REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for clofentezine in cherries, cucurbits with edible peel, tomatoes and aubergines[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, the United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from Makteshim-Agan UK Ltd to modify the existing MRLs for the active substance clofentezine in several commodities. In order to accommodate for the intended uses of clofentezine, the United Kingdom proposed to raise the existing MRL in cucurbits with edible peel to 0.2 mg/kg and in tomatoes and aubergines to 0.5 mg/kg. No MRL was proposed for cherries as the data were insufficient. The United Kingdom drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA. According to EFSA the data are sufficient to propose a MRL of 0.2 mg/kg on cucurbits with edible peel. An amendment of the MRL is not proposed on cherries as the data were not sufficient and on tomatoes, aubergines and courgettes as long as the toxicity of the metabolites observed in the hydrolysis study is not addressed and information on their possible residue levels in the processed food commodities provided. Adequate analytical enforcement methods are available to control the residues of clofentezine in the commodities under consideration. Based on the risk assessment results, EFSA concludes that the proposed use of clofentezine on cucumbers and gherkins will not result in a consumer exposure exceeding the toxicological reference value for clofentezine. However, the overall risk assessment in the framework of this opinion should be considered as provisional pending the conclusion on the toxicology of the metabolite 2-chlorobenzonitrile.

KEY WORDS

clofentezine, fruits and vegetables, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, tetrazine acaricide, 2-chlorobenzonitrile

[1] On request from the European Commission, Question No EFSA-Q-2014-00138, approved on 25 September 2014.

[2] Correspondence: pesticides.mrl@efsa.europa.eu

Suggested citation: European Food Safety Authority, 2014. Reasoned opinion on the modification of the existing MRLs for clofentezine in cherries, cucurbits with edible peel, tomatoes and aubergines. EFSA Journal 2014;12(10):3860, 22 pp. doi:10.2903/j.efsa.2014.3860

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, the United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from Makteshim-Agan UK Ltd to modify the existing MRLs for the active substance clofentezine in several commodities. In order to accommodate for the intended uses of clofentezine, the United Kingdom proposed to raise the existing MRL in cucurbits with edible peel to 0.2 mg/kg and in tomatoes and aubergines to 0.5 mg/kg. No MRL was proposed for cherries as the data were insufficient. The United Kingdom drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 27 February 2014.

EFSA bases its assessment on the evaluation report, the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC, the revised Commission Review Report on clofentezine, the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance clofentezine and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) Evaluation report.

The toxicological profile of clofentezine was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.02 mg/kg bw per day. No ARfD was deemed necessary. Further information on the toxicological relevance of the clofentezine metabolites was requested as part of the response to the confirmatory data requirements.

The metabolism of clofentezine in primary crops was investigated after foliar application in fruit crops during the peer review. The residue definition for enforcement was set as clofentezine. Pending the assessment of the data on the toxicity of the plant metabolite 2-chlorobenzonitrile, a provisional residue definition for risk assessment was proposed as clofentezine and 2-chlorobenzonitrile expressed as clofentezine. EFSA concludes that the residue definitions for enforcement and for risk assessment (provisional) are applicable to the crops under consideration.

EFSA concludes that the submitted supervised residue trials are sufficient to propose a MRL of 0.2 mg/kg on cucurbits with edible peel. A MRL value of 0.5 mg/kg on tomatoes, extrapolated to aubergines, was derived from the indoor residue trials on tomatoes. No MRL is proposed for the intended use on cherries as the number of submitted trials was insufficient. Adequate analytical enforcement methods are available to control the residues of clofentezine in the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg.

The nature of clofentezine residues in processed commodities was assessed in the framework of the peer review. Clofentezine is totally degraded under sterilisation conditions to form the metabolites hydrazide-hydrazone, 2-chlorobenzamide and 2-chlorobenzonitrile, but the toxicological profile of these components has not been yet assessed. Since tomatoes, aubergines and courgettes are consumed after cooking and processing, EFSA would not recommend the change of the MRL values for these vegetables as long as the toxicity of these metabolites is not addressed and information on their possible residue levels in the processed food commodities provided.

Since no appropriate information was made available, the nature and magnitude of residues in rotational crops could not be finalised in the course of the peer review and in the framework of this MRL application. Data on rotational crops are required. When granting an authorisation for a plant protection product Member States should therefore consider specific restrictions to avoid residues of clofentezine and its metabolites in rotational and/or succeeding crops, when necessary.

Residues of clofentezine in commodities of animal origin were not assessed in the framework of this application, since the crops under consideration are normally not fed to livestock.

A provisional consumer risk assessment was performed with revision 2 of the EFSA PRIMo. It is based on the assumption that the toxicology of the metabolite 2-chlorobenzonitrile is covered by the toxicological reference values set for the parent compound. For the calculation of the chronic

exposure, EFSA used the median residue value for cucumbers and gherkins and the existing MRLs as established in Regulation (EC) No 396/2005; for fruit crops the median residue and the MRL values above the LOQ were multiplied by the conversion factor for risk assessment as derived from the submitted residue trials. The estimated exposure was then compared with the toxicological reference value derived for clofentezine. An acute exposure assessment was not conducted as the setting of an ARfD was concluded to be unnecessary for clofentezine.

