REASONED OPINION

Modification of the existing MRLs for triclopyr in various commodities of animal origin[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, Ireland, hereafter referred to as the Evaluating Member State (EMS), compiled an application to modify the existing MRLs for triclopyr in several food commodities of animal origin. In order to accommodate for the European use of triclopyr on grass (pasture), it is proposed to raise the existing MRLs for ruminant meat, liver, kidney, fat and milk. Ireland drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 29 May 2009. The use of triclopyr on pasture was the only representative use evaluated under the peer review; MRL proposals were derived by the experts, but not enforced in the legislation. Ireland as the RMS of the active substance takes now the initiative to propose these MRLs to be included in Annex III of the MRL regulation.

EFSA derives the following conclusions regarding the application, based on the above mentioned evaluation on triclopyr, the EFSA conclusion of the peer review as well as the Draft Assessment Report prepared by Ireland.

The toxicological profile of triclopyr was investigated in the peer review under Directive 91/414/EEC and data were sufficient to conclude on an ADI value of 0.03 mg/kg bw/d and an ARfD of 0.3 mg/kg. In addition, toxicological studies were submitted for the metabolite 3,5,6-trichloro-2-pyridinol (3,5,6-TCP), but the data package was incomplete to derive definitive toxicological reference values. However, the studies demonstrated that the toxicity would be in the same order of magnitude as the parent compound.

The metabolism of triclopyr in grass was investigated in the peer review and parent triclopyr was considered as a major residue of concern. Metabolism of triclopyr in livestock was investigated in lactating goats and in laying hens. In animal tissues triclopyr and its metabolite 3,5,6-TCP were the major components. It is noted, that 3,5,6-TCP is not a specific marker for triclopyr as it is also a major plant and livestock metabolite of the active substances chlorpyrifos and chlorpyrifos-methyl. The peer review did not agree on final enforcement and risk assessment residue definitions for food commodities of animal origin but derived two possible options:

1) “Sum of triclopyr and its metabolite 3,5,6-trichloro-2-pyridinol (3,5,6-TCP), expressed as triclopyr”

1 On request [from the European Commission], Question No EFSA-Q-2009-00649, issued on 3 November 2009.
2 Correspondence: praper.mrl@efsa.europa.eu

Suggested citation: European Food Safety Authority; Modification of the existing MRLs for triclopyr in various commodities of animal origin on request [from the European Commission]. EFSA Journal 2009; 7(11):1369. [33 pp.]. doi:10.2903/j.efsa.2009.1369. Available online: www.efsa.europa.eu

2) Two separate residue definitions: “triclopyr” and “3,5,6-trichloro-2-pyridiniol”

In Regulation (EC) No 396/2005 a residue definition comparable with the first option has been implemented (sum of triclopyr and 3,5,6-trichloro-2-pyridinol). EFSA, however, is of the opinion that enforcement residue definitions should be set separately for triclopyr and 3,5,6-TCP. Also for risk assessment, EFSA is in favour of setting separate residue definitions. The risk assessment of 3,5,6-TCP has to take into account also the contribution of the related compounds chlorpyrifos and chlorpyrifos-methyl. Thus, final MRL proposals for 3,5,6-TCP in animal commodities should reflect the residues resulting from the different sources. Consequently, changing the residue definition for products of animal origin would also require reviewing the uses of chlorpyrifos and chlorpyrifos-methyl. However, in the framework of this application EFSA could only evaluate the use of triclopyr on grass and the impact on food of animal origin regarding the residues of triclopyr and its metabolite. This assessment is considered as the first part of a comprehensive assessment of the three active substances involved which should be completed in the framework of Article 12(2) when the full data packages for the other compounds concerned are presented.

According to a communication from the manufacturer, analytical enforcement methods for the determination of triclopyr and its metabolite 3,5,6-TCP in animal matrices are available, but these methods have not yet been reviewed by the EMS.

A limited number of supervised field trials is available which allows an estimation of the expected residues on grass and which was used to estimate the dietary burden of livestock, but the number of trials is considered not sufficient to derive a MRL proposal triclopyr in grass in case MRLs for feed would be set in the future.

Studies regarding the effects of processing on the nature and magnitude of triclopyr residues were not provided in the peer review and no new studies have been submitted in the framework of the current application. Grass can be consumed either fresh, dried (hay) or fermented (silage). Fermentation can be considered as the most widely applied technology for the preservation of the grass in Europe. EFSA therefore recommends to investigate the effects of fermentation on the nature and magnitude of triclopyr residues in grass.

The indicative livestock dietary burden was calculated with the EFSA livestock dietary burden calculator considering the intake of grass treated with triclopyr. This calculation indicates a significant intake of triclopyr residues by dairy and meat ruminants, exceeding the trigger value of 0.1 mg/kg (dry matter). Livestock feeding studies with lactating cows and calves were used for the estimation of MRLs (according to the proposed residue definition) in the commodities of animal origin. These studies demonstrate that feeding grass which was treated with triclopyr may lead to residues of triclopyr and 3,5,6-TCP exceeding the current MRLs for tissues of ruminants and milk as established in Annex III of Regulation 396/2005. Therefore the amendment of the current MRLs is necessary.

The consumer intake assessment was performed with revision 2 of EFSA PRIMo separately for triclopyr and 3,5,6-TCP. For the chronic intake assessment the existing MRL for rice and the STMR values as derived for the commodities of animal origin following the intake of treated grass were used as input values. The acute intake was calculated with the HR values derived for meat, fat, liver, kidney and the STMR value for milk.

No chronic consumer intake concerns were identified for any of the European diets. The calculated long-term dietary intake related to triclopyr residues in ruminants meat, liver, kidney, fat, milk and rice was 3.4% of the ADI for triclopyr. For 3,5,6-TCP, applying the same ADI as for triclopyr, the dietary intake accounted for 3.7% of the ADI.

No acute intake concerns were identified for the commodities under consideration. For animal products derived from ruminants, the short term intake of triclopyr was less than 0.4%. For 3,5,6-TCP the highest exposure was calculated for bovine liver (3.8 % of the ARfD). It is noted that the risk

assessment for 3,5,6-TCP is only a preliminary assessment which has to be completed with the data resulting from the use of chlorpyrifos and chlorpyrifos-methyl.

In conclusion, EFSA derives the following recommendations:

- The residue definitions for risk assessment and enforcement for commodities of animal origin should be established separately as "triclopyr" and "3,5,6-trichloro-2-pyridinol (3,5,6-TCP)".
- Analytical methods for routine monitoring of triclopyr and 3,5,6-TCP have to be provided and reviewed by the EMS.
- Additional residue trials for grass in compliance with the critical European GAP have to be performed in view of setting MRLs for feed commodities in the future.
- It is also recommended to investigate the nature and magnitude of residues in processed commodities, in particular regarding production of silage.
- Provided that the additional residue trials on grass do not change significantly the indicative dietary burden calculations and sufficiently sensitive analytical enforcement methods are available, the following tentative MRLs could be proposed for triclopyr:

Commodity	**Existing EC MRL (mg/kg)**	**Proposed EC MRL (mg/kg)**	**Justification for the proposal**
Residue definition (enforcement): **Triclopyr**			
Bovine, goat, sheep meat	Currently for all animal commodities the MRLs are set at 0.05* for the sum of triclopyr and 3,5,6-TCP.	0.05 *	No risk for consumers was identified for the proposed MRLs. However, the proposed MRLs are based on a preliminary dietary burden calculation only which has to be confirmed. A validated analytical method for routine monitoring has to be provided.
Bovine, goat, sheep meat		0.05 *	
Bovine, goat, sheep liver		0.05 *	
Bovine, goat, sheep kidney		0.2	
Bovine, goat, sheep fat		0.05 *	
Milk		0.01 *	

* Indicates that the MRL is set at the limit of analytical quantification

- Before separate MRLs for 3,5,6,-TCP can be established, the uses of chlorpyrifos and chlorpyrifos-methyl have to be evaluated concerning the concentration of 3,5,6-TCP residues in plant and animal commodities. A combined risk assessment for the three compounds sharing the common metabolite has to be performed demonstrating that no consumer risk is related to the total 3,5,6-TCP residues.

