REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for dithiocarbamates (expressed as carbon disulfide) in bulb vegetables, cucurbits and asparagus[1]

European Food Safety Authority[2,]

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, Italy, herewith referred to as the evaluating Member State (EMS), received an application from the company BASF Italia Srl. to modify the existing MRLs for dithiocarbamate in cucurbits (edible and inedible peel), onions, shallots, garlic and asparagus, resulting from the use of metiram. In order to accommodate the intended uses, the EMS Italy proposed to raise the existing MRL in garlic from 0.5 mg/kg to 1 mg/kg; for the other crops they considered there was no need to modify the existing EU MRLs. Italy drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA. According to EFSA the data were sufficient to derive MRL proposals of 0.6 mg/kg in garlic and 1.5 mg/kg in cucurbits (with inedible peel). For the uses on other crops a need to modify the existing EU MRLs was not identified. Adequate analytical enforcement methods are available to check the compliance of metiram residues (expressed as carbon disulfide) and the relevant metabolite ethylenethiourea (ETU) in the crops under consideration. EFSA concludes that, the intended use of metiram on garlic and cucurbits (with edible peel) will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern. The exposure situation for the other crops under consideration is not affected by the new uses requested.

KEY WORDS

Metiram, dithiocarbamates (carbon disulfide), propineb, mancozeb, maneb, garlic, onions, cucurbits, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, dithiocarbamate fungicide.

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, Italy, herewith referred to as the evaluating Member State (EMS), received an application from the company BASF Italia Srl. to modify the existing MRLs for dithiocarbamate in cucurbits (edible and inedible peel), onions, shallots, garlic and asparagus, resulting from the use of metiram. In order to accommodate the intended uses, the EMS Italy proposed to raise the existing MRL in garlic from 0.5 mg/kg to 1 mg/kg; for the other crops they considered there was no need to modify the existing EU MRLs. Italy drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 6 January 2012.

EFSA bases its assessment on the evaluation report submitted by the EMS, the Draft Assessment Report (DAR) and its addenda prepared under Council Directive 91/414/EEC, the Commission Review Report on metiram, the JMPR Evaluations, the information submitted by the RMS Italy in the framework of the Article 12 of Regulation (EC) No 396/2005 as well as the conclusions from previous EFSA reasoned opinions on the modification of the existing MRLs for dithiocarbamates.

The toxicological profile of metiram was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI value of 0.03 mg/kg bw per day. No ARfD was deemed necessary.

The metabolism of metiram in primary crops was investigated in the fruit and fruiting vegetables and the root and tuber vegetables crop groups. From these studies the peer review proposed to set the risk assessment and enforcement residue definitions as "metiram, expressed as CS_2". The residue definition according to Regulation (EC) No 396/2005 is set as "dithiocarbamates (dithiocarbamates expressed as CS_2, including maneb, mancozeb, metiram, propineb, thiram and ziram)". For the uses on the crops under consideration, EFSA concludes that the metabolism of metiram is sufficiently addressed and the residue definitions agreed in the peer review are applicable.

EFSA concludes that the submitted supervised residue trials data were sufficient to derive MRL proposals of 0.6 mg/kg in garlic and 1.5 mg/kg in cucurbits (with inedible peel). For the uses on other crops a need to modify the existing EU MRLs was not identified. Adequate analytical enforcement methods are available to check the compliance of metiram residues (expressed as carbon disulfide) and the relevant metabolite ethylenethiourea (ETU) in the crops under consideration.

Studies investigating the nature of metiram residues in processed commodities were assessed in the peer review and showed that the compound is degraded to ETU. Therefore for processed commodities the peer review established the residue definition for the risk assessment as ETU. For enforcement purposes the peer review did not specify which residue definition should be applied. Specific studies for the crops under consideration to assess the magnitude of metiram residues after processing have not been submitted. Since garlic and cucurbits (inedible peel) are expected to be a minor contributor to the overall dietary exposure, specific processing studies for these crops are of lower relevance. Since the metabolism studies gave some indications that the majority of the metiram residues remain on the surface, it would be desirable to get further data on the distribution of the residues between pulp and peel of cucurbits (inedible peel), to allow a peeling factor to be derived.

Metiram and ETU are rapidly degraded in soil, therefore residues in rotational crops of these compounds are not expected. The nature and magnitude of metiram in commodities of animal origin was not assessed in the framework of this application, since the crops under consideration are not fed to livestock.

EFSA performed an indicative consumer risk assessment for the intended uses, taking into account available information for dithiocarbamates which have the same toxicological target, i.e., metiram, maneb, mancozeb and propineb. However, it is noted that the calculations are preliminary because full details on the use pattern for these active substances and underlying residue trials are not available. The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake

Model (PRIMo). For the assessment of the long-term consumer exposure the CS_2 residues originating from maneb, mancozeb or metiram were recalculated to the reference substance propineb by applying the respective combined correction factors (Cf). For garlic the median CS_2 was multiplied by the Cf for metiram and used as an input value. For cucurbits (inedible peel) the median residue value derived from the supervised field trials with metiram multiplied by the Cf for metiram was lower than the input value derived for the existing MRL of 1 mg/kg, which is related to a use of the more toxic substance propineb. Thus, the exposure is calculated with the corrected median value derived from the propineb residue trials on cucurbits.

For other crops EFSA considered only those MRLs which were set above the LOQs and which are related to the use of maneb, mancozeb, metiram and propineb according to Regulation (EC) No 396/2005. The existing MRL was multiplied by the Cf of the most toxic active substance authorized on that crop and this value was used as an input value. When risk assessment values were available, these were multiplied by the Cf of the individual active substance and only the most critical value was used as an input value. The calculated exposure was then compared with the toxicological reference values as derived for propineb.

Acute consumer exposure assessments were not performed due to the low acute toxicity of the active substance metiram.

The total calculated intake values accounted for up to 98.4% of the ADI for the DE child diet. The contribution of residues in garlic to the total consumer exposure was insignificant, accounting for a maximum of 0.065% of the ADI (WHO Cluster diet B). The contribution of residues in cucurbits (edible peel) to the total consumer exposure (in percentage of the ADI) from the existing use of propineb is 4.2% for melons (IE adult diet), 1.25% for pumpkins (WHO Cluster diet D) and 2.7% for watermelons (WHO Cluster diet B). The residues from the new uses on cucurbits (inedible peel) would contribute to less than 0.5% of the ADI individually for each crops of this group.

Pending provision of a full data set on the formation of ETU in processed products from various dithiocarbamates, a comprehensive consumer exposure assessment for ETU residues cannot be performed. However, an indicative risk assessment was performed for those crops under consideration for which the new uses would require the raising of the existing MRL for dithiocarbamates (garlic and cucurbits with inedible peel). The worst case situation was calculated assuming that all metiram residues in the processed crops would be converted to ETU during processing. Since melons and watermelons are mainly consumed raw, the exposure to ETU from the intake of a processed crop is not relevant and was thus not calculated. The calculated chronic and acute consumer exposure to ETU from the intake of garlic would account for 0.4% of the ADI and 0.2% of the ARfD derived for ETU, respectively. The calculated chronic and acute consumer exposure to ETU from the intake of pumpkin would account for 0.6% of the ADI and 31% of the ARfD derived for ETU, respectively.

EFSA concludes that, the intended use of metiram on garlic and cucurbits (with edible peel) will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern. The exposure situation for the other crops under consideration is not affected by the new uses requested.

EFSA notes that the calculated consumer exposure is indicative and conclusions might be subject to changes in the outcome of the review of MRLs for dithiocarbamates which will be performed according to Article 12 of Regulation (EC) No 396/2005.

Thus EFSA proposes to amend the existing MRLs as reported in the summary table.

Summary table

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Dithiocarbamates (dithiocarbamates expressed as CS_2, including maneb, mancozeb, metiram, propineb, thiram and ziram)				
0220010	Garlic	0.5	0.6	The MRL proposal is supported by data and no risk for consumers was identified for the intended use of metiram.
0220020	Onions	1	1	The submitted data support the intended use of metiram and an amendment of the existing MRLs is not necessary.
0220030	Shallots	1	1	
0232000	Cucurbits-edible peel	2	2	
0233000	Cucurbits-inedible peel	1	1.5	The MRL proposal is supported by data and no risk for consumers was identified for the intended outdoor use. The intended indoor use is not sufficiently supported by data.
0270020	Asparagus	0.5	0.5	The intended use pattern indicates no need to modify the existing EU MRL.

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.

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BACKGROUND

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

Italy, hereafter referred to as the evaluating Member State (EMS), received an application from the company BASF Italia Srl.[6] to modify the existing MRLs for dithiocarbamates, resulting from the use of metiram in cucurbits (edible and inedible peel), onions, shallots, garlic and asparagus. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 6 January 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012- 00017 and the following subject:

Metiram - Application to modify the existing MRLs in various crops.