Based on the calculation, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 85 % of the ADI (German child diet). The contribution of residues to the total consumer exposure accounted for 0.4 % of the ADI for cucumbers and 0.05 % of the ADI for gherkins.

EFSA concludes that the proposed use of clofentezine on cucumbers and gherkins will not result in a consumer exposure exceeding the toxicological reference value for clofentezine. However, the overall risk assessment in the framework of this opinion should be considered as provisional pending the conclusion on the toxicology of the metabolite 2-chlorobenzonitrile.

Thus, EFSA proposes to amend the existing MRLs as reported in the summary table.

SUMMARY TABLE

Code number[(a)]	**Commodity**	**Existing EU MRL** (mg/kg)	**Proposed EU MRL (mg/kg)**	**Justification for the proposal**
Enforcement residue definition: Clofentezine (R)				
140020	Cherries	0.02*	No new proposal	The number of trials is not sufficient to derive a MRL proposal for the intended use on cherry.
231010	Tomatoes	0.3	No new proposal	A sufficient number of trials was submitted to derive a MRL proposal of 0.5 mg/kg on tomatoes, extrapolated to aubergines. However, metabolites, whose toxicity has not yet been addressed, are expected to be formed in significant levels in the food commodities after processing. Since their possible impact on the consumer safety cannot be evaluated, EFSA does not recommend the setting of new MRLs on tomatoes and aubergines.
231030	Aubergines	0.02*	No new proposal	
232010	Cucumbers	0.02*	0.2	The MRL proposal is sufficiently supported by data and no consumer health risk was identified for the intended indoor use on cucumbers and gherkins.
232020	Gherkins	0.02*	0.2	
232030	Courgettes	0.02*	No new proposal	Although the MRL proposal of 0.2 mg/kg derived from cucumbers can be extrapolated to courgettes, EFSA does not recommend setting a new MRL on courgettes until the impact on the consumer safety of the metabolites expected to be formed in significant levels in the food commodities after processing is not evaluated.

(a): According to Annex I of Regulation (EC) No 396/2005.
(R): The residue definition differs for the following combinations pesticide-code number: Clofentezine - codes 0500000 and 1000000: Sum of all compounds containing the 2-chlorobenzoyl moiety expressed as clofentezine.
(*): Indicates that the MRL is set at the limit of analytical quantification.

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BACKGROUND

Regulation (EC) No 396/2005[3] establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC[4], repealed by Regulation (EC) No 1107/2009[5], shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

The United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from the company Makteshim-Agan UK Ltd.[6] to modify the existing MRLs for the active substance clofentezine in cherries, cucurbits with edible peel, tomatoes and aubergines. This application was notified to the European Commission and EFSA and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 27 February 2014.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2014-00138 and the following subject:

Clofentezine - Application to modify the existing MRLs in cherries, aubergine, tomato and cucumber.

The United Kingdom proposed to raise the existing MRLs of clofentezine in cucurbits with edible peel to 0.2 mg/kg and in tomatoes and aubergines to 0.5 mg/kg. No MRL was proposed for cherries as the data were insufficient. The existing MRLs on the crops under consideration are at the LOQ of 0.02 mg/kg, except for tomatoes (0.3 mg/kg).

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

TERMS OF REFERENCE

In accordance with 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.

In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible, and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out), 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 deadline for providing the reasoned opinion is 27 May 2014.

[3] Regulation (EC) No 396/2005 of the 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, 16.03.2005, p. 1-16.

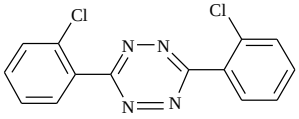
[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1-32.

[5] 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 L 309, 24.11.2009, p. 1-50.

[6] Makteshim-Agan UK Ltd., Unit 16, Thatcham Business Village, Colthrop Way, Thatcham, RG19 4LW, Berkshire, United Kingdom.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Clofentezine is the ISO common name for 3,6-bis (2-chlorophenyl)-1,2,4,5-tetrazine (IUPAC). The chemical structure of the compound is reported below.



Molecular weight: 303.1 g/mol

Clofentezine is a contact acaricide belonging to the tetrazine group. It interferes with cell growth and differentiation during the final stages of embryonic and early larval development. It is used to control mites on a wide range of crops.

Clofentezine was initially included in Annex I of Council Directive 91/414/EEC by Commission Directive 2008/69/EC[7] which entered into force on 1 January 2009 for use as acaricide, according to Article 11(b) of Commission Regulation (EC) No 1490/2002[8] and prior to the finalisation of the review by EFSA. The active substance was evaluated in the framework of Council Directive 91/414/EEC with the United Kingdom designated as rapporteur Member State (RMS). The Draft Assessment Report (DAR), including representative uses on pome fruits, stone fruits, grapes, strawberries and ornamentals, has been peer reviewed and an EFSA conclusion is available (EFSA, 2009).

