

REASONED OPINION OF EFSA

Refined risk assessment regarding certain MRLs of concern for the active substances carbendazim and thiophanate-methyl¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00467 and EFSA-Q-2009-00468)

Issued on 14 May 2009

SUMMARY

On 15 September 2008, EFSA issued a reasoned opinion where certain MRLs of concern were identified for the active substance carbendazim and the lowering of these MRLs was recommended. These recommendations mainly resulted from the fact that not all information was made available to EFSA for refinement of the intake calculations, in particular with regard to the use of thiophanate-methyl, which generates residues of carbendazim as well. Some of the available information also indicated the need for increasing the existing MRLs while this was not covered by the terms of reference provided to EFSA at that time.

The European Commission therefore provided on 26 February 2009 new terms of reference requesting EFSA to review the existing EC MRLs for both carbendazim and thiophanate-methyl in the crops where intake calculations could not be refined. EFSA is no longer requested to assess only the safety of the existing MRLs for these active substances but also to verify whether a modification of the MRLs might be required based on the available data. For this purpose, additional information was provided by the Rapporteur Member State Germany.

As thiophanate-methyl is a precursor of carbendazim and both active substances are closely related, it was decided to address the assessment of both active substances in one reasoned opinion. Based on the information provided by Germany, EFSA derives the following conclusions.

The authorized uses reported by Germany for carbendazim and thiophanate-methyl in citrus fruits, pome fruits, peaches, mangoes and tomatoes are adequately supported by residues trials data and MRL proposals were derived for carbendazim and thiophanate-methyl separately (see table below). The effect of peeling on the magnitude of residues in citrus fruits and mangoes was investigated and relevant processing factors were derived. It should be noted that the nature of residues was not investigated in the framework of this request, nor was the impact of the authorized uses on residues in livestock and/or rotational crops. It is assumed

¹ For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the refined risk assessment regarding certain MRLs of concern for the active substances carbendazim and thiophanate-methyl. *EFSA Scientific Report (2009) 289, 1-29*

that these aspects of the pesticide residues risk assessment were already properly addressed under the former pesticide MRL legislation. Moreover, a review of all existing MRLs for carbendazim and thiophanate-methyl will be performed under Article 12(2) of Regulation (EC) No 396/2005.

Although separate MRLs are proposed for carbendazim and thiophanate-methyl, both active substances share a common mechanism of toxicity. A combined consumer exposure assessment was therefore performed considering the available residues trials data as well as the respective potencies of the active substances. With regard to the chronic exposure, no exceedance of the ADI was identified. The highest chronic exposure was calculated for Irish adults, representing 46% of the ADI. With regard to the acute exposure, no intake concerns were identified for mandarins, lemons, limes, pome fruits, peaches, and mangoes but exceedances of the ARfD were identified for oranges, grapefruits and tomatoes representing 212%, 143% and 119% of the ARfD, respectively.

Fall-back MRLs for oranges, grapefruit and tomatoes were therefore derived based on less critical GAPs and included in a second intake calculation. When these fall-back MRLs are considered, acute exposures are no longer exceeding the ARfD, representing 43%, 40% and 65% of the ARfD, respectively.

MRL recommendations resulting from the assessment are summarized in the table below.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
<i>Residue definition for enforcement: sum of carbendazim and benomyl, expressed as carbendazim</i>			
Grapefruit	0.5	0.2	Based on the use of carbendazim in South-Africa a raising of the MRL could be proposed but for this MRL a risk to consumers was identified. A fall-back MRL is therefore recommended based on the post-harvest use of thiophanate-methyl.
Oranges	0.5	0.2	
Lemons	0.5	0.7	It is proposed to raise the existing MRL based on the use of carbendazim in South-Africa, also covering the post-harvest use of thiophanate-methyl. No risk to consumers is identified.
Limes	0.5	0.7	
Mandarins	0.5	0.7	
Apples	0.2	0.2	The existing MRL is confirmed based on the use of thiophanate-methyl. No risk to consumers is identified.
Pears	0.2	0.2	
Quinces	0.2	0.2	
Medlar	0.2	0.2	
Loquat	2	0.2	No data were made available in support of the existing MRL. It is therefore proposed to lower the MRL based on the use of thiophanate-methyl. No risk to consumers is identified.
Peaches	0.2	0.2	The existing MRL is confirmed based on the use of thiophanate-methyl. No risk to consumers is identified.
Mangoes	0.5	0.5	

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Tomatoes	0.5	0.3	The existing MRL is adequately supported by data but a risk to consumers was identified. A fall-back MRL is proposed based on the outdoor use of thiophanate-methyl.
Residue definition for enforcement: <i>thiophanate-methyl</i>			
Grapefruit	0.1*	6	It is proposed to raise the MRL based on the post-harvest use of thiophanate-methyl. No risk to consumers is identified.
Oranges	0.1*	6	
Lemons	0.1*	6	
Limes	0.1*	6	
Mandarins	0.1*	6	
Apples	0.5	0.5	The existing MRL is confirmed. No risk to consumers is identified.
Pears	0.5	0.5	
Quinces	0.5	0.5	
Medlar	2	0.5	No data were made available in support of the existing MRL. It is therefore proposed to lower the MRL based on the use of thiophanate-methyl. No risk to consumers is identified.
Loquat	2	0.5	
Peaches	2	2	The existing MRL is confirmed. No risk to consumers is identified.
Mangoes	1	1	
Tomatoes	2	1	The existing MRL is adequately supported by data but a risk to consumers was identified. A fall-back MRL is proposed based on the outdoor use of thiophanate-methyl.

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

Key words: carbendazim, thiophanate-methyl, MRLs of concern, Regulation (EC) No 396/2005, refined consumer risk assessment, benzimidazole fungicides, benomyl

TABLE OF CONTENTS

Background	5
Terms of reference	5
The active substances and their use patterns.....	6
Assessment	7
1. Introduction	7
2. Mammalian toxicology	8
3. Residues.....	8
3.1. Magnitude of residues in the raw agricultural commodities	8
3.2. Magnitude of residues in the edible portions.....	12
4. Consumer risk assessment	13
Conclusions and recommendations	15
Documentation provided to EFSA	15
References	17
Appendix A – Good Agricultural Practices (GAPs).....	18
Appendix B – Pesticide Residues Intake Model (PRIMo).....	19
Appendix C – Pesticide Residues Intake Model (PRIMo) with fall-back MRLs	21
Appendix D – Existing EC MRLs.....	23
Glossary / Abbreviations.....	29

BACKGROUND

On 30 June 2008, the European Commission requested EFSA, according to Article 43 of Regulation (EC) No 396/2005, to provide scientific advice on the safety of the existing MRLs for the active substance carbendazim. As a consequence, EFSA issued a reasoned opinion on 15 September 2008 where certain MRLs of concern were identified and the lowering of these MRLs was recommended. These recommendations mainly resulted from the fact that not all information was made available to EFSA for refinement of the intake calculations, in particular with regard to the use of thiophanate-methyl, which generates residues of carbendazim as well. Some of the available information also indicated the need for increasing the existing MRLs while this was not covered by the terms of reference provided to EFSA at that time.

The European Commission therefore provided on 26 February 2009 new terms of reference requesting EFSA to review the existing EC MRLs for both carbendazim and thiophanate-methyl in the crops where intake calculations could not be refined. EFSA was also requested to verify whether a modification of the MRLs might be required based on the available data. For this purpose, additional information was provided by the Rapporteur Member State Germany.

After having accepted the new terms of reference, the request was included in the EFSA Register of Questions as EFSA-Q-2009-00467 and EFSA-Q-2009-00468, for carbendazim and thiophanate-methyl, respectively.

TERMS OF REFERENCE

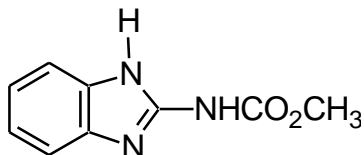
EFSA was requested by the European Commission to review the existing MRLs for carbendazim and thiophanate-methyl in citrus fruits, pome fruits, mangoes and tomatoes. In particular, EFSA is requested to answer the following questions regarding these pesticide-commodity combinations:

- (1) Are the MRLs safe in terms of consumer exposure?
- (2) If they are not safe, what are the levels that are still safe?
- (3) Do the data on authorised uses and the residue trials of both carbendazim and thiophanate-methyl support the existing MRLs?
- (4) If not, what are the appropriate MRLs for these crops, based on the underlying data?
- (5) Are the latter MRLs safe?

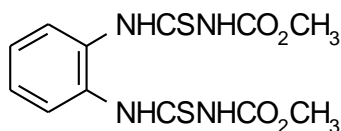
Following personal communication with a representative of the European Commission, peaches was included in the request as well.

