REASONED OPINION OF EFSA

Refined risk assessment regarding certain MRLs of concern for the active substance pirimiphos-methyl[1]

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-00466-2009)

Issued on 20 May 2009

SUMMARY

On 18 September 2008, EFSA issued a reasoned opinion (EFSA, 2008) where a potential long-term consumer risk was identified for pirmiphos-methyl. EFSA recommended the lowering of certain MRLs but also highlighted that certain existing MRLs for cereals could be maintained if a more refined intake calculation proves that these MRLs do not pose a consumer health risk. In order to perform this refined calculations, food consumption data for processed cereal based food commodities were considered necessary.

On 4 March 2009 EFSA received a new mandate from the European Commission together with additional data on food consumption provided by Member States.

EFSA re-calculated the processing factors for cereal based products which were reported in the Draft Assessment Report and concluded that the processing factors derived in the peer review process should be corrected.

The exposure assessment performed in the framework of this assessment was based on

- the detailed food consumption data available for processed cereal based food commodities,
- the STMR values derived from supervised trials on stored cereal grain for the supported uses (barley, millet, oats, sorghum and wheat),
- the proposed lowered MRLs for the other cereals which are no longer supported by the manufacturer,
- the proposed lowered MRL for products of animal origin,
- the existing MRLs for spices and
- the recalculated processing factors for cereal products (processed products based on wheat, barley and oats).

[1] For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the refined risk assessment regarding certain MRLs of concern for the active substance pirimiphos-methyl. *EFSA Scientific Report* (2009) 294, 1-35

The calculated long-term exposure exceeds the ADI for two diets (UK infants- 160% of the ADI and UK toddlers- 116% of the ADI). The main contributing food commodities were identified as wheat bran (up to 115% of the ADI) and wholemeal bread (up to 47% of the ADI).

UK noted that wheat bran is most likely consumed in form of processed wheat bran products such as bran based breakfast cereals. This assumption has a significant impact on the expected consumer exposure since a reduction of residues is expected for bran based breakfast cereals: the contribution of wheat bran in form of breakfast cereals to the total exposure would be only 7% for UK toddlers and 17% for UK infants, provided that the provisional processing factor for bran breakfast cereal is confirmed. In this scenario the total exposure, taking into account all cereals which are supported by the manufacturer (wheat, barley, oats, millet and sorghum) does not exceed the toxicological threshold value.

In order to come to a final conclusion regarding the safety of residues expected on wheat and wheat based products, the effective consumption of wheat bran and wheat bran based products consumed in the UK is required. In addition, further studies investigating the magnitude of pirimiphos-methyl residues in pearl barley and bran breakfast cereals should be performed to confirm the validity of the provisional processing factors for these commodities.

Finally, it is noted that a short-term exposure calculation was not performed because in the reasoned opinion issued in September 2008 an acute consumer risk was not identified with regard to the existing MRLs for cereals[2].

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Residue definition for enforcement: **Pirimiphos-methyl**			
Barley	**5**	**5**	The exposure resulting from residues in millet does not pose a consumer health risk. The maximum intake accounted for 3.5% in the most critical diet (IE adult).
Millet	**5**	**5**	The exposure resulting from residues in millet does not pose a consumer health risk. The maximum intake accounted for 6.2% in the most critical diet (Cluster diet D).
Oats	**5**	**5**	The exposure resulting from residues in millet does not pose a consumer health risk. The maximum intake accounted for 5.9% in the most critical diet (IE adult).

[2] Reasoned opinion of EFSA prepared by PRAPeR on MRLs of concern for the active substance pirimiphos-methyl. EFSA Scientific Report (2008) 164, 1-27

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Sorghum	**5**	**5**	The exposure resulting from residues in millet does not pose a consumer health risk. The maximum intake accounted for 1.2% in the most critical diet (DE child).
Wheat (including triticale)	**5**	**No final conclusion**	**Two options are possible:** **0.05* mg/kg** considering that **t**he consumer exposure resulting from intake of wheat which was treated with pirimiphos-methyl exceeds the ADI for two diets (UK toddler- 108% and UK infants- 147% of the ADI). The highest contribution is related to the intake of wheat bran. **5 mg/kg** would be acceptable assuming that UK infants and toddler consume wheat bran only in processed form as bran based breakfast cereals. In order to conclude on the safety of this MRL for wheat, effective consumption data for wheat bran and wheat bran based products have to be provided and the processing factors for this food commodity has to be confirmed by additional studies.
Buckwheat	**5**	**0.05***	For cereals which are not supported by the manufacturer, EFSA proposed to set the MRLs at the LOQ. See EFSA scientific report (2008) 164.
Maize	**5**	**0.05***	
Rice	**5**	**0.05***	
Rye	**5**	**0.05***	
Spices (seeds)	**5**	**5**	The MRL for spices do not pose a consumer health concern. The intake is insignificant.
Spices (fruit and berries)	**0.1**	**0.1**	
Other plant commodities	**See Appendix B**	**0.05***	See EFSA scientific report (2008) 164.
Products of animal origin	**0.05**	**0.01***	

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

Key words: Pirimiphos-methyl, cereal grains, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, organophosphate

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BACKGROUND

On 30 June 2008, the European Commission requested EFSA, according to Article 43 of Regulation (EC) No 396/2005, to provide scientific advice on the safety of the existing MRLs for the active substance pirimiphos-methyl. As a consequence, EFSA issued a reasoned opinion on 18 September 2008 (EFSA, 2008) where certain MRLs of concern were identified. In order to ensure that consumers are protected adequately, EFSA proposed to delete certain MRLs of concern for fruit, vegetables, and other crops for which no authorisations are in place in EU Member States and for which no import tolerances were requested. For certain cereals (wheat, barley, oats, millet and sorghum) for which the use of pirimiphos-methyl containing plant protection products is still authorised in Member States, EFSA concluded the data provided did not give clear evidence that consumers are not at risk and therefore the lowering of the existing MRLs should be considered. However, EFSA highlighted that the consumer intake calculation could be refined if appropriate information on food consumption of processed cereal based food commodities were provided.

After adoption of this reasoned opinion, several Member States provided details regarding food consumption of cereal based food. In addition, the Rapporteur Member State has submitted an evaluation report in which additional data provided by the manufacturer in September 2008 have been evaluated.

The European Commission submitted a new request to EFSA on 4 March 2009 in which EFSA was asked to review the additional data provided by the manufacturer and Member States and assess their impact on the assessment of MRLs for pirimiphos-methyl in cereals.

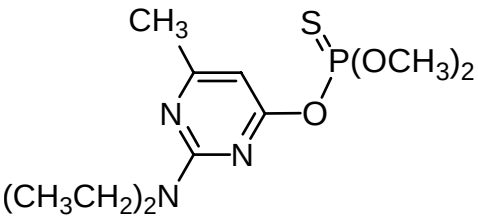
After having accepted the new terms of reference, the request was included in the EFSA Register of Questions as EFSA-Q-2009-00466.

TERMS OF REFERENCE

EFSA was requested by the European Commission to perform a refined risk assessment for the existing MRLs of pirimiphos-methyl for cereals, taking into account the additional information provided by Member States regarding consumption of cereals in processed forms (breakfast cereals, bread, beer etc.). EFSA should also consider the assessment provided by the Rapporteur Member State (United Kingdom), which was submitted in January 2009, as well as the data submitted by the manufacturer of pirimiphos-methyl.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Pirimiphos-methyl is the ISO common name for *O*-2-diethylamino-6-methylpyrimidin-4-yl *O*,*O*-dimethylphosphorothioate (IUPAC).



Pirimiphos-methyl belongs to the class of organothiophosphates. It is a broad spectrum insecticide and acaricide with contact and respiratory action. The biochemical mode of action is via inhibition of the acetyl cholinesterase.

Pirimiphos-methyl was assessed in the second stage of the peer review process under Directive 91/414/EEC with United Kingdom as designated Rapporteur Member State. EFSA organised a consultation of technical experts from Member States who reviewed the draft assessment report prepared by the Rapporteur Member State. The result of the consultation of Member States in the peer review were summarised in the EFSA conclusion (EFSA, 2005). The evaluated representative uses as insecticide comprise spraying to control a broad spectrum of insects in wheat, barley and oats grains during storage and treatment for structural surfaces in empty grain stores at application rates up to 4 g pirimiphos-methyl per ton and 50 g per 100 m², respectively.

The peer review process was finalised with the decision on inclusion of pirimiphos-methyl in Annex I to Directive 91/414/EEC which was published in Directive 2007/52 (EC, 2007) and entered into force on 1 October 2007. The Annex I inclusion was restricted to the use as insecticide for a post-harvest storage treatment only. All approvals of pirimiphos-methyl for other uses had to be revoked by 31 March 2008.

EC MRLs for pirimiphos-methyl in products of plant and animal origin have been set for the first time in 1995 by means of Directives 1995/38/EC and 1995/39/EC. These MRLs have been amended in 2000 for fruit and vegetables (2000/42/EC) and have been transferred to Annex II of Regulation (EC) No 396/2005 without amendments. Additional MRLs for commodities that were not covered by the former European MRL legislation were established in Annex III B by Regulation (EC) No 839/2008. The existing EC MRLs for pirimiphos-methyl are summarised in Appendix B to this document. It is noted that Codex Alimentarius has established CXLs for cereal grains (7 mg/kg, resulting from a post-harvest use of 4 to 8 g a.s./t), wheat bran (15 mg/kg), and certain products of animal origin (all 0.01 mg/kg equivalent to the limit of quantification). In addition, MRLs for spices have been established by Codex (3 mg/kg for spices, seeds, and 0.5 mg/kg for spices, fruits). The residue definition established by Codex Alimentarius comprises also only the parent compound.

ASSESSMENT

1. Introduction

EFSA has issued a reasoned opinion regarding MRLs of concern for the active substance pirimiphos-methyl in September 2008 (EFSA, 2008). EFSA identified a potential chronic health risk and recommended lowering the MRLs for all fruits and vegetables to the appropriate Limit of Quantification (LOQ). This measure is justified because the national authorisations for these commodities expired and no import tolerances have been requested. It was also concluded that the existing MRLs for spices could be maintained as import tolerances if necessary because of the minor contribution to the dietary intake. For products of animal origin EFSA recommended lowering the LOQ form 0.05 mg/kg to 0.01 mg/kg because feeding studies demonstrated that no residues are expected in meat, milk and eggs and adequate analytical methods are available for the proposed lower LOQ.

