REASONED OPINION

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for pirimicarb according to Article 12 of Regulation (EC) No 396/2005[1]

European Food Safety Authority[2, 3]

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ABSTRACT

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the pesticide active substance pirimicarb. In order to assess the occurrence of pirimicarb residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission as well as the European authorisations reported by Member States (incl. the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Some information required by the regulatory framework was found to be missing and a possible acute risk to consumers was identified. Hence, the consumer risk assessment is considered indicative only, some MRL proposals derived by EFSA still require further consideration by risk managers and measures for reduction of the consumer exposure should also be considered.

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KEY WORDS

pirimicarb, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, carbamates, insecticide

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SUMMARY

Pirimicarb was included in Annex I to Directive 91/414/EEC on 01 February 2007, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked the United Kingdom, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 27 July 2011 and, after having considered several comments made by EFSA, the RMS provided on 19 November 2012 a revised PROFile.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS, EFSA issued on 28 October 2013 a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 10 January 2014 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of pirimicarb was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.035 mg/kg bw per d and 0.1 mg/kg bw, respectively. These toxicological reference values can be applied to desmethyl pirimicarb, desmethyl formamido pirimicarb and hydroxypyrimidine metabolites.

Primary crop metabolism of pirimicarb was investigated in three different crop groups following foliar application. Based on these studies, EFSA proposes to define the residue for enforcement in all plant commodities as pirimicarb only and for risk assessment as the sum of pirimicarb, desmethyl pirimicarb and desmethyl formamido pirimicarb, expressed as pirimicarb. Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.01 mg/kg in high water content, high oil content, acidic and dry commodities.

Regarding the magnitude of the residues in primary crops, the available residues data were considered sufficient to derive appropriate MRL proposals and risk assessment values for all commodities under evaluation, except for quinces, stone fruits, cane fruits, onions, tomatoes, aubergines, cucurbits with edible peel, melons, watermelons, Brussels sprouts, head cabbage, leafy brassica, beet leaves, witloof, beans and peas with pods, cardoons, celery, globe artichokes, pulses (dry), linseed, borage, rape seed, maize and herbal infusions where only tentative MRLs could be derived; and for table and wine grapes, flowering brassica, kohlrabi, beans without pods, fresh lentils, leek, mustard seeds and spices (seeds, fruits and berries) where the available data were insufficient to derive tentative MRLs.

The hydrolysis studies demonstrated that under pasteurisation, sterilisation and baking/boiling/brewing conditions, pirimicarb remained stable in processed commodities. Studies investigating the magnitude of residues in processed commodities of fruits and fruiting vegetables, leafy vegetables, legume vegetables and cereals were also reported. Results from these studies were however disregarded as residues in both raw and processed commodities were expressed as the sum of pirimicarb and desmethyl pirimicarb and no information on the level of pirimicarb only was available.

The metabolism of pirimicarb in rotational crops was evaluated in a confined rotational crops metabolism study. It is concluded that metabolic patterns in primary and succeeding crops are similar, but the presence of pirimicarb and pirimicarb metabolites in crops grown in rotation cannot be excluded.

Based on the uses reported by the RMS, significant intakes were calculated for dairy ruminant, meat ruminants, poultry and pigs. The metabolism studies conducted with pirimicarb on poultry showed that residue levels in poultry commodities are expected to remain below the enforcement LOQ of 0.01 mg/kg. Hence, the residue definition in poultry is proposed by default as pirimicarb only. Validated analytical methods for enforcement of this residue definition in poultry commodities are

available. Regarding ruminants, a high level of TRR remains unidentified in the reported metabolism study. Considering also the lack of residue data for some feed items which can lead to an underestimation of the calculated dietary burdens, further clarifications on the identity of the radioactive residue are required. Consequently EFSA cannot conclude on the residue definition in ruminants and the submission of a new metabolism study in ruminants is still required.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. An exceedance of the ARfD was identified for scarole, lettuce, spinach, purslane, cauliflower, broccoli, kale, Chinese cabbage, apple, pear and leek representing 2815 %, 866 %, 728 %, 487 %, 370 %, 326 %, 298 %, 164 %, 126 %, 117 %, 100 % of the ARfD, respectively. Considering fall-back MRLs for these crops (except for cauliflower, broccoli and leek, which were excluded from the calculation), the highest chronic exposure represented 20 % of the ADI (German children) and the highest acute exposure amounted to 99.7 % of the ARfD (rocket).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for pirimicarb. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and exceedences of the ARfD were identified for the existing CXLs in lettuce, apples, pears and peaches, representing 173 %, 123 %, 112 % and 104 % of the ARfD, respectively. Excluding these CXLs from the calculation, the highest chronic exposure represented 20 % of the ADI (German children) and the highest acute exposure amounted to 99.7 % of the ARfD (rocket).

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, some tentative MRLs or existing EU MRLs need to be confirmed by the following data:

- a validated analytical method for enforcement of pirimicarb in herbal infusions and spices;
- a metabolism study in ruminants;
- additional residues trials supporting authorisations on apples, pears, quinces, cherries, peaches, table and wine grapes, cane fruits, melons, watermelons, Brussels sprouts, kale, kohlrabi, scarole, purslane, beet leaves (chard), witloof, fresh beans and peas with pods, fresh beans without pods, fresh lentils, cardoons, celery, linseed, mustard seed, borage, rape seed and spices (seeds, fruits and berries).

It is highlighted, that some of the MRLs derived result from a CXL or from a GAP in one climatic zone only, while other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the need for additional residues trials which are not expected to impact on the validity of the MRLs derived but which might have an impact on certain national authorisations for the following crops:

- hazelnuts, walnuts, apricots, plums, blueberries, currants, gooseberries, parsley root, radishes, onions, tomatoes, peppers, aubergines, cucurbits with edible peel, head cabbage, Chinese cabbage, lettuce, other salads (except scarole), spinach, fresh herbs, fennel, globe artichokes, dry pulses, sunflower seeds, maize, barley, oats, wheat, rye, alfalfa and grass.

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level. The Member States are recommended in any case to reconsider or withdraw their national authorisations on apples, pears, leafy brassica, lettuce, scarole, spinach and purslane in order to ensure that the fall-back MRLs derived in this review are not exceeded for these crops and to withdraw their national authorisations on flowering brassica and leek, for which no fall-back MRL could be derived. Member States granting authorisations for pirimicarb should take the appropriate risk mitigation measures (e.g. definition of pre-planting intervals) in order to avoid the presence of significant residues in rotational crops.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. Storage stability study in acidic commodities and storage conditions of the samples from the supervised residue trials are therefore considered desirable but not essential.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition (existing): sum of pirimicarb and desmethyl pirimicarb, expressed as pirimicarb **Enforcement residue definition (proposed):** pirimicarb					
110010	Grapefruit	3	3	3	Recommended [(a)]
110020	Oranges	3	3	3	Recommended [(a)]
110030	Lemons	3	3	3	Recommended [(a)]
110040	Limes	3	3	3	Recommended [(a)]
110050	Mandarins	3	3	3	Recommended [(a)]
120010	Almonds	1	-	0.02	Recommended [(b)]
120040	Chestnuts	1	-	0.02	Recommended [(b)]
120060	Hazelnuts	1	-	0.02	Recommended [(b)]
120110	Walnuts	1	-	0.02	Recommended [(b)]
130010	Apples	2	1	0.5	Further consideration needed [(c)]
130020	Pears	2	1	0.5	Further consideration needed [(c)]
130030	Quinces	2	1	1.5	Further consideration needed [(d)]
130040	Medlar	2	1	1	Recommended [(a)]
130050	Loquat	2	1	1	Recommended [(a)]
140010	Apricots	2	3	3	Recommended [(e)]
140020	Cherries	5	3	5	Further consideration needed [(d)]
140030	Peaches	2	3	1.5	Further consideration needed [(c)]
140040	Plums	1	3	3	Recommended [(e)]
151010	Table grapes	1	-	1	Further consideration needed [(f)]
151020	Wine grapes	1	-	1	Further consideration needed [(f)]
152000	Strawberries	3	-	1.5	Recommended [(b)]
153010	Blackberries	2	1	4	Further consideration needed [(d)]
153020	Dewberries	2	1	4	Further consideration needed [(d)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
153030	Raspberries	2	1	4	Further consideration needed [(d)]
154010	Blueberries	1	1	1	Recommended [(g)]
154020	Cranberries	1	1	1	Recommended [(g)]
154030	Currants (red, black and white)	1	1	1	Recommended [(g)]
154040	Gooseberries	1	1	1	Recommended [(g)]
154050	Rose hips	1	1	1	Recommended [(a)]
154060	Mulberries	1	1	1	Recommended [(a)]
154070	Azarole (mediteranean medlar)	1	1	1	Recommended [(g)]
154080	Elderberries	2	1	1	Recommended [(a)]
211000	Potatoes	0.2	0.05	0.05	Recommended [(g)]
212010	Cassava	0.5	0.05	0.05	Recommended [(a)]
212020	Sweet potatoes	0.5	0.05	0.05	Recommended [(a)]
212030	Yams	0.5	0.05	0.05	Recommended [(a)]
212040	Arrowroot	0.5	0.05	0.05	Recommended [(a)]
213010	Beetroot	0.5	0.05	0.05	Recommended [(g)]
213020	Carrots	0.5	0.05	0.05	Recommended [(g)]
213030	Celeriac	0.5	0.05	0.05	Recommended [(g)]
213040	Horseradish	0.5	0.05	0.05	Recommended [(g)]
213050	Jerusalem artichokes	0.5	0.05	0.05	Recommended [(g)]
213060	Parsnips	0.5	0.05	0.05	Recommended [(g)]
213070	Parsley root	0.5	0.05	0.05	Recommended [(g)]
213080	Radishes	0.5	0.05	0.05	Recommended [(g)]
213090	Salsify	0.5	0.05	0.05	Recommended [(g)]
213100	Swedes	0.5	0.05	0.05	Recommended [(g)]
213110	Turnips	0.5	0.05	0.05	Recommended [(g)]
220010	Garlic	0.5	0.1	0.1	Recommended [(a)]
220020	Onions	0.5	0.1	0.1	Recommended [(e)]
231010	Tomatoes	1	0.5	0.5	Recommended [(e)]
231020	Peppers	1	0.5	0.5	Recommended [(g)]
231030	Aubergines (egg plants)	1	0.5	0.5	Recommended [(e)]
231040	Okra, lady's fingers	1	0.5	0.5	Recommended [(a)]
232010	Cucumbers	1	1	1	Recommended [(e)]
232020	Gherkins	1	1	1	Recommended [(e)]
232030	Courgettes	1	1	1	Recommended [(e)]
233010	Melons	1	0.2	0.4	Further consideration needed [(d)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
233020	Pumpkins	1	1	1	Recommended [g]
233030	Watermelons	1	-	0.5	Further consideration needed [h]
234000	Sweet corn	0.5	0.05	0.05	Recommended [g]
241010	Broccoli	2	0.5	0.5	Recommended [i]
241020	Cauliflower	2	0.5	0.5	Recommended [i]
242010	Brussels sprouts	1	0.5	0.6	Further consideration needed [d]
242020	Head cabbage	1	0.5	0.5	Recommended [e]
243010	Chinese cabbage	2	0.5	0.5	Recommended [e]
243020	Kale	1	0.3	0.3	Further consideration needed [d]
244000	Kohlrabi	0.5	0.5	0.5	Further consideration needed [j]
251010	Lamb's lettuce	5	-	15	Recommended [b]
251020	Lettuce	5	5	1.5	Recommended [n]
251030	Scarole	1	-	1	Further consideration needed [h]
251040	Cress	5	-	15	Recommended [b]
251050	Land cress	5	-	15	Recommended [b]
251060	Rocket, Rucola	5	-	15	Recommended [b]
251070	Red mustard	5	-	15	Recommended [b]
251080	Leaves and sprouts of Brassica spp	5	-	15	Recommended [b]
252010	Spinach	2	-	0.06	Recommended [b]
252020	Purslane	5	-	0.01*	Further consideration needed [h]
252030	Beet leaves (chard)	5	-	0.06	Further consideration needed [h]
255000	Witloof	2	-	0.05	Further consideration needed [h]
256010	Chervil	5	-	0.8	Recommended [b]
256020	Chives	5	-	0.8	Recommended [b]
256030	Celery leaves	5	-	3	Recommended [b]
256040	Parsley	5	-	3	Recommended [b]
256050	Sage	5	-	0.8	Recommended [b]
256060	Rosemary	5	-	0.8	Recommended [b]
256070	Thyme	5	-	0.8	Recommended [b]
256080	Basil	5	-	0.8	Recommended [b]
256090	Bay leaves (laurel)	5	-	0.8	Recommended [b]
256100	Tarragon	5	-	0.8	Recommended [b]
260010	Beans (fresh, with pods)	1	0.7	1.5	Further consideration needed [d]
260020	Beans (fresh, without pods)	1	0.7	1	Further consideration needed [j]
260030	Peas (fresh, with pods)	1	0.7	1.5	Further consideration needed [d]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
260040	Peas (fresh, without pods)	1	0.7	0.7	Recommended [g]
260050	Lentils (fresh)	0.7	0.7	0.7	Further consideration needed [j]
270010	Asparagus	1	0.01*	0.01*	Recommended [k]
270020	Cardoons	1	-	0.2	Further consideration needed [h]
270030	Celery	5	-	0.15	Further consideration needed [h]
270040	Fennel	5	-	2	Recommended [b]
270050	Globe artichokes	5	5	5	Recommended [e]
270060	Leek	1	-	-	Further consideration needed [l]
270070	Rhubarb	1	-	2	Recommended [b]
300010	Beans (dry)	1	0.2	0.2	Recommended [e]
300020	Lentils (dry)	1	0.2	0.2	Recommended [e]
300030	Peas (dry)	1	0.2	0.2	Recommended [e]
300040	Lupins (dry)	1	0.2	0.2	Recommended [e]
401010	Linseed	0.1	-	0.05	Further consideration needed [h]
401030	Poppy seed	0.5	-	0.05	Recommended [b]
401050	Sunflower seed	0.5	0.1	0.1	Recommended [g]
401060	Rape seed	0.2	0.05	0.05	Further consideration needed [d]
401080	Mustard seed	0.1	-	0.1	Further consideration needed [f]
401120	Borage	0.1	-	0.05	Further consideration needed [h]
401130	Gold of pleasure	0.1	-	0.05	Recommended [b]
500010	Barley grain	0.5	0.05	0.05	Recommended [g]
500020	Buckwheat grain	0.2	0.05	0.05	Recommended [a]
500030	Maize grain	0.2	0.05	0.05	Recommended [e]
500040	Millet grain	0.2	0.05	0.05	Recommended [a]
500050	Oats grain	0.5	0.05	0.05	Recommended [g]
500070	Rye grain	0.5	0.05	0.05	Recommended [g]
500080	Sorghum grain	0.2	0.05	0.05	Recommended [g]
500090	Wheat grain	0.5	0.05	0.05	Recommended [g]
631000	Herbal infusions (dried, flowers)	5	-	10	Further consideration needed [h]
632000	Herbal infusions (dried, leaves)	5	-	10	Further consideration needed [h]
633000	Herbal infusions (dried, roots)	5	-	0.01	Further consideration needed [h]
810000	Spices (seeds)	5	5	5	Further consideration needed [j]
810000	Spices (fruits and berries)	0.05*	-	0.05	Further consideration needed [f]
900010	Sugar beet (root)	0.5	-	0.01*	Recommended [b]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
900030	Chicory roots	0.05*	-	0.01*	Recommended [(b)]
-	Other products of plant origin	See App. C.1	-	-	Further consideration needed [(m)]
1016010	Poultry meat	0.05*	0.01*	0.01*	Recommended [(k)]
1016020	Poultry fat	0.05*	0.01*	0.01*	Recommended [(k)]
1016030	Poultry liver	0.05*	0.01*	0.01*	Recommended [(k)]
1030000	Birds' eggs	0.05*	0.01*	0.01*	Recommended [(k)]
Enforcement residue definition: sum of pirimicarb and desmethyl pirimicarb, expressed as pirimicarb					
1011010	Swine muscle	0.05*	0.01*	0.05	Further consideration needed [(j)]
1011020	Swine fat (free of lean muscle)	0.05*	0.01*	0.05	Further consideration needed [(j)]
1011030	Swine liver	0.05*	0.01*	0.05	Further consideration needed [(j)]
1011040	Swine kidney	0.05*	0.01*	0.05	Further consideration needed [(j)]
1012010	Bovine muscle	0.05*	0.01*	0.05	Further consideration needed [(j)]
1012020	Bovine fat	0.05*	0.01*	0.05	Further consideration needed [(j)]
1012030	Bovine liver	0.05*	0.01*	0.05	Further consideration needed [(j)]
1012040	Bovine kidney	0.05*	0.01*	0.05	Further consideration needed [(j)]
1013010	Sheep muscle	0.05*	0.01*	0.05	Further consideration needed [(j)]
1013020	Sheep fat	0.05*	0.01*	0.05	Further consideration needed [(j)]
1013030	Sheep liver	0.05*	0.01*	0.05	Further consideration needed [(j)]
1013040	Sheep kidney	0.05*	0.01*	0.05	Further consideration needed [(j)]
1014010	Goat muscle	0.05*	0.01*	0.05	Further consideration needed [(j)]
1014020	Goat fat	0.05*	0.01*	0.05	Further consideration needed [(j)]
1014030	Goat liver	0.05*	0.01*	0.05	Further consideration needed [(j)]
1014040	Goat kidney	0.05*	0.01*	0.05	Further consideration needed [(j)]
1020010	Cattle milk	0.05*	0.01*	0.05	Further consideration needed [(j)]
1020020	Sheep milk	0.05*	0.01*	0.05	Further consideration needed [(j)]
1020030	Goat milk	0.05*	0.01*	0.05	Further consideration needed [(j)]
-	Other product of animal origin	See App. C.1	-	-	Further consideration needed [(m)]

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix D).
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(c): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; CXL is higher, supported by data but a risk to consumers cannot be excluded (combination E-VI in Appendix D).
(d): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).
(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix D).

(f): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix D).

(g): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix D).

(h): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).

(i): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level is not supported by data and a risk to consumers cannot be excluded for the existing EU MRL (combination B-VII in Appendix D).

(j): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition for ruminant products); existing CXL is covered by the existing EU MRL (combination C-III in Appendix D).

(k): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).

(l): GAP evaluated at EU level is not supported by data and a risk to consumers cannot be excluded for the existing EU MRL; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination B-I in Appendix D).

(m): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

(n): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; CXL is higher, supported by data but a risk to consumers cannot be excluded (combination G-VI in Appendix D).

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BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting and the review of pesticide MRLs at European level. Article 12(2) of that regulation stipulates that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[5] before 02 September 2008. As pirimicarb was included in Annex I to the above mentioned directive on 01 February 2007, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-608 was included in the EFSA Register of Questions.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that in the framework of Directive 91/414/EEC only a few representative uses are evaluated, while MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the EU, and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

In order to gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities and;
- the analytical methods for enforcement of the proposed MRLs.

United Kingdom, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for pirimicarb. The requested information was submitted to EFSA on 27 July 2011 and subsequently checked for completeness. On 19 November 2011, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 28 October 2013 and submitted to Member States (MS) for commenting. All MS comments received by 10 January 2014 were considered by EFSA in the finalisation of the reasoned opinion.

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1-16.

[5] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32.

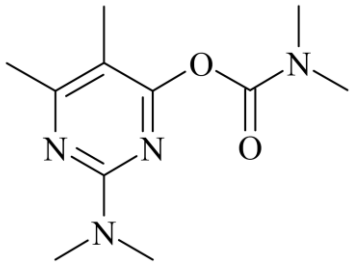
TERMS OF REFERENCE

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

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



Pirimicarb belongs to the group of carbamate compounds. It is an insecticide specific to aphids that acts by inhibiting the acetylcholinesterase enzyme.

Pirimicarb was evaluated in the framework of Directive 91/414/EEC with the United Kingdom being the designated rapporteur Member State (RMS). The representative use supported for the peer review process was the outdoor foliar application on wheat. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2006/39/EC[6], which entered into force on 01 February 2007. According to Regulation (EU) No 540/2011[7], pirimicarb is deemed to have been approved under Regulation (EC) No 1107/2009[8]. This approval is restricted to uses as insecticide only.

The EU MRLs for pirimicarb are established in Annexes IIIA of Regulation (EC) No 396/2005. Since the entry into force of that regulation, EFSA recommended the modification of the existing MRL for fennel (EFSA, 2009) which was legally implemented in Regulation (EU) No 750/2010[9]. All existing EU MRLs, which are established for the sum of pirimicarb and desmethyl pirimicarb[10] expressed as

[6] Commission Directive 2006/39/EC of 12 April 2006 amending Council Directive 91/414/EEC to include clodinafop, pirimicarb, rimsulfuron, tolclofos-methyl and triticonazole as active substances. OJ L 104, 13.4.2006, p. 30–35.

[7] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1-186.

[8] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ 309, 24.11.2009, p. 1-50.

[9] Commission Regulation (EU) No 750/2010 of 7 July 2010 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for certain pesticides in or on certain products. OJ L 220, 21.8.2010, p. 1–56.

[10] Desmethyl pirimicarb: 5,6-dimethyl-2-(methylamino)pyrimidin-4-yl dimethylcarbamate. See Appendix E.

pirimicarb, are summarised in Appendix C.1 to this document. CXLs for pirimicarb were also established by the Codex Alimentarius Commission and are reported in Appendix C.2 to this reasoned opinion. These CXLs refer to parent compound only.

For the purpose of this MRL review, the critical uses of pirimicarb currently authorised within the EU, have been collected by the RMS and reported in the PROFile. The additional GAPs reported during the consultation of Member States were also considered (see Appendix A). Several outdoor and indoor foliar applications (1 to 4) are authorised on a wide range of crops, at rates up to 0.730 kg a.s./ha. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (United Kingdom, 2003, 2005), the conclusion on the peer review of the pesticide risk assessment of the active substance pirimicarb (EFSA, 2005), the JMPR Evaluation report (FAO, 2006), the previous reasoned opinion on pirimicarb (EFSA, 2009) as well as the evaluation reports submitted during the consultation of Member States (Belgium, 2014a, 2014b; France, 2010, 2014; Germany, 2014a, 2014b; Netherlands, 2006, 2013; Spain, 2014; United Kingdom, 2014a, 2014b). The assessment is performed in accordance with the legal provisions of the Uniform Principles for Evaluation and Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[11] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a-b, 2011 and OECD, 2011).

1. Methods of analysis

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

During the peer review under Directive 91/414/EEC, an analytical method using GC-NPD, and its ILV were evaluated and validated for the determination of pirimicarb in plant matrices with an LOQ of 0.01 mg/kg in dry commodities (wheat grain) and an LOQ of 0.05 mg/kg in straw (United Kingdom, 2003). However this method is not highly specific.

In addition, a HPLC-MS/MS method reported in the JMPR Evaluation was validated for the determination of pirimicarb with an LOQ of 0.01 mg/kg in high water content (apple), high oil content (oilseed), acidic (orange) and dry (maize grain) commodities. This method can be confirmed by a GC-NPD method also validated for the determination of pirimicarb with an LOQ of 0.01 mg/kg in both high water content (apple) and dry commodities (wheat grain) and an LOQ of 0.05 mg/kg in straw (FAO, 2006). Nevertheless, no ILV is available for these methods.

The multi-residue QuEChERS method in combination with HPLC-MS/MS, as described by CEN (2008), is also reported for the analysis of pirimicarb with an LOQ of 0.01 mg/kg in high water content, high oil content, acidic and dry commodities (Table 1-1).

Hence it is concluded that pirimicarb can be enforced in food of plant origin with an LOQ of 0.01 mg/kg in high water content, high oil content, acidic and dry commodities. Analytical methods fully validated for the determination of pirimicarb in herbal infusions (dried flowers, dried leaves and dried roots) and spices (seeds, fruits and berries) are however still missing and therefore required.

[11] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

Table 1-1: Recovery data for the analysis of pirimicarb in different crop groups using the QuEChERS method in combination with LC-MS/MS (EURL, 2013)

Commodity group	Spiking levels (mg/kg)	Recoveries			No of labs
		Mean (%)	RSD (%)	n	
Acidic	0.01 0.10	94.8 96.7	10.0 9.4	10 10	2
Dry (cereals, dry pulses)	0.01 0.10	97.4 96.6	4.3 4.5	10 10	2
Fatty (oils)	0.01 0.10	107.0 95.6	4.4 3.3	5 5	1
Watery	0.01 0.10	101.1 94.5	4.3 5.9	15 10	2

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

During the peer review under Directive 91/414/EEC, an analytical method using GC-NPD was evaluated but this method cannot be considered acceptable since it requires the use of chloroform. A GC-MS method was also evaluated but, according to the current guidelines, cannot be considered validated due to the low number of validation data available (United Kingdom, 2003).

In addition, a HPLC-MS/MS method and its ILV reported in the JMPR Evaluation was validated for the determination of pirimicarb in food of animal origin with an LOQ of 0.01 mg/kg in milk, meat, fat, liver, kidney and eggs. This method can be confirmed by a GC-NPD method validated at the same LOQ (FAO, 2006).

Hence it is concluded that pirimicarb can be enforced in food of animal origin with an LOQ of 0.01 mg/kg in milk, meat, fat, liver, kidney and eggs.

2. Mammalian toxicology

The toxicological assessment of pirimicarb was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by EFSA (2005). These toxicological reference values are summarised in Table 2-1.

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 per d	12-month dog	100
ARfD	EFSA	2005	0.1 mg/kg bw	Acute neurotoxicity	100

Regarding hydroxypyrimidine metabolites (R31805[12], R34865[13] and R31680[14] identified mainly in metabolism studies on livestock), as well as desmethyl pirimicarb, desmethylformamido pirimicarb [15]

[12] R31805: 2-dimethylamino-5,6-dimethylpyrimidin-4-ol. See Appendix E.
[13] R34865: 5,6-dimethyl-2-(methylamino)pyrimidin-4-ol. See Appendix E.
[14] R31680: 2-amino-5,6-dimethylpyrimidin-4-ol. See Appendix E.
[15] Desmethylformamido pirimicarb: 5,6-dimethyl-2-(methylamino) pyrimidin-4-ol. See Appendix E.

and R35140[16] (identified in the plant metabolism studies), toxicity is deemed covered by the toxicity of the parent compound and therefore the toxicological reference values reported in Table 2-1 should apply to these metabolites as well.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of pirimicarb was investigated for foliar application on cereals (wheat), on fruits and fruiting vegetables (apple), on root and tuber vegetables (potato) and on leafy vegetables (lettuce), using ^{14}C-pyrimidine-labelled pirimicarb (United Kingdom, 2003). The characteristics of these studies are summarised in Table 3-1.

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

Group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks
Fruits and fruiting vegetable	Apple	^{14}C-pyrimidine	Foliar treatment, G	1.1	3	21	-
Leafy vegetables	Lettuce	^{14}C-pyrimidine	Foliar treatment, G	0.26	3	3, 7	-
Root and tuber vegetables	Potato	^{14}C-pyrimidine	Foliar treatment, F [(b)]	0.75 2.75	2 4	17 18	-
Cereals	Wheat	^{14}C-pyrimidine	Foliar treatment, F [(b)]	0.28	2	14	-

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): Outdoor pots/tubs.