THE ACTIVE SUBSTANCES AND THEIR USE PATTERNS

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



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



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, fruit 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.

Both carbendazim and thiophanate-methyl have been assessed in the first stage of the peer review process under Directive 91/414/EEC with Germany being the designated Rapporteur Member State. For this stage of the work programme, EFSA was not yet involved. During the peer review of carbendazim, safe uses were demonstrated on wheat, rye, triticale, barley, oats, oilseed rape (all for Northern EU), sugar beet (Northern and Southern EU) and maize (Southern EU). As a result a decision on inclusion of carbendazim in Annex I to Directive 91/414/EEC was published by Directive 2006/135/EEC and entered into force on 1 January 2007. This inclusion, however, will expire on 31 December 2009 and is linked to specific restrictions. In particular, only uses on cereals, rapeseed, sugar beet and maize may be authorised with respective application rates of 0.25 kg/ha, 0.25 kg/ha, 0.075 kg/ha and 0.1 kg/ha. For thiophanate-methyl, the peer review revealed safe uses in Northern and Southern Europe for cereals, oilseed rape, pulses, legume vegetables and several fruiting crops. The subsequent inclusion of thiophanate-methyl in Annex I to Directive 91/414/EEC was published by Directive 2005/53/EC, which entered into force on 01 March 2006. Unlike carbendazim, the Annex I inclusion of thiophanate-methyl is valid for a period of 10 years without particular restrictions.

EC MRLs for carbendazim and thiophanate-methyl in products of plant and animal origin have been set for the first time in 1993 by means of Directive 93/57/EC and Directive 93/58/EC. These MRLs were initially set for the sum of carbendazim, benomyl and thiophanate-methyl because at that time analytical methods were not able to differentiate between the three substances. In the meantime, an analytical method differentiating

thiophanate-methyl from the two other substances was made available. MRLs for these active substances have therefore been revised in 2006, resulting in separate MRL proposals for thiophanate-methyl and for the sum of carbendazim and benomyl. These MRLs have been modified on several occasions in order to consider new uses and were transferred to Annex II of Regulation (EC) No 396/2005 without any 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 carbendazim and thiophanate-methyl are summarized in Appendix D. It is noted that CXLs for carbendazim and thiophanate-methyl were also established by the Codex Alimentarius. These CXLs, however, still refer to the sum of carbendazim, benomyl and thiophanate-methyl, which is not in line with the residue definitions currently established at European level.

EFSA is now requested by the European Commission to review the existing MRLs for carbendazim and thiophanate-methyl in citrus fruits, pome fruits, peaches, mangoes and tomatoes. For this purpose, several GAPS were reported by Germany (see Appendix A). These GAPS mainly include foliar and post-harvest treatments with thiophanate-methyl as well as a foliar treatment of citrus fruits with carbendazim in South Africa. It is noted that uses of carbendazim within the European Community were not considered in this assessment as they are no longer compliant with the restrictions set out in Annex I to Directive 91/414/EEC.

ASSESSMENT

1. Introduction

Although separate MRLs are currently set for thiophanate-methyl and carbendazim, it was decided to report the assessment of both active substances in one reasoned opinion because thiophanate-methyl is a precursor of carbendazim. This means that the use of thiophanate-methyl as a pesticide will generate residues of both thiophanate-methyl and carbendazim. It is noted that the active substance benomyl is also a precursor of carbendazim but the use of benomyl was phased out within the European Community. Benomyl was therefore not further considered in the framework of this assessment.

The terms of reference provided by the European Commission refer specifically to a number of crops and explicitly request EFSA to assess the validity of the existing MRL based on the underlying authorizations. The approach followed in this reasoned opinion is therefore slightly different compared to the approach applied in the previous reasoned opinion for carbendazim (EFSA, 2008). EFSA first reviewed the residues trials data which are in compliance with the authorizations reported by Germany for the commodities under assessment (see Appendix A). In addition, the effect of peeling for the relevant fruit crops was investigated. Based on the residue levels obtained intake calculations were performed and recommendations for the setting of MRLs were derived.

It should be noted that the nature of residues was not investigated in the framework of this request, nor was the impact of the authorized uses on residues in livestock and/or rotational crops. It is assumed that these aspects of the pesticide residues risk assessment were already properly addressed under the former pesticide MRL legislation. Moreover, a review of all existing MRLs for carbendazim and thiophanate-methyl will be performed under Article 12(2) of Regulation (EC) No 396/2005.

2. Mammalian toxicology

The toxicological properties of both carbendazim (European Commission, 2007) and thiophanate-methyl (European Commission, 2005) were peer reviewed in the framework of Directive 91/414/EEC. 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 (mg/kg bw/d)	Study relied upon	Safety factor
<i>Carbendazim</i>					
ADI	COM	2007	0.02	developmental study in rats and rabbits	500
ARfD	COM	2007	0.02	developmental study in rats and rabbits	500
<i>Thiophanate-methyl</i>					
ADI	COM	2005	0.08	1 year dog study, 2 year rat study	100
ARfD	COM	2005	0.2	developmental study in rabbits	100

3. Residues

3.1. Magnitude of residues in the raw agricultural commodities

Germany reported an adequate number of residues trials in support of the GAPs for carbendazim and thiophanate-methyl. It is noted that some of the trials were slightly under dosed, in particular for pome fruits, peaches and tomatoes, but still within the acceptable range of $\pm 25\%$ of the GAP. The residue levels of carbendazim and thiophanate-methyl resulting from the supported uses are reported separately in Table 3-1. The overall availability of residues trials is considered acceptable to propose appropriate MRL as well as corresponding risk assessment values.

The assessment for mangoes is based on the Brazilian GAP as no data are available for the African GAPs. Additionally, the levels of carbendazim and thiophanate-methyl were not measured separately in the Brazilian trials. Both MRL proposals for carbendazim and thiophanate-methyl are therefore derived based on the total residue. As this is expected to overestimate the real residue levels, the approach was considered acceptable for a minor crop only.

The level of 1.80 mg/kg for thiophanate-methyl in tomatoes was identified as a possible outlier using the Dixon-Q test but a possible cause for this higher level was not made available in the residues trials. Additionally, this level of 1.81 mg/kg should be considered together with the corresponding level of carbendazim (0.23 mg/kg), which is in the range of the other carbendazim values. It was therefore decided by EFSA to consider the value of 1.81 mg/kg for thiophanate-methyl in tomatoes as a valid result.

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

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)	STMR (b) (mg/kg)	HR (c) (mg/kg)	MRL proposal (mg/kg)	Comments
<u>Residue definition for enforcement: sum of carbendazim and benomyl, expressed as carbendazim</u>							
Citrus fruits: - Oranges - Grapefruit - Mandarins - Lemons - Limes	Import (ZA)	Outdoor	0.05; 0.15; 0.15; 0.20; 0.22; 0.24; 0.24; 0.24; 0.27; 0.27; 0.30; 0.31; 0.34; 0.35; 0.44; 0.60	0.26	0.60	0.7	Combined dataset on oranges (8) and lemons (8) resulting from the foliar treatment with carbendazim can be extrapolated to the whole group. Rmax = 0.591 Rber = 0.635
	EU	Post-harvest use	0.06; 0.06; 0.08; 0.08; 0.08; 0.08; 0.09; 0.09	0.08	0.09	0.2	Combined dataset on oranges (4) and mandarins (4) resulting from the post-harvest treatment with thiophanate-methyl can be extrapolated to the whole group. Rmax = 0.115 Rber = 0.165
Pome fruits: - Apples - Pears - Loquat - Medlar - Quinces	NEU	Outdoor	0.04; 0.07; 0.08; 0.08; 0.08; 0.09; 0.12; 0.16	0.08	0.16	0.2	Dataset on apples resulting from the use of thiophanate-methyl can be extrapolated to the whole group. Rmax = 0.204 Rber = 0.195
	SEU	Outdoor	0.03; 0.03; 0.04; 0.04; 0.04; 0.07; 0.09; 0.09; 0.12	0.04	0.12	0.2	Dataset on apples resulting from the use of thiophanate-methyl can be extrapolated to the whole group. Rmax = 0.160 Rber = 0.180
Peaches	SEU	Outdoor	0.04; 0.04; 0.04; 0.06; 0.07; 0.08; 0.08; 0.09	0.07	0.09	0.2	Complete dataset on peaches resulting from the use of thiophanate-methyl Rmax = 0.128 Rber = 0.160

