REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for thiophanate-methyl and carbendazim in apples and pears[1]

European Food Safety Authority[2]

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SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, Sweden, hereafter referred to as the evaluating Member State (EMS), received an application from the company Nisso Chemical Europe GmbH to modify the existing MRLs for the active substances thiophanate-methyl and carbendazim in apples and pears. In order to accommodate for the intended use of thiophanate-methyl on apples and pears in Sweden, the EMS proposes to raise the existing MRLs both for thiophanate-methyl and carbendazim. The EMS Sweden drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 11 July 2011.

EFSA derives the following conclusions based on the submitted evaluation report prepared by Sweden, the Draft Assessment Report (DAR) prepared by the rapporteur Member State Germany under Directive 91/414/EEC, the EC review report on thiophanate-methyl and the previously issued EFSA reasoned opinion on the MRLs of concern for the active substances carbendazim and thiophanate-methyl.

The toxicological profiles of thiophanate-methyl and carbendazim were assessed in the framework of the peer review under Directive 91/414/EEC. For thiophanate-methyl the peer review proposed an ADI of 0.08 mg/kg bw/day and an ARfD of 0.2 mg/kg bw. For carbendazim an ADI value of 0.02 mg/kg bw/day and an ARfD of 0.02 mg/kg bw has been derived.

The metabolism of thiophanate-methyl in primary crops was investigated in fruits, root vegetables, cereals and pulses. From these studies the peer review concluded to establish the residue definition for risk assessment as the "sum of thiophanate-methyl and carbendazim, expressed as carbendazim". The enforcement residue definition is established as parent thiophanate-methyl according to Regulation (EC) No 396/2005. For the use on the crops under consideration EFSA concludes that the metabolism of thiophanate-methyl is addressed and that the residue definitions derived by the peer review are applicable.

The proposed extrapolation of residue data from apples to pears is sufficiently supported by data. EFSA concludes that a MRL of 0.8 mg/kg for thiophanate-methyl and a MRL of 0.3 mg/kg for

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carbendazim would be required to support the intended use of thiophanate-methyl on apples and pears in Sweden. Analytical methods are available to control the compliance of carbendazim residues in the commodities under consideration at a validated LOQ of 0.01 mg/kg. An analytical enforcement method for the determination of thiophanate-methyl residues in apples and pears is available, but a validation of the method in an independent laboratory (ILV) is lacking.

The effects of processing on the nature of thiophanate-methyl have not been investigated and therefore adequate studies to address this data gap have to be provided. There is some evidence that degradation to carbendazim might occur but the possible formation of other degradation products needs to be further explored. According to the peer review, carbendazim is stable under standard hydrolysis studies simulating pasteurisation, baking or sterilisation. The effect of processing on the magnitude of thiophanate-methyl and carbendazim residues in apples was investigated in two studies submitted in the framework of the current application. Apples were processed into juice, puree and canned apple. Residues of thiophanate-methyl and carbendazim were determined in final processed products as well as in various intermediate products. Study results indicate a reduction of thiophanate-methyl residues in all processed products. A concentration of carbendazim residues is observed in wet and dry apple pomace. No study details have been provided as well as the number of studies is insufficient to propose the derived processing factors for enforcement purposes.

Since the proposed use of thiophanate-methyl is on permanent crops the investigation of residues in rotational crops/succeeding crops is not required.

Apple pomace can be fed to cattle and therefore the nature and magnitude of thiophanate-methyl and carbendazim residues in livestock and potential carry-over of residues in commodities of animal origin was investigated. The livestock dietary burden was calculated considering the livestock intake of thiophanate-methyl and carbendazim residues from the apple pomace as well as from all other potential feed crops for which the existing EU MRLs for thiophanate-methyl and carbendazim are set above the LOQ. The calculated dietary burden is exceeded for all livestock species, but the livestock intake is driven mainly by the existing uses of thiophanate-methyl and carbendazim and the contribution of the apple pomace to the total livestock exposure is low. Therefore the modification of the MRLs for commodities of animal origin was not further investigated in the framework of the current application.

Consumer intake calculation was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). Since both active substances share a common mechanism of toxicity, a combined consumer exposure assessment was performed considering the available residue data for carbendazim and thiophanate-methyl as well as the respective toxicological potencies of the active substances (calculation of the toxicologically adjusted sum of carbendazim and thiophanate-methyl). To calculate the chronic exposure for the crops under consideration, EFSA used the median residue value as derived from the residue trials on apples. The same input value was used for pears. For other commodities of plant and animal origin the toxicologically adjusted sum of the existing EU MRLs for thiophanate-methyl and carbendazim as established in Regulation (EC) No 396/2005 were used as input values in the chronic exposure calculation. For citrus fruit the risk assessment values from the previously issued EFSA reasoned opinion were available to refine the consumer exposure calculation.

The acute exposure assessment was performed only with regard to apples and pears, assuming the consumption of a large portion of the food item as reported in the national food surveys containing residues at the highest level as observed in supervised field trials. The estimated exposure was then compared with the toxicological reference values derived for carbendazim.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values ranged from 10- 49 % of the ADI (maximum for IE adult diet). The contribution of residues to the total consumer exposure (% of the ADI) accounted for a maximum of 9% for apples (DE child diet) and 0.5% of the ADI (DK child diet).

Using the internationally agreed standard methodology, based on the highest residue observed in residue trials, no acute consumer risk was identified. The calculated maximum exposure in percentage of the ARfD was 98% for apples and 91% for pears. Taking into account the uncertainties regarding the input values for the consumer risk assessment (see section 3.1.1.2) the result of the exposure assessment might underestimate the actual consumer exposure.

EFSA notes that in case apples and pears contain carbendazim residues at the proposed MRL of 0.3 mg/kg (not considering an additional contribution of thiophanate residues), the narrow margin of safety to the acute reference dose (for carbendazim) is not sufficient to exclude the consumer health risk in all cases (i.e. high consumption of unpeeled fruit and high variability (VF of 7) within a batch). Taking into account that the consumer group for which the highest exposure is estimated are infants, it is most likely that the fruits are consumed after peeling. However, since detailed consumption figures reporting separately the consumption of unpeeled, peeled and processed apples and pears and an accurate peeling factor are not available to EFSA, the estimation of the actual exposure for this sub-group of the population could not be further refined.

EFSA concludes that the intended use of thiophanate-methyl does not lead to a chronic consumer intake risk, but a potential acute exposure cannot be excluded for apples and pears containing residues of thiophanate-methyl and carbendazim at the level of the MRLs that would be required for the intended use.

The recommendations of EFSA are compiled in the table below:

Code number[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Thiophanate-methyl				The MRL proposals are supported by residue data and no chronic consumer intake concerns were identified for the proposed use. Acute consumer exposure concerns cannot be excluded if apples and pears contain residues at the level of the MRL which would be required to support the intended use of thiophanate-methyl in Sweden. A study on effects of processing on the nature of thiophanate-methyl residues has to be submitted.
0130010	Apples	0.5	No new proposal	
0130020	Pears	0.5	No new proposal	
Enforcement residue definition: Carbendazim				
0130010	Apples	0.2	No new proposal	
0130020	Pears	0.2	No new proposal	

[a] according to Annex I of Regulation (EC) No 396/2005

KEY WORDS

Thiophanate-methyl, carbendazim, apples, pears, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, benzimidazole fungicides

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BACKGROUND

Regulation (EC) No 396/2005[3] establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC[4], repealed by Regulation (EC) No 1107/2009[5], shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

Sweden, hereafter referred to as the evaluating Member State (EMS), received an application from the company Nisso Chemical Europe GmbH[6] to modify the existing MRLs for the active substances thiophanate-methyl and carbendazim in apples and pears, as a result of the intended use of thiophanate-methyl. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the applications, the evaluation report and the supporting dossier to EFSA on 11 July 2011. The application on thiophanate-methyl was included in the EFSA Register of Questions with two different reference numbers EFSA-Q-2011-00892 (for thiophanate-methyl) and EFSA-Q-2011-00893 (for carbendazim) with the following subjects:

Thiophanate-methyl - Application to modify the existing MRLs in apples and pears.

Carbendazim - Application to modify the existing MRLs in apples and pears.

The EMS proposed the MRL of 0.6 or 0.8 mg/kg for thiophanate-methyl and an MRL of 0.3 or 0.4 mg/kg for carbendazim in apples and pears, respectively.

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

TERMS OF REFERENCE

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

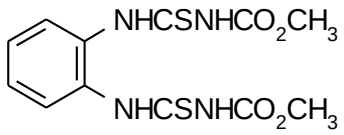
In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 11 October 2011.

[3] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005. OJ L 70, 16.3.2005, p. 1-16.
[4] Council Directive 91/414/EEC of 15 July 1991, OJ L 230, 19.8.1991, p. 1-32.
[5] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009. OJ L 309, 24.11.2009, p. 1-50.
[6] Nisso Chemical Europe GmbH, Berliner Allee 42, 40212, Düsseldorf, Germany

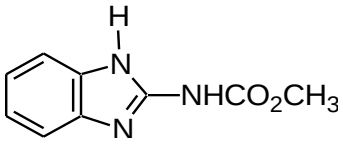
THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Thiophanate-methyl is the ISO common name for dimethyl 4,4'-(o-phenylene)bis(3-thioallophanate) (IUPAC).



Molecular weight: 342.4 g/mol

Carbendazim is the ISO common name for methyl benzimidazol-2-ylcarbamate (IUPAC).



Molecular weight: 191.21 g/mol

Both active substances belong to the class of benzimidazole fungicides. They are systemic compounds with protective and curative action against a wide range of diseases in cereals, fruits and vegetables. As thiophanate-methyl is a precursor of carbendazim, both substances share a similar mode of action. In particular, carbendazim acts on the beta-tubulin synthesis, inhibiting the development of the germ tubes, the formation of appressoria, and the growth of mycelia.

Thiophanate-methyl has been assessed in the first stage of the peer review process under Directive 91/414/EEC with Germany being the designated rapporteur Member State (RMS). At that time EFSA was not involved in the peer review and therefore no EFSA conclusion is available. Thiophanate-methyl was included in Annex I to Directive 91/414/EEC by means of Directive 2005/53/EC[7], which entered into force on 1 March 2006. The approval of thiophanate-methyl is valid until 28 February 2016.