Lettuce

TRR in lettuce decreased slightly from 3 to 7 DAT (13.7 to 12 mg eq/kg). Pirimicarb was the most important component of the residue for both samplings, decreasing from 52 % TRR (7.1 mg/kg) to 38 % TRR (4.6 mg/kg) between the two sampling times. Metabolite desmethyl pirimicarb was detected at 2.3-2.5 mg/kg (17 and 21 % TRR) in 3 and 7 DAT samples, respectively. Metabolites R31805 and desmethylformamido pirimicarb were only present at relatively low amounts in the 3 DAT samples (3.5 % TRR, 0.5 mg/kg and 0.6 % TRR, 0.09 mg/kg respectively), but their levels increased in 7 DAT samples to 8.5 % TRR (1.02 mg/kg) and 6 % TRR (0.7 mg/kg). Part of these residues was present under conjugated forms or bound to the matrix (up to 2.8 % TRR under conjugated form and 1.1 % TRR bound to the matrix for R31805 in 7 DAT samples). No other single compound was detected at levels above 4.5 % TRR (0.6 mg/kg).

[16] R35140: 2-amino-5,6-dimethylpyrimidin-4-yl dimethylcarbamate. See Appendix E.

Potato

Potato plants were treated twice at 0.75 kg a.s./ha (low dose), which is in accordance with the application rate authorised in the EU, or four times at 2.7 kg a.s./ha (high dose). The PHI was less critical than the reported GAPs (17-18 days instead of 3 days). The TRR in tuber amounted to 0.04 mg eq/kg and 0.23 mg eq/kg for low and high dose, respectively. No single compound was detected above 0.01 mg eq/kg for the low dose. Dimethylguanidine[17] and methylguanidine[18]were the only identified compounds at low dose (15 and 4 % TRR respectively, both below 0.01 mg /kg) and the only identified compounds above 0.01 mg/kg at high dose (0.06 mg/kg, 24 % TRR and 0.01 mg/kg, 4 % TRR, respectively). For high dose, 34 % of dimethylguanidine (0.019 mg/kg) and 21 % of methyguanidine (0.002 mg/kg) were under conjugated forms. In addition, conjugates of two unidentified compounds were detected at 0.02 mg/kg (9-10 % TRR). No other single compound was detected at levels above 5.5 % TRR (0.01 mg/kg).

Apple

Apple trees were treated three times at 1.1 kg a.s./ha, which is in accordance with the application rate authorised in the EU. The PHI is less critical than the reported GAPs (21 days instead of 3 days). TRR in fruits was 2.4 mg eq/kg. Parent pirimicarb was the main component of the TRR in fruits, accounting for 30 % TRR (0.7 mg/kg). Desmethyl pirimicarb and desmethylformamido pirimicarb were detected but remained minor (1.8 % TRR, 0.04 mg/kg and 1.2 % TRR, 0.03 mg/kg respectively). No other single compound was detected above 5.5 % TRR and 0.01 mg/kg. The remaining residue comprised a large number of distinct unidentified metabolites, all below 1.5 % TRR (0.04 mg/kg), except two polar compounds accounting together for 10 % TRR (0.24 mg/kg).

Wheat

Wheat plants were treated twice at 0.28 kg a.s./ha and a PHI of 14 days, which is more critical than the reported GAP (*ca.* 2N). The highest TRR was identified in straw (14.3 mg eq./kg), TRR in grain being significantly lower (0.7 mg eq/kg). Pirimicarb was the major compound in wheat grain, accounting for 25 % TRR (0.17 mg/kg). Metabolites desmethyl pirimicarb, R31805 and desmethylformamido pirimicarb were only present in relatively low amounts (1-3 % TRR and 0.01-0.02 mg/kg). 8 % TRR (0.05 mg/kg) was incorporated as starch and 5 % TRR (0.04 mg/kg) could not be extracted. The remaining residues (*ca*. 41 %TRR) were further characterised as 8 unidentified polar compounds (individually quantified at up to 6.5 % TRR and 0.04 mg/kg). Acid hydrolysis of these compounds did not release any of the already identified compounds. Therefore, there is no evidence that those compounds are conjugates of already identified metabolites. In straw, pirimicarb was the major identified compound, accounting for 13 % TRR (1.9 mg/kg). Metabolites desmethyl pirimicarb, R31805 and desmethylformamido pirimicarb were only present in relatively low amounts: 0.8 mg/kg (5 % TRR), 0.3 mg/kg (2 % TRR) and 0.2 mg/kg (2 % TRR). 48 % of the remaining TRR was further characterised: results showed that it was composed of several unidentified compounds, none accounting for more than 3.8 % TRR (0.5 mg/kg). Acid hydrolysis of these compounds did not release any of the already identified compounds. Therefore, there is no evidence that those compounds are conjugates of already identified metabolites. The most abundant compound after hydrolysis accounted for 8 % TRR (1.1 mg/kg).

Overall assessment

Parent pirimicarb is the most important compound in all crops. The metabolism of pirimicarb in plants involves cleavage and/or oxidation of the methylated amine group on the pyrimidine ring (to form respectively desmethyl pirimicarb and desmethyl formamido pirimicarb), cleavage of the carbamate

[17] 1,1-dimethylguanidine. See Appendix E.
[18] 1-methylguanidine. See Appendix E.

group to form hydroxypyrimidine compounds and cleavage of the pyrimidine ring to form guanidines, demonstrating an extensive breakdown of the active substance.

The metabolism studies show that the metabolic pathway is similar in all crops. Consequently, the residue for risk assessment in all plant commodities is defined as the sum of pirimicarb, desmethyl pirimicarb and desmethylformamido pirimicarb, expressed as pirimicarb. EFSA proposes to change the residue definition for enforcement by excluding desmethyl pirimicarb and desmethyl formamido pirimicarb, as, on the basis of the metabolism study and the residue trials, parent is deemed to be a sufficient marker of the residue (see Section 3.1.1.2). Validated analytical methods for enforcement of the proposed residue definition are available except for herbal infusions and spices (see also Section 1.1).

3.1.1.2. Magnitude of residues

According to the RMS, the active substance pirimicarb is authorised in northern and southern Europe for foliar application in a large number of crops, both under outdoor and indoor conditions (see Appendix A). To assess the magnitude of pirimicarb residues resulting from the authorised GAPs, EFSA considered all residue trials reported in the PROFile, including residue trials evaluated in the framework of the peer review (EFSA, 2005) or in the framework of a previous MRL application (EFSA, 2009) and additional data submitted during the consultation of Member States (Belgium, 2014a, 2014b; France, 2010, 2014; Germany, 2014a; Netherlands, 2006, 2013; Spain, 2014; United Kingdom, 2014a, 2014b). All available residue trials that, according to the RMS, comply with the authorised GAPs, are summarised in Table 3-2.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). For most of the supported GAPs, data were sufficient to derive (tentative) MRLs and risk assessment values and the following considerations were made by EFSA:

- Almonds, chestnuts, hazelnuts, walnuts: residue trials supporting the southern use were performed according to a more critical GAP (2 applications instead of 1). However, this is considered acceptable as all results were below the LOQ and a no residues situation is expected. Further residue trials are therefore not required. No residue trials compliant with the northern use on hazelnuts and walnuts are available. Although appropriate MRL and risk assessment values can be derived from the southern data, 4 residue trials on hazelnuts and 4 residue trials on walnuts compliant with the northern outdoor GAP are required.

- Apples pears and quinces: no residue trials compliant with the northern use on quinces and the southern use on pome fruit are available. Although tentative MRL and risk assessment values for quinces can be derived from overdosed trials (2 applications instead 1) and appropriate MRL and risk assessment values for apples and pears can be derived from northern data, 8 residue trials on apples compliant with the southern GAP on pome fruit and 4 trials on apples compliant with the northern GAP on quinces are still required.

- Cherries: the number of residue trials supporting the northern use is not compliant with the requirements on this crop (4 trials instead of 8); moreover southern residue trials were overdosed and no residue trials compliant with the indoor use are available. Although tentative MRL and risk assessment values can be derived from the overdosed southern trials, 4 additional trials on cherries compliant with the northern GAP, 4 trials on cherries compliant with the southern GAP and 8 trials on cherries compliant with the indoor GAP are still required.

- Peaches and apricots: according to the current guidance document, a minimum of 4 trials performed on apricots is needed for deriving a common MRL on apricots and peaches. The available dataset supporting the northern GAP is not compliant with this data requirement as

only trials on peaches were reported. Therefore, 4 additional residue trials performed on apricots and compliant with the northern GAP are required. Moreover, southern trials were overdosed (2 x 0.350-0.638 kg a.s./ha instead of 1 x 0.375 kg a.s./ha). Although tentative MRL and risk assessment values can be derived from these trials, 4 trials on peaches compliant with the southern GAP and 4 trials on apricots compliant with the southern GAP are still required.

- Plums: no residue trials compliant with the northern outdoor, the southern outdoor and the indoor uses are available. Although tentative MRL and risk assessment values can be derived from 4 overdosed northern trials, 8 trials compliant with the northern GAP, 8 trials compliant with the southern GAP and 8 trials compliant with the indoor GAP are still required.

- Strawberries: no residue trials compliant with northern and southern outdoor GAPs are available. However, considering the available overdosed trials performed in northern and southern Europe and the results from the indoor trials, the indoor use is clearly the most critical and further residue trials are not required.

- Blackberries, raspberries, dewberries: the number of residue trials on raspberries supporting the northern outdoor GAP on cane fruits is not compliant with the requirements for extrapolation (5 trials instead of 6). In addition, no residue trials are available to support the indoor uses on raspberries and blackberries. Therefore, 1 additional trial on raspberries compliant with the northern GAP on cane fruits and 4 residue trials on raspberries compliant with the indoor GAP on raspberries and blackberries are required.

- Blueberries, currants (red, black and white) and gooseberries: no residue trials are available to support the indoor uses on blueberries, currants and gooseberries. Although appropriate MRL and risk assessment values can be derived from northern trials, 4 residue trials on currants compliant with the indoor GAP on blueberries, currants and gooseberries are required.

- Potato: the number of residue trials supporting the northern outdoor and the southern outdoor uses is not compliant with the data requirements for this crop. Moreover the trials supporting the southern use were overdosed (3 x 0.3-0.4 kg a.s./ha instead of 2 x 0.25 kg a.s./ha). However, as all results were below the LOQ and a no residues situation is expected, further residue trials are not required.

- Other root and tuber vegetables except sugar beet: all available residue trials supporting the northern use were overdosed; moreover for carrots the numbers of residue trials supporting both northern and southern outdoor uses are not compliant with the requirements for this crop (4 trials instead of 8). However, as residues were always below the LOQ and a no residue situation is expected, further residue trials are not required. However, no residue trials compliant with the indoor GAPs on parsley root and radishes are available. Although appropriate MRL and risk assessment values can be derived from the outdoor data, 4 trials on parsley root and 4 trials on radishes, all compliant with the indoor GAPs are still required.

- Onions: results from the residue trials supporting the northern outdoor GAP are not compliant with the residue definition for enforcement (data on pirimicarb only not available). Considering that almost all results were below the LOQ and assuming also pirimicarb residues being present at levels below the LOQ, tentative MRL and risk assessment values were derived. Consequently 8 residue trials on onions performed according to the residue definitions for enforcement and risk assessment and supporting the northern outdoor GAP are still required.

- Tomatoes, aubergines: no residue trials compliant with the southern outdoor use or the indoor use are available. Although tentative MRL and risk assessment values can be derived from a combined dataset of over and underdosed indoor residue trials, 8 residue trials compliant with

the southern outdoor GAP on tomatoes and aubergines and 8 trials on tomatoes compliant with the indoor GAP on tomatoes and aubergines are still required.

- Peppers: no residue trials compliant with the southern outdoor use are available. However, considering the available overdosed trials performed in southern Europe and the results from the indoor trials, the indoor use is clearly the most critical and further residue trials are not required.

- Cucurbits, edible peel: the number of residue trials compliant with the northern outdoor and the southern outdoor GAPs for gherkins and courgettes are not compliant with the data requirements for these crops (1 trial in NEU and 3 trials in SEU) and no residue trials compliant with the indoor use on cucurbits with edible peel are available. Although tentative MRL and risk assessment values for gherkins and courgettes can be derived from southern outdoor trials (4 of which overdosed) and tentative MRL and risk assessment values for cucumbers can be derived from indoor trials compliant with a less critical GAP (PHI of 3 days instead of 1), 7 additional trials compliant with the northern GAP on courgettes and gherkins, 5 additional trials compliant with the southern GAP on courgettes and gherkins and 8 trials on cucumbers compliant with the indoor GAP on cucurbits with edible peel are still required.

- Melons: no residue trials compliant with the northern outdoor GAP are available and the numbers of residue trials supporting the southern outdoor and the indoor GAPs are not compliant with the data requirements for this crop (4 trials in SEU and 5 indoor trials instead of 8). Although tentative MRL and risk assessment values can be derived from the indoor GAP, 8 trials compliant with the northern outdoor GAP, 4 additional trials compliant with the southern GAP and 3 additional trials compliant with the indoor GAP are still required.

- Watermelons: the number of residue trials supporting the indoor GAP is not compliant with the data requirements for this crop (4 trials instead of 8). Although tentative MRL and risk assessment values can be derived from these trials, 4 additional trials on melons compliant with the indoor GAP are still required.

- Brussels sprouts: no residue trials compliant with the northern outdoor use are available. Although tentative MRL and risk assessment values can be derived from residue trials compliant with a more critical GAP (2 applications instead of 1), 4 trials on Brussels sprouts compliant with the northern outdoor GAP are still required.

- Head cabbage: no residue trials compliant with the northern outdoor and the indoor GAPs are available. Although tentative MRL and risk assessment values can be derived from overdosed northern trials (2 x 0.375 kg a.s./ha instead of 2 x 0.25 kg a.s./ha), 8 trials compliant with the northern outdoor GAP and 8 trials compliant with the indoor GAP are still required.

- Leafy brassica: no residue trials are available to support the southern use on leafy brassica and the indoor use on Chinese cabbage. Moreover trials supporting the outdoor northern GAP were overdosed (2 applications instead of 1). Although tentative MRL and risk assessment values can be derived from these overdosed trials, 4 residue trials on kale compliant with the northern outdoor GAP on leafy brassica, 4 residue trials on kale compliant with the southern outdoor GAP on leafy brassica and 4 residue trials compliant with the indoor GAP on Chinese cabbage are required.

  It is noted that for leafy brassica a fall-back northern outdoor GAP has been evaluated in this review (2x210 g a.s./ha; PHI 3d) (United Kingdom, 2014a). However, the number of residue trials supporting this GAP is not compliant with the data requirements (3 trials on kale instead of 4). Therefore, only tentative MRL and risk assessment values can be derived and 1 additional trial on kale compliant with the northern outdoor GAP is still required.

- Lettuce and other salad plants including brassicacea and purslane: appropriate MRLs and risk assessment values can be derived from the indoor dataset; however for all other GAPs the number of trials was not compliant with the requirements (4 trials instead of 8 and no information about lettuce varieties provided). Moreover trials supporting the northern use on lambs' lettuce, lettuce and scarole and trials supporting the southern use on lettuce and scarole were overdosed (2 application instead of 1 and 2x0.5 kg as/ha instead of 1x0.375 kg as/ha, respectively). Consequently, 8 trials on lettuce open leaf varieties supporting the NEU on lamb's lettuce, lettuce and scarole, 8 trials on lettuce open leaf varieties supporting the NEU on other salads and purslane and 8 trials on lettuce open leaf varieties supporting the SEU on lettuce and scarole, are still required.

  It is noted that for lettuce, a fall-back indoor GAP, fully supported by data, has been also evaluated in this review (2x0.250 kg a.s./ha; PHI 7d) (France, 2014; United Kingdom, 2014b).

- Beet leaves (chards): no residue trials are available to support the northern outdoor use. Although tentative MRL and risk assessment values can be derived from overdosed trials on spinach (2 applications instead of 1), 4 trials compliant with the northern outdoor GAP on beet leaves are still required.

- Witloof: no residue trials compliant with the northern outdoor and the indoor GAPs are available. Although tentative MRL and risk assessment values can be derived from trials compliant with a more critical GAP (application rate of 0.380-0.390 kg/ha instead of 0.250 kg as/ha), 4 residue trials compliant with the northern GAP and 4 residue trials compliant with the indoor GAP are still required.

- Fresh herbs: no information on the varieties of lettuce tested in the trials supporting the northern uses is available. Moreover trials supporting the northern GAP on parsley were overdosed (2 applications instead of 1). Although appropriate MRLs and risk assessment values can be derived from the indoor dataset, 4 residue trials supporting the outdoor northern use on celery leaves, 4 residue trials supporting the outdoor northern use on parsley and 4 residue trials supporting the outdoor northern use on all the other fresh herbs are still required.

- Beans and peas with pods: no residue trials compliant with the northern or the indoor uses are available and the number of residue trials compliant with the southern outdoor GAP is not compliant with the data requirements for these crops (1 trial instead of 8). Although tentative MRL and risk assessment values can be derived from this trial and 4 overdosed trials (2x0.475-0.5 kg as/ha instead of 1 x 0.375 kg/ha), 8 trials compliant with the northern GAP on beans and peas with pods, 8 residue trials compliant with the southern GAP on beans and peas with pods and 8 trials compliant with the indoor GAP on beans and peas with pods are still required.

- Peas without pods: the number of residue trials supporting the northern outdoor and the southern outdoor uses is not compliant with the data requirements for this crop. Moreover the trials were compliant with a more critical GAP (2x0.375 kg as/ha, 3d PHI instead of 3x0.25 kg as/ha, 3d PHI for the northern use and 1x0.375 kg as/ha, 7d PHI for the southern use). However, as all results were below the LOQ and a no residues situation is expected, further residue trials are not required.

- Asparagus: the number of residue trials supporting the northern outdoor use and the number of residue trials supporting the southern outdoor use are not compliant with the data requirements for this crop (2 instead of 4). Moreover the trials were compliant with a more critical GAP (2x0.5 kg as/ha instead of 1x0.375 kg as/ha). However, as all results were below the LOQ and a no residues situation is expected further residue trials are not required.

- Cardoons: no residue trials compliant with the northern outdoor use or with the southern outdoor use are available. Although tentative MRL and risk assessment values can be derived from southern overdosed trials (2 applications instead of 1), 4 residue trials compliant with the northern outdoor GAP and 4 residue trials compliant with the southern outdoor GAP are still required.

- Celery: the number of residue trials supporting the northern outdoor use is not compliant with the data requirements on this crop (3 trials instead of 4). Although tentative MRL and risk assessment values can be derived from the available data, 1 additional trial compliant with the northern outdoor GAP on celery is still required.

- Fennel: it is noted that the assessment was based on the Belgian indoor GAP (2x0.200 kg as/ha, PHI 7d) evaluated by EFSA in the framework of Article 10 of the Regulation 396/2005 (EFSA, 2009), while another GAP, reported by the Netherlands is still authorised (2x0.400 kg as/ha, PHI of 7 d) on this crop. However, no residue trials are available to support this GAP. Therefore, 4 indoor residue trials on fennel supporting the NL GAP are still required.

- Globe artichokes: no residue trials compliant with the northern use are available. Although tentative MRL and risk assessment values can be derived from overdosed trials (2x0.38 kg as/ha instead of 0.25 kg as/ha), 4 trials compliant with the northern GAP are still required.

- Dry beans and peas: no residue trials compliant with the northern use are available. Although tentative MRL and risk assessment values can be derived from 4 overdosed trials (2x0.38 kg as/ha instead of 4x0.25 kg as/ha), 8 trials on dry beans or peas compliant with the northern GAP are still required.

- Dry lentils and lupins: no residue trials compliant with the northern use are available. Although tentative MRL and risk assessment values can be derived from overdosed trials (2 applications instead of 1), 4 trials on dry lentils and 4 trials on dry lupins all compliant with the northern GAP are still required.

- Sunflower: the number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop (4 trials instead of 8). Although appropriate MRL and risk assessment values can be derived from southern data, 4 additional trials compliant with the northern GAP are still required.

- Rape seed, linseed, borage: the number of residue trials supporting the northern outdoor GAP on rape seed, linseed, borage is not compliant with the data requirements for rape seed (4 trials instead of 8); moreover 2 of the available trials were compliant with a less critical GAP (PHI of 19-21 days instead of 14). Although tentative MRL and risk assessment values can be derived from available trials, 6 additional trials on rapeseed compliant with the northern GAP on rape seed, linseed and borage are still required. In addition, the number of residue trials supporting the southern outdoor GAP on rapeseed is not compliant with the data requirements for this crop (2 trials instead of 8). Therefore 6 additional residue trials supporting the southern outdoor GAP on rapeseed are also still required.

- Barley, oats (grain): the number of residue trials supporting the northern and southern outdoor GAP is not compliant with the data requirements for this crop (4 trials in NEU and 3 in SEU instead of 8). Moreover, except for one trial conducted in northern Europe, the trials were compliant with a more critical GAP (NEU: 2 x 0.15 kg a.s./ha instead of 2 x 0.125 kg a.s./ha, the 25 % rule being already used for PHI; SEU: 2 x 0.21 kg a.s./ha instead of 2 x 0.125 kg a.s./ha). However, the reduced number of residue trials and the deviation from the GAPs are

considered acceptable in this case because all results were below the LOQ and a no residues situation is expected. Further residue trials are therefore not required.

It is noted that, for barley and oats, the assessment was based on the French GAP (2x0.125 kg as/ha, PHI 35d) for which residue trials were available, while other GAPs, reported by the Netherlands (barley only) and Belgium during the Member States consultation, are still authorised (4x0.125 kg as/ha, PHI of 4 d and 2x0.125 kg as/ha, PHI 7 d, respectively). However, no residue trials are available to support these GAPs. Therefore, 4 northern outdoor residue trials on barley supporting the Belgian GAPs on barley and oats and the Dutch GAP on barley are still required.

- Barley, oats (straw): only 1 residue trial compliant with the northern use is available and no residue trials compliant with the southern use are available. Although the setting of MRL is currently not mandatory in feedstuff and tentative risk assessment values can be derived from overdosed trials (NEU: 2x0.15 kg a.s./ha instead of 2x0.125 kg as/ha, the 25 % rule being already considered for PHI; SEU: 2x0.21 kg as/ha instead of 2x0.125 kg as/ha), 3 additional residue trials on barley compliant with the northern GAP and 4 residue trials on barley compliant with the southern GAP are still required.

- Maize (grain): the number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop (5 trials instead of 8). Although tentative MRL and risk assessment values can be derived from available data, 3 additional trials compliant with the northern GAP are still required.

- Wheat, rye (grain): the number of residue trials supporting the northern and southern outdoor GAP is not compliant with the data requirements for this crop (7 trials in NEU and 2 in SEU instead of 8). Moreover, the trials from southern Europe were compliant with a more critical GAP (2 x 0.21 kg a.s./ha instead of 2 x 0.125 kg a.s./ha). However, as all results were below the LOQ and a no residues situation is expected, further residue trials are not required.

  It is noted that, for wheat and rye, the assessment was based on the French GAP (2x0.125 kg as/ha, PHI 35d) for which residue trials were available, while other GAPs, reported by the Netherlands (wheat only) and Belgium during the Member States consultation, are still authorised (4x0.125 kg as/ha, PHI of 4 d and 2x125 kg as/ha, PHI 7 d, respectively). However, no residue trials are available to support these GAPs. Therefore, 4 northern outdoor residue trials on wheat supporting the Belgian GAPs on wheat and rye and the Dutch GAPs on wheat are still required.

- Wheat (straw): no residue trials compliant with the southern use are available. Although MRL and risk assessment values can be derived from the northern data, 4 residue trials compliant with the southern use are required.

- Herbal infusions (dried flowers), herbal infusions (dried leaves): the number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop (2 trials instead of 4). Although tentative MRL and risk assessment values can be derived from these trials and 2 trials compliant with a less critical GAP (1 application instead of 2), 2 additional trials compliant with the northern GAP on herbal infusions are still required.

- Chicory roots: no residue trials compliant with the northern use are available. However, in 4 overdosed trials (2x0.5 kg as/ha instead of 0.375 kg as/ha), all results were below or at the LOQ and a no residues situation is expected. Therefore, further residue trials are not required.

For all other crops, no trials were available and it was not possible to derive MRLs or risk assessment values; consequently the following data gaps were identified:

- Table and wines grapes: considering that wines grapes is a major crop in both northern and southern Europe, 8 residue trials on grapes compliant with the indoor use on table and wine grapes are required.

- Flowering brassica: according to the current rules for extrapolation, 4 residue trials on cauliflower and 4 residue trials on broccoli compliant with the northern outdoor GAP on flowering brassica and 4 residue trials on cauliflower and 4 residue trials on broccoli compliant with the indoor GAP on flowering brassica are required.

- Kohlrabi: considering that this is a minor crop, 4 residue trials on kohlrabi compliant with the northern outdoor GAP and 4 residue trials on kohlrabi compliant with the indoor GAP are required.

- Beans without pods: considering that this is a minor crop in Europe, 4 residue trials compliant with the southern outdoor GAP and 4 residue trials compliant with the indoor GAP are required.

- Leek: considering that this is a major crop in northern Europe, 8 residue trials compliant with the northern outdoor GAP and 8 residue trials compliant with the indoor GAP are required.

- Fresh lentils: considering that this is crop a minor in Europe, 4 residue trials compliant with the northern outdoor GAP are required.

- Mustard seed: considering that this is a minor crop, 4 residue trials compliant with the northern GAP are required.

- Spices (seeds), spices (fruits and berries): considering that these crops are minor, 4 residue trials on spices (seeds) and 4 residue trials on spices (fruits and berries), all compliant with the northern GAP are required.

- Alfalfa, grass: considering that these crops are only used as feed items, 4 residue trials compliant with the northern GAP are required.

The potential degradation of residues during storage of the residue trials samples was also assessed. In the framework of the peer review, storage stability of pirimicarb was demonstrated for a period of 12 months at -18°C in dry commodities (wheat grain and straw) (EFSA, 2005). Storage stability of pirimicarb in commodities with high water content (apple, cabbage, cucumber, tomato, lettuce, beans, potato, artichoke and asparagus) and high oil content (oilseed rape) was also assessed by JMPR (FAO, 2006) and deemed acceptable for a storage period of 12 months. Authorised uses are also reported on acidic commodities (citrus, wines and berries), however considering that pirimicarb showed to be stable for 12 months in a large number of commodities, a study investigating storage stability in this type of matrix is only desirable. In addition, the storage conditions were not reported for all residue trials available. Considering that storage stability in plants was demonstrated for 12 months, this information would be desirable in order to confirm the validity of the residue trials reported.

Consequently, the available residues data were considered sufficient to derive appropriate MRL proposals and risk assessment values for all commodities under evaluation, except for quinces, stone fruits, cane fruits, tomatoes, aubergines, cucurbits with edible peel, melons, watermelons, Brussels sprouts, head cabbage, leafy brassica, beet leaves, witloof, onions, beans and peas with pods, cardoons, celery, globe artichokes, pulses (dry), linseed, borage, rape seed, maize and herbal infusions where only tentative MRLs are derived; and for table and wine grapes, flowering brassica, kohlrabi, beans without pods, fresh lentils, leek, mustard seeds and spices (seeds, fruits and berries) where the available data were insufficient to derive tentative MRLs (see also Table 3-2). Median conversion factors for enforcement to risk assessment were derived for each commodity, considering only residues of pirimicarb, desmethyl pirimicarb and desmethyl formamido pirimicarb above the LOQ.

When relevant, datasets on a same commodity but from different climatic conditions (NEU, SEU or indoor) were pooled for the calculation of a common CF. Where several uses are authorised for one commodity, the final MRL proposal was derived from the most critical use and indicated in bold in Table 3-2. Tentative MRLs were also derived for feed crops (cereal straw, maize forage, sugar beet tops and fodder beet) in view of the future need to set MRLs in feed items.