Commodity	Region ^(a)	Outdoor /Indoor	Individual trial results (mg/kg)	STMR ^(b) (mg/kg)	HR ^(c) (mg/kg)	MRL proposal (mg/kg)	Comments
Mangoes	Import (BR)	Outdoor	<0.05; 0.12; 0.12; 0.35	0.12	0.35	0.5	Complete dataset on mangoes resulting from the use of thiophanate-methyl. Residue levels were determined as the sum of thiophanate-methyl and carbendazim and expressed as carbendazim. This is considered acceptable for a minor crop (worst case). Rmax = 0.833 Rber = 0.355
Tomatoes	EU	Indoor	0.05; 0.05; 0.07; 0.07; 0.11; 0.15; 0.18; 0.23	0.09	0.23	0.4	Complete dataset on tomatoes resulting from the use of thiophanate-methyl Rmax = 0.327 Rber = 0.315
	SEU	Outdoor	0.03; 0.05; 0.05; 0.06; 0.06; 0.09; 0.16; 0.25	0.06	0.25	0.3	Complete dataset on tomatoes resulting from the use of thiophanate-methyl Rmax = 0.332 Rber = 0.215
<u>Residue definition for enforcement: <i>thiophanate-methyl</i></u>							
Citrus fruits: - Oranges - Grapefruit - Mandarins - Lemons - Limes	EU	Indoor	1.40; 1.70; 2.00; 2.40; 2.60; 2.90; 3.10; 4.30	2.5	4.3	6	Combined dataset on oranges (4) and mandarins (4) resulting from the European post-harvest treatment with thiophanate-methyl can be extrapolated to the whole group. Rmax = 5.467 Rber = 5.900
Pome fruits: - Apples - Pears - Loquat	NEU	Outdoor	0.03; 0.07; 0.12; 0.14; 0.15; 0.24; 0.26; 0.42	0.15	0.42	0.5	Dataset on apples resulting from the Northern European use of thiophanate-methyl can be extrapolated to the whole group. Rmax = 0.575 Rber = 0.490

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)	STMR (b) (mg/kg)	HR ^(c) (mg/kg)	MRL proposal (mg/kg)	Comments
- Medlar - Quinces	SEU	Outdoor	0.03; 0.05; 0.14; 0.20; 0.20; 0.24; 0.25; 0.32; 0.35	0.20	0.35	0.5	Dataset on apples resulting from the Southern European use of thiophanate-methyl can be extrapolated to the whole group. Rmax = 0.530 Rber = 0.500
Peaches	SEU	Outdoor	0.20; 0.27; 0.27; 0.34; 0.45; 0.51; 0.74; 0.78	0.40	0.78	2	Complete dataset on peaches resulting from the use of thiophanate-methyl Rmax = 1.143 Rber = 1.135
Mangoes	Import (BR)	Outdoor	<0.1; 0.20; 0.20; 0.60	0.2	0.6	1	Complete dataset on mangoes resulting from the use of thiophanate-methyl. Residue levels were determined as the sum of thiophanate-methyl and carbendazim and expressed as thiophanate-methyl. This is considered acceptable for a minor crop (worst case). Rmax = 1.416 Rber = 0.600
Tomatoes	EU	Indoor	0.18; 0.23; 0.23; 0.25; 0.35; 0.42; 0.47; 1.80	0.3	1.8	2	Complete dataset on tomatoes resulting from the use of thiophanate-methyl Rmax = 2.208 Rber = 0.865
	SEU	Outdoor	0.14; 0.20; 0.21; 0.23; 0.44; 0.48; 0.53; 0.55	0.34	0.55	1	Complete dataset on tomatoes resulting from the use of thiophanate-methyl Rmax = 0.884 Rber = 0.985

(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.

3.2. Magnitude of residues in the edible portions

Citrus fruits and mangoes are usually consumed after removal of the peel. The effect of peeling was therefore further investigated in these fruit crops and processing factors were derived (see Table 3-2).

The processing factor for carbendazim in citrus fruits was reported by Germany. It is based on the carbendazim levels measured in citrus peel and pulp after foliar application of carbendazim. Carbendazim levels were also measured following post-harvest treatment with thiophanate-methyl but in this case all residue levels in the pulp were below the LOQ, which would result in an overestimation of the processing factor. The processing factor derived from the foliar application of carbendazim was therefore considered to be more relevant and to cover the post-harvest treatment with thiophanate-methyl as well.

The processing factor for thiophanate-methyl was not reported by Germany, but based on the available trials for the post-harvest treatment with thiophanate-methyl EFSA was able to derive a median processing factor. For this purpose, only the trials with positive findings in the pulp were considered because residue levels below the LOQ tend to bias the resulting processing factor. In addition, residue levels were selected regardless of the PHI because decline of residues after the post-harvest treatment is limited.

The processing factor for carbendazim and thiophanate-methyl in mangoes was derived from levels observed following the foliar application of thiophanate-methyl. It is noted that both factors are based on the residue levels measured for the sum of both compounds. Considering however that mangoes is a minor crop and that residue levels in the raw agricultural commodities are already expected to overestimate real residue levels (see section 3.1), this processing factor is considered acceptable for risk assessment.

Table 3-2. Overview of the available processing factors

Processed commodity	Number of trials	Median PF ^(a)	Comments
<u>Residue definition for enforcement: <i>sum of carbendazim and benomyl, expressed as carbendazim</i></u>			
Citrus fruits, peeled	16	0.46	Derived from carbendazim levels following foliar treatment with carbendazim. Covers carbendazim levels resulting from the post-harvest treatment with thiophanate-methyl as well.
Mangoes, peeled	4	0.40	Derived from the levels of carbendazim and thiophanate-methyl (sum) following foliar treatment with thiophanate-methyl. Considered acceptable for risk assessment of a minor crop.
<u>Residue definition for enforcement: <i>thiophanate-methyl</i></u>			
Citrus fruits, peeled	10	0.11	Derived from thiophanate-methyl levels following a post-harvest treatment with thiophanate-methyl. Only trials with measurable residues in the pulp were considered.

Processed commodity	Number of trials	Median PF ^(a)	Comments
Mangoes, peeled	4	0.40	Derived from the levels of carbendazim and thiophanate-methyl (sum) following foliar treatment with thiophanate-methyl. Considered acceptable for risk assessment of a minor crop.

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

4. Consumer risk assessment

Both acute and chronic intake calculations were performed for the sum of benomyl, carbendazim and thiophanate-methyl using revision 2 of the EFSA PRIMo. Although MRLs for carbendazim and benomyl are proposed separately from the MRLs for thiophanate-methyl, the three active substances share a same mechanism of toxicity. Therefore a combined risk assessment needs to be performed considering their respective potencies. As the ADI for thiophanate-methyl is 4 times higher than the ADI 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 from the ARfD values. As benomyl is no longer authorised for use within the European Community, it is not expected to contribute to the toxicological burden. It is noted that ideally potency factors should be based on more detailed information rather than the toxicological reference values. Nevertheless, in this particular case the uncertainty is reduced by the fact that thiophanate-methyl is a precursor of carbendazim.

The input values used for both the chronic and the acute intake calculations are summarized in Table 4-1. These values are equal to the sum of the STMR and HR values derived under section 3.1, expressed as carbendazim and considering the lower potency of thiophanate-methyl. For citrus fruits and mangoes, the processing factors derived in section 3.2 were also considered. Besides the input values listed in Table 4-1, all residues resulting from uses on other crops need to be considered for the chronic intake assessment, including information on authorized uses and STMR values. As this information is currently not available to EFSA, it was decided to include all existing EC MRLs for carbendazim and thiophanate-methyl in the chronic intake calculations. For each commodity, the existing MRLs were summed considering a potency factor of 0.25 for thiophanate-methyl (see Appendix D). It is noted by EFSA that this conservative approach is expected to overestimate the chronic exposure significantly.

Detailed results of the intake calculations are included in Appendix B. The results were compared to the toxicological reference values for carbendazim because the input values were also expressed as carbendazim. With regard to the chronic exposure, no exceedance of the ADI was identified. The highest chronic exposure was calculated for Irish adults, representing 46% of the ADI. With regard to the acute exposure, no intake concerns were identified for mandarins, lemons, limes, pome fruits, peaches, and mangoes but exceedances of the ARfD were identified for oranges, grapefruits and tomatoes representing 212%, 143% and 119% of the ARfD, respectively.

Based on the above results, a consumer risk for the proposed MRLs in oranges, grapefruit and tomatoes cannot be excluded. EFSA therefore investigated the possibility of setting fall back MRLs for these crops. For oranges and grapefruits two types of applications were evaluated: a

foliar treatment with carbendazim and a post-harvest treatment with thiophanate-methyl. In Table 3-1 it can be seen that the levels of carbendazim residues are mainly driven by the foliar treatment with carbendazim. Only considering the post-harvest use of thiophanate-methyl in these two crops would result in lower carbendazim levels, requiring a MRL of 0.2 mg/kg, compared to the MRL of 0.7 mg/kg initially proposed. For tomatoes, a fall-back MRL of 0.3 mg carbendazim/kg and 1 mg thiophanate-methyl/kg can be proposed based on the outdoor use of thiophanate-methyl in Southern Europe (see Table 3-1).

