

REASONED OPINION OF EFSA

MRLs of concern for the active substance procymidone, taking into account revised toxicological reference values¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2008-786)

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SUMMARY

EFSA self-tasked to revise the previously performed risk assessment of MRLs established for procymidone (EFSA 2008) because Member States and the European Commission agreed on lower toxicological reference values. The ADI was lowered from 0.025 mg/kg bw/d to 0.0028 mg/kg bw/d. The new ARfD was established at a level of 0.012 mg/kg bw instead of 0.035 mg/kg bw.

In conclusion, EFSA proposes to change the following MRLs in order to reduce the acute and/or consumer exposure to a level where no negative consumer health effects are expected:

Overview of the proposed EC MRLs

Commodity	Current MRL (mg/kg)	Proposed MRL (mg/kg)	Justification for the proposal
Pears	1	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement). (For details see EFSA 2008)
Apricots	2	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Peaches	2	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)

¹ For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on MRLs of concern for the active substance procymidone (revised risk assessment). *EFSA Scientific Report* (2009) 227, 1-26

Commodity	Current MRL (mg/kg)	Proposed MRL (mg/kg)	Justification for the proposal
Plums	2	0.02*	Deletion of MRL is recommended because European uses are not longer authorised and consumers' risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Table grapes	5	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Wine grapes	5	0.02*	Deletion of the MRL is recommended because no European uses are authorised and a consumer risk cannot be excluded if the CXL is considered (even after refined intake calculations). It should be noted that wine with residues up to 0.7 mg/kg and grape juice with residues up to 0.3 mg/kg do not pose an acute consumer risk. See 4.1.1
Strawberries	5	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Raspberries	10	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Kiwi	5	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Tomatoes	2	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Peppers	2	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Aubergines (egg plants)	2	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Cucumbers	1	0.02*	Deletion of MRL is recommended because European uses are not longer authorised and consumers' risk cannot be excluded if the CXL is considered (even after refinement). (For details see EFSA 2008)

Commodity	Current MRL (mg/kg)	Proposed MRL (mg/kg)	Justification for the proposal
Gherkins	1	0.02*	Deletion of MRL is recommended because European uses are not longer authorised. The CXL of 2 mg/kg is not acceptable from a consumer point of view. . See 4.1.3
Courgettes	1	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Melons	1	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Pumpkins	1	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Watermelons	1	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Lamb's lettuce	5	0.02*	Deletion of MRL is recommended because European uses are not authorised and no CXL is allocated for this crop. See 4.1.4
Lettuce	5	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Scarole (broad-leaf endive)	5	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Rocket, Rucola	5	0.02*	Deletion of MRL is recommended because European uses are not authorised and no CXL is allocated for these crops. See 4.1.4
Witloof	2	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Beans (with pods)	2	1	Lowering of the MRL at the level of 1 mg/kg (CXL) is recommended because European authorisations have been withdrawn. See 4.1.2
Sunflower seed	1	0.2	Lowering of the MRL at the level of 0.2 mg/kg (CXL) is recommended because European authorisations have been withdrawn. See 5.1.2
Rape seed	1	0.02	Deletion of MRL may be considered in order to reduce the calculated chronic exposure. See 5.1.2

Commodity	Current MRL (mg/kg)	Proposed MRL (mg/kg)	Justification for the proposal
Soya bean	1	0.02	Deletion of MRL may be considered in order to reduce the calculated chronic exposure. See 5.1.2
Products of animal origin	0.05*	0.02*	The lowering of the LOQ may be considered in order to reduce the calculated chronic exposure. See 5.1.1
Further remarks:			
Garlic, onions, shallots	0.2		No action necessary from a consumer safety point of view. CXL for onions is established at 0.2 mg/kg.
Okras, lady fingers	2		No action necessary from a consumer safety point of view. However, since the European authorisations have been withdrawn and in the absence of international obligations a deletion could be considered as a risk management measure.
Cress, land cress, red mustard, leaves and sprouts of Brassica	5		No action necessary from a consumer safety point of view. However, since the European authorisations have been withdrawn and in the absence of international obligations a deletion could be considered as a risk management measure.
Peas (with pods)	1		No action necessary from a consumer safety point of view.
Peas (without pods)	0.3		No action necessary from a consumer safety point of view.
Dry peas	0.2		No action necessary from a consumer safety point of view.

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

Key words: Procymidone, MRLs of concern, Regulation (EC) No 396/2005, dicarboximide, consumer risk assessment

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BACKGROUND

MRLs for procymidone in cereals, products of animal origin, fruit, and vegetables have been set at the European level in 1993 and 1998. These MRLs are still valid since they were transferred to the new MRL legislation (Regulation (EC) No 396/2005) without amendments.

The active substance procymidone was subject to the peer review under Directive 91/414/EEC which was finalised in 2006 with the inclusion of the active substance in Annex I of this Directive (Commission Directive 2006/132/EC, corrected by Commission Decision 2007/452/EC). The agreed toxicological reference values were published in the Review Report SANCO/4064/2001 final (January 2007) (ADI 0.025 mg/kg bw/d, ARfD 0.035 mg/kg bw). Procymidone was included in Annex I only for a limited period of time (expiry date 30 June 2008) due to the several areas of concern that were identified during the peer review.

The European Commission, as a consequence of the results of the review programme, became also aware of possible concerns in relation to the safety of certain existing MRLs for procymidone and therefore asked EFSA to provide a scientific opinion regarding potential consumer risks associated with these MRLs.

EFSA issued a reasoned opinion on this question on 15 September 2008 (EFSA 2008). The risk assessment was based on the agreed toxicological reference values derived in the peer review under Directive 91/414/EEC.