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

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Enforcement residue definition: pirimicarb **Risk assessment definition:** sum of pirimicarb, desmethyl pirimicarb and desmethyl formamido pirimicard, expressed as pirimicarb									
Hazelnuts Walnuts Almonds Chestnuts	NEU	Outdoor	-	-	-	-	-	-	No trials available. No uses on almonds and chestnuts authorised in NEU.
	SEU	Outdoor	4x<0.02	4x<0.05	0.02	0.02	0.02	1.0	Trials on walnuts overdosed (2x0.375 kg as/ha) acceptable as residue were always below the LOQ.
Apples Pears	NEU	Outdoor	0.25; 0.37; 0.05; 0.20[(e)]; 0.22[(e)]; 0.19[(e)]; 0.08; 0.99[(e)]; 0.32	0.30; 0.42; 0.06; 0.23[(e)]; 0.24[(e)]; 0.20[(e)]; 0.09; 1.03[(e)]; 0.34	**0.22**	**0.99**	**1.5**	1.3	Trials on apples compliant with GAP (Belgium, 2014b). R_{ber} = 0.71 R_{max} = 0.59 MRL_{OECD} = 0.8
	SEU	Outdoor	0.15; 0.25; 0.14; 0.04; 0.14; 0.29; 0.17; 0.06[(g)]	0.17; 0.28; 0.20; 0.05; 0.21; 0.35; 0.24; 0.08[(g)]	0.15	0.29	0.5 (tentative)		Trials on apples overdosed (2 applications instead of 1). R_{ber} = 0.46 R_{max} = 0.42 MRL_{OECD} = 0.49
Quinces	NEU	Outdoor	0.16[(f)]; 0.36[(g)]; 0.02; 0.20; 0.22; 0.19; 0.05; 0.99; 0.32	0.19[(f)]; 0.39[(g)]; 0.03; 0.23; 0.24; 0.20; 0.06; 1.03; 0.34	**0.20**	**0.99**	**1.5 (tentative)**		Trials on apples overdosed (2 applications instead of 1) (France, 2010). R_{ber} = 0.68 R_{max} = 1.15 MRL_{OECD} = 1.43

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
	SEU	Outdoor	0.15; 0.25; 0.14; 0.04; 0.14; 0.29; 0.17; 0.06[(g)]	0.17; 0.28; 0.20; 0.05; 0.21; 0.35; 0.24; 0.08[(g)]	0.15	0.29	0.5 (tentative)		Trials on apples overdosed (2 applications instead of 1). R_{ber} = 0.46 R_{max} = 0.42 MRL_{OECD} = 0.49
Cherries	NEU	Outdoor	1.02; 0.78; 0.46; 0.76	1.12; 0.83; 0.48; 0.78	0.77	1.02	3 (tentative)	1.1	Trials on cherries compliant with GAP. R_{ber} = 1.92 R_{max} = 1.94 MRL_{OECD} = 2.27
	SEU	Outdoor	2.0; 1.53; 0.29; 1.14	2.07; 1.60; 0.36; 1.20	**1.34**	**2.00**	**5 (tentative)**		Trials on cherries overdosed (up to 0.750 kg as/ha). R_{ber} = 3.76 R_{max} = 4.97 MRL_{OECD} = 4.14
	EU	Indoor	-	-	-	-	-		No trials available.
Apricots Peaches	NEU	Outdoor	0.44; 0.19; 0.50; 0.34; 0.52	0.46; 0.20; 0.54; 0.35; 0.54	**0.44**	0.52	1.5 (tentative)	1.1	Trials on peaches compliant with GAP. R_{ber} = 1.02 R_{max} = 0.97 MRL_{OECD} = 1.19
	SEU	Outdoor	0.27; 0.20; 0.11; 0.19; 0.09; 0.34; 0.24; 0.36; 0.33; 1.19; 0.25; 0.40	0.29; 0.22; 0.13; 0.21; 0.12; 0.36; 0.27; 0.39; 0.36; 1.27; 0.28; 0.44	0.26	**1.19**	**1.5 (tentative)**		Trials on peaches overdosed (2x0.350-0.638 kg as/ha). R_{ber} = 0.71 R_{max} = 1.12 MRL_{OECD} = 1.48

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Plums	NEU	Outdoor	0.28; 0.34; 0.41; 0.50	0.29; 0.35; 0.43; 0.53	**0.38**	**0.50**	**1.5 (tentative)**	1.1	Trials on plums overdosed (up to 2x0.56 kg as/ha) (Belgium, 2014b). R_{ber} = 0.96 R_{max} = 0.87 MRL_{OECD} = 1.15
	SEU	Outdoor	0.35; 0.19; 0.11; 0.34	0.37; 0.26; 0.12; 0.37	0.27	0.35	0.9 (tentative)		Trials on plums overdosed (up to 0.75 kg as/ha). R_{ber} = 0.70 R_{max} = 0.85 MRL_{OECD} = 0.74
	EU	Indoor	-	-	-	-	-		No trials available.
Table grapes Wine grapes	EU	Indoor	-	-	-	-	-	-	No trials available.

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Strawberries	NEU	Outdoor	0.25; 0.21; 0.40; 0.76; 0.07; 0.27; 0.18; 0.12;	0.27; 0.22; 0.40; 0.81; 0.07; 0.27; 0.20; 0.14	0.23	0.76	1.5 (tentative)	1.1	Trials on strawberries overdosed (0.375 kg as/ha). R_{ber} = 0.74 R_{max} = 0.98 MRL_{OECD} = 1.15
	SEU	Outdoor	0.33; 0.53; 0.26; 0.16	0.37; 0.58; 0.29; 0.19	0.30	0.53	1.5 (tentative)		Trials on strawberries overdosed (2x0.45-0.50 kg as/ha). R_{ber} = 0.96 R_{max} = 1.12 MRL_{OECD} = 0.96
	EU	Indoor	0.25; 0.20; 0.26; 0.35; 0.32; 0.18; 0.12; 0.44; 0.51; 0.59; 1.10; 1.40	0.27; 0.21; 0.27; 0.38; 0.34; 0.19; 0.13; 0.45; 0.53; 0.63; 1.18; 1.44	**0.34**	**1.40**	**1.5**		Trials on strawberries performed at 2x0.375 kg as/ha (within 25%). R_{ber} = 0.99 R_{max} = 1.16 MRL_{OECD} = 1.51
Blackberries Dewberries Raspberries	NEU	Outdoor	2.1[(h)]; 0.47[(h)]; 0.36; 0.76; 0.43	2.18[(h)]; 0.51[(h)]; 0.39; 0.82; 0.45	0.47	2.10	4 (tentative)	1.1	Trials on raspberries compliant with GAP. R_{ber} = 2.86 R_{max} = 3.89 MRL_{OECD} = 3.74
	EU	Indoor	-	-	-	-	-		No trials available. No indoor use on dewberries.

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement	Risk assessment					
Blueberries Currants (red, black and white) Cranberries Gooseberries Azaroles	NEU	Outdoor	0.30; 0.38; 0.16; 0.16[h]; 0.34[h]; 0.25[h]; 0.09[h]; 0.24[h]	0.32; 0.40; 0.18; 0.19[h]; 0.37[h]; 0.25[h]; 0.11[h]; 0.25[h]	0.25	0.38	0.8	1.1	Trials compliant on currants with GAP (Belgium, 2014a). R_{ber} = 0.66 R_{max} = 0.56 MRL_{OECD} = 0.72
	EU	Indoor	-	-	-	-	-		No trials available. No indoor use on cranberries and azaroles.
Potatoes	NEU	Outdoor	2x<0.01	2x<0.02	0.01	0.01	0.01*	1.0	Trials compliant with GAP.
	SEU	Outdoor	6x<0.01	6x<0.02	0.01	0.01	0.01*		Trials on potatoes overdosed (3x0.3-0.4 kg as/ha) accepted as residues were always below the LOQ.
Carrots	NEU	Outdoor	4x<0.01	4x<0.02	0.01	0.01	0.01*	1.0	Trials on carrots compliant with a more critical GAP (2x0.375 kg as/ha, 7d), accepted as all residues are below the LOQ.
	SEU	Outdoor	4x<0.01	4x<0.02	0.01	0.01	0.01*		Trials on carrots compliant with GAP.

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Beetroot Celeriac Horseradish Jerusalem artichokes Parsnips Parsley root Radishes Salsify Swedes Turnips	NEU	Outdoor	4x<0.01	4x<0.02	0.01	0.01	0.01*	1.0	Trials on carrots compliant with a more critical GAP (2x0.375 kg as/ha, 7d), accepted as all residues are below the LOQ.
	EU	Indoor	-	-	-	-	-		No trials available. Indoor uses only authorised on parsley root and radishes.
Onions	NEU	Outdoor	-	7x<0.02; 0.06	0.01	0.01	0.01* (tentative)	6.0[(i)]	Trials on onions compliant with GAP. Data on pirimicarb only not available but tentatively assumed to be below the LOQ.
Tomatoes Aubergines (egg plants)	SEU	Outdoor	0.03; <0.01; 0.07; 0.08; 0.03; 0.08; <0.01	0.05; <0.02; 0.09; 0.10; 0.04; 0.09; <0.02	0.03	0.08	0.2 (tentative)	1.3	Trials on tomatoes overdosed (2x0.475-0.650 kg as/ha). Extrapolation to aubergines possible (France, 2010). R_{ber} = 0.24 R_{max} = 0.23 MRL_{OECD} = 0.27
	EU	Indoor	0.16; 0.15; 0.04; 0.04; 0.05; 0.07; 0.10; 0.05	0.17; 0.16; 0.05; 0.05; 0.06; 0.08; 0.12; 0.06	**0.06**	**0.16**	**0.3 (tentative)**		Trials on tomatoes under and overdosed (2x0.325-1.25 kg as/ha, 3d). R_{ber} = 0.27 R_{max} = 0.24 MRL_{OECD} = 0.28

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Peppers	SEU	Outdoor	0.08; 0.03; 0.02; 0.01; 0.04; 0.05; 0.04; 0.09	0.11; 0.04; 0.03; 0.02; 0.06; 0.07; 0.05; 0.10	0.04	0.09	0.2 (tentative)	1.4	Trials on peppers overdosed (2x0.5 kg as/ha). R_{ber} = 0.14 R_{max} = 0.13 MRL_{OECD} = 0.16
	EU	Indoor	0.03; 0.15; 0.06; 0.05; 0.05; 0.20; 0.20; <0.01; 0.01; 0.06; 0.09; 0.09; 0.22	0.04; 0.16; 0.07; 0.06; 0.06; 0.24; 0.25; 0.02; 0.02; 0.07; 0.1; 0.1; 0.26	**0.06**	**0.22**	**0.4**		Trials on peppers compliant with GAP. R_{ber} = 0.35 R_{max} = 0.29 MRL_{OECD} = 0.39
Cucumbers	SEU	Outdoor	3x<0.01; 0.03	3x<0.02; 0.05	0.01	0.03	0.07	1.3	Trials on cucumbers compliant with GAP (Spain, 2014). R_{ber} = 0.07 R_{max} = 0.05 MRL_{OECD} = 0.06
	EU	Indoor	Cucumbers: 0.09; 0.14; 0.12; 0.05; 0.20; 0.18; 0.25 Courgettes: 0.06; 0.10	Cucumbers: 0.13; 0.19; 0.18; 0.08; 0.26; 0.24; 0.32 Courgettes: 0.07; 0.11	**0.12**	**0.25**	**0.4 (tentative)**		Combined dataset on cucumbers and courgettes conducted with a less critical PHI (3d). R_{ber} = 0.33 R_{max} = 0.38 MRL_{OECD} = 0.4

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement	Risk assessment					
Courgettes Gherkins	NEU	Outdoor	0.02; 0.03[j]; 0.02[j]; 0.03[j]	0.04; 0.05[j]; 0.04[j]; 0.06[j]	0.03	0.03	0.08 (tentative)	1.3	Trials on courgettes. Extrapolation to gherkins possible. R_{ber} = 0.06 R_{max} = 0.05 MRL_{OECD} = 0.08
	SEU	Outdoor	0.01; 0.27; 0.06; 0.04;0.04; 0.04; 0.16	0.02; 0.29; 0.08; 0.07;0.05; 0.05; 0.18	0.04	**0.27**	**0.5 (tentative)**		Trials on cucumbers and courgettes. Extrapolation to courgettes and gherkins possible. Last 4 trials overdosed (0.47-0.53 kg as/ha). R_{ber} = 0.32 R_{max} = 0.41 MRL_{OECD} = 0.46
	EU	Indoor	Cucumbers: 0.09; 0.14; 0.12; 0.05; 0.20; 0.18; 0.25; Courgettes: 0.06; 0.10	Cucumbers: 0.13; 0.19; 0.18; 0.08; 0.26; 0.24; 0.32; Courgettes: 0.07; 0.11	**0.12**	0.25	0.4 (tentative)		Direct extrapolation from EU indoor GAP on cucumbers. R_{ber} = 0.33 R_{max} = 0.38 MRL_{OECD} = 0.4
Melons	NEU	Outdoor	-	-	-	-	-	1.3	No trials available.
	SEU	Outdoor	0.07; 0.14; 0.03; 0.07	0.08; 0.15; 0.05; 0.09	0.03	0.14	0.3 (tentative)		Trials on melons compliant with GAP (Spain, 2014). R_{ber} = 0.14 R_{max} = 0.20 MRL_{OECD} = 0.23

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
	EU	Indoor	0.10; 0.04; 0.17; 0.05; 0.02	0.39; 0.05; 0.20; 0.07; 0.03	**0.05**	**0.17**	**0.4 (tentative)**		Trials on melons compliant with GAP (Spain, 2014). R_{ber} = 0.27 R_{max} = 0.33 MRL_{OECD} = 0.32
Pumpkins Watermelons	EU	Indoor	0.10; 0.04; 0.17; 0.02	0.39; 0.05; 0.20; 0.03	0.07	0.17	0.5 (tentative on water-melon)	1.3	Trials on melons compliant with GAP for pumpkins and watermelon (Spain, 2014). R_{ber} = 0.31 R_{max} = 0.43 MRL_{OECD} = 0.35
Sweet corn	NEU	Outdoor	5x<0.001	5x<0.002	0.001	0.001	0.01*	1.0	Trials on sweet corn compliant with GAP. Residues analysed in kernel.
	SEU	Outdoor	<0.01; 0.02; <0.01; <0.01;	<0.02; 0.03; <0.02; <0.02	**0.01**	**0.02**	**0.04**		Trials on sweet corn compliant with GAP. R_{ber} = 0.04 R_{max} = 0.04 MRL_{OECD} = 0.03
Flowering brassica	NEU	Outdoor	-	-	-	-	-	-	No trials available.
	EU	Indoor	-	-	-	-	-	-	No trials available.
Brussels sprouts	NEU	Outdoor	0.06; 0.10; 0.05; 0.36; <0.1; <0.1; <0.1; <0.1	0.11; 0.15; 0.10; 0.46; <0.2; <0.2; <0.2; <0.2	0.10	0.36	0.6 (tentative)	1.7	Trials on Brussels sprouts performed with 2 applications instead of 1. R_{ber} = 0.2 R_{max} = 0.44 MRL_{OECD} = 0.52

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement	Risk assessment					
Head cabbage	NEU	Outdoor	0.05; <0.05; <0.05; <0.05; <0.05; <0.05; 0.04; 0.03	0.1; <0.1; <0.1; <0.1; <0.1; <0.1; 0.08; 0.06	0.05	0.05	0.1 (tentative)	2.0	Trials on head cabbage overdosed (2x0.375 kg as/ha). R_{ber} = 0.1 R_{max} = 0.07 MRL_{OECD} = 0.08
	EU	Indoor	-	-	-	-	-		No trials available
Leafy brassica	NEU	Outdoor	2.1; 1.6; 0.49; 0.31[k]; 0.35[k]	2.84; 2.8; 1.04; 0.82[k]; 0.93[k]	0.49	2.10	5 (tentative)	2.1	Trials on kale compliant with a more critical GAP (2 applications instead of 1). (Netherlands, 2013). R_{ber} = 3.70 R_{max} = 4.44 MRL_{OECD} = 4.27
	NEU	Outdoor (fall-back)	0.08; 0.1; 0.05	0.39; 0.29; 0.27	0.05	0.08	0.3 (tentative)		Trials on kale compliant with GAP (United Kingdom, 2014a). R_{ber} = - R_{max} = 0.27 MRL_{OECD} = 0.23
	SEU	Outdoor	-	-	-	-	-	-	No trials available.
	EU	Indoor	-	-	-	-	-	-	No trials available. No indoor use on kale.
Kohlrabi	NEU	Outdoor	-	-	-	-	-	-	No trials available.
	EU	Indoor	-	-	-	-	-	-	

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Lamb's lettuce Lettuce Scarole (broad-leaf endive) Cress Land cress Rocket, rucola Red mustard Leaves and sprouts of Brassica spp Purslane Spinach	NEU (Lamb's lettuce, lettuce & scarole)	Outdoor	0.02; 0.02; <0.01; 0.07; 0.03	0.43; 0.18; <0.02; 0.65; 0.21	0.02	0.07	0.15 (tentative)	2.8	Trials on lettuce overdosed (2 applications instead of 1) (France, 2010).
	NEU (spinach)	Outdoor	<0.02; 0.03; <0.02; <0.02	0.14; 0.71; 0.23; <0.05	0.02	0.03	0.06		Trials on spinach compliant with GAP (France, 2010). R_{ber} = 0.06 R_{max} = 0.05 MRL_{OECD} = 0.04
	NEU (other salads)	Outdoor	<0.01; <0.01; <0.01; <0.01	<0.02; <0.02; <0.02; 0.08	0.01	0.01	0.01* (tentative)		Trials on lettuce compliant with GAP (Germany, 2014). No information on whether or not trials were performed on open leaves varieties is available.
	SEU (lettuce & scarole)	Outdoor	0.25; 0.37; 0.02; 0.02	0.69; 1.37; 0.11; 0.07	0.14	0.37	1.0 (tentative)		Trials on lettuce overdosed (2x0.5 kg as/ha, PHI 7 d). R_{ber} = 0.68 R_{max} = 1.06 MRL_{OECD} = 0.86
	EU	Indoor	0.76[(l)]; 0.9[(l)]; 1.1[(l)]; 0.35[(l)]; 0.24[(l)]; 2.1; 5.6; 4; 0.27; 1.1; 0.21; 0.89; 0.05; 0.58; 0.44; 2.2; 0.02; 11.5	1.96[(l)]; 1.79[(l)]; 1.74[(l)]; 1.28[(l)]; 1.74[(l)]; 3.07; 8; 5.7; 1.97; 2.9; 0.61; 2.29; 0.3; 1.51; 0.94; 5.28; 0.34; 14.6	**0.83**	**11.5**	**15**		Trials on lettuce compliant with GAP (Netherlands, 2006). R_{ber} = 4.25 R_{max} = 8.74 MRL_{OECD} = 13.12

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
	EU (lettuce)	Indoor (fall-back)	0.14[(l)]; <0.01[(l)]; 0.03[(l)]; 0.11[(l)]; 0.11[(l)]; 0.07; 0.82; 0.03	0.64[(l)]; 0.08[(l)]; 0.36[(l)]; 0.64[(l)]; 0.32[(l)]; 0.74; 1.34; 0.29	0.09	0.82	1.5		Trials on lettuce compliant with GAP (United Kingdom, 2014b). R_{ber} = 0.27 R_{max} = 1.02 MRL_{OECD} = 1.24
Beet leaves (chard)	NEU	Outdoor	<0.02; 0.03; <0.02; <0.02	0.14; 0.71; 0.23; <0.05	0.02	0.03	0.06 (tentative)	2.8	Trials on spinach overdosed (2 applications instead of 1) (France, 2010). R_{ber} = 0.06 R_{max} = 0.05 MRL_{OECD} = 0.04
Witloof	NEU	Outdoor	0.023; <0.02; <0.02; <0.02	<0.05; <0.05; <0.05; <0.05	0.02	0.02	0.05 (tentative)	2.8	Trials on witloof overdosed (2x0.38 kg as/ha, PHI 7 d) (France, 2010).
	EU	Indoor	-	-	-	-	-		No trials available.
Chervil Chives Sage Rosemary Thyme Basil Bay leaves (laurel) Tarragon	NEU	Outdoor	<0.01; <0.01; <0.01; <0.01	<0.02; <0.02; <0.02; 0.08	0.01	0.01	0.01* (tentative)	2.8	Trials on lettuce compliant with GAP on fresh herbs. No information on whether or not varieties were open leaves.
	EU	Indoor	0.21; 0.36; 0.22; 0.02; 0.11	0.67; 0.85; 0.71; 0.20; 0.84	**0.21**	**0.36**	**0.8**		Trials on lettuce (open leaves varieties) compliant with GAP on fresh herbs (UK, 2014). R_{ber} = 0.58 R_{max} = 0.72 MRL_{OECD} = 0.70

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Celery leaves	NEU	Outdoor	<0.01; <0.01; <0.01; <0.01	<0.02; <0.02; <0.02; <0.02	0.01	0.01	0.01* (tentative)	2.8	Trials on lettuce compliant with GAP on celery leaves (Germany, 2014). No information on whether or not trials were performed on open leaves varieties is available.
	EU	Indoor	0.76; 0.9; 1.1; 0.35; 0.24	1.96; 1.79; 1.74; 1.28; 1.74	**0.76**	**1.10**	**3**		Trials on lettuce (open leaves varieties) compliant with GAP on celery leaves (United Kingdom, 2014a). R_{ber} = 2.0 R_{max} = 2.21 MRL_{OECD} = 2.13
Parsley	NEU	Outdoor	<0.02; 0.03; <0.02; <0.02	0.14; 0.71; 0.23; <0.05	0.02	0.03	0.06 (tentative)	2.8	Trials on spinach overdosed (2 applications instead of 1) (France, 2010). R_{ber} = 0.06 R_{max} = 0.05 MRL_{OECD} = 0.04
	EU	Indoor	0.76; 0.9; 1.1; 0.35; 0.24	1.96; 1.79; 1.74; 1.28; 1.74	**0.76**	**1.10**	**3**		Trials on lettuce (open leaves varieties) compliant with GAP on parsley (United Kingdom, 2014a). R_{ber} = 2.0 R_{max} = 2.21 MRL_{OECD} = 2.13

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Beans (fresh, with pods) Peas (fresh, with pods)	NEU	Outdoor	0.25; 0.08; 0.16; 0.22; 0.01; 0.11; 0.04; 0.35	0.30; 0.24; 0.27; 0.44; 0.03; 0.2; 0.1; 0.46	0.14	0.35	0.7 (tentative)	1.7	Trials on beans with pods overdosed (2 applications instead of 1). Extrapolation to peas with pods possible. R_{ber} = 0.48 R_{max} = 0.52 MRL_{OECD} = 0.61
	SEU	Outdoor	0.28; 0.12; 0.73; 0.14; 0.16	0.37; 0.16; 0.96; 0.20; 0.33	**0.16**	**0.73**	**1.5 (tentative)**		First trial on beans compliant with GAP. Other trials overdosed (2x0.475-0.5 kg as/ha). Extrapolation to peas with pods possible. R_{ber} = 1.01 R_{max} = 1.36 MRL_{OECD} = 1.31
	EU	Indoor	-	-	-	-	-		No trials available.
Beans (fresh, without pods)	SEU	Outdoor	-	-	-	-	-	-	No trials available.
	EU	Indoor	-	-	-	-	-	-	No trials available.

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Peas (fresh, without pods)	NEU	Outdoor	<0.01; <0.01	<0.02; <0.02	0.01	0.01	0.01*	1.0	Trials on peas without pods conducted with a more critical GAP (2x0.375 kg as/ha, 3d) acceptable as no residue was detected in seeds (France, 2010).
	SEU	Outdoor	<0.01; <0.01	<0.02; <0.02	0.01	0.01	0.01*		Trials on peas without pods conducted with a more critical GAP (2x0.375 kg as/ha, PHI 3d), deemed acceptable as no residue was detected in seeds (France, 2010).
Lentils (fresh)	NEU	Outdoor	-	-	-	-	-	-	No trials available.
Asparagus	NEU	Outdoor	2x<0.01	2x<0.02	0.01	0.01	0.01*	1.0	Trials on asparagus overdosed (2x0.5 kg as/ha) acceptable as residues were always below the LOQ.
	SEU	Outdoor	2x<0.01	2x<0.02	0.01	0.01	0.01*		Trials on asparagus overdosed (2x0.5 kg as/ha) acceptable as residues were always below the LOQ.

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Cardoons	NEU	Outdoor	-	-	-	-	-	1.5	No trials available.
	SEU	Outdoor	0.10; 0.049; 0.035; 0.064	0.133; 0.072; 0.05; 0.098	0.06	0.10	0.2 (tentative)		Trials on cardoons overdosed (2 applications instead of 1). R_{ber} = 0.18 R_{max} = 0.21 MRL_{OECD} = 0.19
Celery	NEU	Outdoor	0.008; 0.03; 0.04	0.04; 0.08; 0.09	0.03	0.04	0.15 (tentative)	1.7 [(m)]	Trials on celery compliant with GAP (UK, 2014). R_{ber} = - R_{max} = 0.15 MRL_{OECD} = = 0.09
Fennel Rhubarb	NEU	Outdoor	0.008; 0.03; 0.04	0.04; 0.08; 0.09	0.03	0.04	0.15 (tentative)	**1.7**	Direct extrapolation from celery. R_{ber} = - R_{max} = 0.15 MRL_{OECD} = = 0.09
	EU	Indoor	0.141; 0.194; 0.33; 0.702	0.23; 0.35; 0.55; 1.98	**0.26**	**0.70**	**2**		Trials on celery compliant with GAP on fennel (EFSA, 2009) and on rhubarb. A more critical GAP has been notified on fennel but it is not supported by data. R_{ber} = 1.22 R_{max} = 1.64 MRL_{OECD} = 1.35

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement	Risk assessment					
Globe artichokes	NEU	Outdoor	0.31;0.19;0.23;0.09;0.26;0.52	0.45;0.22;0.29;0.11;0.3;0.61	0.25	0.52	0.9 (tentative)	1.2	Trials on artichokes overdosed (2x0.38 kg as/ha). R_{ber} = 0.73 R_{max} = 0.80 MRL_{OECD} = 0.85
Leek	NEU	Outdoor	-	-	-	-	-	-	No trials available.
	EU	Indoor	-	-	-	-	-	-	No trials available.
Beans (dry) Peas (dry)	NEU	Outdoor	<0.01; 0.05; <0.01; 0.04	<0.02; 0.06; <0.02; 0.05	0.03	0.05	0.15 (tentative)	1.4 [n]	Trials on dry beans overdosed (2x0.38 kg as/ha). Extrapolation to dry peas possible. Metabolites were below the LOQ. R_{ber} = 0.1 R_{max} = 0.13 MRL_{OECD} = 0.11
Lentils (dry) Lupins (dry)	NEU	Outdoor	0.01; 0.03; <0.01; 0.05	0.02; 0.04; <0.02; 0.06	0.02	0.05	0.15 (tentative)	1.4 [n]	Trials on dry beans overdosed (2x0.38 kg as/ha). Metabolites were below the LOQ. R_{ber} = 0.09 R_{max} = 0.12 MRL_{OECD} = 0.10
Poppy seed Gold of pleasure	NEU	Outdoor	<0.01; 0.02; 0.01; 0.02	<0.02; 0.03; 0.02; 0.03	0.02	0.02	0.05	1.4 [n]	Residue trials on rape seed compliant with GAP (France, 2010). Metabolites were below the LOQ. R_{ber} = 0.04 R_{max} = 0.04 MRL_{OECD} = 0.04

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Sunflower seed	NEU	Outdoor	0.03; 0.04; 0.01; <0.01	0.04; 0.05; 0.02; <0.02	**0.02**	0.04	0.08 (tentative)	1.4	Trials on sunflower seed performed with 3 app instead of 2 accepted as first application is not expected to impact on the final residue. R_{ber} = 0.08 R_{max} = 0.1 MRL_{OECD} = 0.08
	SEU	Outdoor	0.03; 0.01; 0.01; 0.05; 0.03; 0.01; <0.01; <0.01	0.04; 0.02; 0.02; 0.07; 0.04; 0.02; <0.02; <0.02	0.01	**0.05**	**0.08**		Trials on sunflower seed performed with 3 applications instead of 2 accepted as first application is not expected to impact on the final residue. R_{ber} = 0.06 R_{max} = 0.07 MRL_{OECD} = 0.08
Linseed Rape seed Borage	NEU	Outdoor	0.02; <0.01; <0.01[(o)]; 0.02[(o)]	0.03; <0.02; <0.02[(o)]; 0.03[(o)]	**0.01**	**0.02**	**0.05 (tentative)**	1.4 [(n)]	Trials on rape seed compliant with GAP. Metabolites were below the LOQ. R_{ber} = 0.04 R_{max} = 0.04 MRL_{OECD} = 0.04
	SEU	Outdoor	<0.01; <0.01	<0.02; <0.02	0.01	0.01	0.01* (tentative)		Trials on rape seed compliant with GAP (France, 2010). No uses authorised on linseed and borage in SEU.
Mustard seed	NEU	Outdoor	-	-	-	-	-	-	No trials available.

