0.7	Apples	0.6	Tomatoes	0.4	Wheat	0.5
1.6	FI adult	0.7	Tomatoes	0.3	Wine grapes	0.2	Apples	0.3

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Ethephon is unlikely to present a public health concern.

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

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 variabilty factor of 3.

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
91.9	Tomatoes	0.79 / -	66.6	Tomatoes	0.79 / -	71.2	Wine grapes	1.5 / -	71.2	Wine grapes	1.5 / -
78.4	Apples	0.4 / -	66.0	Cherries	2.7 / -	29.2	Table grapes	0.46 / -	29.2	Table grapes	0.46 / -
66.0	Cherries	2.7 / -	60.2	Table grapes	0.46 / -	24.1	Tomatoes	0.79 / -	22.9	Cherries	2.7 / -
60.2	Table grapes	0.46 / -	57.8	Apples	0.4 / -	22.9	Cherries	2.7 / -	19.4	Tomatoes	0.79 / -
23.3	Wine grapes	1.5 / -	23.3	Wine grapes	1.5 / -	18.0	Apples	0.4 / -	14.9	Apples	0.4 / -
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---		
		*****)**				*****)**
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
98.7	Grape juice	1.5 / -		11.6	Wine	1.5 / -
40.8	Apple juice	0.4 / -		5.3	Apple juice	0.4 / -
27.5	Tomato juice	0.79 / -		3.0	Tomato (preserved-	0.79 / -
1.4	Wine	1.5 / -		1.2	Raisins	1.5 / -
1.4	Wheat flour	0.06 / -		0.5	Bread/pizza	0.06 / -

*) 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:

For Ethephon IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

APPENDIX B.3 – PRIMO INCLUDING SAFE EC MRL PROPOSALS AND ALL CXLS

Ethephon			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0.05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.03**	ARfD (mg/kg bw):	**0.05**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
4	52
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	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	pTMRLs at LOQ (in % of ADI)
52.2	DE child	38.0	Apples	4.1	Wheat	3.0	Cherries	2.9
33.3	NL child	19.9	Apples	4.9	Milk and milk products: Cattle	4.7	Wheat	5.7
23.1	WHO Cluster diet B	8.5	Wheat	4.2	Tomatoes	3.2	Apples	1.6
16.9	DK child	7.3	Apples	5.5	Wheat	1.9	Rye	0.2
14.0	ES child	4.4	Wheat	3.6	Apples	2.1	Milk and milk products: Cattle	3.1
13.7	FR infant	7.9	Apples	4.3	Milk and milk products: Cattle	0.8	Wheat	4.6
13.4	WHO cluster diet D	6.5	Wheat	2.1	Apples	1.4	Tomatoes	1.2
13.2	PT General population	3.9	Wheat	3.3	Apples	2.6	Wine grapes	0.1
12.9	FR toddler	8.3	Apples	2.6	Wheat	1.0	Tomatoes	0.6
12.7	IT kids/toddler	6.6	Wheat	2.8	Apples	1.9	Tomatoes	0.0
11.7	WHO cluster diet E	3.9	Wheat	2.7	Apples	1.7	Wine grapes	1.3
11.1	SE general population 90th percentile	3.3	Apples	3.2	Wheat	2.1	Milk and milk products: Cattle	2.2
11.0	FR all population	4.1	Wine grapes	3.3	Wheat	1.5	Apples	0.8
10.7	UK Toddler	5.4	Apples	3.9	Wheat	0.8	Tomatoes	0.2
10.3	WHO regional European diet	3.0	Wheat	2.1	Apples	1.5	Tomatoes	1.7
10.1	IE adult	2.6	Apples	2.3	Wheat	1.3	Wine grapes	1.1
9.6	WHO Cluster diet F	3.6	Wheat	2.1	Apples	0.9	Tomatoes	1.3
9.6	LT adult	5.9	Apples	1.1	Wheat	0.8	Tomatoes	1.0
9.5	NL general	3.7	Apples	2.1	Wheat	1.1	Milk and milk products: Cattle	1.6
9.4	IT adult	4.1	Wheat	2.5	Apples	1.6	Tomatoes	0.0
9.2	ES adult	2.4	Apples	2.3	Wheat	1.1	Tomatoes	1.5
9.0	PL general population	6.4	Apples	1.2	Tomatoes	0.7	Cherries	0.0
9.0	UK Infant	4.9	Apples	2.6	Wheat	0.6	Cherries	0.3
7.5	DK adult	2.5	Apples	2.0	Wheat	1.4	Wine grapes	0.2
6.2	UK vegetarian	2.0	Wheat	1.9	Apples	0.8	Wine grapes	0.1
5.1	UK Adult	1.7	Wheat	1.3	Apples	1.1	Wine grapes	0.1
4.3	FI adult	1.3	Apples	1.0	Wheat	0.6	Tomatoes	0.0