In 2010, and taking into account the recommendations of the EFSA conclusion, the Annex I inclusion was amended by Commission Directive 2010/39/EU[9]. Confirmatory data referring to the toxicological and environmental risks of clofentezine metabolites and a monitoring report on the potential for long-range atmospheric transport were requested; information to be provided to the European Commission by 30 June 2012 and 31 July 2013, respectively. The United Kingdom informed that these confirmatory data have been submitted by the applicant, but not yet fully evaluated by the RMS (United Kingdom, 2013). Therefore, a final decision on the toxicological relevance of clofentezine metabolites for the consumer risk assessment is still pending.

In accordance with Commission Implementing Regulation (EU) No 540/2011[10] clofentezine is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

The EU MRLs for clofentezine are established in Annexes II and IIIB of Regulation (EC) No 396/2005. The existing EU MRLs for clofentezine on cherries, cucurbits with edible peel and aubergines are set at the LOQ of 0.02 mg/kg, while at 0.3 mg/kg in tomatoes. Codex Alimentarius has established CXLs for a wide range of commodities, including cherries, cucumbers and tomatoes, for which the CXL is set at 0.5 mg/kg.

The details of the intended GAPs for clofentezine are given in Appendix A.

[7] Commission Directive 2008/69/EC of 1 July 2008 amending Council Directive 91/414/EEC to include clofentezine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen as active substances OJ L 172, 02.07.2008, p. 9–14.

[8] Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000, OJ L 224, 21.08.2012, p. 23–48.

[9] Commission Directive 2010/39/EU of 22 June 2010 amending Annex I to Council Directive 91/414/EEC as regards the specific provisions relating to the active substances clofentezine, diflubenzuron, lenacil, oxadiazon, picloram and pyriproxyfen. OJ L 156, 23.06.2010, p. 7–11.

[10] Commission Implementing Regulation (EU) No 540/2011 of 23 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, 11.06.2011, p. 1-186.

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (United Kingdom, 2013), the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (United Kingdom, 2005, 2008), the revised Commission Review Report on clofentezine (EC, 2010b), the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance clofentezine (EFSA, 2009) and the JMPR Evaluation report (FAO, 2007). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the 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, 2010c, 2011; OECD, 2011).

Since the evaluation of the toxicological relevance of clofentezine metabolites for the consumer risk assessment as requested according to Commission Directive 2010/39/EU (confirmatory data) is not yet finalised, the conclusions reached in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the review.

1. Method of analysis

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

During the peer review under Council Directive 91/414/EEC, an analytical method using liquid chromatography (LC) coupled with ultraviolet (UV) detection was considered as sufficiently validated for the determination of clofentezine residues in high water (apples, pears) and high acid (grapes, strawberries) content matrices at the LOQ of 0.01 mg/kg. An independent laboratory validation (ILV) was available but no confirmatory method (EFSA, 2009).

The LC method coupled with tandem mass spectrometry detection (LC-MS/MS) assessed by the RMS (United Kingdom, 2008) was not peer reviewed in support to the Annex I inclusion due to the restrictions on the acceptance of the submission of further data (EFSA, 2009). This method, resubmitted in the framework of this MRL application, was concluded to be adequately validated to control clofentezine residues in high water and high acid content commodities at the LOQ of 0.01 mg/kg (United Kingdom, 2008, 2013). An ILV is available.

The multi-residue QuEChERS method using LC-MS/MS quantification described in the European Standard EN 15662:2008 is also applicable (CEN, 2008). This method analyses clofentezine residues in matrices with high water content at the lowest LOQ of 0.001 mg/kg.

Since the commodities under consideration belong to the group of high water content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRLs for clofentezine are available.

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

Analytical methods for the determination of clofentezine residues in food of animal origin are not assessed in the current application, since the crops under consideration are normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance clofentezine was assessed in the framework of the peer review under Council Directive 91/414/EEC (EFSA, 2009). The data were sufficient to derive toxicological reference values which are compiled in Table 2-1.

[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 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Clofentezine					
ADI	EC	2010	0.02 mg/kg bw per day	2 yr rat, supported by 1 yr dog	100
ARfD	EC	2010	Not necessary.		

It is noted that further information on the toxicological relevance of the metabolites observed in the plant metabolism and in the standard hydrolysis processing studies (2-chlorobenzonitrile, hydrazide-hydrazone and 2-chlorobenzamide) was requested as part of the response to the confirmatory data requirements (EC, 2010b). These metabolites were not found in rat metabolism.

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 clofentezine in primary crops was investigated in apple, lemon, peach and grape (fruit crop group) in the framework of the peer review under Council Directive 91/414/EEC (United Kingdom, 2005; EFSA, 2009). The overview of the metabolism study designs is presented in the table below.

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

Crop group	Crops	Application[(a)]	Sampling
Fruit	apples	onto fruit surface, 0.03 % and 0.76 % a.s. formulation, F(b)	75 DAT
		onto fruit surface, 0.06 % and 0.48 % a.s. formulation, F(b)	25, 64 DAT
	peaches	onto fruit surface, 0.01 % and 0.1 % a.s. formulation, G(b)	62 DAT
		onto fruit surface, 2 × 0.1 % a.s. formulation, 2nd appl. 8 days prior DAT, G(b)	70 DAT
	grapes	onto fruit surface, 0.01 % and 0.1 % a.s. formulation, G(b)	0, 24/25, 45/46 DAT
	lemons	onto leaf surface, 350 µL/leaf of 0.03 % a.s. formulation, G(b)	0, 10, 25, 54, 103 DAT

(a): According to the RMS, the concentrations in % equated to kg a.s./hL as field rates (United Kingdom, 2005).
(b). Outdoor/field application (F) or glasshouse/protected crops/indoor application (G).
(c): The apples were harvested at 72 DAT, then allowed to fully ripe for an extra 3 days (United Kingdom, 2005).

The results of the metabolism studies are detailed in the EFSA conclusion (EFSA, 2009). The metabolic pattern was shown to be similar, the parent clofentezine and the metabolite 2-chlorobenzonitrile being the main components of the residues. Based on these studies, the peer review established the residue definition for monitoring as clofentezine for the fruit and fruiting vegetables group only. This residue definition is identical to the current residue definition set under Regulation (EC) No 396/2005.

For risk assessment the residue definition was provisionally proposed as clofentezine and 2-chlorobenzonitrile expressed as clofentezine, awaiting information on the toxicological relevance of the metabolite 2-chlorobenzonitrile and its possible residue levels in treated crops.

For the uses on the crops under consideration, EFSA concludes that the residue definitions for enforcement and risk assessment (provisional) proposed in the peer review are applicable.

3.1.1.2. Magnitude of residues

Several samples from the submitted residue trials were analysed for both parent clofentezine and 2-chlorobenzonitrile. Since 2-chlorobenzonitrile was never found above the LOQ, the LOQ value was summed up as such without adjustment for molecular weight to express the residues according to the residue definition for risk assessment (i.e. as clofentezine equivalents).

a. Cherries

Five supervised residue trials on cherries conducted over two seasons in Denmark and Germany and reflecting the intended GAP (i.e. within the 25 % deviation) were submitted. 2-chlorobenzonitrile was analyses in three trials only and was not found (<LOD of 0.005 mg/kg). Due to the lack of relevant information, the results of three studies conducted in 1983 were disregarded.

According to the EU guidelines (EC, 2011), cherries are a major crop in the northern European Union (NEU) and at least eight GAP-compliant residue trials are required to derive a MRL. Hence, EFSA confirms the conclusion of the EMS that the available number of trials is not sufficient to derive a MRL proposal for the intended use in the NEU on cherries.

b. Tomatoes, Aubergines

Indoor: Seven supervised residue trials on tomatoes conducted over two seasons in Germany, Hungary, Poland, Italy and Spain and reflecting the intended GAPs were submitted. The metabolite 2-chlorobenzonitrile was analysed for in four trials only and was not found.

Outdoor: Six supervised residue trials on tomatoes conducted over two seasons in Greece, Italy and Spain are reflecting the intended SEU GAP. The metabolite 2-chlorobenzonitrile was not analysed for.

Tomato is a major crop and at least, eight trials are required to derive a MRL. Normally, the available number of trials is not sufficient to derive a MRL proposal for each intended use on tomatoes separately (EC, 1997b). However, a MRL proposal of 0.5 mg/kg is derived from seven indoor trials, considering that the residue levels observed under indoor conditions are confirmed by the outdoor trials were similar residues levels were observed (U-Test, 5%). No additional trails are therefore requested and the MRL proposal can be extrapolated to aubergines (EC, 2011).

c. Cucurbits with edible peel

Eight supervised residue trials conducted indoor on cucumbers over two seasons in Germany, Poland, France, Italy and Spain are reflecting the intended GAP. The metabolite 2-chlorobenzonitrile, which was analysed in six trials, was never found (<LOD of 0.003 mg/kg). Data on cucumbers can be extrapolated to the whole group of cucurbits with edible peel (EC, 2011). The data are sufficient to derive the MRL proposal for the intended use on cucurbits with edible peel of 0.2 mg/kg.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 3-2. The median CF of 1.2 was derived to perform a risk assessment according to the provisional residue definition for fruit crops, which includes the metabolites 2-chlorobenzonitrile.

The storage stability of clofentezine in primary crops was investigated in the DAR under Council Directive 91/414/EEC (EFSA, 2009). Residues of clofentezine were found to be stable at ≤ -18 °C for up to 12-24 months in high water content matrices. The storage stability of 2-chlorobenzonitrile in primary crops was investigated in the framework of the current MRL application (United Kingdom, 2013) and residues of this metabolite were found to be stable at ≤ -18 °C for up to nine months in high water content matrices (apples).

As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated (up to twelve months for clofentezine and seven months for the metabolite), it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the LC-MS/MS methods used to analyse clofentezine and its metabolite 2-chlorobenzonitrile in the supervised residue trial samples have been sufficiently validated and were proven to be fit for the purpose (United Kingdom, 2013).

EFSA concludes that the data are sufficient to propose a MRL of 0.2 mg/kg for the intended use on cucurbits with edible peel. A MRL of 0.5 mg/kg is proposed for the intended indoor and SEU uses on tomatoes and aubergines. No MRL is proposed for the intended use on cherries as the submitted data were insufficient.

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

Commodity	Residue region (a)	Individual trial results (mg/kg)		Median residue (mg/kg) (c)	Highest residue (mg/kg) (d)	MRL proposal (mg/kg)	Median CF (e)	Comments (f)
		Enforcement residue definition (b) (clofentezine)	risk assessment residue definition (provisional) (clofentezine and 2-CBN expressed as clofentezine)					
Cherry	NEU Outdoor	0.01; 0.02; 0.05; 0.06; 0.11	0.02; 0.03; 0.07 (2-CBN: 3 × <0.01)					Insufficient number of trials to derive a MRL proposal.
Tomato→ Aubergine	EU Indoor	0.04; 0.06; 0.08; 0.10; 0.11; 0.13; 0.28	0.09; 0.11; 0.14; 0.29 (2-CBN: 4 × <0.01)	0.11	0.28	0.5	1.2	MRL_{OECD} = 0.43/0.5
	SEU Outdoor	0.03; 0.07; 3 × 0.23; 0.25	Samples not analysed for 2-CBN					Insufficient number of SEU trials to derive a separate MRL proposal.
Cucumber → cucurbits edible peel	EU Indoor	3 × 0.02; 0.03; 0.04; 0.05; 0.05, 0.11	3x 0.03; 0.04; 0.05; 0.06 (2-CBN: 4 × <0.01)	0.04	0.11	0.2		MRL_{OECD} = 0.16/0.2

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. indoor use) or Import (country code) (EC, 2011).
(b): Underlined values are for the samples which were analysed for clofentezine and 2-chlorobenzonitrile.
(c): Median value of the individual trial results according to the residue definition for enforcement.
(d): Highest value of the individual trial results according to the residue definition for enforcement.
(e): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial where the metabolite included in the provisional residue definition for risk assessment was analysed.
(f): Statistical estimation of MRLs according to the unrounded/rounded values according to the OECD methodology (OECD, 2011).
Legenda: 2-CBN = 2-chlorobenzonitrile.

3.1.1.3. Effect of industrial processing and/or household preparation

The standard hydrolysis study, investigated during the peer review, is summarised in Table 3.3. Clofentezine is totally degraded under sterilisation conditions to form the metabolites hydrazide-hydrazone, 2-chlorobenzamide and 2-chlorobenzonitrile and a limited degradation to hydrazide-hydrazone (12.4 % AR) was observed under baking/boiling conditions. None of these metabolites was detected in the rodent metabolism and, therefore, information on their toxicity and their residue levels in the processed fractions were requested in the conclusion of the peer review (EFSA, 2009). Provisionally, for processed commodities, the residue definition for monitoring was proposed as clofentezine and its metabolite 2-chlorobenzonitrile (EFSA, 2009).

Table 3-3: Standard hydrolysis study with clofentezine (% Applied Radioactivity)

Compounds	**Pasteurisation** pH 4(90 °C)	**Boiling** pH 5 (100 °C)	**Sterilisation** pH 6 (120 °C)
Clofentezine	99.3	89.4	n.d.
Hydrazide-hydrazone	n.d.	12.4	77.6
2-chlorobenzonitrile	n.d.	n.d.	4.9
2-chlorobenzamide	n.d.	n.d.	17.0

Legenda: n.d.= not detected.

Studies to assess the magnitude of clofentezine residues in processed products obtained from the crops under consideration were not submitted in the framework of this MRL application. These studies are not necessary for cucumbers and gherkins which are mostly eaten raw. In contrast, tomatoes, aubergines and courgettes are often eaten cooked or after processing. Having regard to the residue levels observed the raw commodity (up to 0.28 mg/kg, see Table 3.2), it cannot be excluded that the metabolites identified under the standard hydrolysis conditions are present in significant levels after processing. Their impact on the consumer safety cannot be evaluated since their toxicity has not been yet assessed.

EFSA would therefore not recommend the change/setting of the existing MRL values for tomatoes, aubergines and courgettes as long as the toxicity of these potential metabolites is not addressed and information on their possible residue levels in the processed commodities provided.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Cucurbits, tomatoes and aubergines can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. The soil degradation studies demonstrated that the degradation rate of clofentezine is slow; the maximum DT_{90} in field studies was 640.5 days (EFSA, 2009), which is above the trigger value of 100 days. Thus, regardless from the persistence of its soil metabolites, further studies investigating the nature and magnitude of clofentezine uptake in rotational crops are required (EC, 1997c).

3.1.2.2. Nature and magnitude of residues

Insufficient information on residues in rotational crops were provided in the course of the peer review under Council Directive 91/414/EEC, and the submission of rotational crop studies was therefore identified as a data gap in the EFSA conclusion (EFSA, 2009).

A metabolism study on rotational crops was provided in the framework of this MRL application and assessed by the EMS (United Kingdom, 2013). This study should be considered as not appropriate to address the residues in rotational crops, since conducted on spinaches (leafy vegetables), carrots (root vegetables) and fresh beans (oilseed/pulses) with a single plant back interval of seven days at a dose rate of 0.178 kg a.s./ha (0.9N). Additional plant back intervals should be investigated and a cereal crop included in the study. EFSA is therefore of the opinion that the submitted study is not adequate to

address the nature and uptake of clofentezine residues in rotational crops and that additional rotational crop studies conducted according to relevant guidelines should be provided.

Considering the high persistence of the active substance in the soil, when granting an authorisation for a plant protection product containing clofentezine, Member States should propose specific restrictions with regards to residues on rotational and/or succeeding crops, when necessary.

3.2. Nature and magnitude of residues in livestock

Since the crops under consideration are not normally fed to livestock, the nature and magnitude of clofentezine residues in livestock is not assessed in the framework of this application (EC, 1996).

4. Consumer risk assessment

The provisional consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population [12] (EFSA, 2007).

The metabolite 2-chlorobenzonitrile has been provisionally included in the residue definition for risk assessment (EFSA, 2009). Further clarification concerning its toxicity and its residue levels in plant commodities is needed in order to conclude on a final residue definition. Meanwhile, for risk assessment purpose, its toxicity is assumed to be covered by the ADI proposed for the parent compound.

For the calculation of the chronic exposure, EFSA used the median residue value as derived from the residue trials on cucumbers (see Table 3-2) for cucumbers and gherkins. For the remaining commodities the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 was used. To take into account in the assessment the possible residues originated from the metabolite 2-chlorobenzonitrile, the median residue value for cucumbers and gherkins and the commodities with a MRL above the LOQ, all belonging to the fruit crop group except liver of ruminants, were multiplied by the CF of 1.2 derived from the submitted residue trials. No CF for risk assessment is available for the liver of ruminants.

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (i.e. the ADI), a consumer health risk can be excluded with a high probability.

An acute consumer exposure assessment was not performed because no ARfD was deemed necessary for the active substance.

The input values used for the dietary exposure calculation are summarised in Table 4-1.

[12] The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

Table 4-1: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment	
	Input value (mg/kg)	**Comment**
Residue definition for risk assessment: Clofentezine and 2-chlorobenzonitrile, expressed as clofentezine (fruit crops, provisional)		
Cucumbers, gherkins	0.05 (0.04 × 1.2)	Median residue × CF (cucumber, EU)
Citrus, pome fruits, plums, wine grapes, strawberries, cane fruits, currants, mulberries, bananas, tomatoes, melons	MRL × CF (1.2)	See MRLs in Commission Regulation (EC) No 839/2008[13]
Other commodities of food and animal origin	MRL	

The estimated exposure was then compared with the toxicological reference value derived for clofentezine (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

Based on the calculation, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 85 % of the ADI (German child diet). The contribution of residues in the crops under consideration to the total consumer exposure accounted for 0.4 % of the ADI for cucumbers and 0.05 % of the ADI for gherkins.

It is noted that the consumer risk assessment is indicative and affected by the uncertainty related to the assumption on the toxicological relevance of the metabolite 2-chlorobenzonitrile which was provisionally included in the residue definition and the use for the existing uses on fruit crops of a CF derived from the residue trials reflecting the intended uses on the crops under consideration. Considering that this metabolite was never detected in these residue trials, its contribution to the overall exposure is expected to be negligible.

EFSA concludes that the intended use of clofentezine on cucumbers and gherkins will not result in a consumer exposure exceeding the toxicological reference value for clofentezine. However, the overall risk assessment in the framework of this opinion should be considered as provisional.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of clofentezine was assessed in the framework of the peer review under Council Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.02 mg/kg bw per day. No ARfD was deemed necessary. Further information on the toxicological relevance of the clofentezine metabolites was requested as part of the response to the confirmatory data requirements.

The metabolism of clofentezine in primary crops was investigated after foliar application in fruit crops during the peer review. The residue definition for enforcement was set as clofentezine. Pending the assessment of the data on the toxicity of the plant metabolite 2-chlorobenzonitrile, a provisional residue definition for risk assessment was proposed as clofentezine and 2-chlorobenzonitrile expressed

[13] Commission Regulation (EC) No 839/2008 of 31 July 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards Annexes II, III and IV on maximum residue levels of pesticides in or on certain products,. OJ L 234, 30.08.2008, p. 1-216.

as clofentezine. EFSA concludes that the residue definitions for enforcement and for risk assessment (provisional) are applicable to the crops under consideration.

EFSA concludes that the submitted supervised residue trials are sufficient to propose a MRL of 0.2 mg/kg on cucurbits with edible peel. A MRL value of 0.5 mg/kg on tomatoes, extrapolated to aubergines, was derived from the indoor residue trials on tomatoes. No MRL is proposed for the intended use on cherries as the number of submitted trials was insufficient. Adequate analytical enforcement methods are available to control the residues of clofentezine in the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg.

The nature of clofentezine residues in processed commodities was assessed in the framework of the peer review. Clofentezine is totally degraded under sterilisation conditions to form the metabolites hydrazide-hydrazone, 2-chlorobenzamide and 2-chlorobenzonitrile, but the toxicological profile of these components has not been yet assessed. Since tomatoes, aubergines and courgettes are consumed after cooking and processing, EFSA would not recommend the change of the MRL values for these vegetables as long as the toxicity of these metabolites is not addressed and information on their possible residue levels in the processed food commodities provided.

Since no appropriate information was made available, the nature and magnitude of residues in rotational crops could not be finalised in the course of the peer review and in the framework of this MRL application. Data on rotational crops are required. When granting an authorisation for a plant protection product Member States should therefore consider specific restrictions to avoid residues of clofentezine and its metabolites in rotational and/or succeeding crops, when necessary.

Residues of clofentezine in commodities of animal origin were not assessed in the framework of this application, since the crops under consideration are normally not fed to livestock.

A provisional consumer risk assessment was performed with revision 2 of the EFSA PRIMo. It is based on the assumption that the toxicology of the metabolite 2-chlorobenzonitrile is covered by the toxicological reference values set for the parent compound. For the calculation of the chronic exposure, EFSA used the median residue value for cucumbers and gherkins and the existing MRLs as established in Regulation (EC) No 396/2005; for fruit crops the median residue and the MRL values above the LOQ were multiplied by the conversion factor for risk assessment as derived from the submitted residue trials. The estimated exposure was then compared with the toxicological reference value derived for clofentezine. An acute exposure assessment was not conducted as the setting of an ARfD was concluded to be unnecessary for clofentezine.

Based on the calculation, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 85 % of the ADI (German child diet). The contribution of residues to the total consumer exposure accounted for 0.4 % of the ADI for cucumbers and 0.05 % of the ADI for gherkins.

EFSA concludes that the proposed use of clofentezine on cucumbers and gherkins will not result in a consumer exposure exceeding the toxicological reference value for clofentezine. However, the overall risk assessment in the framework of this opinion should be considered as provisional pending the conclusion on the toxicology of the metabolite 2-chlorobenzonitrile.

RECOMMENDATIONS

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: Clofentezine (R)				
140020	Cherries	0.02*	No new proposal	The number of trials is not sufficient to derive a MRL proposal for the intended use on cherry.
231010	Tomatoes	0.3	No new proposal	A sufficient number of trials was submitted to derive a MRL proposal of

Code number[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Justification for the proposal
231030	Aubergines	0.02*	No new proposal	0.5 mg/kg on tomatoes, extrapolated to aubergines. However, metabolites, whose toxicity has not yet been addressed, are expected to be formed in significant levels in the food commodities after processing. Since their possible impact on the consumer safety cannot be evaluated, EFSA does not recommend the setting of new MRLs on tomatoes and aubergines.
232010	Cucumbers	0.02*	0.2	The MRL proposal is sufficiently supported by data and no consumer health risk was identified for the intended indoor use on cucumbers and gherkins.
232020	Gherkins	0.02*	0.2	
232030	Courgettes	0.02*	No new proposal	Although the MRL proposal of 0.2 mg/kg derived from cucumbers can be extrapolated to courgettes, EFSA does not recommend setting a new MRL on courgettes until the impact on the consumer safety of the metabolites expected to be formed in significant levels in the food commodities after processing is not evaluated.

(a): According to Annex I of Regulation (EC) No 396/2005.
(R): The residue definition differs for the following combinations pesticide-code number: Clofentezine - codes 0500000 and 1000000: Sum of all compounds containing the 2-chlorobenzoyl moiety expressed as clofentezine.
(*): Indicates that the MRL is set at the limit of analytical quantification.

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APPENDICES

Appendix A. Good Agricultural Practice (GAPs)

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
				type (d - f)	conc. a.s. (i)	Method kind (f - h)	Growth stage & season (j)	number min-max (k)	interval min-max	kg as/hL min max	Water L/ha min-max	kg a.s./ha min max		
Cherry	NEU	F	*Panonychus ulmi*	SC	500 g/L	Foliar spray	BBCH 53-61	1	-	0.02-0.05	400-1000	0.2	45	
Aubergine	EU	G	*Tetranychus urticae*	SC	500 g/L	Foliar spray	BBCH 61-89	1	-	0.02	1000	0.2	3	
	SEU	F												
Tomatoes	EU	G	*Tetranychus urticae*	SC	500 g/L	Foliar spray	BBCH 21-69	1	-	0.02	1000	0.2	3	
	SEU	F												
Cucurbits, edible peel	EU	G	*Tetranychus urticae*	SC	500 g/L	Foliar spray	BBCH 61-89	1	-	0.02	1000	0.2	3	

Remarks:
(a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(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, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
(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 - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (Growth stages of mono-and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing)

Appendix B. Pesticide Residue Intake Model (PRIMO)

Clofentezine				
Status of the active substance:	approved	Code no.		
LOQ (mg/kg bw):	0.05	proposed LOQ:		
Toxicological end points				
ADI (mg/kg bw/day):	0.02	ARfD (mg/kg bw):	n.n.	
Source of ADI:	EC	Source of ARfD:	EC	
Year of evaluation:	2010	Year of evaluation:	2010	

Provisional consumer risk assessment

Chronic risk assessment - refined calculations

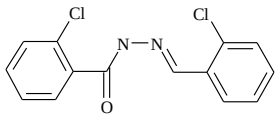
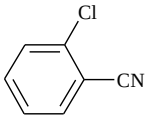
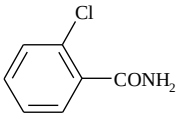
TMDI (range) in % of ADI minimum - maximum	
11	85
No of diets exceeding ADI:	---

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)
85.4	DE child	36.2	Apples	18.6	Bananas	11.4	Oranges	5.8
70.9	NL child	20.4	Bananas	19.0	Apples	9.4	Oranges	10.4
43.9	IE adult	9.4	Bananas	7.5	Wine grapes	3.1	Oranges	3.9
42.9	FR toddler	15.5	Bananas	7.9	Apples	7.5	Strawberries	2.5
39.1	SE general population 90th percentile	21.7	Bananas	3.2	Apples	3.1	Milk and milk products: Cattle	4.6
35.8	WHO Cluster diet B	10.8	Wine grapes	5.6	Tomatoes	3.8	Bananas	5.0
35.5	UK Toddler	12.9	Bananas	5.9	Oranges	5.1	Apples	3.5
34.8	FR all population	24.0	Wine grapes	3.0	Bananas	1.4	Apples	1.9
34.4	FR infant	8.6	Bananas	7.5	Apples	6.4	Milk and milk products: Cattle	8.1
33.7	UK Infant	17.5	Bananas	4.7	Apples	3.9	Oranges	2.2
32.5	ES child	12.1	Bananas	6.5	Oranges	3.4	Apples	5.5
29.2	PT General population	14.9	Wine grapes	4.1	Bananas	3.2	Apples	1.5
29.2	DK child	13.7	Bananas	7.0	Apples	2.0	Pears	2.5
26.0	WHO cluster diet E	9.6	Wine grapes	4.4	Bananas	2.5	Apples	3.7
22.8	NL general	4.5	Oranges	3.8	Wine grapes	3.8	Bananas	3.3
22.1	WHO Cluster diet F	6.8	Bananas	3.6	Wine grapes	2.6	Oranges	3.4
19.6	ES adult	4.3	Bananas	3.9	Oranges	2.5	Wine grapes	2.7
19.3	DK adult	8.4	Wine grapes	4.5	Bananas	2.4	Apples	1.0
18.1	UK vegetarian	4.9	Wine grapes	4.5	Bananas	2.6	Oranges	1.1
18.0	WHO regional European diet	4.6	Bananas	2.0	Apples	2.0	Tomatoes	3.8
17.8	IT kids/toddler	6.4	Bananas	2.7	Apples	2.6	Tomatoes	1.3
16.9	UK Adult	6.5	Wine grapes	4.2	Bananas	1.7	Oranges	1.0
14.4	WHO cluster diet D	2.2	Wine grapes	2.0	Apples	1.8	Tomatoes	3.7
12.4	PL general population	6.1	Apples	2.3	Bananas	1.6	Tomatoes	0.6
12.2	FI adult	3.0	Bananas	2.9	Oranges	1.8	Wine grapes	0.6
11.2	LT adult	5.6	Apples	1.1	Tomatoes	1.0	Milk and milk products: Cattle	2.2
11.1	IT adult	2.5	Bananas	2.4	Apples	2.1	Tomatoes	0.9

Conclusion:

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

Appendix C. List of metabolites and related structural formula

Code/Trivial name	Chemical name	Structural formula
Hydrazide-hydrazone (AE C593600; FBC 93600)	2-chloro-*N*'-[(2-chlorophenyl) methylidene] benzohydrazide	
2-chlorobenzonitrile (AE F023666) MW 137.5 g/mol	2-chlorobenzonitrile	
2-chlorobenzamide (AE F092117)	2-chlorobenzamide	

ABBREVIATIONS

ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CEN	European Committee for Standardisation (Comité Européen de Normalisation,)
CF	conversion factor for enforcement to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
DAR	Draft Assessment Report
DAT	days after treatment
DT_{90}	period required for 90 % dissipation (define method of estimation)
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
ha	hectare
hL	hectolitre
i.e.	that is (id est, *Latin*)
ILV	independent laboratory validation
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
L	litre
LC	liquid chromatography
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MSD	mass spectrometry detector

MS/MS	tandem mass spectrometry
MW	molecular weight
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	Southern European Union
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UV	ultra-violet (detector)
WHO	World Health Organization
yr	year