REASONED OPINION

Setting of new MRLs for amisulbrom in wine and table grapes[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, The United Kingdom, hereafter referred to as the Evaluating Member State (EMS), received an application from Nissan Chemical Europe S.A.R.L. to set new MRLs for amisulbrom in table and wine grapes. In order to accommodate for a new use of amisulbrom in Spain, Italy, Germany, Austria and Portugal, it is proposed to set MRLs in table and wine grapes at 0.3 mg/kg. The United Kingdom drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 8 July 2009. It should be noted that amisulbrom is considered as a new active substance and the peer review process of amisulbrom has not yet been finalized by EFSA.

Based on this evaluation report and the Draft Assessment Report (DAR) prepared by The United Kingdom as the designated Rapporteur Member State (RMS) under Directive 91/414/EEC, EFSA derived the following conclusions regarding this application.

The toxicological properties of amisulbrom have been investigated by the manufacturer. The RMS considered them as sufficient to derive an ADI value of 0.098 mg/kg bw/d. Because of its acute toxicity profile, an ARfD of 0.3 mg/kg bw was proposed by the RMS.

Metabolism of amisulbrom was investigated in grapes and in potatoes after foliar application. Studies indicate extensive metabolism of amisulbrom in the plants yielding a wide range of metabolites, but none of them, including triazole derivative metabolites, were present in significant amounts. Based on metabolism studies, EFSA proposes parent amisulbrom as the residue definition for risk assessment and enforcement for crops like grapes belonging to the group of fruits and fruiting vegetables and root and tuber vegetables. A validated multi-residue method for enforcement of amisulbrom in high acid commodities is available with the LOQ of 0.01 mg/kg. A sufficient number of supervised residue field trials performed according to the proposed GAP were submitted to demonstrate that a MRL of 0.3 mg/kg would be required.

Amisulbrom residues in rotational crops were not investigated since grapevines are a perennial crop. Also the nature and magnitude of amisulbrom residues in the livestock was not investigated considering that grapes are not a livestock feeding item.

Hydrolyses studies demonstrate that under conditions simulating boiling, brewing, baking and sterilisation, amisulbrom is hydrolysed to the toxicologically relevant degradation product 3-bromo-6-

1 On request from the European Commission, Question No EFSA-Q-2009-00699, issued on 12 October 2009.
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For citation purposes: European Food Safety Authority; Setting of new MRLs for amisulbrom in wine and table grapes on request from the European Commission. EFSA Journal 2009; 7(10):1349. [20 pp.]. doi:10.2903/j.efsa.2009.1349. Available online: www.efsa.europa.eu

fluoro-2-methyl-1-(1*H*-1,2,4-triazol-3-ylsulfonyl)indole (IT-4). At a lower temperature and pH (90°C, pH4), amisulbrom can be considered as stable. Since metabolite IT-4 accounts for a high proportion of the applied radioactivity, it should be included in the residue definition for processed commodities which undergo boiling, brewing, baking or sterilizations. However, this extended residue definition is of no relevance for grapes for which heat treatment is limited to pasteurization of juice and heating of the grape mash in the production of red wine (maximum 60°C).

Processing studies investigating the magnitude of residues in pasteurized grape juice and raisins are available which allowed deriving the following processing factors:

- Grapes, pasteurized juice: 0.1
- Grapes, raisins: 2.3
- Grapes, wine: 0.01

The consumer intake assessment was performed with revision 2 of EFSA PRIMo to estimate the consumer exposure to amisulbrom residues. For the chronic intake assessment the STMR as derived from the supervised field trials was used as an input value for table and wine grapes. For the acute intake assessment, the HR value from the supervised residue field trials was used as an input value. Currently no MRLs are set for amisulbrom at the Community level and therefore the consumer intake assessment was performed only with regard to the intake of grapes treated with amisulbrom.

No long-term intake concerns were identified for any of the European diets. The total calculated intake values for table and wine grapes accounted for a maximum of 0.12% of the ADI.