The manufacturer of procymidone submitted a new dossier in support of the application to prolong the Annex I inclusion beyond 30 June 2008. The Rapporteur Member State France who assessed the data concluded on significantly lower ADI and ARfD values (ADI 0.0028 mg/kg bw/d, ARfD 0.012 mg/kg bw) compared with the values allocated in 2007. Member States and the European Commission recently confirmed that these toxicological reference values should be used for the risk assessment of MRLs although there was no formal adoption of these values by the Standing Committee on Food Chain and Animal Health.

TERMS OF REFERENCE

The Pesticides Unit (PRAPeR) self-tasked to revise the risk assessment performed in the reasoned opinion of EFSA on MRLs of concern for the active substance procymidone (EFSA Scientific Report (2008) 165, 1-33), using the new agreed toxicological reference values proposed by the Rapporteur Member State France (ADI 0.0028 mg/kg bw/d, ARfD 0.012 mg/kg bw).

Since this task consists of scientific work involving the application of well-established scientific principles which does not require scientific evaluation by the Scientific Committee or a Scientific Panel, the task is allocated to the Pesticides Unit (PRAPeR).

The deadline for revision of the EFSA reasoned opinion is 31 January 2009.

ASSESSMENT

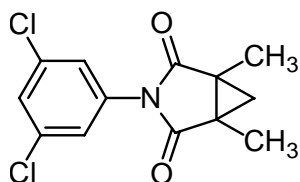
In line with the approach applied in the EFSA opinion regarding MRLs of concern for the active substance procymidone (EFSA 2008), EFSA first identifies the MRLs of concern using the screening methodology (scenario 1). In contrast to the previous opinion, the new, agreed toxicological reference values (ADI = 0.0028 mg/kg bw/d, ARfD = 0.012 mg/kg bw) are used instead of the values agreed in the peer review in 2007.

In case the rough screening reveals a potential consumer concern with regard to the acute intake, EFSA performs a refined acute and chronic risk assessment calculation (scenario 2) according to the agreed European methodology which should reduce the uncertainties of the first screening. In a second step EFSA proposes further options to refine the chronic intake calculations. These more realistic refined intake calculations should provide the basis to decide in which cases risk management decisions have to be taken to solve the consumer risk.

It should also be stressed that the evaluation presented in this report is intended to provide an opinion on the consumer safety of the existing MRLs, but not to review the scientific background of all the established European MRLs.

1. Introduction

Procymidone is the ISO common name for N-(3,5-dichlorophenyl)-1,2-dimethylcyclopropane-1,2-dicarboximide (IUPAC).



Procymidone belongs to the class of dicarboximide fungicides. It is moderately systemic and it is an inhibitor of triglyceride synthesis in fungi.

Procymidone has been assessed in the framework of Directive 91/414/EEC in the first stage with France being the designated Rapporteur Member State. The resulting decision on inclusion in Annex I to Directive 91/414/EEC, which was published in Directive 2006/132/EC and entered into force on 1 January 2007, was linked to specific risk mitigation measures. The Annex I inclusion was restricted to the use as fungicide only on:

- cucumbers in greenhouses (closed hydroponic systems) at application rates not exceeding 0.75 kg a.s./ha per application
- plums (for processing) at application rates not exceeding 0.75 kg a.s./ha per application.

In accordance with the provisions of Directive 91/414/EEC, the manufacturer of procymidone submitted further data in order to renew the Annex I inclusion beyond June 2008. These data were evaluated by the Rapporteur Member State in an addendum to the Draft Assessment Report (France 2007). EFSA was not requested by the European Commission to organise a peer review of the new submitted data.

The Annex I inclusion expired on 30 June 2008 because no proposal regarding the renewal of the Annex I inclusion or a specific non-inclusion decision was prepared by the European Commission on this active substance. As a consequence, the above mentioned uses had to be revoked by 1 July 2008.

Member States and the European Commission agreed that the toxicological reference values proposed by the Rapporteur Member State France should be used at European level. On 10 November 2008, the updated ADI and ARfD were included in document 3010 (http://ec.europa.eu/food/plant/protection/evaluation/index_en.htm), which is the reference document regarding the review programme under 91/414/EEC and gives the current status of the active substances as regards Directive 91/414/EEC and the setting of EU MRLs under Directive 90/642/EEC, 86/362/EEC and 86/363/EEC.

2. Maximum Residue Levels

The list of MRLs established at EU level can be found in the EFSA opinion on MRLs of concern for the active substance procymidone (EFSA 2008).

3. Mammalian toxicology

3.1.1.1. Acceptable Daily Intake (ADI)

In the peer review an ADI of 0.025 mg/kg bw/day was assigned, the value being based on the NOAEL for the rat multi-generation study, 2.5 mg/kg bw/day (50 ppm), and a safety factor of 100. The effects noted at 250 ppm (12.5 mg/kg bw/day) were reduced anogenital distance, hypospadias, testicular atrophy and undescended testes.

Considering the additional information submitted in the framework of the renewal of the Annex I inclusion, the RMS concluded that increased weight of the testes and decreased weight of the prostate, epididymis and seminal vesicles were seen even at 50 ppm. Thus, the following assessment factors are proposed:

- a 3-fold factor (LOAEL → NOEL),
- a 3-fold factor for interspecies variability
- a 10-fold factor for intraspecies variability
- a 10-fold factor for the severity of the effects

giving an ADI of $\frac{2.5}{3 \times 3 \times 10 \times 10} = 0.0028$ mg/kg bw/day.

[Considering the 50 ppm level as a true LOAEL, the use of a safety factor of 1000 would lead to the similar result of $\frac{2.5}{1000} = 0.0025$ mg/kg bw/day.]

Consequently, a **revised ADI of 0.0028 mg/kg bw/day** was proposed in the addendum to the Draft Assessment Report (August 2007). This proposal was not peer-reviewed.

