REASONED OPINION OF EFSA

Inclusion of potassium tri-iodide in Annex IV of Regulation (EC) No 396/2005[1]

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2008-724)

Issued on 26 February 2009

SUMMARY

The United Kingdom has received an application from Exponent International Ltd. to establish import tolerances for potassium tri-iodide on bananas, melons and grapes. Although no Rapporteur Member State was appointed for this active substance which is not covered by the peer review under Directive 91/414/EEC, the United Kingdom prepared an evaluation report on this subject which was submitted to the European Commission and forwarded to EFSA on 26 September 2008. In the conclusion the United Kingdom states that it would be unnecessary and inappropriate to establish import tolerances or MRLs for iodine releasing plant protection products. Therefore the United Kingdom recommended to include potassium tri-iodide in Annex IV of Regulation (EC) No 396/2005 as an active substance which should be exempted from the setting of MRLs.

Based on the information available, EFSA derives the following conclusions regarding the application:

No studies regarding the metabolism of potassium tri-iodide have been submitted. Although it is likely that the terminal residue in treated food is iodine, further information on the stability of potassium tri-iodide on treated plants and in soil would be desirable.

Residue trials on bananas, grapes and melons were submitted. For the analytical method used for analysing these supervised field trials no validation data have been provided. In order to confirm the validity of the supervised field trials, this information is indispensible.

Other deficiencies were identified regarding the supervised field trials, in particular for the data submitted for bananas and grapes. Since the trials in bananas were performed at significantly lower dose rates compared with the GAP, the residue concentration of less than 0.008 mg/kg in the harvested product might underestimate the iodine concentration resulting from the use as authorised. The iodine concentration in grapes treated with potassium tri-iodide according to the GAP was in a range of 0.172 to 0.464 mg/kg. However, also the untreated control samples contained significant residue levels (0.223 to 0.4 mg/kg). These

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values are 20 to 40- times higher than the iodine concentrations in grapes reported for untreated grapes in the open literature. Therefore clarification on the high background levels would be required. No residues were measured in melons treated according to the GAP.

A final exposure assessment aiming to estimate whether the use of plant protection product containing potassium-tri-iodide on bananas, melons and grapes contributes significantly to the overall dietary intake of iodine and whether the additional intake is expected to lead to an excess of the recommended upper intake levels, could not be performed because of the lack of reliable residue data. However, EFSA performed a preliminary exposure assessment regarding iodine resulting from food treated with potassium tri-iodide is based on the residue results provided for grapes and melons (0.464 mg/kg and 0.008 mg/kg, respectively). The results for bananas are not included in the calculations because the dose rate used in the trials did not match with the GAP. The intake for adults and children, expressed in terms of the reference value of 130 µg/d and 70 µg/d, respectively, was calculated to be up to 95 % for adults and up to 8.4 % for children. In comparison with the upper intake value of 600 µg/d and 200 µg/d recommended for adults and children, the intake accounts for 19% and 3 %, respectively. The main contributions were related to table and wine grapes.

EFSA concludes that based on the data provided the consumer risk assessment cannot be finalised. In order to estimate the dietary exposure resulting from the use of potassium tri-iodide further validation data regarding the analytical methods used in the supervised field trials and representative field trials according to the GAP are required. If the results of the supervised field trials are confirmed, grapes seem to be a significant source of iodine intake and the need for setting of MRLs should be further considered.

No validated analytical methods for enforcement have been provided. In case the need for setting MRLs is substantiated, analytical methods would be required.

EFSA concludes that the available information do not allow to derive MRL proposals.

The decision whether MRLs should be established or whether an active substance should be included in Annex IV of Regulation 396/2005 is a risk management decision. However, it should be noted that according to Article 5 of this Regulation a pre-condition for an inclusion of a substance is that the compound has been evaluated under Directive 91/414/EEC. For the active substance concerned this condition is not fulfilled.

Key words: potassium tri-iodide, bananas, melons, grapes, MRL application, Regulation (EC) No 396/2005, consumer risk assessment

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party demonstrating a legitimate interest in health, including civil society organisations as well as commercially interested parties may submit an application to set or to modify an MRL in accordance with the provisions of Article 7 of that regulation. In case of applications for import tolerances the applications shall be submitted to the Rapporteur Member State designated pursuant to Directive 91/414/EEC, or if no Rapporteur has been designated, applications shall be made to Member States designated by the Commission according to the comitology procedure as outlined in Article 45(2) of the Regulation.

For potassium tri-iodide no Rapporteur Member State was designated at EU level. The applicant Exponent International Ltd[2] submitted an application to establish import tolerances for potassium tri-iodide to the United Kingdom, hereafter referred to as the Evaluating Member State (EMS). The EMS concluded that the setting of import tolerances for the uses in bananas, grapes and melons is not necessary. Instead the EMS proposed to include the active substance potassium tri-iodide in Annex IV of the Regulation (EC) No 396/2005.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the evaluation report to EFSA on 26 September 2008. No further documentation was provided. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2008-724 and the following subject:

Potassium Tri-Iodide - Application to include the active substance in Annex IV to Regulation (EC) No 396/2005.

TERMS OF REFERENCE

According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the Evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the request to include the active substance potassium tri-iodide in Annex IV of the regulation.

According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. In this particular case the calculated deadline for providing the reasoned opinion is 26 December 2008.

[2] Exponent International Ltd., The Lenz, Hornbeam Park, Harrogate, HG2 8RE, United Kingdom

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Potassium tri-iodide (KI_3) is an active substance which is not covered by the EU review programme according to Directive 91/414/EEC.

Potassium tri-iodide is used in third countries as pesticide to control pests on different crops. According to the information summarised in the evaluation report, it is used as fungicide on bananas (foliar treatment), as soil treatment for the control of nematodes and soil borne pathogens in grapes and melons. The uses refer to two EC formulations (AJ1629 57EC and AJ1629 474EC). No information is provided in which third countries these uses are authorised. In Appendix A the information regarding the GAP is summarised.

In bananas, the product is applied at a rate of 0.0056 kg a.s. per hectare, with up to 32 treatments per crop with an interval of 7 to 21 days.

In grapes a drip irrigation in the spring (about 20 cm vine growth) and after harvest at a rate of 76 kg a.s./ha is authorised. The total amount per hectare is 152 kg per year.

In melons, a pre- and post-planting soil treatment via drench irrigation is authorised with a rate of 1.67 kg a.s/ha (total rate up to 3.3 kg/ha).

Currently, no MRLs are established for this active substance in Regulation 396/2005. Also Codex Alimentarius did not establish MRLs for potassium tri-iodide.

ASSESSMENT

1. Methods of analysis

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

According to the EMS the only residue of concern is iodine. The report prepared by the EMS refers to publicly available analytical methods for iodine without giving further details. No specific analytical methods are available which would allow to distinguish between naturally occurring iodine in food and residues resulting from the use of potassium tri-iodide in plant protection products.

The applicability of the existing analytical methods to measure iodine residues in treated crops for enforcement purposes can not be assessed because no validation data are available. However, if the compound is exempted from the setting of MRLs no analytical methods would be required.

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

No information is provided in the evaluation report.

2. Mammalian toxicology

Iodine is an essential trace element which is required by humans for the synthesis of thyroid hormones, thyroxine (T4) and triiodothyronine (T3) which are iodinated molecules of the essential amino acid tyrosine; they regulate cellular oxidation and hence affect calorigenesis, thermoregulation, and intermediary metabolism.

Iodine occurs in food as inorganic iodide, which is readily and completely absorbed from the gastrointestinal tract. Other forms of iodine in foods are reduced to iodide before absorption. Absorbed iodine is distributed throughout the body via the circulatory system.

Iodine deficiencies stimulate TSH (thyroid stimulating hormone) secretion which results in thyroid hypertrophy. The enlargement of the thyroid gland due to deficiency is called endemic goiter. With severe and prolonged iodine deficiency, the effects of a deficient supply of thyroid hormones may occur. It is characterised by reduced metabolic rate, cold intolerance, weight gain, puffy facial features, edema, a hoarse voice and mental sluggishness. Iodine deficiency during pregnancy, infancy or early childhood may cause endemic cretinism. In order to prevent endemic goiter and the further consequences iodine supplementation programs have been developed in many countries. Iodine is added to salt in several European countries (WHO, 1989).

The nutritional requirement for iodine varies for individuals depending on age. In Table 2-1, a summary of population reference intake values derived by different scientific bodies are given.

Table 2-1: Population reference intake values

Body, year	Age	Iodine
SCF, 1992	1 to 3	70 µg/day
	4 to 6	90 µg/day
	7 to 10	100 µg/day
	11 to 14	120 µg/day
	15 to 17	130 µg/day
	Adults	130 µg/day
	Pregnancy	130 µg/day
	Lactation	160 µg/day
IoM, 2001	1 to 3	90 µg/day
	4 to 8	90 µg/day
	9 to 13	120 µg/day
	14 to 18	150 µg/day
	Pregnancy	220 µg/day
	Lactation	290 µg/day
	Adults	150 µg/day
UK DoH, 1991	1 to 3	70 µg/day
	4 to 6	100 µg/day
	7 to 10	110 µg/day
	11 to 14	130 µg/day
	15 to 17	140 µg/day
	Adults	140 µg/day
	Pregnancy	140 µg/day
	Lactation	140 µg/day

Body, year	Age	Iodine
WHO/FAO, 2002	0-59 months	90 µg/day
	6-12 years	120 µg/day
	13+ years	150 µg/day
	Pregnancy	200 µg/day
	Lactation	200 µg/day
D-A-CH, 2000	1 to 4	100 µg/day
	4 to 7	120 µg/day
	7 to 10	140 µg/day
	10 to 13	180 µg/day
	13 to 51	200 µg/day
	51+	180 µg/day
	Pregnancy	230 µg/day
	Lactation	260 µg/day
NNR, 2004	2 to 5	90 µg/day
	6 to 9	120 µg/day
	10 to 13	150 µg/day
	Adults	150 µg/day
AFSSA, Martin, 2001	1 to 3	80 µg/day
	4 to 6	90 µg/day
	7 to 9	120 µg/day
	10+ years	150 µg/day
	Pregnancy	200 µg/day
	Lactation	200 µg/day

Although iodine is an essential component of the diet, intakes in excess of physiological requirements may produce adverse effects, particularly on the thyroid gland and the regulation of thyroid hormone production and secretion.

The tolerable upper intake levels as derived by different bodies are shown in Table 2-2.

Table 2-2: Tolerable upper intake level in healthy populations (µg / day)

Reference	Age	Iodine
SCF, 2002	1 to 3	200 µg/d
	4 to 6	250 µg/d
	7 to 10	300 µg/d
	11 to 14	450 µg/d
	15 to 17	500 µg/d
	Adults	600 µg/d
	Pregnancy	600 µg/d
	Lactation	600 µg/d
IoM, 2001	1 to 3	200 µg/d
	4 to 8	300 µg/d
	9 to 13	600 µg/d
	14 to 18	900 µg/d
	Pregnancy	900 – 1100 µg/d
	Lactation	900 – 1100 µg/d
	Adults	1100 µg/d

Reference	Age	Iodine
Expert group on Vitamins and Minerals, 2003 (UK EVM)	Insufficient data	0.015 mg/kg/d bw expected to be without adverse effects
WHO/FAO, 2002	Premature	300 µg/kg/d bw
	0–6 months	150 µg/kg/d bw
	7–12 months	140 µg/kg/d bw
	1–6 years	50 µg/kg/d bw
	7–12 years	50 µg/kg/d bw
	13+ years	30 µg/kg/d bw
	Pregnancy	40 µg/kg/d bw
	Lactation	40 µg/kg/d bw

Food sources of iodine that have caused adverse effects include naturally-occurring iodine in water supplies, sea weed, and ground beef containing thyroid tissue. Other food sources of iodine causing adverse effects include those foods to which iodine was added as part of a supplementation program (e.g. iodized water, bread or salt) and milk which contained iodine resulting from feed supplements and iodophor utter disinfectants. Another major sources of iodine that have caused adverse effects are iodine-containing pharmaceuticals (WHO, 1989).

3. Nature and magnitude of residues in plant

3.1. Primary crops

3.1.1. Nature of residues

No metabolism studies have been provided for potassium tri-iodide. In the evaluation report the United Kingdom proposed that the residue of concern is iodine, which is released from the product applied. Further information regarding the stability of the tri-iodide ion after foliar treatment and soil treatment would be desirable to support the assumption that iodine is the main terminate residue.

3.1.2. Magnitude of residues

No information regarding the storage stability of iodine residues in treated corps was submitted. The samples of the supervised field trials were stored below 10° C for a not specified time. Further information regarding storage stability and the storage period would be required in order to conclude on the validity of the results of the supervised field trials.

The samples of the supervised residue studies were analysed with ion selective electrode method for measuring the iodide residues in combusted plant material. The method is capable to measure iodide ions only. Since the residue of concern is iodine, more information should be provided regarding the formation of iodide during the combustion of plant material and the possibility of loss of iodine. Since no validation data are submitted for this method, it is not possible to conclude on the validity of the supervised field trials analysed with this method.

3.1.2.1. Bananas

Two residue trials with a single aerial spray treatment with a dose rate of 0.0057 kg a.s./ha were submitted. Residues were detectable in bananas at 0 and 7 days after treatment (0.053 to 0.065 mg/kg). Four days after treatment no residues above the detection limit of 0.008 mg/kg were found.

According to the authorised GAP, the product can be applied up to 32 times per crop with spray intervals from 7 to 21 days. It is therefore concluded that the submitted residue trials are not representative for the GAP.

Eight supervised field trials representative for the GAP, analysed with validated analytical methods, have to be submitted in order to derive an estimate of the expected residue concentration in treated bananas.

3.1.2.2. Melons

8 supervised field trials with an application rate of 1.65 kg a.s/ha and 2 trials with 0.82 kg/ha were reported. In all cases no iodide residues were detectable (<0.008 mg iodide/kg). Also in untreated control samples the residues were below the limit of detection.

However, since the validity of the analytical method applied is not demonstrated by validation data, the results of these trials need to be confirmed.

3.1.2.3. Grapes

Two residue trials with soil treatment of 75 kg a.s./ha are reported. Additional trials with lower application rates have been performed (0.5N and 0.7N). The residue levels in the trials corresponding to the GAP ranged from 0.172 to 0.464 mg/kg. Also in the untreated control samples concentrations of 0.223 mg/kg and 0.4 mg/kg were observed.

The background level of iodine in grapes is reported to be 0.01 mg/kg (EFSA, 2005). Compared with these data, the residue concentrations in untreated control samples are extremely high and further information should be provided as explanation. It is known that the iodine content of food of plant origin correlates with the iodine concentration in the soil. Therefore further information regarding the iodine concentration in soil on the location of the supervised field trial should be provided in order to conclude whether the submitted supervised field trials data are representative. If potassium tri-iodide was applied already in previous years, a high soil concentration of iodine may be the reason for the elevated residue concentration in untreated control samples.

In order to conclude on the magnitude of residues in treated grapes, 8 supervised field trials, analysed with validated analytical methods, have to be submitted which reflect the intended GAP. Explanations for the elevated iodine concentration in untreated control samples are required.

3.1.3. Effect of industrial processing and/or household preparation

No processing studies are reported in the evaluation report. However, if the residue concentration observed in the supervised trials are confirmed and the concentrations are significantly above the naturally occurring background levels, processing studies, in particular for wine should be performed.

3.1.4. Rotational crops

In case of import tolerances the question of residues in rotational crops is not relevant.

3.2. Nature and magnitude of residues in livestock

The issue of the nature and magnitude of residues in livestock is not relevant since the crops concerned are normally not fed to animals.

4. Consumer risk assessment

It is known that iodine intake via untreated food can vary to a high degree, depending on the types of food consumed and the origin of the food which correlates with the iodine content of the soil. In particular, food of animal origin is recognised as an important source of iodine intake.

EFSA performed a preliminary exposure assessment regarding iodine resulting from food treated with potassium tri-iodide is based on the residue results provided for grapes and melons (0.464 mg/kg and 0.008 mg/kg, respectively). The results for bananas are not included in the calculations because the dose rate used in the trials did not match with the GAP. However, it should be noted that pending the confirmation of the validity of the supervised residue trials the calculations are should be taken only as an indication of the possible exposure; the final risk assessment which can only be concluded if the open issues as explained in the sections above are clarified. The intake is calculated with the food consumption data as reported in the EFSA PRIMo rev. 2 for chronic intake and compared with the reference values for adults and children (1 to 3 years) on the one hand, and the upper levels for these two groups of population on the other hand (SCF, 1992). The body weights for adults and children (1 to 3 years) are estimated as 60 kg and 10 kg, respectively.

The results in the format of the EFSA PRIMo rev. 2 are presented in Appendix B. In table 4-1 the results of the different scenarios are summarised for the two relevant population subgroups.

Table 4-1: Results of the preliminary exposure assessment of adults and children regarding iodine residues in grapes and melons treated with potassium tri-iodide

	Iodine intake resulting from residues on grapes and bananas		
	in % of the reference value		in % of the upper intake value
Adults: 60kg bw; reference value 130 µg/d (SCF, 1992); Upper intake value: 600 µg/d	FR all population	95.40	19.08
	PT General population	64.22	12.84
	WHO Cluster diet B	49.81	9.96
	WHO cluster diet E	40.85	8.17
	IE adult	35.34	7.07
	DK adult	34.15	6.83
	UK Adult	26.31	5.26
	UK vegetarian	20.68	4.14
	NL general	19.95	3.99
	WHO Cluster diet F	16.49	3.30
	WHO cluster diet D	12.82	2.56
	ES adult	10.76	2.15

	WHO regional European diet	9.02	1.80
	FI adult	7.52	1.50
	PL general population	7.43	1.49
	IT adult	3.08	0.62
	LT adult	0.31	0.06
	SE general population 90th percentile	0.02	0.00
Children 10kg bw; reference value 70 µg/d (SCF 1992); Upper intake value: 200 µg/d	DE child	8.42	2.95
	NL child	5.05	1.77
	UK Toddler	1.86	0.65
	FR toddler	1.38	0.48
	DK child	1.24	0.43
	IT kids/toddler	0.71	0.25
	FR infant	0.53	0.18
	ES child	0.30	0.10
	UK Infant	0.28	0.10

The major source of intake was wine grapes for adults and table grapes for children.

Based on the preliminary exposure assessment it is concluded that iodine residues on grapes treated as reported in the evaluation report, are expected to be a significant contributor to the overall dietary intake of iodine, if the residue levels in grapes are confirmed.

CONCLUSIONS AND RECOMMENDATIONS

The United Kingdom has received an application from Exponent International Ltd. to establish import tolerances for potassium tri-iodide on bananas, melons and grapes. Although no Rapporteur Member State was appointed for this active substance which is not covered by the peer review under Directive 91/414/EEC, the United Kingdom prepared an evaluation report on this subject which was submitted to the European Commission and forwarded to EFSA on 26 September 2008. In the conclusion the United Kingdom states that it would be unnecessary and inappropriate to establish import tolerances or MRLs for iodine releasing plant protection products. Therefore the United Kingdom recommended to include potassium tri-iodide in Annex IV of Regulation (EC) No 396/2005 as an active substance which should be exempted from the setting of MRLs.

Based on the information available, EFSA derives the following conclusions regarding the application:

No studies regarding the metabolism of potassium tri-iodide have been submitted. Although it is likely that the terminal residue in treated food is iodine, further information on the stability of potassium tri-iodide on treated plants and in soil would be desirable.

Residue trials on bananas, grapes and melons were submitted. For the analytical method used for analysing these supervised field trials no validation data have been provided. In order to confirm the validity of the supervised field trials, this information is indispensible.

Other deficiencies were identified regarding the supervised field trials, in particular for the data submitted for bananas and grapes. Since the trials in bananas were performed at significantly lower dose rates compared with the GAP, the residue concentration of less than 0.008 mg/kg in the harvested product might underestimate the iodine concentration resulting from the use as authorised. The iodine concentration in grapes treated with potassium tri-iodide according to the GAP was in a range of 0.172 to 0.464 mg/kg. However, also the untreated control samples contained significant residue levels (0.223 to 0.4 mg/kg). These values are 20 to 40- times higher than the iodine concentrations in grapes reported for untreated grapes in the open literature. Therefore clarification on the high background levels would be required. No residues were measured in melons treated according to the GAP.

A final exposure assessment aiming to estimate whether the use of plant protection product containing potassium-tri-iodide on bananas, melons and grapes contributes significantly to the overall dietary intake of iodine and whether the additional intake is expected to lead to an excess of the recommended upper intake levels, could not be performed because of the lack of reliable residue data. However, EFSA performed a preliminary exposure assessment regarding iodine resulting from food treated with potassium tri-iodide is based on the residue results provided for grapes and melons (0.464 mg/kg and 0.008 mg/kg, respectively). The results for bananas are not included in the calculations because the dose rate used in the trials did not match with the GAP. The intake for adults and children, expressed in terms of the reference value of 130 µg/d and 70 µg/d, respectively, was calculated to be up to 95 % for adults and up to 8.4 % for children. In comparison with the upper intake value of 600 µg/d and 200 µg/d recommended for adults and children, the intake accounts for 19% and 3 %, respectively. The main contributions were related to table and wine grapes.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Pesticide(s) (common name(s)) : **Postassium tri-iodide**
Main uses e.g. insecticide, fungicide : **Fungicide, nematicide**
Use Pattern

1	2	3	4	5	6			7			8	9
Crop and / or situation	F,	Pest or	Formulation		Application			Application rate per treatment			PHI	Remarks:
	G or I	group of pests controlled	Type	Conc. of a.i.	method, kind	growth stage	number (range)	kg a.i./hl	water l/ha	kg a.i./ha	(days)	
(a)	(b)	(c)	(d - f)	(i)	(f - h)	(j)					(k)	(l)
GAP for import tolerance												
Bananas	F	Fungal disease	EC	No information	Spraying	No information	32, 7 to 21 d interval			0.0056	No info	
Grapes	F		EC	No information	Drip irrigation	Spring (20 cm vine growth), After harvest	2			76	No infor	
Melons			EC	No information	Drench irrigation	Pre-planting, early post planting (15 d after planting)	2			1.67	No infor	

APPENDIX B – PRELIMINARY INTAKE CALCULATIONS

Iodine

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
reference intake value (mg/kg bw)	**0.007**	ARfD (mg/kg bw):	**n.n.**
Source	**SCF**		
Year of evaluation:	**1992**	Year of evaluation:	

Calculation based on population reference intake values for 1 to 3 year old children (SCF 1992) of 70 µg/d. Assumed body weight 10 kg.
The diets not relevant for children are shaded in grey.

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

Chronic risk assessment

TMDI (range) in % of ADI
minimum - maximum
27

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of reference intake value	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)
27.26	FR all population	26.5	Wine grapes	0.7	Table grapes	0.0	Melons	
18.35	PT General population	16.5	Wine grapes	1.8	Table grapes	0.0	Melons	
14.23	WHO Cluster diet B	11.9	Wine grapes	2.3	Table grapes	0.1	Melons	
11.67	WHO cluster diet E	10.6	Wine grapes	1.0	Table grapes	0.0	Melons	
10.10	IE adult	8.3	Wine grapes	1.7	Table grapes	0.1	Melons	
9.76	DK adult	9.2	Wine grapes	0.5	Table grapes	0.0	Melons	
8.42	DE child	8.4	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
7.52	UK Adult	7.2	Wine grapes	0.3	Table grapes	0.0	Melons	
5.91	UK vegetarian	5.4	Wine grapes	0.5	Table grapes	0.0	Melons	
5.70	NL general	4.2	Wine grapes	1.5	Table grapes	0.0	Melons	
5.05	NL child	5.0	Table grapes	0.0	Melons	0.0	Wine grapes	
4.71	WHO Cluster diet F	4.0	Wine grapes	0.8	Table grapes	0.0	Melons	
3.66	WHO cluster diet D	2.4	Wine grapes	1.3	Table grapes	0.0	Melons	
3.07	ES adult	2.8	Wine grapes	0.3	Table grapes	0.0	Melons	
2.58	WHO regional European diet	1.5	Wine grapes	1.0	Table grapes	0.0	Melons	
2.15	FI adult	2.0	Wine grapes	0.1	Table grapes	0.0	Melons	
2.12	PL general population	2.1	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
1.86	UK Toddler	1.6	Table grapes	0.2	Wine grapes	0.0	Melons	
1.38	FR toddler	1.4	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
1.24	DK child	1.2	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
0.88	IT adult	0.9	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
0.71	IT kids/toddler	0.7	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
0.53	FR infant	0.5	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.30	ES child	0.2	Table grapes	0.0	Wine grapes	0.0	Melons	
0.28	UK Infant	0.2	Table grapes	0.1	Wine grapes	0.0	Melons	
0.09	LT adult	0.1	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.01	SE general population 90th percentile	0.0	Melons		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

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

Iodine

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
reference intake value (mg/kg bw)	**0.002**	ARfD (mg/kg bw):	**n.n.**
Source	**SCF**		
Year of evaluation:	**1992**	Year of evaluation:	

Calculation based on population reference intake values for adult (SCF 1992) of 130 µg/d. Assumed body weight 60 kg.
The diets not relevant for adults are shaded in grey.

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

Chronic risk assessment

TMDI (range) in % of ADI
minimum - maximum
95

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of reference intake value	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
95.40	FR all population	92.8	Wine grapes	2.5	Table grapes	0.1	Melons	
64.22	PT General population	57.7	Wine grapes	6.5	Table grapes	0.0	Melons	
49.81	WHO Cluster diet B	41.6	Wine grapes	8.1	Table grapes	0.2	Melons	
40.85	WHO cluster diet E	37.2	Wine grapes	3.6	Table grapes	0.0	Melons	
35.34	IE adult	29.0	Wine grapes	6.0	Table grapes	0.3	Melons	
34.15	DK adult	32.3	Wine grapes	1.8	Table grapes	0.0	Melons	
29.47	DE child	29.4	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
26.31	UK Adult	25.1	Wine grapes	1.2	Table grapes	0.0	Melons	
20.68	UK vegetarian	18.9	Wine grapes	1.8	Table grapes	0.0	Melons	
19.95	NL general	14.6	Wine grapes	5.3	Table grapes	0.0	Melons	
17.68	NL child	17.6	Table grapes	0.0	Melons	0.0	Wine grapes	
16.49	WHO Cluster diet F	13.8	Wine grapes	2.6	Table grapes	0.0	Melons	
12.82	WHO cluster diet D	8.4	Wine grapes	4.4	Table grapes	0.1	Melons	
10.76	ES adult	9.7	Wine grapes	1.0	Table grapes	0.1	Melons	
9.02	WHO regional European diet	5.3	Wine grapes	3.6	Table grapes	0.1	Melons	
7.52	FI adult	7.1	Wine grapes	0.4	Table grapes	0.0	Melons	
7.43	PL general population	7.4	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
6.52	UK Toddler	5.7	Table grapes	0.8	Wine grapes	0.0	Melons	
4.82	FR toddler	4.8	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
4.32	DK child	4.2	Table grapes	0.1	Melons		FRUIT (FRESH OR FROZEN)	
3.08	IT adult	3.0	Table grapes	0.1	Melons		FRUIT (FRESH OR FROZEN)	
2.48	IT kids/toddler	2.4	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
1.85	FR infant	1.8	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
1.04	ES child	0.8	Table grapes	0.2	Wine grapes	0.1	Melons	
0.98	UK Infant	0.5	Table grapes	0.4	Wine grapes	0.0	Melons	
0.31	LT adult	0.3	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.02	SE general population 90th percentile	0.0	Melons		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

Conclusion:

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

Iodine			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
Upper Intake level (mg/kg bw)	**0.02**	ARfD (mg/kg bw):	**n.n.**
Source	**SCF**		
Year of evaluation:	**2002**	Year of evaluation:	

Calculation based on upper intake level for children (1 to 3 years) (SCF 2002) of 200 µg/d. Assumed body weight 10 kg.
The diets not relevant for children are shaded in grey.

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

Chronic risk assessment

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

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of reference intake value	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)
9.54	FR all population	9.3	Wine grapes	0.3	Table grapes	0.0	Melons	
6.42	PT General population	5.8	Wine grapes	0.6	Table grapes	0.0	Melons	
4.98	WHO Cluster diet B	4.2	Wine grapes	0.8	Table grapes	0.0	Melons	
4.08	WHO cluster diet E	3.7	Wine grapes	0.4	Table grapes	0.0	Melons	
3.53	IE adult	2.9	Wine grapes	0.6	Table grapes	0.0	Melons	
3.41	DK adult	3.2	Wine grapes	0.2	Table grapes	0.0	Melons	
2.95	DE child	2.9	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
2.63	UK Adult	2.5	Wine grapes	0.1	Table grapes	0.0	Melons	
2.07	UK vegetarian	1.9	Wine grapes	0.2	Table grapes	0.0	Melons	
2.00	NL general	1.5	Wine grapes	0.5	Table grapes	0.0	Melons	
1.77	NL child	1.8	Table grapes	0.0	Melons	0.0	Wine grapes	
1.65	WHO Cluster diet F	1.4	Wine grapes	0.3	Table grapes	0.0	Melons	
1.28	WHO cluster diet D	0.8	Wine grapes	0.4	Table grapes	0.0	Melons	
1.08	ES adult	1.0	Wine grapes	0.1	Table grapes	0.0	Melons	
0.90	WHO regional European diet	0.5	Wine grapes	0.4	Table grapes	0.0	Melons	
0.75	FI adult	0.7	Wine grapes	0.0	Table grapes	0.0	Melons	
0.74	PL general population	0.7	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
0.65	UK Toddler	0.6	Table grapes	0.1	Wine grapes	0.0	Melons	
0.48	FR toddler	0.5	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.43	DK child	0.4	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
0.31	IT adult	0.3	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
0.25	IT kids/toddler	0.2	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
0.18	FR infant	0.2	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.10	ES child	0.1	Table grapes	0.0	Wine grapes	0.0	Melons	
0.10	UK Infant	0.1	Table grapes	0.0	Wine grapes	0.0	Melons	
0.03	LT adult	0.0	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.00	SE general population 90th percentile	0.0	Melons		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

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

Iodine

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
Upper intake level (mg/kg bw)	**0.01**	ARfD (mg/kg bw):	**n.n.**
Source	**SCF**		
Year of evaluation:	**2002**	Year of evaluation:	

Calculation based on the upper intake level for adults (SCF 2002) of 600 µg/d. Assumed body weight 60 kg.
The diets not relevant for adults are shaded in grey.

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

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum	
	19
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of reference intake value	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)
19.08	FR all population	18.6	Wine grapes	0.5	Table grapes	0.0	Melons	
12.84	PT General population	11.5	Wine grapes	1.3	Table grapes	0.0	Melons	
9.96	WHO Cluster diet B	8.3	Wine grapes	1.6	Table grapes	0.0	Melons	
8.17	WHO cluster diet E	7.4	Wine grapes	0.7	Table grapes	0.0	Melons	
7.07	IE adult	5.8	Wine grapes	1.2	Table grapes	0.1	Melons	
6.83	DK adult	6.5	Wine grapes	0.4	Table grapes	0.0	Melons	
5.89	DE child	5.9	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
5.26	UK Adult	5.0	Wine grapes	0.2	Table grapes	0.0	Melons	
4.14	UK vegetarian	3.8	Wine grapes	0.4	Table grapes	0.0	Melons	
3.99	NL general	2.9	Wine grapes	1.1	Table grapes	0.0	Melons	
3.54	NL child	3.5	Table grapes	0.0	Melons	0.0	Wine grapes	
3.30	WHO Cluster diet F	2.8	Wine grapes	0.5	Table grapes	0.0	Melons	
2.56	WHO cluster diet D	1.7	Wine grapes	0.9	Table grapes	0.0	Melons	
2.15	ES adult	1.9	Wine grapes	0.2	Table grapes	0.0	Melons	
1.80	WHO regional European diet	1.1	Wine grapes	0.7	Table grapes	0.0	Melons	
1.50	FI adult	1.4	Wine grapes	0.1	Table grapes	0.0	Melons	
1.49	PL general population	1.5	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
1.30	UK Toddler	1.1	Table grapes	0.2	Wine grapes	0.0	Melons	
0.96	FR toddler	1.0	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.86	DK child	0.8	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
0.62	IT adult	0.6	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
0.50	IT kids/toddler	0.5	Table grapes	0.0	Melons		FRUIT (FRESH OR FROZEN)	
0.37	FR infant	0.4	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.21	ES child	0.2	Table grapes	0.0	Wine grapes	0.0	Melons	
0.20	UK Infant	0.1	Table grapes	0.1	Wine grapes	0.0	Melons	
0.06	LT adult	0.1	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.00	SE general population 90th percentile	0.0	Melons		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

Conclusion:

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

GLOSSARY / ABBREVIATIONS

ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
CXL	Codex Maximum Residue Limit
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
GAP	Good Agricultural Practice
HR	Highest Residue
ILV	Independent Laboratory Validation
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOD	Limit of Detection
LOQ	Limit Of Quantification
MRL	Maximum Residue Limit.
PHI	Pre Harvest Interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
STMR	Supervised Trials Median Residue
TMDI	Theoretical Maximum Daily Intake
UL	Upper Level of Intake