No acute intake concerns were identified for table grapes as the estimated intake of amisulbrom residues accounted for a maximum of 5% of the ARfD. The short-term adult consumer exposure to amisulbrom residues from wine grapes accounted for 0.0127% of the ARfD.

Provisionally EFSA concludes that the intended use of amisulbrom on grapes is acceptable with regard to consumer safety.

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Amisulbrom			
Table and wine grapes	Not set. Default MRL of 0.01 mg/kg is applicable.	Provisional 0.3	Provisional risk assessment did not identify consumer health concerns with regard to the intended use.

As the DAR has not yet been peer reviewed by EFSA, the conclusions reached in this reasoned opinion have to be considered as provisional and might be reconsidered in the light of the outcome of the peer review.

KEY WORDS

Amisulbrom, table and wine grapes, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, triazole, sulphonamide fungicide

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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 requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

The United Kingdom, hereafter referred to as the evaluating Member State (EMS), received an application from the company Nissan Chemical Europe S.A.R.L.[3] to set the MRL for the active substance amisulbrom in table and wine grapes. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 8 July 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00699 and the following subject:

Amisulbrom - Application to set new MRL for amisulbrom in table and wine grapes at 0.3 mg/kg.

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

TERMS OF REFERENCE

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

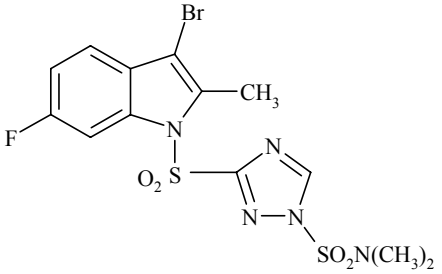
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 8 October 2009.

3 Nissan Chemical Europe S.A.R.L., Parc d`Affaires de Crecy, 2 rue Claude Chappe, 69370, Saint Didier au Mont d`Or, France

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Amisulbrom is the ISO common name for 3-(3-bromo-6-fluoro-2-methylindol-1-ylsulfonyl)-*N*,*N*-dimethyl-1,2,4-triazole-1-sulfonamide (IUPAC):



Amisulbrom is a triazole fungicide. It acts by inhibiting the mitochondrial respiration of fungi. It is used against plant pathogens belonging to the class of *Oomycetes*.

Amisulbrom will be evaluated in the framework of the Directive 91/414/EEC as a new active substance, the United Kingdom is the designated rapporteur Member State. The representative uses supported for the peer review process are foliar application of amisulbrom on grapes and potatoes. The peer review of the active substance by EFSA is currently in the early stage and a final decision concerning an inclusion in Annex I of the Directive is not expected within the next months. The Draft Assessment Report (DAR) has been submitted to EFSA in July 2008.

Since for amisulbrom no specific MRLs have been established in Regulation (EC) No 396/2005, currently the default MRL of 0.01 mg/kg is applicable. Codex Alimentarius has not set CXLs for amisulbron since it has not yet been evaluated by the JMPR.

The applicant now requests the provisional authorization for amisulbrom on table and wine grapes in Austria, Italy, Spain, Germany and Portugal. The active substance will be applied four times per season at an application rate of 0.075 kg a.s./ha at a growth stage of BBCH 12-83. The minimum waiting period is 28 days. The detailed overview of the proposed GAP is provided in Appendix A.

It should be noted that the EMS did not provide information whether provisional authorisations according to the GAPs have already been requested in the EU Member States concerned – Austria, Italy, Spain, Germany and Portugal.

EFSA bases its risk assessment on the evaluation report submitted by the EMS The United Kingdom (2009) and the Draft Assessment Report prepared under Directive 91/414/EEC (The United Kingdom, 2008).

Since the DAR has not yet been peer reviewed, the conclusions reached in this reasoned opinion have to be taken as provisional and might be reconsidered in the light of the outcome of the peer review of the active substance under Directive 91/414/EEC.

ASSESSMENT

1. Methods of analysis

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

An analytical method for the determination of amisulbrom in grapes is reported in the DAR (The United Kingdom, 2008). The multi residue method for the determination of amisulbrom in matrices with high acid content has been sufficiently validated at the LOQ of 0.01 mg/kg. Residues of amisulbrom are extracted with acetonitrile/water, cleaned up on a SPE column and determined by LC-MS/MS.

