

REASONED OPINION OF EFSA

Modification of the existing MRL for dithiocarbamates, expressed as CS₂, in garlic¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2008-733)

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SUMMARY

The United Kingdom received an application from the Horticultural Development Council (HDC) on the modification of the existing MRL for dithiocarbamates in garlic (dithiocarbamates, expressed as CS₂, including maneb, mancozeb, metiram, propineb, thiram and ziram). The United Kingdom as an Evaluating Member State (EMS) drafted an Evaluation Report which was forwarded to the European Commission and to EFSA. The modification was requested in order to accommodate the MRL to the envisaged use in the United Kingdom of a plant protection product containing mancozeb in garlic.

Mancozeb is a substance belonging to the group of dithiocarbamates such as maneb, thiram, metiram, propineb, ziram. Since there is no specific enforcement method for the determination of mancozeb, MRLs were established for CS₂, which is the common moiety for all dithiocarbamates. The current MRL for garlic set in Regulation (EC) No 396/2005 is 0.1 mg/kg which reflects the currently authorised use of mancozeb in some Member States. The applicant proposed to raise the MRL to 0.5 mg/kg as an extrapolation from onions.

EFSA derives the following conclusions regarding the application, based on the Draft Assessment Report prepared by Italy in the framework of Directive 91/414/EEC and the evaluation report prepared by the EMS:

The toxicological profile of mancozeb was investigated under the peer review and data were sufficient to conclude on an ADI value of 0.05 mg/kg bw/d and an ARfD value of 0.6 mg/kg bw/day.

Adequate analytical enforcement methods exist for the determination of CS₂. The conversion factor for recalculating CS₂ to mancozeb is 1.78.

Metabolism studies in four different crop groups indicate that mancozeb is extensively degraded in plants and the majority of the radioactivity is incorporated into naturally-occurring biological molecules. It was concluded that metabolism in all crop categories is

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similar and the residue definition for enforcement purposes can be established as “mancozeb (expressed as CS₂)”. Since no specific analytical methods are available for the individual active substances belonging to the dithiocarbamate group, a screening residue definition was established in Regulation (EC) No 396/2005 as “dithiocarbamates (dithiocarbamates, expressed as CS₂, including maneb, mancozeb, metiram, propineb, thiram and ziram)”. In case of positive findings further investigations are necessary to identify the origin of the CS₂ residue. For propineb, thiram and ziram for which compound specific residue methods are available, separate MRLs have been established in the Regulation (EC) No 396/2005. If the CS₂ residue observed in the screening can not be identified as one of these compounds, the unspecific CS₂ MRL related to a use of mancozeb, metiram or maneb is applicable.

During the peer review the possibility of the formation of metabolite ethylenethiourea (ETU) was identified. ETU is a toxicologically relevant degradation product of maneb, mancozeb and metiram that is formed in crops which undergo heat treatment. ETU should therefore be also considered in a consumer risk assessment of processed commodities.

Regarding rotational crops, no significant residue levels are expected to occur since DT₉₀ value of mancozeb is approximately one day. The residues in commodities of animal origin were not assessed in the framework of this application considering that garlic is not a livestock feedingstuff.

In support of the proposed GAP, the applicant submitted supervised field trials on onions which can be used to extrapolate to garlic. To cover the proposed GAP on garlic an MRL of 0.5 mg/kg is necessary.

A consumer risk assessment was performed for parent compound mancozeb using the EFSA PRIMo-rev.2. EFSA considered only those MRLs which are related to a use of mancozeb alone or in combination with maneb and metiram, and compared the estimated intake with the toxicological reference values for mancozeb. Available STMR values of CS₂ or MRL values of CS₂ were converted to mancozeb by applying the molecular weight conversion factor 1.78. For garlic, the STMR and HR values derived from the supervised trials of mancozeb were used. The chronic dietary risk assessment did not reveal consumer intake concerns. The TMDI values ranged from 11 to 74% of the ADI. For all diets the contribution of garlic is below 0.04% of the ADI. In relation to the MRL proposal for mancozeb in garlic, no acute intake concerns were identified (0.1 % of ARfD).

In a second risk assessment scenario EFSA compared the intake related to the MRLs established for mancozeb alone or in combination with maneb and metiram with the ADI value for metiram (0.03 mg/kg bw/d) and the ARfD value for maneb (0.2 mg/kg bw/d). These toxicological reference values were selected as they are the most critical values for the group of dithiocarbamates for which no specific analytical methods are available. Because of the lack of specific analytical methods the source of the CS₂ residue cannot be identified in enforcement. The chronic intake assessment identified a potential chronic intake concerns for DE child diet amounting for up to 114% of the ADI. The main commodities contributing to the ADI exceedances are apples (49.4%), tomatoes (17.2%), and table grapes (15.5%). EFSA did further refinements taking into account the available food consumption data for German children as reported in the VELs study. Apple juice has significantly higher proportion in the children diet than raw apple therefore EFSA applied the processing factor available for apple juice and then estimated the contribution of apples to the total ADI. After refined calculations the contribution of apples to the ADI decreased from 49 to 23% resulting in a chronic exposure not higher than 91% of the ADI.

No acute intake concerns were identified for garlic.

In addition, EFSA performed theoretical estimation of the possible ETU concentrations formed in processed garlic. The ETU intake was calculated to be insignificant (less than 1 % of the ADI and less than 0.3 % of the ARfD of ETU). No consumer intake concerns are associated with ETU in processed garlic.

It is concluded that the MRL proposal of 0.5 mg/kg in garlic is acceptable with regard to consumer safety.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Garlic	0.1	0.5	No consumer intake concerns are associated with the proposed MRL of 0.5 mg/kg for dithiocarbamates, expressed as CS ₂ , in garlic (resulting from a use of mancozeb).

Key words: Mancozeb, garlic, MRL application, Regulation (EC) No 396/2005, dithiocarbamates, CS₂

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Chapter II of the Regulation, dealing with the procedure to set new MRLs or to amend existing MRLs, entered into force on 2 September 2008.

According to Article 6(2) of Regulation (EC) No 396/2005, The United Kingdom received an application from the Horticultural Development Council (HDC)² on the modification of the existing MRL for mancozeb in garlic. On 26 September 2008, according to Article 9 of Regulation (EC) No 396/2005, the Evaluation Report prepared by the EMS on this subject was submitted to the European Commission and forwarded to EFSA.

After the receipt of the Evaluation Report, EFSA included the application in the EFSA Register of Questions with the number EFSA-Q-2008-733 and the following subject:

Mancozeb - Application to modify the existing MRL for dithiocarbamates (dithiocarbamates expressed as CS₂, including maneb, mancozeb, metiram, propineb, thiram and ziram) in garlic from 0.1 mg/kg to 0.5 mg/kg.

TERMS OF REFERENCE

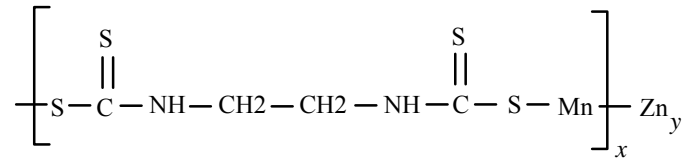
In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA was requested to provide a reasoned opinion on the risks to consumer associated with the application to modify an MRL for mancozeb in garlic from 0.1 mg/kg to 0.5 mg/kg. The EFSA opinion shall be based in particular on the Evaluation Report prepared by the Evaluating Member State the United Kingdom.

In accordance with Article 11 of Regulation (EC) No 396/2005, the reasoned opinion shall be provided as soon as possible, at the latest within three months from the date of receipt of the application. In this case the deadline for submission of the reasoned opinion is 26 December 2008.

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THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Mancozeb is the ISO common name for manganese ethylenbis dithiocarbamate (polymeric) complex with zinc salt, having the following structural formula:



Mancozeb is an ethylene bisdithiocarbamate (EBDC) fungicide. It is effective against a wide range of foliar fungal diseases. It is known to disrupt the respiratory activity of the target fungi. Mancozeb is a contact fungicide and is used on a wide variety of crops in agriculture and horticulture.

