

REASONED OPINION

Modification of the existing MRL for pirimicarb in fennel¹

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SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, Belgium, hereafter referred to as the Evaluating Member State (EMS), compiled an application to modify the existing MRL for pirimicarb in fennel. In order to accommodate for a new use of pirimicarb in Belgium, it is proposed to raise the existing MRL for fennel from 1.0 mg/kg to 5.0 mg/kg. Belgium 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 29 May 2009 and updated on 4 August 2009.

EFSA derives the following conclusions regarding the application based on the above mentioned evaluation report, the EFSA conclusion on the peer review of pirimicarb and the Draft Assessment Report prepared by The United Kingdom.

The metabolism of pirimicarb in primary crops is elucidated in four crop groups and a general residue definition for plant commodities was established in the peer review as “the sum of pirimicarb, desmethylpirimicarb and desmethylformamido pirimicarb, expressed as pirimicarb”. Since fennel belongs to a crop group for which the metabolism was addressed under the peer review, it is concluded that no additional studies are necessary with regard to nature of pirimicarb residues in fennel. Adequate analytical methods are available to control the compliance of the proposed MRL for pirimicarb.

The submitted supervised residues field trials indicate that the current MRL of 1 mg/kg does not accommodate the intended GAP in Belgium and a higher MRL of 5 mg/kg would be necessary.

The occurrence of pirimicarb residues in rotational crops was also investigated. It is concluded that significant residues of pirimicarb and metabolites relevant for the residue definition will not be present in rotational or succeeding crops provided that the active substance is applied according to the intended GAP. Fennel is not used as a livestock feed therefore the nature and magnitude of pirimicarb residues in commodities of animal origin was not investigated in the framework of the current application.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs and the STMR value for fennel as derived from the intended use as the input values. For refined calculations EFSA looked for available STMR values for several other crops as reported by the MS in the framework of setting the temporary MRLs for

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pirimicarb. The acute intake assessment was performed with regard to fennel only, using the HR value as an input value which was derived from the intended use.

Consumer intake calculations did not identify long-term intake concerns for any of the European diets. The total calculated intake values ranged from 10.7 – 64.4% of the ADI. The contribution of fennel to the total dietary intake is insignificant, accounting for a maximum of 0.125% of the ADI for IT adult diet.

Using the currently agreed risk assessment methodology by using the 97.5th or 95th percentile consumption for the critical European consumer (Dutch adult: large portion 308 g/day, intake 4.89 g/kg bw, 63 kg bw *or* German child: 65.7 g/day, intake 4.07 g/kg bw, 16.16 kg bw), the highest residue value measured in supervised field trials, and a variability factor of 5 or 7 accounting for inhomogeneous distribution of residues on individual fennel bulbs, no acute intake concerns were identified and the estimated short-term intake accounted for up to 51.8 % of the ARfD for adults and 40.3% of the ARfD for children. This calculation is considered as a sufficiently conservative approach to ensure consumer safety because it is assuming a coincidence of the worst case consumption, high residues and the worst case distribution of residues within the commodity.

EFSA concludes that the intended use of pirimicarb on fennel is sufficiently supported by data and no risk for consumer health is identified. The MRL proposal is presented in the table below:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
The sum of pirimicarb, desmethylpirimicarb and desmethylformamido pirimicarb, expressed as pirimicarb			
Fennel	1	5	MRL proposal is sufficiently supported by data and no risk for consumer health was identified for the proposed use.

KEY WORDS

Pirimicarb, fennel, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, carbamate insecticide/aphicide.

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that where a Member State considers that the modification of an MRL is necessary, that Member State may compile and evaluate an application to modify the MRL in accordance with the provisions of Article 7 of that regulation.

Belgium, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRL for the active substance pirimicarb in fennel. This application was notified to the European Commission and EFSA and subsequently evaluated in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 29 May 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00646 and the following subject:

Pirimicarb - Application to modify the existing MRL for pirimicarb in fennel from 1 mg/kg to 5 mg/kg.

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

On 3 July 2009 some data requirements were identified, which prevented EFSA to conclude on the consumer risk assessment. An updated evaluation report, addressing those data requirements, was submitted by the EMS on 5 August 2009 and taken into consideration by EFSA for finalization of this reasoned opinion.

TERMS OF REFERENCE

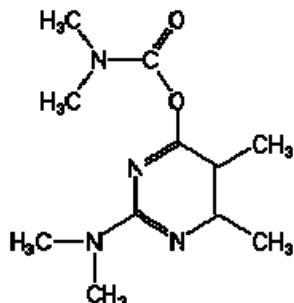
According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months 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 30 September 2009.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Pirimicarb is the ISO common name of 2-dimethylamino-5,6-dimethylpyrimidin-4-yl dimethylcarbamate (IUPAC):



MW: 238.3

Pirimicarb is an insecticide belonging to the chemical class of carbamates. It acts by inhibiting the acetylcholinesterase.