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Barley grain Oats grain	NEU	Outdoor	<0.01; <0.01; <0.01; <0.01	<0.02; <0.02; <0.02; <0.02	0.01	0.01	0.01*	1.0	Trials on barley slightly overdosed (2x0.15 kg/ha) accepted as results are below the LOQ. Extrapolation to oats possible.
	SEU	Outdoor	<0.01; <0.01; <0.01	<0.02; <0.02; <0.02	0.01	0.01	0.01*		Trials on barley overdosed (2 x 0.21 kg as/ha), accepted as no residue above the LOQ. Extrapolation to oats possible.
Barley straw Oats straw	NEU	Outdoor	0.02; <0.01; 0.03; 0.02	0.07; <0.02; 0.05; 0.04	0.02	0.03	0.07	2.0	Trials on barley conducted with a slightly more critical dose (2x0.15 kg/ha). Extrapolation to oats possible. R_{ber} = 0.06 R_{max} = 0.06 MRL_{OECD} = 0.06
	SEU	Outdoor	0.1; 0.05; <0.01	0.2; 0.11; 0.03	**0.05**	**0.10**	**0.4**		Trials on barley overdosed (2x0.21 kg as/ha). Extrapolation to oats possible. R_{ber} = - R_{max} = 0.40 MRL_{OECD} = 0.23

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Maize grain	NEU	Outdoor	<0.01; 0.02; <0.01; <0.01; <0.01	<0.02; 0.04; <0.02; <0.02, <0.02	**0.01**	**0.02**	**0.03 (tentative)**	1.0	Trials on maize compliant with GAP. R_{ber} = 0.03 R_{max} = 0.03 MRL_{OECD} = 0.03
	SEU	Outdoor	<0.01; <0.01; <0.01; <0.01; <0.01; <0.01; <0.01; <0.01	<0.02; <0.02; <0.02; <0.02; <0.02; <0.02; <0.02; <0.02	0.01	0.01	0.01*		Trials on maize compliant with GAP.
Sorghum grain	SEU	Outdoor	<0.01; <0.01; <0.01; <0.01; <0.01; <0.01; <0.01; <0.01	<0.02; <0.02; <0.02; <0.02; <0.02; <0.02; <0.02; <0.02	0.01	0.01	0.01*	1.0	Direct extrapolation from maize.
Maize (forage)	NEU	Outdoor	<0.01; <0.01	<0.02; <0.02	0.01	0.01	0.01*	1.0	Trials on maize (whole plant) compliant with GAP (France, 2010).
	SEU	Outdoor	<0.01; <0.01; <0.01	<0.02; <0.02; <0.02	0.01	0.01	0.01*		Trials on maize (whole plant) compliant with GAP (France, 2010).

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement	Risk assessment					
Wheat grain Rye grain	NEU	Outdoor	7x<0.01	7x<0.02	0.01	0.01	0.01*	1.0	Trials on wheat compliant with GAP. Extrapolation to rye possible.
	SEU	Outdoor	<0.01; <0.01	<0.02; <0.02;	**0.01**	**0.01**	**0.01***		Trials on wheat overdosed (2x0.21 kg as/ha), acceptable as residues are below the LOQ. No use on rye in SEU. R_{ber} = 0.06 R_{max} = 0.05 MRL_{OECD} = 0.06
Wheat straw Rye straw	NEU	Outdoor	<0.01; <0.01; 0.03; 0.02; 0.07; <0.05; 0.02; 0.18	<0.02; <0.02; 0.11; 0.04; 0.22; 0.13; 0.06; 0.38	0.03	0.18	0.3 (tentative)	2.1	Trials on wheat compliant with GAP. Extrapolation to rye possible. R_{ber} = 0.14 R_{max} = 0.26 MRL_{OECD} = 0.29
	SEU	Outdoor	-	-	-	-	-		No trials available.
Herbal infusions (dried flowers) Herbal infusions (dried leaves)	NEU	Outdoor	4.4; 3.2; 2.4; 1.3	5; 3.6; 2.8; 1.6	2.80	4.40	10[p] (tentative)	1.2	Trials on chamomile. Last 2 trials performed with 1 application only (Germany, 2014). R_{ber} = 8.2 R_{max} = 9.55 MRL_{OECD} = 8.48
Herbal infusions (dried roots)	NEU	Outdoor	4x<0.01	4x<0.02	0.01	0.01	0.01*[p] (tentative)	1.0	Trials on carrots compliant with a more critical GAP (2x0.375 kg/ha, 7d) acceptable as all residues are below the LOQ.

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Spices (seeds) Spices (fruits and berries)	NEU	Outdoor	-	-	-	-	-	-	No trials available.
Sugar beet (root) Fodder beet (root)	NEU	Outdoor	<0.01; <0.01; <0.01; <0.01; 0.01; <0.01; <0.01; <0.01	<0.02; <0.02; <0.02; <0.02; 0.02; <0.02; <0.02; <0.02	0.01	0.01	0.01*	1.0	Trials on sugar beet compliant with GAP. Extrapolation to fodder beet possible.
Sugar beet (leaves) Fodder beet (leaves)	NEU	Outdoor	0.73; 0.41; 0.25; 0.15; 0.25; 0.30; 0.09; 0.22	1.34; 0.91; 0.68; 0.61; 0.47; 0.55; 0.14; 0.50	0.25	0.73	1 (tentative)	2.2	Trials on sugar beet compliant with GAP. Extrapolation to fodder beet possible. R_{ber} = 0.76 R_{max} = 0.93 MRL_{OECD} = 1.09
Chicory roots	NEU	Outdoor	<0.01; <0.01; <0.01; 0.01	<0.05; <0.05; <0.05; 0.05	0.01	0.01	0.01*	1.0	Trials on chicory roots overdosed (2x0.5 kg as/ha) accepted as residues were always below or at the LOQ.
Alfalfa Grass	NEU	Outdoor	-	-	-	-	-	-	No trials available. Use on grass is for seed production.

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e outdoor use) or Import (country code) (EC, 2011).
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(e): Results taken at longer PHI (7 days instead of 3), because residue level was higher than at the authorised PHI.
(f): Results taken at longer PHI (21 days instead of 7), because residue level was higher than at the authorised PHI.
(g): Results taken at longer PHI (14 days instead of 7), because residue level was higher than at the authorised PHI.
(h): Results taken at shorter/longer PHI (2 or 4 days instead of 3). This deviation is deemed acceptable since the considered crops are minor.
(i): The conversion factor is based on a single value above the LOQ out of 8 and should therefore be considered as a worst case.
(j): Results taken at longer PHI (3 days instead of 1), used to derive tentative MRL and risk assessment values.
(k): Results taken at longer PHI (4 days instead of 3), used to derive tentative MRL and risk assessment values.

(l): Residue trials conducted on open-leaves varieties (United Kingdom, 2014b).
(m): the CF factor derived from the complete indoor dataset has been considered for risk assessment.
(n): As levels of desmethyl pirimicarb and desmethyl formamido pirimicarb were below the LOQ in all available trials on pulses and oilseeds (except sunflower), the conversion factor derived from sunflower (1.4) was applied to all commodities belonging to pulses and oilseeds metabolism group.
(o): Results taken at longer PHI (19-21 days instead of 14), used to derive tentative MRL and risk assessment values.
(p): No analytical method is available for this group; therefore, the MRL and risk assessment values are tentative.
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of pirimicarb was investigated by France in the framework of a national authorisation and the registration report including the evaluation of these studies was submitted along with the PROFile (France, 2010). Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). From these studies, it was concluded that processing by pasteurisation, baking/brewing/boiling and sterilisation is not expected to have a significant impact on the composition of residues in matrices of plant origin. The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops.

Processing studies on apples, plums, tomatoes, barley, lettuce and brassica were also assessed by France (France, 2010). Results from these new processing studies were disregarded as residues in both raw and processed commodities were expressed as sum of pirimicarb and desmethyl pirimicarb and no information on the level of pirimicarb only was available. Nevertheless, further processing studies are not required as they are not expected to affect the outcome of the risk assessment but, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops under consideration, except permanent crops (orchards and vineyard), may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, the available field studies indicate that the DT_{90} value for pirimicarb amounts for a maximum of 190 days. Laboratory studies (aerobic) also indicate that DT_{90} values are 288 days for desmethyl pirimicarb, 632 days for R31805 and more than 398 days for R34865 (United Kingdom, 2003). According to the European guidelines on rotational crops (EC, 1997c), further investigation of residues in rotational crops is relevant.

3.1.2.2. Nature and magnitude of residues

The metabolism of pirimicarb in rotational crops – lettuce, radish, millet – has been evaluated under the peer review (United Kingdom, 2003). One confined rotational crop study investigating the nature of residues following different plant-back intervals is available. The characteristics of this study are summarised in Table 3-3.

In commodities used as food items sampled at harvest, TRR accounted for 0.3, 0.37 and 0.13 mg eq/kg in lettuce; 0.18, 0.06 and 0.03 mg eq/kg in radish root and 0.26, 0.13 and 0.07 mg eq/kg in millet grain, sown 29, 61 and 119 DAT, respectively. In commodities used as feed items only, TRR accounted for 1.8, 1.1 and 0.33 mg eq/kg in radish leaves; 1.8, 0.6 and 0.2 mg eq/kg in millet forage, 1.6, 0.6 and 0.2 mg eq/kg in millet hay and 5, 1.4 and 1.0 mg eq/kg in straw, sown 29, 61 and 119 DAT, respectively.

In radish roots, 32-56 % TRR (0.01-0.07 mg/kg) was identified, among which 18-39 % TRR (0.01-0.03 mg/kg) corresponded to pirimicarb, desmethyl pirimicarb and desmethyl formamido pirimicard. 9-20 % TRR (<0.01-0.03 mg/kg) was identified as hydroxypyridine metabolites (R31805 under free and conjugated form, R34865 and R31680). 23-41 % TRR (0.01-0.07 mg/kg) was characterized as polar compounds and 3-9.5 % TRR (<0.01-0.02 mg/kg) as non polar compounds.

In lettuce, 20-26 % TRR (0.03-0.08 mg/kg) was identified, among which 2-7 % TRR (0.01-0.03 mg/kg) corresponded to pirimicarb, desmethyl pirimicarb and desmethyl formamido pirimicard. 13-16 % TRR (0.02-0.05 mg/kg) was identified as hydroxypyridine metabolites.

32-43 % TRR (0.04-0.1 mg eq/kg) was characterized as polar compounds and 3-9.5 % TRR (<0.01-0.02 mg/kg) as non polar compounds.

Table 3-3: Summary of available metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks
Leafy vegetables	Lettuce	^{14}C-pyrimidine	Bare soil, F	1.48	29 61 119	46 58 56	-
Root and tuber vegetables	Radish				29 61 119	32 37 40	-
Cereals	Millet				29 61 119	32[(b)], 55[(c)], 89[(d)] 28[(b)], 56[(c)], 98[(d)] 15[(b)], 40[(c)], 82[(d)]	-

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G).
(b): Sampling of forage.
(c): Sampling of hay.
(d): Sampling of straw and grain.

In cereal grain, 14-23 % TRR (0.02-0.06 mg/kg) was identified, among which 0-7 % TRR (up to 0.01 mg/kg) corresponded to pirimicarb, desmethyl pirimicarb and desmethyl formamido pirimicard . 11-14 %TRR (<0.01-0.03 mg/kg) were identified as hydroxypyridine metabolites. 49-60 % TRR (0.04-0.1 mg/kg) was characterized as polar compounds and up to 8 % TRR (0.02 mg/kg) as non polar compounds.

In cereal forage, 18-30 % TRR (0.04-0.5 mg/kg) was identified, among which 2-8 % TRR (0.01-0.07 mg/kg) corresponded to pirimicarb, desmethyl pirimicarb and desmethyl formamido pirimicard . 14-23 % TRR (0.03-0.4 mg/kg) was identified as hydroxypyridine metabolites. 36-48 % TRR (0.08-0.6 mg/kg) was characterized as polar compounds and up to 5-15 % TRR (<0.01-0.3 mg/kg) as non polar compounds.

In cereal hay, 18-27% TRR (0.03-0.4 mg eq/kg) was identified, among which up to 2% TRR (0.04 mg/kg) corresponded to pirimicarb, desmethyl pirimicarb and desmethyl formamido pirimicard. 18-23% TRR (0.03-0.4 mg/kg) was identified as hydroxypyridine metabolites. 35-42% TRR (0.07-0.6 mg/kg) was characterized as polar compounds and up to 5-17% TRR (0.01-0.3 mg/kg) as non polar compounds.

In cereal straw, 18-24 % TRR (0.2-1.1 mg eq/kg) was identified, among which 1-2 % TRR (0.01-0.09 mg/kg) corresponded to pirimicarb, desmethyl pirimicarb and desmethyl formamido pirimicard and 15-22 % TRR (0.2-1 mg/kg) were identified as hydroxypyridine metabolites. 36-45 % TRR (0.4-1.8 mg/kg) was characterized as polar compounds and 9-10 % TRR (0.09-0.5 mg/kg) as non polar compounds.

In radish leaves, 33-44 % TRR (0.1-0.6 mgq/kg) was identified, among which 4-6 % TRR (0.01-0.08 mg/kg) corresponded to pirimicarb, desmethyl pirimicarb and desmethyl formamido pirimicard. 27-30 % TRR (0.09-0.5 mg/kg) was identified as hydroxypyridine metabolites. 28-40 % TRR (0.1-0.5 mg/kg) was characterized as polar compounds and 10-13 % TRR (0.04-0.08 mg/kg) as non polar compounds.

In most of the plant commodities, hydroxypyridine metabolites were the major compounds identified. Metabolic patterns in primary and succeeding crops are similar and the same residue definitions are set for primary crops can be proposed. Considering that the application rate in the study corresponded to 1.5 times the application rate reported in the PROFile (total application rate for pulses in northern Europe and cucumbers in southern Europe), the presence of pirimicarb and metabolites relevant for the residue definition cannot be excluded in rotational or succeeding crops. Consequently, EFSA concludes that Member States granting authorisations for pirimicarb should take the appropriate risk mitigation measures (e.g. definition of pre-planting intervals) in order to avoid the presence of significant residues in rotational crops.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

Pirimicarb is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarised in Table 3-4. For apple pomace, cereal bran, maize silage and oilseed meals, default processing factors of 2.5, 8, 1 and 2, respectively, have been included in the calculation in order to consider the potential concentration of residues in these commodities. Concentration of residues in this commodity is therefore not expected. It is highlighted that for some feed items, no residue data were available (grass, alfalfa forage). The animal intake of pirimicarb residues via these commodities has therefore not been assessed and may have been underestimated.

Table 3-4: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of pirimicarb, desmethyl pirimicarb and desmethylformamido pirimicarb, expressed as pirimicarb				
Cabbage	0.10	Median residue x CF	0.10	Highest residue x CF
Kale	1.03	Median residue x CF	4.41	Highest residue x CF
Sugar beet and fodder beet, leaves	0.53	Median residue x CF	1.53	Highest residue x CF
Maize silage	0.01*	Median residue x CF	0.01*	Median residue x CF
Apple pomace	0.72	Median residue x CF x 2.5	0.72	Median residue x CF x 2.5
Wheat, rye grain	0.01*	Median residue x CF	0.01*	Median residue x CF
Barley, oat grain	0.01*	Median residue x CF	0.01*	Median residue x CF
Maize grain	0.01*	Median residue x CF	0.01*	Median residue x CF
Wheat, rye bran	0.08	Median residue x CF x 8	0.08	Median residue x CF x 8
Wheat, rye straw	0.06	Median residue x CF	0.38	Highest residue x CF
Barley, oat straw	0.11	Median residue x CF	0.22	Highest residue x CF
Peas and beans (dry)	0.04	Median residue x CF	0.04	Median residue x CF
Lupins (dry)	0.03	Median residue x CF	0.03	Median residue x CF
Potatoes	0.01*	Median residue x CF	0.01*	Highest residue x CF

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Turnips	0.01*	Median residue x CF	0.01*	Highest residue x CF
Swedes	0.01*	Median residue x CF	0.01*	Highest residue x CF
Sugar and fodder beet, root	0.01*	Median residue x CF	0.01*	Highest residue x CF
Rape seed meal Linseed meal	0.03	Median residue x CF x 2	0.03	Median residue x CF x 2
Sunflower seed meal	0.06	Median residue x CF x 2	0.06	Median residue x CF x 2

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

The results of the calculations are reported in Table 3-5. The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.

Table 3-5: Results of the dietary burden calculation

	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: sum of pirimicarb, desmethyl pirimicarb and desmethylformamido pirimicarb, expressed as pirimicarb					
Dairy ruminants	0.10	0.41	Kale	11.3	Y
Meat ruminants	0.11	0.48	Kale	11.2	Y
Poultry	0.03	0.10	Kale	1.63	Y
Pigs	0.05	0.19	Kale	4.81	Y

3.2.2. Nature and magnitude of residues

The nature of pirimicarb residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (United Kingdom, 2003). Reported metabolism studies include one study in lactating goats and one study in laying hens using [^{14}C]-pyrimidine-labelled pirimicarb. The characteristics of these studies are summarised in Table 3-6.

A lactating goat was dosed with 0.68 mg/kg bw per d of pirimicarb, corresponding to approximately 1.4 times the exposure of meat ruminant. Studies demonstrate that transfer of residues to milk and tissues is significant. 74 % of the total administrated dose was excreted, 2.7 % was recovered in organs and 0.3 % was found in milk. The remaining 23 % was not recovered. No accumulation was observed in milk as the TRR remained steady during the five days (0.04-0.07 mg eq/kg). Highest residue levels were found in liver (0.45 mg eq/kg) and in kidney (0.35 mg eq/kg). TRR in muscle and fat was lower, amounting to 0.08 and 0.05 mg eq/kg, respectively.

Pirimicarb was not detected in any analysed sample. Hydroxypyrimidine compounds (R31805, R34865 and R31680) were detected at levels between 0.01-0.03 mg/kg in the different organs and in milk. The sum of these compounds accounted for 29 % TRR in milk (0.03 mg/kg), 14% TRR in liver (0.07 mg/kg), 10 % TRR in kidney (0.04 mg/kg) and 10 % TRR in muscle (<0.01 mg/kg). In milk, the metabolite R406405[19] was also identified at level of 0.01 mg/kg (14 % TRR) and the remaining extracted radioactivity (34 % TRR, 0.03 mg/kg) was characterised as largely polar (United Kingdom,

[19]R406405: 5-hydroxymethyl-6-methyl-2-(methylamino)pyrimidin-4-ol. See Appendix E.

2003). In kidney, muscle and liver, 75 % (0.3 mg/kg), 68 % (0.06 mg eq/kg) and 65 % TRR (0.33 mg/kg) were characterised as unknown polar compounds, none exceeding 10 % TRR (FAO, 2006). The sample of fat submitted to analysis contained 0.02 mg eq/kg. 94 % TRR remained unextracted in the analysed sample and no further characterisation was reported.

Table 3-6: Summary of available metabolism studies in livestock

Group	Species	Label position	No of animal	Application details		Sample details	
				Rate (mg/kg bw per d)	Duration (days)	Commodity	Time
Lactating ruminants	Goat	^{14}C-pyrimidine	1	0.68	5	Milk	Twice daily
						Urine and faeces	Daily
						Tissues	At sacrifice
Laying poultry	Hens	^{14}C-pyrimidine	10	0.72	10	Eggs	-
						Excreta	-
						Tissues	-

In the reported metabolism study, a high level of TRR remains unidentified, especially in liver (65 % TRR), kidney (75 % TRR) and muscle (68 % TRR). According to JMPR the unidentified radioactivity contained up to 8 metabolites each representing less than 10 % TRR. However, considering also the lack of residue data for some feed items which can lead to an underestimation of the calculated dietary burdens (see also Section 3.2.1), further clarifications on the identity of the radioactive residue are required. Consequently EFSA cannot conclude on the residue definition in ruminants and the submission of a new metabolism study in ruminants is still required. If transfer of pirimicarb residue to animal commodities cannot be excluded from this study, a ruminant feeding study should be submitted as well. Meanwhile, no MRL nor risk assessment values can be proposed. It is noted by EFSA that the different residue definition, which includes parent compound only, derived in the framework of the peer review (EFSA, 2005) was based on a dietary burden 20-60 times lower (for dairy and meat ruminants, respectively) and it is considered no longer appropriate.

Laying hens were dosed with 0.72 mg/kg bw per d of pirimicarb, corresponding to approximately 7.2 times the exposure of poultry. Studies demonstrate that transfer of residues to eggs and tissues occurs. 88 % of the total administrated dose was excreted, 0.9% was recovered in organs and 0.1-0.2 % was found in eggs. The remaining 11 % was not recovered. The TRR reached a plateau on day 3 in egg whites at 0.09 mg eq/kg and on day 7 in egg yolks at 0.15 mg eq/kg. Highest residue levels were found in liver (0.3 mg eq/kg) and in muscle (0.12-0.15 mg eq/kg). TRR in fat was lower, with 0.02 mg eq/kg.

Pirimicarb was not detected in any analysed sample. Hydroxypyrimidine compounds (R31805, R34865 and R31680) were detected at levels between 0.01-0.07 mg/kg in the different organs and in eggs. The sum of these compounds accounted for 33 % TRR in egg yolk (0.05 mg/kg) and 65 % TRR in egg white (0.05 mg/kg), 16 % TRR in liver (0.05 mg/kg) and 32-47 % TRR in muscle (0.04-0.07 mg/kg). In egg whites and yolk, the remaining extracted radioactivity (34% TRR, 0.03 mg/kg) was characterised as generally more polar than identified metabolites (United Kingdom, 2003). In muscle and liver, 24-37 % (0.04-0.05 mg/kg) and 62 % TRR (0.17 mg/kg) were characterised as polar compounds. In fat, 83 % TRR remained unextracted.

According to the above mentioned metabolism study, it is concluded that, after exposure to the maximum dietary burden (about 7.2 times lower than the dose level of the metabolism studies; see

also Section 3.2.1), residue levels in poultry commodities are expected to remain below the enforcement LOQ of 0.01 mg/kg. Hence, the residue definition in poultry is proposed by default as pirimicarb only. No poultry feeding study is needed. MRLs and risk assessment values for the relevant commodities in poultry can be established at the LOQ level. Validated analytical methods for enforcement of the proposed residue definition in poultry commodities are available (see also Section 1.1).

4. Consumer risk assessment

In the framework of this review, only the uses of pirimicarb reported by the RMS in Appendix A were considered, however the use of pirimicarb was previously also assessed by the JMPR (FAO, 2006). The CXLs, resulting from this assessment by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. In order to facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs (see Appendix C.2).

4.1. Consumer risk assessment without consideration of the existing CXLs

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). Input values for the exposure calculations were derived in compliance with Appendix D and are summarised in Table 4-1. The tentative median and highest residue values selected for chronic and acute intake calculations are based on the residue levels in the raw agricultural commodities reported in Section 3. For those commodities where data were insufficient to derive an MRL in Section 3, EFSA considered the existing EU MRL multiplied by the following conversion factors for an indicative calculation: 1.3 for fruits and spices (fruits and berries), 1.4 for fruiting vegetables, spices (seeds) and for pulses and oilseeds, 1.7 for stem vegetables and fresh legume vegetables, 1 for root and tuber vegetables, 2.8 for lettuces, brassica and herbs. The contributions of other commodities, for which no GAP was reported in the framework of this review, were not included in the calculation.