Mancozeb has been assessed in the stage one of the peer review according to the provisions established in Directive 91/414/EEC with Italy being the designated Rapporteur Member State. It is included in the Annex I of this Directive by the Commission Directive 2005/72/EC and is authorized for the use as a fungicide only. The representative uses evaluated under the peer review contain foliar use on apples, grapes, tomatoes and potatoes.

In the European Community no specific MRLs are set for mancozeb, but for a group of dithiocarbamates comprising maneb, mancozeb, metiram, propineb, thiram, ziram. The residues are expressed as a carbon disulphide (CS₂) which is the common moiety for all dithiocarbamates. In addition, specific MRLs have been established for propineb, thiram and ziram, the three dithiocarbamates, for which specific analytical methods are available. The maximum residue values for the dithiocarbamates are set in the Annex II and Annex IIIB of the Regulation (EC) No 396/2005 and are summarized in the Appendix C.

The current MRL for garlic is 0.1 mg/kg (expressed as CS₂) which originates from the use of mancozeb. The applicant proposed to set an MRL of 0.5 mg/kg for garlic.

In Codex Alimentarius the CXL is set for garlic at the level of 0.5 mg/kg, reflecting the critical use of mancozeb.

The application in the United Kingdom which triggered the MRL request refers to an outdoor spray application of mancozeb on garlic, bulb onions and shallots with four applications with an application rate of 1.95 kg a.s./ha per treatment. The minimum waiting period is 28 days. The GAP is given in Appendix A.

ASSESSMENT

1. Methods of analysis

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

No specific enforcement method is available for mancozeb. Under the peer review of mancozeb, several analytical methods were submitted by applicant and assessed by the Rapporteur Member State Italy (Italy, 2000). Generally, all analytical methods are based on the conversion of dithiocarbamates to CS₂ which is then measured by chromatography or colorimetry. These methods would not allow distinguishing which active substance belonging to the group of dithiocarbamates was originally applied on the crop. Therefore the CS₂ method is supposed as a screening tool. In case of positive findings, the origin of the residue should be identified by analysing the sample with specific methods which are available for thiram, propineb and ziram.

Sufficient validation data are available for five analytical methods for the determination of dithiocarbamates (expressed as CS₂) in commodity groups with high water and high acid content and in dry commodities. The achievable LOQ is in the range of 0.01-0.1 mg/kg. However, it should be taken into consideration that these analytical methods are unable to distinguish between naturally occurring CS₂ levels and the ones arising from the use of dithiocarbamates.

It is concluded that adequate analytical methods are available for the enforcement of an MRL of mancozeb (expressed as CS₂) in garlic.

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

Since garlic is not used as a livestock feedingstuff, no analytical methods are required for determination of mancozeb in the food of animal origin.

2. Mammalian toxicology

The toxicological reference values for mancozeb were derived in the peer review under Directive 91/414/EEC and are compiled in the Table 2-1 (European Commission, 2005). The table also reports the toxicological reference values for maneb and metiram, which are the active substances for which no specific enforcement methods are available.

In addition, since ethylenethiourea (ETU) is a metabolite and degradation product of maneb, mancozeb and metiram that is formed under high temperatures and has higher toxicity than parent compounds, its reference values are also included 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
Mancozeb					
ADI	COM	2005	0.05	2 yr rat	100
ARfD	COM	2005	0.6	Rat teratogenicity	100
Maneb					
ADI	COM	2005	0.05	Rat multigeneration	100
ARfD	COM	2005	0.2	Rat developmental	100
Metiram					
ADI	COM	2005	0.03	2 yr rat	100
ARfD	Not necessary				
ETU					
ADI	COM	2005	0.002	1 yr dog	100
ARfD	COM	2005	0.05	Rat teratogenicity	100

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Under the peer review of Directive 91/414/EEC the metabolism studies were submitted for the following crop categories (Italy, 2000):

- pulses and oilseed (soybeans)- foliar application, 2x 3.36 kg a.s./ha
- fruits and fruiting vegetables (tomato)- foliar application 9x 2.7 kg a.s./ha
- root and tuber vegetables (potatoes, sugar beet)- foliar application 3x 2.24 kg a.s./ha (sugar beet) and 3x 4.0 kg a.s./a and 3x 1.7 kg a.s./ha (potato)

- cereals (wheat)-foliar application 3 x 2.24 kg a.s./ha

Metabolism studies indicate that mancozeb is extensively degraded in plants and the majority of the radioactivity is incorporated into naturally-occurring biological molecules, such as simple and complex sugars (up to 41% of the TRR), starch (up to 27%), protein and amino acids (up to 45%), oil or lipid (up to 14%) and lignin (up to 23%). The level of toxicologically significant metabolite ethylenethiourea (ETU) was below the limit of quantification in all crop matrices and ETU was not detected as part of the metabolism study in any crop except for potato (0.0007 mg/kg). Considering the low levels of ETU and that no other studies identified this metabolite, ETU is not included in the residue definition for unprocessed primary crops.

The proposed metabolic pathway for formation of natural products is either through glycine or through enzyme-catalysed, oxidative cleavage into single carbon units of radiolabelled ethylene backbone of mancozeb, allowing for more direct metabolism.

It was concluded that metabolism in all crop categories is similar and the residue definition for enforcement purposes in all plant products can be established as “mancozeb (expressed as CS₂)”. In Regulation (EC) No 396/2005 it was decided to establish a screening residue definition (dithiocarbamates, expressed as CS₂, including maneb, mancozeb, metiram, propineb, thiram and ziram). In addition, specific residue definitions have been established for the active substances for which specific analytical methods for enforcement are available, i.e. propineb, thiram and ziram.

Residue definition for the risk assessment in raw commodities is established as “mancozeb (expressed as CS₂)”. For processed commodities see Section 3.1.1.3.

Since garlic belong to the category of root and tuber vegetables, it is concluded that metabolism of mancozeb in garlic is sufficiently addressed and no additional metabolism studies are necessary.

3.1.1.2. Magnitude of residues

Storage stability

Under the peer review of mancozeb, the storage stability data were submitted for high water and high acid content commodities - apples, tomatoes and grapes respectively (Italy, 2000). It is demonstrated that under conditions of frozen storage residues of mancozeb are stable for up to two years. Since garlic belong to the group of commodities with high water content, the storage stability demonstrated for apples and tomatoes is representative also for garlic.

The supervised field trial samples were stored for maximum of 5 months at the temperature of ≤-18°C (The United Kingdom, 2006). It is concluded that analytical results are reliable with regard to storage stability.

Analytical methods

For the analysis of supervised field trial samples, a method specific to CS₂ was used, which complies with the residue definition established for enforcement purposes (The United Kingdom, 2006). The residue levels were reported as CS₂, but also as mancozeb after being converted by applying the molecular weight conversion factor of 1.78. According to the evaluation of the EMS, the analytical method applied for analysing supervised field trial samples is sufficiently validated and fit for purpose.

Residue trials

Applicant submitted eight supervised field trials supporting the GAP on garlic for which an authorisation was requested in The United Kingdom. The proposed GAP refers to the application rate of 4 x 1.95 kg a.s./ha and the PHI of 28 days. Supervised field trials residue data are summarized in the Table 3-1. More details concerning supervised field residue trials can be found in Appendix B.

All trials were designed as residue decline studies. Since in three trials the residue levels are higher at longer PHI, EFSA took into account these higher values in the MRL calculations. The residue levels were expressed as CS₂ and then converted to mancozeb by applying the molecular weight conversion factor of 1.78. The residue levels from all trials were in the range of 0.04 – 0.45 mg/kg CS₂.

The CS₂ concentration measured in untreated control samples were in the range of 0.03 to 0.42 mg/kg (The United Kingdom, 2006). The CS₂ methods are known to produce false positive CS₂ results for crops containing phytoenic CS₂, such as glucosinolates and mustard oils. For garlic no specific data are available, but it is assumed that the background CS₂ level might be comparable.