The EMS Italy proposed to only raise the existing MRL in garlic from 0.5 mg/kg to 1 mg/kg; for other crops the EMS recommended no modification of the existing EU MRLs.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

TERMS OF REFERENCE

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

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

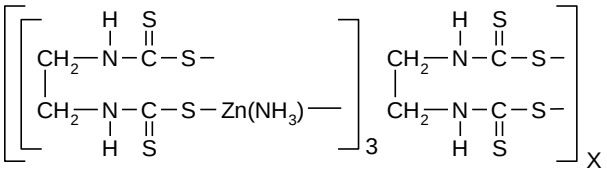
In this particular case the calculated deadline for providing the reasoned opinion is 6 April 2012.

[3] Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.
[4] Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32
[5] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009. OJ L 309, 24.11.2009, p.1-50
[6] BASF Italia Srl, APE/S, Marconato 8, 20811, Cesano Maderno MB, Italy

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Metiram is a name used for zinc ammoniate ethylenebis(dithiocarbamate) – poly[ethylenebisthiuramdisulfide)] (IUPAC). There is no ISO common name for metiram.

The chemical structure of the metiram (mixed precipitate of the ammonia complex of zinc-[N,N-1,2-ethylene-bis-(dithiocarbamate)] and N,N-poly-1,2-ethylene-bis-(thiocarbamoyl)-disulfide) is reported here.



Molecular weight: $[1088.6]_x$ g/mol

Metiram is an ethylene*bis*dithiocarbamate (EBDC) fungicide. It is non-systemic with protective action. Metiram is used against downy mildews, rust fungi and a number of leaf spot fungi.

Metiram was evaluated in the framework of Council Directive 91/414/EEC with Italy designated as rapporteur Member State (RMS). Metiram was included in Annex I of this Directive by Directive 2005/72/EC[7] for uses as fungicide only. The representative uses evaluated by the peer review were foliar applications on potatoes and grapes. Since the peer review was performed before EFSA was involved, an EFSA conclusion is not available.

In the European Union no specific MRLs are set for metiram, but for a group of dithiocarbamates comprising maneb, mancozeb, metiram, propineb, thiram, and ziram. The residues are expressed as carbon disulfide (CS_2) which is the common moiety generated by analytical procedures 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 dithiocarbamates are set in Annexes II and IIIB of Regulation (EC) No 396/2005 and are summarised in Appendix C. The existing EU MRL (expressed as a CS_2) for garlic is set at 0.5 mg/kg (resulting from the use of mancozeb only), 1 mg/kg in onions and shallots (uses of mancozeb and maneb), 2 mg/kg for cucurbits (with edible peel) (uses of mancozeb and propineb), 1 mg/kg in cucurbits (with inedible peel) (uses of mancozeb, maneb and propineb) and 0.5 mg/kg in asparagus (resulting from the use of mancozeb only).

Codex Alimentarius has established CXLs for dithiocarbamates in a wide range of food commodities, including most of the crops under consideration (except shallots, and gherkins). The CXLs are set at 0.5 mg/kg in garlic (resulting from the use of mancozeb), 0.5 mg/kg in onions (resulting from the use of mancozeb), 2 mg/kg in cucumbers (resulting from the use of maneb), 1 mg/kg in courgettes (resulting from the use of mancozeb), 1 mg/kg in watermelon (resulting from the use of maneb), 0.5 mg/kg in melons (resulting from the use of mancozeb), 0.1 mg/kg in pumpkins (resulting from the use of mancozeb) and 0.1 mg/kg in asparagus (resulting from the use of mancozeb).

The applicant applied for new GAPs for metiram on garlic, onions, shallots, cucurbits (with edible and inedible peel) and asparagus which could have required the modification of the existing MRLs for dithiocarbamates. Details of the intended GAPs for metiram are given in Appendix A.

[7] Commission Directive 2005/72/EC of 21 October 2005, OJ L 279, 22.10.2005, p.63-69.

ASSESSMENT

EFSA based its assessment on the evaluation report submitted by the EMS (Italy, 2010b), the Draft Assessment Report (DAR) (and its addenda) prepared under Council Directive 91/414/EEC (Italy, 2000, 2003), the Commission Review Report on metiram (EC, 2005) and other dithiocarbamates (EC, 2003, 2005b, 2009), the JMPR Evaluation (FAO, 1995, 1993), the previously issued EFSA reasoned opinions on the modification of the existing MRLs for dithiocarbamates (EFSA, 2009, 2010, 2011) and the information submitted by the RMS Italy in the framework of Article 12 of Regulation (EC) No 396/2005(Italy, 2008a, 2008b, 2009, 2010a). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[8] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

1. Method of analysis

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

Analytical methods for the determination of metiram and the relevant metabolite ethylenethiourea (ETU[9]) in plant commodities were assessed in the peer review under Directive 91/414/EEC (Italy, 2000; 2002). Generally, the analytical methods for the determination of dithiocarbamate residues rely on acid hydrolysis to release CS_2 which is then measured by chromatography or colorimetry.

According to the peer review, for the determination of metiram residues (determined and expressed as CS_2) in plant matrices, adequate enforcement methods are available. The principle of the methods is a reductive cleavage of the molecule and photometric determination of CS_2 moiety. For the determination of residues with the colorimetric method good recoveries were demonstrated for the concentration range of 0.02-0.2 mg/kg. In case of interferences, GC-FID or GC-FPD methods can be used (Italy, 2000). The ILV was also performed for the above mentioned methods which were considered appropriate for the determination of CS_2 moiety in plant matrices with high water-, high acid-, high oil content and in dry matrices where an LOQ of 0.02 mg/kg was achieved.

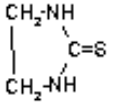
It is noted that these methods do no distinguish which active substance belonging to the group of dithiocarbamates was originally applied to the crop. Therefore the CS_2 method functions as a screening tool. In case of positive findings, the origin of the residue can then be identified by analysing the sample with specific methods where available. Currently specific methods are available for thiram, propineb and ziram. The analytical methods described do not discriminate between phytogenic CS_2 and CS_2 resulting from the use of dithiocarbamate containing pesticides (Perz *et al*., 2000). In addition, laboratories analysing samples for dithiocarbamates must pay particular attention to sample preparation, as dithiocarbamates exhibit low stability in plant matrices, leading to possible losses of CS_2 (Crnogorac *et al.*, 2008).

In the framework of the peer review, the availability of analytical enforcement methods for the determination of ETU residues in plant matrices was also investigated (Italy, 2000, 2002). It was concluded that adequate analytical methods based on HPLC with electrochemical detection are available to control ETU residues in plant matrices with high water and high acid content at the validated LOQ of 0.02 mg/kg.

It is concluded that adequate analytical enforcement methods are available to check the compliance of the residues of metiram (expressed as CS_2) and the ETU, that is primarily generated when processing includes heating or when food is cooked, in the crops under consideration. It is noted, that garlic,

[8] Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

[9] Ethylenethiourea: 4,5-Dihydro-1H-imidazol-2-thione (MW=102.16 g/mol)



onions and shallots have high natural CS_2 background levels which are expected to interfere with the levels of CS_2 detected by the analytical method.

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

Analytical methods for the determination of residues in food of animal origin were not assessed in the current application, since the crops under consideration are normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance metiram was assessed in the framework of the peer review under Directive 91/414/EEC (EC, 2005a). The data were sufficient to derive toxicological reference values for metiram which are compiled in the table below. The table also reports the toxicological reference values for other dithiocarbamates. It is noted that metiram shares a common toxic effect on the thyroid (regarding the long-term toxicity) with maneb, mancozeb and propineb (EC, 2005b, 2009, 2003a).Thiram (EC, 2003b) and ziram (EC, 2004) were shown to have a different critical effect with regard to their long-term toxicity.

Since ethylenethiourea (ETU) is a transformation/ degradation product of ethylene*bis*dithiocarbamates that is formed under high temperatures and has higher toxicity than the parent compounds, its reference values are also included in the table below.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Metiram					
ADI	EC	2005	0.03 mg/kg bw per day	2 years, rat	100
ARfD	EC	2005	Not necessary		
Ethylenethiourea (ETU)					
ADI	EC	2005	0.002 mg/kg bw per day	1 yr dog	100
ARfD	EC	2005	0.05 mg/kg bw	Rat teratogenicity	100
Mancozeb					
ADI	EC	2005	0.05 mg/kg bw per day	2 yr rat	100
ARfD	EC	2005	0.6 mg/kg bw	Rat teratogenicity	100
Maneb					
ADI	EC	2005	0.05 mg/kg bw per day	Rat multi-generation	100
ARfD	EC	2005	0.2 mg/kg bw	Rat developmental	100
Propineb					
ADI	EC	2003	0.007 mg/kg bw per day	Chronic rat	100
ARfD	EC	2003	0.1 mg/kg bw	Developmental toxicity, rat	100
Thiram					
ADI	EC	2003	0.01 mg/kg bw per day	2 yr rat, supported by the findings in dogs	100
ARfD	EC	2003	0.6 mg/kg bw	Acute neurotoxicity rats	100
Ziram					
ADI	EC	2004	0.006 mg/kg bw per day	2 yr rat	100

ARfD	EC	2004	0.08 mg/kg bw	Rat developmental	100

Considering the relative toxicological potencies of metiram, maneb, mancozeb and propineb, toxicological equivalence factors (TEFs) have been calculated (see Table 2-2), based on the ADI of propineb. Moreover, considering the conversion of the parent substances to CS_2 equivalents, combined correction factors (Cf) were derived. These combined correction factors need to be considered in the combined risk assessment for the four active substances (see section 4).