Pirimicarb is considered as a stage two active substance according to Commission Directive 91/414/EEC with The United Kingdom being the designated rapporteur Member State. The peer review of pirimicarb is finalized and EFSA conclusion was issued on 10 August 2005 (EFSA, 2005). Pirimicarb is included in Annex I to Directive 91/414/EEC with Commission Directive 2006/39/EC which entered into force on 1 February 2007. The representative uses evaluated under the peer review cover foliar application on cereals (wheat) only.

The current EU MRLs are established in Annex III of Regulation (EC) No 396/2005 (see Appendix C). The current MRL for fennel is set at 1 mg/kg. The enforcement residue definition for pirimicarb is set as “the sum of pirimicarb, desmethylpirimicarb (R34836³) and desmethylformamido pirimicarb (R34885)⁴, expressed as pirimicarb” and is identical to the residue definition set by Codex Alimentarius. Codex Alimentarius has set CXLs for a wide range of commodities but no CXL is set for fennel.

The GAP for which an authorization is requested in Belgium, refers to an indoor application of pirimicarb on fennel for a maximum of 3 applications with 0.2 kg a.s./ha. The PHI is 7 days. The summary of the GAP is available in Appendix A.

EFSA bases its assessment on the evaluation report submitted by Belgium (2009), the draft assessment report (United Kingdom, 2003) and the EFSA conclusion (EFSA, 2005).

³ R34836 (desmethylpirimicarb): 5,6-dimethyl-2-(methylamino)pyrimidin-4-yl dimethylcarbamate

⁴ R34885 (desmethylformamido pirimicarb): 5,6-dimethyl-2-(methylformamido)pyrimidin-4-yl dimethylcarbamate

ASSESSMENT

1. Methods of analysis

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

Availability of analytical enforcement methods for the determination of pirimicarb residues in plant commodities was investigated under the peer review of Directive 91/414/EEC (The United Kingdom, 2003). Only single residue methods are applicable due to the nature of residues.

Since cereals were the crop for which the representative use was evaluated in the peer review, no analytical enforcement methods have been reported for other plant matrices. The EMS Belgium reported validated enforcement method RAM 265/03 for the determination of pirimicarb, desmethylpirimicarb (R34836) and R238177⁵ in plant matrices with high water content (lettuce, beans with pods) and high oil content (maize grain, seeds). The method uses LC/MS/MS detection and is validated at the LOQ of 0.01 mg/kg for each compound. The method is not validated for desmethylformamido pirimicarb (R34885) which is relevant pirimicarb metabolite included in the enforcement and risk assessment residue definition for plants.

In the database developed by the Community Reference Laboratories (CRL) for Residues of Pesticides (www.crl-pesticides.eu), a wide range of validation data have been submitted regarding analytical methods to determine pirimicarb, desmethylpirimicarb and desmethylformamido pirimicarb in different plant matrices. For matrices with high water content (where fennel belongs to) the validated LOQ is 0.01 mg/kg for each analyte. The validation data refer to the QuEChERS and ChemElut methods.

According to the evaluation of pirimicarb by the JMPR, the method RAM 265 (with versions 01/02/03/04) was developed for the determination of pirimicarb and its carbamate metabolites (R34836, R34885 and R238177) in several plant matrices. In the RAM 265/01 (determination of parent, R34836, R34885) quantification is performed with GC/NPD, while in versions RAM 265 02, /03, /04 (determination of R34836, R34885 and R238177) quantification is done by GC-NPD and HPLC/MS/MS (WHO/FAO, 2006).

EFSA thereby concludes that adequate analytical enforcement methods are available for the control of the compliance of proposed MRL for pirimicarb in fennel with the LOQ of 0.03 mg/kg, corresponding to 0.01 mg/kg for each individual compound.

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

Fennel is not a livestock feed therefore analytical methods for the determination of pirimicarb residues in the food of animal origin is not of relevance for the current application.

2. Mammalian toxicology

Toxicity of pirimicarb was investigated in the framework of the peer review and data were sufficient to conclude on following toxicological reference values (The United Kingdom, 2003):

⁵ R238177: 2-dimethylamino-6-hydroxymethyl -5-methylpyrimidin-4-yl dimethylcarbamate

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Pirimicarb					
ADI	EFSA	2005	0.035 mg/kg bw/d	1 yr dog	100
ARfD	EFSA	2005	0.1 mg/kg bw	Acute neurotoxicity	100

Several pirimicarb metabolites – desmethylpirimicarb (R34836), desmethylformamido pirimicarb (R34885) and R35140⁶ - are in the same range of toxicity as parent pirimicarb and are considered as toxicologically relevant.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The nature of pirimicarb residues in plants was investigated in the framework of the peer review of Directive 91/414/EEC in the following crop categories (The United Kingdom, 2003):

- leafy vegetables: lettuce (foliar application 3 x 0.26 kg a.s./ha)
- root and tuber vegetables: potato (foliar application 2 x 0.75 kg a.s./ha and 4 x 2.75 kg a.s./ha)
- fruits and fruiting vegetables: apples (foliar application 3 x 1.1 kg a.s./ha)
- cereals: wheat (2 x 0.15-0.21 kg a.s./ha)