To derive an MRL proposal for enforcement purposes, the results reported for onions are used. The statistical methodology R_{ber} and R_{max} would justify an MRL proposal of 0.5 mg/kg. The STMR and HR were 0.16 mg/kg and 0.45 mg/kg respectively. Submitted trials are sufficient for extrapolating from onions to garlic.

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

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement	Risk assessment					
Enforcement residue definition : mancozeb expressed as CS₂									
Garlic	NEU	Outdoor	0.04; 0.06; 0.1; 0.129; 0.197; 0.21; 0.292; 0.448	0.07; 0.11; 0.18; 0.229; 0.350; 0.37; 0.519; 0.795	0.163	0.45	0.5	1.78	R _{ber} =0.54mg/kg CS ₂ R _{max} = 0.62 mg/kg CS ₂

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

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

3.1.1.3. Effect of industrial processing and/or household preparation

Under the peer review of Directive 91/414/EEC the effects of the processing on the nature of mancozeb residues was investigated in the hydrolysis study (Italy, 2000). The only degradation product of toxicological significance formed at elevated temperatures is ethylenethiourea (ETU). For processed commodities a consumer risk assessment has to be performed regarding the potential consumer health risks related to ETU. The toxicological reference values for this substance are summarized in Table 2-1.

Applicant has not submitted information concerning the magnitude of ETU residues in processed garlic. However, EFSA performed theoretical estimation on the possible consumer exposure to ETU from processed garlic, assuming that residues of mancozeb in garlic are at the proposed MRL. From the processing studies submitted in the framework of the peer review, it was estimated that ETU concentration in processed products accounts for 0.2-30% of the mancozeb concentration in raw products (Italy, 2000). Under the worst case situation, the levels of mancozeb in raw garlic would theoretically result in the formation of 0.27 mg/kg of ETU in the processed garlic. That constitutes less than 1 % of the ADI and 0.3 % of the ARfD of ETU.

However, the calculation is considered as a gross overestimation, because the following aspects were not taken into account:

- the decrease of mancozeb residues by removing the detachable skin of garlic. Mancozeb residues are known to be surface residues and during the peer review it was concluded that combination of washing, scrubbing and drying would remove approx. 70-90% of the residues (Italy, 2000)
- the ratio between raw and processed garlic in the diet
- the naturally occurring CS₂ levels in garlic (see section 3.1.1.2.).

Taking into account the above mentioned, EFSA considers that no consumer intake concerns are associated with the levels of ETU in processed garlic.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Ethylene bisdithiocarbamates (EBDC) show rapid biodegradation in soil (Italy, 2000). The highest degradation rate is observed in the sandy loam soil with a half-life of 2.1 hour (0.09 days). The half-life of EBIS in the humic sand soil is 3.1 hour (0.13 days) and in loam soil 3.6 hour (0.15 days). The DT₉₀ is 6.9 (0.29 d), 10.2 (0.43 d) and 12.1 (0.50 d) hours for the sandy loam soil, humic sand soil, and the loam soil respectively.

Since DT₉₀ value of mancozeb is approximately 1 day, no rotational crop metabolism studies are necessary.

3.2. Nature and magnitude of residues in livestock

Since garlic is not used as a livestock feedingstuff the nature and magnitude of mancozeb residues in livestock was not assessed with regard to the current application.

4. Consumer risk assessment

The consumer risk assessment regarding the parent compound mancozeb was performed with the EFSA PRIMo-rev.2 (Pesticide Residue Intake Model). In scenario 1 EFSA took into account only those MRLs which have been established following the critical use of mancozeb alone or in the combination with other dithiocarbamates. CS₂ values recalculated to mancozeb were used in the intake calculations and compared with the toxicological reference values established for mancozeb. For garlic the STMR and HR values derived for the supervised field trials were used in the calculation. For other commodities, the following input values were applied in the chronic risk assessment calculation:

- 1) For products for which only the use of mancozeb is authorized: MRL values of CS₂ or the available STMR values of CS₂ as obtained from supervised field trials recalculated to mancozeb with the molecular weight conversion factor of 1.78.
- 2) For products for which there are critical uses of mancozeb, maneb and metiram together with other dithiocarbamates propineb, thiram and ziram: MRL values of CS₂ or the available STMR values of CS₂ for maneb, mancozeb or metiram, recalculated to mancozeb with the molecular weight conversion factor of 1.78.
- 3) Products, for which the MRLs are based on the uses of thiram, propineb or ziram, where not taken into account in the consumer intake calculation.
- 4) MRLs established at the LOQ are not included in the consumer intake calculation.

The current MRL values for dithiocarbamates (expressed as CS₂) are compiled in Appendix C Part I. The products and corresponding uses of dithiocarbamates are compiled in Appendix C Part II.

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
Mancozeb, expressed as CS ₂				
Garlic	0.28	STMR ^a *CF ^b (The united Kingdom, 2006)	1.42	HR*CF ^b (The United Kingdom, 2006)
Citrus fruit, except mandarins	0.75	STMR ^a *CF ^b *PF ^d (Italy, 2007)	Acute risk assessment was performed only with regard to garlic.	
Mandarins	0.6	STMR ^a *CF ^b *PF ^d (Italy, 2007)		
Pome fruit	1.23	STMR ^a *CF ^b (Italy, 2007)		
Stone fruit	1.00	STMR ^a *CF ^b (Italy, 2007)		
Plums	0.36	STMR _{me} *CF ^b (Italy, 2007)		
Table grapes	3.67	STMR ^a *CF ^b (Italy, 2007)		
Wine grapes	0.37	STMR ^a *CF ^b *PF ^d (Italy, 2007)		

Currants (red, black and white), cranberries, gooseberries	4.09	STMR ^a *CF ^b (Italy, 2007)
Table olives	3.28	STMR ^a *CF ^b (Italy, 2007)
Mangoes	1.19	STMR ^a *CF ^b (Italy, 2007)
Bananas	0.62	STMR ^a *CF ^b (Italy, 2007)
Papaya	12.46	MRL CS ₂ *CF ^b
Beetroot	0.53	STMR ^a *CF ^b (Italy, 2007)
Potatoes	0.37	MRL CS ₂ *CF ^b *PF ^d (Italy, 2007)
Carrots, horseradish, parsnips, parsley root, salsify	0.18	STMR ^a *CF ^b (Italy, 2007)
Celeriac	0.36	STMR ma*CF ^b
Onions	0.46	STMR ^a *CF ^b (Italy, 2007)
Shallots, spring onions	1.78	MRL CS ₂ *CF ^b
Tomatoes	5.34	MRL*CF ^b (Italy, 2007)
Peppers	2.9	STMR ^a *CF ^b (Italy, 2007)
Aubergines	5.34	MRL CS ₂ *CF ^b
Okra	0.15	STMR ^a *CF ^b (Italy, 2007)
Cucurbits (edible peel)	1.12	STMR ^a *CF ^b (Italy, 2007)
Cucurbits (inedible peel)	0.45	STMR ^a *CF ^b (Italy, 2007)
Broccoli	0.48	STMR ^a *CF ^b (Italy, 2007)
Cauliflower	0.85	STMR ^a *CF ^b (Italy, 2007)
Brussels sprouts	0.09	STMR ^a *CF ^b (Italy, 2007)
Head cabbage	0.66	STMR ^a *CF ^b (Italy, 2007)
Leafy brassicas	0.37	STMR ^a *CF ^b (Italy, 2007)
Lettuce and other salad plants	0.55	STMR ^a *CF ^b (Italy, 2007)
Kohlrabi	0.25	STMR ^a *CF ^b (Italy, 2007)
Watercress	0.16	STMR ^a *CF ^b (Italy, 2007)
Witloof	0.36	STMR ^a *CF ^b (Italy, 2007)
Herbs	0.55	STMR ^a *CF ^b (Italy, 2007)
Beans (with pods)	0.43	STMR ^a *CF ^b (Italy, 2007)
Beans (without pods)	0.18	STMR ^a *CF ^b (Italy, 2007)
Peas (with pods)	0.23	STMR ^a *CF ^b (Italy, 2007)
Peas (without pods)	0.09	STMR ^a *CF ^b (Italy, 2007)
Asparagus	0.09	STMR ^a *CF ^b (Italy, 2007)
Leek	0.43	STMR ^a *CF ^b (Italy, 2007)
Rhubarb	0.16	STMR ^a *CF ^b (Italy, 2007)
Beans (dry)	0.18	STMR ^a *CF ^b (Italy, 2007)

Peas (dry)	0.18	STMR ^a *CF ^b (Italy, 2007)	
Rape seed	0.16	STMR ^a *CF ^b (Italy, 2007)	
Olive for oil production	3.28	STMR ^a *CF ^b (Italy, 2007)	
Barley, oats	1.37	STMR ^a *CF ^b (Italy, 2007)	
Rye, Wheat	0.02	STMR _{ma} ^a *CF ^b (Italy, 2007)	
Orange juice ^c	0.75	STMR ^a *CF ^b *PF ^d (Italy, 2007)	
Apple juice ^c	2.76	MRL *CF ^b *PF ^d (Italy, 2007)	

^a – STMR of CS₂ for mancozeb.