EFSA concludes that there is an adequate analytical method available to control the compliance of the proposed MRL in grapes.

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

Grapes are not used as a livestock feed and therefore the availability of analytical enforcement methods was not investigated under the current application.

2. Mammalian toxicology

The toxicological reference values for amisulbrom as derived by the RMS in the DAR (The United Kingdom, 2008) are compiled in the table below:

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Amisulbrom					
ADI	DAR	2008	0.098 mg/kg bw/d	Multigeneration	100
ARfD	DAR	2008	0.3 mg/kg bw	Rabbit developmental	100

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The nature of amisulbrom residues in primary plants was investigated in potatoes and grapes and the respective studies are reported in the DAR (The United Kingdom, 2008). The studies were performed in accordance with the following conditions:

- grapes (fruit and fruiting vegetables): foliar application 4 x 0.075 kg a.s/ha and 4 x 0.0914 - 0.096 kg a.s./ha

- potatoes (root and tuber vegetables): foliar application 5 x 0.10 kg a.s./ha.

Metabolism studies were performed using ^{14}C-indole (indole study) and ^{14}C-triazole (triazole study) labelled amisulbrom.

Treated grape bunches were sampled 3 hours and 28 hours after last application. Immediately after the application the TRR in grapes was 0.251 mg/kg (indole study) and 0.364 mg/kg (triazole study). 28 DAT the TRR accounted for 0.319 mg/kg (indole study) and 0.231 mg/kg (triazole study). Significantly higher TRR levels were found in foliage 28 DAT, accounting for 3.019 mg/kg (indole study) and 3.576 mg/kg (triazole study). The majority of residue could be removed from the surface of grapes with acetonitrile and the relative proportion of radiolabelled material in the surface wash decreased between the last application and harvest, indicating that amisulbrom penetrates fruit.

At each sampling the majority of the TRR in grapes was parent amisulbrom accounting for 67% TRR (0.22 mg/kg, indole study) and 70% TRR (0.16 mg/kg triazole study). There were also several metabolites present, none of them exceeding 2.3% TRR, except IT-9[4] which was present at 3% TRR (0.01 mg/kg, indole study). Only in the triazole study triazole derivative metabolites were identified: triazole acetic acid (T-6)[5] which accounted for 0.6% TRR (0.001 mg/kg), triazole alanine[6] which accounted for 2% TRR (0.005 mg/kg) and 1,2,4-triazole[7] which accounted for up to 0.9% TRR (0.002 mg/kg). There were also up to 26 unidentified metabolites and polar material distributed between the surface washes, organo-soluble extracts and aqueous extracts – these metabolites in total accounted for 4% TRR (0.012 mg/kg indole study) and 13%TRR (0.03 mg/kg triazole study) in grapes. The levels of individual metabolites were all ≤2% TRR (0.005 mg/kg) except one polar metabolite which was present at 5% TRR. It was concluded in the DAR that all unidentified metabolites were below 10% TRR and represent very small absolute amounts.

In grape foliage the majority of residue was amisulbrom accounting for 35-38% TRR (1.07-1.4 mg/kg). A wide range of metabolites similarly to grapes was identified but none of them exceeded 10% TRR. The metabolite IT-9 was again the highest individual metabolite in the foliage accounting for up to 7.1 % TRR (0.213 mg/kg, indole study). Levels of triazole derivative metabolites were below 0.8% TRR (0.03 mg/kg).

The metabolism of amisulbrom in grapes involves a complex series of reactions including cleavage of the sulfonamide side chain on the triazole ring, debromination, oxidation/hydroxylation, cleavage of the sulfonyl bridge between indole and triazole moieties, indole ring opening and reaction of triazole with L-serine.