In lettuce, the most representative crop for fennel, at the PHI of 3 and 7 days, the major component of the TRR consisted of parent pirimicarb (51.7% and 38.4%) and carbamate metabolite desmethylpirimicarb (R34836) (17.0% and 20.9%). Other carbamate metabolites R35140 and desmethylformamido pirimicarb (R34885) in lettuce at the 7 day PHI accounted for up to 2.0% TRR (0.24 mg/kg) and 1.2% TRR (0.14 mg/kg) respectively. Hydroxypyrimidines R318905⁷ and R34865⁸ were also identified in treated lettuce amounting for up to 8% TRR (1.02 mg/kg) and 6 % (0.72 mg/kg) respectively.

In potatoes the largest part of the TRR remained in the aqueous phase (>81 % TRR) with no single component exceeding 0.01 mg/kg.

In mature apples (fruit) the parent pirimicarb accounted for up to 30.3% TRR (0.72 mg/kg) being the major component of the TRR.

In cereals the total radioactivity was higher in straw (14.3 mg/kg) than in grain (0.674 mg/kg). Parent pirimicarb was the major component of the TRR both in grain (25.5%) and straw (13.4%). All other

⁶ R35140: 2-amino-5,6-dimethylpyrimidin-4-yl dimethylcarbamate

⁷ R31805:5,6-dimethyl-2-dimethylamino-4-hydroxypyrimidine

⁸ R34865:5,6,-dimethyl -4-hydroxy-2-methylaminopyrimidine

pirimicarb metabolites were below 10% of the TRR, the highest being desmethylpirimicarb (R34836) which accounted for 4.4% TRR (0.63 mg/kg) in wheat straw. In wheat grain R35140 was not present.

Metabolism studies indicate that pirimicarb in plants undergoes extensive metabolism yielding diverse range of metabolites. The early stages of metabolism involve modification of the dimethylamino moiety and loss of carbamate moiety which subsequently results in hydroxypyrimidine metabolites. Parent pirimicarb is the major residue of concern in plants. The carbamate metabolite desmethylpirimicarb (R34836) was found in significant levels only in lettuce. Other carbamate metabolites were also present but at lower levels than the parent compound: R35140 and desmethylformamido pirimicarb (R34885). Even though these two carbamate metabolites were present in lower amounts than desmethylpirimicarb (R34836), they represent a similar toxicological burden due to their higher acute toxicity. The peer review concluded that residue definition for enforcement and risk assessment should be established as the sum of pirimicarb, desmethylpirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb. The molecular weight correction factors for recalculating desmethylpirimicarb and desmethylformamido pirimicarb to pirimicarb are 1.06 and 0.95, respectively.

Since fennel belongs to a crop group (leafy vegetables) for which the metabolism was addressed under the peer review, it is concluded that no additional studies are necessary with regard to nature of pirimicarb residues in fennel.

3.1.1.2. Magnitude of residues

In support of the intended GAP in Belgium (NEU) the applicant submitted four indoor residue trials on celery. Trials were performed over one season in 2004. Data on celery can be extrapolated to fennel. Samples were analyzed separately for pirimicarb, desmethylpirimicarb and desmethylformamido pirimicarb. The results of these trials, expressed as sum of pirimicarb and the two metabolites, are summarized in Table 3-1. It is noted that the molecular weight correction factors for the metabolites were not applied because they are of no practical significance.

It is concluded that residues data are sufficient to derive the MRL proposal and risk assessment values.

The storage stability of pirimicarb in dry commodities (cereals) was investigated in the framework of the peer review (The United Kingdom, 2003). Pirimicarb in wheat grain and straw is stable for up to 12 months when stored deep frozen. Celery and fennel are crops with high water content. The EMS Belgium submitted a storage stability study for pirimicarb (reported also in the JMPR Evaluation of pirimicarb (WHO/FAO,2006)), desmethylpirimicarb (R34836) and R238177 in lettuce. The study was performed according to the GLP and is considered acceptable. It was concluded that pirimicarb and its carbamate metabolites are stable in lettuce for at least 1 year when samples are stored below -18°C. No data are available on the storage stability of desmethylformamido pirimicarb (R 34885) in plants, but due to chemically similar structures of carbamate metabolites it can be assumed that it is as stable as other metabolites for which the storage stability is demonstrated. Celery samples prior analyses were stored deep frozen for a period not exceeding 12 months. Therefore it is concluded that analytical results are valid with regard to storage stability.

According to the EMS, the analytical method used for analyzing the supervised residue trials samples was sufficiently validated.