Table 2-2: Overview of the toxicological equivalence factors and molecular weight correction factors

Compound	ADI (mg/kg bw per day)	Toxicological equivalence factor (TEF)	Molecular weight (g/mol)	Molecular weight/carbon disulfide[a]	Combined correction factor (Cf) (=TEF*MW)
Propineb	0.007	1	289.8	1.86	1.86
Metiram	0.03	0.23	1088.7	1.79	0.41
Mancozeb	0.05	0.14	271.3	1.78	0.25
Maneb	0.05	0.14	265.3	1.75	0.25

(a): molecular weight of carbon disulfide (CS_2): 76.1 g/mol

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of metiram in primary crops was evaluated by the RMS Italy in the framework of the peer review under Directive 91/414/EEC (Italy, 2000). The overview of the metabolism study designs is presented in the table below.

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

Group	Crop	Label position	Application details				
			Method, F or G[(a)]	Rate (kg a.s./ha)	No/ Interval (d)	Sampling	Remarks
Fruits and fruiting vegetable	Apples	*(ethylene-^{14}C)*	F/G	1.5	5	82 DALA	Deficiencies identified in the study [b]
		(thiocarbonyl-^{14}C)	F/F	3.0	2	3 DALA	
		Mixture of radiolabelled (ethylene-^{14}C) and non-radiolabelled metiram	F/F	4.5 (1st appl.) and 3.4 for (2nd, 3rd and 4th appl.)	4/30	Before and after each appl. and *ca.*15 and 27 DALA	Deficiencies identified in the study [c]

Group	Crop	Label position	Application details				
			Method, F or G[(a)]	Rate (kg a.s./ha)	No/ Interval (d)	Sampling	Remarks
Root and tuber vegetables	Potatoes	*(ethylene^{14}C)*	F/G	2	4	1 DALA (leaves and tubers), 34 DALA (leaves, tubers, roots)	Deficiencies identified in the study [d]
		(thiocarbonyl-^{14}C)	F/G	2	2	28 DALA (tops and tubers)	
		(ethylene^{14}C)	F/F	1.8 (first 2 appl.) and 3.6 (last two appl.)	4/2-3 weeks	5, 7 , 21 DALA (leaves and tubers)	

(a): Outdoor/field use (F) or glasshouse/protected crops/indoor application (G)
(b): No clear identification or quantification of metabolites was performed (Italy, 2000)
(c): Long intervals between applications; only minor parts of TRR have been separated and identified (Italy, 2000)
(d): Study could not provide a clear and complete definition of radioactive residues (Italy, 2000)
n.r. not reported in the DAR

In the whole **apple** the total radioactive residues 27 DAT accounted for 8.9-12.7 mg eq./kg. The radioactivity was significantly higher in apple peel (11.1 mg eq./kg) than in apple pulp (1.3 mg eq./kg). In a single apple analysed, 61.1% f the TRR was found on apple surface; 18.8% TRR in the peel and 13.1% TRR in the pulp. The TRR on the surface consisted of parent metiram (9.4% TRR), ethylene*bis*isothiocyanate sulfide (EBIS) (3.2% TRR), ETU (1.4% TRR), ethyleneurea (EU) (1.2% TRR) and creatinine (1.7% TRR). Parent metiram was not detected in the apple peel and pulp. The TRR of the whole apple sample consisted of parent metiram (9.4%; 1.02 mg/kg), EBIS (3.8%; 0.27 mg/kg), EU (3.7%; 0.13 mg/kg) and ETU (1.8%; 0.07 mg/kg). The unidentified radioactivity accounted for 35.9% (3.9 mg/kg). The radioactivity was detected in fractions containing specific types of natural products, indicating the incorporation of ^{14}C-metiram into natural constituents.

In **potatoes**, the radioactivity was similarly distributed between pulp (1.15 mg/kg) and peel (2.1 mg/kg). The extractability was 58% TRR. Major metabolites were creatinine (14.3% TRR (0.16 mg/kg) in pulp and 12% TRR (0.25 mg/kg) in peel), allantoin (11% TRR (0.13 mg/kg) in pulp and 11.8% TRR (0.25 mg/kg) in peel), creatine (8% TRR), and glycine (8% TRR).

Minor metabolites were the EU (4.8% (0.055 mg/kg) in pulp and 3.36 % (0.07) in peel), ETU (0.97% (0.01 mg/kg) in pulp and 1.95% (0.04 mg/kg) in peel), hydantoin, ethylene thiuram monosulfide (DIDT)/carbimide (3% (0.035 mg/kg)). A significant part of the radioactivity was incorporated into natural constituents (such as starch, amino acids, cellulose).

The studies indicate a low translocation of radioactivity from the treated parts to untreated parts. Similar metabolites were identified in both crops. Metiram was shown to be the main residue on the surface; the residues taken up by the plant are to a major extent metabolised and incorporated into natural pant constituents. Generally, the metabolism of various ethylene*bis*dithiocarbamates proceeds by a similar pathway.

The peer review proposed to set the risk assessment and enforcement residue definitions as "metiram, expressed as CS_2". The residue definition according to Regulation (EC) No 396/2005 is set as "dithiocarbamates (dithiocarbamates expressed as CS_2, including maneb, mancozeb, metiram, propineb, thiram and ziram)". The JMPR has established comparable risk assessment and enforcement residue definitions for dithiocarbamates for plant commodities being "total dithiocarbamates, determined as CS_2, evolved during acid digestion and expressed as mg CS_2/kg".

Residue definitions refer to two crop categories- fruit and fruiting vegetables and root and tuber vegetables. For the uses on the crops under consideration, EFSA concludes that the metabolism of metiram is sufficiently addressed and the residue definitions agreed in the peer review are applicable.

3.1.1.2. Magnitude of residues

a. Onions, garlic, shallots

The applicant submitted in total 8 GAP compliant residue trials on onions, representing the intended SEU outdoor use of metiram. The trials were performed in various southern European Member States in 2005 and 2006. Samples were analysed for CS_2 and ETU. Residues of ETU were below the LOQ of 0.01 mg/kg in all samples. Information on residues in untreated control samples was not provided.

The applicant proposes residue data extrapolation from bulb onions to garlic and shallots. According to the EC guidance document (EC, 2011), such an extrapolation is acceptable. The number of submitted residue trials is sufficient to derive a MRL proposal of 0.6 mg/kg in onions, garlic and shallots. The existing EU MRL for dithiocarbamates in onions and shallots is set at 1 mg/kg and thus EFSA agrees with the EMS that there is no need to modify the existing EU MRL in these crops. Since the existing MRL for garlic is 0.5 mg/kg, a modification of the existing MRL would be necessary for garlic.

b. Cucurbits (edible peel): cucumbers, gherkins, courgettes

In support of the SEU outdoor use, the applicant submitted in total 7 GAP compliant residue trials on zucchini (4 trials) and cucumbers (3 trials). Trials have been performed in various SEU Member States in 2005 and 2006.

In support of the indoor use, the applicant submitted in total 7 GAP compliant residue trials on zucchini (3 trials) and cucumbers (4 trials). Trials have been performed in various southern European Member States in 2005, 2006 and 2007.

Samples were analysed for CS_2, and ETU. Residues of ETU were within a range of <0.01 -0.024 mg/kg. The applicant proposes to extrapolate the residue data to the whole group of cucurbits with edible peel. According to the EC guidance document, an extrapolation to the whole group is acceptable either from cucumbers or from courgettes (EC, 2011). Considering that residues of CS_2 were in the same range in cucumbers and courgettes, EFSA is of the opinion that trials could be combined to derive a MRL proposal for the whole group of cucurbits (with edible peel).

The indoor use results in a slightly more critical residue situation and was therefore used to derive a MRL proposal of 0.6 mg/kg for cucurbits with edible peel. The existing EU MRL for dithiocarbamates in cucurbits with edible peel is set at 2 mg/kg. EFSA agrees with the opinion of the EMS that there is no need to modify the existing EU MRL for cucurbits with edible peel.

c. Cucurbits (inedible peel): melons, watermelons, pumpkins

No residue trials have been submitted in support of the indoor use.