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Ethephon is unlikely to present a public health concern.

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

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 variabilty factor of 3.

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): 6			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** 6			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** 2			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** 1		
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	****)**
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
742.6	Apples	3.79 / 0.51	547.4	Apples	3.79 / 0.69	170.1	Apples	3.79 / 2.22	141.6	Apples	3.79 / 2.67
302.3	Peppers	2.4 / 0.79	215.9	Peppers	2.4 / 1.11	108.9	Figs	2.73 / 2.5	99.8	Figs	2.73 / -
197.7	Tomatoes	1.7 / 0.85	191.1	Melons	0.63 / 0.32	78.4	Peppers	2.4 / -	71.2	Wine grapes	1.5 / -
191.1	Melons	0.63 / 0.32	160.7	Cherries	6.57 / 4.08	71.2	Wine grapes	1.5 / -	69.8	Blueberries	11 / -
160.7	Cherries	6.57 / 4.08	143.3	Tomatoes	1.7 / 1.18	69.8	Blueberries	11 / -	56.0	Peppers	2.4 / -
107.4	Table grapes	0.82 / 0.76	107.4	Table grapes	0.82 / 0.76						
No of critical MRLs (IESTI 1) 7						**No of critical MRLs (IESTI 2)** 6					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: 1						**No of commodities for which ARfD/ADI is exceeded:** ---					
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
386.2	Apple juice	3.79 / 0.98				49.8	Apple juice	3.79 / -			
98.7	Grape juice	1.5 / -				11.6	Wine	1.5 / -			
76.9	Blueberries	5.3 / -				6.5	Tomato (preserved-	1.7 / -			
59.3	Tomato juice	1.7 / -				6.0	Bread/pizza	0.68 / -			
16.1	Wheat flour	0.68 / -				1.3	Pineapples preserved	0.243 / -			

*) 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:

For Ethephon IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 7 commodities.

Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 6 commodities.

For processed commodities, the ARfD/ADI was exceeded in one or several cases.

APPENDIX B.4 – PRIMO INCLUDING SAFE EC MRL PROPOSALS AND SAFE CXLS

Ethephon			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0.05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.03**	ARfD (mg/kg bw):	**0.05**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
3 19