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

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STM (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement (sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb)	Risk assessment (sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb)					
Celery → Fennel	NEU	Indoor	0.23; 0.35; 0.55; 1.98	0.23; 0.35; 0.55; 1.98	0.45	1.98	5	1.0	R _{max} =4.96 mg/kg R _{ber} =3.25 mg/kg

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

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

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

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

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of pirimicarb residues was not investigated in the peer review since the representative use of pirimicarb on wheat supported in the peer review was not expected to result in pirimicarb residues above 0.1 mg/kg in processed products (The United Kingdom, 2003). According to the JMPR, pirimicarb is stable under the standard hydrolysis conditions used to simulate major processing conditions (WHO/FAO, 2006). The only carbamate degradate observed was desmethylpirimicarb (<0.8% of the total radioactivity) and this metabolite was also found in plant metabolism studies.

The applicant has not submitted studies on the effect of processing on the magnitude of pirimicarb residues in processed fennel. Such studies, however, are not requested taking into account the low contribution of pirimicarb residues in fennel to the total dietary intake.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Fennel is a crop for which a crop rotation is of relevance. The rate of degradation of pirimicarb and its metabolites in soil was investigated under the peer review (The United Kingdom, 2003). The available field studies indicate that DT₉₀ value for pirimicarb amounts for a maximum of 190 days. The laboratory studies (aerobic) indicate that DT₉₀ value for pirimicarb accounts for >372 days, for desmethylpirimicarb (R34836) 288 days, for R31805 632 days and R34865 more than 398 days.

Thus, consideration has to be given to possible pirimicarb residues in rotational crops.

3.1.2.2. Nature of residues

The nature of pirimicarb residues in rotational crops was investigated under the peer review of Directive 91/414/EEC (The United Kingdom, 2003). A confined rotational crop study was carried out by applying ¹⁴C-pirimicarb on a bare soil at an application rate of 1.480 kg a.s./ha. Lettuce, radish and millet were sown/planted 29, 61 and 119 DAT and were harvested at maturity.

In all crops residue levels decreased as the rotation interval increased. Higher level of total radioactivity was identified in radish leave and millet forage, hay and straw (1.5 mg/kg to 5.04 mg/kg 29 DAT) in comparison to lettuce, radish roots and millet grain (0.179 mg/kg to 0.299 mg/kg 29 DAT). Only in radish roots parent pirimicarb was the major component of the TRR exceeding 10%. Also metabolite R34836 exceeded 10% in radish roots (14.5% TRR 61 DAT). All other carbamate metabolites were below 10% TRR. Significantly higher levels of several hydroxypyrimidines were identified in all crops. Hydroxypyrimidine R31680⁹, however, was the only substance exceeding 10% TRR in radish leaves (61 and 119 DAT), hay (all DAT), straw (29 and 119 DAT) and in grain (61 DAT).

Generally, peer review concluded that the observed metabolic pattern in rotational crops is similar with the one observed in primary crops and the same residue definition is therefore applicable to the succeeding or rotational crops.

⁹ R31680:2-amino-5,6-dimethyl-4-hydroxypyrimidine

3.1.2.3. Magnitude of residues

The confined rotational crop study as reported in section 3.1.2.2. was used also to estimate the magnitude of pirimicarb residues in rotational crops. The application rate tested in the rotational crop study (1.48 kg a.s./ha) corresponds approximately 7 times the individual application rate foreseen in fennel (0.2 kg a.s./ha) or 2.3 times the seasonal application rate.

In lettuce, in all rotation intervals, the residues relevant for the residue definition were very low, not exceeding 0.023 mg/kg which was the highest residue value (desmethulpirimicarb R34865 in 61 DAT). Parent pirimicarb and relevant metabolites did not exceed 0.011 mg/kg. Metabolite R35140 accounted for 0.018 mg/kg 29 DAT.

In radish roots, the highest levels of residues were identified 29 DAT accounting for 0.014 mg/kg for metabolite R31680, 0.017 mg/kg for pirimicarb and 0.013 mg/kg for desmethylpirimicarb (R34836). In radish leaves parent pirimicarb accounted for a maximum of 0.018 mg/kg (29 DAT) and metabolite R34836 accounted for 0.056 mg/kg. All other metabolites (mainly hydroxypyrimidines) were all above 0.01 mg/kg but not exceeding 0.176 mg/kg (metabolite R31680, 29 DAT)

In millet grain residues were very low; the highest residue level was 0.017 mg/kg (metabolite R31680 29 DAT). Parent pirimicarb and relevant residues all were below 0.005 mg/kg.

In millet forage the parent pirimicarb was highest in samples from 29 DAT accounting for up to 0.019 mg/kg along with desmethylformamido pirimicarb (R34885) and desmethylpirimicarb (R34836) which accounted for 0.026 mg/kg each. Metabolite R35140 accounted for 0.048 mg/kg 29 DAT. Hydroxypyrimidines were again above 0.01 mg/kg, but not exceeding 0.15 mg/kg (metabolite R31680, 29 DAT). In millet hay and straw the parent pirimicarb was below 0.01 mg/kg in all samples. Relevant carbamate residues in hay were below 0.025 mg/kg (29 DAT), except R35140 which accounted for 0.037 mg/kg 29 DAT. Hydroxypyrimidines in all hay and straw samples exceeded 0.01 mg/kg, accounting for a maximum of 0.165 mg/kg and 0.56 mg/kg of metabolite R31680, respectively.