The manufacturer informed the Rapporteur Member State that the post-harvest treatment on storage is only supported for wheat (including triticale), barley, oats, sorghum and millet. For other cereal grains (buckwheat, maize, rye, rice) the authorisations will be withdrawn and consequently the MRL should be lowered to the LOQ of 0.05 mg/kg. The structural treatment of empty storage rooms is not expected to lead to residues above the LOQ. Although the use pattern will be restricted to several cereals only, the consumer exposure calculation resulted in an exceedance of the ADI for 5 diets (IT children, WHO cluster diet E, IE adult, WHO cluster diet D and B). These calculations were based on the assumption that oats and wheat are consumed in processed form as rolled oats or wheat flour, respectively and that the residues are reduced as expected from processing studies (processing factor of rolled oats 0.14 and for wheat flour 0.24). EFSA concluded that further refined intake calculations would be possible if more detailed data regarding the consumption of processed cereal based commodities in different diets would be available.

The European Commission asked Member States to provide more detailed consumption data for processed cereal based food commodities if these data are available for national food surveys. Such data were submitted by Ireland and Denmark.

In response to the EFSA reasoned opinion, the manufacturer of pirimiphos-methyl also provided a position paper (September 2008) for the intended EU use pattern (Appendix A) to support

- the EU MRL of 5 mg /kg in barley, millet, oats, sorghum and wheat associated with the use of pirimiphos-methy to treat cereal grains post-harvest as a single application at a rate of 4 g a.s./t,
- the EU MRL of 0.05 mg/kg in other cereals to allow for the possibility of application to empty cereal storehouses and
- the EU MRL of 0.01 mg/kg in meat, milk and eggs.

In January 2009 the Rapporteur Member State prepared a document in which the data provided by the manufacturer were evaluated and a refined consumer risk assessment was presented.

EFSA is now requested by the European Commission to review the MRLs for cereals taking into account the additional information made available by Member States, the manufacturer and the Rapporteur. In the mandate submitted to EFSA the European Commission stresses

that the possibility to use information on percentage crop treated should not be considered in the refinement of the dietary exposure assessment because the percentage crop treated may change over time and there is no legal requirement to do a new risk assessment when a change in percentage crop treated occurs.

2. Mammalian toxicology

The toxicological propoerties of pirimiphos-methyl were assessed in the peer review under Directive 91/414/EEC. The toxicological reference values derived are summarised in Table 2-1.

Table 2-1. **Overview of the toxicological reference values**

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Pirimiphos-methyl					
ADI	EFSA	2005	0.004	2 year rat, 2 year dog, supported by human data	100
ARfD	EFSA	2005	0.15	Rat, acute neurotoxicity	100

It should be noted that JMPR reviewed the toxicological data of pirimiphos-methyl in 2006 and derived higher ADI and ARfD values (0.03 mg/kg and 0.2 mg/kg). The ADI established by JMPR is based on a NOAEL of 0.25 mg/kg bw per day in a 28-day and a 58-day study in human volunteers, and a safety factor of 10. The ARfD is based on a NOAEL of 0.15 mg/kg b.w. (inhibition of acetylcholine esterase activity in rats from a single-dose study of neurotoxicity). The ARfD of JMPR and EFSA are based on the same study, the difference is due to different practice of the rounding of values.

3. Residues

The residue definition derived in the peer review for both enforcement and risk assessment comprises only the parent compound pirimiphos-methyl.

The same residue definition has been established by Codex Alimentarius.

3.1. Magnitude of residues in unprocessed cereals

In the Draft Assessment Report results of four trials representing the intended GAP were presented (two trials in wheat, one trial in oats and one trial in barley). In addition, four trials in support of the treatment of empty stores were submitted. The results of these trials are summarised in Table 3-1.

Table 3-1 Summary of critical residues data presented in the Draft Assessment Report

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/ comments	MRL	STMR (b)
Cereal grain	N	1.1, 2.5, 2.8, 3.2	Stored grain treatment	5	2.65
Cereal grain	N/S	4 x <0.05	Empty stores	0.05*	<0.05

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a)	Recommendation/ comments	MRL	STMR (b)
			(structural treatment)		

It should be mentioned that for the post-harvest use of an active substance in major crops like cereal grains usually a set of 8 supervised field trials has to be provided. However, since the measured pirimiphos-methyl residues in cereal are in the same range as the application rate it is concluded that no decline is expected during storage. Additional studies would not change significantly the conclusion on the MRL and the STMR.

3.2. Effect of industrial processing and/or household preparation

The use of the correct processing factors is a crucial point in the assessment of the MRLs for pirimiphos-methyl in cereals. Processing factors for processed cereal commodities were reported in the Draft Assessment Report (UK, 2003) which were also taken over in the EFSA conclusion (EFSA, 2005). In 2003, JMPR assessed the active substance and derived processing factors which differ from the values calculated by the RMS. A comparison of the processing factors of JMPR and EU Peer Review were reported in the EFSA reasoned opinion on the MRLs of concern (EFSA, 2008).

In the framework of this request, EFSA recalculated the processing factors taking into account the information reported in the Draft Assessment Report. The results of the calculation of the processing factors are summarised in Table 3-2. The RMS UK confirmed the correctness of the values derived by EFSA and stresses that the values reported in the DAR and the EFSA conclusion should be corrected accordingly.

The processing factors derived by JMPR are mentioned in the comments field in table 3-2. It should be noted that the values recalculated by EFSA are comparable with the values derived from JMPR, except for bran breakfast cereal. In order to find out the reason for this significant discrepancy the data presented in the original study (Hayward, 1989) were verified. The residues in the unprocessed grain of 9.1 mg/kg were reduced in the commercial preparation of bran breakfast cereals to 2 mg/kg and 4 mg/kg, depending on the process which requires different bran fractions and different thermic profiles. The process which involves a short cooking process and a long drying stage at moderate high temperatures leads to higher residues compared with the process with a long cooking period and a short drying stage at high temperature.

It should be noted that for pearl barley and for bran breakfast cereals the number of processing studies is not sufficient to derive final processing factors and the values for these processed commodities reported in table 3-1 should be considered as provisional. It is recommended to perform further studies to confirm these provisional processing factors.

Table 3-2. **Overview of the available processing studies reported in the Draft Assessment Report**

Residues unprocessed grain (mg/kg)	Residues processed product (mg/kg)	PF	Comment [3]

Residues unprocessed grain (mg/kg)	Residues processed product (mg/kg)	PF	Comment [3]
Wheat	**Bran**		
4.7	16.3	3.47	Processing Study Hayward, 1990
3.3	10.1	3.06	Processing Study Hayward, 1990
3.15	8.47	2.69	Processing study Bullock, 1974
3.1	7.42	2.39	Processing study Bullock, 1974
3.17	6.46	2.04	Processing study Bullock, 1974
2.9	4.46	1.54	Processing study Bullock, 1974
9.1	14.18	1.56	Processing study Hayward, 1989
9.11	15.72	1.73	Processing study Hayward, 1990
	Bran median PF	**2.22**	JMPR derived a PF of **2.2** (JMPR, 2003)

Wheat	**Flour**		
4.7	1.2	0.26	Processing Study Hayward, 1990
3.3	0.6	0.18	Processing Study Hayward, 1990
3.15	0.52	0.17	Processing study Bullock, 1974
3.1	0.59	0.19	Processing study Bullock, 1974
3.17	0.58	0.18	Processing study Bullock, 1974
2.9	0.56	0.19	Processing study Bullock, 1974
	Flour median PF	**0.19**	JMPR derived a PF of **0.17** (JMPR, 2003)

Wheat	**Wholemeal flour**		
4.7	3.2	0.68	Processing Study Hayward, 1990
3.3	2.5	0.76	Processing Study Hayward, 1990
2.48	1.14	0.46	Processing study Bullock, 1974
2.23	1.69	0.76	Processing study Bullock, 1974
2.03	1.74	0.86	Processing study Bullock, 1974
1.86	1.49	0.80	Processing study Bullock, 1974
	Wholemeal flour median PF	**0.76**	JMPR derived a PF of **0.71** (JMPR, 2003)

Wheat	**Bread white**		
4.7	0.8	0.17	Processing Study Hayward, 1990
3.3	0.4	0.12	Processing Study Hayward, 1990
3.15	0.23	0.07	Processing study Bullock, 1974
3.1	0.23	0.07	Processing study Bullock, 1974
3.17	0.36	0.11	Processing study Bullock, 1974
2.9	0.43	0.15	Processing study Bullock, 1974
	Bread white, median PF	**0.12**	JMPR derived a PF of **0.097** (JMPR, 2003)

Wheat	**Bread wholemeal**		
4.7	2.6	0.55	Processing Study Hayward, 1990
3.3	2.3	0.70	Processing Study Hayward, 1990
2.48	0.64	0.26	Processing study Bullock, 1974
2.23	0.79	0.35	Processing study Bullock, 1974
2.03	0.93	0.46	Processing study Bullock, 1974
1.86	0.73	0.39	Processing study Bullock, 1974

Residues unprocessed grain (mg/kg)	Residues processed product (mg/kg)	PF	Comment [3]
	Bread wholemeal, median PF	**0.43**	JMPR derived a PF of **0.36** (JMPR, 2003)

Wheat	**Bran breakfast cereal:** two ways to produce bran breakfast cereal were investigated: Method 1 uses a mixture of heavy bran, light bran and flour. Method 2 uses just light bran. [1]		
9.11	2	0.22 – method 1	Processing Study Hayward, 1989
9.11	4	0.44 – method 2	Processing Study Hayward, 1989
	Bran breakfast cereal, median PF	**0.33** [2]	JMPR reported a PF of **2.3 to 4**. The JMPR assessment is based on the same study.

Barley	**Barley pearl**		
1.1	0.1	0.09	Hayward GJ, Harradine KJ. 1989, 1990
	Barley pearl, median PF	**0.09** [2]	

Barley	**Barley beer**		
1.2	0.01	0.008	Anderson and Hayward, 1990
2.2	0.01	0.005	Anderson and Hayward, 1990
4	0.01	0.003	Processing study Bullock, 1974
6	0.01	0.002	Processing study Bullock, 1974
	Barley beer, median PF	**0.004**	**STMR-P for beer** was calculated to be **0.01 mg/kg**. (JMRP, 2003)
Oats	**Oats, rolled**		
3.2	0.08	0.03	Hayward GJ, Harradine KJ. 1989, 1990
4 trials: 1.35 to 2.45	0.15 to 0.23	0.18	Scrimshaw and Milhan, 2003
	Oats rolled, median PF	**0.18**	JMPR concluded that less than **4%** of the residues in treated oat grain was found in rolled oats, but there were insufficient data to calculate a processing factor (JMPR 2003)

(1) Processing wheat grain to processed fractions ant do bran breadfast cereals on a commercial scale showed a concentration of pirimiphos-methyl in fine bran (PF 1.7) and light bran (PR 1.6) but a reduction in heavy bran (0.7).