In mature potato tubers, the TRR was low accounting for 0.006 mg/kg (indole study) and 0.022 mg/kg (triazole study). The majority of this radioactivity was extractable (82.2% TRR) and was largely water soluble (60.1% TRR). In potato foliage the majority of radioactivity was in acetonitrile surface washes (72.3% TRR or 2.251 mg/kg (indole study) and 77.0% TRR or 4.651 mg/kg (triazole study)). Amisulbrom was the major radioactive residue in foliage at harvest, accounting for 74.8% TRR (2.329 mg/kg) and 77.9% TRR (4.701 mg/kg) in indole and triazole study, respectively. Results indicate that amisulbrom penetrates the plant matrices over time.

Finally, it was concluded that the only relevant residue in grapes and potatoes is parent amisulbrom and the residue definition for risk assessment and enforcement should be set as parent amisulbrom only. Metabolism study results indicate that the concentrations of triazole derivative metabolites in grapes will be low.

[4] IT-9: 2-[(1-*N*,*N*-dimethylaminosulfonyl-1,2,4-triazol-3-yl)sulfonylamino]-4-fluorobenzoic acid
[5] Triazole acetic acid (T-6): 2-(1,2,4-triazol-1-yl)acetic acid
[6] Triazole alanine: 2-amino-3-(1,2,4-triazol-1-yl)propanoic acid
[7] 1H-1,2,4-triazole

3.1.1.2. Magnitude of residues

In support of the intended GAP for table and wine grapes, the applicant submitted nine supervised residue field trials on wine grapes (red and white grape varieties), reflecting the NEU use and nine residue trials reflecting the SEU use. The supervised field trials were performed over two seasons in 2003 and 2004 in France (9 trials), Germany (4 trials), Spain (3 trails) and Italy (2 trials). The number of residue trials is sufficient to derive risk assessment values and the MRL proposal. A summary of residue trials data is available in Table 3-1.

The storage stability of amisulbrom residues under freezer conditions (approximately -18°C) was confirmed in grapes and potatoes for at least 12 months and in processed fractions of grapes for at least 6 months. In addition, the stability of amisulbrom in the final extracts of grapes and potatos was confirmed for at least 8 days under freezer storage conditions (The United Kingdom, 2008). The supervised field trials samples prior analyses were stored –18°C for a maximum of 137 days (ca. 4.5 months) meaning that the freezer storage stability of amisulbrom in grapes over this time period has been demonstrated.

Amisulbrom residues in the supervised field trial samples were determined using the validated method NAS 490/042294 where quantification was performed with LC-MS/MS. The achievable LOQ was 0.01 mg/kg. It is concluded that the method is satisfactory validated and fit for purpose.

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

Commodity	Region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) [(b)]	HR (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement (amisulbrom)	Risk assessment (amisulbrom)					
Amisulbrom									
Wine grapes → table and wine grapes	NEU	Outdoor	3 x 0.03; 2 x 0.05; 0.1; 0.11; 0.12; 0.22	3 x 0.03; 2 x 0.05; 0.1; 0.11; 0.12; 0.22	0.05	0.22	0.3	1.0	R_{ber}=0.23 mg/kg R_{max}=0.27 mg/kg
	SEU	Outdoor	0.05; 3 x 0.08; 0.09; 0.1; 0.11; 0.12; 0.23	0.05; 3 x 0.08; 0.09; 0.1; 0.11; 0.12; 0.23	**0.095**	**0.23**	**0.3**	**1.0**	R_{ber}=0.24mg/kg R_{max}=0.28 mg/kg

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

3.1.1.3. Effect of industrial processing and/or household preparation

The effects of the processing on the nature of residues have been investigated in a hydrolysis study simulating pasteurization, sterilisation, baking, brewing and boiling (The United Kingdom, 2008). ^{14}C-indole and ^{14}C-triazole labelled amisulbrom was used in test solutions.

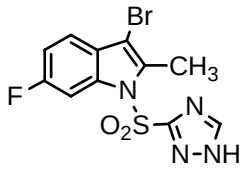
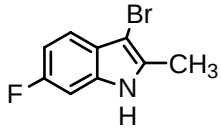
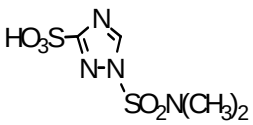
Under conditions simulating pasteurization (pH 4, 90ºC, 20 min.), amisulbrom was slightly hydrolysed, forming IT-4[8] at 8.5% of the AR.