Since the intended seasonal application rate of pirimicarb on fennel is more than two times lower than the one investigated in the rotational crop studies, EFSA concludes that significant residues of pirimicarb and metabolites relevant for the residue definition will not be present in rotational or succeeding crops provided that the active substance is applied according to the intended GAP.

3.2. Nature and magnitude of residues in livestock

Fennel is not a livestock feeding item therefore nature and magnitude of pirimicarb residues in livestock is not relevant for the current application.

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model). For the chronic intake assessment EFSA used the following input values: existing MRLs as established in Annex III Regulation (EC) No 396/2005 and the STMR value for fennel as derived from the intended use. For refined calculations EFSA looked for available STMR values for several other crops as reported by the MS in the framework of setting the temporary MRLs for pirimicarb.

The acute intake assessment was performed with regard to fennel only, using the HR value as an input value which was derived from the intended use.

Input values are summarized in Table 4-1.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of pirimicarb, desmethylpirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb				
Fennel	0.45	STMR	1.98	HR
Citrus fruit	0.01	Codex STMR (EC, 2008)	Not relevant	
Pome fruit	0.34	STMR (Belgium, 2007)		
Tomatoes, aubergines, cucumbers, courgettes	0.07	STMR (Denmark, 2007)		
Beans and peas (with pods)	0.1	STMR (Denmark, 2007)		
Celery	0.45	STMR (Belgium, 2007)		
Globe artichokes	0.69	STMR (EC, 2008)		
Other food commodities	MRL	See Appendix C		

Summary of intake calculations are available in Appendix B.

Consumer intake calculations did not identify long-term intake concerns for any of the European diets. The total calculated intake values ranged from 10.7 – 64.4% of the ADI. The contribution of fennel to the total dietary intake is insignificant, accounting for a maximum of 0.125% of the ADI for IT adult diet.

Using the currently agreed risk assessment methodology by using the 97.5th and 95th percentile consumption for the critical European consumer (Dutch adult: large portion 308 g/day, intake 4.89 g/kg bw, 63 kg bw *or* German child: 65.7 g/day, intake 4.07 g/kg bw, 16,16 kg bw), the HR value derived from the supervised field trials and a variability factor of 5 or 7 accounting for inhomogeneous distribution of residues on individual fennel bulbs, no acute intake concerns were identified and the estimated short-term intake accounted for up to 51.8 % of the ARfD for adults and 40.3% of the ARfD for children. Thus, EFSA concludes that the intended use of pirimicarb on fennel is acceptable as it will not raise any health concerns to consumers.

It is noted, that replacing the HR with the proposed MRL in exposure calculation, may lead to an exceedance of the ARfD (131% for adults and 102% for children). However, this calculation is considered as over-conservative because it is assuming a coincidence of extreme consumption, a residue concentration at the highest legal value and the worst case distribution of residues within the commodity¹⁰. This combination of events is not very likely to occur in reality.

¹⁰ According to EFSA opinion on the appropriate variability factor to be used for acute dietary exposure assessment of pesticide residues in fruit and vegetables (EFSA, 2005a), the “true” variability factor in monitoring samples would be lower than 7 in 98.5% of the cases.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The metabolism of pirimicarb in primary crops is elucidated in four crop groups and a general residue definition for plant commodities was established in the peer review as “the sum of pirimicarb, desmethylpirimicarb and desmethylformamido pirimicarb, expressed as pirimicarb”. Since fennel belongs to a crop group for which the metabolism was addressed under the peer review, it is concluded that no additional studies are necessary with regard to nature of pirimicarb residues in fennel. Adequate analytical methods are available to control the compliance of the proposed MRL for pirimicarb.

The submitted supervised residues field trials indicate that the current MRL of 1 mg/kg does not accommodate the intended GAP in Belgium and a higher MRL of 5 mg/kg would be necessary.

The occurrence of pirimicarb residues in rotational crops was also investigated. It is concluded that significant residues of pirimicarb and metabolites relevant for the residue definition will not be present in rotational or succeeding crops provided that the active substance is applied according to the intended GAP. Fennel is not used as a livestock feed therefore the nature and magnitude of pirimicarb residues in commodities of animal origin was not investigated in the framework of the current application.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the existing MRLs and the STMR value for fennel as derived from the intended use as the input values. For refined calculations EFSA looked for available STMR values for several other crops as reported by the MS in the framework of setting the temporary MRLs for pirimicarb. The acute intake assessment was performed with regard to fennel only, using the HR value as an input value which was derived from the intended use.

Consumer intake calculations did not identify long-term intake concerns for any of the European diets. The total calculated intake values ranged from 10.7 – 64.4% of the ADI. The contribution of fennel to the total dietary intake is insignificant, accounting for a maximum of 0.125% of the ADI for IT adult diet.