3.1.1.2. Acute reference dose (ARfD)

The acute reference dose allocated in 2007 in the peer review (0.035 mg/kg) was based on one developmental toxicity study in rats (reduced anogenital distance, hypospadias, testicular atrophy, undescended testes) with a NOEL of 3.5 mg/kg bw/d.

In the addendum to the Draft Assessment Report (France 2007) the RMS proposed the following assessment factors:

- a 3-fold factor for interspecies variability
- a 10-fold factor for intraspecies variability
- a 10-fold factor for the severity of the effects

giving an ArfD of $\frac{3.5}{3 \times 10 \times 10} = 0.012$ mg/kg bw/d.

Consequently, a **revised ARfD of 0.012 mg/kg bw** was proposed in the addendum to the Draft Assessment Report (France 2007). This value is not peer-reviewed.

Table 3-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
ADI	FR	2007	0.0028	Two generation study in rats	900
ARfD	FR	2007	0.012	Rat developmental study	300

4. Identification of the MRLs of concern

4.1. MRLs of concern regarding the acute consumer intake

Applying the same approach as in the EFSA opinion issued on 15 September 2008 (EFSA 2008), but basing the calculations on the new agreed ARfD value, a potential acute intake concern is identified with the screening methodology for 24 different food commodities (see Appendix 1). 19 of these commodities were already discussed in detail in the first opinion issued in September 2008 and the conclusions and recommendations derived there are still valid.

For wine grapes the conclusion derived in the first opinion has to be revised. For four additional commodities (beans with pods, gherkins, rocket and lamb's lettuce) a discussion and a refined intake calculation is reported below.

The MRLs for **garlic, onions, shallots (all 0.2 mg/kg), okras (2 mg/kg), cress (5 mg/kg), peas (with pods) (1 mg/kg), peas (without pods) (0.3 mg/kg), dry peas (0.2 mg/kg), sunflower seed, rape seed and soya bean (all 1 mg/kg)** are the only MRLs established above the LOQ which do not exceed the ARfD. They are therefore not further discussed in the context of the acute risk assessment, but are considered in section 5 with regard to refinements of the chronic intake calculations.

4.1.1. Revised acute risk assessment for wine grapes

The current EC MRL for wine grapes is 5 mg/kg. The CXL is established at the same level.

In the EFSA Scientific Report (EFSA 2008) it was concluded that the refined risk assessment for the MRL for wine grapes does not identify a consumer risk.

However, applying the lower ARfD value of 0.012 mg/kg bw, the exposure exceeds the ARfD for the critical consumer. The exposure of adults amounts for 273% of the ARfD if the calculation includes the processing factor of 0.3 and the HR derived from the Codex data (4.6 mg/kg).

Also the intake resulting from residues in grape juice calculated with the MRL-p of 0.8 mg/kg exceeds the ARfD (219% of the ARfD). The processing factor of 0.16 is derived from data presented in the addendum of the DAR (France 2007).

Conclusion:

EFSA proposes that the MRL of 5 mg/kg should be also considered for deletion because European uses are no longer authorised and even after refinement a consumer risk cannot be excluded.

As proposed by the RMS (France 2008), transitional measures for the marketing of wine produced under the current MRL legislation should be established. However, EFSA does not support the setting of a MRL of 1 mg/kg for unprocessed wine grapes. It should be clear that the interim measure should only be applicable for wine and not for unprocessed grapes. The following considerations should be taken into account for defining a transitional solution for wine produced under the old legislation:

- The maximum wine consumption, re-calculated from the consumption figure of wine grapes is 1.287 g wine/d (corresponding with the critical wine grape consumption of 1802 g and a conversion factor of 1.4, meaning that 1.4 kg wine grapes are necessary to produce 1 kg of wine).
- The RMS reported in the DAR addendum that procymidone is the only residue in fresh wine, but in aged wine higher amounts of 3,5-dichloroaniline (3,5-DCA) are expected.
- 3,5-DCA is a common metabolite for procymidone, iprodione and vinclozolin.
- 3,5-DCA is a metabolite of toxicological concern which should therefore also be considered in the intake assessment. It occurs as minor metabolite in rats.
- Data presented in the DAR addendum (France 2007) showed that 3,5-DCA residues in wine occurred at concentrations up to 50% of the parent compound. In a French survey (France 2005) 3,5-DCA concentrations of 10% of the procymidone residues were measured.
- Considering a molecular weight of 284.1 for procymidone and a molecular weight of 162 for 3,5-DCA, a conversion factor of 1.7 is calculated to recalculate 3,5-dichloroaniline to procymidone.
- The half-life of procymidone residues in wine is about 200 d.

For wine, the safety threshold residue, corresponding to 100% of the ARfD, is calculated to be 0.7 mg/kg. The threshold residue for grape juice is 0.36 mg/kg.

It should be noted that residues in wine up to 0.7 mg/kg and residues in grape juice up to 0.3 mg/kg are not considered to be of acute consumer concern. As an interim measure to ensure the marketing of wine and juice produced under the current MRL legislation, the setting of a safety MRL for wine and grape juice may be considered. In this case EFSA proposes to include also the metabolite 3,5-dichloroaniline in the residue definition for enforcement for wine. This metabolite is not expected in grape juice.

4.1.2. Beans (with pods)

The existing MRL for beans with pods is 2 mg/kg. The CXL is 1 mg/kg. The use of procymidone on beans is no longer authorised in Europe.

According to JMPR Report (1993), GAPs were reported from 6 countries (PHI 7 to 14 days, maximum dose rate of 0.75 kg/ha). The residues range between 0.1 and 0.8 mg/kg. If the HR of 0.8 mg/kg is used in the IESTI calculation, the ARfD is not exceeded (76% of the ARfD). No STMR value was reported.