Table 4-1: Input values for the consumer risk assessment (without consideration of CXLs)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of pirimicarb, desmethyl pirimicarb and desmethyl formamido pirimicarb, expressed as pirimicarb				
Almonds	0.02	Median residue x CF [(a)]	0.02	Highest residue x CF [(a)]
Chestnuts	0.02	Median residue x CF [(a)]	0.02	Highest residue x CF [(a)]
Hazelnuts	0.02	Median residue x CF [(a)]	0.02	Highest residue x CF [(a)]
Walnuts	0.02	Median residue x CF [(a)]	0.02	Highest residue x CF [(a)]
Apples, pears	0.29	Median residue x CF [(a)]	1.29	Highest residue x CF [(a)]
	0.19	Median residue x CF (tentative, fall-back) [(b)]	0.38	Highest residue x CF (tentative, fall-back) [(b)]
Quinces	0.26	Median residue x CF (tentative) [(c)]	1.29	Highest residue x CF (tentative) [(c)]
Apricots Peaches	0.48	Median residue x CF (tentative) [(c)]	1.31	Highest residue x CF (tentative) [(c)]
Cherries	1.47	Median residue x CF (tentative) [(c)]	2.20	Highest residue x CF (tentative) [(c)]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Plums	0.41	Median residue x CF (tentative) [c]	0.55	Highest residue x CF (tentative) [c]
Table grapes, Wine grapes	1.30	EU MRL x CF [d]	1.30	EU MRL x CF [d]
Strawberries	0.37	Median residue x CF [a]	1.21	Highest residue x CF [a]
Blackberries, Dewberries, Raspberries	0.52	Median residue x CF (tentative) [c]	2.31	Highest residue x CF (tentative) [c]
Blueberries, Cranberries, Currants (red, black and white), Gooseberries, Azarole (mediteranean medlar)	0.27	Median residue x CF [a]	0.42	Highest residue x CF [a]
Potatoes, Beetroot, Carrots, Celeriac, Horseradish, Jerusalem artichokes, Parsnips, Parsley root, Radishes, Salsify, Swedes, Turnips	0.01*	Median residue x CF [a]	0.01*	Highest residue x CF [a]
Onions	0.06	Median residue x CF (tentative) [c]	0.06	Highest residue x CF (tentative) [c]
Tomatoes, Aubergines (egg plants)	0.08	Median residue x CF (tentative) [c]	0.21	Highest residue x CF (tentative) [c]
Peppers	0.08	Median residue x CF [a]	0.31	Highest residue x CF [a]
Cucumbers	0.16	Median residue x CF (tentative) [c]	0.33	Highest residue x CF (tentative) [c]
Gherkins Courgettes	0.16	Median residue x CF (tentative) [c]	0.35	Highest residue x CF (tentative) [c]
Melons	0.09	Median residue x CF (tentative) [c]	0.22	Highest residue x CF (tentative) [c]
Pumpkins	0.09	Median residue x CF [a]	0.22	Highest residue x CF [a]
Watermelons	0.09	Median residue x CF (tentative) [c]	0.22	Highest residue x CF (tentative) [c]
Sweet corn	0.01	Median residue x CF [a]	0.02	Highest residue x CF [a]
Broccoli, Cauliflower	5.6	EU MRL x CF [d]	5.6	EU MRL x CF [d]
Brussels sprouts	0.17	Median residue x CF (tentative) [c]	0.61	Highest residue x CF (tentative) [c]
Head cabbage	0.10	Median residue x CF (tentative) [c]	0.10	Highest residue x CF (tentative) [c]
Chinese cabbage Kale	1.03	Median residue x CF (tentative) [c]	4.41	Highest residue x CF (tentative) [c]
	0.17	Median residue x CF (tentative, fall-back) [b]	0.21	Highest residue x CF (tentative, fall-back) [b]
Kohlrabi	1.40	EU MRL x CF [d]	1.40	EU MRL x CF [d]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Lamb's lettuce, Cress, Land cress, Rocket, Rucola, Red mustard, Leaves and sprouts of Brassica spp	2.31	Median residue x CF [(a)]	32.2	Highest residue x CF [(a)]
Lettuce	2.31	Median residue x CF [(a)]	32.2	Median residue x CF [(a)]
	0.38	Median residue x CF (fall-back)[(e)]	2.30	Highest residue x CF (fall-back)[(e)]
Scarole (broad-leaf endive)	2.31	Median residue x CF [(a)]	32.2	Median residue x CF [(a)]
	0.38	Median residue x CF (tentative, fall-back)[(b)]	1.04	Highest residue x CF (tentative, fall-back)[(b)]
Spinach	2.31	Median residue x CF [(a)]	32.2	Highest residue x CF [(a)]
	0.06	Median residue x CF (tentative fall-back)[(b)]	0.08	Highest residue x CF (tentative fall-back)[(b)]
Purslane	2.31	Median residue x CF [(a)]	32.2	Highest residue x CF [(a)]
	0.03	Median residue x CF (tentative, fall-back)[(b)]	0.03	Highest residue x CF (tentative, fall-back)[(b)]
Beet leaves (chards)	0.06	Median residue x CF (tentative) [(c)]	0.08	Highest residue x CF (tentative) [(c)]
Witloof	0.06	Median residue x CF (tentative) [(c)]	0.06	Highest residue x CF (tentative) [(c)]
Chervil, Chives, Sage, Rosemary, Thyme, Basil, Bay leaves (laurel), Tarragon	0.59	Median residue x CF [(a)]	1.01	Highest residue x CF [(a)]
Celery leaves, Parsley	2.13	Median residue x CF [(a)]	3.08	Highest residue x CF [(a)]
Beans (fresh, with pods) Peas (fresh, with pods)	0.27	Median residue x CF (tentative) [(c)]	1.24	Highest residue x CF (tentative) [(c)]
Beans (fresh, without pods)	1.70	EU MRL x CF [(d)]	1.70	EU MRL x CF [(d)]
Peas (fresh, without pods)	0.01*	Median residue x CF [(a)]	0.01*	Highest residue x CF [(a)]
Lentils (fresh)	1.19	EU MRL x CF [(d)]	1.19	EU MRL x CF [(d)]
Asparagus	0.01*	Median residue x CF [(a)]	0.01*	Highest residue x CF [(a)]
Cardoons	0.08	Median residue x CF (tentative) [(c)]	0.15	Highest residue x CF (tentative) [(c)]
Celery	0.05	Median residue x CF (tentative) [(c)]	0.07	Highest residue x CF (tentative) [(c)]
Fennel, Rhubarb	0.44	Median residue x CF [(a)]	1.19	Highest residue x CF [(a)]
Globe artichokes	0.29	Median residue x CF (tentative) [(c)]	0.62	Highest residue x CF (tentative) [(c)]
Leek	1.7	EU MRL x CF [(d)]	1.7	EU MRL x CF [(d)]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Beans (dry), Peas (dry)	0.04	Median residue x CF (tentative) [c]	0.07	Highest residue x CF (tentative) [c]
Lupins (dry), Lentils (dry)	0.03	Median residue x CF (tentative) [c]	0.07	Highest residue x CF (tentative) [c]
Linseed, Rape seed, Borage	0.02	Median residue x CF (tentative) [c]	0.03	Highest residue x CF (tentative) [c]
Poppy seed, Gold of pleasure	0.02	Median residue x CF [a]	0.03	Highest residue x CF [a]
Sunflower seed	0.03	Median residue x CF [a]	0.07	Highest residue x CF [a]
Mustard seed	0.14	EU MRL x CF [d]	0.14	EU MRL x CF [d]
Barley grain, Oats grain	0.01*	Median residue x CF [a]	0.01*	Highest residue x CF [a]
Maize grain	0.01	Median residue x CF (tentative) [c]	0.02	Highest residue x CF (tentative) [c]
Sorghum grain	0.01*	Median residue x CF [a]	0.01*	Highest residue x CF [a]
Wheat grain, Rye grain	0.01*	Median residue x CF [a]	0.01*	Highest residue x CF [a]
Herbal infusions (dried, flowers), Herbal infusions (dried, leaves)	3.22	Median residue x CF (tentative) [c]	5.07	Highest residue x CF (tentative) [c]
Herbal infusions (dried, roots)	0.01*	Median residue x CF (tentative) [c]	0.01*	Highest residue x CF (tentative) [c]
Spices (seeds)	7.0	EU MRL x CF [d]	7.0	EU MRL x CF [d]
Spices (fruits and berries)	0.07	EU MRL x CF [d]	0.07	EU MRL x CF [d]
Sugar beet (root)	0.01*	Median residue x CF [a]	0.01*	Highest residue x CF [a]
Chicory roots	0.01*	Median residue x CF [a]	0.01*	Highest residue x CF [a]
Risk assessment residue definition: sum of pirimicarb and desmethyl pirimicarb, expressed as pirimicarb				
Swine meat	0.05	EU MRL [f]	0.05	EU MRL [f]
Swine fat (free of lean meat)	0.05	EU MRL [f]	0.05	EU MRL [f]
Swine liver	0.05	EU MRL [f]	0.05	EU MRL [f]
Swine kidney	0.05	EU MRL [f]	0.05	EU MRL [f]
Bovine meat	0.05	EU MRL [f]	0.05	EU MRL [f]
Bovine fat	0.05	EU MRL [f]	0.05	EU MRL [f]
Bovine liver	0.05	EU MRL [f]	0.05	EU MRL [f]
Bovine kidney	0.05	EU MRL [f]	0.05	EU MRL [f]
Sheep meat	0.05	EU MRL [f]	0.05	EU MRL [f]
Sheep fat	0.05	EU MRL [f]	0.05	EU MRL [f]
Sheep liver	0.05	EU MRL [f]	0.05	EU MRL [f]
Sheep kidney	0.05	EU MRL [f]	0.05	EU MRL [f]
Goat meat	0.05	EU MRL [f]	0.05	EU MRL [f]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Goat fat	0.05	EU MRL [(f)]	0.05	EU MRL [(f)]
Goat liver	0.05	EU MRL [(f)]	0.05	EU MRL [(f)]
Goat kidney	0.05	EU MRL [(f)]	0.05	EU MRL [(f)]
Cattle milk	0.05	EU MRL [(f)]	0.05	EU MRL [(f)]
Sheep milk	0.05	EU MRL [(f)]	0.05	EU MRL [(f)]
Goat milk	0.05	EU MRL [(f)]	0.05	EU MRL [(f)]
Risk assessment residue definition: pirimicarb				
Poultry meat	0.01*	Median muscle [(g)]	0.01*	Highest muscle [(g)]
Poultry fat	0.01*	Median residue [(g)]	0.01*	Highest residue [(g)]
Poultry liver	0.01*	Median residue [(g)]	0.01*	Highest residue [(g)]
Birds' eggs	0.01*	Median residue [(g)]	0.01*	Highest residue [(g)]

(*): Indicates that the input value is set at the limit of analytical quantification.
(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in Section 3 are used for the exposure calculations.
(b): Most critical GAP leads to an exceedance of the ARfD for pirimicarb in this commodity; although not sufficiently supported by data, the fall-back GAP and risk assessment values derived in Section 3 are used for indicative exposure calculations.
(c): Use reported by the RMS is not fully supported by data but the risk assessment values derived in Section 3 are used for indicative exposure calculations.
(d): Use reported by the RMS is not supported by data; the existing EU MRL multiplied by a conversion factor for risk assessment is used for indicative exposure calculations (also assuming the existing residue definition).
(e): Most critical GAP leads to an exceedance of the ARfD for pirimicarb in this commodity; the fall-back GAP is fully supported by data for this commodity and risk assessment values derived in Section 3 are used for the second exposure calculations.
(f): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not supported by data; the existing EU MRL is used for indicative exposure calculations.
(g): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is fully supported by data; the risk assessment values derived in Section 3 are used for the exposure calculations.

The calculated exposures were compared with the toxicological reference values derived for pirimicarb (see Table 2-1); detailed results of the calculations are presented as EU scenario 1 in Appendix B.1. The highest chronic exposure was calculated for Dutch children, representing 33% of the ADI. With regard to the acute exposure, an exceedance of the ARfD was identified for scarole, lettuce, spinach, purslane, cauliflower, broccoli, kale, Chinese cabbage, apple, pear and leek representing 2815 %, 866 %, 728 %, 487 %, 370 %, 326 %, 298 %, 164 %, 126 %, 117 %, 100 % of the ARfD, respectively. A second exposure calculation was therefore performed, considering fall-back MRLs of 1.5 mg/kg for scarole (based on the southern outdoor GAP) and lettuce (based on a fall-back indoor GAP), 0.06 mg/kg for spinach (based on the northern outdoor GAP), 0.01 mg/kg for purslane (based on the northern outdoor GAP), 0.3 mg/kg for leafy brassica (based on a fall-back northern outdoor GAP), 0.5 mg/kg in apples and pears (based on the southern outdoor GAP). No fall-back MRL could be identified for cauliflower, broccoli and leek; therefore, these crops were excluded from the calculation. According to the results of this second calculation (see Appendix B.2 – EU scenario 2), the highest chronic exposure declined to 20 % of the ADI for German children; the highest acute exposure is then calculated for rocket, representing 99.7 % of the ARfD.

Based on the above calculations, EFSA concludes that the use of pirimicarb on crops fully supported by data (footnotes (a) and (g) in Table 4-1), is acceptable with regard to consumer exposure, except for apples, pears, lettuce, scarole, spinach and purslane. For the other crops, major uncertainties remain

due to the data gaps identified in Section 3, in particular with regard to the data on the magnitude of residues and the residue definition in animal commodities. However considering tentative MRLs or the existing EU MRLs in the exposure, calculation did not indicate a risk to consumers, except for cauliflower, broccoli, Chinese cabbage, kale and leek.

4.2. Consumer risk assessment with consideration of the existing CXLs

In order to include the CXLs in the calculations of the consumer exposure, all data relevant to the consumer exposure assessment have been collected from JMPR evaluations and reported in Appendix C.2 to this document. These CXLs were compared with the EU MRL proposals in compliance with Appendix D and input values resulting from this comparison are summarised in Table 4-2.

Table 4-2: Input values for the consumer risk assessment (with consideration of CXLs)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of pirimicarb, desmethyl pirimicarb and desmethyl formamido pirimicarb, expressed as pirimicarb				
Citrus fruits	0.02	Median x CF (CXL) [(a)]	0.08	Highest x CF (CXL) [(a)]
Almonds	0.02	Median residue x CF [(b)]	0.02	Highest residue x CF [(b)]
Chestnuts	0.02	Median residue x CF [(b)]	0.02	Highest residue x CF [(b)]
Hazelnuts	0.02	Median residue x CF [(b)]	0.02	Highest residue x CF [(b)]
Walnuts	0.02	Median residue x CF [(b)]	0.02	Highest residue x CF [(b)]
Apples, Pears	0.20	Median x CF (CXL) [(a)]	1.14	Highest x CF (CXL) [(a)]
	0.19	Median residue x CF (tentative, fall-back) [(c)]	0.38	Highest residue x CF (tentative, fall-back) [(c)]
Medlar, Loquat	0.20	Median x CF (CXL) [(a)]	1.14	Highest x CF (CXL) [(a)]
Quinces	0.26	Median residue x CF (tentative) [(d)]	1.29	Highest residue x CF (tentative) [(d)]
Apricots, Plums	0.31	Median x CF (CXL) [(a)]	2.07	Highest x CF (CXL) [(a)]
Peaches	0.31	Median x CF (CXL) [(a)]	2.07	Highest x CF (CXL) [(a)]
	0.48	Median residue x CF (tentative, fall-back) [(c)]	1.31	Highest residue x CF (tentative, fall-back) [(c)]
Cherries	1.47	Median residue x CF (tentative) [(d)]	2.20	Highest residue x CF (tentative) [(d)]
Table grapes, Wine grapes	1.30	EU MRL x CF [(e)]	1.30	EU MRL x CF [(e)]
Strawberries	0.37	Median residue x CF [(b)]	1.21	Highest residue x CF [(b)]
Blackberries, Dewberries, Raspberries	0.52	Median residue x CF (tentative) [(d)]	2.31	Highest residue x CF (tentative) [(d)]
Blueberries, Cranberries, Currants (red, black and white), Gooseberries, Rose hips, Mulberries, Azaroles, Elderberries	0.19	Median x CF (CXL) [(a)]	0.82	Highest x CF (CXL) [(a)]
Root and tuber vegetables	0.01	Median x CF (CXL) [(a)]	0.02	Highest x CF (CXL) [(a)]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Garlic, Onions	0.02	Median x CF (CXL) [(a)]	0.12	Highest x CF (CXL) [(a)]
Tomatoes, Peppers, Aubergines (egg plants), Okra, lady's finger	0.10	Median x CF (CXL) [(a)]	0.29	Highest x CF (CXL) [(a)]
Cucumbers, Gherkins, Courgettes	0.14	Median x CF (CXL) [(a)]	0.53	Highest x CF (CXL) [(a)]
Melons	0.09	Median residue x CF (tentative) [(d)]	0.22	Highest residue x CF (tentative) [(d)]
Pumpkins	0.14	Median x CF (CXL) [(a)]	0.53	Highest x CF (CXL) [(a)]
Watermelons	0.09	Median residue x CF (tentative) [(d)]	0.22	Highest residue x CF (tentative) [(d)]
Sweet corn	0.01	Median x CF (CXL) [(a)]	0.02	Highest x CF (CXL) [(a)]
Broccoli, Cauliflower	0.11	Median x CF (CXL) [(a)]	1.15	Highest x CF (CXL) [(a)]
Brussels sprouts	0.17	Median residue x CF (tentative) [(d)]	0.61	Highest residue x CF (tentative) [(d)]
Head cabbage	0.11	Median x CF (CXL) [(a)]	1.15	Highest x CF (CXL) [(a)]
Chinese cabbage	0.11	Median x CF (CXL) [(a)]	1.15	Highest x CF (CXL) [(a)]
Kale	0.17	Median residue x CF (tentative, fall-back) [(f)]	0.21	Highest residue x CF (tentative, fall-back) [(f)]
Kohlrabi	1.40	EU MRL x CF [(e)]	1.40	EU MRL x CF [(e)]
Lamb's lettuce, Cress, Land cress, Rocket, Rucola, Red mustard, Leaves and sprouts of Brassica spp	2.31	Median residue x CF [(b)]	32.2	Highest residue x CF [(b)]
Lettuce	0.78	Median x CF (CXL) [(a)]	6.44	Highest x CF (CXL) [(a)]
	0.38	Median residue x CF (fall-back) [(g)]	2.30	Highest residue x CF (fall-back) [(g)]
Scarole (broad-leaf endive)	0.38	Median residue x CF (tentative, fall-back)[(f)]	1.04	Highest residue x CF (tentative, fall-back)[(f)]
Spinach	0.06	Median residue x CF (tentative, fall-back)[(f)]	0.08	Highest residue x CF (tentative, fall-back)[(f)]
Purslane	0.03	Median residue x CF (tentative, fall-back)[(f)]	0.03	Highest residue x CF (tentative, fall-back)[(f)]
Beet leaves (chards)	0.06	Median residue x CF (tentative) [(d)]	0.08	Highest residue x CF (tentative) [(d)]
Witloof	0.06	Median residue x CF (tentative) [(d)]	0.06	Highest residue x CF (tentative) [(d)]
Chervil, Chives, Sage, Rosemary, Thyme, Basil, Bay leaves (laurel), Tarragon	0.59	Median residue x CF [(b)]	1.01	Highest residue x CF [(b)]
Celery leaves, Parsley	2.13	Median residue x CF [(b)]	3.08	Highest residue x CF [(b)]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Beans (fresh, with pods) Peas (fresh, with pods)	0.27	Median residue x CF (tentative) [(d)]	1.24	Highest residue x CF (tentative) [(d)]
Beans (fresh, without pods)	1.70	EU MRL x CF [(e)]	1.70	EU MRL x CF [(e)]
Peas (fresh, without pods)	0.07	Median x CF (CXL) [(a)]	0.07	Highest x CF (CXL) [(a)]
Lentils (fresh)	1.19	EU MRL x CF [(e)]	1.19	EU MRL x CF [(e)]
Asparagus	0.01*	Median residue x CF [(b)]	0.01*	Highest residue x CF [(b)]
Cardoons	0.08	Median residue x CF (tentative) [(d)]	0.15	Highest residue x CF (tentative) [(d)]
Celery	0.05	Median residue x CF (tentative) [(d)]	0.07	Highest residue x CF (tentative) [(d)]
Fennel, Rhubarb	0.44	Median residue x CF [(b)]	1.19	Highest residue x CF [(b)]
Globe artichokes	0.46	Median x CF (CXL) [(a)]	3.12	Highest x CF (CXL) [(a)]
Beans (dry), Peas (dry), Lupins (dry), Lentils (dry)	0.07	Median x CF (CXL) [(a)]	0.17	Highest x CF (CXL) [(a)]
Linseed, Rape seed, Borage	0.02	Median residue x CF (tentative) [(d)]	0.03	Highest residue x CF (tentative) [(d)]
Poppy seed, Gold of pleasure	0.02	Median residue x CF [(b)]	0.03	Highest residue x CF [(b)]
Sunflower seed	0.014	Median x CF (CXL) [(a)]	0.07	Highest x CF (CXL) [(a)]
Mustard seed	0.14	EU MRL x CF [(e)]	0.14	EU MRL x CF [(e)]
Cereals grain	0.01	Median x CF (CXL) [(a)]	0.02	Highest x CF (CXL) [(a)]
Herbal infusions (dried, flowers), Herbal infusions (dried, leaves)	3.22	Median residue x CF (tentative) [(d)]	5.07	Highest residue x CF (tentative) [(d)]
Herbal infusions (dried, roots)	0.01*	Median residue x CF (tentative) [(d)]	0.01*	Highest residue x CF (tentative) [(d)]
Spices (seeds)	7.0	EU MRL x CF [(e)]	7.0	EU MRL x CF [(e)]
Spices (fruits and berries)	0.07	EU MRL x CF [(e)]	0.07	EU MRL x CF [(e)]
Sugar beet (root)	0.01*	Median residue x CF [(b)]	0.01*	Highest residue x CF [(b)]
Chicory roots	0.01*	Median residue x CF [(b)]	0.01*	Highest residue x CF [(b)]
Risk assessment residue definition: sum of pirimicarb and desmethyl pirimicarb, expressed as pirimicarb				
Swine meat	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Swine fat (free of lean meat)	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Swine liver	0.05	EU MRL [(h)]	0.05	EU MRL [(g)]
Swine kidney	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Bovine meat	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Bovine fat	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Bovine liver	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Bovine kidney	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Sheep meat	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Sheep fat	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Sheep liver	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Sheep kidney	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Goat meat	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Goat fat	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Goat liver	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Goat kidney	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Cattle milk	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Sheep milk	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Goat milk	0.05	EU MRL [(h)]	0.05	EU MRL [(h)]
Risk assessment residue definition: pirimicarb				
Poultry meat	0.01*	Median muscle [(i)]	0.01*	Highest muscle [(i)]
Poultry fat	0.01*	Median residue [(i)]	0.01*	Highest residue [(i)]
Poultry liver	0.01*	Median residue [(i)]	0.01*	Highest residue [(i)]
Birds' eggs	0.01*	Median residue [(i)]	0.01*	Highest residue [(i)]

(*): Indicates that the input value is set at the limit of analytical quantification.
(a): CXL is supported by data; the corresponding risk assessment values are used for the exposure calculations.
(b): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in Section 3 are used for the exposure calculations.
(c): CXL leads to an exceedance of the ARfD for pirimicarb in this commodity; although not sufficiently supported by data, the fall-back GAP and risk assessment values derived in Section 3 are used for indicative exposure calculations.
(d): Use reported by the RMS is not fully supported by data but the risk assessment values derived in Section 3 are used for indicative exposure calculations.
(e): Use reported by the RMS is not supported by data; the existing EU MRL multiplied by a conversion factor for risk assessment is used for indicative exposure calculations (also assuming the existing residue definition).
(f): Most critical GAP leads to an exceedance of the ARfD for pirimicarb in this commodity; although not sufficiently supported by data, the fall-back GAP and risk assessment values derived in Section 3 are used for indicative exposure calculations.
(g): CXL leads to an exceedance of the ARfD for pirimicarb in this commodity; the fall-back GAP is fully supported by data for this commodity and risk assessment values derived in Section 3 are used for the second exposure calculations.
(h): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not supported by data; the existing EU MRL is used for indicative exposure calculations (also assuming the existing residue definition).
(i): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is fully supported by data; the risk assessment values derived in Section 3 are used for the exposure calculations.

Chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and calculated exposures were compared with the toxicological reference values derived for pirimicarb (see Table 2-1); detailed results of the calculations are presented as Codex scenario 1, in Appendix B.3. The highest chronic exposure was calculated for German children, representing 20 % of the ADI. With regard to the acute exposure, however, an exceedance of the ARfD was identified for lettuce, apples, pears and peaches, representing 173 %, 123 %, 112 % and 104 % of the ARfD, respectively. A

second exposure calculation was therefore performed, excluding these crops. According to the results of this second calculation (see Appendix B.4 – Codex scenario 2), the highest chronic exposure remained unchanged; the highest acute exposure is then calculated for rocket, representing 99.7 % of the ARfD.

Based on the above calculations, EFSA concludes that the CXLs supported by data (footnote a in Table 4-2) are not expected to be of concern for European consumers, except for lettuce, apples, pears and peaches.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of pirimicarb was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.035 mg/kg bw per d and 0.1 mg/kg bw, respectively. These toxicological reference values can be applied to desmethyl pirimicarb, desmethyl formamido pirimicarb and hydroxypyrimidine metabolites.

Primary crop metabolism of pirimicarb was investigated in three different crop groups following foliar application. Based on these studies, EFSA proposes to define the residue for enforcement in all plant commodities as pirimicarb only and for risk assessment as the sum of pirimicarb, desmethyl pirimicarb and desmethyl formamido pirimicarb, expressed as pirimicarb. Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.01 mg/kg in high water content, high oil content, acidic and dry commodities.

Regarding the magnitude of the residues in primary crops, the available residues data were considered sufficient to derive appropriate MRL proposals and risk assessment values for all commodities under evaluation, except for quinces, stone fruits, cane fruits, onions, tomatoes, aubergines, cucurbits with edible peel, melons, watermelons, Brussels sprouts, head cabbage, leafy brassica, beet leaves, witloof, beans and peas with pods, cardoons, celery, globe artichokes, pulses (dry), linseed, borage, rape seed, maize and herbal infusions where only tentative MRLs could be derived; and for table and wine grapes, flowering brassica, kohlrabi, beans without pods, fresh lentils, leek, mustard seeds and spices (seeds, fruits and berries) where the available data were insufficient to derive tentative MRLs.

The hydrolysis studies demonstrated that under pasteurisation, sterilisation and baking/boiling/brewing conditions, pirimicarb remained stable in processed commodities. Studies investigating the magnitude of residues in processed commodities of fruits and fruiting vegetables, leafy vegetables, legume vegetables and cereals were also reported. Results from these studies were however disregarded as residues in both raw and processed commodities were expressed as the sum of pirimicarb and desmethyl pirimicarb and no information on the level of pirimicarb only was available.

The metabolism of pirimicarb in rotational crops was evaluated in a confined rotational crops metabolism study. It is concluded that metabolic patterns in primary and succeeding crops are similar, but the presence of pirimicarb and pirimicarb metabolites in crops grown in rotation cannot be excluded.

Based on the uses reported by the RMS, significant intakes were calculated for dairy ruminant, meat ruminants, poultry and pigs. The metabolism studies conducted with pirimicarb on poultry showed that residue levels in poultry commodities are expected to remain below the enforcement LOQ of 0.01 mg/kg. Hence, the residue definition in poultry is proposed by default as pirimicarb only. Validated analytical methods for enforcement of this residue definition in poultry commodities are available. Regarding ruminants, a high level of TRR remains unidentified in the reported metabolism study. Considering also the lack of residue data for some feed items which can lead to an underestimation of the calculated dietary burdens, further clarifications on the identity of the

radioactive residue are required. Consequently EFSA cannot conclude on the residue definition in ruminants and the submission of a new metabolism study in ruminants is still required.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. An exceedance of the ARfD was identified for scarole, lettuce, spinach, purslane, cauliflower, broccoli, kale, Chinese cabbage, apple, pear and leek representing 2815 %, 866 %, 728 %, 487 %, 370 %, 326 %, 298 %, 164 %, 126 %, 117 %, 100 % of the ARfD, respectively. Considering fall-back MRLs for these crops (except for cauliflower, broccoli and leek, which were excluded from the calculation), the highest chronic exposure represented 20 % of the ADI (German children) and the highest acute exposure amounted to 99.7 % of the ARfD (rocket).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for pirimicarb. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and exceedences of the ARfD were identified for the existing CXLs in lettuce, apples, pears and peaches, representing 173 %, 123 %, 112 % and 104 % of the ARfD, respectively. Excluding these CXLs from the calculation, the highest chronic exposure represented 20 % of the ADI (German children) and the highest acute exposure amounted to 99.7 % of the ARfD (rocket).

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, some tentative MRLs or existing EU MRLs need to be confirmed by the following data:

- a validated analytical method for enforcement of pirimicarb in herbal infusions and spices;
- a metabolism study in ruminants;
- additional residues trials supporting authorisations on apples, pears, quinces, cherries, peaches, table and wine grapes, cane fruits, melons, watermelons, Brussels sprouts, kale, kohlrabi, scarole, purslane, beet leaves (chard), witloof, fresh beans and peas with pods, fresh beans without pods, fresh lentils, cardoons, celery, linseed, mustard seed, borage, rape seed and spices (seeds, fruits and berries).

It is highlighted, that some of the MRLs derived result from a CXL or from a GAP in one climatic zone only, while other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the need for additional residues trials which are not expected to impact on the validity of the MRLs derived but which might have an impact on certain national authorisations for the following crops:

- hazelnuts, walnuts, apricots, plums, blueberries, currants, gooseberries, parsley root, radishes, onions, tomatoes, peppers, aubergines, cucurbits with edible peel, head cabbage, Chinese cabbage, lettuce, other salads (except scarole), spinach, fresh herbs, fennel, globe artichokes, dry pulses, sunflower seeds, maize, barley, oats, wheat, rye, alfalfa and grass.