A second intake calculation was then conducted considering the lower STMR and HR values for oranges, grapefruit and tomatoes. The input values are reported in Table 4-2 and the detailed results of this second calculation are available in Appendix C. When the fall-back MRLs are considered, acute exposures are no longer exceeding the ARfD, representing 43%, 40% and 65% of the ARfD, respectively.

Table 4-1. Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<u>Residue definition for risk assessment: sum of carbendazim, benomyl and thiophanate-methyl, expressed as carbendazim</u>				
Citrus fruits	0.19	$STMR(C) \times PF(C) + 0.25 \times STMR(Th) \times PF(Th)$	0.32	$HR(C) \times PF(C) + 0.1 \times HR(Th) \times PF(Th)$
Pome fruits	0.12	$STMR(C) + 0.25 \times STMR(Th)$	0.20	$HR(C) + 0.1 \times HR(Th)$
Peaches	0.17	$STMR(C) + 0.25 \times STMR(Th)$	0.17	$HR(C) + 0.1 \times HR(Th)$
Mangoes	0.07	$STMR(C) \times PF(C) + 0.25 \times STMR(Th) \times PF(Th)$	0.16	$HR(C) \times PF(C) + 0.1 \times HR(Th) \times PF(Th)$
Tomatoes	0.17	$STMR(C) + 0.25 \times STMR(Th)$	0.41	$HR(C) + 0.1 \times HR(Th)$
Other commodities of plant and animal origin	See Appendix D	$MRL(C) + 0.25 \times MRL(Th)$	Not relevant	

C: carbendazim
Th: thiophanate-methyl

Table 4-2. Input values for the fall-back MRL proposals

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<u>Residue definition for risk assessment: sum of carbendazim, benomyl and thiophanate-methyl, expressed as carbendazim</u>				
Oranges Grapefruits	0.11	$STMR(C) \times PF(C) + 0.25 \times STMR(Th) \times PF(Th)$	0.09	$HR(C) \times PF(C) + 0.1 \times HR(Th) \times PF(Th)$

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Tomatoes	0.15	STMR(C) + 0.25 x STMR(Th)	0.31	HR(C) + 0.1 x HR(Th)

C: carbendazim

Th: thiophanate-methyl

CONCLUSIONS AND RECOMMENDATIONS

On 15 September 2008, EFSA issued a reasoned opinion where certain MRLs of concern were identified for the active substance carbendazim and the lowering of these MRLs was recommended. These recommendations mainly resulted from the fact that not all information was made available to EFSA for refinement of the intake calculations, in particular with regard to the use of thiophanate-methyl, which generates residues of carbendazim as well. Some of the available information also indicated the need for increasing the existing MRLs while this was not covered by the terms of reference provided to EFSA at that time.

The European Commission therefore provided on 26 February 2009 new terms of reference requesting EFSA to review the existing EC MRLs for both carbendazim and thiophanate-methyl in the crops where intake calculations could not be refined. EFSA is no longer requested to assess only the safety of the existing MRLs for these active substances but also to verify whether a modification of the MRLs might be required based on the available data. For this purpose, additional information was provided by the Rapporteur Member State Germany.

As thiophanate-methyl is a precursor of carbendazim and both active substances are closely related, it was decided to address the assessment of both active substances in one reasoned opinion. Based on the information provided by Germany, EFSA derives the following conclusions.

The authorized uses reported by Germany for carbendazim and thiophanate-methyl in citrus fruits, pome fruits, peaches, mangoes and tomatoes are adequately supported by residues trials data and MRL proposals were derived for carbendazim and thiophanate-methyl separately (see table below). The effect of peeling on the magnitude of residues in citrus fruits and mangoes was investigated and relevant processing factors were derived. It should be noted that the nature of residues was not investigated in the framework of this request, nor was the impact of the authorized uses on residues in livestock and/or rotational crops. It is assumed that these aspects of the pesticide residues risk assessment were already properly addressed under the former pesticide MRL legislation. Moreover, a review of all existing MRLs for carbendazim and thiophanate-methyl will be performed under Article 12(2) of Regulation (EC) No 396/2005.

Although separate MRLs are proposed for carbendazim and thiophanate-methyl, both active substances share a common mechanism of toxicity. A combined consumer exposure assessment was therefore performed considering the available residues trials data as well as the respective potencies of the active substances. With regard to the chronic exposure, no exceedance of the ADI was identified. The highest chronic exposure was calculated for Irish adults, representing 46% of the ADI. With regard to the acute exposure, no intake concerns were identified for mandarins, lemons, limes, pome fruits, peaches, and mangoes but

exceedances of the ARfD were identified for oranges, grapefruits and tomatoes representing 212%, 143% and 119% of the ARfD, respectively.

Fall-back MRLs for oranges, grapefruit and tomatoes were therefore derived based on less critical GAPs and included in a second intake calculation. When these fall-back MRLs are considered, acute exposures are no longer exceeding the ARfD, representing 43%, 40% and 65% of the ARfD, respectively.

MRL recommendations resulting from the assessment are summarized in the table below.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Residue definition for enforcement: <i>sum of carbendazim and benomyl, expressed as carbendazim</i>			
Grapefruit	0.5	0.2	Based on the use of carbendazim in South-Africa a raising of the MRL could be proposed but for this MRL a risk to consumers was identified. A fall-back MRL is therefore recommended based on the post-harvest use of thiophanate-methyl.
Oranges	0.5	0.2	
Lemons	0.5	0.7	It is proposed to raise the existing MRL based on the use of carbendazim in South-Africa, also covering the post-harvest use of thiophanate-methyl. No risk to consumers is identified.
Limes	0.5	0.7	
Mandarins	0.5	0.7	
Apples	0.2	0.2	The existing MRL is confirmed based on the use of thiophanate-methyl. No risk to consumers is identified.
Pears	0.2	0.2	
Quinces	0.2	0.2	
Medlar	0.2	0.2	
Loquat	2	0.2	No data were made available in support of the existing MRL. It is therefore proposed to lower the MRL based on the use of thiophanate-methyl. No risk to consumers is identified.
Peaches	0.2	0.2	The existing MRL is confirmed based on the use of thiophanate-methyl. No risk to consumers is identified.
Mangoes	0.5	0.5	
Tomatoes	0.5	0.3	The existing MRL is adequately supported by data but a risk to consumers was identified. A fall-back MRL is proposed based on the outdoor use of thiophanate-methyl.
Residue definition for enforcement: <i>thiophanate-methyl</i>			
Grapefruit	0.1*	6	It is proposed to raise the MRL based on the post-harvest use of thiophanate-methyl. No risk to consumers is identified.
Oranges	0.1*	6	
Lemons	0.1*	6	
Limes	0.1*	6	

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Mandarins	0.1*	6	
Apples	0.5	0.5	The existing MRL is confirmed. No risk to consumers is identified.
Pears	0.5	0.5	
Quinces	0.5	0.5	
Medlar	2	0.5	No data were made available in support of the existing MRL. It is therefore proposed to lower the MRL based on the use of thiophanate-methyl. No risk to consumers is identified.
Loquat	2	0.5	
Peaches	2	2	The existing MRL is confirmed. No risk to consumers is identified.
Mangoes	1	1	
Tomatoes	2	1	The existing MRL is adequately supported by data but a risk to consumers was identified. A fall-back MRL is proposed based on the outdoor use of thiophanate-methyl.

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

DOCUMENTATION PROVIDED TO EFSA

1. Evaluation Report on the MRLs of concern for the active substance carbendazim prepared by the Rapporteur Member State Germany. 24 October 2008.
2. Review of the existing European and Codex MRLs and new MRL proposal for the benomyl group prepared by the Rapporteur Member State Germany. 29 September 2005.