Conclusion:

EFSA proposes to lower the MRL at the level of 1 mg/kg (CXL). The refined acute intake calculation is performed with the HR of 0.8 mg/kg related to the CXL.

4.1.3. Gherkins

The existing MRL for gherkins is 1 mg/kg. A CXL of 2 mg/kg has been established. No authorisation is granted in the EU Member States.

Regarding the MRL for gherkin, the results for cucumbers as reported in the EFSA Scientific Report (EFSA 2008) can be extrapolated.

Conclusion:

Since there is no GAP authorised in the EC MS, the current MRL of 1 mg/kg should be considered for deletion.

4.1.4. Rocket (rucola) and lamb's lettuce

The existing MRL for rucola and lamb's lettuce is 5 mg/kg. No Codex CXL is established for these two specific lettuce varieties.

No residue data are available in support of the current European MRL.

Conclusion:

EFSA proposes to withdraw the MRL for rucola and lamb's lettuce because European uses are no longer authorised and no CXL is allocated for these two crops.

5. Chronic risk assessment for the MRLs of concern

After amending the MRLs as proposed in the EFSA Scientific Report (EFSA 2008) and the additional amendments proposed in section 4.1, the chronic intake still exceeds the ADI in 5 diets (see Appendix 2. Maximum value: French toddler 143% of the ADI). The main contributors in these diets are milk, beans (with pods), sunflower seeds, and soya beans.

In general, a chronic intake concern can be solved by applying one or several of the following measures:

- Refining the intake calculation by replacing one or several MRLs with STMR values or by introduction of processing factors, where appropriate
- Deletion of one or several MRLs
- Lowering the LOQ for one or several commodities

A risk management decision has to be taken which risk mitigation measures should be applied in a given case. However, in the following section, EFSA identifies different options regarding risk mitigation measures in order to reduce the chronic exposure to a level not exceeding the ADI.

5.1.1. Products of animal origin

The current MRLs for products of animal origin are set at the level of 0.05 mg/kg equivalent the LOQ. According to the list of end points presented in the DAR addendum (August 2007), validated analytical methods are available for milk, muscle, liver, kidney and fat with a LOQ of 0.02 mg/kg.

Conclusion:

The lowering of the LOQ of 0.05 to 0.02 mg/kg for products of animal origin may be considered in order to reduce the chronic consumer exposure.

5.1.2. Sunflower seed

The current MRL for sunflower seed is 1 mg/kg. The CXL is 0.2 mg/kg.

No residue data are available in support of the current European GAP.

Conclusion:

There is no justification to keep the current EU MRL. Therefore the lowering of the MRL for sunflower seeds to 0.2 mg/kg (equivalent to the Codex CXL) may be considered in order to reduce the chronic consumer exposure.

5.1.3. Rape seed and soya bean

The current MRL for rape seed and soya bean is 1 mg/kg. No CXL is established for these crops.

No residue data are available in support of the current European GAP.

Conclusion:

The deletion of the MRL for rape seed and soya bean may be considered as possible risk management option in order to reduce the chronic consumer exposure.

By applying the proposed risk mitigation measures reported under 5.1.1 to 5.1.3 the chronic exposure will drop below 100 % of the ADI in all diets (maximum value 92%).

The detailed results of this calculation can be found in Appendix 3.

CONCLUSIONS AND RECOMMENDATIONS

EFSA self-tasked to revise the previously performed risk assessment of MRLs established for procymidone (EFSA 2008) because Member States and the European Commission agreed on lower toxicological reference values. The ADI was lowered from 0.025 mg/kg bw/d to 0.0028 mg/kg bw/d. The new ARfD was established at a level of 0.012 mg/kg bw instead of 0.035 mg/kg bw.

In conclusion, EFSA proposes to change the following MRLs in order to reduce the acute and/or consumer exposure to a level where no negative consumer health effects are expected.

Table 5-1. Overview of the proposed EC MRLs

Commodity	Current MRL (mg/kg)	Proposed MRL (mg/kg)	Justification for the proposal
Pears	1	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement). (For details see EFSA 2008)
Apricots	2	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Peaches	2	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Plums	2	0.02*	Deletion of MRL is recommended because European uses are not longer authorised and consumers' risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Table grapes	5	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Wine grapes	5	0.02*	Deletion of the MRL is recommended because no European uses are authorised and a consumer risk cannot be excluded if the CXL is considered (even after refined intake calculations). It should be noted that wine with residues up to 0.7 mg/kg and grape juice with residues up to 0.3 mg/kg do not pose an acute consumer risk. See 4.1.1
Strawberries	5	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)

Commodity	Current MRL (mg/kg)	Proposed MRL (mg/kg)	Justification for the proposal
Raspberries	10	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Kiwi	5	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Tomatoes	2	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Peppers	2	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Aubergines (egg plants)	2	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Cucumbers	1	0.02*	Deletion of MRL is recommended because European uses are not longer authorised and consumers' risk cannot be excluded if the CXL is considered (even after refinement). (For details see EFSA 2008)
Gherkins	1	0.02*	Deletion of MRL is recommended because European uses are not longer authorised. The CXL of 2 mg/kg is not acceptable from a consumer point of view. See 4.1.3
Courgettes	1	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Melons	1	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Pumpkins	1	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Watermelons	1	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Lamb's lettuce	5	0.02*	Deletion of MRL is recommended because European uses are not authorised and no CXL is allocated for this crop. See 4.1.4