Using the currently agreed risk assessment methodology by using the 97.5th or 95th percentile consumption for the critical European consumer (Dutch adult: large portion 308 g/day, intake 4.89 g/kg bw, 63 kg bw *or* German child: 65.7 g/day, intake 4.07 g/kg bw, 16,16 kg bw), the highest residue measured in supervised field trials value and a variability factor of 5 or 7 accounting for inhomogeneous distribution of residues on individual fennel bulbs, no acute intake concerns were identified and the estimated short-term intake accounted for up to 51.8 % of the ARfD for adults and 40.3% of the ARfD for children. This calculation is considered as a sufficiently conservative approach to ensure consumer safety because it is assuming a coincidence of the worst case consumption, high residues and the worst case distribution of residues within the commodity.

EFSA concludes that the intended use of pirimicarb on fennel is sufficiently supported by data and no risk for consumer health is identified.

RECOMMENDATIONS

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
The sum of pirimicarb, desmethylpirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb			
Fennel	1	5	MRL proposal is sufficiently supported by data and no risk for consumer health was identified for the proposed use.

REFERENCES

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Crop and/or situation	Member State or Country	F G or I	Pests or group of pests controlled	Formulation		Application				Application rate per treatment		PHI (days)
				Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	kg as/hL min max	kg as/ha min max	
fennel	Belgium (NEU)	G	Aphids	WG	50%	Spray		1-3	3 weeks		0.2	7

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Pirimicarb			
Status of the active substance:	Included	Code no.	128
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.035	ARfD (mg/kg bw):	0.1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2005	Year of evaluation:	2006

Input values for acute risk assessment: fennel-HR =1.98 mg/kg. Input values for chronic risk assessment: STMR for fennel-0.45 mg/kg; citrus fruit-0.01 mg/kg; pome fruit-0.34 mg/kg; tomatoes, aubergines, cucumbers, courgettes-0.07 mg/kg; beans and peas (with pods)-0.1 mg/kg; celery-0.45 mg/kg; globe artichokes-0.69 mg/kg.

Chronic risk assessment - refined calculations								
		TMDI (range) in % of ADI minimum - maximum						
		11 64						
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)
64.4	WHO Cluster diet B	12.2	Wheat	5.5	Olives for oil production	5.1	Wine grapes	
60.5	UK Toddler	32.7	Sugar beet (root)	5.6	Wheat	3.1	Bananas	
59.6	DE child	11.7	Apples	5.9	Wheat	5.1	Cherries	
58.2	IE adult	5.1	Sweet potatoes	3.6	Wine grapes	3.3	Wheat	
54.3	NL child	6.8	Wheat	6.2	Apples	4.9	Bananas	
46.0	UK Infant	14.4	Sugar beet (root)	5.5	Milk and cream,	4.2	Bananas	
44.3	FR toddler	5.7	Milk and cream,	5.3	Strawberries	4.0	Spinach	
35.3	DK child	7.9	Wheat	6.3	Rye	3.3	Bananas	
35.0	WHO cluster diet E	5.6	Wheat	4.6	Wine grapes	2.2	Potatoes	
33.2	ES child	6.3	Wheat	6.0	Lettuce	2.9	Bananas	
32.4	WHO cluster diet D	9.3	Wheat	2.3	Potatoes	1.5	Cherries	
31.7	WHO regional European diet	5.4	Lettuce	4.2	Wheat	2.3	Potatoes	
31.6	FR all population	11.4	Wine grapes	4.7	Wheat	2.7	Other lettuce and other salad	
31.3	SE general population 90th percentile	5.2	Bananas	4.6	Wheat	2.4	Potatoes	
30.7	IT kids/toddler	9.5	Wheat	4.2	Lettuce	2.0	Peaches	
30.1	FR infant	4.2	Strawberries	3.8	Carrots	3.7	Milk and cream,	
29.8	PT General population	7.1	Wine grapes	5.6	Wheat	3.0	Potatoes	
27.7	WHO Cluster diet F	5.1	Wheat	4.3	Lettuce	1.9	Potatoes	
27.5	ES adult	7.7	Lettuce	3.4	Wheat	1.2	Peaches	
27.3	IT adult	5.9	Wheat	5.4	Lettuce	2.3	Other lettuce and other salad	
23.9	NL general	3.0	Wheat	1.8	Wine grapes	1.7	Lettuce	
23.5	UK vegetarian	5.4	Sugar beet (root)	2.9	Wheat	2.3	Wine grapes	
20.9	UK Adult	5.7	Sugar beet (root)	3.1	Wine grapes	2.4	Wheat	
16.4	DK adult	4.0	Wine grapes	2.9	Wheat	1.1	Bananas	
12.9	PL general population	2.0	Apples	2.0	Potatoes	1.3	Cherries	
12.3	LT adult	1.8	Potatoes	1.8	Apples	1.5	Rye	
10.7	FI adult	1.4	Wheat	1.1	Lettuce	1.0	Rye	

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

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations
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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 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)
40.3	Fennel	1.98 / -	40.3	Fennel	1.98 / -	51.8	Fennel	1.98 / -	37.8	Fennel	1.98 / -	
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:			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)	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 Pirimicarb IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