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	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	pTMRLs at LOQ (in % of ADI)
18.5	WHO Cluster diet B	8.5	Wheat	5.2	Tomatoes	1.9	Wine grapes	1.6
16.2	DE child	5.6	Apples	4.1	Wheat	2.4	Milk and milk products: Cattle	2.9
15.3	NL child	4.9	Milk and milk products: Cattle	4.7	Wheat	3.0	Apples	5.7
10.7	WHO cluster diet D	6.5	Wheat	1.7	Tomatoes	0.8	Milk and milk products: Cattle	1.2
10.2	ES child	4.4	Wheat	2.1	Milk and milk products: Cattle	1.7	Tomatoes	3.1
9.8	IT kids/toddler	6.6	Wheat	2.4	Tomatoes	0.4	Apples	0.0
9.7	DK child	5.5	Wheat	1.9	Rye	1.1	Apples	0.2
9.4	FR all population	4.1	Wine grapes	3.3	Wheat	0.7	Tomatoes	0.8
9.1	PT General population	3.9	Wheat	2.6	Wine grapes	1.5	Tomatoes	0.1
8.7	WHO cluster diet E	3.9	Wheat	1.7	Wine grapes	0.9	Tomatoes	1.3
7.8	SE general population 90th percentile	3.2	Wheat	2.1	Milk and milk products: Cattle	1.3	Tomatoes	2.2
7.7	WHO Cluster diet F	3.6	Wheat	1.2	Tomatoes	0.7	Milk and milk products: Cattle	1.3
7.6	WHO regional European diet	3.0	Wheat	1.9	Tomatoes	0.8	Milk and milk products: Cattle	1.7
7.0	FR infant	4.3	Milk and milk products: Cattle	1.2	Apples	0.8	Wheat	4.6
6.8	IT adult	4.1	Wheat	2.0	Tomatoes	0.4	Apples	0.0
6.3	IE adult	2.3	Wheat	1.3	Wine grapes	0.7	Tomatoes	1.1
6.3	ES adult	2.3	Wheat	1.3	Tomatoes	0.8	Milk and milk products: Cattle	1.5
6.1	UK Toddler	3.9	Wheat	1.0	Tomatoes	0.8	Apples	0.2
6.0	FR toddler	2.6	Wheat	1.3	Tomatoes	1.2	Apples	0.6
5.9	NL general	2.1	Wheat	1.1	Milk and milk products: Cattle	0.7	Tomatoes	1.6
5.0	DK adult	2.0	Wheat	1.4	Wine grapes	0.7	Tomatoes	0.2
4.5	LT adult	1.1	Tomatoes	1.1	Wheat	0.9	Apples	1.0
4.4	UK Infant	2.6	Wheat	0.7	Apples	0.6	Tomatoes	0.3
4.4	UK vegetarian	2.0	Wheat	1.1	Tomatoes	0.8	Wine grapes	0.1
3.8	UK Adult	1.7	Wheat	1.1	Wine grapes	0.7	Tomatoes	0.1
3.1	FI adult	1.0	Wheat	0.7	Tomatoes	0.5	Blueberries	0.0
2.9	PL general population	1.5	Tomatoes	1.0	Apples	0.2	Cherries	0.0

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Ethephon is unlikely to present a public health concern.

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

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 variabilty factor of 3.

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
91.9	Tomatoes	0.79 / -	68.1	Blueberries	11 / -	71.2	Wine grapes	1.5 / -	71.2	Wine grapes	1.5 / -
78.4	Apples	0.4 / -	66.6	Tomatoes	0.79 / -	69.8	Blueberries	11 / -	69.8	Blueberries	11 / -
68.1	Blueberries	11 / -	66.0	Cherries	2.7 / -	29.2	Table grapes	0.46 / -	29.2	Table grapes	0.46 / -
66.0	Cherries	2.7 / -	60.2	Table grapes	0.46 / -	24.1	Tomatoes	0.79 / -	22.9	Cherries	2.7 / -
60.2	Table grapes	0.46 / -	57.8	Apples	0.4 / -	22.9	Cherries	2.7 / -	19.4	Tomatoes	0.79 / -
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---		
		*****)**				*****)**
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
98.7	Grape juice	1.5 / -		11.6	Wine	1.5 / -
76.9	Blueberries	5.3 / -		6.0	Bread/pizza	0.68 / -
40.8	Apple juice	0.4 / -		5.3	Apple juice	0.4 / -
27.5	Tomato juice	0.79 / -		3.0	Tomato (preserved-	0.79 / -
16.1	Wheat flour	0.68 / -		1.3	Pineapples preserved	0.243 / -

*) 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:

For Ethephon IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

APPENDIX C – EXISTING EC MRLS

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethephon
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*
110030	Lemons (Citron, lemon)	0,05*
110040	Limes	0,05*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,05*
110990	Others	0,05*
120000	(ii) Tree nuts (shelled or unshelled)	0,1
120010	Almonds	0,1
120020	Brazil nuts	0,1
120030	Cashew nuts	0,1
120040	Chestnuts	0,1
120050	Coconuts	0,1
120060	Hazelnuts (Filbert)	0,1
120070	Macadamia	0,1
120080	Pecans	0,1
120090	Pine nuts	0,1
120100	Pistachios	0,1
120110	Walnuts	0,1
120990	Others	0,1
130000	(iii) Pome fruit	
130010	Apples (Crab apple)	0,5
130020	Pears (Oriental pear)	0,05*
130030	Quinces	0,05*
130040	Medlar	0,05*
130050	Loquat	0,05*
130990	Others	0,05*
140000	(iv) Stone fruit	
140010	Apricots	0,05*
140020	Cherries (sweet cherries, sour cherries)	3
140030	Peaches (Nectarines and similar hybrids)	0,05*
140040	Plums (Damson, greengage, mirabelle)	0,05*
140990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethephon
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	
151010	Table grapes	1 (0,05*)[a]
151020	Wine grapes	1
152000	(b) Strawberries	0,05*
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,05*
153030	Raspberries (Wineberries)	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,05*
154020	Cranberries	0,05*
154030	Currants (red, black and white)	5 (0,05*)[a]
154040	Gooseberries (Including hybrids with other ribes species)	0,05*
154050	Rose hips	0,05*
154060	Mulberries (arbutus berry)	0,05*
154070	Azarole (mediteranean medlar)	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethephon
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,05*
163070	Guava	0,05*
163080	Pineapples	2 (0,5)[a]
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,05*
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethephon
213010	Beetroot	0,05*
213020	Carrots	0,05*
213030	Celeriac	0,05*
213040	Horseradish	0,05*
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,05*
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,05*
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	0,05*
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	1
231020	Peppers (Chilli peppers)	3 (0,05*)[a]
231030	Aubergines (egg plants) (Pepino)	0,05*
231040	Okra, lady's fingers	0,05*
231990	Others	0,05*
232000	(b) Cucurbits - edible peel	0,05*
232010	Cucumbers	0,05*
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson))	0,05*
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano)	0,05*
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethephon
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	0,05*
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*
251010	Lamb´s lettuce (Italian cornsalad)	0,05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,05*
251040	Cress	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,05*
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory,)	0,05*
256060	Rosemary	0,05*
256070	Thyme (marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	0,05*
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	0,1*
401020	Peanuts	0,1*
401030	Poppy seed	0,1*
401040	Sesame seed	0,1*
401050	Sunflower seed	0,1*
401060	Rape seed (Bird rapeseed, turnip rape)	0,1*
401070	Soya bean	0,1*
401080	Mustard seed	0,1*
401090	Cotton seed	2
401100	Pumpkin seeds	0,1*
401110	Safflower	0,1*
401120	Borage	0,1*
401130	Gold of pleasure	0,1*
401140	Hempseed	0,1*
401150	Castor bean	0,1*
401990	Others	0,1*
402000	(ii) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	
500010	Barley	0,5
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*
500070	Rye	0,5
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	0,2
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,1*
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethephon
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Aril	0,1*
870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	0,05*
900010	Sugar beet (root)	0,05*
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*

(*) Indicates lower limit of analytical determination

([a]) Value voted by the Standing Committee on the Food Chain and Animal Health in June 2009 but not yet legally implemented.