Carbendazim was also assessed in the first stage of the peer review process under Directive 91/414/EEC with Germany being the designated RMS. Carbendazim was included in Annex I to Directive 91/414/EEC by Directive 2006/135/EC[8] for a limited period until 31 December 2010. The manufacturer resubmitted a dossier with a view to review the Annex I inclusion. Consequently the expiry date for the Annex I inclusion of carbendazim was prolonged until 13 June 2011 by Commission Directive 2010/70/EU[9]. EFSA was involved in the Annex I renewal peer review of carbendazim and thus an EFSA conclusion is available (EFSA, 2010). According to Implementing Regulation (EU) No 542/2011[10] carbendazim is approved and the period of approval expires on 30 November 2014. The approval is restricted for use as fungicide only on cereals, rape seed, sugar and fodder beet and maize.

The existing EU MRLs are set separately for thiophanate-methyl and carbendazim in Annexes II and IIIB of Regulation (EC) No 396/2005 (see Appendix C). The existing EU MRL for thiophanate-methyl in apples and pears is set at 0.5 mg/kg. The existing EU MRL of 0.2 mg/kg for carbendazim in apples and pears results from the use of thiophanate-methyl since the use of carbendazim on pome

[7] Commission Directive 2005/53/EC of 16 September 2005, OJ L 241, 17.9.2005, 51-56 pp.
[8] Commission Directive 2006/135/EC of 11 December 2006, OJ L 349, 12.12.2006, 37-41 pp.
[9] Commission Directive 2010/70/EU of 28 October 2010, OJ L 283, 29.10.2010, 27 pp.
[10] Commission Implementing Regulation (EU) No 542/2011, OJ L 153, 11.6.2011, 189-191 pp.

fruit is not allowed at EU level. The Codex Alimentarius Commission has established a CXL of 3 mg/kg for pome fruit based on a more critical use of benomyl and the CXL refers to the sum of residues of benomyl, carbendazim and thiophanate-methyl, expressed as carbendazim.

The intended GAP in Sweden for which a modification of the existing MRLs for thiophanate-methyl and carbendazim is requested refers to an outdoor foliar treatment of apple and pear trees with thiophanate-methyl 14 days before harvest. The details of the GAP are given in Appendix A.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Sweden, 2011), the Draft Assessment Reports (DAR) on thiophanate-methyl and carbendazim (Germany, 1997, 2009) and addenda prepared under Council Directive 91/414/EEC (Germany, 2000, 2003), the Commission review report on thiophanate-methyl (EC, 2005), the EFSA conclusion on the peer review of carbendazim (EFSA, 2010) as well as the conclusions from a previous EFSA reasoned opinion on the MRLs of concern for thiophanate-methyl and carbendazim (EFSA, 2009). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products set out in Regulation (EU) No 546/2011[11] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2004, 2008, 2010, 2011; OECD, 2011a, 2011b).

1. Methods of analysis

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

Analytical methods for the determination of thiophanate-methyl and carbendazim residues in plant commodities were assessed in the framework of the peer review (Germany, 2003; EFSA, 2010).

Residues of thiophanate methyl in matrices with high water content can be determined using a HPLC-MS/MS method with the LOQ of 0.01 mg/kg (Germany, 2003). A validation of the method in an independent laboratory (ILV) has to be performed.

Residues of carbendazim can be determined in matrices with high water content also applying HPLC-MS/MS method with the validated LOQ of 0.01 mg/kg (EFSA, 2010).

EFSA therefore concludes that adequate enforcement methods are available to monitor residues of thiophanate-methyl and carbendazim in apples and pears.

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

Analytical methods for the determination of thiophanate-methyl and carbendazim residues in animal matrices were assessed in the framework of the peer review (Germany, 2003; EFSA, 2010).

Residues of thiophanate-methyl in muscle, eggs and liver can be determined using HPLC-UV method at the validated LOQ of 0.05 mg/kg (Germany, 2003). The method is not considered as fully validated, since for the lowest fortification level of 0.05 mg/kg only 1 determination (liver) or 3 determinations (muscle, eggs) were made although a minimum of 5 determinations per fortification level should be made (EC, 2000). A validation of the method in an independent laboratory (ILV) must be performed.

The method validation data for the determination of thiophanate-methyl residues in milk, fat, and kidney are not available and have to be provided in case MRLs in animal commodities are to be proposed.

Residues of carbendazim can be determined using HPLC-MS/MS method in meat, milk, eggs and fat at the validated LOQ of 0.05 mg/kg. Acceptable methods for the determination of carbendazim in liver and kidney are missing. No adequate analytical enforcement methods are currently available for

[11] Commission Regulation (EU) No 546/2011 of 10 June 2011, OJ L 155,11.6.2011, p.127-174

the determination of carbendazim metabolite 5-OH-carbendazim (as included in the residue definition for animal matrices) in animal matrices (EFSA, 2010).

No MRL proposals for residues in the animal commodities are proposed in the framework of the current application. However the data gaps identified regarding the validation of analytical methods for the determination of thiophanate-methyl and carbendazim residues in animal matrices need to be addressed in the MRL review according to the Article 12 of Regulation (EC) No 396/2005.

2. Mammalian toxicology

The toxicological properties of both thiophanate-methyl and carbendazim were peer reviewed in the framework of Directive 91/414/EEC (EC, 2005; EFSA, 2010). The toxicological reference values that were derived for both active substances are summarized in the table below.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Thiophanate-methyl					
ADI	EC	2005	0.08 mg/kg bw/d	1 year dog study, 2 year rat study	100
ARfD	EC	2005	0.2 mg/bw d	developmental study in rabbits	100
Carbendazim					
ADI	EFSA	2010	0.02 mg/kg bw/d	developmental study in rats and rabbits	500
ARfD	EFSA	2010	0.02 mg/bw d	developmental study in rats and rabbits	500

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of thiophanate-methyl in primary crops has been evaluated by the peer review under Directive 91/414/EEC (Germany, 1997, 2000, 2003) as well as by the JMPR (FAO, 1998). The overview of the metabolism study designs is presented in the table below.

Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Label position	Application details				
			Method, F, G or P[(a)]	**Rate**	**No/ Interval**	**Sampling (DAT)**	**Remarks**
Fruits and fruiting vegetable	Apples	^{14}C- thiophanate-methyl ^{35}S-thiophanate-methyl	a) petiole injection b) leaf dotting	Preparation of 1000 mg/L suspension of 70%WP	1	14 (leaves) 0, 7, 14, 28, 54, 90 (leaves)	Study I and II Studies from 1970, 1971. FAO, 1998; Germany, 1997
		phenyl-U-^{14}C – thiophanate-methyl	foliar	3.9 kg a.s./ha	3/7 days	1, 7	Study III Germany, 2000; FAO, 1998
	Grapes	14 C- thiophanate - methyl 35S-thiophanate-methyl phenyl-U-^{14}C – thiophanate-methyl	leaf dotting	1000 mg/L suspension of 70%WP	1	0, 7, 14, 28, 54, 90 (leaves)	Study from 1971. FAO, 1998; Germany, 1997
Root and tuber vegetables	Sugar beets	^{14}C- thiophanate-methyl	foliar	0.39 kg a.s./ha	3/10, 32 days	After each application (foliage) and at harvest 21 DAT (foliage and root)	Germany, 2003
Pulses and oilseeds	Soya beans	phenyl-U-^{14}C – thiophanate-methyl	foliar	700 mg a.s./L (0.12mg) + 50 mg non-labelled thiophanate-methyl in 50 ml water	1	10 (pods, leaves)	Some plants grown indoor, some outdoor. Study from 1977. FAO, 1998; Germany 1997
	Green bean plants	^{14}C- thiophanate-methyl ^{35}S-thiophanate-methyl	Foliar (spotting on leaf)	250 µl	at 2 leaf stage	14	Study I FAO, 1998; Germany 1997
			culture solution	20 ml solution	-	1,7 and 14	Study II Root uptake investigated FAO, 1998; Germany 1997
		phenyl-U-^{14}C – thiophanate-methyl	foliar	50 mg/L	plants with 3-4 cm pods	14 (pods, leaves, stems)	Study III FAO, 1998; Germany 1997
	Lima beans	^{14}C- thiophanate-methyl	foliar	1.18 kg a.s./ha	2/7 days	28 (pods), 35(foliage)	Germany, 2003
Cereals	Wheat	^{14}C- thiophanate-methyl	foliar	0.75 kg a.s./ha	1	0, 28, 69 (harvest), grain straw	Germany, 2003

(a): Outdoor/field use (F) or glasshouse/ /indoor application (G) or protected (P)

It is noted that the studies I and II on apple and green beans, the study on grapes and the study on soybeans are from 70`s and have not been performed in compliance with the currently applicable

guidelines on the performance of metabolism studies in plants. The application rates are also not clearly expressed. The studies do not provide the information on the nature of thiophanate-methyl in the relevant edible parts of these crops (fruits). Therefore EFSA focused on more recent studies.

In lima bean pods 28 DAT, the total radioactivity accounted for 0.047 mg eq./kg. In bean foliage 35 DAT the TRR accounted for 1.36 mg eq./kg. Carbendazim was identified as the most abundant metabolite (25.5% in foliage (35 DAT)). The radioactivity in pods was low and thus not identified.

In apples (study III) 1 and 7 DAT the radioactivity was mainly found in the fruit surface rinse (97-93%) with low levels in the peel (2.6-7%). The main component of the TRR in apple was thiophanate-methyl, accounting for 64.5% (3.3 mg/kg) 1 day after treatment and 44.5% (0.96 mg/kg) 7 days after the treatment. The most abundant metabolite was carbendazim (22% (1.15 mg/kg) 1 day after treatment and 33% (0.72 mg/kg) 7 days after treatment). Other metabolites were individually below 10% of the TRR.

The distribution of radioactivity in sugar beet at harvest indicates the accumulation in the stem (2.8 mg eq./kg) with lower levels being present in the root (0.12 mg eq./kg). The main components of the TRR were parent thiophanate-methyl (41% TRR in foliage and 27% in root), carbendazim (26% in foliage and 15.4% in root) and allophanate (FH-432)[12] (13% in foliage).