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level. The Member States are recommended

in any case to reconsider or withdraw their national authorisations on apples, pears, leafy brassica, lettuce, scarole, spinach and purslane in order to ensure that the fall-back MRLs derived in this review are not exceeded for these crops and to withdraw their national authorisations on flowering brassica and leek, for which no fall-back MRL could be derived. Member States granting authorisations for pirimicarb should take the appropriate risk mitigation measures (e.g. definition of pre-planting intervals) in order to avoid the presence of significant residues in rotational crops.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. Storage stability study in acidic commodities and storage conditions of the samples from the supervised residue trials are therefore considered desirable but not essential.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition (existing): sum of pirimicarb and desmethyl pirimicarb, expressed as pirimicarb **Enforcement residue definition (proposed):** pirimicarb					
110010	Grapefruit	3	3	3	Recommended [(a)]
110020	Oranges	3	3	3	Recommended [(a)]
110030	Lemons	3	3	3	Recommended [(a)]
110040	Limes	3	3	3	Recommended [(a)]
110050	Mandarins	3	3	3	Recommended [(a)]
120010	Almonds	1	-	0.02	Recommended [(b)]
120040	Chestnuts	1	-	0.02	Recommended [(b)]
120060	Hazelnuts	1	-	0.02	Recommended [(b)]
120110	Walnuts	1	-	0.02	Recommended [(b)]
130010	Apples	2	1	0.5	Further consideration needed [(c)]
130020	Pears	2	1	0.5	Further consideration needed [(c)]
130030	Quinces	2	1	1.5	Further consideration needed [(d)]
130040	Medlar	2	1	1	Recommended [(a)]
130050	Loquat	2	1	1	Recommended [(a)]
140010	Apricots	2	3	3	Recommended [(e)]
140020	Cherries	5	3	5	Further consideration needed [(d)]
140030	Peaches	2	3	1.5	Further consideration needed [(c)]
140040	Plums	1	3	3	Recommended [(e)]
151010	Table grapes	1	-	1	Further consideration needed [(f)]
151020	Wine grapes	1	-	1	Further consideration needed [(f)]
152000	Strawberries	3	-	1.5	Recommended [(b)]
153010	Blackberries	2	1	4	Further consideration needed [(d)]
153020	Dewberries	2	1	4	Further consideration needed [(d)]
153030	Raspberries	2	1	4	Further consideration needed [(d)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
154010	Blueberries	1	1	1	Recommended [g]
154020	Cranberries	1	1	1	Recommended [g]
154030	Currants (red, black and white)	1	1	1	Recommended [g]
154040	Gooseberries	1	1	1	Recommended [g]
154050	Rose hips	1	1	1	Recommended [a]
154060	Mulberries	1	1	1	Recommended [a]
154070	Azarole (mediteranean medlar)	1	1	1	Recommended [g]
154080	Elderberries	2	1	1	Recommended [a]
211000	Potatoes	0.2	0.05	0.05	Recommended [g]
212010	Cassava	0.5	0.05	0.05	Recommended [a]
212020	Sweet potatoes	0.5	0.05	0.05	Recommended [a]
212030	Yams	0.5	0.05	0.05	Recommended [a]
212040	Arrowroot	0.5	0.05	0.05	Recommended [a]
213010	Beetroot	0.5	0.05	0.05	Recommended [g]
213020	Carrots	0.5	0.05	0.05	Recommended [g]
213030	Celeriac	0.5	0.05	0.05	Recommended [g]
213040	Horseradish	0.5	0.05	0.05	Recommended [g]
213050	Jerusalem artichokes	0.5	0.05	0.05	Recommended [g]
213060	Parsnips	0.5	0.05	0.05	Recommended [g]
213070	Parsley root	0.5	0.05	0.05	Recommended [g]
213080	Radishes	0.5	0.05	0.05	Recommended [g]
213090	Salsify	0.5	0.05	0.05	Recommended [g]
213100	Swedes	0.5	0.05	0.05	Recommended [g]
213110	Turnips	0.5	0.05	0.05	Recommended [g]
220010	Garlic	0.5	0.1	0.1	Recommended [a]
220020	Onions	0.5	0.1	0.1	Recommended [e]
231010	Tomatoes	1	0.5	0.5	Recommended [e]
231020	Peppers	1	0.5	0.5	Recommended [g]
231030	Aubergines (egg plants)	1	0.5	0.5	Recommended [e]
231040	Okra, lady's fingers	1	0.5	0.5	Recommended [a]
232010	Cucumbers	1	1	1	Recommended [e]
232020	Gherkins	1	1	1	Recommended [e]
232030	Courgettes	1	1	1	Recommended [e]
233010	Melons	1	0.2	0.4	Further consideration needed [d]
233020	Pumpkins	1	1	1	Recommended [g]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
233030	Watermelons	1	-	0.5	Further consideration needed [h]
234000	Sweet corn	0.5	0.05	0.05	Recommended [g]
241010	Broccoli	2	0.5	0.5	Recommended [i]
241020	Cauliflower	2	0.5	0.5	Recommended [i]
242010	Brussels sprouts	1	0.5	0.6	Further consideration needed [d]
242020	Head cabbage	1	0.5	0.5	Recommended [e]
243010	Chinese cabbage	2	0.5	0.5	Recommended [e]
243020	Kale	1	0.3	0.3	Further consideration needed [d]
244000	Kohlrabi	0.5	0.5	0.5	Further consideration needed [j]
251010	Lamb's lettuce	5	-	15	Recommended [b]
251020	Lettuce	5	5	1.5	Recommended [n]
251030	Scarole	1	-	1	Further consideration needed [h]
251040	Cress	5	-	15	Recommended [b]
251050	Land cress	5	-	15	Recommended [b]
251060	Rocket, Rucola	5	-	15	Recommended [b]
251070	Red mustard	5	-	15	Recommended [b]
251080	Leaves and sprouts of Brassica spp	5	-	15	Recommended [b]
252010	Spinach	2	-	0.06	Recommended [b]
252020	Purslane	5	-	0.01*	Further consideration needed [h]
252030	Beet leaves (chard)	5	-	0.06	Further consideration needed [h]
255000	Witloof	2	-	0.05	Further consideration needed [h]
256010	Chervil	5	-	0.8	Recommended [b]
256020	Chives	5	-	0.8	Recommended [b]
256030	Celery leaves	5	-	3	Recommended [b]
256040	Parsley	5	-	3	Recommended [b]
256050	Sage	5	-	0.8	Recommended [b]
256060	Rosemary	5	-	0.8	Recommended [b]
256070	Thyme	5	-	0.8	Recommended [b]
256080	Basil	5	-	0.8	Recommended [b]
256090	Bay leaves (laurel)	5	-	0.8	Recommended [b]
256100	Tarragon	5	-	0.8	Recommended [b]
260010	Beans (fresh, with pods)	1	0.7	1.5	Further consideration needed [d]
260020	Beans (fresh, without pods)	1	0.7	1	Further consideration needed [j]
260030	Peas (fresh, with pods)	1	0.7	1.5	Further consideration needed [d]
260040	Peas (fresh, without pods)	1	0.7	0.7	Recommended [g]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
260050	Lentils (fresh)	0.7	0.7	0.7	Further consideration needed [j]
270010	Asparagus	1	0.01*	0.01*	Recommended [k]
270020	Cardoons	1	-	0.2	Further consideration needed [h]
270030	Celery	5	-	0.15	Further consideration needed [h]
270040	Fennel	5	-	2	Recommended [b]
270050	Globe artichokes	5	5	5	Recommended [e]
270060	Leek	1	-	-	Further consideration needed [l]
270070	Rhubarb	1	-	2	Recommended [b]
300010	Beans (dry)	1	0.2	0.2	Recommended [e]
300020	Lentils (dry)	1	0.2	0.2	Recommended [e]
300030	Peas (dry)	1	0.2	0.2	Recommended [e]
300040	Lupins (dry)	1	0.2	0.2	Recommended [e]
401010	Linseed	0.1	-	0.05	Further consideration needed [h]
401030	Poppy seed	0.5	-	0.05	Recommended [b]
401050	Sunflower seed	0.5	0.1	0.1	Recommended [g]
401060	Rape seed	0.2	0.05	0.05	Further consideration needed [d]
401080	Mustard seed	0.1	-	0.1	Further consideration needed [f]
401120	Borage	0.1	-	0.05	Further consideration needed [h]
401130	Gold of pleasure	0.1	-	0.05	Recommended [b]
500010	Barley grain	0.5	0.05	0.05	Recommended [g]
500020	Buckwheat grain	0.2	0.05	0.05	Recommended [a]
500030	Maize grain	0.2	0.05	0.05	Recommended [e]
500040	Millet grain	0.2	0.05	0.05	Recommended [a]
500050	Oats grain	0.5	0.05	0.05	Recommended [g]
500070	Rye grain	0.5	0.05	0.05	Recommended [g]
500080	Sorghum grain	0.2	0.05	0.05	Recommended [g]
500090	Wheat grain	0.5	0.05	0.05	Recommended [g]
631000	Herbal infusions (dried, flowers)	5	-	10	Further consideration needed [h]
632000	Herbal infusions (dried, leaves)	5	-	10	Further consideration needed [h]
633000	Herbal infusions (dried, roots)	5	-	0.01	Further consideration needed [h]
810000	Spices (seeds)	5	5	5	Further consideration needed [j]
810000	Spices (fruits and berries)	0.05*	-	0.05	Further consideration needed [f]
900010	Sugar beet (root)	0.5	-	0.01*	Recommended [b]
900030	Chicory roots	0.05*	-	0.01*	Recommended [b]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
-	Other products of plant origin	See App. C.1	-	-	Further consideration needed [m]
1016010	Poultry meat	0.05*	0.01*	0.01*	Recommended [k]
1016020	Poultry fat	0.05*	0.01*	0.01*	Recommended [k]
1016030	Poultry liver	0.05*	0.01*	0.01*	Recommended [k]
1030000	Birds' eggs	0.05*	0.01*	0.01*	Recommended [k]
Enforcement residue definition: sum of pirimicarb and desmethyl pirimicarb, expressed as pirimicarb					
1011010	Swine muscle	0.05*	0.01*	0.05	Further consideration needed [j]
1011020	Swine fat (free of lean muscle)	0.05*	0.01*	0.05	Further consideration needed [j]
1011030	Swine liver	0.05*	0.01*	0.05	Further consideration needed [j]
1011040	Swine kidney	0.05*	0.01*	0.05	Further consideration needed [j]
1012010	Bovine muscle	0.05*	0.01*	0.05	Further consideration needed [j]
1012020	Bovine fat	0.05*	0.01*	0.05	Further consideration needed [j]
1012030	Bovine liver	0.05*	0.01*	0.05	Further consideration needed [j]
1012040	Bovine kidney	0.05*	0.01*	0.05	Further consideration needed [j]
1013010	Sheep muscle	0.05*	0.01*	0.05	Further consideration needed [j]
1013020	Sheep fat	0.05*	0.01*	0.05	Further consideration needed [j]
1013030	Sheep liver	0.05*	0.01*	0.05	Further consideration needed [j]
1013040	Sheep kidney	0.05*	0.01*	0.05	Further consideration needed [j]
1014010	Goat muscle	0.05*	0.01*	0.05	Further consideration needed [j]
1014020	Goat fat	0.05*	0.01*	0.05	Further consideration needed [j]
1014030	Goat liver	0.05*	0.01*	0.05	Further consideration needed [j]
1014040	Goat kidney	0.05*	0.01*	0.05	Further consideration needed [j]
1020010	Cattle milk	0.05*	0.01*	0.05	Further consideration needed [j]
1020020	Sheep milk	0.05*	0.01*	0.05	Further consideration needed [j]
1020030	Goat milk	0.05*	0.01*	0.05	Further consideration needed [j]
-	Other product of animal origin	See App. C.1	-	-	Further consideration needed [m]

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix D).
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(c): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; CXL is higher, supported by data but a risk to consumers cannot be excluded (combination E-VI in Appendix D).
(d): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).
(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix D).

(f): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix D).
(g): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix D).
(h): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).
(i): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level is not supported by data and a risk to consumers cannot be excluded for the existing EU MRL (combination B-VII in Appendix D).
(j): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition for ruminant products); existing CXL is covered by the existing EU MRL (combination C-III in Appendix D).
(k): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).
(l): GAP evaluated at EU level is not supported by data and a risk to consumers cannot be excluded for the existing EU MRL; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination B-I in Appendix D).
(m): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).
(n): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; CXL is higher, supported by data but a risk to consumers cannot be excluded (combination G-VI in Appendix D).

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on pirimicarb prepared by the rapporteur Member State United Kingdom in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 27 July 2011. Last updated on 19 November 2012.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Appendix A.1 – Critical GAPs currently authorised within the EU

Appendix A.2 – Critical GAPs currently authorised within the EU for which a potential acute concern was identified

Appendix A.3 – Fall-back GAPs identified by EFSA supporting the demonstrated safe EU MRL proposals

APPENDIX A.1 – CRITICAL GAPS CURRENTLY AUTHORISED WITHIN THE EU

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application								Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Hazelnuts	*Corylus avellana*	NEU	Outdoor	PL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	1				0.38	kg a.i./ha	7	No details of growth stages or number of applications originally reported. It is assumed that one application is intended.
Walnuts	*Juglans regia*	NEU	Outdoor	NL	aphids and wooly aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2			0.25	0.37	kg a.i./ha	7	
Apples	*Malus domesticus*	NEU	Outdoor	BE	Aphids	WG	50.0	% (w/w)	Foliar treatment - spraying	n.a.	n.a.	1	2				0.38	kg a.i./ha	3	
Pears	*Pyrus communis*	NEU	Outdoor	BE	Aphids	WG	50.0	% (w/w)	Foliar treatment - spraying	n.a.	n.a.	1	2				0.38	kg a.i./ha	3	
Quinces	*Cydonia oblonga*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Apricots	*Prunus armeniaca*	NEU	Outdoor	BE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.38	kg a.i./ha	3	
Cherries	*Prunus cerasus, Prunus avium*	NEU	Outdoor	NL	Aphidoidea	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.37	kg a.i./ha	7	
Peaches	*Prunus persica*	NEU	Outdoor	BE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.38	kg a.i./ha	3	
Plums	*Prunus domestica*	NEU	Outdoor	BE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.38	kg a.i./ha	3	
Strawberries	*Fragaria x ananassa*	NEU	Outdoor	BE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.20	kg a.i./ha	3	BE proposes in answer to questions raised in the MSCR to take into account a new cGAP on strawberries: 2x375g/ha, 3d, which has been submitted but not authorised for the time being by MS.
Blackberries	*Rubus fruticosus*	NEU	Outdoor	BE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	3	
Dewberries	*Rubus ceasius*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	3	
Raspberries	*Rubus idaeus*	NEU	Outdoor	BE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	3	
Blueberries	*Vaccinium corymbosum*	NEU	Outdoor	BE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	3	
Cranberries	*Vaccinium macrocarpon*	NEU	Outdoor	BE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	3	
Currants (red, black and white)	*Ribes nigrum, rubrum*	NEU	Outdoor	BE, FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	3	
Gooseberries	*Ribes uva-crispa*	NEU	Outdoor	BE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	3	
Azarole (mediteranean medlar)	*Crataegus azarolus*	NEU	Outdoor	BE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	3	
Potatoes	*Tuber form Solanum Spp*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Beetroot	*Beta vulgaris subsp. Vulgaris*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	1				0.38	kg a.i./ha	7	
Carrots	*Daucus carota*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	NL GAP: 2x250g/ha, 7d
Celeriac	*Apium graveolens var. rapaceum*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Horseradish	*Armoracia rusticana*	NEU	Outdoor	BE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.20	kg a.i./ha	7	
Jerusalem artichokes	*Helianthus tuberosus*	NEU	Outdoor	DE	Aphids	ME	8.3	g/l	Foliar treatment - spraying	n.a.	n.a.	2	2	10	14		0.15	kg a.i./ha	7	
Parsnips	*Pastinaca sativa*	NEU	Outdoor	BE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.20	kg a.i./ha	7	
Parsley root	*Petroselinum crispum*	NEU	Outdoor	BE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.20	kg a.i./ha	7	
Radishes	*Raphanus sativus var. saitvus*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Salsify	*Tragopogon porrifolius*	NEU	Outdoor	BE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.20	kg a.i./ha	7	
Swedes	*Brassica napus var. napobrassica*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Turnips	*Brassica rapa*	NEU	Outdoor	SE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	13	45	2	2				0.15	kg a.i./ha	7	
Onions	*Allium cepa*	NEU	Outdoor	CZ	Aphidoidea	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2			0.15	0.25	kg a.i./ha	14	
Gherkins	*Cucumis sativus*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2			0.05	0.25	kg a.i./ha	1	
Courgettes	*Cucurbita pepo var. melopepo*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	1	
Melons	*Cucumis melo*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.20	kg a.i./ha	3	
Sweet corn	*Zea mays var. sacharata*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application								Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
							Content			Growth stage		Number		Interval (days)							
Common name	Scientific name					Type	Conc.	Unit	Method	From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate	Max. rate	Rate Unit		
Broccoli	*Brassica oleracea var. italica*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	3	
Cauliflower	*Brassica oleracea var. botrytis*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	3	
Brussels sprouts	*Brassica oleracea var. gemmifera*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	3	
Head cabbage	*Brassica oleracea convar capitata*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	3	
Chinese cabbage	*Brassica pekinensis*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	3	
Kale	*Brassica oleracea convar. Acephalea*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	3	
Kohlrabi	*Brassica oleracea convar. acephala, var. gongylodes*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Lamb's lettuce	*Valerianella locusta*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Lettuce	*Lactuca sativa*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Scarole (broad-leaf endive)	*Cichorium endiva*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Cress	*Lepidium sativum*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Land cress	*Barbarea verna*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Rocket, Rucola	*Eruca sativa (Diplotaxis spec.)*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Red mustard	*Brassica juncea var. rugosa*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Leaves and sprouts of Brassica spp	*Brassica spp*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Spinach	*Spinacia oleracea*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.38	kg a.i./ha	7	
Purslane	*Portulaca oleracea*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Beet leaves (chard)	*Beta vulgaris*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Witloof	*Cichorium intybus. var. Foliosum*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Chervil	*Anthriscus cerefolium*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Chives	*Allium schoenoprasum*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Celery leaves	*Apium graveolens var. seccalinum*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	14	DE: 3x150g/ha, 7d BE: 1x200g/ha, 7d
Parsley	*Petroselinum crispum*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	1				0.38	kg a.i./ha	7	
Sage	*Salvia officinalis*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Rosemary	*Rosmarinus officinalis*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Thyme	*Thymus spp.*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Basil	*Ocimum basilicum*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Bay leaves (laurel)	*Laurus nobilis*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Tarragon	*Artemisia dracunculus*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Beans (with pods)	*Phaseolus vulgaris,*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	DE: 3x250g/ha, 3d
Beans (without pods)	*Phaseolus vulgaris*	NEU	Outdoor	DE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	3				0.25	kg a.i./ha	3	
Peas (with pods)	*Pisum sativum*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	DE: 3x250g/ha, 3d
Peas (without pods)	*Pisum sativum*	NEU	Outdoor	DE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	3				0.25	kg a.i./ha	3	FR: 1x375g/ha, 7d
Lentils (fresh)	*Lens culinaris syn. L. esculenta*	NEU	Outdoor	DE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	3				0.25	kg a.i./ha	3	FR: 1x375g/ha, 7d
Asparagus	*Asparagus officinalis*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	200	
Cardoons	*Cynara cardunculus*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Celery	*Apium graveolens var. dulce*	NEU	Outdoor	UK	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	6				0.14	kg a.i./ha	3	NL: 2x250g/ha, 14d
Fennel	*Foeniculum vulgare*	NEU	Outdoor	UK	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	6				0.14	kg a.i./ha	3	NL: 2x250g/ha, 7d
Globe artichokes	*Cynara scolymus*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Leek	*Allium porrum*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Rhubarb	*Rheum x hybridum*	NEU	Outdoor	UK	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	6				0.14	kg a.i./ha	3	NL: 2x250g/ha, 7d

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application								Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
							Content			Growth stage		Number		Interval (days)							
Common name	Scientific name					Type	Conc.	Unit	Method	From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate	Max. rate	Rate Unit		
Beans (dry)	*Phaseolus vulgaris*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	4				0.25	kg a.i./ha	7	
Lentils (dry)	*Lens culinaris syn. L. esculenta*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	14	
Peas (dry)	*Pisum sativum*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	4				0.25	kg a.i./ha	7	
Lupins	*Lupinus spp.*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	14	
Linseed	*Linum usitatissimum*	NEU	Outdoor	UK	Aphids	WG	500.0	g/kg	Foliar treatment - spraying				2				0.21	kg a.i./ha	14	
Poppy seed	*Papaver somniferum*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	21	
Sunflower seed	*Helianthus annuus*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.25	kg a.i./ha	21	
Rape seed	*Brassica napus*	NEU	Outdoor	CZ	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	79	1	2			0.15	0.25	kg a.i./ha	14	Note: PHI 14 days for 1 application and 21 days for 2 applications
Mustard seed	*Brassica nigra*	NEU	Outdoor	PL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2			0.13	0.25	kg a.i./ha	7	
Borage	*Borago officinalis*	NEU	Outdoor	UK	Aphids	WG	500.0	g/kg	Foliar treatment - spraying				2				0.21	kg a.i./ha	14	
Gold of pleasure	*Camelina sativa*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.25	kg a.i./ha	21	
Barley	*Hordeum spp.*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	51	89	1	2				0.13	kg a.i./ha	35	More critical GAPs notified by BE (PHI of 7) and by NL (4x125 g/ha, 4d) but not supported by data.
Maize	*Zea mays*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	16	55	1	2				0.20	kg a.i./ha	80	
Oats	*Avena fatua*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	51	89	1	2				0.13	kg a.i./ha	35	A more cGAP (PHI of 7) notified by BE but not supported by data.
Rye	*Secale cereale*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	51	89	1	2				0.13	kg a.i./ha	35	A more cGAP (PHI of 7) notified by BE but not supported by data.
Wheat	*Triticum aestivum*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	51	89	1	2				0.13	kg a.i./ha	35	More critical GAPs notified by BE (PHI of 7) and by NL (4x125 g/ha, 4d) but not supported by data.
Herbal infusions (flowers)	*Not specified*	NEU	Outdoor	DE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying				2				0.13	kg a.i./ha	7	
Herbal infusions (leaves)	*Not specified*	NEU	Outdoor	DE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying				2				0.13	kg a.i./ha	7	
Herbal infusions (roots)	*Not specified*	NEU	Outdoor	UK	Aphids	WG	500.0	g/kg	Foliar treatment - spraying				2				0.14	kg a.i./ha	3	
Spices (seeds)	*Not specified*	NEU	Outdoor	DE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	49		3				0.13	kg a.i./ha	n.a.	
Spices (fruits and berries)	*Not specified*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	21	NL use on caraway
Sugar beet	*Beta vulgaris*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Chicory roots	*Cichorium intybus*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Alfalfa	*Medicago Sativa*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	0	
Fodder beet	*Beta vulgaris*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	
Grass	*not specified*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	0	For seed production.
Maize (for forage)	*Zea mays*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying			1	2				0.20	kg a.i./ha	60	

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application								Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
							Content			Growth stage		Number		Interval (days)							
Common name	Scientific name					Type	Conc.	Unit	Method	From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate	Max. rate	Rate Unit		
Almonds	*Prunus dulcis*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	69		1				0.38	kg a.i./ha	14	
Chestnuts	*Castanea sativa*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	14	
Hazelnuts	*Corylus avellana*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	14	
Walnuts	*Juglans regia*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	14	
Apples	*Malus domesticus*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Pears	*Pyrus communis*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Quinces	*Cydonia oblonga*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Apricots	*Prunus armeniaca*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Cherries	*Prunus cerasus, Prunus avium*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Peaches	*Prunus persica*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Plums	*Prunus domestica*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Strawberries	*Fragaria x ananassa*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Potatoes	*Tuber form Solanum Spp*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.25	kg a.i./ha	7	
Carrots	*Daucus carota*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Tomatoes	*Lycopersicum esculentum*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	3	
Peppers	*Capsicum annuum, var grossum and var. longum*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	3	
Aubergines (egg plants)	*Solanum melongena*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	3	
Cucumbers	*Cucumis sativus*	SEU	Outdoor	ES	Aphids				Foliar treatment - spraying	n.a.	n.a.		2				0.50	kg a.i./ha	7	
Gherkins	*Cucumis sativus*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	3	
Courgettes	*Cucurbita pepo var. melopepo*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	3	
Melons	*Cucumis melo*	SEU	Outdoor	ES	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.38	kg a.i./ha	3	
Sweet corn	*Zea mays var. sacharata*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.20	kg a.i./ha	7	
Chinese cabbage	*Brassica pekinensis*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.38	kg a.i./ha	7	
Kale	*Brassica oleracea convar. Acephalea*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.38	kg a.i./ha	7	
Lettuce	*Lactuca sativa*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Scarole (broad-leaf endive)	*Cichorium endiva*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Beans (with pods)	*Phaseolus vulgaris,*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Beans (without pods)	*Phaseolus vulgaris*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Peas (with pods)	*Pisum sativum*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Peas (without pods)	*Pisum sativum*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Asparagus	*Asparagus officinalis*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	200	
Cardoons	*Cynara cardunculus*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Sunflower seed	*Helianthus annuus*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.25	kg a.i./ha	21	
Rape seed	*Brassica napus*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.25	kg a.i./ha	21	
Barley	*Hordeum spp.*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	51	89	1	2				0.13	kg a.i./ha	35	
Maize	*Zea mays*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	16	55	1	2				0.20	kg a.i./ha	80	
Oats	*Avena fatua*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	51	89	1	2				0.13	kg a.i./ha	35	
Sorghum	*Sorghum bicolor*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	16	55	1	2				0.20	kg a.i./ha	80	
Wheat	*Triticum aestivum*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	51	89	1	2				0.13	kg a.i./ha	35	
Maize (for forage)	*Zea mays*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying			1	2				0.20	kg a.i./ha	60	

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application								Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
							Content			Growth stage		Number		Interval (days)							
Common name	Scientific name					Type	Conc.	Unit	Method	From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate	Max. rate	Rate Unit		
Cherries	*Prunus cerasus, Prunus avium*	NEU/SEU	Indoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.37	kg a.i./ha	7	
Plums	*Prunus domestica*	NEU/SEU	Indoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.37	kg a.i./ha	7	
Table grapes	*Vitis euvitis*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Wine grapes	*Vitis euvitis*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Strawberries	*Fragaria x ananassa*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Blackberries	*Rubus fruticosus*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Raspberries	*Rubus idaeus*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Blueberries	*Vaccinium corymbosum*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Currants (red, black and white)	*Ribes nigrum, rubrum*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Gooseberries	*Ribes uva-crispa*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Parsley root	*Petroselinum crispum*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Radishes	*Raphanus sativus var. saitvus*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Tomatoes	*Lycopersicum esculentum*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	1	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Peppers	*Capsicum annuum, var grossum and var. longum*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	3	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Aubergines (egg plants)	*Solanum melongena*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	1	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
							Content			Growth stage		Number		Interval (days)						
Common name	Scientific name					Type	Conc.	Unit	Method	From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate	Max. rate	Rate Unit		
Cucumbers	*Cucumis sativus*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	1	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Gherkins	*Cucumis sativus*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	1	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Courgettes	*Cucurbita pepo var. melopepo*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	1	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Melons	*Cucumis melo*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	3	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Pumpkins	*Cucurbita maxima*	NEU/SEU	Indoor	ES	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.38	kg a.i./ha	3	
Watermelons	*Citrullus lanatus*	NEU/SEU	Indoor	ES	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.38	kg a.i./ha	3	
Broccoli	*Brassica oleracea var. italica*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Cauliflower	*Brassica oleracea var. botrytis*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Head cabbage	*Brassica oleracea convar capitata*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Chinese cabbage	*Brassica pekinensis*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Kohlrabi	*Brassica oleracea convar. acephala, var. gongylodes*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Lamb's lettuce	*Valerianella locusta*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Lettuce	*Lactuca sativa*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Scarole (broad-leaf endive)	*Cichorium endiva*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Cress	*Lepidium sativum*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Land cress	*Barbarea verna*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application								Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
							Content			Growth stage		Number		Interval (days)							
Common name	Scientific name					Type	Conc.	Unit	Method	From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate	Max. rate	Rate Unit		
Rocket, Rucola	*Eruca sativa (Diplotaxis spec.)*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Red mustard	*Brassica juncea var. rugosa*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Leaves and sprouts of Brassica spp	*Brassica spp*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Spinach	*Spinacia oleracea*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Purslane	*Portulaca oleracea*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Witloof	*Cichorium intybus. var. Foliosum*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Chervil	*Anthriscus cerefolium*	NEU/SEU	Indoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	10	
Chives	*Allium schoenoprasum*	NEU/SEU	Indoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	10	
Celery leaves	*Apium graveolens var. seccalinum*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Parsley	*Petroselinum crispum*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Sage	*Salvia officinalis*	NEU/SEU	Indoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	10	
Rosemary	*Rosmarinus officinalis*	NEU/SEU	Indoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	10	
Thyme	*Thymus spp.*	NEU/SEU	Indoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	10	
Basil	*Ocimum basilicum*	NEU/SEU	Indoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	10	
Bay leaves (laurel)	*Laurus nobilis*	NEU/SEU	Indoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	10	
Tarragon	*Artemisia dracunculus*	NEU/SEU	Indoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	10	
Beans (with pods)	*Phaseolus vulgaris,*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Peas (with pods)	*Pisum sativum*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Peas (without pods)	*Pisum sativum*	NEU/SEU	Indoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	4	
Fennel	*Foeniculum vulgare*	NEU/SEU	Indoor	BE	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	3	21			0.20	kg a.i./ha	7	A more cGAP (fumigation at 2 x 0.4 kg a.s./ha, PHI 7 days) notified by NL but not supported by data.
Leek	*Allium porrum*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Rhubarb	*Rheum x hybridum*	NEU/SEU	Indoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.25	kg a.i./ha	7	