^b – molecular weight conversion factor from CS₂ to mancozeb – 1.78; Conversion factors for maneb =1.75; Conversion factors for metiram=1.79 (Italy, 2000)

^c – used only in the consumer intake calculations for metiram

ma- maneb

me- metiram

^d - PF - Processing factors: 0.14 for citrus fruit and orange juice, 0.7 for potatoes (Italy, 2007); 0.1 for wine grapes, 0.31 for apple juice (Italy, 2000)

The summary of the intake calculations can be found in Appendix D. The chronic dietary risk assessment did not reveal consumer intake concerns. The TMDI values ranged from 11 to 74 % of the ADI. For all diets the contribution of garlic is below 0.04% of the ADI. In relation to the MRL proposal for mancozeb in garlic, no acute intake concerns were identified (0.1 % of ARfD).

In a second risk assessment scenario EFSA compared the intake related to the MRLs established for mancozeb alone or in combination with maneb and metiram with the ADI value for metiram (0.03 mg/kg bw/d) and the ARfD value for maneb (0.2 mg/kg bw/d). These toxicological reference values were selected as they are the most critical values for the group of dithiocarbamates for which no specific analytical methods are available. Because of the lack of specific analytical methods the source of the CS₂ residue cannot be identified in enforcement. The chronic intake assessment identified a potential chronic intake concerns for DE child diet amounting for up to 114% of the ADI. The main commodities contributing to the ADI exceedances are apples (49%), tomatoes (17.2%), and table grapes (15.5%). EFSA did further refinements taking into account the available food consumption data for German children as reported in the VELS study (Germany, 2005). Apple juice has significantly higher proportion in the children diet than raw apple (see Table 4-1) therefore EFSA applied the processing factor available for apple juice and then estimated the contribution of apples to the total ADI. After refined calculations the contribution of apples to the ADI decreased from 49 to 23% resulting in a chronic exposure not higher than 91% of the ADI. No acute intake concerns were identified for garlic. The summary of the intake calculations can be found in Appendix E.

Table 4-2. **Apple consumption data for German children**

Commodity	NEDI (g/d)	MRL (mg/kg)	STMR mancozeb (STMR CS ₂ *CF)	Intake (mg/kg bw/d)	The contribution of apples to the total ADI with PF applied (%)
Apples, total	194.9	5	1.23	0.0148	23.2
Apples, raw	37.9	5	1.23	0.0028	9.6
Apples, processed	6.8	5	1.23	0.0005	1.7
Apples, portion in juice	150.2	5	0.38131	0.0035	11.8

¹ - STMR value with processing factor of 0.31 for apple juice (Italy, 2000)

It is concluded that the MRL proposal of 0.5 mg/kg for mancozeb in garlic is acceptable regarding consumer safety.

CONCLUSIONS AND RECOMMENDATIONS

The United Kingdom received an application from the Horticultural Development Council (HDC) on the modification of the existing MRL for dithiocarbamates in garlic (dithiocarbamates, expressed as CS₂, including maneb, mancozeb, metiram, propineb, thiram and ziram). The United Kingdom as an Evaluating Member State (EMS) drafted an Evaluation Report which was forwarded to the European Commission and to EFSA. The modification was requested in order to accommodate the MRL to the envisaged use in the United Kingdom of a plant protection product containing mancozeb in garlic.

Mancozeb is a substance belonging to the group of dithiocarbamates such as maneb, thiram, metiram, propineb, ziram. Since there is no specific enforcement method for the determination of mancozeb, MRLs were established for CS₂, which is the common moiety for all dithiocarbamates. The current MRL for garlic set in Regulation (EC) No 396/2005 is 0.1 mg/kg which reflects the currently authorised use of mancozeb in some Member States. The applicant proposed to raise the MRL to 0.5 mg/kg as an extrapolation from onions.

EFSA derives the following conclusions regarding the application, based on the Draft Assessment Report prepared by Italy in the framework of Directive 91/414/EEC and the evaluation report prepared by the EMS:

The toxicological profile of mancozeb was investigated under the peer review and data were sufficient to conclude on an ADI value of 0.05 mg/kg bw/d and an ARfD value of 0.6 mg/kg bw/day.

Adequate analytical enforcement methods exist for the determination of CS₂. The conversion factor for recalculating CS₂ to mancozeb is 1.78.

Metabolism studies in four different crop groups indicate that mancozeb is extensively degraded in plants and the majority of the radioactivity is incorporated into naturally-occurring biological molecules. It was concluded that metabolism in all crop categories is similar and the residue definition for enforcement purposes can be established in all plant products as “mancozeb (expressed as CS₂)”. Since no specific analytical methods are available for the individual active substances belonging to the dithiocarbamate group, a screening residue definition was established in Regulation (EC) No 396/2005 as “dithiocarbamates (dithiocarbamates, expressed as CS₂, including maneb, mancozeb, metiram, propineb, thiram and ziram)”. In case of positive findings further investigations are necessary to identify the origin of the CS₂ residue. For propineb, thiram and ziram for which compound specific residue methods are available, separate MRLs have been established in the Regulation (EC) No 396/2005. If the CS₂ residue observed in the screening can not be identified as one of these compounds, the unspecific CS₂ MRL related to a use of mancozeb, metiram or maneb is applicable.

During the peer review the possibility of the formation of metabolite ethylenethiourea (ETU) was identified. ETU is a toxicologically relevant degradation product of maneb, mancozeb and metiram that is formed in crops which undergo heat treatment. ETU should therefore be also considered in a consumer risk assessment of processed commodities.

Regarding rotational crops, no significant residue levels are expected to occur since DT₉₀ value of mancozeb is approximately one day. The residues in commodities of animal origin were not assessed in the framework of this application considering that garlic is not a livestock feedingstuff.

In support of the proposed GAP, the applicant submitted supervised field trials on onions which can be used to extrapolate to garlic. To cover the proposed GAP on garlic an MRL of 0.5 mg/kg is necessary.

A consumer risk assessment was performed for parent compound mancozeb using the EFSA PRIMo-rev.2. EFSA considered only those MRLs which are related to a use of mancozeb alone or in combination with maneb and metiram, and compared the estimated intake with the toxicological reference values for mancozeb. Available STMR values of CS₂ or MRL values of CS₂ were converted to mancozeb by applying the molecular weight conversion factor 1.78. For garlic, the STMR and HR values derived from the supervised trials of mancozeb were used. The chronic dietary risk assessment did not reveal consumer intake concerns. The TMDI values ranged from 11 to 74% of the ADI. For all diets the contribution of garlic is below 0.04% of the ADI. In relation to the MRL proposal for mancozeb in garlic, no acute intake concerns were identified (0.1 % of ARfD).