(2) The calculated PF is considered as provisional only since the required minimum number of studies (at least 3 studies) is not available.

(3) The reference to the studies can be found in the DAR, Annex B.7 (UK, 2003).

For the refined exposure assessment in the framework of this report, EFSA uses the re-calculated median processing factors as reported in table 3-1, including also the provisional processing factors for wheat bran breakfast cereal and pearl barley.

4. Consumer risk assessment

4.1. Food consumption data

In the refined long-term consumer exposure calculations particular attention was paid to the food consumption data for cereals, in particular for processed cereal based food.

In the framework of this assessment EFSA received detailed consumption data for individual cereal based food commodities. EFSA also revisited the food consumption data submitted in 2006 when EFSA started to collect data for the EFSA PRIMo (EFSA, 2007) regarding the reported cereal based food items. Also the details reported in the GEMS food database (WHO, 2006) were re-analysed under this point of view. It should be stressed that the comparison of the information on processed food is hampered by the fact that currently no agreed food classification system for processed food is established. In Appendix C the consumption data for processed cereal products are listed as reported in the original source without making the effort to classify the data or to develop food categories for processed commodities. In fact, for the following diets more detailed consumption data for cereal based products could be derived:

- DK, adults and children (email submitted to EFSA in February 2009)
- ES, adult and children (detailed consumption figures were reported in the data submitted to EFSA in 2006)
- IE, adults (email submitted to the European Commission in January 2009)[3]
- IT, adults and children (detailed consumption figures were reported in the data submitted to EFSA in 2006)
- UK adults, vegetarians, toddlers and infants (consumption figures were reported in the document regarding MRL proposal for pirimiphos-methyl, UK 2009)
- WHO cluster diet B, D, E and F (details reported in the GEMS food consumption database, WHO, 2006)

It should be mentioned that, EFSA had doubts regarding the UK consumption data for wheat bran. The consumption for UK infants were in the same order of magnitude as wholemeal bread (0.81 g/kg bw and 0.78 g/kg bw, respectively). According to a personal communication from the contact person in the UK (Donal Griffin, Chemicals Regulation Directorate, 19/05/2009) the majority of bran consumption by UK toddlers and UK infants is most likely in form of processed bran cereals. The survey from which the data were derived is 17 years old and data on processed commodities have been taken from a relatively small number of consumers. It is therefore concluded by the contact person that the data should be treated with caution. This is an important information which was also considered in the exposure assessment (see 4.3).

4.2. Long-term exposure assessment

For the long-term consumer exposure assessment the food commodities as reported in Appendix C have been multiplied with the STMR value and the corresponding processing factor for the commodity concerned. For processed commodities for which no equivalent

[3] The consumption figure for barley (beer) was recalculated to beer by applying the conversion factor of 5 used by GEMS food (i.e. 0.2 g of barley is needed to make 1 g of beer).

processing factor was available, EFSA selected a process which was considered to present the processing conditions best. In Table 4-1 the input values for the refined intake calculations are summarised.

Table 4-1. **Input values for the long-term consumer exposure assessment**

Groups of crops and examples of individual products within the groups to which the MRLs apply	**STMR (mg/kg)**	**PF**	**Description PF**	**Resulting input values for refined calculations**
CEREALS				
Barley	2.65			
Barley from breakfast cereals		0.090	Barley pearl	0.24
Barley from lager		0.004	Barley - beer	0.01
Barley from stout		0.004	Barley - beer	0.01
Barley from malt		0.004	Barley - beer	0.01
Pot barley		0.09	Barley pearl	0.24
Barley, pearled		0.09	Barley pearl	0.24
Barley flour and grits		0.09	Barley pearl	0.24
Barley beer		0.004	Barley - beer	0.01
Barley grain		0.09	Barley pearl	0.24
Other barley products		0.09	Barley pearl	0.24
Buckwheat	0.05	1.00		0.05
Maize	0.05	1.00		0.05
Millet	2.65	1.00		2.65
Oats	2.65			
Oats in porredge		0.18	Rolled oats	0.48
Oats from breakfast cereal		0.18	Rolled oats	0.48
Oats from oatscakes		0.12	Wheat white bread	0.32
Oats rolled		0.18	Rolled oats	0.48
Other oats products		0.18	Rolled oats	0.48
Rice	0.05	1.00		0.05
Rye	0.05	1.00		0.05
Sorghum	2.65	1.00		2.65
Wheat	2.65			
White bread		0.12	Wheat white bread	0.32
Whole meal bread		0.43	Wheat wholemeal bread	1.14
Pasta		0.19	Wheat flour	0.50
Cakes including cookies		0.19	Wheat flour	0.50
Flour as ingredient		0.19	Wheat flour	0.50
Flour from biscuits		0.19	Wheat flour	0.50
Flour from bread		0.19	Wheat flour	0.50
Flour from breakfast cereal		0.19	Wheat flour	0.50
Flour from cakes and buns		0.19	Wheat flour	0.50
Flour from pastry and pastry pies		0.19	Wheat flour	0.50
Flour from pasta and noodels		0.19	Wheat flour	0.50
Flour from pizza		0.19	Wheat flour	0.50
Flour from packet/jarred sauce/soups etc		0.19	Wheat flour	0.50
Flour from crumb(batter coating		0.19	Wheat flour	0.50
Wheat bran		2.22	Wheat bran	5.88
Cereals - sweet products		0.19	Wheat flour	0.50
Bread/pizza (with veg, with other ingredients)		0.12	Wheat white bread	0.32
Bread substitute		0.12	Wheat white bread	0.32
Pasta (durum whet, egg noodles, filled)		0.19	Wheat flour	0.50
Churros		0.19	Wheat flour	0.50
Bread roll		0.12	Wheat white bread	0.32

Groups of crops and examples of individual products within the groups to which the MRLs apply	STMR (mg/kg)	PF	Description PF	Resulting input values for refined calculations
Triticale flour		0.19	Wheat flour	0.50
Wheat bulgur wholemeal		0.76	Wheat wholemeal flour	2.01
Wheat flour		0.19	Wheat flour	0.50
Wheat macaroni		0.19	Wheat flour	0.50
Wheat pastry		0.12	Wheat white bread	0.32
White bread		0.12	Wheat white bread	0.32
Whole meal bread		0.43	Wheat wholemeal bread	1.14
Wheat germ				
Other wheat products (not specified)		0.19	Wheat flour	0.50
Other cereal	0.05	0.19	Wheat flour	0.01
PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS		-		
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		-	No processing data available	0.01
Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd		-	No processing data available	0.01
Birds' eggs		-	No processing data available	0.01

4.3. Results of the refined intake calculation

In Appendix D the results of the long-term exposure calculation, expressed in % of the ADI, are reported in detail for the individual diets and food items. To summarise, the total daily intake of pirmiphos-methyl was in the range of 0 to 162% of the ADI for the different diets. For two diets the ADI was exceeded (UK infants: 162 % and UK toddler: 116 % of the ADI). The main contributors to the overall dietary burden were wheat bran (115 % and 48% for UK infants and toddlers, respectively) and wholemeal bread (23% and 44% for UK infants and toddlers).

The contribution of the different cereals and of animal products to the overall dietary burden is also displayed in the Figure 4-1.

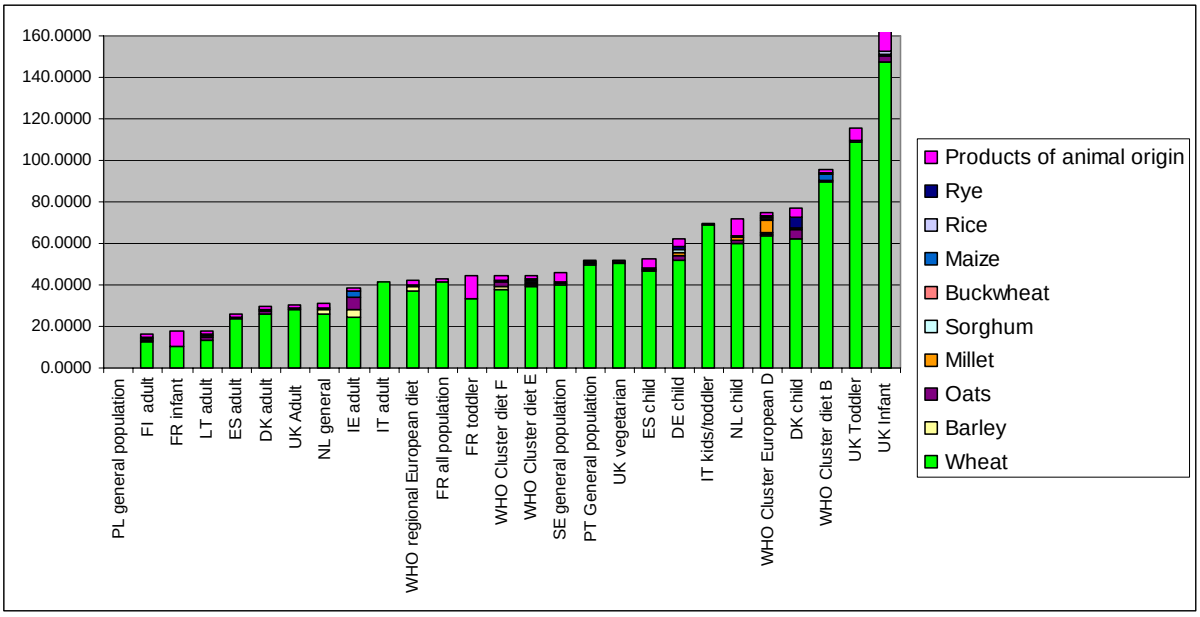


Figure 4-1: Contribution of cereals and products of animal origin to the expected total dietary intake of European consumers (refined intake calculation, based on detailed food consumption data, including processing factors)

Since the consumption data for wheat bran reported by UK is affected by some uncertainties (see section 4.1), EFSA also calculated a second scenario which is based on the assumption that wheat bran is consumed in form of bran breakfast cereal only and for which a lower processing factor should be applied (PF 0.33). In this case, the exposure would be significantly lower for some diets (75.2% and 64.9% of the ADI for UK toddlers and UK infants and 39.2% and 22.6% for UK vegetarians and UK adults). The results of the calculation of this scenario are presented in Appendix E. The impact of the assumption that all wheat bran is consumed as bran based breakfast cereal is shown in Figure 4-2. However, it should also be noted that the processing factor for bran based breakfast cereal is only provisional and should be confirmed by further studies.