APPENDIX C – EXISTING EC MRLS

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	3.00
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	3.00
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	3.00
110030	Lemons (Citron, lemon)	3.00
110040	Limes	3.00
110050	Mandarins (Clementine, tangerine and other hybrids)	3.00
110990	Others	3.00
120000	(ii) Tree nuts (shelled or unshelled)	1.00
120010	Almonds	1.00
120020	Brazil nuts	1.00
120030	Cashew nuts	1.00
120040	Chestnuts	1.00
120050	Coconuts	1.00
120060	Hazelnuts (Filbert)	1.00
120070	Macadamia	1.00
120080	Pecans	1.00
120090	Pine nuts	1.00
120100	Pistachios	1.00
120110	Walnuts	1.00
120990	Others	1.00
130000	(iii) Pome fruit	2.00
130010	Apples (Crab apple)	2.00
130020	Pears (Oriental pear)	2.00
130030	Quinces	2.00
130040	Medlar	2.00
130050	Loquat	2.00
130990	Others	2.00
140000	(iv) Stone fruit	
140010	Apricots	2.00

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
140020	Cherries (sweet cherries, sour cherries)	5.00
140030	Peaches (Nectarines and similar hybrids)	2.00
140040	Plums (Damson, greengage, mirabelle)	1.00
140990	Others	1.00
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	1.00
151010	Table grapes	1.00
151020	Wine grapes	1.00
152000	(b) Strawberries	3.00
153000	(c) Cane fruit	2.00
153010	Blackberries	2.00
153020	Dewberries (Loganberries, Boysenberries, and cloudberrys)	2.00
153030	Raspberries (Wineberries)	2.00
153990	Others	2.00
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries cowberries (red bilberries))	1.00
154020	Cranberries	1.00
154030	Currants (red, black and white)	1.00
154040	Gooseberries (Including hybrids with other ribes species)	1.00
154050	Rose hips	1.00
154060	Mulberries (arbutus berry)	1.00
154070	Azarole (mediterranean medlar)	1.00
154080	Elderberries (Black chokeberry (appleberry), mountain	2.00

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
	ash, azarole, buckthorn (sea shallowthorn), hawthorn, service berries, and other treeberries)	
154990	Others	1.00
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	1.00
161010	Dates	1.00
161020	Figs	1.00
161030	Table olives	1.00
161040	Kumquats (Marumi kumquats, nagami kumquats)	1.00
161050	Carambola (Bilimbi)	1.00
161060	Persimmon	1.00
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	1.00
161990	Others	1.00
162000	(b) Inedible peel, small	1.00
162010	Kiwi	1.00
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	1.00
162030	Passion fruit	1.00
162040	Prickly pear (cactus fruit)	1.00
162050	Star apple	1.00
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy sapote)	1.00
162990	Others	1.00
163000	(c) Inedible peel, large	
163010	Avocados	1.00

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
163020	Bananas (Dwarf banana, plantain, apple banana)	1.00
163030	Mangoes	1.00
163040	Papaya	1.00
163050	Pomegranate	1.00
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	1.00
163070	Guava	1.00
163080	Pineapples	0,5
163090	Bread fruit (Jackfruit)	1.00
163100	Durian	1.00
163110	Soursop (guanabana)	1.00
163990	Others	1.00
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,2
212000	(b) Tropical root and tuber vegetables	0,5
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,5
212020	Sweet potatoes	0,5
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,5
212040	Arrowroot	0,5
212990	Others	0,5
213000	(c) Other root and tuber vegetables except sugar beet	0,5
213010	Beetroot	0,5
213020	Carrots	0,5
213030	Celeriac	0,5
213040	Horseradish	0,5
213050	Jerusalem artichokes	0,5

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
213060	Parsnips	0,5
213070	Parsley root	0,5
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,5
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	0,5
213100	Swedes	0,5
213110	Turnips	0,5
213990	Others	0,5
220000	(ii) Bulb vegetables	0,5
220010	Garlic	0,5
220020	Onions (Silverskin onions)	0,5
220030	Shallots	0,5
220040	Spring onions (Welsh onion and similar varieties)	0,5
220990	Others	0,5
230000	(iii) Fruiting vegetables	
231000	(a) Solanaceae	1.00
231010	Tomatoes (Cherry tomatoes,)	1.00
231020	Peppers (Chilli peppers)	1.00
231030	Aubergines (egg plants) (Pepino)	1.00
231040	Okra, lady's fingers	1.00
231990	Others	1.00
232000	(b) Cucurbits - edible peel	1.00
232010	Cucumbers	1.00
232020	Gherkins	1.00
232030	Courgettes (Summer squash, marrow (patisson))	1.00
232990	Others	1.00
233000	(c) Cucurbits-inedible peel	1.00
233010	Melons (Kiwano)	1.00
233020	Pumpkins (Winter squash)	1.00