In a second risk assessment scenario EFSA compared the intake related to the MRLs established for mancozeb alone or in combination with maneb and metiram with the ADI value for metiram (0.03 mg/kg bw/d) and the ARfD value for maneb (0.2 mg/kg bw/d). These toxicological reference values were selected as they are the most critical values for the group of dithiocarbamates for which no specific analytical methods are available. Because of the lack of specific analytical methods the source of the CS₂ residue cannot be identified in enforcement. The chronic intake assessment identified a potential chronic intake concerns for DE child diet amounting for up to 114% of the ADI. The main commodities contributing to the ADI exceedances are apples (49%), tomatoes (17.2%), and table grapes (15.5%). EFSA did further refinements taking into account the available food consumption data for German children as reported in the VELs study. Apple juice has significantly higher proportion in the children diet than raw apple therefore EFSA applied the processing factor available for apple juice and then estimated the contribution of apples to the total ADI. After refined calculations the contribution of apples to the ADI decreased from 49 to 23% resulting in a chronic exposure not higher than 91% of the ADI.

No acute intake concerns were identified for garlic.

In addition, EFSA performed theoretical estimation of the possible ETU concentrations formed in processed garlic. The ETU intake was calculated to be insignificant (less than 1 % of the ADI and less than 0.3 % of the ARfD of ETU). No consumer intake concerns are associated with ETU in processed garlic.

It is concluded that the MRL proposal of 0.5 mg/kg in garlic is acceptable with regard to consumer safety.

Table 5-1. Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Garlic	0.1	0.5	No consumer intake concerns are associated with the proposed MRL of 0.5 mg/kg for dithiocarbamates, expressed as CS ₂ , in garlic (resulting from a use of mancozeb).

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- Italy, 2000. Monograph prepared in the context of the inclusion of the following active substance in Annex I of the Council Directive 91/414/EEC- Mancozeb. September, 2000.
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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Crop and/or situation	F or G	Pest or group of pests controlled	Formulation rate per treatment		Application				Application rate per treatment			PHI (days)	Remarks: (m) e.g. minimum realistic PHI
			Type	Conc. of as	method, kind if other than spray	growth stage	number (range)	Interval (days)	kg as/hl, where appropriate	water l/ha	kg as/ha, where appropriate		
Bulb onion, garlic and shallot	F	Fungal foliar disease especially downy mildew (<i>Peronospora destructor</i>)	WG	750 g/kg	Conventional hydraulic sprayers including air assisted hydraulic sprayers	Growth stage 49 at last treatment (June to October)	max 7.8 kg as/ha	7	0.195–0.975 kg as/hl	200–1000 l/ha	1.95 kg as/ha	28 days	Residue trials support 4 applications of 2.5 kg formulated product/ha 'Dithane 945'. First application at growth stage 41-45.

APPENDIX B –SUMMARY OF FIELD RESIDUE TRIALS

Report No Study No Location incl. postal code	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment.			Dates of treatment(s) or no. of treatments and last date (d)	Growth stage at last treatment	Portion analysed	Residues (mg/kg)		DALT/ PHI (days) (f)	Remarks (g)
				kg as/ha	Water (L/ha)	kg as/hL				CS ₂ mg/ kg	Mancozeb mg/kg		
Study No: GHE-P-10769 (DP 134291) Trial number: A/UK/F/03/38 Location: Hum Farm, Newborough, PE6 7RL, UK.	Bulb onion 'Sherpa'	1) 12/03/2003 3) 07/08/2003 – 02/10/2003	Hydraulic spray boom sprayer	1) 2.262 2) 2.119 3) 1.762 4) 1.714	1) 226 2) 211 3) 176 4) 171	1) 1.000 2) 1.004 3) 1.001 4) 1.002	1) 15/07/2003 2) 22/07/2003 3) 31/07/2003 4) 07/08/2003	22-41 cm crop height; BBCH growth stage 49	Onion bulb	0.190 1.497 4.313 0.456 <u>0.292</u> 0.269 0.185	0.338 2.658 7.660 0.810 <u>0.519</u> 0.478 0.328	Mean background -0 0 14 28 42 56	Storage period 124 days.
Study No: GHE-P-10769 (DP 134291) Trial number: A/NF/F/03/39 Location: 17, rue Chémy, F-08310, Aussance, France.	Bulb onion 'Summit'	1) 08/05/2003 3) 26/08/2003 – 21/10/2003	Conventional broadcast application with hand held boom sprayer.	1) 2.017 2) 2.033 3) 1.933 4) 2.100	1) 403 2) 407 3) 387 4) 420	1) 0.500 2) 0.500 3) 0.499 4) 0.500	1) 05/08/2003 2) 12/08/2003 3) 19/08/2003 4) 26/08/2003	50 cm crop height; BBCH growth stage 47	Onion bulb	0.104 0.076 1.019 0.142 0.082 <u>0.129</u> 0.109	0.185 0.135 1.810 0.253 0.145 <u>0.229</u> 0.194	Mean background -0 0 14 26 42 56	Storage period 105 days.

Report No Study No Location incl. postal code	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment.			Dates of treatment(s) or no. of treatments and last date (d)	Growth stage at last treatment	Portion analysed	Residues (mg/kg)		DALT/ PHI (days) (f)	Remarks (g)
				kg as/ha	Water (L/ha)	kg as/hL				CS ₂ mg/ kg	Mancozeb mg/kg		
Study No: GHE-P-10769 (DP 134291) Trial number: A/NF/F/03/41 Location : 1, rue Charles de Gaulle, F- 51400, Livry Louvercy, France	Bulb onion 'Takmark'	1) 12/03/2003 3) 23/09/2003 – 08/10/2003	Conventional broadcast application with hand held boom sprayer.	1) 1.917 2) 1.967 3) 2.067 4) 2.000	1) 383 2) 393 3) 413 4) 400	1) 0.501 2) 0.501 3) 0.500 4) 0.500	1) 05/08/2003 2) 12/08/2003 3) 19/08/2003 4) 26/08/2003	50 cm crop height; BBCH growth stage 47	Onion bulb	0.127 <u>0.197</u> 0.186	0.225 <u>0.350</u> 0.330	Mean background 28 43	Storage period 77 days.
Study No: GHE-P-10769 (DP 134291) Trial number: A/BE/F/03/40 Location : Hervé Dumont de Chassart. Rue Dominique Seret, 34, 6210 Villers-Perwin, Belgium.	Bulb onion 'TEX 2095'	1) 28/05/2003 3) 15/10/2003 – 30/10/2003	Broadcast foliar application with horizontal boom sprayer.	1) 1.967 2) 1.984 3) 2.033 4) 2.050	1) 300 2) 303 3) 310 4) 313	1) 0.656 2) 0.655 3) 0.656 4) 0.655	1) 27/08/2003 2) 03/09/2003 3) 11/09/2003 4) 17/09/2003	BBCH growth stage 45	Onion bulb	0.423 <u>0.448</u> 0.249	0.751 <u>0.795</u> 0.443	Mean background 28 43	Storage period 51 days.

Report No Study No Location incl. postal code	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment.			Dates of treatment(s) or no. of treatments and last date (d)	Growth stage at last treatment	Portion analysed	Residues (mg/kg)		DALT/ PHI (days) (f)	Remarks (g)
				kg as/ha	Water (L/ha)	kg as/hL				CS ₂ mg/ kg	Mancozeb mg/kg		
Study No: GHE-P-11051 (DP 134292) Trial number: A/UK/F/04/33 Location: Hum Farm, Newborough, PE6 7RL, UK.	Bulb onion 'Shepa'	1)01/03/2004 3) 17/08/2004– 12/10/2004	Hand hydraulic spray boom sprayer	1)1.757 2)2.042 3)2.037 4)2.116	1)264 2)306 3)306 4)318	1)0.666 2)0.667 3)0.667 4)0.665	1)20/07/2004 2)27/07/2004 3)08/08/2004 4)17/08/2004	35–68 cm crop height; BBCH growth stage 43–49.	Onion bulb	0.15 0.20 0.22 0.04 0.06 0.07 <u>0.10</u>	0.26 0.35 0.39 0.07 0.11 0.13 <u>0.18</u>	Mean background -0 0 14 28 42 56	Storage period 72 days.
Study No: GHE-P-11051 (DP 134292) Trial number: A/NF/F/04/32 Location : F- 51400, Sept Saulx, France.	Bulb onion 'Takmark'	1)08/04/2004 3)05/08/2004– 30/09/2004	Conventional broadcast application with hand held boom sprayer.	1)1.844 2)2.000 3)1.978 4)2.000	1)553 2)600 3)593 4)600	1)0.333 2)0.333 3)0.334 4)0.333	1)15/07/2004 2)22/07/2003 3)29/07/2003 4)05/08/2003	70 cm crop height; BBCH growth stage 45	Onion bulb	0.12 0.06 0.32 0.38 0.07 <u>0.21</u> 0.15	0.22 0.10 0.57 0.67 0.12 <u>0.37</u> 0.26	Mean background -0 0 14 28 42 56	Storage period 84 days.