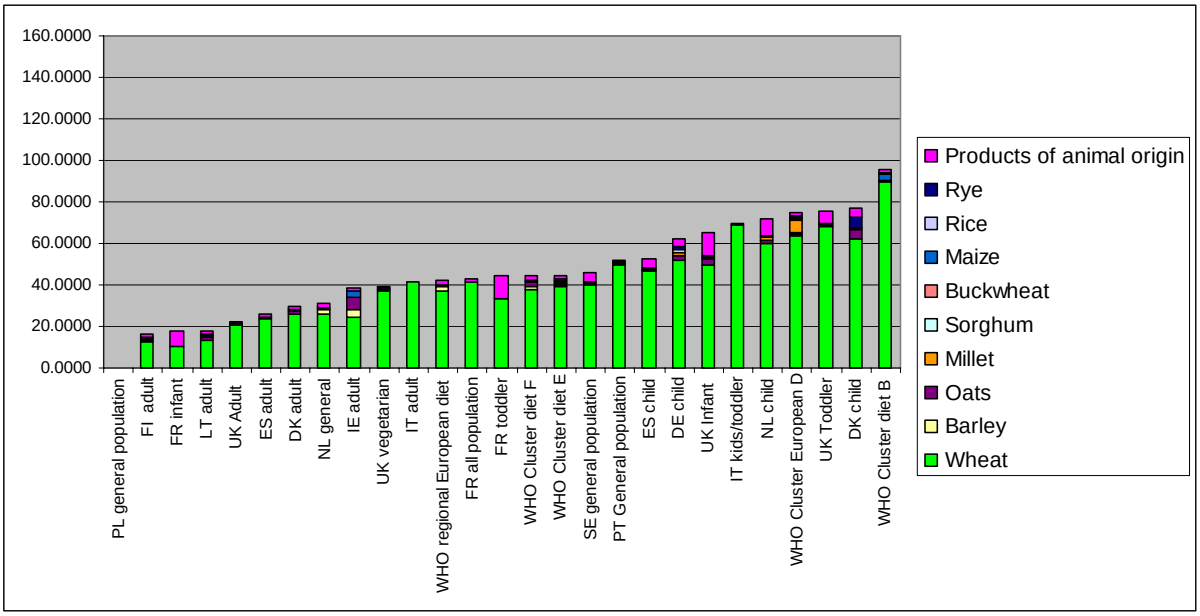


Figure 4-2: Contribution of cereals and products of animal origin to the expected total dietary intake of European consumers (refined intake calculation based on detailed food consumption and on the assumption that wheat bran is consumed in form of bran based breakfast cereals)

In the framework of this assessment no short-term exposure assessment was performed because in the EFSA opinion on pirimiphos-methyl issued in September 2008 (EFSA, 2008) it was clearly demonstrated that the existing MRLs do not pose an acute consumer concern except for melons. Since the melon MRL will be lowered from 1 mg/kg to 0.05 mg/kg, a short-term consumer risk can be excluded also for this food item.

EFSA concludes that a potential long-term consumer health risk cannot be excluded following the consumption of cereal products produced from wheat, barley, oats, millet and sorghum which was treated with pirmiphos-methyl at an application rate of 4 g/t. The intake concern is mainly related to the consumption of wheat by UK toddlers and UK infants. According to the UK, the food consumption data for wheat bran which is the wheat commodity which contributes the most are questionable and most likely refer to the consumption of wheat bran breakfast cereal. The exposure assessment reflecting these assumptions indicate that the long-term consumer risk for might be acceptable (Appendix E, scenario 2). However, a confirmation of the assumption regarding the consumption of bran and/or bran based breakfast cereal and a confirmation of the provisional processing factor for bran breakfast cereal would be required to base a final decision on this scenario.

CONCLUSIONS AND RECOMMENDATIONS

On 18 September 2008, EFSA issued a reasoned opinion (EFSA, 2008) where a potential long-term consumer risk was identified for pirmiphos-methyl. EFSA recommended the lowering of certain MRLs but also highlighted that certain existing MRLs for cereals could be maintained if a more refined intake calculation proves that these MRLs do not pose a consumer health risk. In order to perform this refined calculations, food consumption data for processed cereal based food commodities were considered necessary.

On 4 March 2009 EFSA received a new mandate from the European Commission together with additional data on food consumption provided by Member States.

EFSA re-calculated the processing factors for cereal based products which were reported in the Draft Assessment Report and concluded that the processing factors derived in the peer review process should be corrected.

The exposure assessment performed in the framework of this assessment was based on

- the detailed food consumption data available for processed cereal based food commodities,
- the STMR values derived from supervised trials on stored cereal grain for the supported uses (barley, millet, oats, sorghum and wheat),
- the proposed lowered MRLs for the other cereals which are no longer supported by the manufacturer,
- the proposed lowered MRL for products of animal origin,
- the existing MRLs for spices and
- the recalculated processing factors for cereal products (processed products based on wheat, barley and oats).

The calculated long-term exposure exceeds the ADI for two diets (UK infants- 160% of the ADI and UK toddlers- 116% of the ADI). The main contributing food commodities were identified as wheat bran (up to 115% of the ADI) and wholemeal bread (up to 47% of the ADI).

UK noted that wheat bran is most likely consumed in form of processed wheat bran products such as bran based breakfast cereals. This assumption has a significant impact on the expected consumer exposure since a reduction of residues is expected for bran based breakfast cereals: the contribution of wheat bran in form of breakfast cereals to the total exposure would be only 7% for UK toddlers and 17% for UK infants, provided that the provisional processing factor for bran breakfast cereal is confirmed. In this scenario the total exposure, taking into account all cereals which are supported by the manufacturer (wheat, barley, oats, millet and sorghum) does not exceed the toxicological threshold value.

In order to come to a final conclusion regarding the safety of residues expected on wheat and wheat based products, the effective consumption of wheat bran and wheat bran based products consumed in the UK is required. In addition, further studies investigating the magnitude of pirimiphos-methyl residues in pearl barley and bran breakfast cereals should be performed to confirm the validity of the provisional processing factors for these commodities.

Finally, it is noted that a short-term exposure calculation was not performed because in the reasoned opinion issued in September 2008 an acute consumer risk was not identified with regard to the existing MRLs for cereals[4].

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Residue definition for enforcement: **Pirimiphos-methyl**			
Barley	**5**	**5**	The exposure resulting from residues in millet does not pose a consumer health risk. The maximum intake accounted for 3.5% in the most critical diet (IE adult).
Millet	**5**	**5**	The exposure resulting from residues in millet does not pose a consumer health risk. The maximum intake accounted for 6.2% in the most critical diet (Cluster diet D).
Oats	**5**	**5**	The exposure resulting from residues in millet does not pose a consumer health risk. The maximum intake accounted for 5.9% in the most critical diet (IE adult).
Sorghum	**5**	**5**	The exposure resulting from residues in millet does not pose a consumer health risk. The maximum intake accounted for 1.2% in the most critical diet (DE child).
Wheat (including triticale)	**5**	**No final conclusion**	**Two options are possible:** **0.05* mg/kg** considering that **t**he consumer exposure resulting from intake of wheat which was treated with pirimiphos-methyl exceeds the ADI for two diets (UK toddler- 108% and UK infants- 147% of the ADI). The highest contribution is related to the intake of wheat bran. **5 mg/kg** would be acceptable assuming that UK infants and toddler consume wheat bran only in processed form as bran based breakfast cereals. In order to conclude on the safety of this MRL for wheat, effective consumption data for wheat bran and wheat bran based products have to be provided and the processing factors for this food commodity has to be confirmed by additional studies.
Buckwheat	**5**	**0.05***	For cereals which are not supported by the

[4] Reasoned opinion of EFSA prepared by PRAPeR on MRLs of concern for the active substance pirimiphos-methyl. EFSA Scientific Report (2008) 164, 1-27

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Maize	**5**	**0.05***	manufacturer, EFSA proposed to set the MRLs at the LOQ. See EFSA scientific report (2008) 164.
Rice	**5**	**0.05***	
Rye	**5**	**0.05***	
Spices (seeds)	**5**	**5**	The MRL for spices do not pose a consumer health concern. The intake is insignificant.
Spices (fruit and berries)	**0.1**	**0.1**	
Other plant commodities	**See Appendix B**	**0.05***	See EFSA scientific report (2008) 164.
Products of animal origin	**0.05**	**0.01***	

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

DOCUMENTATION PROVIDED TO EFSA

1. MRL proposal for pirimiphos methyl associated with existing EC MRLs- Rev. 3, January 2009. Prepared by the Rapporteur Member State UK.
2. Pirimiphos-methyl: Chronic Dietary Risk Assessment. Syngenta Position Document, 15 September 2008.
3. Food consumption data provided by Ireland, Denmark by email.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Intended EU use patterns for pirimiphos-methyl

Crop and/ or situation (a)	Member State or Country	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment (L/tonne, kg as/tonne)			PHI (days) (l)	Remarks (m)
				Type (d-f)	Conc. of as (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applica-tions (min)	kg as/hL min max	water L/t min max	kg as/t min max		
Wheat, Barley, Oats, Millet, Sorghum	EU	I	Pests of stored grain	EC	500	Spray	After harvest	1	-		1	0.004	-	
Structural treatment	EU	I	Pests of stored grain	EC	500	Spray	Before storage	1	-		-	-	-	0.05 kg as/100m^2

APPENDIX B – EXISTING EC MRLS

Pesticides - Web Version - EU MRLs (File created on 12/05/2009 17:59)

Pesticide residues and maximum residue levels (mg/kg)