In support of the intended SEU outdoor use the applicant submitted in total 8 residue trials on melons. Trials were performed with 4 instead of the intended 3 applications. Considering the fast decline of metiram residues within 7 day spraying intervals, the higher number of applications was not considered to have affected the final residues in the crop. Trials have been carried out in various southern European Member States in 2005 (outdoor trials) and 2006 (indoor trials). Samples were analysed for CS_2, and ETU. The ETU was within a range of <0.01-0.032 mg/kg.

The applicant proposed to extrapolate the residue data from melons to the whole group of cucurbits (inedible peel). According to the EC guidance document (EC, 2011), such an extrapolation is acceptable. An MRL proposal of 1.5 mg/kg is derived for the whole group of cucurbits (inedible peel)

which is higher than the existing MRL of 1 mg/kg. Since the pulp and the peel was not analysed separately it was not possible to derive a peeling factor.

d. Asparagus

No residue trials supporting the intended NEU and SEU outdoor uses were submitted. The applicant claims that the treatment occurs after the harvest of asparagus stems and is directed to the remaining inedible plant only. The application would occur about 9 months before the next harvest of the crop. As the treated parts of the plant are removed from the field before the next vegetation period, cross-contamination can be excluded. Thus, no residues are expected in asparagus stems in the year following the treatment. According to the EMS, the existing EU MRL of 0.5 mg/kg for dithiocarbamates in asparagus is sufficient to cover the intended uses of metiram on asparagus. EFSA shares the view of the EMS that under these use conditions no residues are expected in edible parts of asparagus.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3-2.

The storage stability of metiram and its metabolite ETU in primary crops was investigated in the DAR under Directive 91/414/EEC (Italy, 2000; 2002) as well as the studies submitted for the JMPR evaluation of metiram (FAO, 1995). Metiram residues are stable in apple, potatoes, tomatoes, sugar beet (high water content commodities) and grapes (high acid content commodities) for a period of 12 months when stored deep frozen (Italy, 2000; FAO, 1995). No significant formation of the ETU from metiram during the storage period was observed. The supervised residue trial samples of cucurbits with inedible peel were stored under conditions for which integrity of the samples was demonstrated. Some residue trial samples were stored for a longer period: 404 days 4 outdoor trials of cucumbers and courgettes, 439 days 4 indoor residue trials samples of cucumbers and courgettes and 415 days 4 residue trials on onions. The demonstrated storage stability interval of 1 year for metiram was thus exceeded by 39-74 days. Since in high water content matrices metiram residues at the end of the 12 month storage interval were still above 75% of the initial residues, EFSA is of the opinion that a significant decrease of metiram residues was not likely to occur in the residue trial samples. However, the storage stability of metiram residues over longer storage periods (>12 months) would have to be confirmed in the framework of the MRL review according to Article 12 of Regulation (EC) No 396/2005.

The storage stability of the ETU in frozen samples strongly depends on the type of matrix and the storage intervals. From the studies submitted for the JMPR evaluation of metiram, the ETU was stable for 12 months in apple sauce (fresh and cooked), apple baby food and 3 months on dry pomace; in wet apple pomace and potatoes the ETU disappeared within 2 weeks; in sugar beet the ETU disappeared within 1 month (FAO, 1995). According to the JMPR evaluation of ethylenethiourea (FAO, 1993), more than 70% of the ETU remained in tomato and wheat matrices after 12 months storage at -20°C. ETU residues in the apple matrix had declined to less than 70% after 6 months storage and to less than 50% after 12 months. ETU residues were shown to be stable in 3-6 month tests at -20 ± 5°C in stored analytical samples of dry beans, corn, lettuce (marginal stability), meat, milk, raw potato (marginal stability), and tomato (FAO, 1993). Residue trial samples prior to analysis for the ETU were stored maximum 202 days in case of cucumbers, 208 days in case of melons and 415 for onions. The storage stability studies performed with ETU give contradictious results for high water content matrices and therefore the validity of residue trials data is further to be demonstrated by providing adequate storage stability studies of ETU in plant matrices.

According to the EMS, the analytical methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (Italy, 2010b).

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

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (metiram, expressed as CS_2)	**Risk assessment** (metiram, expressed as CS_2)					
Onions → garlic, shallots	SEU	Outdoor	5 x <0.168; 0.18[f]; 0.21; 0.24	5 x <0.168; 0.18[f]; 0.21; 0.24 *Metiram[h]: 5 x <0.3; 0.328; 0.378; 0.43*	**0.17**	**0.24**	**0.6**	**1.0**	R_{ber}= 0.41 R_{max}= 0.27 MRL_{OECD} = 0.55/0.6 Existing MRL for onions and shallots: 1 mg/kg, garlic: 0.5 mg/kg
Cucumbers, courgettes → cucurbits (edible peel)	SEU	Outdoor	2 x <0.056; <0.056[g]; 0.07[g]; 0.157; 0.215[g]; 0.25[g]	2 x <0.056; ≤0.056[g]; 0.07[g]; 0.157; 0.215[g]; 0.25[g] *Metiram[h]: 2 x <0.1; <0.1[g]; 0.125[g]; 0.28; 0.384[g]; 0.448*	0.07	0.25	0.5	1.0	$R_{ber\ outdoor}$= 0.43 $R_{max\ outdoor}$ = 0.41 $MRL_{OECD\ outdoor}$ = 0.46/0.5
	EU	Indoor	<0.056[g]; <0.058[g]; 0.087; 0.10; 0.201[g]; 0.21; 0.353	<0.056[g]; <0.058[g]; 0.087; 0.10; 0.201[g]; 0.21; 0.353 *Metiram[h]: <0.1[g]; <0.01[g]; 0.155; 0.18; 0.36[g]; 0.376; 0.632*	**0.1**	**0.35**	**0.6**	**1.0**	$R_{ber\ indoor}$= 0.42 $R_{max\ indoor}$= 0.52 $MRL_{OECD\ indoor}$= 0.59/0.6 Existing MRL for cucurbits (edible peel): 1 mg/kg
Melons → watermelons, pumpkins	SEU	Outdoor	2 x <0.056; 0.061; 0.063; 0.093; 0.099; 0.132; 0.713	2 x <0.056; 0.061; 0.063; 0.093; 0.099; 0.132; 0.713 *Metiram[h]: 2 x <0.1; 0.109; 0.112; 0.166; 0.178; 0.236; 1.276*	**0.08**	**0.71**	**1.5**	**1.0**	R_{ber}= 0.25 R_{max}= 0.88 MRL_{OECD} = 1.06/1.5 Existing MRL for cucurbits (inedible peel): 1 mg/kg
	EU	Indoor	-	-	No residue trials submitted.				
Asparagus	SEU	Outdoor	-	-	No residue trials submitted, but "no residue" situation is likely.				

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (metiram, expressed as CS_2)	Risk assessment (metiram, expressed as CS_2)					
	NEU	Outdoor	-	-					

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (*i.e.* outdoor use) or Import (country code) (EC, 2011).
(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 residue trial.
(e): Statistical estimation of MRLs according to the EU methodology (R_{ber}, R_{max}; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).
(f): Residues higher within a trial at a longer PHI of 14 days.
(g): Residue trials with courgettes.
(h): Metiram concentrations reported in the evaluation report (Italy, 2010), derived by recalculating the CS_2 to metiram applying the molecular weight conversion factor of 1,79
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of metiram residues has been investigated in the framework of the peer review (Italy, 2010b) in a hydrolysis study simulating pasteurisation, baking/brewing/boiling and sterilisation (20 minutes at 90°C, pH 4; 60 minutes at 100°C pH 5; 20 minutes at 120°C, pH 6). Under these processing conditions metiram partially or fully degrades to ethylenethiourea (ETU), which accounts for up to 51.9% (of the applied radioactivity (AR)) after pasteurisation, 88.4% after baking/brewing/boiling and 98.6% after sterilisation conditions.

Therefore for processed commodities the peer review established the residue definition for the risk assessment as ethylenethiourea (ETU). For enforcement purposes the peer review did not specify which residue definition should be applied.

Specific studies for the crops under consideration to assess the magnitude of metiram residues after processing have not been submitted. Such studies are required in order to perform a consumer exposure assessment to ETU. The requirement for studies will be further considered in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005. However, since garlic and cucurbits (inedible peel) are expected to be a minor contributor to the overall dietary exposure (see also section 4), specific processing studies for these crops are of lower relevance. Since the metabolism studies gave some indications that the majority of the metiram residues remain on the surface, it would be desirable to get further data on the distribution of the residues on pulp and peel of cucurbits (inedible peel), which would allow a peeling factor to be derived.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

The crops under consideration can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. The soil degradation studies demonstrated that the degradation rate of metiram and its metabolite ETU is rapid; the maximum DT_{90f} for both compounds is <14 days (EC, 2005), which is below the trigger value of 100 days. Thus, no further studies investigating the nature and magnitude of these compounds uptake in rotational crops are required.