APPENDIX A.2 – CRITICAL GAPS CURRENTLY AUTHORISED WITHIN THE EU FOR WHICH A POTENTIAL ACUTE CONCERN WAS IDENTIFIED

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application								Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Apples	*Malus domesticus*	NEU	Outdoor	BE	Aphids	WG	50.0	% (w/w)	Foliar treatment - spraying	n.a.	n.a.	1	2				0.38	kg a.i./ha	3	
Pears	*Pyrus communis*	NEU	Outdoor	BE	Aphids	WG	50.0	% (w/w)	Foliar treatment - spraying	n.a.	n.a.	1	2				0.38	kg a.i./ha	3	
Broccoli	*Brassica oleracea var. italica*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	3	
Cauliflower	*Brassica oleracea var. botrytis*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	3	
Chinese cabbage	*Brassica pekinensis*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	3	
Kale	*Brassica oleracea convar. Acephalea*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	3	
Leek	*Allium porrum*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	

n.a.: not applicable

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application								Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Broccoli	*Brassica oleracea var. italica*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Cauliflower	*Brassica oleracea var. botrytis*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Lettuce	*Lactuca sativa*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Scarole (broad-leaf endive)	*Cichorium endiva*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Spinach	*Spinacia oleracea*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Purslane	*Portulaca oleracea*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).
Leek	*Allium porrum*	NEU/SEU	Indoor	NL	Aphids	FU	100.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.40	kg a.i./ha	7	Note: One smoke generator with 10 g a.i. Per 700 m2 corresponds to 0.4 kg a.i./ha. PHI of 7 days (in the period of 1/3-1/11) or 14 days (in the period of 1/11-1/3).

n.a.: not applicable

APPENDIX A.3 – FALL-BACK GAPS IDENTIFIED BY EFSA SUPPORTING THE DEMONSTRATED SAFE EU MRL PROPOSALS

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Chinese cabbage	*Brassica pekinensis*	NEU	Outdoor	UK	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.21	kg a.i./ha	3	Fall-back GAP (UK, 2014)
Kale	*Brassica oleracea convar. Acephalea*	NEU	Outdoor	UK	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.21	kg a.i./ha	3	Fall-back GAP (UK, 2014)
Scarole (broad-leaf endive)	*Cichorium endiva*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Spinach	*Spinacia oleracea*	NEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		2				0.38	kg a.i./ha	7	
Purslane	*Portulaca oleracea*	NEU	Outdoor	NL	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	7	

n.a.: not applicable

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Apples	*Malus domesticus*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	
Pears	*Pyrus communis*	SEU	Outdoor	FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.		1				0.38	kg a.i./ha	7	

n.a.: not applicable

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Lettuce	*Lactuca sativa*	NEU/SEU	Indoor	UK, FR	Aphids	WG	500.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	1	2				0.25	kg a.i./ha	14	Fall-back GAP (FR, 2014; UK, 2014)

n.a.: not applicable

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Appendix B.1 – EU scenario 1 including all EU MRL proposals resulting from the GAPs reported by the RMS

Appendix B.2 – EU scenario 2 including demonstrated safe EU MRL proposals resulting from the GAPs reported by the RMS

Appendix B.3 – EU/Codex scenario 1 including demonstrated safe EU MRL proposals and all CXLs

Appendix B.4 – EU/Codex scenario 2 including demonstrated safe EU MRL proposals and demonstrated safe CXLs

APPENDIX B.1 – EU SCENARIO 1 INCLUDING ALL EU MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

Pirimicarb			
Status of the active substance:	**Included**	Code no.	
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:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**2001**	Year of evaluation:	**2001**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
4	33
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)
33.1	NL child	7.5	Cauliflower	5.2	Apples	4.2	Milk and cream,	
32.8	FR toddler	6.3	Broccoli	6.3	Broccoli	5.7	Milk and cream,	
29.5	DE child	9.9	Apples	4.7	Table grapes	2.1	Cauliflower	
22.7	WHO Cluster diet B	6.7	Wine grapes	2.4	Lettuce	1.6	Other flowering brassica	
22.2	FR all population	14.9	Wine grapes	1.4	Cauliflower	1.3	Other lettuce and other salad	
22.0	IE adult	4.6	Wine grapes	3.3	Broccoli	2.6	Cauliflower	
19.9	FR infant	4.7	Broccoli	3.7	Milk and cream,	2.9	Spinach	
16.5	WHO cluster diet E	6.0	Wine grapes	1.1	Broccoli	1.1	Beans (without pods)	
15.8	NL general	3.8	Cauliflower	2.3	Wine grapes	1.2	Broccoli	
14.1	PT General population	9.2	Wine grapes	1.2	Beans (without pods)	1.0	Table grapes	
13.3	UK Infant	5.5	Milk and cream,	4.0	Cauliflower	1.3	Apples	
13.2	WHO regional European diet	3.5	Cauliflower	2.5	Lettuce	0.9	Wine grapes	
10.8	UK Toddler	3.0	Milk and cream,	1.8	Cauliflower	1.4	Apples	
10.2	ES adult	3.5	Lettuce	1.5	Wine grapes	0.9	Cauliflower	
9.9	UK vegetarian	3.0	Wine grapes	1.8	Cauliflower	1.4	Broccoli	
9.7	ES child	2.8	Lettuce	1.8	Milk and cream,	0.9	Apples	
9.5	SE general population 90th percentile	1.8	Milk and cream,	1.3	Broccoli	1.3	Broccoli	
9.3	DK child	1.9	Apples	1.8	Milk and cream,	0.9	Lettuce	
9.1	WHO Cluster diet F	2.2	Wine grapes	2.0	Lettuce	1.1	Broccoli	
9.1	IT adult	2.5	Lettuce	1.0	Other lettuce and other salad plants	0.8	Cauliflower	
9.1	DK adult	5.2	Wine grapes	0.8	Milk and cream,	0.6	Apples	
9.0	UK Adult	4.0	Wine grapes	1.2	Broccoli	1.0	Cauliflower	
8.1	WHO cluster diet D	1.3	Wine grapes	0.7	Milk and cream,	0.7	Table grapes	
7.8	IT kids/toddler	1.9	Lettuce	0.7	Other lettuce and other salad plants	0.7	Apples	
6.8	PL general population	1.7	Apples	1.5	Cauliflower	1.2	Table grapes	
4.2	FI adult	1.1	Wine grapes	0.8	Milk and cream,	0.5	Lettuce	
3.9	LT adult	1.5	Apples	0.6	Milk and cream,	0.4	Lettuce	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs 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					

The acute risk assessment is based on the ARfD.
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.
In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): 11			No of commodities for which ARfD/ADI is exceeded (IESTI 2): 8			No of commodities for which ARfD/ADI is exceeded (IESTI 1): 7			No of commodities for which ARfD/ADI is exceeded (IESTI 2): 7		
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)
2815.1	Scarole (broad-leaf	32.2 / 1.14	2815.1	Scarole (broad-leaf	32.2 / 1.14	353.9	Lettuce	32.2 / 9.09	302.6	Purslane	32.2 / 10.64
866.3	Lettuce	32.2 / 3.71	727.8	Spinach	32.2 / 4.42	332.7	Purslane	32.2 / 9.67	287.8	Spinach	32.2 / 11.19
727.8	Spinach	32.2 / 4.42	519.8	Lettuce	32.2 / 6.19	287.8	Spinach	32.2 / 11.19	285.7	Scarole (broad-leaf endive)	32.2 / 11.27
486.5	Purslane	32.2 / 6.61	370.1	Cauliflower	5.6 / 1.51	285.7	Scarole (broad-leaf	32.2 / 11.27	212.3	Lettuce	32.2 / 15.16
370.1	Cauliflower	5.6 / 1.51	368.9	Purslane	32.2 / 8.72	177.8	Cauliflower	5.6 / 3.15	177.8	Cauliflower	5.6 / 3.15
326.2	Broccoli	5.6 / 1.71	233.0	Broccoli	5.6 / 2.4	157.5	Chinese cabbage	4.41 / 2.8	157.5	Chinese cabbage	4.41 / 2.8
298.1	Kale	4.41 / 1.47	213.0	Kale	4.41 / 2.07	119.4	Broccoli	5.6 / 4.68	119.4	Broccoli	5.6 / 4.68
163.8	Chinese cabbage	4.41 / 2.69	163.8	Chinese cabbage	4.41 / 2.69						
126.1	Apples	1.287 / 1.02	99.7	Rocket, Rucola	32.2 / -						
117.2	Pears	1.287 / 1.09	92.9	Apples	1.287 / -						
100.2	Leek	1.7 / 1.69	90.4	Lamb's lettuce	32.2 / -						
99.7	Rocket, Rucola	32.2 / -									
90.4	Lamb's lettuce	32.2 / -									
No of critical MRLs (IESTI 1) 11						No of critical MRLs (IESTI 2) 8					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				No of commodities for which ARfD/ADI is exceeded: ---			
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
65.6	Apple juice	1.287 / -		8.5	Apple juice	1.287 / -	
42.8	Grape juice	1.3 / -		5.0	Wine	1.3 / -	
27.7	Raspberries juice	2.31 / -		2.6	Peach preserved with	1.309 / -	
23.4	Peach juice	1.309 / -		1.5	Quince jelly	1.287 / -	
22.5	Pear juice	1.287 / -		0.5	Raisins	1.3 / -	

*) 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.
The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 11 commodities.
Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 8 commodities.
For processed commodities, no exceedance of the ARfD/ADI was identified.

APPENDIX B.2 – EU SCENARIO 2 INCLUDING DEMONSTRATED SAFE EU MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

Pirimicarb

Status of the active substance:	Included	Code no.	
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:	COM	Source of ARfD:	COM
Year of evaluation:	2001	Year of evaluation:	2001

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
3	20
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)
20.0	DE child	6.5	Apples	4.7	Table grapes	2.0	Milk and cream,	
17.5	FR all population	14.9	Wine grapes	0.4	Table grapes	0.4	Milk and cream,	
15.9	WHO Cluster diet B	6.7	Wine grapes	1.3	Table grapes	1.2	Beans (without pods)	
14.6	NL child	4.2	Milk and cream,	3.4	Apples	2.8	Table grapes	
13.7	PT General population	9.2	Wine grapes	1.2	Beans (without pods)	1.0	Table grapes	
12.4	WHO cluster diet E	6.0	Wine grapes	1.1	Beans (without pods)	0.8	Kohlrabi	
12.2	IE adult	4.6	Wine grapes	1.0	Table grapes	0.9	Beans (without pods)	
10.9	FR toddler	5.7	Milk and cream,	1.4	Apples	0.9	Beans (with pods)	
8.5	UK Infant	5.5	Milk and cream,	0.8	Apples	0.3	Cherries	
7.6	FR infant	3.7	Milk and cream,	1.3	Apples	0.7	Beans (with pods)	
7.6	DK adult	5.2	Wine grapes	0.8	Milk and cream,	0.4	Apples	
7.1	UK Toddler	3.0	Milk and cream,	0.9	Apples	0.9	Table grapes	
6.9	NL general	2.3	Wine grapes	0.9	Milk and cream,	0.9	Table grapes	
6.7	WHO cluster diet D	1.3	Wine grapes	0.7	Milk and cream,	0.7	Table grapes	
6.2	DK child	1.8	Milk and cream,	1.3	Apples	0.7	Cucumbers	
6.0	WHO regional European diet	0.9	Wine grapes	0.7	Milk and cream,	0.6	Table grapes	
5.8	WHO Cluster diet F	2.2	Wine grapes	0.6	Milk and cream,	0.4	Table grapes	
5.7	UK Adult	4.0	Wine grapes	0.4	Milk and cream,	0.2	Apples	
5.5	ES child	1.8	Milk and cream,	0.6	Apples	0.5	Lettuce	
5.4	ES adult	1.5	Wine grapes	0.7	Milk and cream,	0.6	Lettuce	
5.3	UK vegetarian	3.0	Wine grapes	0.5	Milk and cream,	0.3	Apples	
5.2	SE general population 90th percentile	1.8	Milk and cream,	0.6	Apples	0.4	Beans (without pods)	
4.1	PL general population	1.2	Table grapes	1.1	Apples	0.4	Cherries	
3.7	IT kids/toddler	0.5	Peaches	0.5	Apples	0.4	Table grapes	
3.7	IT adult	0.5	Peaches	0.5	Table grapes	0.4	Apples	
3.0	FI adult	1.1	Wine grapes	0.8	Milk and cream,	0.2	Apples	
2.9	LT adult	1.0	Apples	0.6	Milk and cream,	0.2	Cucumbers	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs 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					
The acute risk assessment is based on the ARfD. For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation. In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3. **Threshold MRL** is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.											
Unprocessed commodities	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
	IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	99.7	Rocket, Rucola	32.2 / -	99.7	Rocket, Rucola	32.2 / -	60.5	Lamb's lettuce	32.2 / -	60.5	Lamb's lettuce	32.2 / -
	90.6	Scarole (broad-leaf	1.036 / -	90.6	Scarole (broad-leaf	1.036 / -	41.3	Table grapes	1.3 / -	41.3	Table grapes	1.3 / -
	90.4	Lamb's lettuce	32.2 / -	90.4	Lamb's lettuce	32.2 / -	32.4	Kohlrabi	1.4 / -	30.8	Wine grapes	1.3 / -
	85.1	Table grapes	1.3 / -	85.1	Table grapes	1.3 / -	31.1	Fennel	1.19 / -	23.7	Kohlrabi	1.4 / -
	77.7	Peaches	1.309 / -	70.1	Kohlrabi	1.4 / -	30.8	Wine grapes	1.3 / -	22.7	Fennel	1.19 / -
	No of critical MRLs (IESTI 1)		---				**No of critical MRLs (IESTI 2)**		---			
Processed commodities	**No of commodities for which ARfD/ADI is exceeded:**		---				**No of commodities for which ARfD/ADI is exceeded:**		---			
			***)						***)			
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
	42.8	Grape juice	1.3 / -				5.0	Wine	1.3 / -			
	27.7	Raspberries juice	2.31 / -				2.6	Peach preserved with syrup	1.309 / -			
	23.4	Peach juice	1.309 / -				2.5	Apple juice	0.377 / -			
	19.2	Apple juice	0.377 / -				1.5	Quince jelly	1.287 / -			
	7.7	Plums juice	0.55 / -				0.5	Raisins	1.3 / -			

*) 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 B.3 – EU/CODEX SCENARIO 1 INCLUDING DEMONSTRATED SAFE EU MRL PROPOSALS AND ALL CXLS

Pirimicarb			
Status of the active substance:	**Included**	Code no.	
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:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**2001**	Year of evaluation:	**2001**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	3 20
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)
20.4	DE child	6.7	Apples	4.7	Table grapes	2.0	Milk and cream,	
17.6	FR all population	14.9	Wine grapes	0.4	Table grapes	0.4	Milk and cream,	
16.5	WHO Cluster diet B	6.7	Wine grapes	1.3	Table grapes	1.2	Beans (without pods)	
15.3	NL child	4.2	Milk and cream,	3.5	Apples	2.8	Table grapes	
13.7	PT General population	9.2	Wine grapes	1.2	Beans (without pods)	1.0	Table grapes	
12.6	WHO cluster diet E	6.0	Wine grapes	1.1	Beans (without pods)	0.8	Kohlrabi	
12.5	IE adult	4.6	Wine grapes	1.0	Table grapes	0.9	Beans (without pods)	
11.5	FR toddler	5.7	Milk and cream,	1.5	Apples	0.9	Beans (with pods)	
8.7	UK Infant	5.5	Milk and cream,	0.9	Apples	0.3	Cherries	
7.9	FR infant	3.7	Milk and cream,	1.4	Apples	0.7	Beans (with pods)	
7.6	DK adult	5.2	Wine grapes	0.8	Milk and cream,	0.4	Apples	
7.4	UK Toddler	3.0	Milk and cream,	1.0	Apples	0.9	Table grapes	
7.3	NL general	2.3	Wine grapes	0.9	Milk and cream,	0.9	Table grapes	
6.7	WHO cluster diet D	1.3	Wine grapes	0.7	Milk and cream,	0.7	Table grapes	
6.6	WHO regional European diet	0.9	Wine grapes	0.8	Lettuce	0.7	Milk and cream,	
6.3	DK child	1.8	Milk and cream,	1.3	Apples	0.7	Table grapes	
6.2	ES child	1.8	Milk and cream,	0.9	Lettuce	0.6	Apples	
6.2	WHO Cluster diet F	2.2	Wine grapes	0.7	Lettuce	0.6	Milk and cream,	
6.1	ES adult	1.5	Wine grapes	1.2	Lettuce	0.7	Milk and cream,	
6.0	UK Adult	4.0	Wine grapes	0.4	Milk and cream,	0.3	Lettuce	
5.7	UK vegetarian	3.0	Wine grapes	0.5	Milk and cream,	0.3	Apples	
5.3	SE general population 90th percentile	1.8	Milk and cream,	0.6	Apples	0.4	Beans (without pods)	
4.1	PL general population	1.2	Table grapes	1.1	Apples	0.4	Cherries	
4.1	IT adult	0.8	Lettuce	0.5	Table grapes	0.4	Apples	
4.1	IT kids/toddler	0.7	Lettuce	0.5	Apples	0.4	Tomatoes	
3.2	FI adult	1.1	Wine grapes	0.8	Milk and cream,	0.2	Apples	
3.1	LT adult	1.0	Apples	0.6	Milk and cream,	0.2	Tomatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs 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					

The acute risk assessment is based on the ARfD.
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.
In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): 4			No of commodities for which ARfD/ADI is exceeded (IESTI 2): 1			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)
173.3	Lettuce	6.44 / 3.71	104.0	Lettuce	6.44 / 6.19	70.8	Lettuce	6.44 / -	60.5	Lamb's lettuce	32.2 / -
122.9	Peaches	2.071 / 1.68	99.7	Rocket, Rucola	32.2 / -	60.5	Lamb's lettuce	32.2 / -	42.5	Lettuce	6.44 / -
112.1	Apples	1.144 / 1.02	90.6	Scarole (broad-leaf	1.036 / -	49.6	Fennel	1.8954 / -	41.3	Table grapes	1.3 / -
104.2	Pears	1.144 / 1.09	90.4	Lamb's lettuce	32.2 / -	41.3	Table grapes	1.3 / -	41.0	Chinese cabbage	1.148 / -
99.7	Rocket, Rucola	32.2 / -	90.1	Peaches	2.071 / -	41.0	Chinese cabbage	1.148 / -	36.4	Cauliflower	1.148 / -
90.6	Scarole (broad-leaf	1.036 / -									
90.4	Lamb's lettuce	32.2 / -									
No of critical MRLs (IESTI 1) 4						No of critical MRLs (IESTI 2) 1					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				No of commodities for which ARfD/ADI is exceeded: ---			
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
58.3	Apple juice	1.144 / -		7.5	Apple juice	1.144 / -	
42.8	Grape juice	1.3 / -		5.0	Wine	1.3 / -	
37.1	Peach juice	2.071 / -		4.2	Peach preserved with	2.071 / -	
28.9	Plums juice	2.071 / -		1.5	Quince jelly	1.287 / -	
27.7	Raspberries juice	2.31 / -		0.8	Orange juice	0.0792 / -	

*) 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.
The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 4 commodities.
Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.
For processed commodities, no exceedance of the ARfD/ADI was identified.

APPENDIX B.4 – EU/CODEX SCENARIO 2 INCLUDING DEMONSTRATED SAFE EU MRL PROPOSALS AND DEMONSTRATED SAFE CXLS

Pirimicarb			
Status of the active substance:	Included	Code no.	
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:	COM	Source of ARfD:	COM
Year of evaluation:	2001	Year of evaluation:	2001

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	3 20
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)
20.2	DE child	6.5	Apples	4.7	Table grapes	2.0	Milk and cream,	
17.6	FR all population	14.9	Wine grapes	0.4	Table grapes	0.4	Milk and cream,	
16.3	WHO Cluster diet B	6.7	Wine grapes	1.3	Table grapes	1.2	Beans (without pods)	
15.1	NL child	4.2	Milk and cream,	3.4	Apples	2.8	Table grapes	
13.9	PT General population	9.2	Wine grapes	1.2	Beans (without pods)	1.0	Table grapes	
12.5	WHO cluster diet E	6.0	Wine grapes	1.1	Beans (without pods)	0.8	Kohlrabi	
12.4	IE adult	4.6	Wine grapes	1.0	Table grapes	0.9	Beans (without pods)	
11.4	FR toddler	5.7	Milk and cream,	1.4	Apples	0.9	Beans (with pods)	
8.7	UK Infant	5.5	Milk and cream,	0.8	Apples	0.3	Cherries	
7.9	FR infant	3.7	Milk and cream,	1.3	Apples	0.7	Beans (with pods)	
7.7	DK adult	5.2	Wine grapes	0.8	Milk and cream,	0.4	Apples	
7.4	UK Toddler	3.0	Milk and cream,	0.9	Apples	0.9	Table grapes	
7.1	NL general	2.3	Wine grapes	0.9	Milk and cream,	0.9	Table grapes	
6.7	WHO cluster diet D	1.3	Wine grapes	0.7	Milk and cream,	0.7	Table grapes	
6.2	WHO regional European diet	0.9	Wine grapes	0.7	Milk and cream,	0.6	Table grapes	
6.2	DK child	1.8	Milk and cream,	1.3	Apples	0.7	Table grapes	
5.9	UK Adult	4.0	Wine grapes	0.4	Milk and cream,	0.2	Apples	
5.8	WHO Cluster diet F	2.2	Wine grapes	0.6	Milk and cream,	0.4	Table grapes	
5.8	ES child	1.8	Milk and cream,	0.6	Apples	0.5	Lettuce	
5.6	ES adult	1.5	Wine grapes	0.7	Milk and cream,	0.6	Lettuce	
5.5	UK vegetarian	3.0	Wine grapes	0.5	Milk and cream,	0.3	Apples	
5.3	SE general population 90th percentile	1.8	Milk and cream,	0.6	Apples	0.4	Beans (without pods)	
4.1	PL general population	1.2	Table grapes	1.1	Apples	0.4	Cherries	
3.8	IT kids/toddler	0.5	Peaches	0.5	Apples	0.4	Tomatoes	
3.8	IT adult	0.5	Peaches	0.5	Table grapes	0.4	Apples	
3.1	FI adult	1.1	Wine grapes	0.8	Milk and cream,	0.2	Apples	
3.0	LT adult	1.0	Apples	0.6	Milk and cream,	0.2	Tomatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs 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					
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)
	99.7	Rocket, Rucola	32.2 / -	99.7	Rocket, Rucola	32.2 / -	60.5	Lamb's lettuce	32.2 / -	60.5	Lamb's lettuce	32.2 / -
	90.6	Scarole (broad-leaf	1.036 / -	90.6	Scarole (broad-leaf	1.036 / -	41.3	Table grapes	1.3 / -	41.3	Table grapes	1.3 / -
	90.4	Lamb's lettuce	32.2 / -	90.4	Lamb's lettuce	32.2 / -	41.0	Chinese cabbage	1.148 / -	41.0	Chinese cabbage	1.148 / -
	85.1	Table grapes	1.3 / -	85.1	Table grapes	1.3 / -	36.4	Cauliflower	1.148 / -	36.4	Cauliflower	1.148 / -
	77.7	Peaches	1.309 / -	75.9	Cauliflower	1.148 / -	36.4	Head cabbage	1.148 / -	30.8	Wine grapes	1.3 / -
	No of critical MRLs (IESTI 1)		---				No of critical MRLs (IESTI 2)		---			
Processed commodities	No of commodities for which ARfD/ADI is exceeded:		---				No of commodities for which ARfD/ADI is exceeded:		---			
			***)						***)			
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
	42.8	Grape juice	1.3 / -				5.0	Wine	1.3 / -			
	28.9	Plums juice	2.071 / -				2.6	Peach preserved with syrup	1.309 / -			
	27.7	Raspberries juice	2.31 / -				2.5	Apple juice	0.377 / -			
	23.4	Peach juice	1.309 / -				1.5	Quince jelly	1.287 / -			
	19.2	Apple juice	0.377 / -				0.8	Orange juice	0.0792 / -			

*) 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

The acute risk assessment is based on the ARfD.