(*) Indicates lower limit of analytical determination

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimiphos-methyl (F)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	1
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	1
110030	Lemons (Citron, lemon)	1
110040	Limes	1
110050	Mandarins (Clementine, tangerine and other hybrids)	2
110990	Others	1
120000	(ii) Tree nuts (shelled or unshelled)	0,05*
120010	Almonds	0,05*
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	0,05*
120050	Coconuts	0,05*
120060	Hazelnuts (Filbert)	0,05*
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	0,05*
120110	Walnuts	0,05*
120990	Others	0,05*
130000	(iii) Pome fruit	0,05*
130010	Apples (Crab apple)	0,05*
130020	Pears (Oriental pear)	0,05*
130030	Quinces	0,05*
130040	Medlar	0,05*
130050	Loquat	0,05*
130990	Others	0,05*
140000	(iv) Stone fruit	0,05*
140010	Apricots	0,05*
140020	Cherries (sweet cherries, sour cherries)	0,05*
140030	Peaches (Nectarines and similar hybrids)	0,05*
140040	Plums (Damson, greengage, mirabelle)	0,05*
140990	Others	0,05*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	
151010	Table grapes	0,05*
151020	Wine grapes	2
152000	(b) Strawberries	0,05*
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,05*
153030	Raspberries (Wineberries)	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,05*
154020	Cranberries	0,05*
154030	Currants (red, black and white)	0,05*
154040	Gooseberries (Including hybrids with other ribes species)	0,05*
154050	Rose hips	0,05*
154060	Mulberries (arbutus berry)	0,05*
154070	Azarole (mediteranean medlar)	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	
162010	Kiwi	2
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	0,05*
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,05*
163070	Guava	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,05*
213020	Carrots	1
213030	Celeriac	0,05*
213040	Horseradish	0,05*
213050	Jerusalem artichokes	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimiphos-methyl (F)
213060	Parsnips	0,05*
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,05*
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	0,05*
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	1
231020	Peppers (Chilli peppers)	1
231030	Aubergines (egg plants) (Pepino)	0,05*
231040	Okra, lady' s fingers	0,05*
231990	Others	0,05*
232000	(b) Cucurbits - edible peel	
232010	Cucumbers	0,1
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson))	0,05*
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	
233010	Melons (Kiwano)	1
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	1
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	1
241020	Cauliflower	1
241990	Others	1
242000	(b) Head brassica	
242010	Brussels sprouts	2
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	0,05*
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*
251010	Lamb´s lettuce (Italian cornsalad)	0,05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,05*
251040	Cress	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner' s lettuce), garden purslane, common purslane, sorrel, glassworth)	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,05*
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory,)	0,05*
256060	Rosemary	0,05*
256070	Thyme (marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	0,05*
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	2
280020	Wild (Chanterelle, Truffle, Morel ,)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimiphos-methyl (F)
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	0,05*
401000	(i) Oilseeds	0,05*
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,05*
401070	Soya bean	0,05*
401080	Mustard seed	0,05*
401090	Cotton seed	0,05*
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	5
500010	Barley	5
500020	Buckwheat	5
500030	Maize	5
500040	Millet (Foxtail millet, teff)	5
500050	Oats	5
500060	Rice	5
500070	Rye	5
500080	Sorghum	5
500090	Wheat (Spelt Triticale)	5
500990	Others	5
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)	
631000	(a) Flowers	0,3
631010	Camomille flowers	0,3
631020	Hybiscus flowers	0,3
631030	Rose petals	0,3
631040	Jasmine flowers	0,3
631050	Lime (linden)	0,3
631990	Others	0,3
632000	(b) Leaves	0,3
632010	Strawberry leaves	0,3
632020	Rooibos leaves	0,3
632030	Maté	0,3
632990	Others	0,3
633000	(c) Roots	0,3
633010	Valerian root	0,3
633020	Ginseng root	0,3
633990	Others	0,3
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,05*
800000	8. SPICES	
810000	(i) Seeds	5
810010	Anise	5
810020	Black caraway	5
810030	Celery seed (Lovage seed)	5
810040	Coriander seed	5
810050	Cumin seed	5
810060	Dill seed	5
810070	Fennel seed	5
810080	Fenugreek	5
810090	Nutmeg	5
810990	Others	5
820000	(ii) Fruits and berries	0,1
820010	Allspice	0,1
820020	Anise pepper (Japan pepper)	0,1
820030	Caraway	0,1
820040	Cardamom	0,1
820050	Juniper berries	0,1
820060	Pepper, black and white (Long pepper, pink pepper)	0,1
820070	Vanilla pods	0,1
820080	Tamarind	0,1
820990	Others	0,1
830000	(iii) Bark	0,05*
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*
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	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pirimiphos-methyl (F)
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

Substance	Legislation	Entry in to force
Pirimiphos-methyl (F)		
	Reg. (EC) No 839/2008	01/09/2008

APPENDIX C – FOOD CONSUMPTION DATA

Chronic consumption data

		Body weight (in kg)															
		74.00	68.50	77.10	60.00	75.20	66.50	63.00	63.00	62.80	60.00	60.00	76.00	66.70	60.00	60.00	60.00
		food intake (g/kg bw / d)															
Code no.	Groups of crops and examples of individual products within the groups to which the MRLs apply	DK adult	ES adult	FI adult	FR all population	IE adult	IT adult	LT adult	NL general	PL general population	PT General population	SE general population 90th percentile	UK Adult	UK vegetarian	WHO regional European diet	WHO Cluster diet B	WHO cluster European D
500000	CEREALS	2.8959	3.1642	1.9118	3.4083	6.6077	5.0492	2.7144	2.7706	0.0010	5.3750	5.0000	2.0944	2.5252	3.6983	11.8867	8.4017
500010	Barley		0.4921	0.0236	0.0067	1.2407	0.0093	0.0599	0.3746		0.0300		0.0263	0.0195	0.3300	0.2800	0.2200
	Barley from breakfast cereals					0.0650											
	Barley from lager		0.4921			4.1300											
	Barley from stout					7.4650											
	Barley from malt					0.2550											
	Pot barley																0.0667
	Barley, pearled															0.0067	0.0067
	Barley flour and grits															0.0050	0.0050
	Barley beer															0.2800	0.2200
	Barley grain																
	Other barley products			0.0236	0.0067		0.0093	0.0599	0.3746		0.0300		0.0263	0.0195	0.3300		
500020	Buckwheat			0.0012		0.2779		0.2136	0.0111							0.0017	0.0267
500030	Maize		0.0823	0.0259		2.2952	0.0182	0.0077	0.0475	0.0010	0.4750		0.0023	0.0079	0.1467	2.4733	0.5300
500040	Millet								0.0013								0.0933
500050	Oats	0.1149		0.0852		0.1822	0.0002	0.0907	0.0316		0.0300		0.0171	0.0480	0.0333	0.0083	0.0700
	Oats in porredge					0.1770											
	Oats from breakfast cereal					0.2130											
	Oats from oatscakes					0.1580											
	Oats rolled															0.0050	0.0367
	Other oats products	0.1149		0.0852			0.0002	0.0907	0.0316		0.0300		0.0171	0.0480	0.0333	0.0033	0.0333
500060	Rice	0.0865	0.2419	0.1090	0.1133	0.1702	0.1789	0.2140	0.1600		0.7850	0.4017	0.3658	0.3823	0.1967	0.5267	0.5533
500070	Rye	0.6811		0.6827		0.1463		1.0767	0.0700		0.1367	0.2950	0.0066	0.0195	0.0250	0.0617	0.4050
500080	Sorghum								0.0016								
500090	Wheat	2.0135	2.3479	0.9841	3.2883	2.2952	4.1355	1.0519	2.0730		3.9183	3.2017	1.6763	2.0480	2.9667	8.5350	6.5033
	White bread	0.662162	1.2360										0.9079	0.9210			
	Whole meal bread	0.216216	0.0791										0.2000	0.9210			
	Pasta	0.189189	0.2472														
	Cakes including cookies	0.527027	0.3588														
	Flour as ingredient		0.0511			0.2720											
	Flour from biscuits					0.1360											
	Flour from bread					0.9790											
	Flour from breakfast cereal					0.2010											
	Flour from cakes and buns					0.1300											
	Flour from pastry and pastry pies					0.1340											
	Flour from pasta and noodels					0.1590											
	Flour from pizza					0.1410											
	Flour from packet/jarred sauces/gravy etc					0.0240											
	Flour from crumb(batter coating					0.0760											
	Wheat bran												0.0618	0.1030			
	Cereals - sweet products						0.6707										
	Bread/pizza (with veg, with other ingredients)						2.3302										
	Bread substitute																
	Pasta (durum whet, egg noodles, filled)						1.1006										
	Churros		0.0200														
	Bread roll		0.3088														
	Triticale flour															1.4850	
	Wheat bulgur wholemeal															0.1700	0.0033
	Wheat flour															4.9383	5.0000
	Wheat macaroni															0.0183	0.0300
	Wheat pastry															0.0183	0.0433
	White bread															0.0017	0.0017
	Whole meal bread															0.0017	0.0017
	Wheat germ															0.0217	0.0217
	Other wheat products (not specified)	0.4189	0.0468	0.9841	3.2883	0.0432	0.0340	1.0519	2.0730		3.9183	3.2017	0.5066	0.1030	2.9667		
500990	Other cereal						0.7071										
1000000	PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS	7.5554	7.8928	6.8257	4.4450	5.9601		5.9920	8.1979			17.6900	4.4645	3.6732	9.3917	7.1850	7.1133
1010000	Meat, preparations of meat, offals,	1.8243	2.4379	0.9270	1.4667	2.9043		1.7046	1.3433			4.4000	1.1592	0.0660	3.9233	3.4800	1.6433
1020000	Milk and cream, not concentrated, nor	5.3649	4.9513	5.6730	2.6783	2.7832		3.9606	6.5621			12.3750	2.9987	3.2579	4.8217	3.1767	5.0433
1030000	Birds' eggs	0.3662	0.4658	0.2257	0.3000	0.2726		0.3269	0.2925			0.8833	0.3066	0.3493	0.6250	0.4950	0.4083