In spring wheat grain at harvest very low amount of radioactivity was identified (0.003 mg/kg) and was thus not further characterized. In straw 69 DAT the total radioactivity accounted for 1.15 mg/kg and the only identified metabolite was carbendazim, accounting for 4% of the TRR. The rest of the radioactivity was explained by being incorporated in natural compounds.

The metabolism of thiophanate-methyl has been investigated in four crop categories - pulses, root vegetables, fruits and cereals - to conclude that, generally, similar metabolism of the active substance is expected in all crop groups investigated. Thiophanate-methyl is decreasing with time while the main metabolite carbendazim is formed. Although the percentage of carbendazim increases along time, the actual amounts of it decrease.

Based on results of the metabolism studies, the peer review concluded that the risk assessment and enforcement residue definition should be set as "thiophanate-methyl and carbendazim, expressed as carbendazim". Following the development of analytical enforcement methods which are able to determine thiophanate-methyl and carbendazim separately, the enforcement residue definition in plant commodities recently was split and separate residue definitions were established for thiophanate-methyl and carbendazim according to Regulation (EC) No 396/2005.

For apples and pears, EFSA concludes that the metabolism of thiophanate-methyl is sufficiently investigated. It is just noted that the metabolism studies on apples have been performed with shorter PHI intervals than in the intended GAP and thus do not provide information on the proportions of thiophanate-methyl and carbendazim at PHI intervals exceeding 7 days. The submitted residue trials on apples (see Appendix D) indicate that in some cases carbendazim residues in apples occur at higher levels at a longer PHI interval of 20-21 days. Nevertheless, taking into account the findings of the metabolism studies, EFSA is of the opinion that qualitative differences in residue composition are not expected at these longer PHI intervals (14-20 days) and that thiophanate-methyl and carbendazim are the main residues in apples and pears.

3.1.1.2. Magnitude of residues

In support of the intended use the applicant submitted 8 GAP compliant residue trials on apples, which were performed in various northern Member States in 2009/2010. Six trials were designed as

[12] dimethyl 4,4`-(*o*-phenylene) bisallophanate

residue decline studies providing data on residue levels in apples on the day of the treatment and 1, 3, 7-8, 13-15, 21-22 and 26-28 days after the treatment. In another two trials the samples were analyzed for residues 7-8 and 14 days after the treatment. The individual residue values for thiophanate-methyl and carbendazim in each residue trial at various PHI intervals are given in Appendix D.

Samples were analyzed separately for thiophanate-methyl and carbendazim. In some of the decline studies the maximum carbendazim residue concentration was not observed at the intended PHI, but at a later sampling date (21/22 day PHI). This data gives an indication that the maximum residue concentration for carbendazim might be expected at a longer PHI than 14 days.

The applicant proposes to extrapolate the residue data from apples to pears. According to EU guidelines such an extrapolation is acceptable (EC, 2011) and sufficient number of trials has been submitted.

Separate enforcement residue definitions are set for thiophanate-methyl and carbendazim and therefore separate MRL proposals were derived from the trials supporting the intended use (Table 3-2).

The risk assessment residue definition for thiophanate-methyl in plant commodities is established as the sum of thiophanate-methyl and carbendazim, expressed as carbendazim. Both substances share the same mechanism of toxicity and therefore the input values for the risk assessment are derived by calculating the sum of thiophanate-methyl and carbendazim (observed within a sample) adjusted for their toxicological potencies. As the ADI value for thiophanate-methyl is 4 times higher than the ADI value for carbendazim, a potency factor of 0.25 is derived for thiophanate-methyl compared to carbendazim. Similarly, a potency factor of 0.1 on a short term basis can be derived taking into account that thiophanate-methyl has a 10 times lower acute toxicity than carbendazim.

Thus, the input values for the chronic exposure calculation were derived after calculating the toxicologically adjusted sum of carbendazim and thiophanate-methyl for the residues measured in the individual trials according to the following equations:

Toxicologically adjusted sum for the chronic exposure: R (th)[13]*0.25 + R(c)[14]

From the 8 results the median value was selected as input value for the chronic exposure assessment.

Similarly, for the acute exposure assessment the input values were calculated according to the following equation:

Toxicologically adjusted sum for the acute exposure: R (th) *0.10 + R(c)

From the 8 results, the highest value was selected as input value for the acute exposure assessment.

Since residues of thiophanate-methyl and carbendazim in some trials were higher at a longer PHI interval of 21 days, the risk assessment values were derived for all samples taken at a PHI interval of 14 days and 21 days (see Appendix D). In Table 3-3 the results are summarised. Considering that the carbendazim residues might be higher at a later PHI than 14 days, the risk assessment values derived by the methodology explained above are affected by uncertainties, underestimating the actual risk assessment values.

The storage stability of thiophanate-methyl in primary crops was investigated in a study submitted in the framework of the current application (Sweden, 2011). Residues of thiophanate-methyl in apple were stable for a minimum of 3 years when stored at -15 to -20ºC. As the supervised residue trial

[13] R (th): residue concentration of thiophanate-methyl, expressed in mg/kg
[14] R (c): residue concentration of carbendazim, expressed in mg/kg

samples were stored under conditions for which integrity of the samples was demonstrated (maximum storage interval of 85 days -18ºC), it is concluded that the residue data are valid with regard to the storage stability. The storage stability of carbendazim was investigated in the framework of the peer review and the submitted studies indicate that carbendazim residues are stable in matrices with high water content for at least 30 months (tomato fruit) when stored deep frozen (EFSA, 2010).

According to the EMS, the analytical methods used to analyse supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (Sweden, 2011).

EFSA concludes that the intended use of thiophanate-methyl on apples and pears in Sweden is sufficiently supported by residue data and an MRL of 0.8 mg/kg for thiophanate-methyl and an MRL of 0.3 mg/kg for carbendazim would be required.

Table 3-2: Overview of the available residues trials data

Commodity	Region [(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)[e]	Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	Comments
Enforcement residue definition (1): Thiophanate-methyl							
Apples → Pears	NEU	Outdoor	0.056[b]; 0.13; 0.04; 0.43; 0.07[b]; 0.31; 0.20; 0.16	0.15	0.43	**0.8**	OECD MRL[c] =0.8 (rounded) and 0.72 (unrounded)
Enforcement residue definition (2): Carbendazim							
Apples → Pears	NEU	Outdoor	0.053[b]; 0.08; 0.10; 0.12[b]; 0.15[b]; 0.14; 0.18; 0.09	0.11	0.18	**0.3[d]**	OECD MRL[c] =0.4 (rounded) and 0.34 (unrounded)

(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) : Residue value within a trial higher at a longer PHI interval of 21-22 days.
(c): The MRL calculated using the OECD MRL calculator (OECD, 2011b)
(d) : Due to a narrow safety margin for acute exposure, an MRL of 0.3 mg/kg is proposed.
(e): Results for thiophanate-methyl matches with the results for carbendazim in the same sample.

Table 3-3: Overview of the derived risk assessment values

Commodity	Region [(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)	Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	Comments
Chronic risk assessment residue definition: thiophanate-methyl and carbendazim, expressed as carbendazim (thiophanate-methyl *0.25 plus carbendazim)							
Apples → Pears	NEU	Outdoor	0.07; 0.11; 0.11; 0.19; 0.17; 0.22; 0.23; 0.13	**0.15**	-	-	The results are reported in the same order as in Table 3-2. (Appendix D)
Acute risk assessment residue definition: thiophanate-methyl and carbendazim, expressed as carbendazim (thiophanate-methyl *0.1 plus carbendazim)							
Apples → Pears	NEU	Outdoor	0.06; 0.09; 0.10; 0.15; 0.16; 0.17; 0.20; 0.11	-	**0.2**	-	The results are reported in the same order as in Table 3-2 (Appendix D)

3.1.1.3. Effect of industrial processing and/or household preparation

The nature of *carbendazim* under processing conditions simulating pasteurisation, baking or sterilisation was investigated in the framework of the peer review and study results indicate that significant degradation of carbendazim does not occur (EFSA, 2010).

The effect of processing on the nature of *thiophanate-methyl* has not been investigated. The formation of the more toxic metabolite carbendazim or other degradation products under various processing conditions should be further investigating. Therefore EFSA concludes that studies investigating the effect of processing on the nature of thiophanate-methyl would have to be performed according to the currently applicable EU guidelines.

In the framework of the current application the effect of processing on the magnitude of thiophanate-methyl and carbendazim residues was investigated in two studies with apples (Sweden, 2011). Apples were treated according to the intended GAP and samples were taken on the 3rd day after application. Apples were processed into juice, puree and canned apple. The residues of thiophanate-methyl and carbendazim were determined separately in washed apple, wet pomace, dry pomace, peels, juice, puree, peeled apple, blanched apples, blanching water, apple cores and canned apple.

Study results indicate a reduction of thiophanate-methyl residues in all processing products. An increase of carbendazim residues is observed in wet and dry apple pomace which can be related either to higher dry matter content (dry apple pomace) or as a result from the degradation of thiophanate-methyl.

An overview of the derived indicative processing factors is given in a Table 3-4.

Table 3-4: Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Enforcement residue definition: Thiophanate-methyl				
Apple, peeled	1	<0.30	1	Residues of thiophanate-methyl <0.01 mg/kg in peeled apple.
Apples, juice	2	0.20	1	-
Apples, wet pomace	2	0.44	1	-
Apples, dry pomace	2	<0.20	1	Residues of thiophanate-methyl <0.01 mg/kg in dry pomace.
Apples, puree	2	0.20	1	-
Apples, canned	2	<0.20	1	Residues of thiophanate-methyl <0.01 mg/kg in canned apples.
Enforcement residue definition: sum of benomyl and carbendazim expressed as carbendazim				
Apple, peeled	1	0.30	1	-
Apples, juice	2	0.69	1	-
Apples, wet pomace	2	2.60	1	-
Apples, dry pomace	2	8.19	1	-
Apples, puree	2	0.48	1	

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Apples, canned	2	0.23	1	Residues of carbendazim at <0.01 mg/kg in canned apples.

(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.

No study details have been provided. The number of studies is not sufficient as well as the nature of thiophanate-methyl under processing conditions has not been investigated and therefore EFSA does not recommend inclusion of the processing factors in Annex VI of Regulation (EC) No 396/2005.