KEY WORDS

Triclopyr, food commodities of animal origin, grass, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, pyridine herbicides, 3,5,6-trichloro-2-pyridinol, chlorpyrifos, chlorpyrifos-methyl

TABLE OF CONTENTS

BACKGROUND

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

Ireland, hereafter referred to as the evaluating Member State (EMS), compiled an application to modify the existing MRLs and risk enforcement residue definitions for the active substance triclopyr in several animal commodities. This application was notified to the European Commission and EFSA and subsequently evaluated in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 29 May. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00649 and the following subject:

Triclopyr - Application to modify the existing MRLs for sum of triclopyr + 3,5,6 trichlor-2-pyridinol in bovine meat from 0.05 mg/kg to 0.2 mg/kg, in bovine fat from 0.05* mg/kg to 0.2 mg/kg, in bovine kidney from 0.05 mg/kg to 2 mg/kg, in bovine liver from 0.05* mg/kg to 2 mg/kg and in cattle milk from 0.05* mg/kg to 0.03 mg/kg.*

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation. Before finalising the reasoned opinion, the EMS was invited to provide comments which were received on 30 October 2009.

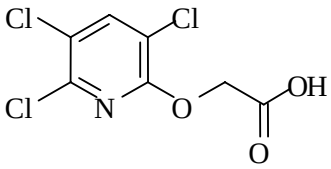
TERMS OF REFERENCE

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

According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided. In this particular case the calculated deadline for providing the reasoned opinion is 29 August 2009.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Triclopyr is the ISO common name for 3,5,6-trichloro-2-pyridyloxyacetic acid (IUPAC).



MW: 256.47

Log P_{OW}= -0.45 (pH 7)

Triclopyr is a synthetic auxin. It is used as herbicide against broad leaved weeds. Triclopyr is taken up via leaves and roots causing cessation of normal growth and death of plants. Grass is unaffected at normal application rates.

Triclopyr was peer reviewed under Commission Directive 91/414/EEC as a stage two active substance with Ireland being the designated Rapporteur Member State. The peer review of triclopyr is finalized and an EFSA conclusion was issued on 14 December 2005. The active substance was included in Annex I of Directive 91/414/EEC by Commission Directive 2006/74/EC which entered into force on 1 June 2007. The evaluated representative uses cover broadcast spraying or spot treatment to control a wide spectrum of broad-leaved weeds in pasture, forestry, grassland at an application rate up to 1.44 kg a.s./ha.

The EU MRLs for triclopyr are established in Annex III of Regulation (EC) No 396/2005 (Appendix C). Currently triclopyr is only authorised for uses on rice and non-food crops. Thus, all MRLs for plant commodities are set at the LOQ of 0.1 mg/kg, except rice for which the MRL is set at 1 mg/kg. The EU MRLs for animal commodities are set at the LOQ of 0.05 mg/kg. In Regulation (EC) No 396/2005 the enforcement residue definition for plant commodities contains the parent compound only, whereas for animal commodities it is defined as "sum of triclopyr and 3,5,6 trichloro-2-pyridinol".

It should be noted, that the metabolite *3,5,6-trichloro-2-pyridinol* (3,5,6-TCP) is not a specific animal metabolite of triclopyr, but it is also a plant and animal metabolite resulting from the use of chlorpyrifos and chlorpyrifos-methyl.

Triclopyr has not been peer reviewed by the JMPR and therefore no CXLs are currently set for the active substance.

The use of triclopyr on pasture which is the basis of the MRL application discussed in the reasoned opinion, has already been evaluated under the peer review. However, the specific MRL proposals for animal commodities derived under the peer review were not included in the MRL legislation. Ireland as the RMS of the active substance takes now the initiative to propose these MRLs to be transferred to the MRL legislation. The critical GAP on pasture is defined as a single application of triclopyr on grass at an application rate of 1.44 kg a.s./ha with the minimum PHI of 7 days. The details of this GAP as authorised in the United Kingdom and Ireland are summarized in Appendix A.

EFSA bases its conclusions on the evaluation report prepared by the EMS Ireland, the Draft Assessment Report (Ireland, 2003) and the EFSA conclusion on the peer review of triclopyr (EFSA, 2005).

ASSESSMENT

1. Methods of analysis

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

The analytical method for the determination of triclopyr residues in grass (as animal feed) was evaluated in the framework of the peer review of Directive 91/414/EEC (Ireland, 2003). Triclopyr residues in grass can be determined using GC/ECD detection; the validated LOQ is 0.05 mg/kg. The multi-residue method DFG S19 is not applicable for the determination of triclopyr residues in grass due to complex extraction and derivatisation required. Analytical enforcement methods for the determination of residues of triclopyr and 3,5,6-TCP in plant commodities intended for human consumption are not relevant for the current application, but should be provided for rice, the only crop for which currently a MRL is established above the LOQ. Further needs for a specific analytical method for 3,5,6-TCP has to be discussed also in the framework of the evaluation of chlorpyrifos and chlorpyrifos-methyl.

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

In the peer review the availability of analytical enforcement methods for the determination of triclopyr residues in commodities of animal origin was investigated (Ireland, 2003). It was concluded that a new analytical method (including ILV data) should be submitted for the determination of parent triclopyr and its metabolite 3,5,6-TCP in matrices of animal origin.

The applicant informed the EMS that analytical methods for routine monitoring are available which will be submitted in the framework of the MRL review according to Article 12(2) of Regulation 396/2005. However, before the proposed MRLs for triclopyr and 3,5,6,-TCP in commodities of animal origin are established, the validated analytical method have to be provided and assessed by the EMS.

2. Mammalian toxicology

Toxicity of triclopyr and its metabolite 3,5,6-trichloro-2-pyridinol (3,5,6-TCP) was investigated in the framework of the peer review of Directive 91/414/EEC (EFSA, 2005). The data provided were sufficient to derive an ADI and an ARfD value for the parent compound.

For 3,5,6-TCP a limited number of toxicological studies were submitted but the data package was incomplete with regard to long term studies. Although the database was not sufficient to derive a final ADI for 3,5,6-TCP, the experts concluded that, since the metabolite did not show a toxicity higher than the parent compound, the ADI of triclopyr can be applied for consumer risk assessment of 3,5,6-TCP. As for the ARfD of 3,5,6-TCP, a tentative value of 0.25 mg/kg bw was derived.

It is noted that no mechanistic information is available to explain the mode of action of 3,5,6-TCP.

Toxicological reference values agreed in the peer review are summarized in Table 2-1.

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

	Source	Year	Value	Study relied upon	Safety factor
Parent compound: triclopyr					
ADI	EFSA	2005	0.03 mg/kg bw/d (triclopyr-acid)	2 yr rats	100
ARfD	EFSA	2005	0.3 mg/kg bw (triclopyr-butoxyethyl ester) [1)]	Rabbit developmental study	100
Relevant metabolite: 3,5,6-trichloro-2-pyridinol (3,5,6-TCP)					
ADI	EFSA	2005	Data package incomplete. Since 3,5,6-TCP dose not show higher toxicity than triclopy, the ADI established for the parent compound may be applied.		
ARfD (tentative)	EFSA	2005	0.25 mg/kg bw	Rabbit teratogenicity	100

[1)] Corresponds to 0.301 mg/kg bw in terms of triclopyr acid (MW triclopyr: 256.5, MW triclopyr butoxyethyl ester: 960)

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Under the peer review the metabolism of triclopyr in plants was investigated in ryegrass, apples and radish (Ireland, 2003):

-apples: foliar application - 0.647 kg a.s./ha; soil application - 1.1 kg a.s./ha

-radish: foliar application - 0.0265 kg a.s./ha; soil application - 1.09 kg a.s./ha

-ryegrass: foliar application - 2.24 kg a.s./ha and 4.48 kg a.s./ha

After foliar application of triclopyr on apples, low residues (<0.020 mg/kg triclopyr equivalents) were found in the harvested and in windfall apples. Approximately 68% of the TRR in the apple pulp was identified as triclopyr and conjugates of triclopyr. Approximately 10% of the apple TRR (0.002 mg/kg triclopyr equivalents) was unextractable. In the leaves, approximately 50% of the TRR was identified as conjugated or free triclopyr.