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
233030	Watermelons	1.00
233990	Others	1.00
234000	(d) Sweet corn	0,5
239000	(e) Other fruiting vegetables	0,5
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	2.00
241020	Cauliflower	2.00
241990	Others	1.00
242000	(b) Head brassica	1.00
242010	Brussels sprouts	1.00
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	1.00
242990	Others	1.00
243000	(c) Leafy brassica	
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	2.00
243020	Kale (Borecole (curly kale), collards)	1.00
243990	Others	2.00
244000	(d) Kohlrabi	0,5
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicaceae	
251010	Lamb's lettuce (Italian cornsalad)	5.00
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	5.00

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	1.00
251040	Cress	5.00
251050	Land cress	5.00
251060	Rocket, Rucola (Wild rocket)	5.00
251070	Red mustard	5.00
251080	Leaves and sprouts of Brassica spp (Mizuna)	5.00
251990	Others	5.00
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	2.00
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	5.00
252030	Beet leaves (chard) (Leaves of beetroot)	5.00
252990	Others	5.00
253000	(c) Vine leaves (grape leaves)	5.00
254000	(d) Water cress	5.00
255000	(e) Witloof	2.00
256000	(f) Herbs	5.00
256010	Chervil	5.00
256020	Chives	5.00
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	5.00
256040	Parsley	5.00
256050	Sage (Winter savory, summer savory,)	5.00

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
256060	Rosemary	5.00
256070	Thyme (marjoram, oregano)	5.00
256080	Basil (Balm leaves, mint, peppermint)	5.00
256090	Bay leaves (laurel)	5.00
256100	Tarragon (Hyssop)	5.00
256990	Others	5.00
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	1.00
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	1.00
260030	Peas (with pods) (Mangetout (sugar peas))	1.00
260040	Peas (without pods) (Garden pea, green pea, chickpea)	1.00
260050	Lentils	0,7
260990	Others	0,7
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	1.00
270020	Cardoons	1.00
270030	Celery	5.00
270040	Fennel	1.00
270050	Globe artichokes	5.00
270060	Leek	1.00
270070	Rhubarb	1.00
270080	Bamboo shoots	1.00
270090	Palm hearts	1.00
270990	Others	1.00
280000	(viii) Fungi	0,5
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,5

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
280020	Wild (Chanterelle, Truffle, Morel .)	0,5
280990	Others	0,5
290000	(ix) Sea weeds	0,5
300000	3. PULSES, DRY	1.00
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	1.00
300020	Lentils	1.00
300030	Peas (Chickpeas, field peas, chickling vetch)	1.00
300040	Lupins	1.00
300990	Others	1.00
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	0,1
401020	Peanuts	0,1
401030	Poppy seed	0,5
401040	Sesame seed	0,1
401050	Sunflower seed	0,5
401060	Rape seed (Bird rapeseed, turnip rape)	0,2
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	1.00
402020	Palm nuts (palmoil kernels)	0,1
402030	Palmfruit	0,1

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
402040	Kapok	0,1
402990	Others	0,1
500000	5. CEREALS	
500010	Barley	0,5
500020	Buckwheat	0,2
500030	Maize	0,2
500040	Millet (Foxtail millet, teff)	0,2
500050	Oats	0,5
500060	Rice	0,2
500070	Rye	0,5
500080	Sorghum	0,2
500090	Wheat (Spelt Triticale)	0,5
500990	Others	0,2
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	5.00
631000	(a) Flowers	5.00
631010	Camomille flowers	5.00
631020	Hybiscus flowers	5.00
631030	Rose petals	5.00
631040	Jasmine flowers	5.00
631050	Lime (linden)	5.00
631990	Others	5.00
632000	(b) Leaves	5.00
632010	Strawberry leaves	5.00
632020	Rooibos leaves	5.00
632030	Maté	5.00
632990	Others	5.00
633000	(c) Roots	5.00
633010	Valerian root	5.00
633020	Ginseng root	5.00
633990	Others	5.00
639000	(d) Other herbal infusions	5.00
640000	(iv) Cocoa	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
	(fermented beans)	
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	4.00
800000	8. SPICES	
810000	(i) Seeds	5.00
810010	Anise	5.00
810020	Black caraway	5.00
810030	Celery seed (Lovage seed)	5.00
810040	Coriander seed	5.00
810050	Cumin seed	5.00
810060	Dill seed	5.00
810070	Fennel seed	5.00
810080	Fenugreek	5.00
810090	Nutmeg	5.00
810990	Others	5.00
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	0,5
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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry - chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
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	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
	water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	
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 quantification

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
bw	body weight
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CS	capsule suspension
CXL	codex maximum residue limit
D	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DP	dustable powder
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GC-NPD	gas chromatography – nitrogen phosphorus detector
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre

LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
PHI	pre harvest interval
ppm	parts per million (10^{-6})
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
SEU	Southern European Union
STMR	supervised trials median residue
TRR	total radioactive residue
UVD	ultra-violet detection
WG	water dispersible granule
WHO	World Health Organisation