3.1.2. Rotational crops

Since the proposed use of thiophanate-methyl is on permanent crops the investigation of residues in rotational crops/succeeding crops is not required.

3.2. Nature and magnitude of residues in livestock

Apple pomace can be fed to dairy and feed cattle (EC, 1996) and therefore the nature and magnitude of thiophanate-methyl and carbendazim residues in livestock has to be further investigated.

3.2.1. Dietary burden of livestock

The median and maximum dietary burden for livestock was calculated using the agreed European methodology (EC, 1996). The input values for the dietary burden calculation were selected according to the FAO recommendations (FAO, 2009) considering the livestock intake of thiophanate-methyl and carbendazim residues from the apple pomace and from all other feed crops for which the existing EU MRLs for thiophanate-methyl and carbendazim are set above the LOQ according to Regulation (No) EC 396/2005 (citrus fruits, pome fruits, soybean, wheat, rye, barley and oats).

Separate dietary burden calculations were performed for carbendazim and thiophanate-methyl. To refine the calculations, EFSA used the risk assessment values as reported in the peer review (Germany, 2003, 2005; EFSA, 2010) and in the previously issued EFSA reasoned opinion on the MRLs of concern (EFSA, 2009). For some commodities EFSA could not retrieve the relevant risk assessment values and therefore the existing EU MRLs were used. The following default processing factors were used: 2.5 for pomace, 8 for wheat and rye bran and 2 for soybean meal.

The input values for the dietary burden calculation are summarized in Table 3-5.

Table 3-5: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residues of **thiophanate-methyl**				
Apple, pear pomace	0.38	Median residue * PF (2.5) (Table 3-2; EFSA, 2009)	0.38	Median residue * PF (2.5) (Table 3-2; EFSA, 2009)

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value** (mg/kg)	**Comment**
Citrus fruit pomace	6.25	Median residue*PF (2.5) (EFSA, 2009)	6.25	Median residue*PF (2.5) (EFSA, 2009)
Soybean	0.3	MRL (Appendix C)	0.3	MRL (Appendix C)
Soybean meal	0.6	MRL* PF(2)	0.6	MRL* PF(2)
Barley, oat grain	0.06	Median residue (SEU use) (Germany, 2003)	0.06	Median residue (SEU use) (Germany, 2003)
Barley, oat straw	0.29	Median residue (SEU use) (Germany, 2003)	0.97	Highest residue (SEU use) (Germany, 2003)
Wheat, rye grain	0.05	MRL (Appendix C)	0.05	MRL (Appendix C)
Wheat, rye bran	0.4	MRL (grain)* PF(8)	0.4	MRL (grain)* PF(8)
Wheat, rye straw	0.34	Median residue (NEU use) (Germany, 2003)	1.63	Highest residue (NEU use) (Germany, 2003)
Residues of **carbendazim**				
Apple, pear pomace	0.28	Median residue *PF (2.6) (Table 3-2; Table 3-4)	0.28	Median residue *PF (2.6) (Table 3-2; Table 3-4)
Apple, pear pomace	0.2[a]	Median residue *PF (2.5) (EFSA, 2009)	0.2[a]	Median residue *PF (2.5) (EFSA, 2009)
Grapefruit, oranges pomace	0.2	Median residue*PF (2.5) (EFSA, 2009)	0.2	Median residue*PF (2.5) (EFSA, 2009)
Lemon, limes, mandarin pomace	0.65	Median residue*PF (2.5) (EFSA, 2009)	0.65	Median residue*PF (2.5) (EFSA, 2009)
Soybean	0.2	MRL (Appendix C)	0.2	MRL (Appendix C)
Soybean meal	0.4	MRL* PF(2)	0.4	MRL* PF(2)
Barley, oat grain	2	MRL (Appendix C)	2	MRL (Appendix C)
Barley, oat straw	0.68	Median residue (SEU use) (Germany, 2003)	1.51	Highest residue (SEU use) (Germany, 2003)
Wheat, rye grain	0.03	Median residue (EFSA, 2010)	0.03	Median residue (EFSA, 2010)
Wheat, rye bran	0.24	MRL (grain)* PF(8)	0.24	MRL (grain)* PF(8)
Wheat, rye straw	0.06	Median residue (Germany, 2009)	1.5	Highest residue (Germany, 2009)

(a) : Used in the calculation of the livestock dietary burden according to scenario 2 only.

In order to estimate the contribution of carbendazim residues in apple pomace to the total livestock dietary exposure from the intended use and from the existing use, EFSA performed two livestock dietary burden calculations. In scenario 1 the apple pomace was included in the dietary burden calculation containing residues according to intended use, whereas in scenario 2 the apple pomace was included containing residues according to the existing uses. Regarding thiophanate-methyl, the new residue dataset will not change the livestock dietary burden since the input values for the new use and the existing use are identical.

The results of the dietary burden calculation are summarized in the tables below.

Table 3-6: Results of the dietary burden calculation **(scenario 1)**

	Maximum dietary burden (mg/kg bw/d)	**Median dietary burden** (mg/kg bw/d)	**Highest contributing commodity**	**Max dietary burden** (mg/kg DM)[(a)]	**Trigger exceeded** (Y/N)
Risk assessment residue definition: Thiophanate-methyl					
Dairy ruminants	0.123	0.113	Orange pomace	3.4	Y
Meat ruminants	0.396	0.366	Orange pomace	9.24	Y
Poultry	0.009	0.009	Soya bean meal	0.14	Y
Pigs	0.009	0.009	Soya bean meal	0.23	Y
Risk assessment residue definition: Carbendazim					
Dairy ruminants	0.062	0.055	Barley grain	1.70	Y
Meat ruminants	0.106	0.106	Barley grain	2.48	Y
Poultry	0.106	0.106	Barley grain	1.67	Y
Pigs	0.078	0.078	Barley grain	1.95	Y

(a): Dry matter feed

Table 3-7: Results of the dietary burden calculation **(scenario 2)**

	Maximum dietary burden (mg/kg bw/d)	**Median dietary burden** (mg/kg bw/d)	**Highest contributing commodity**	**Max dietary burden** (mg/kg DM)[(a)]	**Trigger exceeded** (Y/N)
Risk assessment residue definition: Carbendazim					
Dairy ruminants	0.062	0.055	Barley grain	1.70	Y
Meat ruminants	0.106	0.106	Barley grain	2.48	Y
Poultry	0.106	0.106	Barley grain	1.67	Y
Pigs	0.078	0.078	Barley grain	1.95	Y

(a): Dry matter feed

The calculated dietary burden indicates that the trigger value of 0.1 mg/kg dry matter (DM) is exceeded for all livestock species, but the livestock intake is driven mainly by the existing uses of thiophanate-methyl and carbendazim. The contribution of residues in the apple pomace from the intended use to the total livestock exposure is low. Therefore the modification of the MRLs for commodities of animal origin was not further investigated in the framework of the current application.

The existing EU MRLs for thiophanate-methyl and carbendazim in food commodities of animal origin are set at the LOQ of 0.05 mg/kg according to Regulation (EC) No 396/2005. It is noted that the livestock exposure to thiophanate-methyl and carbendazim residues and the potential carry-over of residues into commodities of animal origin will be further investigated in the framework of Article 12 of Regulation (EC) No 396/2005 when full information on authorized uses will be available to EFSA.

4. Consumer risk assessment

Both acute and chronic intake calculations were performed for the sum of carbendazim and thiophanate-methyl with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This

exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population[15] (EFSA, 2007).

The risk assessment residue definition for thiophanate-methyl in plant commodities is established as the sum of thiophanate-methyl and carbendazim, expressed as carbendazim. Both substances share the same mechanism of toxicity and therefore a combined risk assessment needs to be performed considering their respective potencies. As the ADI value for thiophanate-methyl is 4 times higher than the ADI value for carbendazim, a potency factor of 0.25 is derived for thiophanate-methyl compared to carbendazim. Similarly, a potency factor of 0.1 is calculated taking into account the lower acute toxicity of thiophanate-methyl in comparison with carbendazim.

To calculate the chronic exposure for the crops under consideration, EFSA used the median residue value as derived from the residue trials on apples (see Table 3-3). The same input value was used for pears. For other commodities of plant and animal origin the toxicologically adjusted sum of the existing EU MRLs for thiophanate-methyl and carbendazim as established in Regulation (EC) No 396/2005, were used as input values in the chronic exposure calculation (see Appendix C). For citrus fruits the risk assessment values from the previously issued EFSA reasoned opinion were available to refine the consumer exposure calculation (EFSA, 2009). The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment, does not exceed the toxicological reference value for long-term exposure (i.e. the ADI), a consumer health risk can be excluded with a high probability.

The acute exposure assessment was performed only with regard to apples and pears, assuming the consumption of a large portion of the food item as reported in the national food surveys containing residues at the highest level as observed in supervised field trials (Table 3-3).

The input values used for the dietary exposure calculation are summarized in Table 4-1.

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition for plant commodities: the sum of thiophanate-methyl and carbendazim, expressed as carbendazim				
Apples	0.15	Median residue (Table 3-3)	0.20	Highest residue (Table 3-3)
Pears	0.15	Median residue (apples) (Table 3-3)	0.20	Highest residue (apples) (Table 3-3)
Lemons, mandarins, limes	0.19	Median residue (T)*0.25*PF (T) + Median residue (C)*PF (C) (EFSA, 2009)	Acute risk assessment was undertaken only with regard to the crops under consideration.	

[15] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition for plant commodities: the sum of thiophanate-methyl and carbendazim, expressed as carbendazim				
Oranges, grapefruits	0.11	Median residue (T)*0.25*PF (T) + Median residue (C) *PF (C) (EFSA, 2009)		
Other commodities of plant and animal [a] origin	MRL (C) + 0.25*MRL (T)	Appendix C		

(a): It is noted that the risk assessment residue definition for thiophanate-methyl in commodities of animal origin differs from the risk assessment residue definition in plant commodities. However, as the MRLs for animal commodities are set at the LOQ, no residues are expected and the existing MRL was used as input value

T: Thiophanate-methyl

C: Carbendazim

The estimated exposure was then compared with the toxicological reference values derived for carbendazim (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values ranged from 10- 49 % of the ADI (maximum for IE adult diet). The contribution of residues to the total consumer exposure (% of the ADI) accounted for a maximum of 9% for apples (DE child diet) and 0.5% of the ADI (DK child diet).