Chronic consumption data

		60.00	60.00	16.15	22.00	34.50	8.80	10.60	41.60	17.10	14.60	8.70
Code no.	Groups of crops and examples of individual products within the groups to which the MRLs apply	WHO cluster diet E	WHO Cluster diet F	DE child	DK child	ES child	FR infant	FR toddler	IT kids/toddler	NL child	UK Toddler	UK Infant
500000	CEREALS	6.0717	5.4500	5.5666	10.4227	5.2084	0.9318	2.9811	8.3785	5.6333	4.5736	4.5316
500010	Barley	0.8100	0.6017	0.0124		0.0021			0.0106	0.0257	0.0137	
	Barley from breakfast cereals											
	Barley from lager											
	Barley from stout											
	Barley from malt											
	Pot barley	0.0333	0.2083									
	Barley, pearled	0.0067	0.0150									
	Barley flour and grits	0.0083	0.0150									
	Barley beer	0.8100	0.5377									
	Barley grain								0.0017			
	Other barley products			0.0124		0.0021			0.0089	0.0257	0.0137	
500020	Buckwheat	0.0250	0.0017	0.0062						0.0515		
500030	Maize	0.5550	0.1250	0.1486		0.2877			0.0267	0.1462	0.0120	1.0259
500040	Millet	0.0033		0.0186						0.0240		
500050	Oats	0.0950	0.1483	0.2043	0.3955				0.0005	0.1070	0.0479	0.2529
	Oats in porredge											
	Oats from breakfast cereal											
	Oats from oatscakes											
	Oats rolled	0.0500	0.0783									
	Other oats products	0.0450	0.0700	0.2043	0.3955				0.0005	0.1070	0.0479	0.2529
500060	Rice	0.2100	0.2100	0.2663	0.1045	0.4831	0.0909	0.3585	0.1923	0.3526	0.5753	0.6322
500070	Rye	0.4300	0.7633	0.7926	4.4182					0.1789	0.0068	
500080	Sorghum			0.0186						0.0058		
500090	Wheat	3.9433	3.6000	4.1115	5.5045	4.4355	0.8409	2.6226	6.6465	4.7415	3.9178	2.6207
	White bread				1.7273	2.2233					2.1849	1.1264
	Whole meal bread				0.4545	0.0290					1.5274	0.8161
	Pasta				0.7727	0.5128						
	Cakes including cookies				1.5000	0.7842						
	Flour as ingredient					0.0911						
	Flour from biscuits											
	Flour from bread											
	Flour from breakfast cereal					0.2477						
	Flour from cakes and buns											
	Flour from pastry and pastry pies											
	Flour from pasta and noodels											
	Flour from pizza											
	Flour from packet/jarred sauce/soups etc											
	Flour from crumb(batter coating											
	Wheat bran										0.3241	0.7816
	Cereals - sweet products								1.4447			
	Bread/pizza (with veg, with other ingredients)								3.2216			
	Bread substitute								0.1601			
	Pasta (durum whet, egg noodles, filled)								1.8534			
	Churros					0.0365						
	Bread roll					0.6383						
	Triticale flour	0.0033										
	Wheat bulgur wholemeal	0.0017										
	Wheat flour	3.0267	2.7700									
	Wheat macaroni	0.0767	0.1267									
	Wheat pastry	0.0283	0.0900									
	White bread	0.0017	0.0167									
	Whole meal bread	0.0017	0.0167									
	Wheat germ	0.0150	0.0200									
	Other wheat products (not specified)			4.1115	0.5500		0.8409	2.6226		4.7415		
500990	Other cereal								1.5020			
1000000	PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS	6.5767	7.2800	23.5418	21.8318	17.6495	27.4318	43.2736		32.8450	23.4863	41.9770
1010000	Meat, preparations of meat, offals,	2.9250	2.8417	1.3684	4.1682	4.3817	1.2500	2.6321		2.9327	1.9384	1.9195
1020000	Milk and cream, not concentrated, nor	2.9933	3.9650	14.2910	12.6318	12.5120	25.7386	39.6226		29.3211	20.6575	38.7126
1030000	Birds' eggs	0.6300	0.4567	1.1146	0.8636	0.7241	0.4432	1.0189		0.5912	0.8904	1.3448

APPENDIX D – EXPOSURE ASSESSMENT, SCENARIO 1

The calculation is based on the detailed food consumption data available for processed cereal grain, taking into account the processing factors derived by EFSA after recalculation of the values based on the information reported in the DAR (UK 2003).

Long-term exposure assessment

					daily intake (% of ADI)										
Groups of crops and examples of individual products within the groups to which the MRLs apply	STMR (mg/kg)	input values for refined calculations	PF	Description PF	DK adult	ES adult	FI adult	FR all population	IE adult	IT adult	LT adult	NL general	PL general population	PT General population	SE general population 90th percentile
CEREALS															
Barley	2.65														
Barley from breakfast cereals		0.24	0.090	Barley pearl					0.3876						
Barley from lager		0.01	0.004	Barley - beer		0.1304			1.0945						
Barley from stout		0.01	0.004	Barley - beer					1.9782						
Barley from malt		0.01	0.004	Barley - beer					0.0676						
Pot barley		0.24	0.09	Barley pearl											
Barley, pearled		0.24	0.09	Barley pearl											
Barley flour and grits		0.24	0.09	Barley pearl											
Barley beer		0.01	0.004	Barley - beer											
Barley grain		0.24	0.09	Barley pearl											
Other barley products		0.24	0.09	Barley pearl			0.1404	0.0398		0.0556	0.3569	2.2336		0.1789	
Buckwheat	0.05	0.05	1.00				0.0015		0.3474		0.2670	0.0139			
Maize	0.05	0.05	1.00			0.1029	0.0324		2.8690	0.0227	0.0096	0.0593	0.0013	0.5938	
Millet	2.65	2.65	1.00									0.0841			
Oats	2.65														
Oats in porredge		0.48	0.18	Rolled oats					2.1107						
Oats from breakfast cereal		0.48	0.18	Rolled oats					2.5400						
Oats from oatscakes		0.32	0.12	Wheat white bread					1.2561						
Oats rolled		0.48	0.18	Rolled oats											
Other oats products		0.48	0.18	Rolled oats	1.3698		1.0160			0.0018	1.0818	0.3767		0.3578	
Rice	0.05	0.05	1.00		0.1081	0.3024	0.1363	0.1417	0.2128	0.2237	0.2675	0.2000		0.9813	0.5021
Rye	0.05	0.05	1.00		0.8514		0.8534		0.1828		1.3459	0.0875		0.1708	0.3688
Sorghum	2.65	2.65	1.00									0.1052			
Wheat	2.65														
White bread		0.32	0.12	Wheat white bread	5.264189	9.8261									
Whole meal bread		1.14	0.43	Wheat wholemeal bread	6.159459	2.2547									
Pasta		0.50	0.19	Wheat flour	2.381419	3.1120									
Cakes including cookies		0.50	0.19	Wheat flour	6.633953	4.5163									
Flour as ingredient		0.50	0.19	Wheat flour		0.6433			3.4238						
Flour from biscuits		0.32	0.12	Wheat white bread					1.0812						
Flour from bread		0.32	0.12	Wheat white bread					7.7831						
Flour from breakfast cereal		0.87	0.33	Wheat bran breakfast cereal					4.3944						
Flour from cakes and buns		0.32	0.12	Wheat white bread					1.0335						
Flour from pastry and pastry pies		0.50	0.19	Wheat flour					1.6867						
Flour from pasta and noodels		0.50	0.19	Wheat flour					2.0014						
Flour from pizza		0.32	0.12	Wheat white bread					1.1210						
Flour from packet/jarred sauce/soups etc		0.50	0.19	Wheat flour					0.3021						
Flour from crumb(batter coating		0.50	0.19	Wheat flour					0.9567						
Wheat bran		5.88	2.22	Wheat bran											
Cereals - sweet products		0.50	0.19	Wheat flour						8.4421					
Bread/pizza (with veg, with other		0.32	0.12	Wheat white bread						18.5253					
Bread substitute		0.50	0.19	Wheat flour											
Pasta (durum whet, egg noodles, filled)		0.50	0.19	Wheat flour						13.8538					
Churros		0.50	0.19	Wheat flour		0.2518									
Bread roll		0.32	0.12	Wheat white bread		2.4554									
Triticale flour		0.50	0.19	Wheat flour											
Wheat bulgur wholemeal		2.01	0.76	Wheat wholemeal flour											
Wheat flour		0.50	0.19	Wheat flour											
Wheat macaroni		0.50	0.19	Wheat flour											
Wheat pastry		0.32	0.12	Wheat white bread											
White bread		0.32	0.12	Wheat white bread											
Whole meal bread		1.14	0.43	Wheat wholemeal bread											
Wheat germ															
Other wheat products (not specified)		0.50	0.19	Wheat flour	5.2731	0.5890	12.3873	41.3919	0.5439	0.4275	13.2403	26.0941		49.3220	40.3010
Other cereal	0.05	0.05	1.00							0.8839					
PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS			-												
Meat, preparations of meat, offals, blood, animal fats fresh chilled or		0.01	-		0.456	0.609	0.232	0.367	0.728		0.426	0.336			1.100
Milk and cream, not concentrated, nor containing		0.01	-		1.341	1.238	1.418	0.670	0.696		0.990	1.641			3.094
Birds' eggs		0.01	-		0.092	0.116	0.056	0.075	0.069		0.082	0.073			0.221
TMDI (%of ADI)					**29.930**	**26.148**	**16.274**	**42.685**	**38.864**	**42.436**	**18.067**	**31.304**	**0.001**	**51.604**	**45.586**