Following the soil application, radioactive residues in the apple fruit were very low (<0.01mg/kg triclopyr equivalents). It was stated that no observable effects on tree and fruit development, growth, and morphology occurred compared to the untreated control tree. In apples, the main residue was parent triclopyr.

In radish after foliar application, parent triclopyr accounted for 75% of the TRR (0.27 mg/kg). Results indicated that parent triclopyr was the major residue in radish roots. Analyses of radish leaves also indicate parent triclopyr being the main residue. Soil was also analyzed for triclopyr residues and it

contained in total 0.036 mg/kg triclopyr equivalents. It can not be clearly identified whether the translocation from the plant to soil occurred or whether triclopyr residues in soil resulted from the exposure to the active substance during application.

In radish after soil application, residue levels were 0.6 mg/kg in leaves, 5 mg/kg in roots and 1 mg/kg in soil. In radish roots approximately 97 % of the residues were extracted and consisted mainly from parent triclopyr (3.2 mg/kg) and polar metabolites. Acid hydrolysis of the polar metabolites yielded triclopyr acid (4.6 mg/kg). Approximately 2.6% of the acid hydrolysed extract was characterized as 3,5,6-TCP (0.13 mg/kg). Extraction of leaf samples released 96% (0.6 mg/kg) of the residue. Triclopyr accounted for 42% of the total residue (0.26 mg/kg) in addition to a complex mixture of polar metabolites. In soil 88% of the residue was ether soluble and 84% of this was characterised as triclopyr (0.84 mg/kg) and 3,5,6-TCP (0.03 mg/kg). The most abundant radioactive residue in roots and leaves was free triclopyr. Radio-labelled triclopyr was further metabolised to polar conjugates and when these were hydrolysed triclopyr and small amounts of 3,5,6-trichloro-2-pyridinol (3,5,6-TCP) were liberated.

In ryegrass the concentration of TRR decreased steadily from 168 mg/kg on day 0 to 3.8 mg/kg 91 DAT. In grass, triclopyr undergoes conjugation. The only residues identified after hydrolysis and enzymic treatment was parent triclopyr. The soil samples obtained on 0, 20, 60 and 92 DAT were also analyzed and triclopyr and 3,5,6-TCP were the major components of the TRR in all PHI intervals. The total amounts of residues, however, decrease with longer PHI intervals. At the PHI of 92 days, parent triclopyr accounted for 11% of the TRR and 3,5,6-TCP accounted for 13.2 % of the TRR in soil samples.

The peer review concluded that triclopyr is the major compound identified in vegetal tissues and is present as a free acid and under a complex mixture of conjugated forms. Besides triclopyr, the only identified metabolite was 3,5,6-TCP, present always below 10% of the TRR. Since none of the representative uses concerned commodities for human consumption, a residue definition for plant products was considered not necessary.

On the basis of available metabolism studies, EFSA concludes that metabolism of triclopyr in grass is sufficiently elucidated and no additional metabolism studies are necessary. Triclopyr is considered as the main residue in grass. In view of setting MRLs for feed commodities in the future, EFSA proposes to define the enforcement residue definition as parent compound. Regarding the calculation of dietary burden for livestock the compound of concern is also triclopyr.

3.1.1.2. Magnitude of residues

For the proposed use of triclopyr on grass in Europe, the applicant submitted five supervised field trials concerning the use in the NEU and three trials concerning the use in the SEU. Triclopyr residues ranged from 1.5 to 25.6 mg/kg in grass seven days after application. In three trials the residues of 3,5,6-trichloro-2-pyridinol (3,5,6-TCP) were also measured and were found to be low (0- 24% of the amount of parent). Residue data confirm that parent triclopyr is the major residue in grass for the intended GAP.

Since grass is a major crop in Northern and Southern Europe, at least 8 trials representing each region would be required to derive a MRL proposal. Currently, MRLs are not yet set for grass. EFSA concludes that the available supervised field trials data are insufficient to propose the MRL for triclopyr in grass in case grass will be included in Annex I of Regulation and MRLs would be set in the future. However, the existing residue data for parent triclopyr can be used to perform an indicative calculation of the dietary burden for livestock.

Residue trials data as derived in the supervised field trials are summarized in Table 3-1.

Storage stability studies submitted under the peer review of Directive 91/414/EEC demonstrate that triclopyr and its metabolite 3,5,6-TCP are stable in grass samples for 1 year under deep frozen conditions. However, full details for the validation of the method of analysis used in these storage stability studies were not provided (EFSA, 2005). The storage of supervised residue trial samples prior analyses were in accordance with the demonstrated storage stability conditions for triclopyr residues.

Analytical methods used for analysing supervised field trial samples were considered sufficiently validated and fit for purpose.

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

Commodity	Region [(a)]	Outdoor/ Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement	Risk assessment					
Residue definition for risk assessment and enforcement: triclopyr									
Grass	NEU	Outdoor	1.51; 2.5[(e)]; 13.0; 15.51[(f)]; 25.6	1.51; 2.5; 13.0; 15.51; 25.6	13.0	25.6	-	1.0	Data not sufficient to derive a MRL proposal.
	SEU	Outdoor	19.0; 19.3; 21.0	19.0; 19.3; 21.0	19.3	21.0			

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(e): In this sample, the concentration of 3,5,6-TCP was 0.6 mg/kg.
(f): In this sample, the concentration of 3,5,6-TCP was 0.16 mg/kg.

3.1.1.3. Effect of industrial processing and/or household preparation

The effects of processing on the nature and magnitude of triclopyr in plant and animal commodities were not studied in the peer review, but since the intended use of triclopyr was on grass only, the peer review experts agreed that this information is not necessary. No additional information has been submitted in the framework of the current application.

Grass can be consumed either fresh, dried (hay) or fermented (silage). Fermentation can be considered as the most widely applied technology for the preservation of the grass in Europe. Therefore EFSA recommends that the effects of fermentation on the nature and magnitude of triclopyr residues should be investigated.

3.1.2. Rotational crops

Grass is considered as a perennial crop and in this case the investigation of residue occurrence in rotational crops is not relevant.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

According to Appendix G of the EU Guidance document on livestock feeding studies, grass is a major feed item for meat and dairy ruminants (European Commission, 1996). The expected dietary burden was calculated according the EU Guidance document with the EFSA livestock dietary burden calculator. For grass the STMR value for triclopyr as obtained from the limited number of supervised field trials was used as an input value to calculate the medium and maximum dietary burden for ruminants. The summary of the input values is available in Table 3-2. It is noted that these calculations should be considered as provisional since a full data set of supervised field trials for grass is not available.

Table 3-2. 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: triclopyr				
Grass	19.3	STMR SEU	25.6	HR NEU

Table 3-3. Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded?
Risk assessment residue definition: triclopyr					
Dairy ruminants	4.654545	3.5091	Grass (or grass silage)	128	yes

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded?
Meat ruminants	5.485714	4.1357	Grass (or grass silage)	128	yes

Dietary burden calculation indicates a significant intake of triclopyr residues by dairy and meat ruminants, exceeding the trigger value of 0.1 mg/kg DM (Table 3-3) and in this case the setting of MRLs for the commodities of animal origin has to be considered. For poultry and pigs the intake of grass is not relevant. Thus, no further considerations are necessary regarding the potential presence of triclopyr related residues in food derived from these species.

3.2.2. Nature of residues

Metabolism of triclopyr in livestock was investigated in the framework of the peer review in lactating goats and in laying hens (Ireland, 2003). Lactating goats were fed with ^{14}C-triclopyr for three consecutive days equivalent to a daily dietary intake of 500 mg/kg fresh feed (25 N the feed intake based on residue occurring pasture STMR=19.3 mg/kg). Hens were dosed with approximately 10 mg a.s./kg per day (^{14}C-triclopyr) for ten consecutive days.