REFERENCES

- EFSA, 2008. Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on certain MRLs of concern for the active substance carbendazim. *EFSA Scientific Report* (2008) 158, 1-31.
- European Commission, 2005. Review report for the active substance thiophanate-methyl finalized in the Standing Committee on the Food Chain and Animal Health at its meeting on 15 February 2005 in view of the inclusion of thiophanate-methyl in Annex I of Directive 91/414/EEC. DG SANCO 5032/VI/98-final, 15 February 2005.
- European Commission, 2007. Review report for the active substance carbendazim finalized in the Standing Committee on the Food Chain and Animal Health at its meeting on 3 March 2006 in view of the inclusion of carbendazim in Annex I of Directive 91/414/EEC. DG SANCO 5032/VI/98-final, 5 January 2007.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Critical GAPS for carbendazim reported by Germany

Crop and/or situation	Country	F G or I	Formulation		Application			Application rate per treatment			PHI (d)
			Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	kg as/hL min max	water L/ha min max	kg as/ha min max	
(a)		(b)									(l)
Citrus fruits	South-Africa	F	SC	500 g/L	Spraying		2	0.013			60

Critical GAPS for thiophanate-methyl reported by Germany

Crop and/or situation	Country	F G or I	Formulation		Application			Application rate per treatment			PHI (d)
			Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	kg as/hL min max	water L/ha min max	kg as/ha min max	
(a)		(b)									(l)
Citrus fruits	EU	I	SC	500 g/L	Dipping	Post-harvest	1	0.43			3
Pome fruits	EU	F	SC	500 g/L	Spraying	BBCH 60-69 85-87	2	0.068	1250	0.844	3
Peaches	EU (South)	F	SC	500 g/L	Spraying	BBCH 60-69 85-87	2	0.068	1250	0.844	3
Mangoes	Senegal	F	SC	500 g/L	Spraying	BBCH 85-86	1-2 interval 14 days		2.9 l/tree	0.7	7
	Mali	F	SC	500 g/L	Spraying	BBCH 85-86	1-2 interval 14 days		4 l/tree	0.7	7
	Brazil	F	SC	500 g/L	Spraying	BBCH 81	2 interval 10 days	0.05 – 0.075		0.05 – 0.075	14
Tomatoes	EU (North & South)	G	SC	500 g/L	Spraying	BBCH 89	3	0.092	1150	1.063	3
	EU (South)	F	SC	500 g/L	Spraying	BBCH 89	3	0.092	1150	1.063	3

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Carbendazim			
Status of the active substance:	included	Code no.	
LOQ (mg/kg bw):	0.1	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	0.02
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2007	Year of evaluation:	2007

Scenario 2 - refined calculation

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment - refined calculations								
		TMDI (range) in % of ADI minimum - maximum						
		8 46						
No of diets exceeding ADI: ---								
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)		2nd contributor to MS diet (in % of ADI)		3rd contributor to MS diet (in % of ADI)		pTMRLs at LOQ (in % of ADI)
		Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities		
46.3	IE adult	12.9	Barley	7.8	Wine grapes	2.2	Sweet potatoes	2.5
41.5	WHO Cluster diet B	11.2	Wine grapes	4.8	Wheat	2.9	Barley	3.0
35.9	NL child	9.2	Milk and cream,	3.8	Apples	3.7	Potatoes	10.6
35.6	WHO cluster diet E	10.0	Wine grapes	8.4	Barley	2.4	Potatoes	2.2
35.3	DE child	7.2	Apples	4.5	Milk and cream,	3.6	Oranges	5.4
34.3	UK Toddler	14.3	Sugar beet (root)	6.5	Milk and cream,	2.2	Wheat	7.0
33.3	FR all population	25.0	Wine grapes	1.8	Wheat	0.8	Milk and cream,	1.5
32.9	UK Infant	12.1	Milk and cream,	6.3	Sugar beet (root)	2.6	Oats	12.8
30.1	FR toddler	12.4	Milk and cream,	3.2	Potatoes	1.9	Oranges	13.6
27.7	PT General population	15.6	Wine grapes	3.3	Potatoes	2.2	Wheat	0.1
25.3	WHO Cluster diet F	6.2	Barley	3.7	Wine grapes	2.1	Potatoes	2.4
23.7	DK child	4.1	Oats	3.9	Milk and cream,	3.1	Wheat	5.7
21.0	WHO cluster diet D	3.7	Wheat	2.5	Potatoes	2.3	Barley	2.7
20.8	NL general	3.9	Wine grapes	3.9	Barley	2.1	Milk and cream,	2.6
20.3	WHO regional European diet	3.4	Barley	2.5	Potatoes	1.7	Wheat	3.2
20.1	FR infant	8.0	Milk and cream,	2.6	Potatoes	1.7	Carrots	8.6
18.5	ES adult	5.1	Barley	2.6	Wine grapes	1.5	Milk and cream,	2.6
17.7	DK adult	8.7	Wine grapes	1.7	Milk and cream,	1.2	Oats	2.4
17.6	ES child	3.9	Milk and cream,	2.5	Wheat	2.1	Oranges	5.7
17.2	SE general population 90th percentile	3.9	Milk and cream,	2.6	Potatoes	1.8	Wheat	4.3
16.3	UK vegetarian	5.1	Wine grapes	2.4	Sugar beet (root)	1.2	Wheat	1.2
16.0	UK Adult	6.8	Wine grapes	2.5	Sugar beet (root)	0.9	Wheat	1.2
11.0	IT kids/toddler	3.7	Wheat	1.2	Potatoes	0.6	Potatoes	0.2
9.9	FI adult	1.9	Wine grapes	1.8	Milk and cream,	0.9	Oranges	2.1
9.7	LT adult	2.0	Potatoes	1.2	Milk and cream,	1.1	Apples	1.9
9.0	IT adult	2.3	Wheat	1.0	Tomatoes	0.6	Aubergines (egg plants)	0.2
7.8	PL general population	2.1	Potatoes	1.2	Apples	0.8	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 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 variability 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): 3			No of commodities for which ARfD/ADI is exceeded (IESTI 2): 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)
	212.2	Oranges	0.32 / 0.15	153.3	Oranges	0.32 / 0.2	40.9	Oranges	0.32 / -	33.3	Oranges	0.32 / -
	142.7	Grapefruit	0.32 / 0.22	142.7	Grapefruit	0.32 / 0.22	32.0	Grapefruit	0.32 / -	25.2	Tomatoes	0.41 / -
	119.2	Tomatoes	0.41 / 0.34	86.4	Tomatoes	0.41 / -	31.2	Tomatoes	0.41 / -	23.9	Grapefruit	0.32 / -
	98.0	Apples	0.2 / -	72.2	Apples	0.2 / -	23.7	Mangoes	0.16 / -	23.7	Mangoes	0.16 / -
	91.1	Pears	0.2 / -	67.0	Mandarins	0.32 / -	22.4	Apples	0.2 / -	18.7	Apples	0.2 / -
	No of critical MRLs (IESTI 1)			No of critical MRLs (IESTI 2)			No of critical MRLs (IESTI 1)			No of critical MRLs (IESTI 2)		
	3			2			2			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)
	47.1	Orange juice	0.19 / -	9.6	Orange juice	0.19 / -

*) 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 Carbendazim 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 3 commodities.

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

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

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO) WITH FALL-BACK MRLS

Carbendazim			
Status of the active substance:	included	Code no.	
LOQ (mg/kg bw):	0.1	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	0.02
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2007	Year of evaluation:	2007

Scenario 2 - refined calculation

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment - refined calculations								
		TMDI (range) in % of ADI minimum - maximum						
		8 - 46						
		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)
40.8	WHO Cluster diet B	11.2	Wine grapes	4.8	Wheat	2.9	Barley	3.0
35.3	WHO cluster diet E	10.0	Wine grapes	8.4	Barley	2.4	Potatoes	2.2
34.5	NL child	9.2	Milk and cream,	3.8	Apples	3.7	Potatoes	10.6
33.6	DE child	7.2	Apples	4.5	Milk and cream,	2.3	Wheat	5.4
33.5	UK Toddler	14.3	Sugar beet (root)	6.5	Milk and cream,	2.2	Wheat	7.0
33.1	FR all population	25.0	Wine grapes	1.8	Wheat	0.8	Milk and cream,	1.5
32.3	UK Infant	12.1	Milk and cream,	6.3	Sugar beet (root)	2.6	Oats	12.8
29.2	FR toddler	12.4	Milk and cream,	3.2	Potatoes	1.6	Apples	13.6
27.4	PT General population	15.6	Wine grapes	3.3	Potatoes	2.2	Wheat	0.1
24.9	WHO Cluster diet F	6.2	Barley	3.7	Wine grapes	2.1	Potatoes	2.4
23.6	DK child	4.1	Oats	3.9	Milk and cream,	3.1	Wheat	5.7
20.8	WHO cluster diet D	3.7	Wheat	2.5	Potatoes	2.3	Barley	2.7
20.1	NL general	3.9	Wine grapes	3.9	Barley	2.1	Milk and cream,	2.6
20.0	WHO regional European diet	3.4	Barley	2.5	Potatoes	1.7	Wheat	3.2
19.7	FR infant	8.0	Milk and cream,	2.6	Potatoes	1.7	Carrots	8.6
17.9	ES adult	5.1	Barley	2.6	Wine grapes	1.5	Milk and cream,	2.6
17.6	DK adult	8.7	Wine grapes	1.7	Milk and cream,	1.2	Oats	2.4
16.7	SE general population 90th percentile	3.9	Milk and cream,	2.6	Potatoes	1.8	Wheat	4.3
16.6	ES child	3.9	Milk and cream,	2.5	Wheat	1.2	Oranges	5.7
15.9	UK vegetarian	5.1	Wine grapes	2.4	Sugar beet (root)	1.2	Wheat	1.2
15.7	UK Adult	6.8	Wine grapes	2.5	Sugar beet (root)	0.9	Wheat	1.2
10.6	IT kids/toddler	3.7	Wheat	1.1	Tomatoes	0.6	Potatoes	0.2
9.6	LT adult	2.0	Potatoes	1.2	Milk and cream,	1.1	Apples	1.9
9.4	FI adult	1.9	Wine grapes	1.8	Milk and cream,	0.9	Oats	2.1
8.7	IT adult	2.3	Wheat	0.9	Tomatoes	0.6	Aubergines (egg plants)	0.2
7.7	PL general population	2.1	Potatoes	1.2	Apples	0.7	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 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 IEST1 calculation.