3.2. Nature and magnitude of residues in livestock

Since the crops under consideration and/or their by-products are not normally fed to livestock, the nature and magnitude of metiram residues in livestock was not assessed in the framework of this application.

4. Consumer risk assessment

EFSA performed an indicative consumer risk assessment for the intended uses, taking into account information available for dithiocarbamates which have the same toxicological target, *i.e.* metiram, maneb, mancozeb and propineb. However, it is noted that the calculations are preliminary because full details on the use pattern for these active substances and underlying residue trials are not available. EFSA based the calculations on the following sources:

- Pesticide Residue Overview Files (PROFile) submitted in the framework of Article 12 of Regulation (EC) No 396/2005 for metiram (Italy, 2008a), maneb (Italy, 2009), propineb (Italy, 2010a) and mancozeb (Italy, 2008b). It is noted that the submitted information has not yet been reviewed by EFSA;

- evaluation report submitted by the EMS Italy for metiram (Italy, 2010b);

- previously issued EFSA reasoned opinions on the modification of the existing EU MRLs for dithiocarbamates (EFSA, 2009, 2010, 2011).

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population [10] (EFSA, 2007). For the assessment of the long-term consumer exposure the CS_2 residues originating from maneb, mancozeb or metiram were recalculated to the reference substance propineb by applying the respective combined correction factors (Cf) (see table 2-2). For garlic the median CS_2 residue was multiplied with the Cf for metiram and used as an input value. For cucurbits (inedible peel) the median residue value derived from the supervised field trials with metiram multiplied with the Cf for metiram was lower than the input value derived for the existing MRL of 1 mg/kg which is related to a use of the more toxic substance propineb. Thus, the exposure is calculated with the corrected median value derived from the propineb residue trials on cucurbits. For other crops under consideration the existing uses result in higher residues and therefore the input values were selected according to one of the approaches described below:

- those crops for which the existing EU MRLs according to the Regulation (EC) No 396/2005 are set at the LOQ (0.05 or 0.1 mg/kg), where excluded from the exposure calculation, assuming that there is no use authorized on these crops;

- those crops on which only the use of thiram and ziram is reported, where excluded from the calculation because these substances have a different toxicological target and specific EU MRLs;

- for crops for which median residue values were reported in the available sources, these values were multiplied by the Cf of the individual active substance authorized on that crop; the most critical value was then used as an input value for the exposure calculation;

- for remaining crops the existing MRL as established in Annexes II and IIIB of Regulation (EC) No 396/2005 were multiplied by the Cf of the most toxic active substance authorized on that crop and this value was used as an input value;

- for propineb median residue concentrations were available, expressed as propineb. In this case a recalculation with the combined correction factor was not necessary.

For wine grapes the reduction of residues during processing were considered using a processing factor.

The calculated exposure was then compared with the toxicological reference values as derived for propineb (Table 2-1).

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (*i.e.* the ADI), a consumer health risk can be excluded with a high probability.

Acute consumer exposure was not performed due to the low acute toxicity of the active substance metiram.

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

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

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

Commodity	Chronic exposure assessment	
	Input value (mg/kg)	**Comment**
The CS_2 values originating from the use of maneb, mancozeb, metiram and propineb, were expressed as propineb by applying the combined correction factor (Cf); the calculated chronic exposure was compared with the ADI of propineb, which has the highest toxicity of these active substances who share the common critical effect of the long-term toxicity.		
Garlic	0.07	Median residue (onion) (Table 3-2) *Cf_{me}
Citrus fruits (except mandarins)	0.11	Median residue $(3)_{mz}$ (Italy, 2008b) *Cf_{mz} *PF (0.14) (Italy, 2007)
Mandarins	0.08	Median residue $(2.35)_{mz}$ (Italy, 2008b) *Cf_{mz} *PF (0.14) (Italy, 2007)
Walnuts	0.03	MRL*Cf_{mz}
Pome fruit	0.23	Median residue $(0.56)_{me}$ (Italy, 2008a) *CF_{me}
Apricots	0.11	Median residue $(0.44)_{mz}$ (Italy, 2008b) *Cf_{mz}
Cherries	0.27	Median residue $(0.65)_{me}$ (Italy, 2008a) *Cf_{me}
Peaches	0.11	Median residue $(0.44)_{mz}$ (Italy, 2008b) * Cf_{mz}
Plums	0.08	Median residue $(0.2)_{me}$ (Italy, 2008a)*Cf_{me}
Table grapes	0.52	Median residue $(2.06)_{mz}$ (Italy, 2008b) *Cf_{mz}
Wine grapes	0.03	Median residue $(2.06)_{mz}$ *Cf_{mz} *yield factor $(0.7)^c$ * PF (0.09) (Italy, 2008b)
Blueberries, cranberries, currants (red, black and white), goose berries	1.25	MRL*Cf_{mz}
Table olives	0.46	Median residue $(1.82)_{mz}$ (Italy, 2008b) *Cf_{mz}
Bananas	0.03	Median residue $(0.37)_{me}$ (Italy, 2008a) *CF_{me} *PF $(0.19)_{me}$ (Italy, 2010b)
Mangoes	0.5	MRL *Cf_{mz}
Papaya	1.75	MRL *Cf_{mz}
Potatoes	0.1	Median residue (pr) (Italy, 2010a)
Beetroot	0.13	MRL *Cf_{mz}
Carrots	0.05	MRL *Cf_{mz}
Celeriac	0.19	Median residue $_{pr}$ (Italy, 2010a)
Horseradish	0.05	MRL *Cf_{mz}
Parsnips	0.05	MRL *Cf_{mz}
Parsley root	0.05	MRL *Cf_{mz}
Radishes	0.22	Median residue $(0.89)_{mz}$ *CF_{mz} (EFSA, 2011)
Salsify	0.05	MRL *Cf_{mz}

Commodity	Chronic exposure assessment	
	Input value (mg/kg)	Comment
The CS_2 values originating from the use of maneb, mancozeb, metiram and propineb, were expressed as propineb by applying the combined correction factor (Cf); the calculated chronic exposure was compared with the ADI of propineb, which has the highest toxicity of these active substances who share the common critical effect of the long-term toxicity.		
Onions, shallots, spring onions	0.25	MRL *Cf $_{mz}$
Tomatoes	0.33	Median residue $_{pr}$ (Italy, 2010a)
Peppers	0.41	Median residue (1.63)$_{mz}$ (Italy, 2008b) *Cf $_{mz}$
Aubergines	1.23	MRL*CF $_{me}$
Okra	0.13	MRL *Cf $_{mz}$
Cucurbits (edible peel)	0.53	Median residue (cucumbers) $_{pr}$ (Italy, 2010a)
Melons, watermelons, pumpkins	0.36[a]	Median residue (melons) $_{pr}$ (Italy, 2010a)
Flowering brassica	0.25	MRL *Cf $_{mz}$
Brussels sprouts	0.5	MRL *Cf $_{mz}$
Head cabbage	0.75	MRL *Cf $_{mz}$
Leafy brassica	0.13	MRL *Cf $_{mz}$
Kohlrabi	0.25	MRL *Cf $_{mz}$
Lettuce and other salad plants	0.35	Median residue (0.86) $_{me}$ (Italy, 2010b) *Cf $_{me}$
Purslane	1.25	MRL *Cf $_{mz}$
Watercress	0.08	MRL *Cf $_{mz}$
Witloof	0.13	MRL *Cf $_{mz}$
Herbs	2.05	MRL *Cf $_{me}$
Beans (with pods)	0.25	MRL *Cf $_{mz}$
Beans (without pods)	0.03	MRL *Cf $_{mz}$
Peas (with pods)	0.25	MRL *Cf $_{mz}$
Peas (without pods)	0.01	Median residue (0.056) $_{mz}$ *Cf $_{mz}$ (EFSA, 2010)
Asparagus	0.13	MRL *Cf $_{mz}$
Leek	0.75	MRL *Cf $_{mz}$
Rhubarb	0.13	MRL *Cf $_{mz}$
Beans	0.03	MRL *Cf $_{mz}$
Peas	0.03	MRL *Cf $_{mz}$
Rape seed	0.13	MRL *Cf $_{mz}$
Olives for oil production	0.46	Median residue (1.86) $_{mz}$ (Italy, 2008b) *Cf $_{mz}$
Barley	0.32	Median residue (1.28) $_{ma}$ (Italy, 2009) *Cf $_{ma}$

Commodity	Chronic exposure assessment	
	Input value (mg/kg)	Comment
The CS_2 values originating from the use of maneb, mancozeb, metiram and propineb, were expressed as propineb by applying the combined correction factor (Cf); the calculated chronic exposure was compared with the ADI of propineb, which has the highest toxicity of these active substances who share the common critical effect of the long-term toxicity.		
Oats	0.5	MRL *Cf_{mz}
Rye	0.25	MRL *Cf_{mz}
Wheat	0.06	Median residue (0.23) $_{ma}$ (Italy, 2009) *Cf_{ma}
Hops	16.35	Median residue $_{pr}$ (Italy, 2010a)
Capers	46.5	MRL*Cf_{pr}
Sugar beet	0[b]	See table footnote
Other commodities of plant and animal origin	MRL	See Appendix C

(a): The new intended use of metiram on cucurbits (edible peel) would result in an input value of 0.04 mg/kg; a more critical value representing the existing use on propineb (Italy, 2010) was selected therefore as an input value. No use on pumpkins was reported by the RMS, but, as the existing EU MRL refers to a group tolerance, it was assumed that existing MRL for pumpkins was derived as an extrapolation from melons.