Commodity	Current MRL (mg/kg)	Proposed MRL (mg/kg)	Justification for the proposal
Lettuce	5	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Scarole (broad-leaf endive)	5	0.02*	Deletion of MRL is recommended because European uses are not authorised and a consumer risk cannot be excluded if the CXL is considered (even after refinement) (For details see EFSA 2008)
Rocket, Rucola	5	0.02*	Deletion of MRL is recommended because European uses are not authorised and no CXL is allocated for these crops. See 4.1.4
Witloof	2	0.02*	Deletion of MRL is recommended because European uses are not authorised and CXL are not set (For details see EFSA 2008)
Beans (with pods)	2	1	Lowering of the MRL at the level of 1 mg/kg (CXL) is recommended because European authorisations have been withdrawn. See 4.1.2
Sunflower seed	1	0.2	Lowering of the MRL at the level of 0.2 mg/kg (CXL) is recommended because European authorisations have been withdrawn. See 5.1.2
Rape seed	1	0.02	Deletion of MRL may be considered in order to reduce the calculated chronic exposure. See 5.1.2
Soya bean	1	0.02	Deletion of MRL may be considered in order to reduce the calculated chronic exposure. See 5.1.2
Products of animal origin	0.05*	0.02*	The lowering of the LOQ may be considered in order to reduce the calculated chronic exposure. See 5.1.1
Further remarks:			
Garlic, onions, shallots	0.2		No action necessary from a consumer safety point of view. CXL for onions is established at 0.2 mg/kg.
Okras, lady fingers	2		No action necessary from a consumer safety point of view. However, since the European authorisations have been withdrawn and in the absence of international obligations a deletion could be considered as a risk management measure.
Cress, land cress, red mustard, leaves and sprouts of Brassica	5		No action necessary from a consumer safety point of view. However, since the European authorisations have been withdrawn and in the absence of international obligations a deletion could be considered as a risk management measure.

Commodity	Current MRL (mg/kg)	Proposed MRL (mg/kg)	Justification for the proposal
Peas (with pods)	1		No action necessary from a consumer safety point of view.
Peas (without pods)	0.3		No action necessary from a consumer safety point of view.
Dry peas	0.2		No action necessary from a consumer safety point of view.

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

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- France 2007, Procymidone Addendum to the Draft Assessment Report, RMS France (Ministère de l'Agriculture e de la Pêche), August 2007
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APPENDIX 1– RISK ASSESSMENT SCENARIO 1 (SCREENING METHODOLOGY)

Procymidone			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.0028	ARfD (mg/kg bw):	0.012
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2007	Year of evaluation:	2007

Scenario 1: screening methodology without refinements

Chronic risk assessment

		TMDI (range) in % of ADI minimum - maximum							
		113 992							
		No of diets exceeding ADI:							
		27							
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	pTMRs at LOQ (in % of ADI)	
992.1	WHO Cluster diet B	382.4	Table and wine grapes	277.9	Solanacea	70.8	Lettuce and other salad plants	18.3	
937.6	FR all population	733.6	Table and wine grapes	57.1	Lettuce and other salad plants	35.4	Solanacea	5.1	
676.4	PT General population	494.0	Table and wine grapes	77.7	Solanacea	25.5	Peaches	8.5	
660.0	DE child	226.7	Table and wine grapes	89.8	Solanacea	87.4	Strawberries	21.2	
592.4	WHO cluster diet E	319.9	Table and wine grapes	46.0	Solanacea	35.4	Lettuce and other salad plants	11.2	
567.4	IE adult	208.0	Table and wine grapes	58.4	Solanacea	47.7	Kiwi	14.5	
559.2	NL child	135.8	Table and wine grapes	55.1	Lettuce and other salad plants	52.4	Milk and cream,	19.5	
441.1	FR toddler	111.2	Strawberries	78.8	Beans (with pods)	70.8	Milk and cream,	14.2	
389.0	DK adult	262.5	Table and wine grapes	37.6	Solanacea	23.2	Lettuce and other salad plants	4.7	
381.6	WHO regional European diet	93.7	Solanacea	73.5	Lettuce and other salad plants	68.5	Table and wine grapes	8.7	
365.2	ES adult	95.6	Lettuce and other salad plants	82.2	Table and wine grapes	69.7	Solanacea	5.9	
358.2	SE general population 90th percentile	72.9	Solanacea	72.0	Lettuce and other salad plants	40.5	Table and wine grapes	12.1	
354.8	WHO Cluster diet F	131.0	Table and wine grapes	53.9	Solanacea	53.6	Lettuce and other salad plants	9.6	
337.7	WHO cluster diet D	98.5	Table and wine grapes	81.9	Solanacea	30.9	Cucurbits - inedible peel	11.5	
337.5	NL general	153.4	Table and wine grapes	42.8	Lettuce and other salad plants	35.9	Solanacea	7.6	
323.3	IT adult	99.7	Lettuce and other salad plants	96.2	Solanacea	26.8	Peaches	5.9	
319.3	IT kids/toddler	113.2	Solanacea	73.6	Lettuce and other salad plants	24.9	Peaches	8.9	
304.9	UK Adult	202.3	Table and wine grapes	34.5	Solanacea	20.9	Lettuce and other salad plants	7.1	
304.0	DK child	58.4	Cucurbits - edible peel	54.2	Solanacea	32.5	Table and wine grapes	13.2	
299.0	ES child	79.2	Solanacea	74.5	Lettuce and other salad plants	22.3	Milk and cream,	9.7	
298.2	UK vegetarian	159.0	Table and wine grapes	52.3	Solanacea	25.4	Lettuce and other salad plants	8.0	
293.4	FR infant	87.3	Strawberries	60.1	Beans (with pods)	46.0	Milk and cream,	9.9	
275.7	UK Toddler	50.0	Table and wine grapes	44.0	Solanacea	36.9	Milk and cream,	27.4	
200.1	UK Infant	69.1	Milk and cream,	39.0	Strawberries	26.3	Solanacea	18.1	
176.3	PL general population	69.7	Solanacea	57.2	Table and wine grapes	12.4	Plums	5.2	
157.7	FI adult	57.9	Table and wine grapes	34.3	Solanacea	13.9	Lettuce and other salad plants	4.1	
113.1	LT adult	47.5	Solanacea	14.9	Cucurbits - edible peel	11.3	Lettuce and other salad plants	6.2	

Conclusion:
The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRs were in the range of 113.1 % to 992 % of the ADI.
For 27 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

Acute risk assessment /children	Acute risk assessment / adults / general population
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The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.