In the IEST1 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 IEST2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.

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

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IEST1 1):			No of commodities for which ARfD/ADI is exceeded (IEST1 2):			No of commodities for which ARfD/ADI is exceeded (IEST1 1):			No of commodities for which ARfD/ADI is exceeded (IEST1 2):		
	---			---			---			---		
	IEST1 1 *) **)			IEST1 2 *) **)			IEST1 1 *) **)			IEST1 2 *) **)		
	Highest % of ARfD/ADI		pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI		pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI		pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI		pTMRL/ threshold MRL (mg/kg)
	98.0	Apples	0.2 / -	72.2	Apples	0.2 / -	23.7	Mangoes	0.16 / -	23.7	Mangoes	0.16 / -
	91.1	Pears	0.2 / -	67.0	Mandarins	0.32 / -	23.6	Tomatoes	0.31 / -	19.1	Tomatoes	0.31 / -
90.1	Tomatoes	0.31 / -	65.5	Pears	0.2 / -	22.4	Apples	0.2 / -	18.7	Apples	0.2 / -	
89.0	Mandarins	0.32 / -	65.3	Tomatoes	0.31 / -	21.5	Mandarins	0.32 / -	16.7	Mandarins	0.32 / -	
62.9	Mangoes	0.16 / -	44.9	Mangoes	0.16 / -	21.5	Pears	0.2 / -	16.4	Pears	0.2 / -	
No of critical MRLs (IEST1 1)			---			No of critical MRLs (IEST1 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	Highest % of ARfD/ADI		Processed commodities
		pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)	
27.2		Orange juice	5.5		Orange juice	
		0.11 / -			0.11 / -	

*) The results of the IEST1 calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IEST1 values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL

***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Carbendazim IEST1 1 and IEST1 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 D – Existing EC MRLs

Pesticides - Web Version - EU MRLs (File created on 07/05/2009 10:00)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Carbendazim and benomyl (sum of benomyl and carbendazim expressed as carbendazim) (R)	Thiophanate-methyl (R)	Combined MRL for chronic intake calculations
10000	1. FRUIT FRESH OR FROZEN; NUTS			
110000	(i) Citrus fruit	0,5	0,1*	0,525
110010	Grapefruit (Shaddock's, pomelos, sweeties, tangelo, ugli and other hybrids)	0,5	0,1*	0,525
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,5	0,1*	0,525
110030	Lemons (Citron, lemon)	0,5	0,1*	0,525
110040	Limes	0,5	0,1*	0,525
110050	Mandarins (Clementine, tangerine and other hybrids)	0,5	0,1*	0,525
110990	Others	0,5	0,1*	0,525
120000	(j) Tree nuts (shelled or unshelled)	0,1*	0,2*	0,15
120010	Almonds	0,1*	0,2*	0,15
120020	Brazil nuts	0,1*	0,2*	0,15
120030	Cashew nuts	0,1*	0,2*	0,15
120040	Chestnuts	0,1*	0,2*	0,15
120050	Coconuts	0,1*	0,2*	0,15
120060	Hazelnuts (Filbert)	0,1*	0,2*	0,15
120070	Macadamia	0,1*	0,2*	0,15
120080	Pecans	0,1*	0,2*	0,15
120090	Pine nuts	0,1*	0,2*	0,15
120100	Pistachios	0,1*	0,2*	0,15
120110	Walnuts	0,1*	0,2*	0,15
120990	Others	0,1*	0,2*	0,15
130000	(k) Pome fruit			
130010	Apples (Crab apple)	0,2	0,5	0,325
130020	Pears (Oriental pear)	0,2	0,5	0,325
130030	Quinces	0,2	0,5	0,325
130040	Medlar	0,2	2	0,7
130050	Loquat	2	2	2,5
130990	Others	0,2	0,5	0,325
140000	(l) Stone fruit			
140010	Apricots	0,2	2	0,7
140020	Cherries (sweet cherries, sour cherries)	0,5	0,3	0,575
140030	Peaches (Nectarines and similar hybrids)	0,2	2	0,7
140040	Plums (Damson, greengage, mirabelle)	0,5	0,3	0,575
140990	Others	0,1*	0,1*	0,125

150000	(v) Berries & small fruit			
151000	(a) Table and wine grapes			
151010	Table grapes	0,3	0,1*	0,325
151020	Wine grapes	0,5	3	1,25
152000	(b) Strawberries	0,1*	0,1*	0,125
153000	(c) Cane fruit	0,1*	0,1*	0,125
153010	Blackberries	0,1*	0,1*	0,125
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,1*	0,1*	0,125
153030	Raspberries (Wineberries)	0,1*	0,1*	0,125
153990	Others	0,1*	0,1*	0,125
154000	(d) Others small fruit & berries	0,1*	0,1*	0,125
154010	Blueberries (Bilberries cowberries (red bilberries))	0,1*	0,1*	0,125
154020	Cranberries	0,1*	0,1*	0,125
154030	Currants (red, black and white)	0,1*	0,1*	0,125
154040	Gooseberries (including hybrids with other ribes species)	0,1*	0,1*	0,125
154050	Rose hips	0,1*	0,1*	0,125
154060	Mulberries (arbutus berry)	0,1*	0,1*	0,125
154070	Azorele (Mediterranean medlar)	0,1*	0,1*	0,125
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azorele, buckthorn (sea-sallow thorn), hawthorn, service berries, and other treeberries)	0,1*	0,1*	0,125
154990	Others	0,1*	0,1*	0,125
160000	(vi) Miscellaneous fruit			
161000	(a) Edible peel	0,1*	0,1*	0,125
161010	Dates	0,1*	0,1*	0,125
161020	Figs	0,1*	0,1*	0,125
161030	Table olives	0,1*	0,1*	0,125
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,1*	0,1*	0,125
161050	Carambola (Bilimbi)	0,1*	0,1*	0,125
161060	Persimmon	0,1*	0,1*	0,125
161070	Jambolan (Java plum) (Java apple (water apple), pommerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,1*	0,1*	0,125
161990	Others	0,1*	0,1*	0,125
162000	(b) Inedible peel, small	0,1*	0,1*	0,125
162010	Kiwi	0,1*	0,1*	0,125
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,1*	0,1*	0,125
162030	Passion fruit	0,1*	0,1*	0,125

162040	Pricklypear(cactusfruit)	0,1*	0,1*	0.125
162050	Starapple	0,1*	0,1*	0.125
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy sapote)	0,1*	0,1*	0.125
162990	Others	0,1*	0,1*	0.125
163000	(c) Inedible peel, large			
163010	Avocados	0,1*	0,1*	0.125
163020	Bananas (Dwarf banana, plantain, apple banana)	0,1*	0,1*	0.125
163030	Mangoes	0,5	1	0.75
163040	Papaya	0,2	1	0.45
163050	Pomegranate	0,1*	0,1*	0.125
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,1*	0,1*	0.125
163070	Guava	0,1*	0,1*	0.125
163080	Pineapples	0,1*	0,1*	0.125
163090	Breadfruit (Jackfruit)	0,1*	0,1*	0.125
163100	Durian	0,1*	0,1*	0.125
163110	Soursop (guanabana)	0,1*	0,1*	0.125
163990	Others	0,1*	0,1*	0.125
200000	2. VEGETABLES FRESH OR FROZEN			
210000	(i) Root and tuber vegetables	0,1*	0,1*	0.125
211000	(a) Potatoes	0,1*	0,1*	0.125
212000	(b) Tropical root and tuber vegetables	0,1*	0,1*	0.125
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,1*	0,1*	0.125
212020	Sweet potatoes	0,1*	0,1*	0.125
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,1*	0,1*	0.125
212040	Arrowroot	0,1*	0,1*	0.125
212990	Others	0,1*	0,1*	0.125
213000	(c) Other root and tuber vegetables except sugarbeet	0,1*	0,1*	0.125
213010	Beetroot	0,1*	0,1*	0.125
213020	Carrots	0,1*	0,1*	0.125
213030	Celeriac	0,1*	0,1*	0.125
213040	Horseradish	0,1*	0,1*	0.125
213050	Jerusalem artichokes	0,1*	0,1*	0.125
213060	Parsnips	0,1*	0,1*	0.125
213070	Parsley root	0,1*	0,1*	0.125
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,1*	0,1*	0.125
213090	Salsify (Scorzoneria, Spanish salsify)	0,1*	0,1*	0.125