In goats triclopyr was the predominant component of both urine and faeces (79 to 92% of TRR), while significant quantities of 3,5,6-trichloro-2-pyridinol (3,5,6-TCP) were found in urine (5 to 16% of TRR). In liver, the TRR accounted for 0.3 mg/kg (<0.1% of the total dose); it mainly consisted of 3,5,6-TCP (0.244 mg/kg). Also in kidney 3,5,6-TCP and triclopyr were the main compounds identified (triclopyr: 59% TRR (0.2 mg/kg) and 3,5,6-TCP:17% TRR (0.07 mg/kg)). In muscle the 3,5,6-TCP was the only component identified and accounted for 37% TRR (0.02 mg/kg). In fat (composite sample of omental and perirenal fat) the 3,5,6-TCP and triclopyr accounted for 49% TRR (0.14 mg/kg) and 34% TRR (0.09 mg/kg), respectively. In milk the maximum TRR was at or below 0.21 mg eq/kg in each of the collected milk fraction of the 3 days. Low concentrations of 3,5,6-TCP were found (maximum concentration measured 0.004 mg eq/kg), whereas the tricolopyr residues were the major fraction (less than 0.162 mg eq/kg). Small quantities of polar conjugates were also found in milk (less than 0.032 mg/kg).

In hens triclopyr was found to be the major residue identified, accounting for up to 90% of the total residue in liver, kidneys and skin. In other tissues the amount of residues present was low and they were not identified.

Generally, metabolism studies indicate no accumulation of the residues in any of the animal tissues. The extractability of residues in edible organs and tissues is high. Triclopyr and 3,5,6-TCP were found to be the compounds of relevance and their relative amounts vary according to the tissue. Triclopyr is the predominant compound in milk, while 3,5,6-TCP is the major metabolite in liver, kidney, muscle and fat. No other metabolite was present in significant levels. It is noted, that 3,5,6-TCP is not a specific marker for triclopyr as it is also a major metabolism product of the active substances chlorpyrifos and chlorpyrifos-methyl. The peer review did not derive a final decision regarding the residue definitions for enforcement and risk assessment, but proposed two possible options:

Option 1) “the sum of triclopyr and its metabolite 3,5,6-trichloro-2-pyridinol (3,5,6-TCP) expressed as triclopyr”;

Option 2) separate residue definitions: “triclopyr” and “3,5,6-trichloro-2-pyridiniol”.

In Regulation (EC) No 396/2005 the first option has been implemented (sum of triclopyr and 3,5,6-trichloro-2-pyridinol[3]). EFSA, however, is of the opinion that the enforcement residue definition should be set separately for triclopyr and 3,5,6-TCP. Also for the risk assessment EFSA is in favour of splitting the residue definition (option 2). It is noted that the risk assessment of 3,5,6-TCP has to take into account also the contribution of the related compounds chlorpyrifos and chlorpyrifos-methyl. Thus, final MRL proposals for 3,5,6-TCP in animal commodities should reflect the residues resulting from the different sources.

Consequently, changing the residue definition for products of animal origin would also require to review the uses of chlorpyrifos and chlorpyrifos-methyl. However, in the framework of this application EFSA could only evaluate the use of triclopyr on grass and the impact on food of animal origin regarding the residues of triclopyr and its metabolite. This assessment is considered as the first part of a comprehensive assessment of the three active substances involved which should be completed in the framework of Article 12(2) when the full data packages for the other compounds concerned are presented. Currently the RMS for chlorpyrifos and chlorpyrifos-methyl is still working on the completion of the evaluation reports under Article 12(2). The conclusions derived in the following sections are therefore not intended to lead to an immediate amendment of Regulation (EC) No 396/2005, but should be combined with the evaluation of chlorpyrifos and chlorpyrifos-methyl conclusions at a later stage.

3.2.3. Magnitude of residues

In the framework of the peer review, non-GLP livestock feeding studies with dairy ruminants, calves and hens were assessed (Ireland, 2003). Since the dietary burden calculated for poultry did not exceed the trigger value, the feeding study for hens is not further discussed in the framework of this application.

Triclopyr was administered to lactating ruminants at dosing levels of 3, 10, 30, 100, 300 and 1000 mg triclopyr/kg feed for 14 consecutive days. The highest dose for ruminants represents approximately 40 times the highest residue concentrations observed in the supervised field trials in grass (HR 25.6 mg/kg). Assuming an average body weight of 550 kg and a feed consumption of 20 kg per day, the test animals received approximately dose levels of 0.36 to 36.36 mg/kg bw/d. Following the final dosing after 14 days, a group of cows was fed with regular diet to determine the disappearance of triclopyr and its metabolites in milk. The samples of animal tissues and milk were analysed for triclopyr and its metabolite 3,5,6-TCP separately. For the estimation of residues in liver, kidney, fat and muscle, calves (average body weight 220 kg) were dosed with triclopyr in the feed at dose levels of 10, 30, 100, 300 and 1000 mg triclopyr/kg feed (average daily feed consumption 6.8 kg). Thus, the dose rates were calculated to range from 0.3 mg/kg bw at the lowest feeding level to 31 mg/kg bw at the highest dose rate.

Triclopyr: In milk no residues above the LOQ of 0.01 mg/kg were observed except at the highest dosing levels of 300 and 1000 mg/kg feed where residues below or at 0.04 mg/kg ocurred. The decline of residues below 0.01 mg/kg was rapid when cows returned to a normal diet without triclopyr. In cream residues ranged between <0.05 - 0.06 mg/kg and 0.12 - 0.28 mg/kg at the feeding dose levels of 100 mg/kg and 1000 mg/kg, respectively.

The average residues of triclopyr in the animal tissues of all dose groups ranged from <0.05 mg/kg to 3.5 mg/kg. At the expected dietary exposure significant residues above the LOQ are only expected in kidney. The detailed results of the feeding study are summarised in table 3-3.

[3] It is noted that the wording in the legislation (sum of triclopyr and 3,5,6-trichloro-2-pyridinol) deviates slightly from the proposal of the peer review (sum of triclopyr and its metabolite 3,5,6-trichloro-2-pyridinol (3,5,6-TCP) expressed as triclopyr). According to the latter the 3,5,6-TCP residues have to be recalculated to triclopyr by using the molecular weight conversion factor of 1.29 (MW for triclopyr: 256.5, MW for 3,5,6-TCP: 198.45).

3,5,6-TCP: In milk and cream residues of 3,5,6-TCP were only observed at the highest dose levels. The average residues in milk at 1000 mg/kg feed were 0.23 mg/kg in milk and 0.1 mg/kg in cream.

Average residues of 3,5,6-TCP in animal tissues of all dose groups ranged from <0.05 mg/kg to 11.8 mg/kg. Residue levels of 3,5,6-TCP were generally higher in all animal tissues and milk when compared to the parent compound (see table 3-4).

The calculated dietary burden for ruminants (see 3.2.1.) indicates that relevant dose levels from the feeding study would be between 100 and 300 mg/kg triclopyr feed. EFSA obtained risk assessment values and MRL proposals for each residue definition separately (Table 3-4 and Table 3-5). It should be noted that the MRL proposal for 3,5,6-TCP is based on the assumption that livestock is not exposed to 3,5,6-TCP residues from grass and that the 3,5,6-TCP is formed solely as the metabolite of triclopyr in the animal metabolism.

In conclusion, the feeding studies demonstrated that the MRLs for triclopyr currently established in Annex III of Regulation 396/2005 (for all products of animal origin: 0.05 mg/kg for the residue definition sum of triclopyr and 3,5,6-TCP) are not sufficient to accommodate for the use of triclopyr in grass. Significant residues above the LOQ of 0.05 mg/kg are expected for all tissues of ruminants and milk.