Using the internationally agreed standard methodology, based on the highest residue observed in residue trials, no acute consumer risk was identified. The calculated maximum exposure in percentage of the ARfD was 98% for apples and 91% for pears. Taking into account the uncertainties regarding the input values for the consumer risk assessment (see section 3.1.1.2) the result of the exposure assessment might underestimate the actual consumer exposure.

EFSA notes that in case apples and pears contain carbendazim residues at the proposed MRL of 0.3 mg/kg, the narrow margin of safety to the acute reference dose (for carbendazim) is not sufficient to exclude the consumer health risk in all cases (i.e. high consumption of unpeeled fruit and high variability (VF of 7) within a batch)[16]. Taking into account that the consumer group for which the highest exposure is estimated are infants, it is most likely that the fruits are consumed after peeling. However, since detailed consumption figures reporting separately the consumption of unpeeled, peeled and processed apples and pears and an accurate peeling factor are not available to EFSA, the estimation of the actual exposure for this sub-group of the population could not be further refined.

EFSA concludes that the intended use of thiophanate-methyl does not lead to a chronic consumer intake risk, but a potential acute exposure cannot be excluded for apples and pears containing residues of thiophanate-methyl and carbendazim at the level of the MRLs that would be required for the intended use.

[16] Calculation for the critical consumer using MRL of 0.3 mg/kg for carbendazim and a variability factor of 7 results in an acute exposure of 147% for apples (UK infant diet) and 137% of ARfD for pears (DE child) (the occurrence of thiophanate-methyl residues in the same sample is not considered in this calculation). In this calculation the contribution of thiophanate-methyl residues to the dietary toxicological burden which might be present at the same time are not considered.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profiles of thiophanate-methyl and carbendazim were assessed in the framework of the peer review under Directive 91/414/EEC. For thiophanate-methyl the peer review proposed an ADI of 0.08 mg/kg bw/day and an ARfD of 0.2 mg/kg bw. For carbendazim an ADI value of 0.02 mg/kg bw/day and an ARfD of 0.02 mg/kg bw has been derived.

The metabolism of thiophanate-methyl in primary crops was investigated in fruits, root vegetables, cereals and pulses. From these studies the peer review concluded to establish the residue definition for risk assessment as the "sum of thiophanate-methyl and carbendazim, expressed as carbendazim". The enforcement residue definition is established as parent thiophanate-methyl according to Regulation (EC) No 396/2005. For the use on the crops under consideration EFSA concludes that the metabolism of thiophanate-methyl is addressed and that the residue definitions derived by the peer review are applicable.

The proposed extrapolation of residue data from apples to pears is sufficiently supported by data. EFSA concludes that a MRL of 0.8 mg/kg for thiophanate-methyl and a MRL of 0.3 mg/kg for carbendazim would be required to support the intended use of thiophanate-methyl on apples and pears in Sweden. Analytical methods are available to control the compliance of carbendazim residues in the commodities under consideration at a validated LOQ of 0.01 mg/kg. An analytical enforcement method for the determination of thiophanate-methyl residues in apples and pears is available, but a validation of the method in an independent laboratory (ILV) is lacking.

The effects of processing on the nature of thiophanate-methyl have not been investigated and therefore adequate studies to address this data gap have to be provided. There is some evidence that degradation to carbendazim might occur but the possible formation of other degradation products needs to be further explored. According to the peer review, carbendazim is stable under standard hydrolysis studies simulating pasteurisation, baking or sterilisation. The effect of processing on the magnitude of thiophanate-methyl and carbendazim residues in apples was investigated in two studies submitted in the framework of the current application. Apples were processed into juice, puree and canned apple. Residues of thiophanate-methyl and carbendazim were determined in final processed products as well as in various intermediate products. Study results indicate a reduction of thiophanate-methyl residues in all processed products. A concentration of carbendazim residues is observed in wet and dry apple pomace. No study details have been provided as well as the number of studies is insufficient to propose the derived processing factors for enforcement purposes.

Since the proposed use of thiophanate-methyl is on permanent crops the investigation of residues in rotational crops/succeeding crops is not required.

Apple pomace can be fed to cattle and therefore the nature and magnitude of thiophanate-methyl and carbendazim residues in livestock and potential carry-over of residues in commodities of animal origin was investigated. The livestock dietary burden was calculated considering the livestock intake of thiophanate-methyl and carbendazim residues from the apple pomace as well as from all other potential feed crops for which the existing EU MRLs for thiophanate-methyl and carbendazim are set above the LOQ. The calculated dietary burden is exceeded for all livestock species, but the livestock intake is driven mainly by the existing uses of thiophanate-methyl and carbendazim and the contribution of the apple pomace to the total livestock exposure s low. Therefore the modification of the MRLs for commodities of animal origin was not further investigated in the framework of the current application.

Consumer intake calculation was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). Since both active substances share a common mechanism of toxicity, a combined

consumer exposure assessment was performed considering the available residue data for carbendazim and thiophanate-methyl as well as the respective toxicological potencies of the active substances (calculation of the toxicologically adjusted sum of carbendazim and thiophanate-methyl). To calculate the chronic exposure for the crops under consideration, EFSA used the median residue value as derived from the residue trials on apples. The same input value was used for pears. For other commodities of plant and animal origin the toxicologically adjusted sum of the existing EU MRLs for thiophanate-methyl and carbendazim as established in Regulation (EC) No 396/2005 were used as input values in the chronic exposure calculation. For citrus fruit the risk assessment values from the previously issued EFSA reasoned opinion were available to refine the consumer exposure calculation.

The acute exposure assessment was performed only with regard to apples and pears, assuming the consumption of a large portion of the food item as reported in the national food surveys containing residues at the highest level as observed in supervised field trials. The estimated exposure was then compared with the toxicological reference values derived for carbendazim.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake values ranged from 10- 49 % of the ADI (maximum for IE adult diet). The contribution of residues to the total consumer exposure (% of the ADI) accounted for a maximum of 9% for apples (DE child diet) and 0.5% of the ADI (DK child diet).

Using the internationally agreed standard methodology, based on the highest residue observed in residue trials, no acute consumer risk was identified. The calculated maximum exposure in percentage of the ARfD was 98% for apples and 91% for pears. Taking into account the uncertainties regarding the input values for the consumer risk assessment (see section 3.1.1.2) the result of the exposure assessment might underestimate the actual consumer exposure.

EFSA notes that in case apples and pears contain carbendazim residues at the proposed MRL of 0.3 mg/kg (not considering an additional contribution of thiophanate residues), the narrow margin of safety to the acute reference dose (for carbendazim) is not sufficient to exclude the consumer health risk in all cases (i.e. high consumption of unpeeled fruit and high variability (VF of 7) within a batch). Taking into account that the consumer group for which the highest exposure is estimated are infants, it is most likely that the fruits are consumed after peeling. However, since detailed consumption figures reporting separately the consumption of unpeeled, peeled and processed apples and pears and an accurate peeling factor are not available to EFSA, the estimation of the actual exposure for this sub-group of the population could not be further refined.

EFSA concludes that the intended use of thiophanate-methyl does not lead to a chronic consumer intake risk, but a potential acute exposure cannot be excluded for apples and pears containing residues of thiophanate-methyl and carbendazim at the level of the MRLs that would be required for the intended use.

RECOMMENDATIONS

Code number[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Thiophanate-methyl				The MRL proposals are supported by residue data and no chronic consumer intake concerns were identified for the proposed use. Acute consumer exposure concerns cannot be excluded if apples and pears contain residues at the level of the
0130010	Apples	0.5	No new proposal	
0130020	Pears	0.5	No new proposal	
Enforcement residue definition: Carbendazim				

Code number[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
0130010	Apples	0.2	No new proposal	MRL which would be required to support the intended use of thiophanate-methyl in Sweden. A study on effects of processing on the nature of thiophanate-methyl residues has to be submitted.
0130020	Pears	0.2	No new proposal	

[a] according to Annex I of Regulation (EC) No 396/2005

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Appendix A. GOOD AGRICULTURAL PRACTICES (GAPS)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Apples, pears	SE	F	*Monilia, Venturia, Gloesporium*	WG	704 g/kg	spray	2 weeks before harvest	1	-	0.0675	1000	0.675	14	

Remarks:
(a) For crops, EU or other classifications, e.g.Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (Growth stages of mono-and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing)

Appendix B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

			Thiophanate-methyl and carbendazim, expressed as carbendazim					**Prepare workbook for refined calculations**		
			Status of the active substance:	**Included**	Code no.					
			LOQ (mg/kg bw):		proposed LOQ:					
			Toxicological end points					**Undo refined calculations**		
			ADI (mg/kg bw/day):	**0.02**	ARfD (mg/kg bw):	**0.02**				
			Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**				
			Year of evaluation:	**2010**	Year of evaluation:	**2010**				

Residue values expressed as carbendazim by applying toxicological potency factors to thiophanate-methyl residue values (0.25 for chronic RA and 0.1 for acute RA). Toxicological reference values are as derived for carbendazim