Under conditions simulating baking, brewing and boiling (pH 5, 100ºC for 60 min.), amisulbrom was partially hydrolysed, with the formation of IT-4 (approx. 45% of the applied radioactivity (AR)). Under conditions simulating sterilisation (pH 6, 120ºC for 20 min.), amisulbrom was extensively hydrolysed, with the formation of IT-4, I-1[9] and T-1[10] at approximately 58%, 35% and 18% AR, respectively. Study results indicate a significant degradation of amisulbrom with increasing temperatures and pH. According to the toxicity studies reported in the DAR, IT-4 is a major rat metabolism product (21.8% in plasma) for which the RMS assumes that its acute toxic properties might be higher than for parent amisulbrom (The United Kingdom, 2008).

Since metabolite IT-4 accounts for a high proportion of the AR, the RMS proposed to set the residue definition for processed commodities which undergo boiling, brewing, baking and sterilizations as "the sum of amisulbrom and IT-4". Pasteurization does not result in a significant degradation of amisulbrom; therefore the residue definition is not applicable to pasteurized products.

According to the EU Guidance document 7035/VI/95 rev.5, grapes may undergo pasteurization (juice production) and heating of grape mash in the production of red wine (2 minutes at 60°C) (European Commission, 1997). Therefore EFSA considers that the residue definition for processed grape products should only include the parent compound.

Table 3-2. Compounds identified in hydrolysis of amisulbrom

IT-4 3-bromo-6-fluoro-2-methyl-1-(1*H*-1,2,4-triazol-3-ylsulfonyl)indole	
I-1 3-bromo-6-fluoro-2-methylindole	
T-1 1-(*N*,*N*-dimethylaminosulfonyl)-1,2,4-triazole-3-sulfonic acid	

The studies on the effects of processing on the magnitude of residues in wine, grape juice and raisins are available and have been reported in the DAR (The United Kingdom, 2008). Grapes were obtained from commercially productive vineyards, treated four times at an application rate of 0.075 kg a.s./ha

[8] IT-4: 3-bromo-6-fluoro-2-methyl-1-(1*H*-1,2,4-triazol-3-ylsulfonyl)indole
[9] I-1: 3-bromo-6-fluoro-2-methylindole *(CAS No and CA name not allocated)*
[10] T-1: 1-(*N*,*N*-dimethylaminosulfonyl)-1,2,4-triazole-3-sulfonic acid (*CAS No and CA name not allocated)*

and 0.1875 kg a.s./ha. Samples were taken 28 DAT, according to the intended GAP. The residues in the unprocessed grapes ranged from 0.277 to 1.43 mg/kg.

In young and stored wine no residues above the limit of detection or limit of quantification were measurable. Thus, a theoretical worst case processing factor of 0.01 is calculated. Also in grape juice a significant reduction of residues was observed. In raisins, however, higher residues compared with the raw unprocessed grapes were observed. The processing factors derived are summarised in table 3-3.

Table 3-3. Overview of the available processing studies

Processed commodity	No. of studies	Median PF [(a)]	Median CF [(b)]	Comments
Amisulbrom				
Grapes, pasteurised juice	5	0.1	1.0	In two trials residues in pasteurized juice were < LOQ of 0.01 mg/kg.
Grapes, raisins	5	2.3	1.0	
Grapes, wine	5	0.01	1.0	Young wine after filtration and stored wine: in 4 trials, respectively, the residues were below the limit of detection, in one trial the residues were below the limit of quantification.

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

These processing factors are recommended to be included in Annex VI of Regulation (EC) No. 396/2005.

3.1.2. Rotational crops

Grapevines are a perennial crop. Therefore the nature and magnitude of amisulbrom residues in rotational crops was not investigated under the current application.