	(Spanish oysterplant)			
213100	Sweedes	0,1*	0,1*	0.125
213110	Tumips	0,1*	0,1*	0.125
213990	Others	0,1*	0,1*	0.125
220000	(ii) Bulb vegetables	0,1*	0,1*	0.125
220010	Garlic	0,1*	0,1*	0.125
220020	Onions (Silverskin onions)	0,1*	0,1*	0.125
220030	Shallots	0,1*	0,1*	0.125
220040	Spring onions (Welsh onion and similar varieties)	0,1*	0,1*	0.125
220990	Others	0,1*	0,1*	0.125
230000	(iii) Fruiting vegetables			
231000	(a) Solanacea			
231010	Tomatoes (Cherry tomatoes,)	0,5	2	1
231020	Peppers (Chili peppers)	0,1*	0,1*	0.125
231030	Aubergines (eggplants) (Pepino)	0,5	2	1
231040	Okra, lady's fingers	2	1	2.25
231990	Others	0,1*	0,1*	0.125
232000	(b) Cucurbits - edible peel	0,1*	0,1*	0.125
232010	Cucumbers	0,1*	0,1*	0.125
232020	Gherkins	0,1*	0,1*	0.125
232030	Courgettes (Summersquash, marrow (patisson))	0,1*	0,1*	0.125
232990	Others	0,1*	0,1*	0.125
233000	(c) Cucurbits - inedible peel	0,1*		
233010	Melons (Kiwano)	0,1*	0,3	0.175
233020	Pumpkins (Wintersquash)	0,1*	0,5	0.225
233030	Watermelons	0,1*	0,3	0.175
233990	Others	0,1*	0,3	0.175
234000	(d) Sweet corn	0,1*	0,1*	0.125
239000	(e) Other fruiting vegetables	0,1*	0,1*	0.125
240000	(iv) Brassica vegetables			
241000	(a) Flowering brassica	0,1*	0,1*	0.125
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,1*	0,1*	0.125
241020	Cauliflower	0,1*	0,1*	0.125
241990	Others	0,1*	0,1*	0.125
242000	(b) Head brassica			
242010	Brussels sprouts	0,5	1	0.75
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,1*	0,1*	0.125
242990	Others	0,1*	0,1*	0.125
243000	(c) Leafy brassica	0,1*	0,1*	0.125
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow	0,1*	0,1*	0.125

	cabbage)			
243020	Kale (Borecole (curly kale), collards)	0,1*	0,1*	0.125
243990	Others	0,1*	0,1*	0.125
244000	(d) Kohlrabi	0,1*	0,1*	0.125
250000	(v) Leaf vegetables & fresh herbs	0,1*	0,1*	0.125
251000	(a) Lettuce and other salad plants including Brassicaceae	0,1*	0,1*	0.125
251010	Lamb's lettuce (Italian comsalad)	0,1*	0,1*	0.125
251020	Lettuce (Head lettuce, lolo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,1*	0,1*	0.125
251030	Scarole (broad leaf endive) (Wild chirony, red-leaved chirony, radicchio, curd leaf endive, sugar loaf)	0,1*	0,1*	0.125
251040	Cress	0,1*	0,1*	0.125
251050	Land cress	0,1*	0,1*	0.125
251060	Rocket, Rucola (Wild rocket)	0,1*	0,1*	0.125
251070	Red mustard	0,1*	0,1*	0.125
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,1*	0,1*	0.125
251990	Others	0,1*	0,1*	0.125
252000	(b) Spinach & similar (leaves)	0,1*	0,1*	0.125
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,1*	0,1*	0.125
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,1*	0,1*	0.125
252030	Beet leaves (chard) (Leaves of beetroot)	0,1*	0,1*	0.125
252990	Others	0,1*	0,1*	0.125
253000	(c) Vine leaves (grape leaves)	0,1*	0,1*	0.125
254000	(d) Water cress	0,1*	0,1*	0.125
255000	(e) Witloof	0,1*	0,1*	0.125
256000	(f) Herbs	0,1*	0,1*	0.125
256010	Chervil	0,1*	0,1*	0.125
256020	Chives	0,1*	0,1*	0.125
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiaceae)	0,1*	0,1*	0.125
256040	Parsley	0,1*	0,1*	0.125
256050	Sage (Winter savory, summer savory,)	0,1*	0,1*	0.125
256060	Rosemary	0,1*	0,1*	0.125
256070	Thyme (marjoram, oregano)	0,1*	0,1*	0.125
256080	Basil (Balm leaves, mint, peppermint)	0,1*	0,1*	0.125
256090	Bay leaves (laurel)	0,1*	0,1*	0.125
256100	Tarragon (Hyssop)	0,1*	0,1*	0.125
256990	Others	0,1*	0,1*	0.125
260000	(vi) Legume vegetables (fresh)		0,1*	

260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,2	0,1*	0.225
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	0,1*	0,1*	0.125
260030	Peas (with pods) (Mangetout (sugar peas))	0,2	0,1*	0.225
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,1*	0,1*	0.125
260050	Lentils	0,1*	0,1*	0.125
260990	Others	0,1*	0,1*	0.125
270000	(vii) Stem vegetables (fresh)		0,1*	
270010	Asparagus	0,1*	0,1*	0.125
270020	Cardoons	0,1*	0,1*	0.125
270030	Celery	0,1*	0,1*	0.125
270040	Fennel	0,1*	0,1*	0.125
270050	Globe artichokes	0,1*	0,1*	0.125
270060	Leek	0,1*	0,1*	0.125
270070	Rhubarb	0,1*	0,1*	0.125
270080	Bamboo shoots	0,1*	0,1*	0.125
270090	Palm hearts	0,1*	0,1*	0.125
270990	Others	0,1*	0,1*	0.125
280000	(viii) Fungi		0,1*	
280010	Cultivated (Common mushroom, Oyster mushroom, Shiitake)	1	0,1*	1.025
280020	Wild (Chanterelle, Truffle, Morel,)	0,1*	0,1*	0.125
280990	Others	0,1*	0,1*	0.125
290000	(ix) Sea weeds			
300000	3. PULSES, DRY	0,1*	0,1*	0.125
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	0,1*	0,1*	0.125
300020	Lentils	0,1*	0,1*	0.125
300030	Peas (Chickpeas, field peas, chickling vetch)	0,1*	0,1*	0.125
300040	Lupins	0,1*	0,1*	0.125
300990	Others	0,1*	0,1*	0.125
400000	4. OILSEEDS AND OIL FRUITS			
401000	(i) Oilseeds			
401010	Linseed	0,1*	0,1*	0.125
401020	Peanuts	0,1*	0,1*	0.125
401030	Poppy seed	0,1*	0,1*	0.125
401040	Sesame seed	0,1*	0,1*	0.125
401050	Sunflower seed	0,1*	0,1*	0.125
401060	Rapeseed (Bird rapeseed, turnip rape)	0,1*	0,1*	0.125
401070	Soya bean	0,2	0,3	0.275