Chronic risk assessment - refined calculations

				TMDI (range) in % of ADI minimum - maximum						
				10	49					
			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)		
49.0	IE adult	12.9	Barley	7.8	Wine grapes	2.3	Sweet potatoes			
48.9	WHO Cluster diet B	11.2	Wine grapes	8.5	Tomatoes	4.7	Wheat			
38.4	DE child	9.1	Apples	4.3	Milk and cream,	2.7	Tomatoes			
37.3	NL child	8.8	Milk and cream,	4.7	Apples	3.8	Potatoes			
37.1	WHO cluster diet E	10.0	Wine grapes	8.4	Barley	2.5	Potatoes			
35.6	UK Toddler	14.9	Sugar beet (root)	6.2	Milk and cream,	2.3	Potatoes			
34.5	FR all population	25.0	Wine grapes	1.8	Wheat	1.2	Tomatoes			
33.4	UK Infant	11.6	Milk and cream,	6.6	Sugar beet (root)	2.6	Oats			
31.0	FR toddler	11.9	Milk and cream,	3.3	Potatoes	2.1	Tomatoes			
30.5	PT General population	15.6	Wine grapes	3.5	Potatoes	2.5	Tomatoes			
26.7	WHO Cluster diet F	6.3	Barley	3.7	Wine grapes	2.2	Potatoes			
25.3	DK child	4.1	Oats	3.8	Milk and cream,	3.0	Wheat			
23.2	WHO cluster diet D	3.6	Wheat	2.8	Tomatoes	2.6	Potatoes			
23.0	WHO regional European diet	3.4	Barley	3.0	Tomatoes	2.6	Potatoes			
21.4	NL general	3.9	Wine grapes	3.9	Barley	2.0	Milk and cream,			
20.5	FR infant	7.7	Milk and cream,	2.7	Potatoes	1.9	Apples			
20.2	ES adult	5.1	Barley	2.6	Wine grapes	2.2	Tomatoes			
19.3	ES child	3.8	Milk and cream,	2.7	Tomatoes	2.4	Wheat			
19.0	SE general population 90th percentile	3.7	Milk and cream,	2.7	Potatoes	2.1	Tomatoes			
18.8	DK adult	8.7	Wine grapes	1.6	Milk and cream,	1.2	Oats			
17.4	UK vegetarian	5.1	Wine grapes	2.5	Sugar beet (root)	1.7	Tomatoes			
16.9	UK Adult	6.8	Wine grapes	2.6	Sugar beet (root)	1.2	Tomatoes			
14.6	IT kids/toddler	3.9	Tomatoes	3.7	Wheat	1.2	Peaches			
12.2	IT adult	3.2	Tomatoes	2.3	Wheat	1.3	Peaches			
11.2	LT adult	2.1	Potatoes	1.7	Tomatoes	1.4	Apples			
10.4	FI adult	1.9	Wine grapes	1.7	Milk and cream,	1.2	Tomatoes			
10.2	PL general population	2.4	Tomatoes	2.2	Potatoes	1.5	Apples			

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of Thiophanate-methyl and carbendazim, expressed as carbendazim 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)
	98.0	Apples	0.2 / -	72.2	Apples	0.2 / -	22.4	Apples	0.2 / -	18.7	Apples	0.2 / -
	91.1	Pears	0.2 / -	65.5	Pears	0.2 / -	21.5	Pears	0.2 / -	16.4	Pears	0.2 / -
	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)			
	*) 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 Thiophanate-methyl 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. Appendix C. EXISTING EU MAXIMUM RESIDUE LIMITS (MRLs)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiophanate-methyl (R)	Carbendazim and benomyl (sum of benomyl and carbendazim expressed as carbendazim) (R)	Combined MRLs for the chronic RA ((MRL (T)*0.25)+ MRL (C))
100000	1. FRUIT FRESH OR FROZEN; NUTS			
110000	(i) Citrus fruit			
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)	6	0,2	1.70
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	6	0,2	1.70
110030	Lemons (Citron, lemon)	6	0,7	2.20
110040	Limes	6	0,7	2.20
110050	Mandarins (Clementine, tangerine, mineola and other hybrids)	6	0,7	2.20
110990	Others	0,1*	0,1*	0.13
120000	(ii) Tree nuts (shelled or unshelled)	0,2*	0,1*	0.15
120010	Almonds	0,2*	0,1*	0.15
120020	Brazil nuts	0,2*	0,1*	0.15
120030	Cashew nuts	0,2*	0,1*	0.15
120040	Chestnuts	0,2*	0,1*	0.15
120050	Coconuts	0,2*	0,1*	0.15
120060	Hazelnuts (Filbert)	0,2*	0,1*	0.15
120070	Macadamia	0,2*	0,1*	0.15
120080	Pecans	0,2*	0,1*	0.15
120090	Pine nuts	0,2*	0,1*	0.15
120100	Pistachios	0,2*	0,1*	0.15
120110	Walnuts	0,2*	0,1*	0.15
120990	Others	0,2*	0,1*	0.15
130000	(iii) Pome fruit			0.00
130010	Apples (Crab apple)	0,5	0,2	0.33
130020	Pears (Oriental pear)	0,5	0,2	0.33
130030	Quinces	0,5	0,2	0.33
130040	Medlar	2	0,2	0.70
130050	Loquat	2	2	2.50
130990	Others	0,5	0,2	0.33
140000	(iv) Stone fruit			0.00
140010	Apricots	2	0,2	0.70
140020	Cherries (sweet cherries, sour cherries)	0,3	0,5	0.58
140030	Peaches (Nectarines and similar hybrids)	2	0,2	0.70
140040	Plums (Damson, greengage, mirabelle, sloe)	0,3	0,5	0.58
140990	Others	0,1*	0,1*	0.13
150000	(v) Berries & small fruit			0.00
151000	(a) Table and wine grapes			0.00
151010	Table grapes	0,1*	0,3	0.33
151020	Wine grapes	3	0,5	1.25
152000	(b) Strawberries	0,1*	0,1*	0.13
153000	(c) Cane fruit	0,1*	0,1*	0.13
153010	Blackberries	0,1*	0,1*	0.13
153020	Dewberries (Loganberries, boysenberries, and cloudberries)	0,1*	0,1*	0.13
153030	Raspberries (Wineberries, arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x idaeus))	0,1*	0,1*	0.13
153990	Others	0,1*	0,1*	0.13
154000	(d) Other small fruit & berries	0,1*	0,1*	0.13
154010	Blueberries (Bilberries)	0,1*	0,1*	0.13
154020	Cranberries (Cowberries (red bilberries))	0,1*	0,1*	0.13
154030	Currants (red, black and white)	0,1*	0,1*	0.13
154040	Gooseberries (Including hybrids with other ribes species)	0,1*	0,1*	0.13
154050	Rose hips	0,1*	0,1*	0.13
154060	Mulberries (arbutus berry)	0,1*	0,1*	0.13
154070	Azarole (mediteranean medlar) (Kiwiberry (Actinidia arguta))	0,1*	0,1*	0.13
154080	Elderberries (Black chokeberry (appleberry), mountain ash, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,1*	0,1*	0.13
154990	Others	0,1*	0,1*	0.13
160000	(vi) Miscellaneous fruit			0.00
161000	(a) Edible peel	0,1*	0,1*	0.13
161010	Dates	0,1*	0,1*	0.13
161020	Figs	0,1*	0,1*	0.13
161030	Table olives	0,1*	0,1*	0.13
161040	Kumquats (Marumi kumquats, nagami kumquats, limequats (Citrus aurantifolia x Fortunella	0,1*	0,1*	0.13

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiophanate-methyl (R)	Carbendazim and benomyl (sum of benomyl and carbendazim expressed as carbendazim) (R)	Combined MRLs for the chronic RA ((MRL (T)*0.25)+ MRL (C))
	spp.))			
161050	Carambola (Bilimbi)	0,1*	0,1*	0.13
161060	Persimmon	0,1*	0,1*	0.13
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry Surinam cherry (grumichama Eugenia uniflora),)	0,1*	0,1*	0.13
161990	Others	0,1*	0,1*	0.13
162000	(b) Inedible peel, small	0,1*	0,1*	0.13
162010	Kiwi	0,1*	0,1*	0.13
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi), mangosteen)	0,1*	0,1*	0.13
162030	Passion fruit	0,1*	0,1*	0.13
162040	Prickly pear (cactus fruit)	0,1*	0,1*	0.13
162050	Star apple	0,1*	0,1*	0.13
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,1*	0,1*	0.13
162990	Others	0,1*	0,1*	0.13
163000	(c) Inedible peel, large			0.00
163010	Avocados	0,1*	0,1*	0.13
163020	Bananas (Dwarf banana, plantain, apple banana)	0,1*	0,1*	0.13
163030	Mangoes	1	0,5	0.75
163040	Papaya	1	0,2	0.45
163050	Pomegranate	0,1*	0,1*	0.13
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,1*	0,1*	0.13
163070	Guava (Red pitaya or dragon fruit (Hylocereus undatus))	0,1*	0,1*	0.13
163080	Pineapples	0,1*	0,1*	0.13
163090	Bread fruit (Jackfruit)	0,1*	0,1*	0.13
163100	Durian	0,1*	0,1*	0.13
163110	Soursop (guanabana)	0,1*	0,1*	0.13
163990	Others	0,1*	0,1*	0.13
200000	2. VEGETABLES FRESH OR FROZEN			0.00
210000	(i) Root and tuber vegetables	0,1*	0,1*	0.13
211000	(a) Potatoes	0,1*	0,1*	0.13
212000	(b) Tropical root and tuber vegetables	0,1*	0,1*	0.13
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,1*	0,1*	0.13
212020	Sweet potatoes	0,1*	0,1*	0.13
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,1*	0,1*	0.13
212040	Arrowroot	0,1*	0,1*	0.13
212990	Others	0,1*	0,1*	0.13
213000	(c) Other root and tuber vegetables except sugar beet	0,1*	0,1*	0.13
213010	Beetroot	0,1*	0,1*	0.13
213020	Carrots	0,1*	0,1*	0.13
213030	Celeriac	0,1*	0,1*	0.13
213040	Horseradish (Angelica roots, lovage roots, gentiana roots,)	0,1*	0,1*	0.13
213050	Jerusalem artichokes	0,1*	0,1*	0.13
213060	Parsnips	0,1*	0,1*	0.13
213070	Parsley root	0,1*	0,1*	0.13
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (Cyperus esculentus))	0,1*	0,1*	0.13
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,1*	0,1*	0.13
213100	Swedes	0,1*	0,1*	0.13
213110	Turnips	0,1*	0,1*	0.13
213990	Others	0,1*	0,1*	0.13
220000	(ii) Bulb vegetables	0,1*	0,1*	0.13
220010	Garlic	0,1*	0,1*	0.13
220020	Onions (Silverskin onions)	0,1*	0,1*	0.13
220030	Shallots	0,1*	0,1*	0.13
220040	Spring onions (Welsh onion and similar varieties)	0,1*	0,1*	0.13
220990	Others	0,1*	0,1*	0.13
230000	(iii) Fruiting vegetables			0.00
231000	(a) Solanacea			0.00
231010	Tomatoes (Cherry tomatoes, tree tomato, Physalis, gojiberry, wolfberry (Lycium barbarum and L. chinense))	1	0,3	0.55
231020	Peppers (Chilli peppers)	0,1*	0,1*	0.13
231030	Aubergines (egg plants) (Pepino)	2	0,5	1.00
231040	Okra, lady's fingers	1	2	2.25
231990	Others	0,1*	0,1*	0.13
232000	(b) Cucurbits - edible peel	0,1*	0,1*	0.13
232010	Cucumbers	0,1*	0,1*	0.13
232020	Gherkins	0,1*	0,1*	0.13
232030	Courgettes (Summer squash, marrow (patisson))	0,1*	0,1*	0.13
232990	Others	0,1*	0,1*	0.13