(b): No residues are expected in sugar

(c): Consumption figures in the EFSA PRIMo are expressed as wine grapes. Since it is assumed that all wine grapes are consumed as wine, the consumption is recalculated to wine using a yield factor (1 kg of wine grapes is needed to produce 0.7 kg of wine) to perform the refined intake calculation for wine grapes.

The results of the intake calculation are presented in Appendix B to this reasoned opinion.

The total calculated intake values accounted for up to 98.4% of the ADI for the DE child diet (with highest contribution of apples (39.6%)). Further refinement of the consumer exposure assessment is possible, considering that apples are consumed to a major part as juice and that would reduce the total calculated consumer exposure below 100% of the ADI[11].

The contribution of residues in garlic to the total consumer exposure was insignificant, accounting for a maximum of 0.065% of the ADI (WHO Cluster diet B). The contribution of residues in cucurbits (edible peel) to the total consumer exposure (in percentage of the ADI) from the existing use of propineb is 4.2% for melons (IE adult diet), 1.25% for pumpkins (WHO Cluster diet D) and 2.7% for watermelons (WHO Cluster diet B). The residues from the new uses on cucurbits (inedible peel) would contribute to less than 0.5% of the ADI individually for each crops of this group. For all other crops under consideration the existing uses are more critical and therefore the new uses do not affect the consumer exposure to dithiocarbamate residues.

EFSA notes that the calculated consumer exposure is indicative and conclusions might be subject to changes in the outcome of the review of MRLs for dithiocarbamates which will be performed according to Article 12 of Regulation (EC) No 396/2005.

Pending a full data set on the formation of ETU in processed products from various dithiocarbamates, a comprehensive consumer exposure assessment of ETU residues cannot be performed at this stage

[11] According to the consumption data for German children (Banasiak *et al*, 2005), 77% of the apple intake by consists of apple juice. By applying an indicative processing factor of 0.05 for metiram residues in apple juice (Italy, 2010b), the contribution of residues in apple to the total exposure would account for 9.3% of the ADI, whereas in the unrefined calculation performed with the EFSA PRIMo the contribution of apples accounted for 46.3% of the ADI. Considering this refinement the resulting exposure accounts for *ca.* 70% of the ADI.

and will be considered in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005. However, an indicative risk assessment was performed for those crops under consideration for which the new uses would require the raising of the existing MRL for dithiocarbamates (garlic and cucurbits with inedible peel). The worst case situation was calculated assuming that all metiram residues in the processed crops would be converted to ETU during processing; the molecular weight conversion factor of 0.36[12] was applied to express metiram residues as ETU. Since melons and watermelons are mainly consumed raw, the exposure to ETU from the intake of a processed crop is not relevant and was thus not calculated. The calculated chronic and acute consumer exposure to ETU from the intake of garlic would account for 0.4% of the ADI and 0.2% of the ARfD derived for ETU, respectively. The calculated chronic and acute consumer exposure to ETU from the intake of pumpkin would account for 0.6% of the ADI and 31% of the ARfD derived for ETU, respectively. The results of the intake calculation are presented in Appendix B to this reasoned opinion.

EFSA concludes that the intended use of metiram on garlic and cucurbits with edible peel will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a public health concern. The exposure situation for the other crops under consideration is not affected by the new uses requested.

[12] MW ETU (102.16 g/mol); MW metiram (1088.6 g/ml). One molecule of metiram is expected to form 4 molecules of ETU = 0.36

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of metiram was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI value of 0.03 mg/kg bw per day. No ARfD was deemed necessary.

The metabolism of metiram in primary crops was investigated in the fruit and fruiting vegetables and the root and tuber vegetables crop groups. From these studies the peer review proposed to set the risk assessment and enforcement residue definitions as "metiram, expressed as CS_2". The residue definition according to Regulation (EC) No 396/2005 is set as "dithiocarbamates (dithiocarbamates expressed as CS_2, including maneb, mancozeb, metiram, propineb, thiram and ziram)". For the uses on the crops under consideration, EFSA concludes that the metabolism of metiram is sufficiently addressed and the residue definitions agreed in the peer review are applicable.

EFSA concludes that the submitted supervised residue trials data were sufficient to derive MRL proposals of 0.6 mg/kg in garlic and 1.5 mg/kg in cucurbits (with inedible peel). For the uses on other crops a need to modify the existing EU MRLs was not identified. Adequate analytical enforcement methods are available to check the compliance of metiram residues (expressed as carbon disulfide) and the relevant metabolite ethylenethiourea (ETU) in the crops under consideration.

Studies investigating the nature of metiram residues in processed commodities were assessed in the peer review and showed that the compound is degraded to ETU. Therefore for processed commodities the peer review established the residue definition for the risk assessment as ETU. For enforcement purposes the peer review did not specify which residue definition should be applied. Specific studies for the crops under consideration to assess the magnitude of metiram residues after processing have not been submitted. Since garlic and cucurbits (inedible peel) are expected to be a minor contributor to the overall dietary exposure, specific processing studies for these crops are of lower relevance. Since the metabolism studies gave some indications that the majority of the metiram residues remain on the surface, it would be desirable to get further data on the distribution of the residues between pulp and peel of cucurbits (inedible peel), to allow a peeling factor to be derived.

Metiram and ETU are rapidly degraded in soil, therefore residues in rotational crops of these compounds are not expected. The nature and magnitude of metiram in commodities of animal origin was not assessed in the framework of this application, since the crops under consideration are not fed to livestock.

EFSA performed an indicative consumer risk assessment for the intended uses, taking into account available information for dithiocarbamates which have the same toxicological target, i.e., metiram, maneb, mancozeb and propineb. However, it is noted that the calculations are preliminary because full details on the use pattern for these active substances and underlying residue trials are not available. The consumer risk assessment was performed with revision 2 of the EFSA Pesticides Residues Intake Model (PRIMo). For the assessment of the long-term consumer exposure the CS_2 residues originating from maneb, mancozeb or metiram were recalculated to the reference substance propineb by applying the respective combined correction factors (Cf). For garlic the median CS_2 was multiplied by the Cf for metiram and used as an input value. For cucurbits (inedible peel) the median residue value derived from the supervised field trials with metiram multiplied by the Cf for metiram was lower than the input value derived for the existing MRL of 1 mg/kg, which is related to a use of the more toxic substance propineb. Thus, the exposure is calculated with the corrected median value derived from the propineb residue trials on cucurbits.

For other crops EFSA considered only those MRLs which were set above the LOQs and which are related to the use of maneb, mancozeb, metiram and propineb according to Regulation (EC) No 396/2005. The existing MRL was multiplied by the Cf of the most toxic active substance authorized

on that crop and this value was used as an input value. When risk assessment values were available, these were multiplied by the Cf of the individual active substance and only the most critical value was used as an input value. The calculated exposure was then compared with the toxicological reference values as derived for propineb.

Acute consumer exposure assessments were not performed due to the low acute toxicity of the active substance metiram.

The total calculated intake values accounted for up to 98.4% of the ADI for the DE child diet. The contribution of residues in garlic to the total consumer exposure was insignificant, accounting for a maximum of 0.065% of the ADI (WHO Cluster diet B). The contribution of residues in cucurbits (edible peel) to the total consumer exposure (in percentage of the ADI) from the existing use of propineb is 4.2% for melons (IE adult diet), 1.25% for pumpkins (WHO Cluster diet D) and 2.7% for watermelons (WHO Cluster diet B). The residues from the new uses on cucurbits (inedible peel) would contribute to less than 0.5% of the ADI individually for each crops of this group.

Pending provision of a full data set on the formation of ETU in processed products from various dithiocarbamates, a comprehensive consumer exposure assessment for ETU residues cannot be performed. However, an indicative risk assessment was performed for those crops under consideration for which the new uses would require the raising of the existing MRL for dithiocarbamates (garlic and cucurbits with inedible peel). The worst case situation was calculated assuming that all metiram residues in the processed crops would be converted to ETU during processing. Since melons and watermelons are mainly consumed raw, the exposure to ETU from the intake of a processed crop is not relevant and was thus not calculated. The calculated chronic and acute consumer exposure to ETU from the intake of garlic would account for 0.4% of the ADI and 0.2% of the ARfD derived for ETU, respectively. The calculated chronic and acute consumer exposure to ETU from the intake of pumpkin would account for 0.6% of the ADI and 31% of the ARfD derived for ETU, respectively.