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethephon
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethephon
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethephon
1017050	Edible offal	0,05*
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

APPENDIX D – EXISTING CXLS

Summary of CXLs for ethephon in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
120060	Hazelnuts	Ethephon	0.2	Ethephon	n.k.	n.c.	1	n.c.	0.05	0.1	n.a.	1	1994	No	Based on USA trials according to appropriate GAP.
120110	Walnuts	Ethephon	0.5	Ethephon	n.k.	n.c.	1	n.c.	0.04	0.27	n.a.	1	1994	No	Based on USA trials according to appropriate GAP.
130010	Apples	Ethephon	5	Ethephon	n.k.	n.c.	1	n.c.	0.945	3.79	n.a.	1	1994	No	Based on EU and USA trials according to appropriate GAP.
140020	Cherries	Ethephon	10	Ethephon	n.k.	n.c.	1	n.c.	2.5	6.57	n.a.	1	1994	No	Based on USA trials data. HR of 7.58 excluded due to higher application rate.
151010	Table grapes	Ethephon	1	Ethephon	0.31	0.82	7	n.c.	0.31	0.82	n.a.	1	1999	No	Based on trials conducted in France and the USA.
151020	Wine grapes	Ethephon	1	Ethephon	0.31	0.82	7	n.c.	0.31	0.82	n.a.	1	1999	No	
154010	Blueberries	Ethephon	20	Ethephon	n.k.	n.c.	1	n.c.	5.3	11	n.a.	1	1994	No	All trials conducted in the USA. 14+ day PHI values considered relevant to GAP.
161020	Figs	Ethephon	10	Ethephon	n.k.	n.c.	1	n.c.	0.9	2.73	n.a.	1	1994	No	All trials conducted in Canada. 21-41 day PHI considered relevant to GAP (STMR based on the highest residue for each trial with PHIs within this range). Residue values and CXL refer to the dry fruit.
163080	Pineapples	Ethephon	2	Ethephon	0.13	0.97	5	n.c.	0.13	0.97	1	1	1999	No	All trials were conducted outside the EU according to non-EU GAP. Residues relate to the whole fruit. Where pulp was analysed residues were all <0.1 mg/kg and a MPF of 1 was estimated from 3 trials
231010	Tomatoes	Ethephon	2	Ethephon	0.41	1.7	7	n.c.	0.405	1.7	n.a.	1	1999	No	All trials conducted in the USA according to GAP.
231020	Peppers	Ethephon	5	Ethephon	n.k.	n.c.	1	n.c.	0.98	2.4	n.a.	1	1999	No	All trials conducted in the USA according to GAP.
233010	Melons	Ethephon	1	Ethephon	0.24	0.63	5	n.c.	0.24	0.63	n.k.	1	1999	No	All trials conducted in the USA according to GAP. All cantaloupe samples used to set specific CXL. Peel/pulp distribution was not considered.
401090	Cotton seed	Ethephon	2	Ethephon	n.k.	n.c.	1	n.c.	0.215	2.13	n.k.	1	1994	No	All trials conducted in the USA according to GAP.
500010	Barley grain	Ethephon	1	Ethephon	n.k.	n.c.	1	n.c.	0.05	0.5	n.k.	1	1994	No	CXL based on data from many countries including some non-EU according to GAP. The exact STMR could not be calculated as ranges were given for some results but will be below 0.05 as this is where the majority of results fell.
500070	Rye grain	Ethephon	1	Ethephon	n.k.	n.c.	1	n.c.	0.13	0.24	n.k.	1	1994	Yes	All trials compliant with the GAP were from EU countries.
500090	Wheat grain	Ethephon	1	Ethephon	n.k.	n.c.	1	n.c.	0.3	0.68	n.k.	1	1994	No	All trials relevant to the GAP were conducted in the USA.

(*) Indicates the lower limit of analytical quantification.