Report No Study No Location incl. postal code	Commodity / Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Method of treatment (c)	Application rate per treatment.			Dates of treatment(s) or no. of treatments and last date (d)	Growth stage at last treatment	Portion analysed	Residues (mg/kg)		DALT/ PHI (days) (f)	Remarks (g)
				kg as/ha	Water (L/ha)	kg as/hL				CS ₂ mg/ kg	Mancozeb mg/kg		
Study No: GHE-P-11051 (DP 134292) Trial number: A/NF/F/04/31 Location: Place de Primat, F-08250, Olizy- Primat, France	Bulb onion 'Athos'	1) 17/03/2004 3) 27/08/2004 – 10/09/2004	Conventional broadcast application with hand held boom sprayer.	1) 2.111 2) 1.867 3) 2.000 4) 2.022	1) 633 2) 560 3) 600 4) 607	1) 0.333 2) 0.333 3) 0.333 4) 0.333	1) 09/07/2004 2) 16/07/2004 3) 23/07/2004 4) 30/07/2004	60 cm crop height; BBCH growth stage 47	Onion bulb	0.03 <u>0.06</u> 0.06	0.06 <u>0.11</u> 0.10	Mean background 28 42	Storage period 61 days.
Study No: GHE-P-11051 (DP 134292) Trial number: A/BE/F/04/34 Location: 4, Rue de Chassart, 6221 Saint-Amand, Belgium.	Bulb onion 'Summit F1'	1) 28/05/2003 3) 23/08/2004 – 06/09/2004	Broadcast foliar application with horizontal boom sprayer.	1) 1.946 2) 1.943 3) 1.971 4) 2.013	1) 386 2) 386 3) 392 4) 400	1) 0.504 2) 0.503 3) 0.503 4) 0.503	1) 05/07/2004 2) 12/07/2004 3) 19/07/2004 4) 26/07/2004	35–40 cm crop height, BBCH growth stage 46	Onion bulb	0.03 <u>0.04</u> 0.03	0.06 <u>0.07</u> 0.05	Mean background 28 42	Storage period 72 days.

(a) According to Codex (or other *e.g.* EU) classification)

(b) Only if relevant

(c) High or low volume spraying, spreading, dusting, *etc.*, overall, broadcast, type of equipment used must be indicated

(d) Year must be indicated

(e) BBCH Monograph, Growth Stages of Plants, 1997, (Blackwell, ISBN 3-8263-3152-4)

(f) Minimum number of days after last treatment/application (Label pre-harvest interval, PHI, underline)

(g) Remarks may include: inadequacies, climatic conditions, reference to analytical method, information concerning the metabolites included, the method of storage, storage stability, analysis date

APPENDIX C – CURRENT MRL VALUES AS IN REGULATION 396/2005/EC

Part I

* - limit of quantification

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	i) Citrus fruit	5 (ft)
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	5
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	5
110030	Lemons (Citron, lemon)	5
110040	Limes	5
110050	Mandarins (Clementine, tangerine and other hybrids)	5
110990	Others	5
120000	(ii) Tree nuts (shelled or unshelled)	
120010	Almonds	0,05*
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	0,05*
120050	Coconuts	0,05*
120060	Hazelnuts (Filbert)	0,05*
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	0,05*
120110	Walnuts	0,1
120990	Others	0,05*
130000	iii) Pome fruit	5
130010	Apples (Crab apple)	5
130020	Pears (Oriental pear)	5
130030	Quinces	5
130040	Medlar	5
130050	Loquat	5

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)
130990	Others	5
140000	(iv) Stone fruit	
140010	Apricots	2
140020	Cherries (sweet cherries, sour cherries)	2
140030	Peaches (Nectarines and similar hybrids)	2
140040	Plums (Damson, greengage, □rench□as)	2
140990	Others	0,05*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	5
151010	Table grapes	5
151020	Wine grapes	5
152000	(b) Strawberries	10
153000	© Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,05*
153030	Raspberries (Wineberries)	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries cowberries (red bilberries))	5
154020	Cranberries	5
154030	Currants (red, black and white)	5
154040	Gooseberries (Including hybrids with other ribes species)	5
154050	Rose hips	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)
154060	Mulberries (arbutus berry)	0,05*
154070	Azarole (mediteranean medlar)	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea shallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	5
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	5
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	© Inedible peel, large	
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	2
163030	Mangoes	2
163040	Papaya	7
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,05*
163070	Guava	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,3
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)
213000	© Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,5
213020	Carrots	0,2
213030	Celeriac	0,3
213040	Horseradish	0,2
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,2
213070	Parsley root	0,2
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,2
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	
220010	Garlic	0,1
220020	Onions (Silverskin onions)	1
220030	Shallots	1
220040	Spring onions (Welsh onion and similar varieties)	1
220990	Others	0,05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	3
231020	Peppers (Chilli peppers)	5
231030	Aubergines (egg plants) (Pepino)	3
231040	Okra, lady's fingers	0,5
231990	Others	0,05*
232000	(b) Cucurbits – edible peel	2
232010	Cucumbers	2
232020	Gherkins	2

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)
232030	Courgettes (Summer squash, marrow (patisson))	2
232990	Others	2
233000	© Cucurbits-inedible peel	1
233010	Melons (Kiwano)	1
233020	Pumpkins (Winter squash)	1
233030	Watermelons	1
233990	Others	1
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	1
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	1
241020	Cauliflower	1
241990	Others	1
242000	(b) Head brassica	
242010	Brussels sprouts	2
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	3
242990	Others	0,05*
243000	© Leafy brassica	0,5
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,5
243020	Kale (Borecole (curly kale), collards)	0,5
243990	Others ()	0,5
244000	(d) Kohlrabi	1
250000	(v) Leaf vegetables & fresh herbs	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)
251000	(a) Lettuce and other salad plants including Brassicacea	5
251010	Lamb's lettuce (Italian cornsalad)	5
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	5
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	5
251040	Cress	5
251050	Land cress	5
251060	Rocket, Rucola (Wild rocket)	5
251070	Red mustard	5
251080	Leaves and sprouts of □rench □as □pp (Mizuna)	5
251990	Others	5
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner □s lettuce), garden purslane, common purslane, sorrel, glasswort)	5
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	© Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,3
255000	(e) Witloof	0,5
256000	(f) Herbs	5
256010	Chervil	5
256020	Chives	5

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	5
256040	Parsley	5
256050	Sage (Winter savory, summer savory,)	5
256060	Rosemary	5
256070	Thyme (marjoram, oregano)	5
256080	Basil (Balm leaves, mint, peppermint)	5
256090	Bay leaves (laurel)	5
256100	Tarragon (Hyssop)	5
256990	Others	5
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (□rench beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	1
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,1
260030	Peas (with pods) (Mangetout (sugar peas))	1
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,1
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,5
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	3