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

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

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

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 EU MAXIMUM RESIDUE LIMITS (MRLS) AND CODEX LIMITS (CXLS)

Appendix C.1 – Existing EU MRLs

Appendix C.2 – Existing CXLs

APPENDIX C.1 – EXISTING EU MRLS

(Pesticides - Web Version - EU MRLs - File created on 17/07/2013 13:37)

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
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	3
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	3
110030	Lemons (Citron, lemon)	3
110040	Limes	3
110050	Mandarins (Clementine, tangerine and other hybrids)	3
110990	Others	3
120000	(ii) Tree nuts (shelled or unshelled)	1
120010	Almonds	1
120020	Brazil nuts	1
120030	Cashew nuts	1
120040	Chestnuts	1
120050	Coconuts	1
120060	Hazelnuts (Filbert)	1
120070	Macadamia	1
120080	Pecans	1
120090	Pine nuts	1
120100	Pistachios	1
120110	Walnuts	1
120990	Others	1
130000	(iii) Pome fruit	2
130010	Apples (Crab apple)	2
130020	Pears (Oriental pear)	2
130030	Quinces	2
130040	Medlar	2
130050	Loquat	2
130990	Others	2
140000	(iv) Stone fruit	
140010	Apricots	2
140020	Cherries (sweet cherries,	5
	sour cherries)	
140030	Peaches (Nectarines and similar hybrids)	2
140040	Plums (Damson, greengage, mirabelle)	1
140990	Others	1
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	1
151010	Table grapes	1
151020	Wine grapes	1
152000	(b) Strawberries	3
153000	(c) Cane fruit	2
153010	Blackberries	2
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	2
153030	Raspberries (Wineberries)	2
153990	Others	2
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries cowberries (red bilberries))	1
154020	Cranberries	1
154030	Currants (red, black and white)	1
154040	Gooseberries (Including hybrids with other ribes species)	1
154050	Rose hips	1
154060	Mulberries (arbutus berry)	1
154070	Azarole (mediteranean medlar)	1
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	2
154990	Others	1
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	1
161010	Dates	1
161020	Figs	1
161030	Table olives	1
161040	Kumquats (Marumi kumquats, nagami kumquats)	1
161050	Carambola (Bilimbi)	1
161060	Persimmon	1
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	1
161990	Others	1
162000	(b) Inedible peel, small	1
162010	Kiwi	1
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	1
162030	Passion fruit	1
162040	Prickly pear (cactus fruit)	1
162050	Star apple	1
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	1
162990	Others	1
163000	(c) Inedible peel, large	
163010	Avocados	1
163020	Bananas (Dwarf banana, plantain, apple banana)	1
163030	Mangoes	1
163040	Papaya	1
163050	Pomegranate	1
163060	Cherimoya (Custard apple,	1
	sugar apple (sweetsop) , llama and other medium sized Annonaceae)	
163070	Guava	1
163080	Pineapples	0.5
163090	Bread fruit (Jackfruit)	1
163100	Durian	1
163110	Soursop (guanabana)	1
163990	Others	1
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
213060	Parsnips	0.5
213070	Parsley root	0.5
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0.5
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	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
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) Solanacea	1
231010	Tomatoes (Cherry tomatoes,)	1
231020	Peppers (Chilli peppers)	1
231030	Aubergines (egg plants) (Pepino)	1
231040	Okra, lady's fingers	1
231990	Others	1
232000	(b) Cucurbits - edible peel	1
232010	Cucumbers	1
232020	Gherkins	1
232030	Courgettes (Summer squash, marrow (patisson))	1
232990	Others	1
233000	(c) Cucurbits-inedible peel	1
233010	Melons (Kiwano)	1
233020	Pumpkins (Winter squash)	1
233030	Watermelons	1
233990	Others	1
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
241020	Cauliflower	2
241990	Others	1
242000	(b) Head brassica	1
242010	Brussels sprouts	1
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	1
242990	Others	1
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
243020	Kale (Borecole (curly kale), collards)	1
243990	Others	2
244000	(d) Kohlrabi	0.5
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb´s lettuce (Italian cornsalad)	5
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	5
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	1
251040	Cress	5
251050	Land cress	5
251060	Rocket, Rucola (Wild rocket)	5
251070	Red mustard	5
251080	Leaves and sprouts of Brassica spp (Mizuna)	5
251990	Others	5
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	2
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	5
252030	Beet leaves (chard) (Leaves of beetroot)	5
252990	Others	5
253000	(c) Vine leaves (grape leaves)	5
254000	(d) Water cress	5
255000	(e) Witloof	2
256000	(f) Herbs	5
256010	Chervil	5
256020	Chives	5
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	5
256040	Parsley	5
256050	Sage (Winter savory, summer savory,)	5
256060	Rosemary	5
256070	Thyme (marjoram, oregano)	5
256080	Basil (Balm leaves, mint, peppermint)	5
256090	Bay leaves (laurel)	5
256100	Tarragon (Hyssop)	5
256990	Others	5
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	1
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	1
260030	Peas (with pods) (Mangetout (sugar peas))	1
260040	Peas (without pods) (Garden pea, green pea, chickpea)	1
260050	Lentils	0.7
260990	Others	0.7
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	1
270020	Cardoons	1
270030	Celery	5
270040	Fennel	5
270050	Globe artichokes	5
270060	Leek	1
270070	Rhubarb	1
270080	Bamboo shoots	1
270090	Palm hearts	1
270990	Others	1
280000	(viii) Fungi	0.5
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0.5
280020	Wild (Chanterelle, Truffle, Morel ,)	0.5
280990	Others	0.5
290000	(ix) Sea weeds	0.5
300000	3. PULSES, DRY	1
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	1
300020	Lentils	1
300030	Peas (Chickpeas, field peas, chickling vetch)	1
300040	Lupins	1
300990	Others	1
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

Code number	Groups and examples of individual products to which the MRLs apply [(a)]	Pirimicarb: sum of pirimicarb and desmethyl pirimicarb expressed as pirimicarb
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
402020	Palm nuts (palmoil kernels)	0.1
402030	Palmfruit	0.1
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
631000	(a) Flowers	5
631010	Camomille flowers	5
631020	Hybiscus flowers	5
631030	Rose petals	5
631040	Jasmine flowers	5
631050	Lime (linden)	5
631990	Others	5
632000	(b) Leaves	5
632010	Strawberry leaves	5
632020	Rooibos leaves	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
632030	Maté	5
632990	Others	5
633000	(c) Roots	5
633010	Valerian root	5
633020	Ginseng root	5
633990	Others	5
639000	(d) Other herbal infusions	5
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	4
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	0.05*
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*
1012040	Kidney	0.05*
1012050	Edible offal	0.05*
1012990	Others	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
1013000	(c) Sheep	0.05*
1013010	Meat	0.05*
1013020	Fat	0.05*
1013030	Liver	0.05*
1013040	Kidney	0.05*
1013050	Edible offal	0.05*
1013990	Others	0.05*
1014000	(d) Goat	0.05*
1014010	Meat	0.05*
1014020	Fat	0.05*
1014030	Liver	0.05*
1014040	Kidney	0.05*
1014050	Edible offal	0.05*
1014990	Others	0.05*
1015000	(e) Horses, asses, mules or hinnies	0.05*
1015010	Meat	0.05*
1015020	Fat	0.05*
1015030	Liver	0.05*
1015040	Kidney	0.05*
1015050	Edible offal	0.05*
1015990	Others	0.05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0.05*
1016010	Meat	0.05*
1016020	Fat	0.05*
1016030	Liver	0.05*
1016040	Kidney	0.05*
1016050	Edible offal	0.05*
1016990	Others	0.05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0.05*
1017010	Meat	0.05*
1017020	Fat	0.05*
1017030	Liver	0.05*
1017040	Kidney	0.05*
1017050	Edible offal	0.05*
1017990	Others	0.05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived	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
	from milk, cheese and curd	
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	0.05*
	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	
1030010	Chicken	0.05*
1030020	Duck	0.05*
1030030	Goose	0.05*
1030040	Quail	0.05*
1030990	Others	0.05*
1040000	(iv) Honey (Royal jelly, pollen)	0.05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0.05*
1060000	(vi) Snails	0.05*
1070000	(vii) Other terrestrial animal products	0.05*

(*) Indicates lower limit of analytical determination

APPENDIX C.2 – EXISTING CXLS

Summary of CXLs for pirimicarb in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
110010	Grapefruit	Pirimicarb	3	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.015	0.08	3	n.c.	0.54	2.2	0.03	1.2	2006	Yes	Trials conducted on orange and mandarin in Spain and Italy according to GAP.
110020	Oranges	Pirimicarb	3	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.015	0.08	3	n.c.	0.54	2.2	0.03	1.2	2006	Yes	
110030	Lemons	Pirimicarb	3	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.015	0.08	3	n.c.	0.54	2.2	0.03	1.2	2006	Yes	
110040	Limes	Pirimicarb	3	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.015	0.08	3	n.c.	0.54	2.2	0.03	1.2	2006	Yes	
110050	Mandarins	Pirimicarb	3	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.015	0.08	3	n.c.	0.54	2.2	0.03	1.2	2006	Yes	
130010	Apples	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.18	0.91	3	n.c.	0.15	0.88	n.a.	1.3	2006	Yes	Trials on apples conducted in the EU according to GAP.
130020	Pears	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.18	0.91	3	n.c.	0.15	0.88	n.a.	1.3	2006	Yes	
130030	Quinces	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.18	0.91	3	n.c.	0.15	0.88	n.a.	1.3	2006	Yes	
130040	Medlar	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.18	0.91	3	n.c.	0.15	0.88	n.a.	1.3	2006	Yes	
130050	Loquat	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.18	0.91	1	n.c.	0.15	0.88	n.a.	1.3	2006	Yes	
140010	Apricots	Pirimicarb	3	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.99	2.1	3	n.c.	0.28	1.9	n.a.	1.1	2006	Yes	Trials on peach, nectarine, plum and cherry were conducted in various EU countries according to GAP.
140020	Cherries	Pirimicarb	3	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.99	2.1	1	n.c.	0.28	1.9	n.a.	1.1	2006	Yes	
140030	Peaches	Pirimicarb	3	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.99	2.1	3	n.c.	0.28	1.9	n.a.	1.1	2006	Yes	
140040	Plums	Pirimicarb	3	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.99	2.1	3	n.c.	0.28	1.9	n.a.	1.1	2006	Yes	

Summary of CXLs for pirimicarb in plant commodities																
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
153010	Blackberries	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.36	0.82	1	n.c.	0.18	0.76	n.a.	1.1	2006	Yes	Trials on currants, gooseberries and raspberries were conducted in Germany according to Netherlands GAP.
153020	Dewberries	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.36	0.82	1	n.c.	0.18	0.76	n.a.	1.1	2006	Yes	
153030	Raspberries	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.36	0.82	1	n.c.	0.18	0.76	n.a.	1.1	2006	Yes	
154010	Blueberries	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.36	0.82	1	n.c.	0.18	0.76	n.a.	1.1	2006	Yes	
154020	Cranberries	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.36	0.82	1	n.c.	0.18	0.76	n.a.	1.1	2006	Yes	
154030	Currants (red, black and white)	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.36	0.82	1	n.c.	0.18	0.76	n.a.	1.1	2006	Yes	
154040	Gooseberries	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.36	0.82	1	n.c.	0.18	0.76	n.a.	1.1	2006	Yes	
154050	Rose hips	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.36	0.82	1	n.c.	0.18	0.76	n.a.	1.1	2006	Yes	
154060	Mulberries	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.36	0.82	1	n.c.	0.18	0.76	n.a.	1.1	2006	Yes	
154070	Azarole (mediteranean medlar)	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.36	0.82	1	n.c.	0.18	0.76	n.a.	1.1	2006	Yes	
154080	Elderberries	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.36	0.82	1	n.c.	0.18	0.76	n.a.	1.1	2006	Yes	

Summary of CXLs for pirimicarb in plant commodities																
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
211000	Potatoes	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	3	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	All trials were conducted in the EU according to various EU GAP. Data were available for carrot, sugar beet and potato. Since the majority of residues were <LOQ an MCF of 2 may not be accurate.
212010	Cassava	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
212020	Sweet potatoes	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	3	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
212030	Yams	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	3	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
212040	Arrowroot	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
213010	Beetroot	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	3	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
213020	Carrots	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	3	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
213030	Celeriac	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	3	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
213040	Horseradish	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
213050	Jerusalem artichokes	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	3	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
213060	Parsnips	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	3	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
213070	Parsley root	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
213080	Radishes	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
213090	Salsify	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
213100	Swedes	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
213110	Turnips	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	3	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	

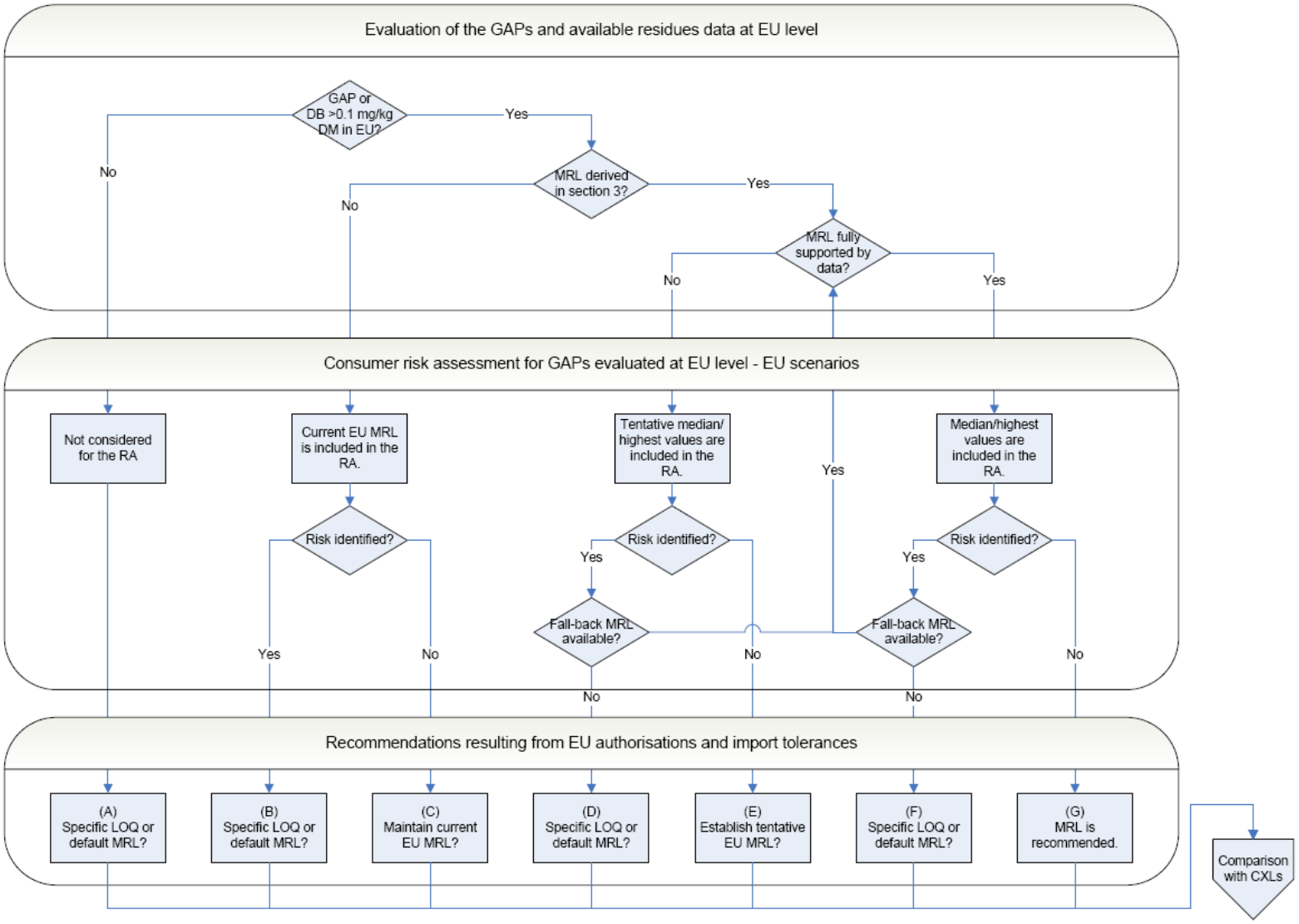
Summary of CXLs for pirimicarb in plant commodities																
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
220010	Garlic	Pirimicarb	0.1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.09	1	n.c.	0.01	0.06	n.a.	2.0	2006	Yes	Extrapolated from onion
220020	Onions	Pirimicarb	0.1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.09	3	n.c.	0.01	0.06	n.a.	2.0	2006	Yes	All trials were conducted in the EU according to various EU GAP.
231010	Tomatoes	Pirimicarb	0.5	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.105	0.25	3	n.c.	0.08	0.22	n.a.	1.3	2006	Yes	All trials were conducted in the EU according to GAP. Data were available for tomato and peppers.
231020	Peppers	Pirimicarb	0.5	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.105	0.25	3	n.c.	0.08	0.22	n.a.	1.3	2006	Yes	
231030	Aubergines (egg plants)	Pirimicarb	0.5	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.105	0.25	3	n.c.	0.08	0.22	n.a.	1.3	2006	Yes	
231040	Okra, lady's fingers	Pirimicarb	0.5	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.105	0.25	1	n.c.	0.08	0.22	n.a.	1.3	2006	Yes	
232010	Cucumbers	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.18	0.44	3	n.c.	0.11	0.41	n.a.	1.3	2006	Yes	All trials were conducted in the EU according to GAP. Data were available for cucumber and courgette.
232020	Gherkins	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.18	0.44	3	n.c.	0.11	0.41	n.a.	1.3	2006	Yes	
232030	Courgettes	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.18	0.44	3	n.c.	0.11	0.41	n.a.	1.3	2006	Yes	
233010	Melons	Pirimicarb	0.2	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.03	0.09	3	n.c.	0.03	0.12	0.3	1.3	2006	Yes	All trials were conducted in the EU according to GAP.
233020	Pumpkins	Pirimicarb	1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.18	0.44	3	n.c.	0.11	0.41	n.a.	1.3	2006	Yes	See comments for cucumber.
234000	Sweet corn	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	All trials were conducted in France according to GAP.
241010	Broccoli	Pirimicarb	0.5	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.05	0.5	3	n.c.	0.04	0.41	n.a.	2.8	2006	Yes	All trials were conducted in the EU according to GAP. Data were available for cauliflower, broccoli, Brussel's sprout and cabbage. The JMPR based CXL on the full dataset but the STMR and HR on cabbage and broccoli respectively. EFSA values are based on full dataset.
241020	Cauliflower	Pirimicarb	0.5	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.05	0.5	3	n.c.	0.04	0.41	n.a.	2.8	2006	Yes	
242010	Brussels sprouts	Pirimicarb	0.5	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.05	0.5	1	n.c.	0.04	0.41	n.a.	2.8	2006	Yes	
242020	Head cabbage	Pirimicarb	0.5	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.05	0.5	3	n.c.	0.04	0.41	n.a.	2.8	2006	Yes	
243010	Chinese cabbage	Pirimicarb	0.5	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.05	0.5	3	n.c.	0.04	0.41	n.a.	2.8	2006	Yes	

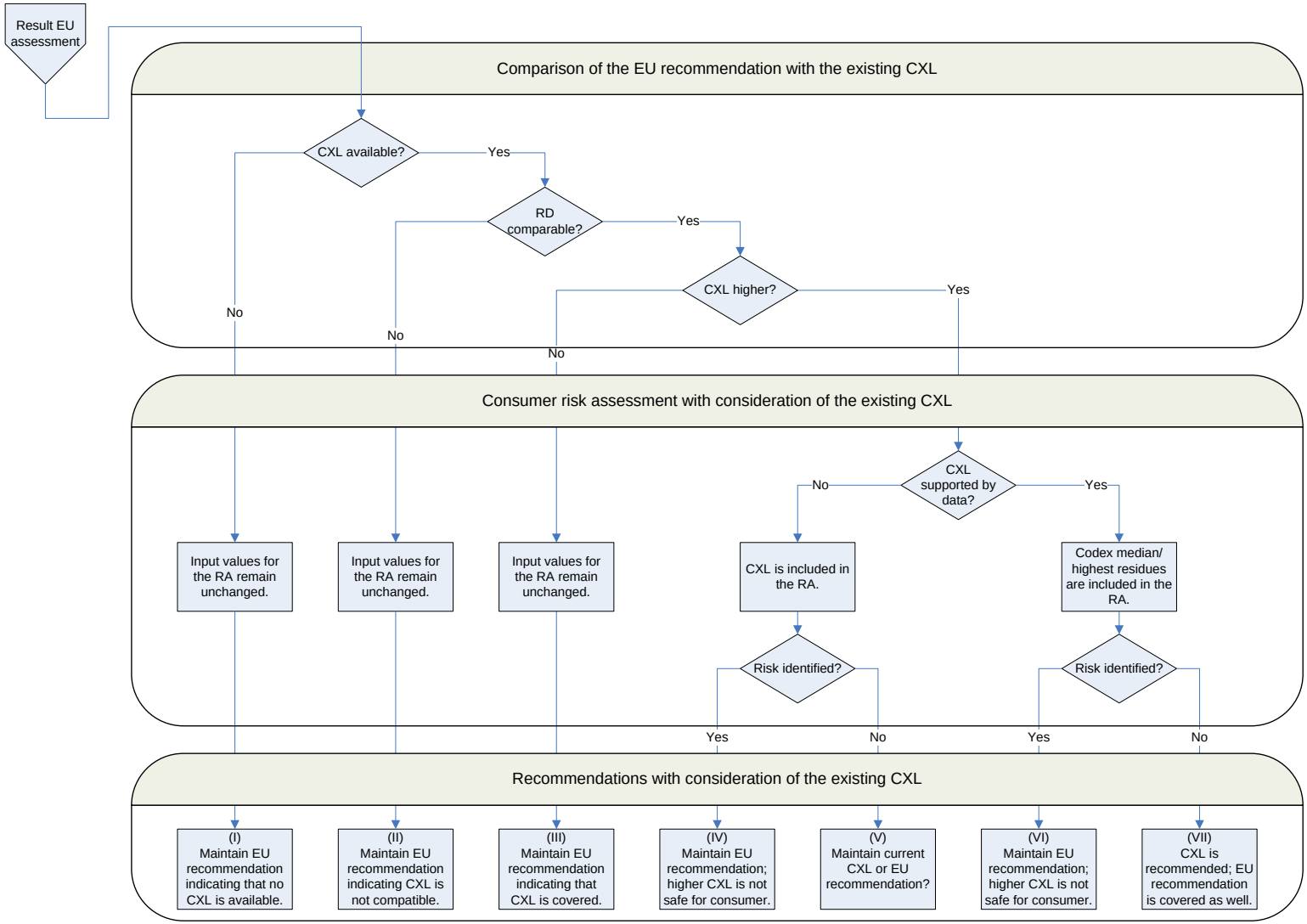
Summary of CXLs for pirimicarb in plant commodities																
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
243020	Kale	Pirimicarb	0.3	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.31	0.6	1	n.c.	0.075	0.15	n.a.	2.8	2006	Yes	All trials were conducted in the UK according to GAP.
244000	Kohlrabi	Pirimicarb	0.5	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.05	0.5	3	n.c.	0.04	0.41	n.a.	2.8	2006	Yes	See comments for flowering brassicae.
251020	Lettuce	Pirimicarb	5	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	2	3	3	n.c.	0.28	2.3	n.a.	2.8	2006	Yes	All trials were conducted in the EU according to GAP.
260010	Beans (fresh, with pods)	Pirimicarb	0.7	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.27	0.59	1	n.c.	0.04	0.4	n.a.	1.7	2006	Yes	All trials were conducted in the EU according to GAP. Data were available for peas and beans with and without pods.
260020	Beans (fresh, without pods)	Pirimicarb	0.7	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb	0.27	0.59	1	n.c.	0.04	0.4	n.a.	1.7	2006	Yes	
260030	Peas (fresh, with pods)	Pirimicarb	0.7	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.27	0.59	1	n.c.	0.04	0.4	n.a.	1.7	2006	Yes	
260040	Peas (fresh, without pods)	Pirimicarb	0.7	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.27	0.59	1	n.c.	0.04	0.4	n.a.	1.7	2006	Yes	
260050	Lentils (fresh)	Pirimicarb	0.7	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.27	0.59	1	n.c.	0.04	0.4	n.a.	1.7	2006	Yes	
270010	Asparagus	Pirimicarb	0.01 *	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0	0	3	n.c.	0.0	0.0	n.a.	1.0	2006	Yes	Trials were conducted in Greece and Germany according to GAP. All residue were <LOQ.
270050	Globe artichokes	Pirimicarb	5	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.69	2.8	3	n.c.	0.38	2.6	n.a.	1.2	2006	Yes	Trials were conducted in France and Spain according to GAP.
300010	Beans (dry)	Pirimicarb	0.2	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.075	0.15	1	n.c.	0.05	0.12	n.a.	1.4	2006	Yes	Trials were conducted in France and Spain according to GAP.
300020	Lentils (dry)	Pirimicarb	0.2	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.075	0.15	1	n.c.	0.05	0.12	n.a.	1.4	2006	Yes	
300030	Peas (dry)	Pirimicarb	0.2	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.075	0.15	1	n.c.	0.05	0.12	n.a.	1.4	2006	Yes	
300040	Lupins (dry)	Pirimicarb	0.2	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.075	0.15	1	n.c.	0.05	0.12	n.a.	1.4	2006	Yes	
401050	Sunflower seed	Pirimicarb	0.1	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.015	0.07	1	n.c.	0.01	0.05	n.a.	1.4	2006	Yes	All trials were conducted in the EU according to GAP.
401060	Rape seed	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.02	1	n.c.	0.01	0.02	n.a.	1.4	2006	Yes	All trials were conducted in the EU according to GAP.

Summary of CXLs for pirimicarb in plant commodities																
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
500010	Barley grain	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.05	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	All trials were conducted in the EU according to GAP. Data were available for barley, maize and wheat.
500020	Buckwheat grain	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.05	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
500030	Maize grain	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.05	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
500040	Millet grain	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.05	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
500050	Oats grain	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.05	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
500070	Rye grain	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.05	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
500080	Sorghum grain	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.05	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
500090	Wheat grain	Pirimicarb	0.05	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.01	0.05	1	n.c.	0.01	0.02	n.a.	1.0	2006	Yes	
810000	Spices (seeds)	Pirimicarb	5	Sum of pirimicarb, desmethyl pirimicarb (R34836) and desmethylformamido pirimicarb (R34885), expressed as pirimicarb.	0.14	3	1	n.c.	0.14	3	n.a.	1.4	2006	No	All spice data were from Egypt. No data on the different residue definitions were provided.

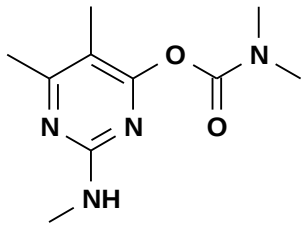
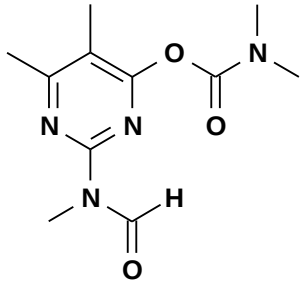
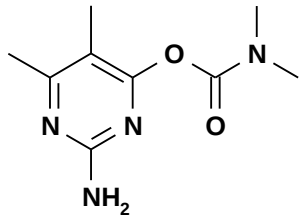
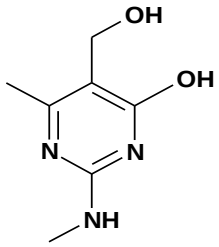
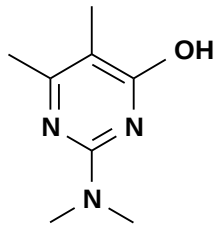
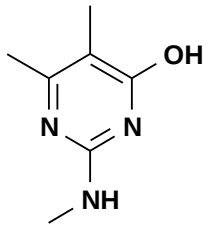
(*) Indicates the lower limit of analytical quantification.
n.a.: not applicable
n.c.: not considered
n.k.: not known

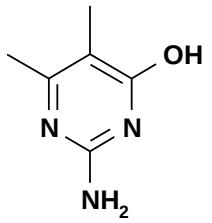
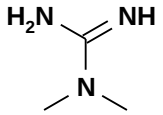
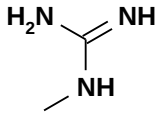
APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
RD comparable?
Yes
CXL higher?
Yes
No
No
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structural formula
Desmethyl pirimicarb	5,6-dimethyl-2-(methylamino)pyrimidin-4-yl dimethylcarbamate	
Desmethylformamido pirimicarb	5,6-dimethyl-2-(methylamino) pyrimidin-4-ol	
R35140	2-amino-5,6-dimethylpyrimidin-4-yl dimethylcarbamate	
R406405	5-hydroxymethyl-6-methyl-2-(methylamino)pyrimidin-4-ol	
R31805	2-dimethylamino-5,6-dimethylpyrimidin-4-ol	
R34865	5,6-dimethyl-2-(methylamino)pyrimidin-4-ol	

Common name	IUPAC name	Structural formula
R31680	2-amino-5,6-dimethylpyrimidin-4-ol	
Dimethylguanidine	1,1-dimethylguanidine	
Methylguanidine	1-methylguanidine	

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DB	dietary burden
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
EFSA	European Food Safety Authority
eq	residue expressed as a.s. equivalent
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC-MS	gas chromatography with mass spectrometry
GC-NPD	gas chromatography with nitrogen/phosphorous detector
ha	hectare

HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
RSD	relative standard deviation
SEU	Southern European Union
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WG	water dispersible granule
WHO	World Health Organization