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiophanate-methyl (R)	Carbendazim and benomyl (sum of benomyl and carbendazim expressed as carbendazim) (R)	Combined MRLs for the chronic RA ((MRL (T)*0.25)+ MRL (C))
233000	(c) Cucurbits-inedible peel		0,1*	0.10
233010	Melons (Kiwano)	0,3	0,1*	0.18
233020	Pumpkins (Winter squash)	0,5	0,1*	0.23
233030	Watermelons	0,3	0,1*	0.18
233990	Others	0,3	0,1*	0.18
234000	(d) Sweet corn	0,1*	0,1*	0.13
239000	(e) Other fruiting vegetables	0,1*	0,1*	0.13
240000	(iv) Brassica vegetables			0.00
241000	(a) Flowering brassica	0,1*	0,1*	0.13
241010	Broccoli (Calabrese, Chinese broccoli, broccoli raab)	0,1*	0,1*	0.13
241020	Cauliflower	0,1*	0,1*	0.13
241990	Others	0,1*	0,1*	0.13
242000	(b) Head brassica			0.00
242010	Brussels sprouts	1	0,5	0.75
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,1*	0,1*	0.13
242990	Others	0,1*	0,1*	0.13
243000	(c) Leafy brassica	0,1*	0,1*	0.13
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), choi sum, peking cabbage (pe-tsai),)	0,1*	0,1*	0.13
243020	Kale (Borecole (curly kale), collards, Portuguese Kale, Portuguese cabbage, cow cabbage)	0,1*	0,1*	0.13
243990	Others	0,1*	0,1*	0.13
244000	(d) Kohlrabi	0,1*	0,1*	0.13
250000	(v) Leaf vegetables & fresh herbs	0,1*	0,1*	0.13
251000	(a) Lettuce and other salad plants including Brassicacea	0,1*	0,1*	0.13
251010	Lamb´s lettuce (Italian cornsalad)	0,1*	0,1*	0.13
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,1*	0,1*	0.13
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,1*	0,1*	0.13
251040	Cress	0,1*	0,1*	0.13
251050	Land cress	0,1*	0,1*	0.13
251060	Rocket, Rucola (Wild rocket)	0,1*	0,1*	0.13
251070	Red mustard	0,1*	0,1*	0.13
251080	Leaves and sprouts of Brassica spp (Mizuna, leaves of peas and radish and other babyleaf brassica crops (crops harvested up to 8 true leaf stage))	0,1*	0,1*	0.13
251990	Others	0,1*	0,1*	0.13
252000	(b) Spinach & similar (leaves)	0,1*	0,1*	0.13
252010	Spinach (New Zealand spinach, amaranthus spinach)	0,1*	0,1*	0.13
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth, Agretti (Salsola soda))	0,1*	0,1*	0.13
252030	Beet leaves (chard) (Leaves of beetroot)	0,1*	0,1*	0.13
252990	Others	0,1*	0,1*	0.13
253000	(c) Vine leaves (grape leaves)	0,1*	0,1*	0.13
254000	(d) Water cress	0,1*	0,1*	0.13
255000	(e) Witloof	0,1*	0,1*	0.13
256000	(f) Herbs	0,1*	0,1*	0.13
256010	Chervil	0,1*	0,1*	0.13
256020	Chives	0,1*	0,1*	0.13
256030	Celery leaves (Fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea leaves)	0,1*	0,1*	0.13
256040	Parsley	0,1*	0,1*	0.13
256050	Sage (Winter savory, summer savory,)	0,1*	0,1*	0.13
256060	Rosemary	0,1*	0,1*	0.13
256070	Thyme (Marjoram, oregano)	0,1*	0,1*	0.13
256080	Basil (Balm leaves, mint, peppermint)	0,1*	0,1*	0.13
256090	Bay leaves (laurel)	0,1*	0,1*	0.13
256100	Tarragon (Hyssop)	0,1*	0,1*	0.13
256990	Others (Edible flowers)	0,1*	0,1*	0.13
260000	(vi) Legume vegetables (fresh)	0,1*		0.03
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,1*	0,2	0.23
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,1*	0,1*	0.13
260030	Peas (with pods) (Mangetout (sugar peas, snow peas))	0,1*	0,2	0.23
260040	Peas (without pods) (Garden pea,	0,1*	0,1*	0.13

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiophanate-methyl (R)	Carbendazim and benomyl (sum of benomyl and carbendazim expressed as carbendazim) (R)	Combined MRLs for the chronic RA ((MRL (T)*0.25)+ MRL (C))
	green pea, chickpea)			
260050	Lentils	0,1*	0,1*	0.13
260990	Others	0,1*	0,1*	0.13
270000	(vii) Stem vegetables (fresh)	0,1*	0,1*	0.13
270010	Asparagus	0,1*	0,1*	0.13
270020	Cardoons	0,1*	0,1*	0.13
270030	Celery	0,1*	0,1*	0.13
270040	Fennel	0,1*	0,1*	0.13
270050	Globe artichokes	0,1*	0,1*	0.13
270060	Leek	0,1*	0,1*	0.13
270070	Rhubarb	0,1*	0,1*	0.13
270080	Bamboo shoots	0,1*	0,1*	0.13
270090	Palm hearts	0,1*	0,1*	0.13
270990	Others	0,1*	0,1*	0.13
280000	(viii) Fungi	0,1*		0.03
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,1*	1	1.03
280020	Wild (Chanterelle, Truffle, Morel, Cep)	0,1*	0,1*	0.13
280990	Others	0,1*	0,1*	0.13
290000	(ix) Sea weeds	0,1	0,1*	0.13
300000	3. PULSES, DRY	0,1*	0,1*	0.13
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,1*	0,1*	0.13
300020	Lentils	0,1*	0,1*	0.13
300030	Peas (Chickpeas, field peas, chickling vetch)	0,1*	0,1*	0.13
300040	Lupins	0,1*	0,1*	0.13
300990	Others	0,1*	0,1*	0.13
400000	4. OILSEEDS AND OILFRUITS			0.00
401000	(i) Oilseeds			0.00
401010	Linseed	0,1*	0,1*	0.13
401020	Peanuts	0,1*	0,1*	0.13
401030	Poppy seed	0,1*	0,1*	0.13
401040	Sesame seed	0,1*	0,1*	0.13
401050	Sunflower seed	0,1*	0,1*	0.13
401060	Rape seed (Bird rapeseed, turnip rape)	0,1*	0,1*	0.13
401070	Soya bean	0,3	0,2	0.28
401080	Mustard seed	0,1*	0,1*	0.13
401090	Cotton seed	0,1*	0,1*	0.13
401100	Pumpkin seeds (Other seeds of cucurbitacea)	0,1*	0,1*	0.13
401110	Safflower	0,1*	0,1*	0.13
401120	Borage	0,1*	0,1*	0.13
401130	Gold of pleasure	0,1*	0,1*	0.13
401140	Hempseed	0,1*	0,1*	0.13
401150	Castor bean	0,1*	0,1*	0.13
401990	Others	0,1*	0,1*	0.13
402000	(ii) Oilfruits	0,1*	0,1*	0.13
402010	Olives for oil production	0,1*	0,1*	0.13
402020	Palm nuts (palmoil kernels)	0,1*	0,1*	0.13
402030	Palmfruit	0,1*	0,1*	0.13
402040	Kapok	0,1*	0,1*	0.13
402990	Others	0,1*	0,1*	0.13
500000	5. CEREALS			0.00
500010	Barley	0,3	2	2.08
500020	Buckwheat (Amaranthus, quinoa)	0,01*	0,01*	0.01
500030	Maize	0,01*	0,01*	0.01
500040	Millet (Foxtail millet, teff)	0,01*	0,01*	0.01
500050	Oats	0,3	2	2.08
500060	Rice	0,01*	0,01*	0.01
500070	Rye	0,05	0,1	0.11
500080	Sorghum	0,01*	0,01*	0.01
500090	Wheat (Spelt, triticale)	0,05	0,1	0.11
500990	Others	0,01*	0,01*	0.01
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*	0,1*	0.13
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*	0,1*	0.13
620000	(ii) Coffee beans	0,1*	0,1*	0.13
630000	(iii) Herbal infusions (dried)	0,1*	0,1*	0.13
631000	(a) Flowers	0,1*	0,1*	0.13
631010	Camomille flowers	0,1*	0,1*	0.13
631020	Hybiscus flowers	0,1*	0,1*	0.13
631030	Rose petals	0,1*	0,1*	0.13
631040	Jasmine flowers (Elderflowers (Sambucus nigra))	0,1*	0,1*	0.13
631050	Lime (linden)	0,1*	0,1*	0.13
631990	Others	0,1*	0,1*	0.13
632000	(b) Leaves	0,1*	0,1*	0.13
632010	Strawberry leaves	0,1*	0,1*	0.13
632020	Rooibos leaves (Ginkgo leaves)	0,1*	0,1*	0.13
632030	Maté	0,1*	0,1*	0.13
632990	Others	0,1*	0,1*	0.13
633000	(c) Roots	0,1*	0,1*	0.13
633010	Valerian root	0,1*	0,1*	0.13
633020	Ginseng root	0,1*	0,1*	0.13