According to the peer review, triclopyr residues are stable in eggs and poultry muscle, fat and liver for up to 3 years and in milk, cream and bovine tissues for up to 1 year.

Table 3-3. Overview of the residues of triclopyr in the livestock following dietary exposure of triclopyr

Commodity	Dietary burden		Results of the livestock feeding study				STMR (mg/kg)	HR (mg/kg)	MRL proposal (mg/kg)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level in mg triclopyr/kg bw/d (in brackets: mg/kg feed)	n	Triclopyr residues Result for enforcement and risk assessment				
					Mean (mg/kg)	Max. (mg/kg)			
Ruminant meat	4.1357	4.1357	3.1 (100)	3	n.a.	n.a.	0.05	0.05	**0.05**
			9.3 (300)		<0.05	<0.05			
			31.0 (1000)		<0.05	0.07			
Ruminant fat	4.1357	4.1357	3.1 (100)	3	<0.05	<0.05	0.05	0.05	**0.05**
			9.3 (300)		<0.05	<0.05			
			31.0 (1000)		0.07	0.18			
Ruminant liver	4.1357	4.1357	3.1 (100)	3	<0.05	<0.05	0.05	0.05	**0.05**
			9.3 (300)		<0.05	<0.05			
			31.0 (1000)		0.14	0.32			
Ruminant kidney	4.1357	4.1357	3.1 (100)		<0.05	0.06	0.08	0.14	**0.2**
			9.3 (300)		0.22	0.51			
			31.0 (1000)		3.49	10.1			
Milk	3.5091	3.5091	3.64 (100)	3	<0.01	<0.01	0.01	0.01	**0.01**
			10.91 (300)		0.01	0.03			
			36.36 (1000)		0.01	0.04			

n.a. samples were not analyzed because samples at higher feeding level were below the LOQ
ND no detectable residue (no difference between control and treated sample)

Table 3-4. Overview residues of 3,5,6-TCP in the livestock following dietary exposure of triclopyr

Commodity	Dietary burden		Results of the livestock feeding study				STMR (mg/kg)	HR (mg/kg)	MRL proposal (mg/kg)
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level in mg triclopyr/kg bw/d (in brackets: mg/kg feed)	n	3,5,6-TCP residues Result for enforcement and risk assessment				
					Mean (mg/kg) 3,5,6-TCP	Max. (mg/kg) 3,5,6-TCP			
Ruminant meat	4.1357	4.1357	3.1 (100)	3	<0.05	<0.05	0.06	0.06	**0.1**
			9.3 (300)		0.11	0.14			
			31.0 (1000)		0.38	0.54			
Ruminant fat	4.1357	4.1357	3.1 (100)	3	0.07	0.08	0.09	0.11	**0.2**
			9.3 (300)		0.22	0.29			
			31.0 (1000)		1.02	1.64			
Ruminant liver	4.1357	4.1357	3.1 (100)	3	0.78	0.89	0.95	1.18	**2**
			9.3 (300)		1.89	2.7			
			31.0 (1000)		5.86	7.06			
Ruminant kidney	4.1357	4.1357	3.1 (100)		0.58	0.85	0.70	1.10	**2**
			9.3 (300)		1.35	2.44			
			31.0 (1000)		11.76	22.0			
Milk	3.5091	3.5091	3.64 (100)	3	0.01	0.02	0.01	0.02	**0.02**
			10.91 (300)		0.02	0.03			
			36.36 (1000)		0.16	0.21			

n.a. samples were not analyzed because samples at higher feeding level were below the LOQ
ND no detectable residue (no difference between control and treated sample)

4. Consumer risk assessment

The consumer intake assessment was performed with the revision 2 of EFSA PRIMo. For the chronic intake assessment the existing MRL for rice and the STMR values as derived for the commodities of animal origin following the intake of treated grass were used as an input values.

For acute intake the STMR value for milk and HR values as derived for commodities of animal origin were used as an input values. Acute intake assessment was performed only with regard to livestock commodities relevant for the current application. EFSA performed risk assessment with regard to consumer exposure to triclopyr and 3,5,6-TCP residues separately.

Input values are summarized in Table 4-1.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: **triclopyr**				
Meat (bovine, sheep and goats)	0.05	STMR	0.05	HR
Liver (bovine, sheep and goats)	0.05	STMR	0.05	HR
Kidney (bovine, sheep and goats)	0.08	STMR	0.13	HR
Fat (bovine, sheep and goats)	0.05	STMR	0.05	HR
Milk (bovine, sheep and goats)	0.01	STMR	0.01	STMR
Rice	1	MRL		Not relevant for acute intake
Risk assessment residue definition: **3,5,6-trichloro-2-pyridinol**				
Meat (bovine, sheep and goats)	0.06	STMR	0.06	HR
Liver (bovine, sheep and goats)	0.95	STMR	1.18	HR
Kidney (bovine, sheep and goats)	0.70	STMR	1.10	HR
Fat (bovine, sheep and goats)	0.09	STMR	0.11	HR
Milk (bovine, sheep and goats)	0.01	STMR	0.01	STMR
Rice	1	MRL		Not relevant for acute intake

The summaries of intake calculations are available in Appendix B.

No chronic consumer intake concerns were identified for any of the European diets. The calculated long-term dietary intake related to residues in meat, liver, kidney, fat, milk (bovine, sheep and goat)

and rice was 3.4% and 3.7% of the ADI for triclopyr and 3,5,6-TCP, respectively. Regarding the food of animal commodities, the contribution of milk was the highest for UK infants and French toddlers, amounting for 1.3% of the ADI for both substances.

No acute intake concerns were identified for the commodities under consideration. For bovine products, the short term intake of triclopyr was less than 0.4% in the case of triclopyr. For 3,5,6-TCP the highest exposure was calculated for bovine liver (3.8 % of the ARfD).

EFSA concludes that the proposed uses of triclopyr on grass will not result in consumer intake concerns. However, the risk assessment for 3,5,6-TCP is only a preliminary assessment which has to be completed with the data resulting from the use of chlorpyrifos and chlorpyrifos-methyl.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The metabolism of triclopyr in grass was investigated in the peer review and parent triclopyr was considered as a major residue of concern. Metabolism of triclopyr in livestock was investigated in lactating goats and in laying hens. In animal tissues triclopyr and its metabolite 3,5,6-TCP were the major components. It is noted, that 3,5,6-TCP is not a specific marker for triclopyr as it is also a major plant and livestock metabolite of the active substances chlorpyrifos and chlorpyrifos-methyl. The peer review did not agree on final enforcement and risk assessment residue definitions for food commodities of animal origin but derived two possible options:

1) "Sum of triclopyr and its metabolite 3,5,6-trichloro-2-pyridinol (3,5,6-TCP), expressed as triclopyr"

2) Two separate residue definitions: "triclopyr" and "3,5,6-trichloro-2-pyridiniol"

In Regulation (EC) No 396/2005 a residue definition comparable with the first option has been implemented (sum of triclopyr and 3,5,6-trichloro-2-pyridinol). EFSA, however, is of the opinion that enforcement residue definitions should be set separately for triclopyr and 3,5,6-TCP. Also for risk assessment, EFSA is in favour of setting separate residue definitions. The risk assessment of 3,5,6-TCP has to take into account also the contribution of the related compounds chlorpyrifos and chlorpyrifos-methyl. Thus, also final MRL proposals for 3,5,6-TCP in animal commodities should reflect the residues resulting from the different sources. Consequently, changing the residue definition for products of animal origin would also require to review the uses of chlorpyrifos and chlorpyrifos-methyl. However, in the framework of this application EFSA could only evaluate the use of triclopyr on grass and the impact on food of animal origin regarding the residues of triclopyr and its metabolite. This assessment is considered as the first part of a comprehensive assessment of the three active substances involved which should be completed in the framework of Article 12(2) when the full data packages for the other compounds concerned are presented.

A limited number of supervised field trials is available which allows an estimation of the expected residues on grass and which was used to estimate the dietary burden of livestock, but the number of trials is considered not sufficient to derive a MRL proposal triclopyr in grass in case MRLs for feed would be set in the future.