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)
270070	Rhubarb	0,5
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,05*
280990	Others	0,05*
290000	(ix). Sea weeds	
300000	3. PULSES, DRY	
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,1
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,1
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	0,1*
401020	Peanuts	0,1*
401030	Poppy seed	0,1*
401040	Sesame seed	0,1*
401050	Sunflower seed	0,1*
401060	Rape seed (Bird rapeseed, turnip rape)	0,5
401070	Soya bean	0,1*
401080	Mustard seed	0,1*
401090	Cotton seed	0,1*
401100	Pumpkin seeds	0,1*
401110	Safflower	0,1*
401120	Borage	0,1*
401130	Gold of pleasure	0,1*
401140	Hempseed	0,1*
401150	Castor bean	0,1*
401990	Others	0,1*
402000	(ii) Oilfruits	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)
402010	Olives for oil production	5
402020	Palm nuts (palmoil kernels)	0,1*
402030	Palmfruit	0,1*
402040	Kapok	0,1*
402990	Others	0,1*
500000	5. CEREALS	
500010	Barley	2
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	2
500060	Rice	0,05*
500070	Rye	1
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	1
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	© Roots	0,1*
633010	Valerian root	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	25
800000	8. SPICES	
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)
840040	Horse-radish	0,1*
840990	Others	0,1*
850000	(v) Buds	
850010	Cloves	0,1*
850020	Capers	25
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Aril	0,1*
870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	2
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	© Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry –chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dithiocarbamates (dithiocarbamates expressed as CS ₂ , including maneb, mancozeb, metiram, propineb, thiram and ziram)
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(iii) Birds □ eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

Part II

The origin of residues for each group of commodities for which an MRL for dithiocarbamates is set:

110000	(i) Citrus fruit (mz) ^a
120110	Walnuts (mz)
130000	(iii) Pome fruit (ma, mz, me, pr, t, z)
140010	Apricots (mz, t)
140020	Cherries (sweet cherries, sour cherries) (mz, me, pr, t, z)
140030	Peaches (Nectarines and similar hybrids) (mz, t)
140040	Plums (Damson, greengage) (mz, me, t, z)
151000	(a) Table and wine grapes (ma, mz, me, pr, t)
152000	(b) Strawberries (t)
154030	Currants (red, black and white) (mz)
161030	Table olives (mz, pr)
163020	Bananas (Dwarf banana, plantain, apple banana) (mz, me)
163030	Mangoes (mz)
163040	Papaya (mz)
211000	(a) Potatoes (ma, mz, me, pr)
213010	Beetroot (mz)
213020	Carrots (mz)
213030	Celeriac (ma, me, pr, t)
213040	Horseradish (mz)
213060	Parsnips (mz)
213070	Parsley root (mz)
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant)) (mz)
220010	Garlic (mz)
220020	Onions (Silverskin onions) (ma, mz)
220030	Shallots (ma, mz)
220040	Spring onions (Welsh onion and similar varieties) (mz)
231010	Tomatoes (Cherry tomatoes,) (mz, me, pr)
231020	Peppers (Chilli peppers) (mz, pr)
231030	Aubergines (egg plants) (Pepino) (mz, me)
231040	Okra, lady's fingers (mz)
232000	(b) Cucurbits – edible peel (mz, pr)
233000	(c) Cucurbits – inedible peel (mz, pr)
241000	(a) Flowering brassicas (mz)
242010	Brussels sprouts (mz)
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage) (mz)
243000	(c) Leafy brassicas (mz)
244000	(d) Kohlrabi (mz)
251000	(a) Lettuce and other salad plants including Brassicacea (mz, me, t)
254000	(d) Water cress (mz)
255000	(e) Witloof (mz)
256000	(f) Herbs (mz, me)
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans) (mz)
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea) (mz)
260030	Peas (with pods) (Mangetout (sugar peas)) (ma, mz)
260040	Peas (without pods) (Garden pea, green pea, chickpea) (mz)
270010	Asparagus (mz)
270060	Leek (ma, mz)

270070	Rhubarb(mz)
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas) (mz)
300030	Peas (Chickpeas, field peas, chickling vetch) (mz)
401060	Rape seed (Bird rapeseed, turnip rape) (ma, mz)
402010	Olives for oil production (mz, pr)
500010	Barley(ma, mz)
500050	Oats(ma, mz)
500070	Rye(ma, mz)
500090	Wheat (Spelt Triticale) (ma, mz)
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder(pr)
^a - In brackets the origin of the residue (ma: maneb mz: mancozeb me: metiram pr: propineb t: thiram z: ziram).	

APPENDIX D- PESTICIDE RESIDUES INTAKE MODEL (PRIMO)- SCENARIO 1

Mancozeb			
Status of the active substance:	Included	Code no.	#N/A
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.05	ARfD (mg/kg bw):	0.6
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2005	Year of evaluation:	2005

For acute RA- HR value of garlic-1.42 mg/kg; For chronic RA- STMR values (mg/kg) for: garlic-0.28; citrus fruit (except mandarins) 0.75; pome fruit-1.23; mandarins-0.6; stone fruit except plums-1.00 plums-0.36; table grapes-0.37; wine grapes - 3.67; blueberries, cranberries gooseberries, currants (red, black and white)-4.09; table olives-3.28; mangoes-1.19; bananas-0.62; papaya-12.46; beetroot-0.53; potatoes-0.37; celeriac-0.36; horseradish, parsley root, parsnips, salsify, carrots -0.18; onions-0.46; shallots, spring onions-1.78; tomatoes-5.34; peppers-2.9; aubergines-5.34; okra-0.15; cucurbits(edible peel)-1.12; cucurbits(inedible peel)-0.45; broccoli-0.48; cauliflower-0.85; Brussels sprouts-0.09; head cabbage-0.66; leafy brassicas--0.37; lettuce and other salad plants, herbs-0.55; kohlrabi-0.25; watercress-0.16; witloof-0.36; beans (with pods)-0.43; beans (without pods)-0.18; peas (with pods)-0.43; peas (without pods)-0.09; asparagus-0.09; leek- 0.43; rhubarb-0.16; beans (dry)-0.18; peas (dry)-0.18; rape seed-0.16; olive for oil production- 3.28; barley, oats--1.37; rye, wheat-0.02.

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum							
		11 --- 74							
		No of diets exceeding ADI: ---							
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet		2nd contributor to MS diet		3rd contributor to MS diet		pTMRLs at LOQ	
		(in % of ADI)	Commodity / group of commodities	(in % of ADI)	Commodity / group of commodities	(in % of ADI)	Commodity / group of commodities	(in % of ADI)	(in % of ADI)
74.1	WHO Cluster diet B	32.9	Tomatoes	12.6	Olives for oil production	3.1	Aubergines (egg plants)		
70.5	DE child	29.6	Apples	10.3	Tomatoes	9.3	Table grapes		
50.2	NL child	15.6	Apples	6.7	Tomatoes	5.6	Table grapes		
33.7	IE adult	4.3	Tomatoes	3.4	Barley	3.0	Aubergines (egg plants)		
31.1	FR toddler	8.3	Tomatoes	6.4	Apples	3.8	Potatoes		
29.3	ES child	10.5	Tomatoes	4.8	Olives for oil production	3.2	Oranges		
27.7	WHO regional European diet	11.7	Tomatoes	3.0	Potatoes	1.6	Apples		
27.6	PT General population	9.6	Tomatoes	4.0	Potatoes	2.6	Apples		
26.5	SE general population 90th percentile	8.2	Tomatoes	3.1	Potatoes	2.6	Apples		
26.3	DK child	5.7	Apples	5.7	Tomatoes	3.7	Cucumbers		
25.9	IT kids/toddler	15.2	Tomatoes	2.2	Apples	1.1	Aubergines (egg plants)		
24.6	WHO cluster diet D	10.8	Tomatoes	3.0	Potatoes	1.6	Apples		
23.8	WHO cluster diet E	5.6	Tomatoes	2.9	Potatoes	2.2	Barley		
23.6	PL general population	9.4	Tomatoes	5.0	Apples	2.6	Potatoes		
23.5	UK Toddler	6.3	Tomatoes	4.2	Apples	3.0	Oranges		
23.1	ES adult	8.4	Tomatoes	2.8	Olives for oil production	1.9	Oranges		
22.4	IT adult	12.4	Tomatoes	2.0	Apples	1.2	Aubergines (egg plants)		
21.1	WHO Cluster diet F	7.3	Tomatoes	2.6	Potatoes	1.6	Barley		
20.1	NL general	4.6	Tomatoes	2.9	Apples	2.2	Oranges		
19.3	FR infant	6.1	Apples	3.1	Potatoes	1.6	Tomatoes		
18.4	UK Infant	3.9	Tomatoes	3.8	Apples	2.4	Potatoes		
17.1	LT adult	6.6	Tomatoes	4.6	Apples	2.4	Potatoes		
16.4	FR all population	4.6	Tomatoes	2.9	Wine grapes	1.3	Olives for oil production		
15.6	UK vegetarian	6.6	Tomatoes	1.5	Apples	1.3	Oranges		
13.0	DK adult	4.4	Tomatoes	1.9	Apples	1.1	Potatoes		
12.3	FI adult	4.6	Tomatoes	1.5	Oranges	1.0	Apples		
11.3	UK Adult	4.7	Tomatoes	1.0	Potatoes	1.0	Apples		