EFSA concludes that, the intended use of metiram on garlic and cucurbits (with edible peel) will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern. The exposure situation for the other crops under consideration is not affected by the new uses requested.

EFSA notes that the calculated consumer exposure is indicative and conclusions might be subject to changes in the outcome of the review of MRLs for dithiocarbamates which will be performed according to Article 12 of Regulation (EC) No 396/2005.

RECOMMENDATIONS

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Dithiocarbamates (dithiocarbamates expressed as CS_2, including maneb, mancozeb, metiram, propineb, thiram and ziram)				
0220010	Garlic	0.5	0.6	The MRL proposal is supported by data and no risk for consumers was identified for the intended use of metiram.
0220020	Onions	1	1	The submitted data support the intended use of metiram and an amendment of the existing MRLs is not necessary.
0220030	Shallots	1	1	
0232000	Cucurbits-edible peel	2	2	
0233000	Cucurbits-inedible peel	1	1.5	The MRL proposal is supported by data and no risk for consumers was identified for the intended outdoor use. The intended indoor use is not sufficiently supported by data.

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
0270020	Asparagus	0.5	0.5	The intended use pattern indicates no need to modify the existing EU MRL.

(a): According to Annex I of Regulation (EC) No 396/2005.
(*): Indicates that the MRL is set at the limit of analytical quantification.

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APPENDICES

A. GOOD AGRICULTURAL PRACTICE (GAPS)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. of a.s. (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	interval min max	kg as/hL min max	water L/ha min max	kg a.s./ha min max		
Cucurbits (edible peel and inedible peel)	CYPRUS, SPAIN, GREECE, ITALY, PORTUGAL	F/G	*Pseudoperono, Spora cubensis*	WG	70	spraying	BBCH 20-89	3	7	0.13-0.28	500-1000	1.26-1.4	3	1.8-2 L product per hectare
Garlic, onion, shallots	CYPRUS, SPAIN, GREECE, ITALY, PORTUGAL, ROMANIA	F	*Peronospora destructor*	WG	70	spraying	BBCH 13-48	6	7	0.13-1.03	150-1000	1.26-1.54	7	1.8-2.2 L product per hectare
Asparagus	CYPRUS, GREECE, BELGIUM, GERMANY	F	*Puccinia asparagi*	WG	70	spraying	n.a.	2-3	n.a.	0.84-1.54	100-150	1.26-1.54	n.a.	Treatments are performed after the harvesting of edible parts.

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

B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Propineb				Prepare workbook for refined calculations	
Status of the active substance:		Code no.			
LOQ (mg/kg bw):		proposed LOQ:			
Toxicological end points				Undo refined calculations	
ADI (mg/kg bw/day):	**0.007**	ARfD (mg/kg bw):	**0.1**		
Source of ADI:	**EC**	Source of ARfD:	**EC**		
Year of evaluation:	**2003**	Year of evaluation:	**2003**		

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	16 - 98
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)
98.4	DE child	39.6	Apples	9.3	Table grapes	5.7	Oranges	
88.3	WHO Cluster diet B	14.5	Tomatoes	12.5	Olives for oil production	7.0	Wheat	
74.4	NL child	20.8	Apples	8.4	Potatoes	5.6	Table grapes	
61.5	DK child	15.8	Rye	12.4	Cucumbers	7.6	Apples	
57.1	IE adult	5.7	Barley	4.9	Aubergines (egg plants)	4.2	Melons	
50.3	FR toddler	8.6	Apples	7.7	Leek	7.2	Potatoes	
43.9	WHO cluster diet E	5.5	Potatoes	3.7	Barley	3.2	Wheat	
43.5	WHO cluster diet D	5.8	Potatoes	5.3	Wheat	4.8	Tomatoes	
43.4	SE general population 90th percentile	6.7	Head cabbage	6.0	Potatoes	3.6	Tomatoes	
41.7	WHO regional European diet	5.7	Potatoes	5.2	Tomatoes	3.9	Head cabbage	
36.6	FR infant	8.2	Apples	5.9	Potatoes	5.1	Courgettes	
35.7	WHO Cluster diet F	4.9	Potatoes	3.2	Tomatoes	3.0	Head cabbage	
34.5	ES child	4.8	Olives for oil production	4.6	Tomatoes	3.7	Apples	
32.6	NL general	3.9	Potatoes	3.9	Apples	2.2	Head cabbage	
31.6	PT General population	7.6	Potatoes	4.2	Tomatoes	3.4	Apples	
31.5	UK Toddler	5.6	Apples	5.0	Potatoes	3.2	Wheat	
29.6	PL general population	6.7	Apples	4.9	Potatoes	4.2	Tomatoes	
29.4	IT kids/toddler	6.7	Tomatoes	5.5	Wheat	2.9	Apples	
29.2	LT adult	6.1	Apples	4.5	Potatoes	4.3	Head cabbage	
28.3	ES adult	3.7	Tomatoes	2.7	Olives for oil production	2.7	Lettuce	
26.9	IT adult	5.5	Tomatoes	3.4	Wheat	2.6	Apples	
26.7	UK Infant	5.1	Apples	4.6	Potatoes	2.2	Wheat	
23.3	FR all population	2.7	Wheat	2.0	Tomatoes	1.9	Wine grapes	
20.6	UK vegetarian	2.9	Tomatoes	2.0	Potatoes	1.9	Apples	
20.2	DK adult	2.6	Apples	2.4	Rye	2.1	Potatoes	
18.0	FI adult	2.4	Rye	2.0	Cucumbers	2.0	Tomatoes	
15.7	UK Adult	2.1	Tomatoes	2.0	Potatoes	1.4	HOPS (dried),	

Conclusion:

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

Ethylenethiourea (ETU)

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.002**	ARfD (mg/kg bw):	**0.05**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2005**	Year of evaluation:	**2005**

The input values for garlic and pumpkin were derived as median residue (for chronic eposure) or highest residue (for acute exposure) for CS2, multiplied with a conversion factor of 1.79 (from CS2 to metiram) and a molecular weight conversion factor of 0.36 (from metiram to ETU).

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
1

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)
0.96	WHO cluster diet D	0.6	Pumpkins	0.3	Garlic		FRUIT (FRESH OR FROZEN)	
0.53	WHO Cluster diet B	0.4	Garlic	0.2	Pumpkins		FRUIT (FRESH OR FROZEN)	
0.42	WHO regional European diet	0.3	Garlic	0.2	Pumpkins		FRUIT (FRESH OR FROZEN)	
0.32	SE general population 90th percentile	0.2	Garlic	0.1	Pumpkins		FRUIT (FRESH OR FROZEN)	
0.21	FR infant	0.2	Pumpkins		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.16	FR all population	0.1	Garlic	0.0	Pumpkins		FRUIT (FRESH OR FROZEN)	
0.14	IT kids/toddler	0.1	Pumpkins	0.1	Garlic		FRUIT (FRESH OR FROZEN)	
0.12	FR toddler	0.1	Pumpkins	0.1	Garlic		FRUIT (FRESH OR FROZEN)	
0.12	ES adult	0.1	Garlic		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.09	ES child	0.1	Garlic		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.09	WHO cluster diet E	0.1	Garlic		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.08	WHO Cluster diet F	0.1	Garlic	0.0	Pumpkins		FRUIT (FRESH OR FROZEN)	
0.08	IT adult	0.0	Garlic	0.0	Pumpkins		FRUIT (FRESH OR FROZEN)	
0.07	NL general	0.1	Pumpkins	0.0	Garlic		FRUIT (FRESH OR FROZEN)	
0.07	DE child	0.0	Garlic	0.0	Pumpkins		FRUIT (FRESH OR FROZEN)	
0.05	UK vegetarian	0.0	Garlic	0.0	Pumpkins		FRUIT (FRESH OR FROZEN)	
0.05	IE adult	0.1	Garlic		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.04	DK adult	0.0	Pumpkins	0.0	Garlic		FRUIT (FRESH OR FROZEN)	
0.03	FI adult	0.0	Pumpkins	0.0	Garlic		FRUIT (FRESH OR FROZEN)	
0.02	NL child	0.0	Pumpkins		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.01	UK Adult	0.0	Garlic	0.0	Pumpkins		FRUIT (FRESH OR FROZEN)	

Conclusion:

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

	Acute risk assessment /children - refined calculations						Acute risk assessment / adults / general population - refined calculations					
	The acute risk assessment is based on the ARfD.											
	For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.											
	In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.											
	Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.											
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
	IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	31.2	Pumpkins	0.457524 / -	31.2	Pumpkins	0.457524 / -	48.4	Pumpkins	0.457524 / -	48.4	Pumpkins	0.457524 / -
	0.2	Garlic	0.154656 / -	0.2	Garlic	0.154656 / -	0.2	Garlic	0.154656 / -	0.2	Garlic	0.154656 / -
	No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:**		---				**No of commodities for which ARfD/ADI is exceeded:**		---			
			***)						***)			
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
	*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported. **) pTMRL: provisional temporary MRL ***) pTMRL: provisional temporary MRL for unprocessed commodity											
	Conclusion:											
	For Ethylenethiourea (ETU) 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.											