According to a communication from the manufacturer, analytical enforcement methods for the determination of triclopyr and its metabolite 3,5,6-TCP in animal matrices are available, but these methods have not yet been reviewed by the EMS.

Studies regarding the effects of processing on the nature and magnitude of triclopyr residues were not provided in the peer review and no new studies have been submitted in the framework of the current application. Grass can be consumed either fresh, dried (hay) or fermented (silage). Fermentation can be considered as the most widely applied technology for the preservation of the grass in Europe. EFSA therefore recommends to investigate the effects of fermentation on the nature and magnitude of triclopyr residues in grass.

The indicative livestock dietary burden was calculated with the EFSA livestock dietary burden calculator considering the intake of grass treated with triclopyr. Dietary burden calculation indicates a significant intake of triclopyr residues by dairy and meat ruminants, exceeding the trigger value of 0.1 mg/kg (dry matter). Livestock feeding studies with lactating cows and calves were used for the estimation of MRLs (according to the proposed residue definition) in the commodities of animal origin. These studies demonstrate that feeding grass which was treated with triclopyr may lead to residues of triclopyr and 2,5,6-TCP exceeding the current MRLs for tissues of ruminants and milk as established in Annex III of Regulation 396/2005.

The consumer intake assessment was performed with revision 2 of EFSA PRIMo separately for triclopyr and 3,5,6-TCP. For the chronic intake assessment the existing MRL for rice and the STMR values as derived for the commodities of animal origin following the intake of treated grass were used as input values. The acute intake was calculated with the HR values derived for meat, fat, liver, kidney and the STMR value for milk.

No chronic consumer intake concerns were identified for any of the European diets. The calculated long-term dietary intake related to residues in bovine meat, liver, kidney, fat, milk and rice was 3.4% and 3.7% of the ADI for triclopyr and 3,5,6-TCP, respectively.

No acute intake concerns were identified for the commodities under consideration. For bovine products, the short term intake of triclopyr was less than 0.4%. For 3,5,6-TCP the highest exposure was calculated for bovine liver (3.8 % of the ARfD). It is noted that the risk assessment for 3,5,6-TCP is only a preliminary assessment which has to be completed with the data resulting from the use of chlorpyrifos and chlorpyrifos-methyl.

RECOMMENDATIONS

Finally, EFSA derives the following recommendations:

- The residue definitions risk assessment and enforcement for commodities of animal origin should be established separately as "Triclopyr" and "3,5,6-trichloro-2-pyridinol (3,5,6-TCP)". The amendment of the MRL legislation regarding the enforcement residue definition should be introduced as soon as the evaluation regarding 3,5,6-TCP is completed and all the outstanding information mentioned in the following bullet points was provided and considered acceptable.

- Analytical methods for routine monitoring of triclopyr and 3,5,6-TCP have to be provided and reviewed by the EMS.

- Additional residue trials for grass in compliance with the critical European GAP have to be performed in view of setting MRLs for feed commodities in the future.

- It is also recommended to investigate the nature and magnitude of residues in processed commodities, in particular regarding production of silage.

- Provided that the additional residue trials on grass do not change significantly the indicative dietary burden calculations and sufficiently sensitive analytical enforcement methods are available, the following tentative MRLs could be proposed for triclopyr:

Commodity	**Existing EC MRL (mg/kg)**	**Proposed EC MRL (mg/kg)**	**Justification for the proposal**
Residue definition (enforcement): **Triclopyr**			
Bovine, goat, sheep meat	Currently for all animal commodities the MRLs are set at 0.05* for the sum of triclopyr and 3,5,6-TCP.	0.05 *	No risk for consumers was identified for the proposed MRLs. However, the proposed MRLs are based on a preliminary dietary burden calculation only which has to be confirmed. A validated analytical method for routine monitoring has to be provided.
Bovine, goat, sheep meat		0.05 *	
Bovine, goat, sheep liver		0.05 *	
Bovine, goat, sheep kidney		0.2	
Bovine, goat, sheep fat		0.05 *	
Milk		0.01 *	

* Indicates that the MRL is set at the limit of analytical quantification

- Before separate MRLs for 3,5,6,-TCP can be established, the uses of chlorpyrifos and chlorpyrifos-methyl have to be evaluated concerning the concentration of 3,5,6-TCP residues in plant and animal commodities. A combined risk assessment for the three compounds sharing the common metabolite has to be performed demonstrating that no consumer risk is related to the total 3,5,6-TCP residues.

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Ireland, 2009: Evaluation report on the modification of the existing MRLs for triclopyr in several commodities of animal origin prepared by Ireland in the framework of Regulation (EC) No 396/2005. January 2009.

EFSA (European Food Safety Authority), 2005. Conclusion regarding the peer review of the pesticide risk assessment of the active substance triclopyr. EFSA Scientific Report (2005) 56, 1-103.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				Type (d)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	No. min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Pasture	UK, IE	F	Broad-leaf weeds	Foliar spray				1				Max 1.44	7	

(a) In case of group of crops the Codex classification should be used
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and sucking insects, soil born insects, foliar fungi
(d) Suspension concentrate (= flowable concentrate) (SC)
(e) Use CIPAC/FAO Codes where appropriate
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants
(i) g/kg or g/l
(j) Growth stage at last treatment
(k) PHI = Pre-harvest interval
(l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Triclopyr			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,03**	ARfD (mg/kg bw):	**0,3**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2005**	Year of evaluation:	**2005**

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

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
	3
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)
3,4	UK Infant	2,1	Rice	1,3	Milk and cream,	0,0	Bovine: Liver	
2,7	FR toddler	1,3	Milk and cream,	1,2	Rice	0,2	Bovine: Meat	
2,6	PT General population	2,6	Rice		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
2,6	UK Toddler	1,9	Rice	0,7	Milk and cream,	0,0	Bovine: Liver	
2,4	NL child	1,2	Rice	1,0	Milk and cream,	0,2	Bovine: Meat	
2,3	ES child	1,6	Rice	0,4	Milk and cream,	0,2	Bovine: Meat	
2,1	WHO cluster diet D	1,8	Rice	0,2	Milk and cream,	0,1	Bovine: Meat	
2,1	WHO Cluster diet B	1,8	Rice	0,1	Bovine: Meat	0,1	Milk and cream,	
1,8	SE general population 90th percentile	1,3	Rice	0,4	Milk and cream,		FRUIT (FRESH OR FROZEN)	
1,4	DE child	0,9	Rice	0,5	Milk and cream,	0,1	Bovine: Meat	
1,4	UK vegetarian	1,3	Rice	0,1	Milk and cream,		FRUIT (FRESH OR FROZEN)	
1,3	UK Adult	1,2	Rice	0,1	Milk and cream,	0,0	Bovine: Liver	
1,3	FR infant	0,9	Milk and cream,	0,3	Rice	0,1	Bovine: Meat	
1,1	ES adult	0,8	Rice	0,2	Milk and cream,	0,1	Bovine: Meat	
1,0	WHO regional European diet	0,7	Rice	0,2	Bovine: Meat	0,2	Milk and cream,	
1,0	WHO Cluster diet F	0,7	Rice	0,1	Bovine: Meat	0,1	Milk and cream,	
0,9	WHO cluster diet E	0,7	Rice	0,1	Bovine: Meat	0,1	Milk and cream,	
0,9	LT adult	0,7	Rice	0,1	Milk and cream,	0,0	Bovine: Meat	
0,9	NL general	0,5	Rice	0,2	Milk and cream,	0,1	Bovine: Meat	
0,8	IE adult	0,6	Rice	0,1	Milk and cream,	0,1	Bovine: Meat	
0,8	DK child	0,4	Milk and cream,	0,3	Rice	0,0	Bovine: Liver	
0,6	IT kids/toddler	0,6	Rice		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,6	IT adult	0,6	Rice		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,6	DK adult	0,3	Rice	0,2	Milk and cream,	0,1	Bovine: Meat	
0,6	FI adult	0,4	Rice	0,2	Milk and cream,		FRUIT (FRESH OR FROZEN)	
0,6	FR all population	0,4	Rice	0,1	Milk and cream,	0,1	Bovine: Meat	
	PL general population		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Triclopyr 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)
0,4	Milk and milk products:	0,01 / -	0,4	Milk and milk	0,01 / -	0,1	Bovine: Meat	0,05 / -	0,1	Bovine: Meat	0,05 / -
0,2	Bovine: Meat	0,05 / -	0,2	Bovine: Meat	0,05 / -	0,1	Sheep: Meat	0,05 / -	0,1	Sheep: Meat	0,05 / -
0,2	Sheep: Meat	0,05 / -	0,2	Sheep: Meat	0,05 / -	0,1	Bovine: Kidney	0,13 / -	0,1	Bovine: Kidney	0,13 / -
0,2	Bovine: Kidney	0,13 / -	0,2	Bovine: Kidney	0,13 / -	0,1	Milk and milk	0,01 / -	0,1	Milk and milk products: Cattle	0,01 / -
0,1	Bovine: Liver	0,05 / -	0,1	Bovine: Liver	0,05 / -	0,0	Bovine: Liver	0,05 / -	0,0	Bovine: Liver	0,05 / -
No of critical MRLs (IESTI 1) ---						**No of critical MRLs (IESTI 2)** ---					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---						**No of commodities for which ARfD/ADI is exceeded:** ---					
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL
***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Triclopyr 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.