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiophanate-methyl (R)	Carbendazim and benomyl (sum of benomyl and carbendazim expressed as carbendazim) (R)	Combined MRLs for the chronic RA ((MRL (T)*0.25)+ MRL (C))
633990	Others	0,1*	0,1*	0.13
639000	(d) Other herbal infusions	0,1*	0,1*	0.13
640000	(iv) Cocoa (fermented beans)	0,1*	0,1*	0.13
650000	(v) Carob (st johns bread)	0,1*	0,1*	0.13
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,1*	0,1*	0.13
800000	8. SPICES	0,1*	0,1*	0.13
810000	(i) Seeds	0,1*	0,1*	0.13
810010	Anise	0,1*	0,1*	0.13
810020	Black caraway	0,1*	0,1*	0.13
810030	Celery seed (Lovage seed)	0,1*	0,1*	0.13
810040	Coriander seed	0,1*	0,1*	0.13
810050	Cumin seed	0,1*	0,1*	0.13
810060	Dill seed	0,1*	0,1*	0.13
810070	Fennel seed	0,1*	0,1*	0.13
810080	Fenugreek	0,1*	0,1*	0.13
810090	Nutmeg	0,1*	0,1*	0.13
810990	Others	0,1*	0,1*	0.13
820000	(ii) Fruits and berries	0,1*	0,1*	0.13
820010	Allspice	0,1*	0,1*	0.13
820020	Anise pepper (Japan pepper)	0,1*	0,1*	0.13
820030	Caraway	0,1*	0,1*	0.13
820040	Cardamom	0,1*	0,1*	0.13
820050	Juniper berries	0,1*	0,1*	0.13
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*	0,1*	0.13
820070	Vanilla pods	0,1*	0,1*	0.13
820080	Tamarind	0,1*	0,1*	0.13
820990	Others	0,1*	0,1*	0.13
830000	(iii) Bark	0,1*	0,1*	0.13
830010	Cinnamon (Cassia)	0,1*	0,1*	0.13
830990	Others	0,1*	0,1*	0.13
840000	(iv) Roots or rhizome	0,1*	0,1*	0.13
840010	Liquorice	0,1*	0,1*	0.13
840020	Ginger	0,1*	0,1*	0.13
840030	Turmeric (Curcuma)	0,1*	0,1*	0.13
840040	Horseradish	0,1*	0,1*	0.13
840990	Others	0,1*	0,1*	0.13
850000	(v) Buds	0,1*	0,1*	0.13
850010	Cloves	0,1*	0,1*	0.13
850020	Capers	0,1*	0,1*	0.13
850990	Others	0,1*	0,1*	0.13
860000	(vi) Flower stigma	0,1*	0,1*	0.13
860010	Saffron	0,1*	0,1*	0.13
860990	Others	0,1*	0,1*	0.13
870000	(vii) Aril	0,1*	0,1*	0.13
870010	Mace	0,1*	0,1*	0.13
870990	Others	0,1*	0,1*	0.13
900000	9. SUGAR PLANTS	0,1*	0,1*	0.13
900010	Sugar beet (root)	0,1*	0,1*	0.13
900020	Sugar cane	0,1*	0,1*	0.13
900030	Chicory roots	0,1*	0,1*	0.13
900990	Others	0,1*	0,1*	0.13
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS			0.00
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*	0,05*	0.06
1011000	(a) Swine	0,05*	0,05*	0.06
1011010	Meat	0,05*	0,05*	0.06
1011020	Fat free of lean meat	0,05*	0,05*	0.06
1011030	Liver	0,05*	0,05*	0.06
1011040	Kidney	0,05*	0,05*	0.06
1011050	Edible offal	0,05*	0,05*	0.06
1011990	Others	0,05*	0,05*	0.06
1012000	(b) Bovine	0,05*	0,05*	0.06
1012010	Meat	0,05*	0,05*	0.06
1012020	Fat	0,05*	0,05*	0.06
1012030	Liver	0,05*	0,05*	0.06
1012040	Kidney	0,05*	0,05*	0.06
1012050	Edible offal	0,05*	0,05*	0.06
1012990	Others	0,05*	0,05*	0.06
1013000	(c) Sheep	0,05*	0,05*	0.06
1013010	Meat	0,05*	0,05*	0.06
1013020	Fat	0,05*	0,05*	0.06
1013030	Liver	0,05*	0,05*	0.06
1013040	Kidney	0,05*	0,05*	0.06
1013050	Edible offal	0,05*	0,05*	0.06
1013990	Others	0,05*	0,05*	0.06
1014000	(d) Goat	0,05*	0,05*	0.06
1014010	Meat	0,05*	0,05*	0.06
1014020	Fat	0,05*	0,05*	0.06
1014030	Liver	0,05*	0,05*	0.06
1014040	Kidney	0,05*	0,05*	0.06
1014050	Edible offal	0,05*	0,05*	0.06
1014990	Others	0,05*	0,05*	0.06

Code number	Groups and examples of individual products to which the MRLs apply (a)	Thiophanate-methyl (R)	Carbendazim and benomyl (sum of benomyl and carbendazim expressed as carbendazim) (R)	Combined MRLs for the chronic RA ((MRL (T)*0.25)+ MRL (C))
1015000	(e) Horses, asses, mules or hinnies	0,05*	0,05*	0.06
1015010	Meat	0,05*	0,05*	0.06
1015020	Fat	0,05*	0,05*	0.06
1015030	Liver	0,05*	0,05*	0.06
1015040	Kidney	0,05*	0,05*	0.06
1015050	Edible offal	0,05*	0,05*	0.06
1015990	Others	0,05*	0,05*	0.06
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*	0,05*	0.06
1016010	Meat	0,05*	0,05*	0.06
1016020	Fat	0,05*	0,05*	0.06
1016030	Liver	0,05*	0,05*	0.06
1016040	Kidney	0,05*	0,05*	0.06
1016050	Edible offal	0,05*	0,05*	0.06
1016990	Others	0,05*	0,05*	0.06
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*	0,05*	0.06
1017010	Meat	0,05*	0,05*	0.06
1017020	Fat	0,05*	0,05*	0.06
1017030	Liver	0,05*	0,05*	0.06
1017040	Kidney	0,05*	0,05*	0.06
1017050	Edible offal	0,05*	0,05*	0.06
1017990	Others	0,05*	0,05*	0.06
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*	0,05*	0.06
1020010	Cattle	0,05*	0,05*	0.06
1020020	Sheep	0,05*	0,05*	0.06
1020030	Goat	0,05*	0,05*	0.06
1020040	Horse	0,05*	0,05*	0.06
1020990	Others	0,05*	0,05*	0.06
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*	0,05*	0.06
1030010	Chicken	0,05*	0,05*	0.06
1030020	Duck	0,05*	0,05*	0.06
1030030	Goose	0,05*	0,05*	0.06
1030040	Quail	0,05*	0,05*	0.01
1030990	Others	0,05*	0,05*	0.06
1040000	(iv) Honey (Royal jelly, pollen)	1	1	1.25
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*	0,05*	0.06
1060000	(vi) Snails	0,05*	0,05*	0.06
1070000	(vii) Other terrestrial animal products	0,05*	0,05*	0.06

(*) Indicates lower limit of analytical determination

(R) = The residue definition differs for the following combinations pesticide-code number: hiofanate-methyl - code 1000000: Carbendazim and thiophanate-methyl, expressed as arbendazim

Appendix D. RESIDUE TRIALS DATA

PHI	Trial 1		RD (chronic exposure)[a]	RD (acute exposure)[b]	Trial 2		RD (chronic exposure)[a]	RD (acute exposure)[b]	Trial 3		RD (chronic exposure)[a]	RD (acute exposure)[b]	Trial 4		RD (chronic exposure)[a]	RD (acute exposure)[b]
	T	C			T	C			T	C			T	C		
3	0.086	0.038			0.44	0.07			0.82	0.1			1.02	0.03		
7-8	0.078	0.06			0.7	0.14			0.8	0.2			0.39	0.07		
13-15	0.023	0.032	0.04	0.03	0.13[c]	0.08[c]	**0.11**	**0.09**	0.04[c]	0.1[c]	**0.11**	**0.10**	0.43[c]	0.08	0.19	0.12
21-22	0.056[c]	0.053[c]	**0.07**	**0.06**	0.03	0.05	0.06	0.05	0.01	0.07	0.07	0.07	0.29	0.12[c]	**0.19**	**0.15**
28	<0.01	0.034			0.02	0.07			<0.01	0.09			0.16	0.09		

PHI	Trial 5		RD (chronic exposure)[a]	RD (acute exposure)[b]	Trial 6		RD (chronic exposure)[a]	RD (acute exposure)[b]	Trial 7		RD (chronic exposure)[a]	RD (acute exposure)[b]	Trial 8		RD (chronic exposure)[a]	RD (acute exposure)[b]
	T	C			T	C			T	C			T	C		
3	0.52	0.01			1.01	0.2			-	-			-	-		
7-8	0.09	0.08			0.73	0.27			0.82	0.23			0..39	0.11		
13-15	0.06	0.04	0.06	0.05	0.31[c]	0.14[c]	**0.22**	**0.17**	0.2[c]	0.18[c]	**0.23**	**0.2**	0.16[c]	0.09[c]	**0.13**	**0.11**
21-22	0.07[c]	0.15[c]	**0.17**	**0.16**	0.11	0.14	0.17	0.15	-	-			-	-		
28	0.01	0.10			0.04	0.10										

(a): Residue trial values expressed according to the risk assessment residue definition (thiophanate-methyl (*0.25)and carbendazim, expressed as carbendazim), considering toxicological potency factor of 0.25 for chronic exposure assessment

(b): Residue trial values expressed according to the risk assessment residue definition (thiophanate-methyl (*0.1) and carbendazim, expressed as carbendazim), considering toxicological potency factor of 0.1 for acute exposure assessment

(c) : The underlined values are selected for deriving the MRL proposals

T: Thiophanate-methyl

C: Carbendazim

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
ca.	circa, approximately
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DE	Germany
DK	Denmark
DM	dry matter
EC	European Commission
EFSA	European Food Safety Authority
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GLP	Good Laboratory Practice
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
i.e.	that is (id est, *Latin*)
ILV	Independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram

IE	Ireland
L	litre
LC	liquid chromatography
LOD	limit of detection
LOQ	limit of quantification (determination)
MRL	maximum residue limit
MS	Member States
MS/MS	tandem mass spectrometry
NEU	northern European Union
OECD	Organization for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RD	residue definition
RMS	rapporteur Member State
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UK	United Kingdom
UV	ultra-violet (detection or detector)
VF	variability factor
WG	water dispersible granule
WHO	World Health Organisation
wk	week
WP	wettable powder
yr	year