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

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1): 24			No of commodities for which ARfD/ADI is exceeded (IESTI 2): 23			No of commodities for which ARfD/ADI is exceeded (IESTI 1): 20			No of commodities for which ARfD/ADI is exceeded (IESTI 2): 20		
	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)
3642.8	Scarole (broad-leaf)	5 / 0.13	3642.8	Scarole (broad-leaf)	5 / 0.13	1322.8	Table grapes	5 / 0.37	1322.8	Table grapes	5 / 0.37	
2728.3	Table grapes	5 / 0.18	2728.3	Table grapes	5 / 0.18	988.3	Wine grapes	5 / 0.5	988.3	Wine grapes	5 / 0.5	
1677.0	Kiwi	5 / 0.29	1290.0	Kiwi	5 / 0.38	457.9	Lettuce	5 / 1.09	441.1	Pumpkins	1 / 0.22	
1264.0	Melons	1 / 0.07	1264.0	Melons	1 / 0.07	441.1	Pumpkins	1 / 0.22	414.7	Aubergines (egg plants)	2 / 0.48	
1121.0	Lettuce	5 / 0.44	1018.9	Watermelons	1 / 0.09	414.7	Aubergines (egg)	2 / 0.48	369.7	Scarole (broad-leaf endive)	5 / 1.35	
1049.6	Peppers	2 / 0.19	749.7	Peppers	2 / 0.26	399.3	Kiwi	5 / 1.25	338.3	Watermelons	1 / 0.29	
1018.9	Watermelons	1 / 0.09	725.5	Peaches	2 / 0.27	369.7	Scarole (broad-leaf)	5 / 1.35	330.7	Raspberries	10 / 3.02	
988.9	Peaches	2 / 0.2	702.2	Tomatoes	2 / 0.28	338.3	Watermelons	1 / 0.29	328.9	Melons	1 / 0.3	
969.1	Tomatoes	2 / 0.2	672.6	Lettuce	5 / 0.74	330.7	Raspberries	10 / 3.02	310.6	Kiwi	5 / 1.6	
773.1	Witloof	2 / 0.25	649.6	Strawberries	5 / 0.76	328.9	Melons	1 / 0.3	274.7	Lettuce	5 / 1.81	
758.9	Pears	1 / 0.13	588.5	Witloof	2 / 0.33	291.3	Peaches	2 / 0.68	225.9	Peaches	2 / 0.88	
649.6	Strawberries	5 / 0.76	545.8	Pears	1 / 0.18	275.4	Witloof	2 / 0.72	225.3	Witloof	2 / 0.88	
548.5	Plums	2 / 0.36	487.3	Cucumbers	1 / 0.2	272.3	Peppers	2 / 0.73	220.2	Strawberries	5 / 2.27	
516.0	Apricots	2 / 0.38	467.5	Raspberries	10 / 2.13	253.7	Tomatoes	2 / 0.78	204.9	Tomatoes	2 / 0.97	
487.3	Cucumbers	1 / 0.2	444.6	Plums	2 / 0.44	224.9	Courgettes	1 / 0.44	194.5	Peppers	2 / 1.02	
467.5	Raspberries	10 / 2.13	416.7	Aubergines (egg)	2 / 0.48	220.2	Strawberries	5 / 2.27	169.2	Courgettes	1 / 0.59	
416.7	Aubergines (egg)	2 / 0.48	412.8	Apricots	2 / 0.48	178.9	Pears	1 / 0.55	164.0	Cucumbers	1 / 0.6	
387.4	Courgettes	1 / 0.25	323.8	Wine grapes	5 / 1.54	164.0	Cucumbers	1 / 0.6	137.0	Pears	1 / 0.73	
323.8	Wine grapes	5 / 1.54	284.6	Pumpkins	1 / 0.35	156.6	Plums	2 / 1.27	128.4	Plums	2 / 1.55	
284.6	Pumpkins	1 / 0.35	276.7	Courgettes	1 / 0.36	127.4	Apricots	2 / 1.56	106.2	Apricots	2 / 1.88	
189.1	Beans (with pods)	2 / 1.05	189.1	Beans (with pods)	2 / 1.05							
135.9	Gherkins	1 / 0.73	129.0	Rocket, Rucola	5 / 3.87							
129.0	Rocket, Rucola	5 / 3.87	117.0	Lamb's lettuce	5 / 4.27							
117.0	Lamb's lettuce	5 / 4.27	98.5	Gherkins	1 / -							
No of critical MRLs (IESTI 1)			24			No of critical MRLs (IESTI 2)			23			

Processed commodities	No of commodities for which ARfD/ADI is exceeded: 7			No of commodities for which ARfD/ADI is exceeded: 1		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
1370.7	Grape juice	5 / 0.36	160.8	Wine	5 / 3.1	
999.0	Raspberries juice	10 / 1	33.5	Peach preserved with syrup	2 / -	
619.2	Kiwi juice	5 / 0.8	31.8	Tomato (preserved-	2 / -	
298.5	Peach juice	2 / 0.67	16.9	Raisins	5 / -	
290.6	Tomato juice	2 / 0.68	1.7	Orange juice	0.02 / -	
232.4	Plums juice	2 / 0.86				
146.0	Pear juice	1 / 0.68				

*) 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

APPENDIX 2– RISK ASSESSMENT SCENARIO 2

Refined acute risk assessment

Procymidone			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.0028	ARfD (mg/kg bw):	0.012
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2007	Year of evaluation:	2007