Long-term exposure assessment

Groups of crops and examples of individual products within the groups to which the MRLs apply	UK Adult	UK vegetarian	WHO regional European diet	WHO Cluster diet B	WHO cluster European D	WHO cluster diet E	WHO Cluster diet F	DE child	DK child	ES child	FR infant	FR toddler	IT kids/toddler	NL child	UK Toddler	UK Infant
CEREALS																
Barley																
Barley from breakfast cereals																
Barley from lager																
Barley from stout																
Barley from malt																
Pot barley					0.3975	0.1988	1.2422									
Barley, pearled				0.0398	0.0398	0.0398	0.0894									
Barley flour and grits				0.0298	0.0298	0.0497	0.0894									
Barley beer				0.0742	0.0583	0.2147	0.1425									
Barley grain													0.0100			
Other barley products	0.1569	0.1162	1.9676					0.0738		0.0125			0.0530	0.1534	0.0817	
Buckwheat				0.0021	0.0333	0.0313	0.0021	0.0077						0.0643		
Maize	0.0029	0.0099	0.1833	3.0917	0.6625	0.6938	0.1563	0.1858		0.3596			0.0333	0.1827	0.0150	1.2823
Millet					6.1833	0.2208		1.2307						1.5885		
Oats																
Oats in porredge																
Oats from breakfast cereal																
Oats from oatscakes																
Oats rolled				0.0596	0.4373	0.5963	0.9341									
Other oats products	0.2040	0.5721	0.3975	0.0398	0.3975	0.5366	0.8348	2.4367	4.7158				0.0057	1.2762	0.5717	3.0155
Rice	0.4572	0.4779	0.2458	0.6583	0.6917	0.2625	0.2625	0.3328	0.1307	0.6039	0.1136	0.4481	0.2403	0.4408	0.7192	0.7902
Rye	0.0082	0.0244	0.0313	0.0771	0.5063	0.5375	0.9542	0.9907	5.5227					0.2237	0.0086	
Sorghum								1.2307						0.3874		
Wheat																
White bread	7.2178	7.3220							13.7318	17.6754					17.3702	8.9552
Whole meal bread	5.6975	26.2370							12.9489	0.8262					43.5117	23.2484
Pasta									9.7267	6.4544						
Cakes including cookies									18.8813	9.8714						
Flour as ingredient										1.1463						
Flour from biscuits																
Flour from bread																
Flour from breakfast cereal										5.4149						
Flour from cakes and buns																
Flour from pastry and pastry pies																
Flour from pasta and noodels																
Flour from pizza																
Flour from packet/jarred sauce/soups etc																
Flour from crumb(batter coating																
Wheat bran	9.0954	15.1487													47.6726	114.9552
Cereals - sweet products													18.1853			
Bread/pizza (with veg, with other													25.6120			
Bread substitute													2.0152			
Pasta (durum whet, egg noodles, filled)													23.3292			
Churros										0.4600						
Bread roll										5.0748						
Triticale flour				18.6924		0.0420										
Wheat bulgur wholemeal				8.5595	0.1678	0.0839										
Wheat flour				62.1613	62.9375	38.0982	34.8674									
Wheat macaroni				0.2308	0.3776	0.9650	1.5944									
Wheat pastry				0.1458	0.3445	0.2253	0.7155									
White bread				0.0133	0.0133	0.0133	0.1325									
Whole meal bread				0.0475	0.0475	0.0475	0.4748									
Wheat germ																
Other wheat products (not specified)	6.3766	1.2962	37.3429					51.7529	6.9231		10.5849	33.0125		59.6839		
Other cereal													1.8776			
PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS																
Meat, preparations of meat, offals, blood, animal fats fresh chilled or	0.290	0.016	0.981	0.870	0.411	0.731	0.710	0.342	1.042	1.095	0.313	0.658		0.733	0.485	0.480
Milk and cream, not concentrated, nor containing	0.750	0.814	1.205	0.794	1.261	0.748	0.991	3.573	3.158	3.128	6.435	9.906		7.330	5.164	9.678
Birds' eggs	0.077	0.087	0.156	0.124	0.102	0.158	0.114	0.279	0.216	0.181	0.111	0.255		0.148	0.223	0.336
TMDI (%of ADI)	**30.333**	**52.123**	**42.511**	**95.711**	**75.099**	**44.494**	**44.308**	**62.435**	**76.997**	**52.304**	**17.557**	**44.279**	**71.362**	**72.212**	**115.822**	**162.741**

Pirimiphos-methyl

Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.004**	ARfD (mg/kg bw):	**0.15**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2007**	Year of evaluation:	**2007**

The calculation is based on the detailed food consumption data available for processed cereal grain, taking into account the processing factors derived by EFSA after recalculation of the values based on the information reported in the DAR (UK 2003).

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

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
163

No of diets exceeding ADI: 2

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
162.7	UK Infant	115.0	Wheat bran	23.2	Whole meal bread	9.7	Milk and cream,	12.6
115.8	UK Toddler	47.7	Wheat bran	43.5	Whole meal bread	17.4	White bread	6.6
95.7	WHO Cluster diet B	62.2	Wheat flour	18.7	Triticale flour	8.6	Wheat bulgur wholemeal	5.7
77.0	DK child	18.9	Cakes including cookies	13.7	White bread	12.9	Whole meal bread	10.1
75.1	WHO cluster European D	62.9	Wheat flour	6.2	Millet	1.3	Milk and cream,	3.7
72.2	NL child	59.7	Other wheat products (not specified)	7.3	Milk and cream,	1.6	Millet	9.1
71.4	IT kids/toddler	25.6	Bread/pizza (with veg, with other	23.3	Pasta (durum whet, egg noodles, filled)	18.2	Cereals - sweet products	2.2
62.4	DE child	51.8	Other wheat products (not specified)	3.6	Milk and cream,	2.4	Other oats products	5.7
52.3	ES child	17.7	White bread	9.9	Cakes including cookies	6.5	Pasta	5.4
52.1	UK vegetarian	26.2	Whole meal bread	15.1	Wheat bran	7.3	White bread	1.4
51.6	PT General population	49.3	Other wheat products (not specified)	1.0	Rice	0.6	Maize	1.7
45.6	SE general population 90th percentile	40.3	Other wheat products (not specified)	3.1	Milk and cream,	1.1	Meat, preparations of meat, offals,	5.3
44.5	WHO cluster diet E	38.1	Wheat flour	1.0	Wheat macaroni	0.7	Milk and cream,	3.4
44.3	WHO Cluster diet F	34.9	Wheat flour	1.6	Wheat macaroni	1.2	Pot barley	3.3
44.3	FR toddler	33.0	Other wheat products (not specified)	9.9	Milk and cream,	0.7	Meat, preparations of meat, offals,	11.3
42.7	FR all population	41.4	Other wheat products (not specified)	0.7	Milk and cream,	0.4	Meat, preparations of meat, offals,	1.3
42.5	WHO regional European diet	37.3	Other wheat products (not specified)	2.0	Other barley products	1.2	Milk and cream,	2.8
42.4	IT adult	18.5	Bread/pizza (with veg, with other	13.9	Pasta (durum whet, egg noodles, filled)	8.4	Cereals - sweet products	1.1
38.9	IE adult	7.8	Flour from bread	4.4	Flour from breakfast cereal	3.4	Flour as ingredient	8.2
31.3	NL general	26.1	Other wheat products (not specified)	2.2	Other barley products	1.6	Milk and cream,	2.4
30.3	UK Adult	9.1	Wheat bran	7.2	White bread	6.4	Other wheat products (not	1.6
29.9	DK adult	6.6	Cakes including cookies	6.2	Whole meal bread	5.3	Other wheat products (not	2.8
26.1	ES adult	9.8	White bread	4.5	Cakes including cookies	3.1	Pasta	2.5
18.1	LT adult	13.2	Other wheat products (not specified)	1.3	Rye	1.1	Other oats products	3.4
17.6	FR infant	10.6	Other wheat products (not specified)	6.4	Milk and cream,	0.3	Meat, preparations of meat, offals,	7.0
16.3	FI adult	12.4	Other wheat products (not specified)	1.4	Milk and cream,	1.0	Other oats products	2.7
0.0	PL general population	0.0	Maize		CEREALS		CEREALS	0.0

Conclusion:

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 0 % to 163 % of the ADI.
For 2 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.

APPENDIX E – EXPOSURE ASSESSMENT, SCENARIO 2

The calculation is based on the detailed food consumption data available for processed cereal grain, taking into account the processing factors derived by EFSA after recalculation of the values based on the information reported in the DAR (UK 2003).It is assumed that wheat bran is consumed in form of bran based breakfast cereals for which a processing factor of 0.33 is applicable.

Long-term exposure assessment

					daily intake (% of ADI)										
Groups of crops and examples of individual products within the groups to which the MRLs apply	STMR (mg/kg)	input values for refined calculations	PF	Description PF	DK adult	ES adult	FI adult	FR all population	IE adult	IT adult	LT adult	NL general	PL general population	PT General population	SE general population 90th percentile
CEREALS															
Barley	2.65														
Barley from breakfast cereals		0.24	0.090	Barley pearl					0.3876						
Barley from lager		0.01	0.004	Barley - beer		0.1304			1.0945						
Barley from stout		0.01	0.004	Barley - beer					1.9782						
Barley from malt		0.01	0.004	Barley - beer					0.0676						
Pot barley		0.24	0.09	Barley pearl											
Barley, pearled		0.24	0.09	Barley pearl											
Barley flour and grits		0.24	0.09	Barley pearl											
Barley beer		0.01	0.004	Barley - beer											
Barley grain		0.24	0.09	Barley pearl											
Other barley products		0.24	0.09	Barley pearl			0.1404	0.0398		0.0556	0.3569	2.2336		0.1789	
Buckwheat	0.05	0.05	1.00				0.0015		0.3474		0.2670	0.0139			
Maize	0.05	0.05	1.00			0.1029	0.0324		2.8690	0.0227	0.0096	0.0593	0.0013	0.5938	
Millet	2.65	2.65	1.00									0.0841			
Oats	2.65														
Oats in porredge		0.48	0.18	Rolled oats					2.1107						
Oats from breakfast cereal		0.48	0.18	Rolled oats					2.5400						
Oats from oatscakes		0.32	0.12	Wheat white bread					1.2561						
Oats rolled		0.48	0.18	Rolled oats											
Other oats products		0.48	0.18	Rolled oats	1.3698		1.0160			0.0018	1.0818	0.3767		0.3578	
Rice	0.05	0.05	1.00		0.1081	0.3024	0.1363	0.1417	0.2128	0.2237	0.2675	0.2000		0.9813	0.5021
Rye	0.05	0.05	1.00		0.8514		0.8534		0.1828		1.3459	0.0875		0.1708	0.3688
Sorghum	2.65	2.65	1.00									0.1052			
Wheat	2.65														
White bread		0.32	0.12	Wheat white bread	5.264189	9.8261									
Whole meal bread		1.14	0.43	Wheat wholemeal bread	6.159459	2.2547									
Pasta		0.50	0.19	Wheat flour	2.381419	3.1120									
Cakes including cookies		0.50	0.19	Wheat flour	6.633953	4.5163									
Flour as ingredient		0.50	0.19	Wheat flour		0.6433			3.4238						
Flour from biscuits		0.50	0.19	Wheat flour					1.7119						
Flour from bread		0.50	0.19	Wheat flour					12.3232						
Flour from breakfast cereal		0.50	0.19	Wheat flour					2.5301						
Flour from cakes and buns		0.50	0.19	Wheat flour					1.6364						
Flour from pastry and pastry pies		0.50	0.19	Wheat flour					1.6867						
Flour from pasta and noodels		0.50	0.19	Wheat flour					2.0014						
Flour from pizza		0.50	0.19	Wheat flour					1.7748						
Flour from packet/jarred sauce/soups etc		0.50	0.19	Wheat flour					0.3021						
Flour from crumb(batter coating		0.50	0.19	Wheat flour					0.9567						
Wheat bran		0.87	0.33	Bran based breakfast cereal											
Cereals - sweet products		0.50	0.19	Wheat flour						8.4421					
Bread/pizza (with veg, with other		0.32	0.12	Wheat white bread						18.5253					
Bread substitute		0.32	0.12	Wheat white bread											
Pasta (durum whet, egg noodles, filled)		0.50	0.19	Wheat flour						13.8538					
Churros		0.50	0.19	Wheat flour		0.2518									
Bread roll		0.32	0.12	Wheat white bread		2.4554									
Triticale flour		0.50	0.19	Wheat flour											
Wheat bulgur wholemeal		2.01	0.76	Wheat wholemeal flour											
Wheat flour		0.50	0.19	Wheat flour											
Wheat macaroni		0.50	0.19	Wheat flour											
Wheat pastry		0.32	0.12	Wheat white bread											
White bread		0.32	0.12	Wheat white bread											
Whole meal bread		1.14	0.43	Wheat wholemeal bread											
Wheat germ															
Other wheat products (not specified)		0.50	0.19	Wheat flour	5.2731	0.5890	12.3873	41.3919	0.5439	0.4275	13.2403	26.0941		49.3220	40.3010
Other cereal	0.05	0.01	0.19	Wheat flour						0.1679					
PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS			-												
Meat, preparations of meat, offals, blood, animal fats fresh chilled or		0.01	-		0.456	0.609	0.232	0.367	0.726		0.426	0.336			1.100
Milk and cream, not concentrated, nor containing		0.01	-		1.341	1.238	1.418	0.670	0.696		0.990	1.641			3.094
Birds' eggs		0.01	-		0.092	0.116	0.056	0.075	0.068		0.082	0.073			0.221
TMDI (%of ADI)					**29.930**	**26.148**	**16.274**	**42.685**	**43.428**	**41.720**	**18.067**	**31.304**	**0.001**	**51.604**	**45.586**