Conclusion:
 The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
 A long-term intake of residues of Mancozeb 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):			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)
	0.1	Garlic	1.424 / -	0.1	Garlic	1.424 / -	0.2	Garlic	1.424 / -	0.2	Garlic	1.424 / -
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:		
	---			---		
	IESTI 1	*)	***)	IESTI 2	*)	***)
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	27.4	Grape juice	5 / -	3.2	Wine	5 / -
	23.4	Apple juice	2.759 / -	3.0	Apple juice	2.759 / -
	14.6	Pear juice	5 / -	1.3	Orange juice	0.7476 / -
	13.3	Elderberry juice	5 / -	1.0	Tomato (preserved-	3 / -
	8.7	Tomato juice	3 / -	1.0	Quince jelly	5 / -

*) 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 Mancozeb 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 E- PESTICIDE RESIDUES INTAKE MODEL (PRIMO)- SCENARIO 2

Metiram			
Status of the active substance:	Included	Code no.	#N/A
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.03	ARfD (mg/kg bw):	0.2
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2005	Year of evaluation:	2005

For acute RA- HR value of garlic-1.42 mg/kg; For chronic RA- STMR values (mg/kg) for: garlic-0.28; citrus fruit (except mandarins) 0.75; pome fruit -1.23; mandarins-0.6; stone fruit except plums-1.00 plums-0.36; table grapes-0.37; wine grapes - 3.67; blueberries cranberries gooseberries, currants (red, black and white)-4.09; table olives-3.28; mangoes-1.19; bananas-0.62; papaya-12.46; beetroot-0.53; potatoes-0.37; celeriac-0.36; horseradish, parsley root, parsnips, salsify, carrots -0.18; onions-0.46; shallots, spring onions-1.78; tomatoes-5.34; peppers-2.9; aubergines-5.34; okra-0.15; cucurbits(edible peel)-1.12; cucurbits(inedible peel)-0.45; broccoli-0.48; cauliflower-0.85; Brussels sprouts-0.09; head cabbage-0.66; leafy brassicas-0.37; lettuce and other salad plants, herbs-0.55; kohlrabi-0.25; watercress-0.16; witloof-0.36; beans (with pods)-0.43; beans (without pods)-0.18; peas (with pods)-0.43; peas (without pods)-0.09; asparagus-0.09; leek- 0.43; rhubarb-0.16; beans (dry)-0.18; peas (dry)-0.18; rape seed-0.16; olive for oil production- 3.28; barley, oats--1.37; rye, wheat-0.02. For processed commodities- orange juice-0.75; apple juice-2.76 mg/kg

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum						
		18	114					
		No of diets exceeding ADI:						
		1	1					
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)
114.2	DE child	49.4	Apples	17.2	Tomatoes	15.5	Table grapes	
97.7	WHO Cluster diet B	54.9	Tomatoes	5.2	Aubergines (egg plants)	4.2	Table grapes	
83.1	NL child	25.9	Apples	11.1	Tomatoes	9.3	Table grapes	
54.8	IE adult	7.1	Tomatoes	5.7	Barley	5.0	Aubergines (egg plants)	
51.8	FR toddler	13.8	Tomatoes	10.7	Apples	6.3	Potatoes	
43.1	WHO regional European diet	19.6	Tomatoes	5.0	Potatoes	2.7	Apples	
42.5	IT kids/toddler	25.4	Tomatoes	3.6	Apples	1.8	Aubergines (egg plants)	
42.4	SE general population 90th percentile	13.6	Tomatoes	5.2	Potatoes	4.3	Apples	
41.7	DK child	9.5	Apples	9.5	Tomatoes	6.1	Cucumbers	
41.4	PT General population	15.9	Tomatoes	6.6	Potatoes	4.3	Apples	
40.0	WHO cluster diet D	18.0	Tomatoes	5.1	Potatoes	2.7	Apples	
39.7	ES child	17.5	Tomatoes	5.4	Oranges	4.7	Apples	
38.9	UK Toddler	10.5	Tomatoes	7.0	Apples	4.9	Oranges	
38.6	PL general population	15.7	Tomatoes	8.4	Apples	4.3	Potatoes	
36.9	WHO cluster diet E	9.4	Tomatoes	4.8	Potatoes	3.7	Barley	
36.6	IT adult	20.7	Tomatoes	3.3	Apples	2.0	Aubergines (egg plants)	
34.5	WHO Cluster diet F	12.1	Tomatoes	4.3	Potatoes	2.7	Barley	
32.8	NL general	7.6	Tomatoes	4.8	Apples	3.7	Oranges	
32.4	ES adult	14.0	Tomatoes	3.2	Oranges	3.1	Apples	
32.1	FR infant	10.2	Apples	5.2	Potatoes	2.6	Tomatoes	
30.7	UK Infant	6.5	Tomatoes	6.4	Apples	4.1	Potatoes	
28.4	LT adult	11.0	Tomatoes	7.6	Apples	4.0	Potatoes	
25.2	UK vegetarian	11.1	Tomatoes	2.4	Apples	2.2	Oranges	
24.7	FR all population	7.7	Tomatoes	4.9	Wine grapes	1.9	Apples	
20.7	DK adult	7.4	Tomatoes	3.2	Tomatoes	1.8	Potatoes	
20.0	FI adult	7.6	Tomatoes	2.4	Oranges	1.7	Apples	
18.4	UK Adult	7.8	Tomatoes	1.7	Potatoes	1.7	Apples	

Conclusion:
 The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 18.4 % to 114 % of the ADI.
 For 1 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

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):			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)
	0.4	Garlic	1.424 / -	0.4	Garlic	1.424 / -	0.5	Garlic	1.424 / -	0.5	Garlic	1.424 / -
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:		
	---			---		
	IESTI 1	*)	***)	IESTI 2	*)	***)
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	82.2	Grape juice	5 / -	9.7	Wine	5 / -
	70.3	Apple juice	2.759 / -	9.1	Apple juice	2.759 / -
	43.8	Pear juice	5 / -	3.8	Orange juice	0.7476 / -
	40.0	Elderberry juice	5 / -	2.9	Tomato (preserved-	3 / -
	26.2	Tomato juice	3 / -	2.9	Quince jelly	5 / -

*) 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 Metiram 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.

GLOSSARY / ABBREVIATIONS

ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
BfR	Bundesinstitut Für Risikobewertung
CXL	Codex Maximum Residue Limit
EBDC	Ethylenebisdithiocarbamates
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
ETU	Ethylenethiourea
GAP	Good Agricultural Practice
HR	Highest Residue
LOD	Limit of Detection
LOQ	Limit Of Quantification
MRL	Maximum Residue Limit
NEDI	National Estimated Dietary Intake
PHI	Pre Harvest Interval
PSD	Pesticide Safety Directorate, United Kingdom
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
STMR	Supervised Trials Median Residue
TRR	Total Radioactive Residue
TMDI	Theoretical Maximum Daily Intake
VELS	Verzehrsstudie zur Ermittlung der Lebensmittelaufnahme von Säuglingen und Kleinkindern für die Abschätzung eines akuten Toxizitätsrisikos durch Rückstände von Pflanzenschutzmitteln
WG	Water Dispersible Granule