Scenario 2: refined intake calculations as proposed to solve acute intake problems

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum							
		10 - 143							
		No of diets exceeding ADI:		6					
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	pTMRs at LOQ (in % of ADI)	
143.1	FR toddler	70.8	Milk and cream,	39.4	Beans (with pods)	5.7	Sunflower seed	16.0	
138.6	WHO Cluster diet B	29.2	Wine grapes	26.5	Sunflower seed	21.7	Soya bean	23.6	
132.5	WHO cluster diet E	26.1	Wine grapes	21.3	Rape seed	20.7	Soya bean	12.6	
132.4	FR all population	65.1	Wine grapes	33.9	Other lettuce and other salad plants	11.8	Sunflower seed	6.4	
112.2	NL child	52.4	Milk and cream,	18.0	Beans (with pods)	4.5	Apples	22.2	
100.9	UK Infant	69.1	Milk and cream,	7.2	Sugar beet (root)	6.2	Peas (without pods)	18.8	
94.4	FR infant	46.0	Milk and cream,	30.0	Beans (with pods)	3.0	Potatoes	11.3	
79.1	WHO Cluster diet F	23.3	Soya bean	11.1	Rape seed	9.7	Wine grapes	10.8	
78.7	PT General population	40.5	Wine grapes	10.9	Soya bean	10.3	Sunflower seed	12.1	
75.9	IE adult	20.4	Wine grapes	7.1	Sunflower seed	6.0	Beans (with pods)	20.3	
75.5	UK Toddler	36.9	Milk and cream,	16.3	Sugar beet (root)	3.2	Peas (without pods)	28.6	
70.2	WHO cluster diet D	17.6	Sunflower seed	13.2	Soya bean	9.0	Milk and cream,	13.5	
67.7	DE child	25.5	Milk and cream,	8.6	Apples	3.1	Sunflower seed	25.3	
65.5	WHO regional European diet	8.6	Milk and cream,	8.3	Peas (with pods)	7.1	Beans (with pods)	10.9	
61.1	ES child	22.3	Milk and cream,	8.5	Beans (with pods)	4.2	Sunflower seed	11.6	
49.8	DK child	22.6	Milk and cream,	4.0	Swine	3.9	Wheat	16.1	
49.7	NL general	11.7	Milk and cream,	10.3	Wine grapes	9.0	Beans (with pods)	8.9	
47.3	SE general population 90th percentile	22.1	Milk and cream,	3.2	Onions	3.0	Potatoes	13.1	
44.9	DK adult	22.7	Wine grapes	9.6	Milk and cream,	1.7	Swine	5.7	
44.1	IT adult	28.2	Other lettuce and other salad plants	5.4	Beans (with pods)	3.0	Wheat	8.2	
43.8	ES adult	8.8	Milk and cream,	8.4	Beans (with pods)	6.8	Wine grapes	7.7	
37.6	IT kids/toddler	19.7	Other lettuce and other salad plants	4.7	Wheat	3.4	Beans (with pods)	11.3	
36.9	UK Adult	17.6	Wine grapes	5.4	Milk and cream,	2.9	Sugar beet (root)	7.8	
35.3	UK vegetarian	13.3	Wine grapes	5.8	Milk and cream,	2.7	Sugar beet (root)	9.1	
25.7	FI adult	10.1	Milk and cream,	5.0	Wine grapes	1.6	Beans (with pods)	4.7	
19.8	LT adult	7.1	Milk and cream,	2.3	Potatoes	2.0	Swine	7.2	
9.6	PL general population	2.5	Potatoes	2.3	Onions	1.5	Apples	6.7	

Conclusion:

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRs were in the range of 9.6 % to 143 % of the ADI. For 6 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

Acute risk assessment /children - refined calculations

Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.

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

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
	IESTI 1 *)		**)	IESTI 2 *)		**)	IESTI 1 *)		**)	IESTI 2 *)		**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
94.5	Beans (with pods)	1 / -	94.5	Beans (with pods)	1 / -	44.2	Beans (with pods)	1 / -	44.2	Beans (with pods)	1 / -	
66.4	Onions	0.2 / -	51.8	Milk and milk	0.05 / -	27.3	Wine grapes	0.138 / -	27.3	Wine grapes	0.138 / -	
51.8	Milk and milk products:	0.05 / -	47.7	Onions	0.2 / -	26.5	Peas (with pods)	1 / -	26.5	Peas (with pods)	1 / -	
28.8	Peas (with pods)	1 / -	28.8	Peas (with pods)	1 / -	24.8	Onions	0.2 / -	17.7	Onions	0.2 / -	
25.6	Sunflower seed	1 / -	25.6	Sunflower seed	1 / -	15.7	Cress	5 / -	15.7	Cress	5 / -	
No of critical MRLs (IESTI 1)			---			No of critical MRLs (IESTI 2)			---			

Processed commodities	No of commodities for which ARfD/ADI is exceeded: 1			No of commodities for which ARfD/ADI is exceeded: ---		
			***)			***)
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
219.3	Grape juice	0.8 / 0.36		44.4	Wine	1.38 / -
17.1	Grapes (raisins)	5 / -		16.9	Raisins	5 / -
8.5	Apple juice	0.02 / -		1.7	Orange juice	0.02 / -
8.3	Orange juice	0.02 / -		1.1	Apple juice	0.02 / -
7.1	Carrot, juice	0.02 / -		0.7	Bread/pizza	0.02 / -

*) 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 Procymidone 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, the ARfD/ADI was exceeded in one or several cases.