Long-term exposure assessment

Groups of crops and examples of individual products within the groups to which the MRLs apply	UK Adult	UK vegetarian	WHO regional European diet	WHO Cluster diet B	WHO cluster European D	WHO cluster diet E	WHO Cluster diet F	DE child	DK child	ES child	FR infant	FR toddler	IT kids/toddler	NL child	UK Toddler	UK Infant
CEREALS																
Barley																
Barley from breakfast cereals																
Barley from lager																
Barley from stout																
Barley from malt																
Pot barley					0.3975	0.1988	1.2422									
Barley, pearled				0.0398	0.0398	0.0398	0.0894									
Barley flour and grits				0.0298	0.0298	0.0497	0.0894									
Barley beer				0.0742	0.0583	0.2147	0.1425									
Barley grain													0.0100			
Other barley products	0.1569	0.1162	1.9676					0.0738		0.0125			0.0530	0.1534	0.0817	
Buckwheat				0.0021	0.0333	0.0313	0.0021	0.0077						0.0643		
Maize	0.0029	0.0099	0.1833	3.0917	0.6625	0.6938	0.1563	0.1858		0.3596			0.0333	0.1827	0.0150	1.2823
Millet					6.1833	0.2208		1.2307						1.5885		
Oats																
Oats in porredge																
Oats from breakfast cereal																
Oats from oatscakes																
Oats rolled				0.0596	0.4373	0.5963	0.9341									
Other oats products	0.2040	0.5721	0.3975	0.0398	0.3975	0.5366	0.8348	2.4367	4.7158				0.0057	1.2762	0.5717	3.0155
Rice	0.4572	0.4779	0.2458	0.6583	0.6917	0.2625	0.2625	0.3328	0.1307	0.6039	0.1136	0.4481	0.2403	0.4408	0.7192	0.7902
Rye	0.0082	0.0244	0.0313	0.0771	0.5063	0.5375	0.9542	0.9907	5.5227					0.2237	0.0086	
Sorghum								1.2307						0.3874		
Wheat																
White bread	7.2178	7.3220							13.7318	17.6754					17.3702	8.9552
Whole meal bread	5.6975	26.2370							12.9489	0.8262					43.5117	23.2484
Pasta									9.7267	6.4544						
Cakes including cookies									18.8813	9.8714						
Flour as ingredient										1.1463						
Flour from biscuits																
Flour from bread																
Flour from breakfast cereal										3.1177						
Flour from cakes and buns																
Flour from pastry and pastry pies																
Flour from pasta and noodels																
Flour from pizza																
Flour from packet/jarred sauce/soups etc																
Flour from crumb(batter coating																
Wheat bran	1.3520	2.2518													7.0865	17.0879
Cereals - sweet products													18.1853			
Bread/pizza (with veg, with other													25.6120			
Bread substitute													1.2728			
Pasta (durum whet, egg noodles, filled)													23.3292			
Churros										0.4600						
Bread roll										5.0748						
Triticale flour				18.6924		0.0420										
Wheat bulgur wholemeal				8.5595	0.1678	0.0839										
Wheat flour				62.1613	62.9375	38.0982	34.8674									
Wheat macaroni				0.2308	0.3776	0.9650	1.5944									
Wheat pastry				0.1458	0.3445	0.2253	0.7155									
White bread				0.0133	0.0133	0.0133	0.1325									
Whole meal bread				0.0475	0.0475	0.0475	0.4748									
Wheat germ																
Other wheat products (not specified)	6.3766	1.2962	37.3429					51.7529	6.9231		10.5849	33.0125		59.6839		
Other cereal													0.3567			
PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS																
Meat, preparations of meat, offals, blood, animal fats fresh chilled or	0.290	0.016	0.981	0.870	0.411	0.731	0.710	0.342	1.042	1.095	0.313	0.658		0.733	0.485	0.480
Milk and cream, not concentrated, nor containing	0.750	0.814	1.205	0.794	1.261	0.748	0.991	3.573	3.158	3.128	6.435	9.906		7.330	5.164	9.678
Birds' eggs	0.077	0.087	0.156	0.124	0.102	0.158	0.114	0.279	0.216	0.181	0.111	0.255		0.148	0.223	0.336
TMDI (%of ADI)	**22.589**	**39.226**	**42.511**	**95.711**	**75.099**	**44.494**	**44.308**	**62.435**	**76.997**	**50.007**	**17.557**	**44.279**	**69.098**	**72.212**	**75.236**	**64.874**

Pirimiphos-methyl

Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.004**	ARfD (mg/kg bw):	**0.15**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2007**	Year of evaluation:	**2007**

The calculation is based on the detailed food consumption data available for processed cereal grain, taking into account the processing factors derived by EFSA after recalculation of the values based on the information reported in the DAR (UK 2003). It is assumed that wheat bran is consumed in form of bran based breakfast cereals for which a processing factor of 0.33 is applicable.

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

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	96
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
95.7	WHO Cluster diet B	62.2	Wheat flour	18.7	Triticale flour	8.6	Wheat bulgur wholemeal	5.7
77.0	DK child	18.9	Cakes including cookies	13.7	White bread	12.9	Whole meal bread	10.1
75.2	UK Toddler	43.5	Whole meal bread	17.4	White bread	7.1	Wheat bran	6.6
75.1	WHO cluster European D	62.9	Wheat flour	6.2	Millet	1.3	Milk and cream,	3.7
72.2	NL child	59.7	Other wheat products (not specified)	7.3	Milk and cream,	1.6	Millet	9.1
69.1	IT kids/toddler	25.6	Bread/pizza (with veg, with other	23.3	Pasta (durum whet, egg noodles, filled)	18.2	Cereals - sweet products	0.6
64.9	UK Infant	23.2	Whole meal bread	17.1	Wheat bran	9.7	Milk and cream,	12.6
62.4	DE child	51.8	Other wheat products (not specified)	3.6	Milk and cream,	2.4	Other oats products	5.7
51.6	PT General population	49.3	Other wheat products (not specified)	1.0	Rice	0.6	Maize	1.7
50.0	ES child	17.7	White bread	9.9	Cakes including cookies	6.5	Pasta	5.4
45.6	SE general population 90th percentile	40.3	Other wheat products (not specified)	3.1	Milk and cream,	1.1	Meat, preparations of meat, offals,	5.3
44.5	WHO cluster diet E	38.1	Wheat flour	1.0	Wheat macaroni	0.7	Milk and cream,	3.4
44.3	WHO Cluster diet F	34.9	Wheat flour	1.6	Wheat macaroni	1.2	Pot barley	3.3
44.3	FR toddler	33.0	Other wheat products (not specified)	9.9	Milk and cream,	0.7	Meat, preparations of meat, offals,	11.3
43.4	IE adult	12.3	Flour from bread	3.4	Flour as ingredient	2.9	Maize	8.2
42.7	FR all population	41.4	Other wheat products (not specified)	0.7	Milk and cream,	0.4	Meat, preparations of meat, offals,	1.3
42.5	WHO regional European diet	37.3	Other wheat products (not specified)	2.0	Other barley products	1.2	Milk and cream,	2.8
41.7	IT adult	18.5	Bread/pizza (with veg, with other	13.9	Pasta (durum whet, egg noodles, filled)	8.4	Cereals - sweet products	0.4
39.2	UK vegetarian	26.2	Whole meal bread	7.3	White bread	2.3	Wheat bran	1.4
31.3	NL general	26.1	Other wheat products (not specified)	2.2	Other barley products	1.6	Milk and cream,	2.4
29.9	DK adult	6.6	Cakes including cookies	6.2	Whole meal bread	5.3	Other wheat products (not	2.8
26.1	ES adult	9.8	White bread	4.5	Cakes including cookies	3.1	Pasta	2.5
22.6	UK Adult	7.2	White bread	6.4	Other wheat products (not specified)	5.7	Whole meal bread	1.6
18.1	LT adult	13.2	Other wheat products (not specified)	1.3	Rye	1.1	Other oats products	3.4
17.6	FR infant	10.6	Other wheat products (not specified)	6.4	Milk and cream,	0.3	Meat, preparations of meat, offals,	7.0
16.3	FI adult	12.4	Other wheat products (not specified)	1.4	Milk and cream,	1.0	Other oats products	2.7
0.0	PL general population	0.0	Maize		CEREALS		CEREALS	0.0

Conclusion:

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

GLOSSARY / ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DTU	Danish Technical University
dw	dry weight
EC	emulsifiable concentrate
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
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10^{-6})
PRIMo	Pesticide Residues Intake Model
PSD	Pesticide Safety Directorate, United Kingdom
RMS	Rapporteur Member State
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
WHO	World Health Organisation