3,5,6,-trichloro-2-pyridinol (3,5,6-TCP)

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,03**	ARfD (mg/kg bw):	**0,25**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2005**	Year of evaluation:	**2005**

The chronic risk assessment is based on the ADI value of triclopyr (which was in the same range as the tentative ADI derived for 3,5,6-TCP,) and the tentative ARfD for 3,5,6-TCP.
The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
4

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)
3,7	UK Infant	2,1	Rice	1,3	Milk and cream,	0,3	Bovine: Liver	
2,8	FR toddler	1,3	Milk and cream,	1,2	Rice	0,3	Bovine: Meat	
2,7	UK Toddler	1,9	Rice	0,7	Milk and cream,	0,1	Bovine: Liver	
2,7	NL child	1,2	Rice	1,0	Milk and cream,	0,2	Bovine: Liver	
2,6	PT General population	2,6	Rice		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
2,5	WHO Cluster diet B	1,8	Rice	0,2	Bovine: Liver	0,2	Bovine: Kidney	
2,4	ES child	1,6	Rice	0,4	Milk and cream,	0,3	Bovine: Meat	
2,2	WHO cluster diet D	1,8	Rice	0,2	Milk and cream,	0,1	Bovine: Meat	
1,8	SE general population 90th percentile	1,3	Rice	0,4	Milk and cream,		FRUIT (FRESH OR FROZEN)	
1,5	IE adult	0,7	Sheep: Liver	0,6	Rice	0,1	Milk and cream,	
1,4	DE child	0,9	Rice	0,5	Milk and cream,	0,1	Bovine: Meat	
1,4	UK vegetarian	1,3	Rice	0,1	Milk and cream,		FRUIT (FRESH OR FROZEN)	
1,4	UK Adult	1,2	Rice	0,1	Milk and cream,	0,0	Bovine: Liver	
1,3	FR infant	0,9	Milk and cream,	0,3	Rice	0,1	Bovine: Meat	
1,2	ES adult	0,8	Rice	0,2	Milk and cream,	0,1	Bovine: Meat	
1,2	DK child	0,4	Milk and cream,	0,4	Bovine: Liver	0,3	Rice	
1,1	WHO regional European diet	0,7	Rice	0,2	Bovine: Meat	0,2	Milk and cream,	
1,1	WHO Cluster diet F	0,7	Rice	0,2	Bovine: Meat	0,1	Milk and cream,	
1,0	WHO cluster diet E	0,7	Rice	0,1	Bovine: Meat	0,1	Milk and cream,	
1,0	NL general	0,5	Rice	0,2	Milk and cream,	0,1	Bovine: Meat	
0,9	LT adult	0,7	Rice	0,1	Milk and cream,	0,1	Bovine: Liver	
0,7	DK adult	0,3	Rice	0,2	Milk and cream,	0,2	Bovine: Liver	
0,6	IT kids/toddler	0,6	Rice		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,6	IT adult	0,6	Rice		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0,6	FR all population	0,4	Rice	0,1	Bovine: Meat	0,1	Milk and cream,	
0,6	FI adult	0,4	Rice	0,2	Milk and cream,		FRUIT (FRESH OR FROZEN)	
	PL general population		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of 3,5,6,-trichloro-2-pyridinol (3,5,6-TCP) 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)
3,8	Bovine: Liver	1,18 / -	3,8	Bovine: Liver	1,18 / -	1,3	Bovine: Liver	1,18 / -	1,3	Bovine: Liver	1,18 / -
1,7	Bovine: Kidney	1,1 / -	1,7	Bovine: Kidney	1,1 / -	0,7	Bovine: Kidney	1,1 / -	0,7	Bovine: Kidney	1,1 / -
0,5	Milk and milk products:	0,01 / -	0,5	Milk and milk	0,01 / -	0,3	Sheep: Liver	1,18 / -	0,3	Sheep: Liver	1,18 / -
0,3	Bovine: Meat	0,06 / -	0,3	Bovine: Meat	0,06 / -	0,1	Bovine: Meat	0,06 / -	0,1	Bovine: Meat	0,06 / -
0,2	Sheep: Meat	0,06 / -	0,2	Sheep: Meat	0,06 / -	0,1	Sheep: Meat	0,06 / -	0,1	Sheep: Meat	0,06 / -
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---						**No of commodities for which ARfD/ADI is exceeded:** ---					
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL
***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For 3,5,6,-trichloro-2-pyridinol (3,5,6-TCP) IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

APPENDIX C – EXISTING EC MRLS

Pesticides - Web Version - EU MRLs (File created on 03/11/2009 12:37)
(R) Residue definition for code 1000000: Sum of triclopyr and 3,5,6 trichloro-2-pyridinol