APPENDIX 3– RISK ASSESSMENT SCENARIO 3

Refined acute risk assessment, including proposals to refine chronic risk assessment

Procymidone			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.0028	ARfD (mg/kg bw):	0.012
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2007	Year of evaluation:	2007

Scenario 3: refined intake calculations as proposed to solve the identified acute and chronic intake problems

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum							
		9 92							
		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	pTMRs at LOQ (in % of ADI)	
92.2	FR toddler	39.4	Beans (with pods)	28.3	Milk and cream,	3.7	Peas (without pods)	46.9	
73.9	NL child	20.9	Milk and cream,	18.0	Beans (with pods)	4.5	Apples	46.3	
64.3	FR infant	30.0	Beans (with pods)	18.4	Milk and cream,	3.0	Potatoes	30.9	
59.7	WHO Cluster diet B	12.0	Beans (with pods)	6.1	Wheat	5.5	Onions	30.4	
57.2	UK Infant	27.7	Milk and cream,	7.2	Sugar beet (root)	6.2	Peas (without pods)	47.8	
55.5	FR all population	33.9	Other lettuce and other salad plants	5.1	Beans (with pods)	2.9	Wine grapes	12.4	
51.3	UK Toddler	16.3	Sugar beet (root)	14.8	Milk and cream,	3.2	Peas (without pods)	44.4	
49.2	WHO cluster diet E	10.0	Beans (with pods)	5.8	Peas (with pods)	4.8	Other lettuce and other salad	19.2	
45.7	DE child	10.2	Milk and cream,	8.6	Apples	2.9	Wheat	37.3	
44.3	IE adult	6.0	Beans (with pods)	3.6	Peas (with pods)	2.5	Sweet potatoes	25.4	
43.7	IT adult	28.2	Other lettuce and other salad plants	5.4	Beans (with pods)	3.0	Wheat	8.2	
41.1	WHO regional European diet	8.3	Peas (with pods)	7.1	Beans (with pods)	3.4	Milk and cream,	17.9	
38.6	ES child	8.9	Milk and cream,	8.5	Beans (with pods)	3.2	Wheat	24.2	
36.9	IT kids/toddler	19.7	Other lettuce and other salad plants	4.7	Wheat	3.4	Beans (with pods)	11.3	
33.1	SE general population 90th percentile	8.8	Milk and cream,	3.2	Onions	3.0	Potatoes	22.6	
30.9	DK child	9.0	Milk and cream,	3.9	Wheat	3.2	Rye	28.7	
30.4	NL general	9.0	Beans (with pods)	4.7	Milk and cream,	2.0	Peas (without pods)	15.2	
29.3	WHO cluster diet D	4.6	Wheat	3.6	Onions	3.6	Milk and cream,	19.1	
26.0	ES adult	8.4	Beans (with pods)	3.5	Milk and cream,	1.7	Wheat	13.6	
25.8	WHO Cluster diet F	3.1	Peas (with pods)	2.8	Milk and cream,	2.6	Wheat	17.1	
21.0	PT General population	3.8	Potatoes	2.8	Wheat	2.5	Onions	14.1	
18.7	UK vegetarian	2.7	Sugar beet (root)	2.3	Milk and cream,	2.2	Beans (with pods)	12.2	
16.0	UK Adult	2.9	Sugar beet (root)	2.1	Milk and cream,	1.6	Beans (with pods)	11.3	
15.0	DK adult	3.8	Milk and cream,	1.4	Wheat	1.2	Onions	12.1	
13.3	FI adult	4.1	Milk and cream,	1.6	Beans (with pods)	1.0	Onions	9.8	
12.1	LT adult	2.8	Milk and cream,	2.3	Potatoes	1.3	Apples	11.5	
9.3	PL general population	2.5	Potatoes	2.3	Onions	1.5	Apples	6.7	

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

Acute risk assessment /children - refined calculations

Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.

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

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1	*)	**)	IESTI 2	*)	**)	IESTI 1	*)	**)	IESTI 2	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	94.5	Beans (with pods)	1 / -	94.5	Beans (with pods)	1 / -	98.8	Wine grapes	0.5 / -	98.8	Wine grapes	0.5 / -
	66.4	Onions	0.2 / -	47.7	Onions	0.2 / -	44.2	Beans (with pods)	1 / -	44.2	Beans (with pods)	1 / -
	32.4	Wine grapes	0.5 / -	32.4	Wine grapes	0.5 / -	26.5	Peas (with pods)	1 / -	26.5	Peas (with pods)	1 / -
	28.8	Peas (with pods)	1 / -	28.8	Peas (with pods)	1 / -	24.8	Onions	0.2 / -	17.7	Onions	0.2 / -
	25.6	Sunflower seed	1 / -	25.6	Sunflower seed	1 / -	15.7	Cress	5 / -	15.7	Cress	5 / -
	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:		
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	IESTI 1	*)	***)	IESTI 2	*)	***)
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	96.0	Grape juice	0.35 / -	16.1	Wine	0.5 / -
	8.5	Apple juice	0.02 / -	1.7	Orange juice	0.02 / -
	8.3	Orange juice	0.02 / -	1.1	Apple juice	0.02 / -
	7.1	Carrot, juice	0.02 / -	0.7	Bread/pizza	0.02 / -
	3.0	Peach juice	0.02 / -	0.4	Pineapples preserved	0.02 / -

*) 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 Procymidone IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

GLOSSARY / ABBREVIATIONS

ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
CXL	Codex Maximum Residue Limit
DAR	Draft Assessment Report prepared under Directive 91/414/EEC
EC	European Community
EFSA	European Food Safety Authority
GAP	Good Agricultural Practice
HR	Highest Residue
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOD	Limit of Detection
LOQ	Limit Of Quantification
MRL	Maximum Residue Limit.
NEU	Northern Europe
PHI	Pre Harvest Interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
SEU	Southern Europe
STMR	Supervised Trials Median Residue
TMDI	Theoretical Maximum Daily Intake