401080	Mustardseed	0,1*	0,1*	0.125
401090	Cottonseed	0,1*	0,1*	0.125
401100	Pumpkinseeds	0,1*	0,1*	0.125
401110	Safflower	0,1*	0,1*	0.125
401120	Borage	0,1*	0,1*	0.125
401130	Gold of pleasure	0,1*	0,1*	0.125
401140	Hempseed	0,1*	0,1*	0.125
401150	Castorbean	0,1*	0,1*	0.125
401990	Others	0,1*	0,1*	0.125
402000	(i) Oilfruits	0,1*	0,1*	0.125
402010	Olives for oil production	0,1*	0,1*	0.125
402020	Palm nuts (palm oil kernels)	0,1*	0,1*	0.125
402030	Palmfruit	0,1*	0,1*	0.125
402040	Kapok	0,1*	0,1*	0.125
402990	Others	0,1*	0,1*	0.125
500000	5. CEREALS			
500010	Barley	2	0,3	2.075
500020	Buckwheat	0,01*	0,01*	0.0125
500030	Maize	0,01*	0,01*	0.0125
500040	Millet (Foxtail millet, teff)	0,01*	0,01*	0.0125
500050	Oats	2	0,3	2.075
500060	Rice	0,01*	0,01*	0.0125
500070	Rye	0,1	0,05	0.1125
500080	Sorghum	0,01*	0,01*	0.0125
500090	Wheat (Spelt/Triticale)	0,1	0,05	0.1125
500990	Others	0,01*	0,01*	0.0125
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA			
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i>)	0,1*	0,1*	0.125
620000	(j) Coffee beans	0,1*	0,1*	0.125
630000	(ii) Herbal infusions (dried)	0,1*	0,1*	0.125
631000	(a) Flowers	0,1*	0,1*	0.125
631010	Camomile flowers	0,1*	0,1*	0.125
631020	Hybiscus flowers	0,1*	0,1*	0.125
631030	Rose petals	0,1*	0,1*	0.125
631040	Jasmine flowers	0,1*	0,1*	0.125
631050	Lime (Linden)	0,1*	0,1*	0.125
631990	Others	0,1*	0,1*	0.125
632000	(b) Leaves	0,1*	0,1*	0.125
632010	Strawberry leaves	0,1*	0,1*	0.125
632020	Rooibos leaves	0,1*	0,1*	0.125
632030	Maté	0,1*	0,1*	0.125
632990	Others	0,1*	0,1*	0.125

633000	(c) Roots	0,1*	0,1*	0.125
633010	Valerian root	0,1*	0,1*	0.125
633020	Ginseng root	0,1*	0,1*	0.125
633990	Others	0,1*	0,1*	0.125
639000	(d) Other herbal infusions	0,1*	0,1*	0.125
640000	(v) Cocoa (fermented beans)	0,1*	0,1*	0.125
650000	(v) Carob (st. johns bread)	0,1*	0,1*	0.125
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,1*	0,1*	0.125
800000	8. SPICES	0,1*	0,1*	0.125
810000	(i) Seeds	0,1*	0,1*	0.125
810010	Anise	0,1*	0,1*	0.125
810020	Black caraway	0,1*	0,1*	0.125
810030	Celery seed (Lovage seed)	0,1*	0,1*	0.125
810040	Coriander seed	0,1*	0,1*	0.125
810050	Cumin seed	0,1*	0,1*	0.125
810060	Dill seed	0,1*	0,1*	0.125
810070	Fennel seed	0,1*	0,1*	0.125
810080	Fenugreek	0,1*	0,1*	0.125
810090	Nutmeg	0,1*	0,1*	0.125
810990	Others	0,1*	0,1*	0.125
820000	(ii) Fruits and berries	0,1*	0,1*	0.125
820010	Allspice	0,1*	0,1*	0.125
820020	Anise pepper (Japan pepper)	0,1*	0,1*	0.125
820030	Caraway	0,1*	0,1*	0.125
820040	Cardamom	0,1*	0,1*	0.125
820050	Juniper berries	0,1*	0,1*	0.125
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*	0,1*	0.125
820070	Vanilla pods	0,1*	0,1*	0.125
820080	Tamarind	0,1*	0,1*	0.125
820990	Others	0,1*	0,1*	0.125
830000	(iii) Bark	0,1*	0,1*	0.125
830010	Cinnamon (Cassia)	0,1*	0,1*	0.125
830990	Others	0,1*	0,1*	0.125
840000	(iv) Roots or rhizome	0,1*	0,1*	0.125
840010	Liquorice	0,1*	0,1*	0.125
840020	Ginger	0,1*	0,1*	0.125
840030	Tumeric (Curcuma)	0,1*	0,1*	0.125
840040	Horseradish	0,1*	0,1*	0.125
840990	Others	0,1*	0,1*	0.125
850000	(v) Buds	0,1*	0,1*	0.125
850010	Cloves	0,1*	0,1*	0.125
850020	Capers	0,1*	0,1*	0.125
850990	Others	0,1*	0,1*	0.125

860000	(v) Flower stigma	0,1*	0,1*	0,125
860010	Saffron	0,1*	0,1*	0,125
860990	Others	0,1*	0,1*	0,125
870000	(vi) Avil	0,1*	0,1*	0,125
870010	Mace	0,1*	0,1*	0,125
870990	Others	0,1*	0,1*	0,125
900000	9. SUGAR PLANTS	0,1*	0,1*	0,125
900010	Sugar beet (root)	0,1*	0,1*	0,125
900020	Sugar cane	0,1*	0,1*	0,125
900030	Chicory roots	0,1*	0,1*	0,125
900990	Others	0,1*	0,1*	0,125
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 or other processed products such as sausages and food preparations based on these	0,05*	0,05*	0,0625
1011000	(a) Swine	0,05*	0,05*	0,0625
1011010	Meat	0,05*	0,05*	0,0625
1011020	Fat free of lean meat	0,05*	0,05*	0,0625
1011030	Liver	0,05*	0,05*	0,0625
1011040	Kidney	0,05*	0,05*	0,0625
1011050	Edible offal	0,05*	0,05*	0,0625
1011990	Others	0,05*	0,05*	0,0625
1012000	(b) Bovine	0,05*	0,05*	0,0625
1012010	Meat	0,05*	0,05*	0,0625
1012020	Fat	0,05*	0,05*	0,0625
1012030	Liver	0,05*	0,05*	0,0625
1012040	Kidney	0,05*	0,05*	0,0625
1012050	Edible offal	0,05*	0,05*	0,0625
1012990	Others	0,05*	0,05*	0,0625
1013000	(c) Sheep	0,05*	0,05*	0,0625
1013010	Meat	0,05*	0,05*	0,0625
1013020	Fat	0,05*	0,05*	0,0625
1013030	Liver	0,05*	0,05*	0,0625
1013040	Kidney	0,05*	0,05*	0,0625
1013050	Edible offal	0,05*	0,05*	0,0625
1013990	Others	0,05*	0,05*	0,0625
1014000	(d) Goat	0,05*	0,05*	0,0625
1014010	Meat	0,05*	0,05*	0,0625
1014020	Fat	0,05*	0,05*	0,0625
1014030	Liver	0,05*	0,05*	0,0625
1014040	Kidney	0,05*	0,05*	0,0625
1014050	Edible offal	0,05*	0,05*	0,0625

1014990	Others	0,05*	0,05*	0,0625
1015000	(e) Horses, asses, mules or hinnies	0,05*	0,05*	0,0625
1015010	Meat	0,05*	0,05*	0,0625
1015020	Fat	0,05*	0,05*	0,0625
1015030	Liver	0,05*	0,05*	0,0625
1015040	Kidney	0,05*	0,05*	0,0625
1015050	Edible offal	0,05*	0,05*	0,0625
1015990	Others	0,05*	0,05*	0,0625
1016000	(f) Poultry - chicken, geese, duck, turkey and Guinea fowl, ostrich, pigeon	0,05*	0,05*	0,0625
1016010	Meat	0,05*	0,05*	0,0625
1016020	Fat	0,05*	0,05*	0,0625
1016030	Liver	0,05*	0,05*	0,0625
1016040	Kidney	0,05*	0,05*	0,0625
1016050	Edible offal	0,05*	0,05*	0,0625
1016990	Others	0,05*	0,05*	0,0625
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*	0,05*	0,0625
1017010	Meat	0,05*	0,05*	0,0625
1017020	Fat	0,05*	0,05*	0,0625
1017030	Liver	0,05*	0,05*	0,0625
1017040	Kidney	0,05*	0,05*	0,0625
1017050	Edible offal	0,05*	0,05*	0,0625
1017990	Others	0,05*	0,05*	0,0625
1020000	(i) 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*	0,0625
1020010	Cattle	0,05*	0,05*	0,0625
1020020	Sheep	0,05*	0,05*	0,0625
1020030	Goat	0,05*	0,05*	0,0625
1020040	Horse	0,05*	0,05*	0,0625
1020990	Others	0,05*	0,05*	0,0625
1030000	(ii) 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*	0,0625
1030010	Chicken	0,05*	0,05*	0,0625
1030020	Duck	0,05*	0,05*	0,0625
1030030	Goose	0,05*	0,05*	0,0625
1030040	Quail	0,05*	0,05*	0,0625
1030990	Others	0,05*	0,05*	0,0625
1040000	(iv) Honey (Royal jelly, pollen)	1	1	1,25
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)			

1060000	(v) Snails			
---------	------------	--	--	--

1070000	(vi) Other terrestrial animal products			
---------	--	--	--	--

GLOSSARY / ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
bw	body weight
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European Union
GAP	good agricultural practice
ha	hectare
hL	hectolitre
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
PF	processing factor
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
SC	suspension concentrate
SEU	Southern European Union
STMR	supervised trials median residue