Code number	Groups and examples of individual products to which the MRLs apply (a)	Triclopyr (R)
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,1*
110000	(i) Citrus fruit	0,1*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,1*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,1*
110030	Lemons (Citron, lemon)	0,1*
110040	Limes	0,1*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,1*
110990	Others	0,1*
120000	(ii) Tree nuts (shelled or unshelled)	0,1*
120010	Almonds	0,1*
120020	Brazil nuts	0,1*
120030	Cashew nuts	0,1*
120040	Chestnuts	0,1*
120050	Coconuts	0,1*
120060	Hazelnuts (Filbert)	0,1*
120070	Macadamia	0,1*
120080	Pecans	0,1*
120090	Pine nuts	0,1*
120100	Pistachios	0,1*
120110	Walnuts	0,1*
120990	Others	0,1*
130000	(iii) Pome fruit	0,1*
130010	Apples (Crab apple)	0,1*
130020	Pears (Oriental pear)	0,1*
130030	Quinces	0,1*
130040	Medlar	0,1*
130050	Loquat	0,1*
130990	Others	0,1*
140000	(iv) Stone fruit	0,1*
140010	Apricots	0,1*
140020	Cherries (sweet cherries, sour cherries)	0,1*
140030	Peaches (Nectarines and similar hybrids)	0,1*
140040	Plums (Damson, greengage, mirabelle)	0,1*
140990	Others	0,1*
150000	(v) Berries & small fruit	0,1*
151000	(a) Table and wine grapes	0,1*
151010	Table grapes	0,1*
151020	Wine grapes	0,1*
152000	(b) Strawberries	0,1*
153000	(c) Cane fruit	0,1*
153010	Blackberries	0,1*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,1*
153030	Raspberries (Wineberries)	0,1*
153990	Others	0,1*
154000	(d) Other small fruit & berries	0,1*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,1*
154020	Cranberries	0,1*
154030	Currants (red, black and white)	0,1*
154040	Gooseberries (Including hybrids with other ribes species)	0,1*
154050	Rose hips	0,1*
154060	Mulberries (arbutus berry)	0,1*
154070	Azarole (mediteranean medlar)	0,1*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,1*
154990	Others	0,1*
160000	(vi) Miscellaneous fruit	0,1*
161000	(a) Edible peel	0,1*
161010	Dates	0,1*
161020	Figs	0,1*
161030	Table olives	0,1*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,1*
161050	Carambola (Bilimbi)	0,1*
161060	Persimmon	0,1*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,1*
161990	Others	0,1*
162000	(b) Inedible peel, small	0,1*
162010	Kiwi	0,1*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,1*
162030	Passion fruit	0,1*
162040	Prickly pear (cactus fruit)	0,1*
162050	Star apple	0,1*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,1*
162990	Others	0,1*
163000	(c) Inedible peel, large	0,1*
163010	Avocados	0,1*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,1*
163030	Mangoes	0,1*
163040	Papaya	0,1*
163050	Pomegranate	0,1*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,1*
163070	Guava	0,1*
163080	Pineapples	0,1*
163090	Bread fruit (Jackfruit)	0,1*
163100	Durian	0,1*
163110	Soursop (guanabana)	0,1*
163990	Others	0,1*
200000	2. VEGETABLES FRESH OR FROZEN	0,1*
210000	(i) Root and tuber vegetables	0,1*
211000	(a) Potatoes	0,1*
212000	(b) Tropical root and tuber vegetables	0,1*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,1*
212020	Sweet potatoes	0,1*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,1*
212040	Arrowroot	0,1*
212990	Others	0,1*
213000	(c) Other root and tuber vegetables except sugar beet	0,1*
213010	Beetroot	0,1*
213020	Carrots	0,1*
213030	Celeriac	0,1*
213040	Horseradish	0,1*
213050	Jerusalem artichokes	0,1*
213060	Parsnips	0,1*
213070	Parsley root	0,1*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,1*
213090	Salsify (Scorzonera,	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Triclopyr (R)
	Spanish salsify (Spanish oysterplant))	
213100	Swedes	0,1*
213110	Turnips	0,1*
213990	Others	0,1*
220000	(ii) Bulb vegetables	0,1*
220010	Garlic	0,1*
220020	Onions (Silverskin onions)	0,1*
220030	Shallots	0,1*
220040	Spring onions (Welsh onion and similar varieties)	0,1*
220990	Others	0,1*
230000	(iii) Fruiting vegetables	0,1*
231000	(a) Solanacea	0,1*
231010	Tomatoes (Cherry tomatoes,)	0,1*
231020	Peppers (Chilli peppers)	0,1*
231030	Aubergines (egg plants) (Pepino)	0,1*
231040	Okra, lady's fingers	0,1*
231990	Others	0,1*
232000	(b) Cucurbits - edible peel	0,1*
232010	Cucumbers	0,1*
232020	Gherkins	0,1*
232030	Courgettes (Summer squash, marrow (patisson))	0,1*
232990	Others	0,1*
233000	(c) Cucurbits-inedible peel	0,1*
233010	Melons (Kiwano)	0,1*
233020	Pumpkins (Winter squash)	0,1*
233030	Watermelons	0,1*
233990	Others	0,1*
234000	(d) Sweet corn	0,1*
239000	(e) Other fruiting vegetables	0,1*
240000	(iv) Brassica vegetables	0,1*
241000	(a) Flowering brassica	0,1*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,1*
241020	Cauliflower	0,1*
241990	Others	0,1*
242000	(b) Head brassica	0,1*
242010	Brussels sprouts	0,1*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,1*
242990	Others	0,1*
243000	(c) Leafy brassica	0,1*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,1*
243020	Kale (Borecole (curly kale), collards)	0,1*
243990	Others	0,1*
244000	(d) Kohlrabi	0,1*
250000	(v) Leaf vegetables & fresh herbs	0,1*
251000	(a) Lettuce and other salad plants including Brassicacea	0,1*
251010	Lamb´s lettuce (Italian cornsalad)	0,1*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,1*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,1*
251040	Cress	0,1*
251050	Land cress	0,1*
251060	Rocket, Rucola (Wild rocket)	0,1*
251070	Red mustard	0,1*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,1*
251990	Others	0,1*
252000	(b) Spinach & similar (leaves)	0,1*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,1*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common	0,1*
	purslane, sorrel, glassworth)	
252030	Beet leaves (chard) (Leaves of beetroot)	0,1*
252990	Others	0,1*
253000	(c) Vine leaves (grape leaves)	0,1*
254000	(d) Water cress	0,1*
255000	(e) Witloof	0,1*
256000	(f) Herbs	0,1*
256010	Chervil	0,1*
256020	Chives	0,1*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,1*
256040	Parsley	0,1*
256050	Sage (Winter savory, summer savory,)	0,1*
256060	Rosemary	0,1*
256070	Thyme (marjoram, oregano)	0,1*
256080	Basil (Balm leaves, mint, peppermint)	0,1*
256090	Bay leaves (laurel)	0,1*
256100	Tarragon (Hyssop)	0,1*
256990	Others	0,1*
260000	(vi) Legume vegetables (fresh)	0,1*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,1*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,1*
260030	Peas (with pods) (Mangetout (sugar peas))	0,1*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,1*
260050	Lentils	0,1*
260990	Others	0,1*
270000	(vii) Stem vegetables (fresh)	0,1*
270010	Asparagus	0,1*
270020	Cardoons	0,1*
270030	Celery	0,1*
270040	Fennel	0,1*
270050	Globe artichokes	0,1*
270060	Leek	0,1*
270070	Rhubarb	0,1*
270080	Bamboo shoots	0,1*
270090	Palm hearts	0,1*
270990	Others	0,1*
280000	(viii) Fungi	0,1*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,1*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,1*
280990	Others	0,1*
290000	(ix) Sea weeds	0,1*
300000	3. PULSES, DRY	0,1*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,1*
300020	Lentils	0,1*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,1*
300040	Lupins	0,1*
300990	Others	0,1*
400000	4. OILSEEDS AND OILFRUITS	0,1*
401000	(i) Oilseeds	0,1*
401010	Linseed	0,1*
401020	Peanuts	0,1*
401030	Poppy seed	0,1*
401040	Sesame seed	0,1*
401050	Sunflower seed	0,1*
401060	Rape seed (Bird rapeseed, turnip rape)	0,1*
401070	Soya bean	0,1*
401080	Mustard seed	0,1*
401090	Cotton seed	0,1*
401100	Pumpkin seeds	0,1*
401110	Safflower	0,1*
401120	Borage	0,1*
401130	Gold of pleasure	0,1*
401140	Hempseed	0,1*
401150	Castor bean	0,1*
401990	Others	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Triclopyr (R)
402000	(ii) Oilfruits	0,1*
402010	Olives for oil production	0,1*
402020	Palm nuts (palmoil kernels)	0,1*
402030	Palmfruit	0,1*
402040	Kapok	0,1*
402990	Others	0,1*
500000	5. CEREALS	
500010	Barley	0,1*
500020	Buckwheat	0,1*
500030	Maize	0,1*
500040	Millet (Foxtail millet, teff)	0,1*
500050	Oats	0,1*
500060	Rice	1
500070	Rye	0,1*
500080	Sorghum	0,1*
500090	Wheat (Spelt Triticale)	0,1*
500990	Others	0,1*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,1*
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Aril	0,1*
870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	0,1*
900010	Sugar beet (root)	0,1*
900020	Sugar cane	0,1*
900030	Chicory roots	0,1*
900990	Others	0,1*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	0,05*
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Triclopyr (R)
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	
*Indicated limit of analytical quantification		

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
Bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
CXL	codex maximum residue limit
D	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K_{oc}	organic carbon adsorption coefficient

L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10^{-6})
PRIMo	Pesticide Residues Intake Model
RMS	rapporteur Member State
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection