European Food Safety Authority

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REASONED OPINION

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

European Food Safety Authority[2, 3]

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ABSTRACT

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the pesticide active substance methyl bromide. Although this active substance is no longer authorised within the European Union, guideline levels for methyl bromide (at point of retail sale or when offered for consumption) and MRLs for bromide ion, which is a relevant metabolite of methyl bromide, were established by the Codex Alimentarius Commission (CXLs). Regarding methyl bromide, the default MRL of 0.01 mg/kg as defined by Regulation (EC) No 396/2005 is compliant with the Codex guideline levels and provides a satisfactory level of protection for the European consumer but it could not be demonstrated that the default MRL can be achieved in routine enforcement. Moreover, based on the assessment of the available data, some CXLs were found not to be adequately supported by data and the consumer risk assessment could not be finalised, as the toxicological reference values of bromide ion need to be revised and only few information on the natural occurrence of bromide ion in food was available to EFSA. Hence, further consideration by risk managers is needed.

KEY WORDS

methyl bromide, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, fumigant, bromide ion

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SUMMARY

A decision not to include methyl bromide in Annex I to Directive 91/414/EEC entered into force on 16 October 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(1) of Regulation (EC) No 396/2005. Considering that the use of methyl bromide is no longer authorised within the European Union and that no import tolerances were notified by the designated rapporteur Member State (United Kingdom), EFSA based its assessment mainly on the conclusions derived in the framework of Directive 91/414/EEC and the MRLs established by the Codex Alimentarius Commission.

On 08 March 2013 EFSA issued a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 10 May 2013 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of methyl bromide was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.001 mg/kg bw per d and 0.003 mg/kg bw, respectively. The toxicological profile of bromide ion, the main metabolite of methyl bromide, was evaluated by JMPR, but EFSA considers that the proposed ADI of 1 mg/kg bw per d is not sufficiently supported by data and that the necessity of an ARfD for bromide ion should be reassessed. Pending a revision of the toxicological profile of bromide ion by JMPR, the values set by JMPR are considered on a tentative basis.

Primary crop metabolism of methyl bromide following post-harvest fumigation was investigated for three different crop groups (fruits/fruiting vegetables, oilseeds and cereals) and a statement was available regarding the use of methyl bromide as soil fumigant. EFSA considers that the residue for enforcement and risk assessment in all commodities should be defined as methyl bromide and bromide ion, separately (based on the differing toxicological properties of both compounds). This residue definition is concordant with the evaluation of JMPR but no validated analytical method for enforcement of methyl bromide is available. Nevertheless, there are indications that bromide ion can be enforced in plant commodities, except in high oil content commodities.

Regarding the magnitude of residues in plant commodities, no CXLs are available for methyl bromide but guideline levels have been established by the Codex Alimentarius Commission indicating that, although significant residue levels may be present on a treated commodity directly after post-harvest fumigation (i.e. at the point of entry of a country), levels of methyl bromide should be below of 0.01 mg/kg at point of retail sale or when offered for consumption. For bromide ion, specific CXLs are available but bromide ion may also occur naturally in food and feed and available data were insufficient to determine whether CXLs were derived from the pesticide use of methyl bromide or whether they are based on the natural occurrence of bromide ion.

Metabolism of methyl bromide or bromide ion in livestock was not investigated in the framework of Directive 91/414/EEC, or by JMPR. On the basis of available data, EFSA considers that methyl bromide is expected to be negligible in animal products, but high residues of bromide ion could be present in these commodities. Nevertheless, no validated analytical method for enforcement of bromide ion in commodities of animal origin is available and, as for plant commodities, EFSA highlights that bromide ion in commodities of animal origin may originate from other sources, including natural occurrence.

As methyl bromide can be present in commodities subject to post-harvest fumigation several days after the end of the treatment, enforcement of methyl bromide is considered relevant in order to check that no methyl bromide remains in commodities proposed for consumption. For this purpose, considering the ADI and ARfD derived by EFSA, the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005 and compliant with the Codex guideline levels for methyl bromide at point of retail sale or when offered for consumption, provides a satisfactory level of protection for the European consumer.

CXLs for bromide ion were considered in a separate calculation of the consumer exposure. The highest chronic exposure was calculated for the WHO Cluster diet B, representing 110.8 % of the ADI. EFSA notes that this exceedance (the only one among all diets included in the PRIMo) is likely to be due to the use of the CXL value as an input value instead of a risk assessment value which is not available for this crop; therefore no refinement could be done on the basis of the available data. Moreover, acute exposure calculations were not carried out because an ARfD was not available for this compound. As the toxicological reference values derived by JMPR and considered in this calculation are not fully supported by EFSA, this risk assessment for bromide ion is subject to a high level of uncertainty.

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005.

Regarding methyl bromide, the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005 and compliant with the Codex guideline levels for methyl bromide at point of retail sale or when offered for consumption, provides a satisfactory level of protection for the European consumer but it was not demonstrated that the default MRL can be achieved in routine enforcement.

Regarding the bromide ion, EFSA does not recommend inclusion of the existing CXLs in Annex II to Regulation (EC) No 396/2005 due to the concerns identified above. EFSA recommend that the toxicological reference values for bromide ion are re-assessed by JMPR and that CXLs for bromide ion are also reconsidered in order to get a better understanding on the levels resulting from natural occurrence and on the MRLs that are still needed for uses outside the European Union. Pending such an assessment by JMPR, no MRLs can be proposed by EFSA for bromide ion.

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BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting and review of pesticide MRLs at European level. Article 12(1) of that regulation stipulates that EFSA shall provide, within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC[5], a reasoned opinion on the review of the existing MRLs for that active substance. As a decision not to include methyl bromide in Annex I to Directive 91/414/EEC entered into force on 16 October 2008, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2009-00014 was included in the EFSA Register of Questions.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that the few representative uses evaluated in the framework of that directive might no longer be relevant because the use of active substances that are not included in Annex I is not allowed within the EU. Moreover, non-included substances might still be authorised in third countries, requiring the establishment of import tolerances in Regulation (EC) No 396/2005.

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

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

United Kingdom, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for methyl bromide and to prepare a supporting evaluation report. Documentation was submitted to EFSA on 28 June 2010 confirming that no import tolerances were notified to the RMS.

A draft reasoned opinion was issued by EFSA on 08 March 2013 and submitted to Member States (MS) for commenting. All MS comments received by 10 May 2013 were considered by EFSA in the finalisation of the reasoned opinion.

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

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

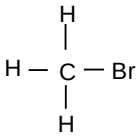
TERMS OF REFERENCE

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

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

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Methyl bromide is the ISO common name for bromomethane (IUPAC).



Methyl bromide can be used as a fumigant with fungicide, herbicide, insecticide, nematicide and rodenticide properties, applied either as a soil fumigant or as a post harvest treatments. Mode of action is described as a non-specific enzyme inhibition following methylation of the protein moiety of the enzymes, particularly any S-H groups.

Methyl bromide was evaluated in the framework of Directive 91/414/EEC with United Kingdom being the designated rapporteur Member State (RMS). The representative use supported for the initial peer review process comprised outdoor and indoor pre-plant soil treatment at a maximal application rate of 50 g/m², stored product fumigation and empty structure fumigation at application rates of 100 to 144 g/m^3. Following the Draft Assessment Report (DAR) submission, and Member State consultation, in accordance with Article 11f of Regulation (EC) No 2229/2004[6] there were clear indications of harmful effects. A first decision on non-inclusion of the active substance was therefore published by means of Commission Decision 2008/753/EC[7], entering into force on 16 October 2008. According to this Commission Decision, any period of grace granted by Member States in accordance with the provisions of Article 4(6) of Directive 91/414/EEC shall expire on 18 March 2010 at the latest. In accordance with Article 13 of Regulation (EC) No 33/2008[8], methyl bromide was then subject to a resubmission procedure and a second peer-review was carried out by EFSA. The representative uses evaluated during this resubmission were limited to fumigation of wood packaging material. However, the additional data and information provided did not permit eliminating all the specific concerns that led to the non-inclusion. Consequently, a final decision confirming the initial non-inclusion was published by means of Commission Decision 2011/120/EU[9]. As EFSA was not yet involved in the first peer review of methyl bromide and that the use of methyl bromide on food or feed

[6] Commission Regulation (EC) No 2229/2004 of 3 December 2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC. OJ L 379, 24.12.2004, p. 13–63.

[7] 2008/753/EC: Commission Decision of 18 September 2008 concerning the non-inclusion of methyl bromide in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. OJ L 258, 26.9.2008, p. 68–69.

[8] Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p.5-12.

[9] 2011/120/EU: Commission Decision of 21 February 2011 concerning the non-inclusion of methyl bromide in Annex I to Council Directive 91/414/EEC. OJ L 47, 22.2.2011, p. 19–20.

crops was no longer supported in the resubmission procedure, the EFSA Conclusion on this active substance does not include a risk assessment for consumers.

The EU MRLs for methyl bromide are established in Annex IIIA of Regulation (EC) No 396/2005. All existing EU MRLs, which are established for the main metabolite in food and feed, bromide ion, are summarised in Appendix B.1 to this document. CXLs for bromide ion were also established by the Codex Alimentarius Commission and are reported in Appendix B.2 to this reasoned opinion. No CXLs for methyl bromide are available, but guidelines levels were established by the Codex Alimentarius Commission and are reported in Appendix B.3. They are indicative values of the expected levels of methyl bromide in treated commodities, either at point of entry into a country, or at point of retail sale or when the commodity is offered for consumption.

According to the decision of non-inclusion in Annex I of Directive 91/414/EEC, plant protection products containing methyl bromide are no longer authorised in EU Member States (authorisations for emergency situations in plant protection granted in application of Article 53 of Regulation (EC) No 1107/2009 are not considered in the context of this Reasoned Opinion). For the purpose of this MRL review, the RMS did not report any use authorised in third countries that might have a significant impact on international trade.

ASSESSMENT

The use of methyl bromide is no longer authorised within the EU (authorisations for emergency situations in plant protection granted in application of Article 53 of Regulation (EC) No 1107/2009 are not considered in the context of this Reasoned Opinion) and no uses authorised in third countries were notified to the RMS. It is also noted that, in line with the Montreal Protocol on Substances that Deplete the Ozone Layer, the use of methyl bromide is currently being phased out on a worldwide level Nevertheless, despite this international phase-out, some particular uses authorised outside the EU may still remain in place for several years depending on the available alternatives and CXLs are still available for this active substance. European consumers may therefore be exposed to residues of this active substance, in particular through imported products, and an assessment of the consumer exposure resulting from these CXLs is carried out by EFSA. EFSA mainly bases its assessment on the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (UK, 2005), the conclusion on the peer review of the pesticide risk assessment of the active substance methyl bromide (EFSA, 2011) as well as the JMPR Evaluation reports (FAO, 1968, 1979, 1983, 1992). The assessment is performed in accordance with the legal provisions of the Uniform Principles for Evaluation and Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[10] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011).

1. Methods of analysis

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

During the peer review under Directive 91/414/EEC, an analytical method using GC-ECD was evaluated for the determination of parent methyl bromide in plant matrices; nevertheless, due to the low recoveries reported, this method cannot be considered validated (United Kingdom, 2005). Moreover, no multi-residue method is reported for analysis of the parent methyl bromide in plant commodities. CEN (2000) reported the European Standard EN 13191-2 for the determination of bromide ion in plant matrices, except high oil content commodities, but detailed validation data for this method are not available to EFSA.

[10] 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.

Hence there is no evidence that parent methyl bromide can be enforced in food of plant origin but there are indications that bromide ion can be enforced in food of plant origin except high oil content commodities.

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

During the peer review under Directive 91/414/EEC, no analytical method was evaluated for the determination of bromide ion in food of animal origin. Hence there is no evidence that bromide ion can be enforced in food of animal origin.

2. Mammalian toxicology

The toxicological assessment of methyl bromide was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by EFSA (EFSA, 2011). These toxicological reference values are summarised in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Methyl bromide					
ADI	EFSA	2011	0.001 mg/kg bw per d	1 year dog	100
ARfD	EFSA	2011	0.003 mg/kg bw	1 year dog (initial effects)	100

No toxicological reference values were established in Europe for bromide ion, which is the main metabolite of methyl bromide in plants. An ADI was determined by JMPR in 1966 on the basis of a minimum pharmacologically effective dosage of about 900 mg of KBr, equivalent to 600 mg of bromide ion. This value was confirmed by JMPR in 1988 by toxicological studies with animals as well as human volunteers. EFSA however does not fully support this ADI because a pharmacologically effective dose can be considered neither as a NOAEL, nor as a LOAEL, and side effects could occur at this dose.

No ARfD was established by JMPR. It was not clearly stated that an ARfD was not necessary but studies of acute toxicity on rats and mice were evaluated by the meeting, who concluded that bromide ion exerts a very low acute toxicity upon oral administration (FAO, 1988). Moreover, the decision that no ARfD is necessary was taken during the expert meeting of September 2007 concerning the refinements of the consumer risk assessment for proposed temporary EU MRLs (EFSA, 2008). However, although reported by EFSA, these refinements were carried out under the responsibility of the European Commission and Member States and therefore, this conclusion on acute toxicity was not fully validatedby EFSA. Therefore, EFSA recommend that the toxicological reference values for bromide ion are re-assessed by JMPR.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of methyl bromide was investigated for post-harvest fumigation on stored cereals (maize, wheat, oatmeal), nuts (almonds) and oilseeds (peanuts) using [^{14}C]-labelled methyl bromide (United Kingdom, 2005). The characteristics of these studies are summarised in Table 3-1.

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

Group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks
Fruits and fruiting vegetable	Almonds	[^{14}C]-labelled methyl bromide	Post-harvest fumigation	48 g/m^3 (3 days-long exposure)	1	1h, 1, 2, 4 and 10[(b)]	
Pulses and oilseeds	Peanuts						
Cereals	Maize, Wheat, Oatmeal						

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): Period of aeration after end of exposure to methyl bromide.

Plant metabolism data show a decline of methyl bromide as the time of aeration increases, with significant formation of methylated proteins. Despite the decline, methyl bromide was still present in the treated products after 10 days of aeration, ranging from 0.02 mg/kg in wheat grain to 0.60 mg/kg in peanuts. Occurrence of inorganic bromide ion was not investigated in this study, but it is stated by JMPR that bromide ion occur significantly after post-harvest fumigation with methyl bromide (FAO, 1992).

No study investigating the metabolism following soil fumigation was reported in the DAR. It was however pointed out that DT_{50} value for methyl bromide in soil under aerobic conditions is up to 1.95 days and this compound is therefore readily degraded and volatilised at ambient temperature and pressure in soil environments. Regarding bromide ion, it is clearly stated in the DAR that methyl bromide use could result in significant soil residues of bromide ion above natural levels (United Kingdom, 2005).

On the basis of the data reported in the DAR, the relevant residue in plants consisted of parent methyl bromide and bromide ion. The two compounds having different toxicological profiles, they should be considered independently, both for enforcement and risk assessment purposes. The conclusions reached by EFSA are in line with those of the JMPR (FAO, 1968, 1979, 1983, 1992). No validated analytical method for enforcement of methyl bromide is available. However, there are indications that bromide ion can be enforced in plant commodities, except in high oil content commodities (see also section 1.1).

EFSA also highlights that bromide ion is not specific to methyl bromide. Indeed, it occurs naturally, especially in seawater. As a consequence, bromide is recovered in soils, with concentration ranging from 1 to 20 mg/kg, as well as in plants products (van Leuwen, F.X.R & Sangster, B., 1988). Moreover, it can be a consequence of the use of other bromide producing fumigants such as dibromomethane. However, those products were also phased out by the Montreal Protocol.

3.1.1.2. Magnitude of residues

The use of methyl bromide is no longer authorised in Europe (authorisations for emergency situations in plant protection granted in application of Article 53 of Regulation (EC) No 1107/2009 are not considered in the context of this Reasoned Opinion) but CXLs have been established for bromide ion (FAO, 1979a, 1979b, 1983, 1992) as well as guideline levels for methyl bromide.

Guideline levels for methyl bromide are established for tree nuts, peanuts, cereals grains and cocoa beans and their corresponding risk assessment values are summarised in appendix B.3. For each

commodity, there are two guideline levels: one corresponding to the levels that could be encountered in the raw agricultural commodity at point of entry in a country (i.e. one day after fumigation) and the other corresponding to the levels that could be encountered in the same commodity at points of retail sale or when offered for consumption. The first values range from 5 (cereals grains and cocoa beans) to 10 (tree nuts and peanuts) mg/kg while the second ones are set to 0.01*mg/kg. These values, in accordance with the metabolism data (see section 3.1.1.1), confirm that residues of unchanged methyl bromide could occur in commodities directly after post-harvest fumigation but the intention is to wait sufficient time before retail/consumption in order to have undetectable residues of methyl bromide.

The existing CXLs for bromide ion and their corresponding risk assessment values are summarised in appendix B.2. As already stated, bromide occurs naturally in plants commodities. Therefore, a comparison for each commodity between the CXL and the natural level of bromide would be useful in order to understand whether CXLs derived by JMPR were derived on the basis of an authorised use for methyl bromide or on the basis of its natural occurrence. However, data reported by JMPR are too limited to make such an assessment and suitable data on the natural occurrence of bromide ion in food and feed are not available to EFSA. Therefore the natural occurrence cannot be taken into account during this review.

3.1.1.3. Effect of industrial processing and/or household preparation

Data on the nature of residues was neither submitted in the framework of Directive 91/414/EEC, nor evaluated by JMPR. Limited data were evaluated on the transfer of methyl bromide for wheat grain to germ, flour and by-products (e.g. bran). No concentration of methyl bromide was observed in this trial. No data regarding transfer of bromide ion is reported in the DAR.

3.1.2. Rotational crops

Considering that methyl bromide is no longer authorised within the EU (authorisations for emergency situations in plant protection granted in application of Article 53 of Regulation (EC) No 1107/2009 are not considered in the context of this Reasoned Opinion), investigation of residues in rotational crops is not deemed relevant.

3.2. Nature and magnitude of residues in livestock

CXLs have been established for crops that may be fed to livestock. Investigation of residues in commodities of animal origin is therefore relevant. Data regarding metabolism of methyl bromide or bromide ion in animals was neither submitted in the framework of Directive 91/414/EEC, nor evaluated by JMPR. However, it was stated in the DAR that methyl bromide is expected to be negligible in animal products, but high residues of bromide ion could be present in these commodities (United Kingdom, 2005). Consequently, bromide ion is deemed to be the only suitable marker in livestock for residues of methyl bromide. However, as for plant, EFSA highlights that bromide ion is not specific to methyl bromide. No validated analytical methods for enforcement of the proposed residue definition is available (see also section 1.2).

4. Consumer risk assessment

As methyl bromide is no longer authorised (authorisations for emergency situations in plant protection granted in application of Article 53 of Regulation (EC) No 1107/2009 are not considered in the context of this Reasoned Opinion), only the existing CXLs should normally be considered for risk assessment. In accordance with the residue definition in plants, methyl bromide and bromide ion are assessed separately.

4.1. Methyl bromide

Guideline levels of 0.01 mg/kg for methyl bromide apply for tree nuts, peanuts, cereals grains and cocoa beans, at point of retail sale or when offered for consumption. The intention is thus to respect a sufficient delay between treatment and consumption in order to have undetectable residues of methyl bromide in raw agricultural commodities. However, on the basis of the available metabolism study and

considering the existing guideline levels for this substance in commodities at the point of entry in the country (i.e. one day after fumigation), methyl bromide can be present in commodities subject to post-harvest fumigation several days after the end of the treatment. Consequently, enforcement of methyl bromide is relevant to check that no methyl bromide remains in commodities proposed for consumption.

In order to assess whether the default MRL of 0.01 mg/kg (compliant with the guideline levels for methyl bromide at point of retail sale or when offered for consumption) is sufficiently protective for European consumers, acute and chronic intake calculations using the toxicological reference values derived by EFSA and default MRL of 0.01 mg/kg for all products of plant and animal origin were performed using revision 2 of the EFSA PRIMo (EFSA, 2007).

The detailed results of the acute and chronic intake calculations for methyl bromide are reported in Appendix A.1. to this document. The highest chronic exposure was calculated for the French toddler, representing 75.8% of the ADI, and the highest acute exposure was calculated for potatoes, representing 51.3% of the ARfD. EFSA highlights that the above calculation does not reflect real exposure of consumers to methyl bromide; it is a theoretical calculation indicating that the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005, provides a satisfactory level of protection for the European consumers.

4.2. Bromide ion

In order to include the CXLs for bromide ion in the calculations of the consumer exposure, all data relevant to the consumer exposure assessment have been collected from JMPR evaluations (FAO, 1968, 1979, 1983, 1992). For the major part of the commodities, the limited nature of the reports could not allow to identify clearly the data used to set the CXLs. Consequently, the CXL values were used for those commodities. All data are reported in Appendix B.2 to this document. Input values used for the exposure calculations are also summarized in Table 4-1. Crops that were not assessed in JMPR evaluations as well as the natural occurrence of bromide ion were not considered in the intake calculations. Pending the revision of the toxicological profile of bromide ion by JMPR, acute exposure calculations were not carried out because an ARfD is not available.

Table 4-1: Input values for the consumer risk assessment (with consideration of CXLs)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: bromide ion		
Citrus fruits	30	CXL[(a)]
Strawberries	30	CXL[(a)]
Avocados	75	CXL[(a)]
Others fruits	20	CXL[(a)]
Radishes	110	Median (CXL)[(b)]
Turnips	100	Median (CXL)[(b)]
Tomatoes	75	CXL[(a)]
Peppers	6,7	Median (CXL)[(b)]
Okra, lady's fingers	87	Median (CXL)[(b)]
Cucumbers	59	Median (CXL)[(b)]
Courgettes	30	Median (CXL)[(b)]
Broccoli	14	Median (CXL)[(b)]

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Head cabbage	100	CXL[(a)]
Lettuce	100	CXL[(a)]
Spinach	170	Median (CXL)[(b)]
Beans (fresh, with pods)	13	Median (CXL)[(b)]
Peas (fresh, with pods)	17	Median (CXL)[(b)]
Celery	300	CXL[(a)]
Cereals grains	50	CXL[(a)]
Spices	400	CXL[(a)]

(a): CXL is not sufficiently supported by data; the existing CXL is used for indicative exposure calculations (value for risk assessment not available).
(b): CXL is not sufficiently supported by data; the corresponding risk assessment values are used for indicative exposure calculations.

Chronic exposure calculations were performed using revision 2 of the EFSA PRIMo and calculated exposures were compared with the ADI derived for bromide ion by JMPR (see section 2); detailed results of the calculations are presented in Appendix A.2. An exceedance of the ADI was calculated for WHO Cluster diet B, representing 110.8 % of the ADI. EFSA highlights that this exceedance (the only one among the different diets) is mainly due to the contribution of wheat grain, for which the CXL value was used as an input value as no risk assessment value is available. Therefore, consumer exposure is deemed overestimated in this calculation. However, no refinement could be done on the basis of the available data. Moreover, considering the high level of uncertainty related to the toxicological reference values included in the above calculations (see also section 2) and considering the lack of knowledge on the supporting data for most of the CXLs for bromide ion, EFSA concludes that there is currently not enough data to finalise the risk assessment on bromide ion.

Consequently, CXLs for bromide ion cannot be recommended by EFSA and considering the lack of knowledge on the natural occurrence of bromide ion EFSA is currently not in a position to recommend alternative MRLs. EFSA recommends that the toxicological reference values for bromide ion are re-assessed by JMPR and that CXLs for bromide ion are also reconsidered in order to get a better understanding on the levels resulting from natural occurrence and on the MRLs that are still needed for uses outside the European Union.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of methyl bromide was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.001 mg/kg bw per d and 0.003 mg/kg bw, respectively. The toxicological profile of bromide ion, the main metabolite of methyl bromide, was evaluated by JMPR, but EFSA considers that the proposed ADI of 1 mg/kg bw per d is not sufficiently supported by data and that the necessity of an ARfD for bromide ion should be reassessed. Pending a revision of the toxicological profile of bromide ion by JMPR, the values set by JMPR are considered on a tentative basis.

Primary crop metabolism of methyl bromide following post-harvest fumigation was investigated for three different crop groups (fruits/fruiting vegetables, oilseeds and cereals) and a statement was available regarding the use of methyl bromide as soil fumigant. EFSA considers that the residue for enforcement and risk assessment in all commodities should be defined as methyl bromide and bromide ion, separately (based on the differing toxicological properties of both compounds). This residue definition is concordant with the evaluation of JMPR but no validated analytical method for

enforcement of methyl bromide is available. Nevertheless, there are indications that bromide ion can be enforced in plant commodities, except in high oil content commodities.

Regarding the magnitude of residues in plant commodities, no CXLs are available for methyl bromide but guideline levels have been established by the Codex Alimentarius Commission indicating that, although significant residue levels may be present on a treated commodity directly after post-harvest fumigation (i.e. at the point of entry of a country), levels of methyl bromide should be below of 0.01 mg/kg at point of retail sale or when offered for consumption. For bromide ion, specific CXLs are available but bromide ion may also occur naturally in food and feed and available data were insufficient to determine whether CXLs were derived from the pesticide use of methyl bromide or whether they are based on the natural occurrence of bromide ion.

Metabolism of methyl bromide or bromide ion in livestock was not investigated in the framework of Directive 91/414/EEC, or by JMPR. On the basis of available data, EFSA considers that methyl bromide is expected to be negligible in animal products, but high residues of bromide ion could be present in these commodities. Nevertheless, no validated analytical method for enforcement of bromide ion in commodities of animal origin is available and, as for plant commodities, EFSA highlights that bromide ion in commodities of animal origin may originate from other sources, including natural occurrence.

As methyl bromide can be present in commodities subject to post-harvest fumigation several days after the end of the treatment, enforcement of methyl bromide is considered relevant in order to check that no methyl bromide remains in commodities proposed for consumption. For this purpose, considering the ADI and ARfD derived by EFSA, the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005 and compliant with the Codex guideline levels for methyl bromide at point of retail sale or when offered for consumption, provides a satisfactory level of protection for the European consumer.

CXLs for bromide ion were considered in a separate calculation of the consumer exposure. The highest chronic exposure was calculated for the WHO Cluster diet B, representing 110.8 % of the ADI. EFSA notes that this exceedance (the only one among all diets included in the PRIMo) is likely to be due to the use of the CXL value as an input value instead of a risk assessment value which is not available for this crop; therefore no refinement could be done on the basis of the available data. Moreover, acute exposure calculations were not carried out because an ARfD was not available for this compound. As the toxicological reference values derived by JMPR and considered in this calculation are not fully supported by EFSA, this risk assessment for bromide ion is subject to a high level of uncertainty.

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005.

Regarding methyl bromide, the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005 and compliant with the Codex guideline levels for methyl bromide at point of retail sale or when offered for consumption, provides a satisfactory level of protection for the European consumer but it was not demonstrated that the default MRL can be achieved in routine enforcement.

Regarding the bromide ion, EFSA does not recommend inclusion of the existing CXLs in Annex II to Regulation (EC) No 396/2005 due to the concerns identified above. EFSA recommend that the toxicological reference values for bromide ion are re-assessed by JMPR and that CXLs for bromide ion are also reconsidered in order to get a better understanding on the levels resulting from natural occurrence and on the MRLs that are still needed for uses outside the European Union. Pending such an assessment by JMPR, no MRLs can be proposed by EFSA for bromide ion.

REFERENCES

CEN (European Committee for Standardization), 2000. Non-fatty food - Determination of bromide residues - Part 2: Determination of inorganic bromide. EN 13191-2, November 2000.

EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95 rev.4.

EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3.

EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6.

EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2.

EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5.

EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3.

EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5.

EC (European Commission), 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010.

EC (European Commission), 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev.4.

EC (European Commission), 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.

EC (European Commission), 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev.8-1.

EC (European Commission), 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9.

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs according to Regulation (EC) No 396/2005 on Maximum Residue Levels of Pesticides in Food and Feed of Plant and Animal Origin. 15 March 2007.

EFSA (European Food Safety Authority) 2008. Addendum to the reasoned opinion published on 15 March 2007 on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs according to Regulation (EC) No 396/2005 on Maximum Residue Levels of Pesticides in Food and Feed of Plant And Animal Origin. February 2008.

EFSA (European Food Safety Authority), 2011. Conclusion on the peer review of the pesticide risk assessment of the active substance methyl bromide. EFSA Journal 2011;9(1):1893, 32 pp. doi:10.2903/j.efsa.2011.1893

FAO (Food and Agriculture Organisation of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed**.** Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

FAO (Food and Agriculture Organisation of the United Nations), 1979a. Pesticide residues in food – 1979. Index and summary 1965-1978. FAO Plant Production and Protection Paper 11.

FAO (Food and Agriculture Organisation of the United Nations), 1979b. Bromide ion. In: Pesticide residues in food – 1979. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 20.

FAO (Food and Agriculture Organisation of the United Nations), 1983. Bromide ion. In: Pesticide residues in food – 1983. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 56.

FAO (Food and Agriculture Organisation of the United Nations), 1988. Bromide ion. In: Pesticide residues in food – 1988. Evaluations. Part II. Toxicology. FAO Plant Production and Protection Paper 93.

FAO (Food and Agriculture Organisation of the United Nations), 1992. Bromide ion. In: Pesticide residues in food – 1992. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 116.

van Leeuwen, F.X.R. & Sangster, B., 1988. The toxicology of bromide ion. CRC Critical Reviews in Toxicology, 18(3), 189-215.

United Kingdom, 2005. Draft assessment report on the active substance methyl bromide prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, October 2005.

APPENDIX A – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Appendix A.1 – Methyl bromide: scenario including default MRL of 0.01 mg/kg.

Appendix A.2 – Bromide ion: Codex scenario 1 including all CXLs.

APPENDIX A.1 – METHYL BROMIDE: SCENARIO INCLUDING DEFAULT MRL OF 0.01 MG/KG.

Methyl bromide			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,001**	ARfD (mg/kg bw):	**0,003**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

Chronic risk assessment

TMDI (range) in % of ADI
minimum - maximum
10 76

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)
75,8	FR toddler	43,3	PRODUCTS OF ANIMAL ORIGIN	17,3	VEGETABLES	11,8	FRUIT (FRESH OR FROZEN)	
70,5	UK Infant	42,0	PRODUCTS OF ANIMAL ORIGIN	10,1	SUGAR PLANTS	6,6	VEGETABLES	
67,0	UK Toddler	23,5	PRODUCTS OF ANIMAL ORIGIN	22,9	SUGAR PLANTS	6,4	FRUIT (FRESH OR FROZEN)	
65,5	NL child	32,8	PRODUCTS OF ANIMAL ORIGIN	15,0	FRUIT (FRESH OR FROZEN)	11,4	VEGETABLES	
64,8	FR infant	27,4	PRODUCTS OF ANIMAL ORIGIN	20,9	VEGETABLES	15,2	FRUIT (FRESH OR FROZEN)	
60,0	DE child	23,5	PRODUCTS OF ANIMAL ORIGIN	23,0	FRUIT (FRESH OR FROZEN)	7,4	VEGETABLES	
47,3	WHO Cluster diet B	14,5	VEGETABLES	11,9	CEREALS	7,2	FRUIT (FRESH OR FROZEN)	
44,7	DK child	21,8	PRODUCTS OF ANIMAL ORIGIN	10,4	CEREALS	7,3	VEGETABLES	
38,6	SE general population 90th percentile	17,7	PRODUCTS OF ANIMAL ORIGIN	10,1	VEGETABLES	5,8	FRUIT (FRESH OR FROZEN)	
35,4	ES child	17,6	PRODUCTS OF ANIMAL ORIGIN	5,6	FRUIT (FRESH OR FROZEN)	5,2	CEREALS	
33,5	IE adult	10,7	FRUIT (FRESH OR FROZEN)	9,0	VEGETABLES	6,6	CEREALS	
30,6	WHO cluster diet E	9,1	VEGETABLES	6,6	PRODUCTS OF ANIMAL ORIGIN	6,1	CEREALS	
29,1	WHO cluster diet D	9,1	VEGETABLES	8,4	CEREALS	7,1	PRODUCTS OF ANIMAL ORIGIN	
27,6	WHO regional European diet	9,4	PRODUCTS OF ANIMAL ORIGIN	9,2	VEGETABLES	3,7	CEREALS	
26,3	WHO Cluster diet F	7,3	PRODUCTS OF ANIMAL ORIGIN	7,1	VEGETABLES	5,5	CEREALS	
22,0	NL general	8,2	PRODUCTS OF ANIMAL ORIGIN	5,9	VEGETABLES	4,9	FRUIT (FRESH OR FROZEN)	
20,0	ES adult	7,9	PRODUCTS OF ANIMAL ORIGIN	4,1	FRUIT (FRESH OR FROZEN)	3,9	VEGETABLES	
19,4	UK vegetarian	3,8	SUGAR PLANTS	3,8	VEGETABLES	3,7	PRODUCTS OF ANIMAL ORIGIN	
18,4	FR all population	6,2	FRUIT (FRESH OR FROZEN)	4,4	PRODUCTS OF ANIMAL ORIGIN	3,7	VEGETABLES	
18,3	PT General population	6,4	FRUIT (FRESH OR FROZEN)	5,5	VEGETABLES	5,4	CEREALS	
18,0	UK Adult	4,5	PRODUCTS OF ANIMAL ORIGIN	4,0	SUGAR PLANTS	3,0	VEGETABLES	
17,4	DK adult	7,6	PRODUCTS OF ANIMAL ORIGIN	3,6	VEGETABLES	3,3	FRUIT (FRESH OR FROZEN)	
16,4	IT kids/toddler	8,4	CEREALS	4,3	VEGETABLES	3,5	FRUIT (FRESH OR FROZEN)	
16,2	LT adult	6,0	PRODUCTS OF ANIMAL ORIGIN	5,1	VEGETABLES	2,7	CEREALS	
14,2	FI adult	6,8	PRODUCTS OF ANIMAL ORIGIN	2,7	VEGETABLES	2,5	FRUIT (FRESH OR FROZEN)	
12,1	IT adult	5,0	CEREALS	4,1	VEGETABLES	2,8	FRUIT (FRESH OR FROZEN)	
9,6	PL general population	6,1	VEGETABLES	3,4	FRUIT (FRESH OR FROZEN)	0,1	PULSES, DRY	

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

Acute risk assessment /children	Acute risk assessment / adults / general population

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)
51,3	Potatoes	0,01 / -	50,6	Melons	0,01 / -	17,6	Pumpkins	0,01 / -	17,6	Pumpkins	0,01 / -
50,6	Melons	0,01 / -	41,4	Milk and milk	0,01 / -	13,5	Watermelons	0,01 / -	13,5	Watermelons	0,01 / -
44,2	Oranges	0,01 / -	40,8	Watermelons	0,01 / -	13,2	Melons	0,01 / -	13,2	Melons	0,01 / -
41,4	Milk and milk	0,01 / -	36,6	Potatoes	0,01 / -	11,9	Chinese cabbage	0,01 / -	11,9	Chinese cabbage	0,01 / -
40,8	Watermelons	0,01 / -	33,7	Pineapples	0,01 / -	10,6	Cauliflower	0,01 / -	10,6	Cauliflower	0,01 / -
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)
17,0	Apple juice	0,01 / -		3,4	Orange juice	0,01 / -
16,5	Orange juice	0,01 / -		2,2	Apple juice	0,01 / -
14,3	Carrot, juice	0,01 / -		1,5	Bread/pizza	0,01 / -
11,0	Grape juice	0,01 / -		1,3	Wine	0,01 / -
6,0	Peach juice	0,01 / -		0,9	Pineapples preserved	0,01 / -

*) 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 Methyl bromide IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

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

Bromide ion			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**1**	ARfD (mg/kg bw):	**Not available**
Source of ADI:	**JMPR**	Source of ARfD:	**-**
Year of evaluation:	**1988**	Year of evaluation:	**-**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
18	111
No of diets exceeding ADI:	1

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)
110,8	WHO Cluster diet B	42,7	Wheat	23,1	Tomatoes	12,4	Maize	
97,8	DE child	24,1	Apples	20,6	Wheat	11,4	Oranges	
80,6	NL child	23,7	Wheat	12,7	Apples	9,4	Oranges	
78,9	DK child	27,5	Wheat	22,1	Rye	9,7	Cucumbers	
72,5	IE adult	11,5	Maize	11,5	Maize	6,2	Barley	
62,6	WHO cluster diet D	32,5	Wheat	7,6	Tomatoes	2,8	Rice	
58,5	IT kids/toddler	33,2	Wheat	10,7	Tomatoes	2,9	Lettuce	
58,5	FR toddler	13,1	Wheat	12,0	Spinach	6,0	Oranges	
54,0	ES child	22,2	Wheat	7,4	Tomatoes	6,5	Oranges	
52,7	WHO cluster diet E	19,7	Wheat	4,1	Barley	4,0	Tomatoes	
50,7	WHO Cluster diet F	18,0	Wheat	5,1	Tomatoes	3,8	Rye	
50,0	SE general population 90th percentile	16,0	Wheat	6,3	Head cabbage	5,7	Tomatoes	
46,8	PT General population	19,6	Wheat	6,7	Tomatoes	5,0	Wine grapes	
46,6	UK Toddler	19,6	Wheat	5,9	Oranges	4,4	Tomatoes	
45,6	WHO regional European diet	14,8	Wheat	8,3	Tomatoes	3,8	Lettuce	
43,8	IT adult	20,7	Wheat	8,7	Tomatoes	3,8	Lettuce	
40,0	UK Infant	13,1	Wheat	5,1	Maize	3,9	Oranges	
39,2	ES adult	11,7	Wheat	5,9	Tomatoes	5,4	Lettuce	
37,6	FR all population	16,4	Wheat	8,0	Wine grapes	3,3	Tomatoes	
36,1	NL general	10,4	Wheat	4,5	Oranges	3,2	Tomatoes	
31,7	FR infant	7,5	Spinach	5,0	Apples	4,2	Wheat	
30,4	UK vegetarian	10,2	Wheat	4,7	Tomatoes	2,6	Oranges	
30,0	LT adult	5,4	Rye	5,3	Wheat	4,7	Tomatoes	
27,2	DK adult	10,1	Wheat	3,4	Rye	3,1	Tomatoes	
23,7	UK Adult	8,4	Wheat	3,3	Tomatoes	2,2	Wine grapes	
22,2	FI adult	4,9	Wheat	3,4	Rye	3,2	Tomatoes	
18,0	PL general population	6,6	Tomatoes	4,1	Apples	3,6	Head cabbage	

Conclusion:

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 18 % to 111 % of the ADI.
For 1 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

APPENDIX B – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLS) AND CODEX LIMITS (CXLS)

Appendix B.1 – Existing EU MRLs

Appendix B.2 – Existing CXLs for bromide ion

Appendix B.3 – Existing guideline levels for methyl bromide

APPENDIX B.1 – EXISTING EU MRLS

(Pesticides - Web Version - EU MRLs - File created on 15/01/2013 11:12)

Code number	Groups and examples of individual products to which the MRLs apply [a]	Bromide ion
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	30
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	30
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	30
110030	Lemons (Citron, lemon)	30
110040	Limes	30
110050	Mandarins (Clementine, tangerine and other hybrids)	30
110990	Others	30
120000	(ii) Tree nuts (shelled or unshelled)	50
120010	Almonds	50
120020	Brazil nuts	50
120030	Cashew nuts	50
120040	Chestnuts	50
120050	Coconuts	50
120060	Hazelnuts (Filbert)	50
120070	Macadamia	50
120080	Pecans	50
120090	Pine nuts	50
120100	Pistachios	50
120110	Walnuts	50
120990	Others	50
130000	(iii) Pome fruit	20
130010	Apples (Crab apple)	20
130020	Pears (Oriental pear)	20
130030	Quinces	20
130040	Medlar	20
130050	Loquat	20
130990	Others	20
140000	(iv) Stone fruit	20
140010	Apricots	20
140020	Cherries (sweet cherries, sour cherries)	20
140030	Peaches (Nectarines and similar hybrids)	20
140040	Plums (Damson, greengage, mirabelle)	20
140990	Others	20
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	20
151010	Table grapes	20
151020	Wine grapes	20
152000	(b) Strawberries	30
153000	(c) Cane fruit	20
153010	Blackberries	20
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	20
153030	Raspberries (Wineberries)	20
153990	Others	20
154000	(d) Other small fruit & berries	5
154010	Blueberries (Bilberries cowberries (red bilberries))	5
154020	Cranberries	5
154030	Currants (red, black and white)	5
154040	Gooseberries (Including hybrids with other ribes species)	5
154050	Rose hips	5
154060	Mulberries (arbutus berry)	5
154070	Azarole (mediteranean medlar)	5
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	5
154990	Others	5
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	20
161010	Dates	20
161020	Figs	20
161030	Table olives	20
161040	Kumquats (Marumi kumquats, nagami kumquats)	20
161050	Carambola (Bilimbi)	20
161060	Persimmon	20
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	20
161990	Others	20
162000	(b) Inedible peel, small	
162010	Kiwi	50
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	50
162030	Passion fruit	20
162040	Prickly pear (cactus fruit)	20
162050	Star apple	20
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	20
162990	Others	20
163000	(c) Inedible peel, large	
163010	Avocados	50
163020	Bananas (Dwarf banana, plantain, apple banana)	50
163030	Mangoes	50
163040	Papaya	50
163050	Pomegranate	50
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	50
163070	Guava	20
163080	Pineapples	50
163090	Bread fruit (Jackfruit)	20
163100	Durian	20
163110	Soursop (guanabana)	20
163990	Others	20
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	50
211000	(a) Potatoes	50
212000	(b) Tropical root and tuber vegetables	50
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	50
212020	Sweet potatoes	50
212030	Yams (Potato bean (yam bean), Mexican yam bean)	50
212040	Arrowroot	50
212990	Others	50
213000	(c) Other root and tuber vegetables except sugar beet	50
213010	Beetroot	50
213020	Carrots	50
213030	Celeriac	50
213040	Horseradish	50
213050	Jerusalem artichokes	50
213060	Parsnips	50
213070	Parsley root	50
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	50
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	50
213100	Swedes	50
213110	Turnips	50
213990	Others	50
220000	(ii) Bulb vegetables	30
220010	Garlic	30
220020	Onions (Silverskin onions)	30
220030	Shallots	30
220040	Spring onions (Welsh onion and similar varieties)	30
220990	Others	30
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	50
231020	Peppers (Chilli peppers)	30
231030	Aubergines (egg plants) (Pepino)	30
231040	Okra, lady's fingers	30
231990	Others	30

Code number	Groups and examples of individual products to which the MRLs apply [a]	Bromide ion
232000	(b) Cucurbits - edible peel	
232010	Cucumbers	50
232020	Gherkins	30
232030	Courgettes (Summer squash, marrow (patisson))	30
232990	Others	30
233000	(c) Cucurbits-inedible peel	30
233010	Melons (Kiwano)	30
233020	Pumpkins (Winter squash)	30
233030	Watermelons	30
233990	Others	30
234000	(d) Sweet corn	30
239000	(e) Other fruiting vegetables	30
240000	(iv) Brassica vegetables	30
241000	(a) Flowering brassica	30
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	30
241020	Cauliflower	30
241990	Others	30
242000	(b) Head brassica	30
242010	Brussels sprouts	30
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	30
242990	Others	30
243000	(c) Leafy brassica	30
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	30
243020	Kale (Borecole (curly kale), collards)	30
243990	Others	30
244000	(d) Kohlrabi	30
250000	(v) Leaf vegetables & fresh herbs	50
251000	(a) Lettuce and other salad plants including Brassicacea	50
251010	Lamb´s lettuce (Italian cornsalad)	50
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce,	50

Code number	Groups and examples of individual products to which the MRLs apply [a]	Bromide ion
	romaine (cos) lettuce)	
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	50
251040	Cress	50
251050	Land cress	50
251060	Rocket, Rucola (Wild rocket)	50
251070	Red mustard	50
251080	Leaves and sprouts of Brassica spp (Mizuna)	50
251990	Others	50
252000	(b) Spinach & similar (leaves)	50
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	50
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	50
252030	Beet leaves (chard) (Leaves of beetroot)	50
252990	Others	50
253000	(c) Vine leaves (grape leaves)	50
254000	(d) Water cress	50
255000	(e) Witloof	50
256000	(f) Herbs	50
256010	Chervil	50
256020	Chives	50
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	50
256040	Parsley	50
256050	Sage (Winter savory, summer savory,)	50
256060	Rosemary	50
256070	Thyme (marjoram, oregano)	50
256080	Basil (Balm leaves, mint, peppermint)	50
256090	Bay leaves (laurel)	50
256100	Tarragon (Hyssop)	50
256990	Others	50

Code number	Groups and examples of individual products to which the MRLs apply [a]	Bromide ion
260000	(vi) Legume vegetables (fresh)	30
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	30
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	30
260030	Peas (with pods) (Mangetout (sugar peas))	30
260040	Peas (without pods) (Garden pea, green pea, chickpea)	30
260050	Lentils	30
260990	Others	30
270000	(vii) Stem vegetables (fresh)	30
270010	Asparagus	30
270020	Cardoons	30
270030	Celery	30
270040	Fennel	30
270050	Globe artichokes	30
270060	Leek	30
270070	Rhubarb	30
270080	Bamboo shoots	30
270090	Palm hearts	30
270990	Others	30
280000	(viii) Fungi	30
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	30
280020	Wild (Chanterelle, Truffle, Morel ,)	30
280990	Others	30
290000	(ix) Sea weeds	5
300000	3. PULSES, DRY	50
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	50
300020	Lentils	50
300030	Peas (Chickpeas, field peas, chickling vetch)	50
300040	Lupins	50
300990	Others	50
400000	4. OILSEEDS AND OILFRUITS	

Code number	Groups and examples of individual products to which the MRLs apply [a]	Bromide ion
401000	(i) Oilseeds	
401010	Linseed	20
401020	Peanuts	50
401030	Poppy seed	20
401040	Sesame seed	20
401050	Sunflower seed	20
401060	Rape seed (Bird rapeseed, turnip rape)	20
401070	Soya bean	20
401080	Mustard seed	20
401090	Cotton seed	20
401100	Pumpkin seeds	20
401110	Safflower	20
401120	Borage	20
401130	Gold of pleasure	20
401140	Hempseed	20
401150	Castor bean	20
401990	Others	20
402000	(ii) Oilfruits	
402010	Olives for oil production	20
402020	Palm nuts (palmoil kernels)	20
402030	Palmfruit	20
402040	Kapok	20
402990	Others	5
500000	5. CEREALS	50
500010	Barley	50
500020	Buckwheat	50
500030	Maize	50
500040	Millet (Foxtail millet, teff)	50
500050	Oats	50
500060	Rice	50
500070	Rye	50
500080	Sorghum	50
500090	Wheat (Spelt Triticale)	50
500990	Others	50
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	70
620000	(ii) Coffee beans	70
630000	(iii) Herbal infusions (dried)	
631000	(a) Flowers	
631010	Camomille flowers	250
631020	Hybiscus flowers	100
631030	Rose petals	50

Code number	Groups and examples of individual products to which the MRLs apply [a]	Bromide ion
631040	Jasmine flowers	50
631050	Lime (linden)	50
631990	Others	50
632000	(b) Leaves	100
632010	Strawberry leaves	100
632020	Rooibos leaves	100
632030	Maté	100
632990	Others	100
633000	(c) Roots	70
633010	Valerian root	70
633020	Ginseng root	70
633990	Others	70
639000	(d) Other herbal infusions	50
640000	(iv) Cocoa (fermented beans)	70
650000	(v) Carob (st johns bread)	70
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	20
800000	8. SPICES	400
810000	(i) Seeds	400
810010	Anise	400
810020	Black caraway	400
810030	Celery seed (Lovage seed)	400
810040	Coriander seed	400
810050	Cumin seed	400
810060	Dill seed	400
810070	Fennel seed	400
810080	Fenugreek	400
810090	Nutmeg	400
810990	Others	400
820000	(ii) Fruits and berries	400
820010	Allspice	400
820020	Anise pepper (Japan pepper)	400
820030	Caraway	400
820040	Cardamom	400
820050	Juniper berries	400
820060	Pepper, black and white (Long pepper, pink pepper)	400
820070	Vanilla pods	400
820080	Tamarind	400
820990	Others	400
830000	(iii) Bark	400
830010	Cinnamon (Cassia)	400
830990	Others	400
840000	(iv) Roots or rhizome	400
840010	Liquorice	400
840020	Ginger	400
840030	Turmeric (Curcuma)	400
840040	Horseradish	400
840990	Others	400
850000	(v) Buds	400
850010	Cloves	400
850020	Capers	400
850990	Others	400
860000	(vi) Flower stigma	400
860010	Saffron	400
860990	Others	400
870000	(vii) Aril	400
870010	Mace	400
870990	Others	400
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	20
900020	Sugar cane	20
900030	Chicory roots	5
900990	Others	5
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	0,05*
	Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*
1060000	(vi) Snails	0,05*
1070000	(vii) Other terrestrial animal products	0,05*

(*) Indicates lower limit of analytical determination

APPENDIX B.2 – EXISTING CXLS FOR BROMIDE ION

Summary of CXLs for bromide ion in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
110010	Grapefruit	Bromide ion	30	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.k.	1	1968	no	The recommendations were made by the JMPR in 1968. Due the the limited nature of the report it is unclear if this is supported by residues data.
110020	Oranges	Bromide ion	30	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.k.	1	1968	no	
110030	Lemons	Bromide ion	30	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.k.	1	1968	no	
110040	Limes	Bromide ion	30	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.k.	1	1968	no	
110050	Mandarins	Bromide ion	30	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.k.	1	1968	no	
130010	Apples	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	Fruits (except as otherwise listed). The recommendations were made by the JMPR in 1968. Due the the limited nature of the report it is unclear if this is supported by residues data.
130020	Pears	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
130030	Quinces	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
130040	Medlar	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
130050	Loquat	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
140010	Apricots	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
140020	Cherries	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
140030	Peaches	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
140040	Plums	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
151010	Table grapes	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
151020	Wine grapes	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
152000	Strawberries	Bromide ion	30	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	The recommendations were made by the JMPR in 1968. Due the the limited nature of the report it is unclear if this is supported by residues data.

Summary of CXLs for bromide ion in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
153010	Blackberries	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	Fruit (except as otherwise listed). The recommendations were made by the JMPR in 1968. Due the the limited nature of the report it is unclear if this is supported by residues data.
153020	Dewberries	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
153030	Raspberries	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
154010	Blueberries	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
154020	Cranberries	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
154030	Currants (red, black and white)	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
154040	Gooseberries	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
154050	Rose hips	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
154060	Mulberries	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
154070	Azarole (mediteranean medlar)	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
154080	Elderberries	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
161010	Dates	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
161020	Figs	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
161030	Table olives	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
161040	Kumquats	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
161050	Carambola	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
161060	Persimmon	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
161070	Jambolan (java plum)	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
162010	Kiwi	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
162020	Lychee (Litchi)	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
162030	Passion fruit	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
162040	Prickly pear (cactus fruit)	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
162050	Star apple	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
162060	American persimmon (Virginia kaki)	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	

Summary of CXLs for bromide ion in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
163010	Avocados	Bromide ion	75	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	The recommendations were made by the JMPR in 1968. Due the the limited nature of the report it is unclear if this is supported by residues data.
163020	Bananas	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	Fruit (except as otherwise listed). The recommendations were made by the JMPR in 1968. Due the the limited nature of the report it is unclear if this is supported by residues data.
163030	Mangoes	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
163040	Papaya	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
163050	Pomegranate	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
163060	Cherimoya	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
163070	Guava	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
163080	Pineapples	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
163090	Bread fruit	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
163100	Durian	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
163110	Soursop (guanabana)	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1968	no	
213080	Radishes	Bromide ion	200	Bromide ion	n.c.	n.c.	1	n.c.	110	180	n.a.	1	1992	no	Based on limited data from the USA.
213110	Turnips	Bromide ion	200	Bromide ion	n.c.	n.c.	1	n.c.	100	160	n.a.	1	1992	no	Based on data from only 2 trials conducted in the USA.
231010	Tomatoes	Bromide ion	75	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	70	n.a.	1	1983	no	No GAP details were provided.
231020	Peppers	Bromide ion	20	Bromide ion	n.c.	n.c.	1	n.c.	6,7	11	n.a.	1	1992	no	Based on limited data from the USA.
231040	Okra, lady's fingers	Bromide ion	200	Bromide ion	n.c.	n.c.	1	n.c.	87	140	n.a.	1	1992	no	Based on limited data from the USA.
232010	Cucumbers	Bromide ion	100	Bromide ion	n.c.	n.c.	1	n.c.	59	76	n.a.	1	1992	no	Based on limited data from the USA.
232030	Courgettes	Bromide ion	200	Bromide ion	n.c.	n.c.	1	n.c.	30	130	n.a.	1	1992	no	Based on limited data from the USA.
241010	Broccoli	Bromide ion	30	Bromide ion	n.c.	n.c.	1	n.c.	14	20	n.a.	1	1992	no	Based on limited data from the USA.
242020	Head cabbage	Bromide ion	100	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979	no	It is unclear whether the proposal is based on actual residue data, or estimated from application rates.
251020	Lettuce	Bromide ion	100	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979	no	It is unclear whether the proposal is based on actual residue data, or estimated from application rates.

Summary of CXLs for bromide ion in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
252010	Spinach	Bromide ion	1000	Bromide ion	n.c.	n.c.	1	n.c.	170	770	n.a.	1	1992	no	CXL database reports 100,000 however it would appear that this is incorrect and the CXL is actually 1000. Based on limited data from the USA.
260010	Beans (fresh, with pods)	Bromide ion	500	Bromide ion	n.c.	n.c.	1	n.c.	13	300	n.a.	1	1992	no	Based on limited data from the USA.
260030	Peas (fresh, with pods)	Bromide ion	500	Bromide ion	n.c.	n.c.	1	n.c.	17	260	n.a.	1	1992	no	Based on limited data from the USA.
270030	Celery	Bromide ion	300	Bromide ion	n.c.	n.c.	1	n.c.	n.c.	178	n.a.	1	1983	no	No GAP details were provided.
500010	Barley grain	Bromide ion	50	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979	no	It is unclear whether the proposal is based on actual residue data, or estimated from application rates.
500020	Buckwheat grain	Bromide ion	50	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979	no	
500030	Maize grain	Bromide ion	50	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979	no	
500040	Millet grain	Bromide ion	50	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979	no	
500050	Oats grain	Bromide ion	50	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979	no	
500060	Rice grain	Bromide ion	50	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979	no	
500070	Rye grain	Bromide ion	50	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979	no	
500080	Sorghum grain	Bromide ion	50	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979	no	
500090	Wheat grain	Bromide ion	50	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979	no	
810000	Spices (seeds)	Bromide ion	400	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	n.k.	no	The origin of these CXLs is unclear. Bromide ion in spices does not appear to have been evaluated by the JMPR in 2004 with other active substanecs.
820000	Spices (fruits and berries)	Bromide ion	400	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	n.k.	no	
830000	Spices (bark)	Bromide ion	400	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	n.k.	no	
840000	Spices (roots and rhizome)	Bromide ion	400	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	n.k.	no	
850000	Spices (buds)	Bromide ion	400	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	n.k.	no	
860000	Spices (flower stigma)	Bromide ion	400	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	n.k.	no	
870000	Spices (aril)	Bromide ion	400	Bromide ion	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	n.k.	no	

APPENDIX B.3 – EXISTING GUIDELINE LEVELS FOR METHYL BROMIDE

Summary of CXLs for methyl bromide in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
120010	Almonds	Methyl Bromide	10	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	Post harves use. GL of 10 applies at point of entry into a country, and in case of cereal for milling, if product has been freely exposed to air for a period of at least 24 h after fumigation and before. A GL of 0.01* also applies to the commodity at point of retail sale or when offered for consumption. This value appears to have been proposed by JMPR 1992 based on the assumption that residues are unlikely to arise from a soil fumigation treatment.
120020	Brazil nuts	Methyl Bromide	10	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
120030	Cashew nuts	Methyl Bromide	10	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
120040	Chestnuts	Methyl Bromide	10	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
120050	Coconuts	Methyl Bromide	10	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
120060	Hazelnuts	Methyl Bromide	10	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
120070	Macadamia	Methyl Bromide	10	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
120080	Pecans	Methyl Bromide	10	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
120090	Pine nuts	Methyl Bromide	10	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
120100	Pistachios	Methyl Bromide	10	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
120110	Walnuts	Methyl Bromide	10	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
401020	Peanuts	Methyl Bromide	10	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	0.01* also applies, see comment for tree nuts.
500010	Barley grain	Methyl Bromide	5	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	Post harves use. GL applies at point of entry into a country, and in case of cereal for milling, if product has been freely exposed to air for a period of at least 24 h after fumigation and before.
500020	Buckwheat grain	Methyl Bromide	5	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
500030	Maize grain	Methyl Bromide	5	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
500040	Millet grain	Methyl Bromide	5	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
500050	Oats grain	Methyl Bromide	5	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
500060	Rice grain	Methyl Bromide	5	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
500070	Rye grain	Methyl Bromide	5	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
500080	Sorghum grain	Methyl Bromide	5	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
500090	Wheat grain	Methyl Bromide	5	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	
640000	Cocoa (fermented beans)	Methyl Bromide	5	Methyl Bromide	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1979-1992	no	Post harves use. GL applies at point of entry into a country, and in case of cereal for milling, if product has been freely exposed to air for a period of at least 24 h after fumigation and before.

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

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DT_{50}	period required for 50 percent dissipation (define method of estimation)
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GC-ECD	gas chromatography with electron capture detection
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOAEL	lowest observed adverse effect level
MRL	maximum residue limit
MS	Member States
NOAEL	no observed adverse effect level
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
RMS	rapporteur Member State
WHO	World Health Organisation