n.a.: not applicable

n.c.: not considered

n.k.: not known

Summary of CXLs for ethephon in livestock commodities										
Commodity code	Commodity name	Values adopted by the CCPR			Critical values of the JMPR evaluation			Comment on the JMPR evaluation		
		Residue definition	Expressed as fat?	CXL (mg/kg)	Residue definition	STMR (mg/kg)	HR (mg/kg)	Year	Based on EU GAP only?	Other comments
1011010	Swine meat	Ethephon	no	0.1 *	Ethephon	n.c.	n.c.	1994	no	Ethephon in cattle and goat feed is unlikely to exceed 2 mg/kg and account for less in poultry feed. As such animal tissues, milk and eggs are not expecetd to contain residues >LOQ.
1011030	Swine liver	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1011040	Swine kidney	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1011050	Swine edible offal	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1012010	Bovine meat	Ethephon	no	0.1 *	Ethephon	n.c.	n.c.	1994	no	Ethephon in cattle and goat feed is unlikely to exceed 2 mg/kg and account for less in poultry feed. As such animal tissues, milk and eggs are not expecetd to contain residues >LOQ
1012030	Bovine liver	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1012040	Bovine kidney	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1012050	Bovine edible offal	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1013010	Sheep meat	Ethephon	no	0.1 *	Ethephon	n.c.	n.c.	1994	no	Ethephon in cattle and goat feed is unlikely to exceed 2 mg/kg and account for less in poultry feed. As such animal tissues, milk and eggs are not expecetd to contain residues >LOQ
1013030	Sheep liver	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1013040	Sheep kidney	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1013050	Sheep edible offal	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1014010	Goat meat	Ethephon	no	0.1 *	Ethephon	n.c.	n.c.	1994	no	Ethephon in cattle and goat feed is unlikely to exceed 2 mg/kg and account for less in poultry feed. As such animal tissues, milk and eggs are not expecetd to contain residues >LOQ
1014030	Goat liver	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1014040	Goat kidney	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1014050	Goat edible offal	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1015010	Horses, asses, mules or hinnies meat	Ethephon	no	0.1 *	Ethephon	n.c.	n.c.	1994	no	Ethephon in cattle and goat feed is unlikely to exceed 2 mg/kg and account for less in poultry feed. As such animal tissues, milk and eggs are not expecetd to contain residues >LOQ
1015030	Horses, asses, mules or hinnies liver	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1015040	Horses, asses, mules or hinnies kidney	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1015050	Horses, asses, mules or hinnies edible offal	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1016010	Poultry meat	Ethephon	no	0.1 *	Ethephon	n.c.	n.c.	1994	no	Ethephon in cattle and goat feed is unlikely to exceed 2 mg/kg and account for less in poultry feed. As such animal tissues, milk and eggs are not expecetd to contain residues >LOQ
1016030	Poultry liver	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1016040	Poultry kidney	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1016050	Poultry edible offal	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	
1020010	Cattle milk	Ethephon	no	0.05 *	Ethephon	n.c.	n.c.	1994	no	Ethephon in cattle and goat feed is unlikely to exceed 2 mg/kg and account for less in poultry feed. As such animal tissues, milk and eggs are not expecetd to contain residues >LOQ
1020020	Sheep milk	Ethephon	no	0.05 *	Ethephon	n.c.	n.c.	1994	no	
1020030	Goat milk	Ethephon	no	0.05 *	Ethephon	n.c.	n.c.	1994	no	
1020040	Horse milk	Ethephon	no	0.05 *	Ethephon	n.c.	n.c.	1994	no	
1030000	Birds' eggs	Ethephon	n.a.	0.2 *	Ethephon	n.c.	n.c.	1994	no	Ethephon in cattle and goat feed is unlikely to exceed 2 mg/kg and account for less in poultry feed. As such animal tissues, milk and eggs are not expecetd to contain residues >LOQ

(*) Indicates the lower limit of analytical quantification.

n.a.: not applicable

n.c.: not considered

ABBREVIATIONS

a.s.	active substance
AChE	acetylcholine esterase
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
EC	European Community
EFSA	European Food Safety Authority
EU	European Union
EW	emulsion, oil in water
GAP	good agricultural practice
GC-FPD	gas chromatography with flame-photometric detection
GC-MS/MS	gas chromatography with tandem mass spectrometry
ha	hectare
hL	hectolitre
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MoS	margin of safety
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor

PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
PROFile	Pesticide Residues Overview File
PSD	Pesticide Safety Directorate, United Kingdom
RMS	rapporteur Member State
SEU	Southern European Union
STMR	supervised trials median residue
TRR	total radioactive residue