C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLS)

(Pesticides - Web Version - EU MRLs (File created on 02/07/2012 13:31))

Code number	Groups and examples of individual products to which the MRLs apply	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
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
130990	Others	5
140000	(iv) Stone fruit	
140010	Apricots	2 (ft)
140020	Cherries (sweet cherries, sour cherries)	2 (ft)
140030	Peaches (Nectarines and similar hybrids)	2 (ft)
140040	Plums (Damson, greengage, mirabelle)	2 (ft)
140990	Others	0,05*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	5 (ft)
151010	Table grapes	5
151020	Wine grapes	5
152000	(b) Strawberries	10 (ft)
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,05*
153030	Raspberries (Wineberries)	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries cowberries (red bilberries))	5
154020	Cranberries	5
154030	Currants (red, black and white)	5 (ft)
154040	Gooseberries (Including hybrids with other ribes species)	5
154050	Rose hips	0,05*
154060	Mulberries (arbutus berry)	0,05*
154070	Azarole (mediteranean medlar)	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	5
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	5 (ft)
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	2 (ft)
163030	Mangoes	2 (ft)
163040	Papaya	7 (ft)
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 (ft)
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,5 (ft)
213020	Carrots	0,2 (ft)
213030	Celeriac	0,3 (ft)
213040	Horseradish	0,2 (ft)
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,2 (ft)
213070	Parsley root	0,2 (ft)
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	2 (ft)
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,2 (ft)
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	
220010	Garlic	0,5 (ft)
220020	Onions (Silverskin onions)	1 (ft)
220030	Shallots	1 (ft)
220040	Spring onions (Welsh onion and similar varieties)	1 (ft)
220990	Others	0,05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	3 (ft)
231020	Peppers (Chilli peppers)	5 (ft)
231030	Aubergines (egg plants) (Pepino)	3 (ft)
231040	Okra, lady's fingers	0,5 (ft)

Code number	Groups and examples of individual products to which the MRLs apply	Dithiocarbamates (dithiocarbamates expressed as CS_2, including maneb, mancozeb, metiram, propineb, thiram and ziram)
231990	Others	0,05*
232000	(b) Cucurbits - edible peel	2 (ft)
232010	Cucumbers	2
232020	Gherkins	2
232030	Courgettes (Summer squash, marrow (patisson))	2
232990	Others	2
233000	(c) Cucurbits-inedible peel	1 (ft)
233010	Melons (Kiwano)	1 (ft)
233020	Pumpkins (Winter squash)	1 (ft)
233030	Watermelons	1 (ft)
233990	Others	1 (ft)
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	1 (ft)
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	1
241020	Cauliflower	1
241990	Others	1
242000	(b) Head brassica	
242010	Brussels sprouts	2 (ft)
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	3 (ft)
242990	Others	0,05*
243000	(c) Leafy brassica	0,5 (ft)
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 (ft)
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	5 (ft)
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 Brassica spp (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, glassworth)	5
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,3 (ft)
255000	(e) Witloof	0,5 (ft)
256000	(f) Herbs	5 (ft)
256010	Chervil	5
256020	Chives	5
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 (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	1 (ft)
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,1 (ft)
260030	Peas (with pods) (Mangetout (sugar peas))	1 (ft)
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,2 (ft)
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,5 (ft)
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	3 (ft)
270070	Rhubarb	0,5 (ft)
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,1 (ft)
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,1 (ft)
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 (ft)
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	
402010	Olives for oil production	5 (ft)
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 (ft)
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	2 (ft)
500060	Rice	0,05*
500070	Rye	1 (ft)
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	1 (ft)
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS	0,1*

Code number	Groups and examples of individual products to which the MRLs apply	Dithiocarbamates (dithiocarbamates expressed as CS_2, including maneb, mancozeb, metiram, propineb, thiram and ziram)
	AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	25 (ft)
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*
840040	Horseradish	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	0,05*
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
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)	0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*
1060000	(vi) Snails	0,05*
1070000	(vii) Other terrestrial animal products	0,05*

(*) Indicates lower limit of analytical determination

(ft): The MRLs expressed as CS_2 can arise from different dithiocarbamates and therefore they do not reflect a single Good Agricultural Practice (GAP). It is therefore not appropriate to use

these MRLs to check compliance with a GAP. In brackets the origin of the residue (ma: maneb mz: mancozeb me: metiram pr: propineb t: thiram z: ziram).
0140010 Apricots
0140020 Cherries (sweet cherries, sour cherries) (mz, me, pr, t, z)
0140030 Peaches (Nectarines and similar hybrids) (mz, t)
0140040 Plums (Damson, greengage, Mirabelle, sloe) (mz, me, t, z)
0151000 (a) Table and wine grapes (ma, mz, me, pr, t)
0152000 (b) Strawberries(t)
0154030 Currants (red, black and white) (mz)
0161030 Table olives(mz, pr)
0163020 Bananas (Dwarf banana, plantain, apple banana) (mz, me, t)
0163030 Mangoes(mz)
0163040 Papaya(mz)
0211000 (a) Potatoes(ma, mz, me, pr)
0213010 Beetroot(mz)
0213020 Carrots(mz)
0213030 Celeriac (ma, me, pr, t)

0213040 Horseradish Angelica roots, lovage roots, gentiana roots) (mz)
0213060 Parsnips(mz)
0213070 Parsley root(mz)
0213080 Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (Cyperus esculentus) (mz)
0213090 Salsify (Scorzonera, Spanish salsify (Spanish oysterplant)) (mz)
0220010 Garlic(mz)
0220020 Onions (Silverskin onions) (ma, mz)
0220030 Shallots(ma, mz)
0220040 Spring onions (Welsh onion and similar varieties) (mz)
0231010 Tomatoes (Cherry tomatoes, tree tomato, Physalis, gojiberry, wolfberry (Lycium barbarum and L. chinense) (ma, mz, me, pr)
0231020 Peppers (Chilli peppers) (mz, pr)
0231030 Aubergines (egg plants) (Pepino) (mz, me)
0231040 Okra, lady's fingers (mz)
0232000 (b) Cucurbits - edible peel (mz, pr)
0233000 (c) Cucurbits-inedible peel (ma, mz, pr)

0233010 Melons (Kiwano)
0233020 Pumpkins (Winter squash)
0233030 Watermelons
0233990 Others
0241000 (a) Flowering brassica (mz)
0242010 Brussels sprouts(mz)
0242020 Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage) (mz)
0243000 (c) Leafy brassica (mz)
0244000 (d) Kohlrabi (mz)
0251000 (a) Lettuce and other salad plants including Brassicacea (mz, me, t)
0254000 (d) Water cress (mz)
0255000 (e) Witloof (mz)
0256000 (f) Herbs (mz, me)
0260010 Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans) (mz)

0260020 Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea) (mz)
0260030 Peas (with pods) (Mangetout (sugar peas, snow peas)) (ma, mz)
0260040 Peas (without pods) (Garden pea, green pea, chickpea) (mz)
0270010 Asparagus (mz)
0270060 Leek (ma, mz)
0270070 Rhubarb (mz)
0300010 Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas) (mz)
0300030 Peas (Chickpeas, field peas, chickling vetch) (mz)
0401060 Rape seed (Bird rapeseed, turnip rape) (ma, mz)
0402010 Olives for oil production (mz, pr)
0500010 Barley(ma, mz)
0500050 Oats (ma, mz)
0500070 Rye (ma, mz)
0500090 Wheat (Spelt, triticale) (ma, mz)
0700000 7. HOPS (dried) , including hop pellets and unconcentrated powder(pr)

ABBREVIATIONS

ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DALA	days after last application
DAR	Draft Assessment Report
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90% dissipation
EFSA	European Food Safety Authority
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionisation detector
FPD	flame photometric detector
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (former GIFAP)
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HS-GS	head-space gas chromatography
HR	highest residue
ILV	independent laboratory validation

IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry
MSD	mass spectrometry detector
NEU	northern European Union
MW	molecular weight
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RD	residue definition
RMS	rapporteur Member State
STMR	supervised trials median residue
SEU	Southern European Union
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detector
WG	water dispersible granule
WHO	World Health Organisation
wk	week
YF	yield factor
yr	year