3.2. Nature and magnitude of residues in livestock

Grapes are not used as a livestock feeding stuff; therefore the nature and magnitude of amisulbrom residues in livestock was not investigated under the current application.

4. Consumer risk assessment

A provisional consumer intake assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment of table grapes, the STMR value as derived from the supervised field trials on grapes was used as input value; the acute intake assessment was performed with the HR value identified in the supervised residue field trials.

For wine grapes the consumption is expressed as unprocessed wine grapes and therefore was re-calculated to wine by applying a yield factor of 0.7 (1 kg of grapes is needed to produce 0.7 kg of wine). The acute exposure is then calculated on the basis of the HR multiplied with the processing factor for wine (0.01, see 3.1.1.3). For the chronic exposure the wine yield factor, the STMR value and the processing factor are inserted in the EFSA PRIMo.

Currently no MRLs are set for amisulbrom at the Community level. Consequently, the consumer intake assessment was performed only with regard to the intake of grapes.

Input values are summarized in the Table 4-1.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Amisulbrom				
Table grapes	0.095	STMR	0.23	HR
Wine grapes	0.001	STMR*yield factor for wine*processing factor	0.0016	HR * yield factor * processing factor

The summary of consumer intake calculations is available in Appendix B.

No long-term intake concerns were identified for any of the European diets. The total calculated intake values for table and wine grapes accounted for a maximum of 0.12% of the ADI.

No acute intake concerns were identified for table grapes as the estimated intake of amisulbrom residues accounted for a maximum of 5% of the ARfD. The short-term adult consumer exposure to amisulbrom residues from wine grapes accounted for 0.0127% of the ARfD.

Provisionally EFSA concludes that the intended use of amisulbrom on grapes is acceptable with regard to consumer safety. However, the risk assessment has to be revised in case the peer review derives different conclusions compared with those used in the framework of this MRL application.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological properties of amisulbrom have been investigated by the manufacturer. The RMS considered them as sufficient to derive an ADI value of 0.098 mg/kg bw/d. Because of its acute toxicity profile an ARfD of 0.3 mg/kg bw was proposed by the RMS.

Metabolism of amisulbrom was investigated in grapes and in potatoes after foliar application. Studies indicate extensive metabolism of amisulbrom in the plants yielding a wide range of metabolites, but none of them, including triazole derivative metabolites, were present in significant amounts. Shortly after application, amisulbrom residues can be washed off the surface, but over time amisulbrom penetrates plant matrices. Based on metabolism studies, EFSA proposes parent amisulbrom as the residue definition for risk assessment and enforcement for crops belonging to the group of fruits and fruiting vegetables and root and tuber vegetables. A validated multi-residue method for enforcement of amisulbrom in high acid commodities is available with the LOQ of 0.01 mg/kg.

A sufficient number of supervised residue field trials performed according to the proposed GAP were submitted to demonstrate that a MRL of 0.3 mg/kg would be required.

Amisulbrom residues in rotational crops were not investigated since grapevines are a perennial crop. Also the nature and magnitude of amisulbrom residues in the livestock was not investigated considering that grapes are not a livestock feeding item.

Hydrolyses studies demonstrate that under conditions simulating boiling, brewing, baking and sterilisation, amisulbrom is hydrolysed to the toxicologically relevant degradation product 3-bromo-6-fluoro-2-methyl-1-(1*H*-1,2,4-triazol-3-ylsulfonyl)indole (IT-4). At a lower temperature and pH (90°C, pH4), amisulbrom can be considered as stable. Since metabolite IT-4 accounts for a high proportion of the applied radioactivity, it should be included in the residue definition for processed commodities which undergo boiling, brewing, baking or sterilization. However, this extended residue definition is of no relevance for grapes since heat treatment of grapes is limited to pasteurization of juice and heating of the grape mash in the production of red wine (maximum 60°C).

Processing studies investigating the magnitude of residues in pasteurized grape juice and raisins are available which allowed deriving the following processing factors:

- Grapes, pasteurized juice: 0.1
- Grapes, raisins: 2.3
- Grapes, wine: 0.01

The consumer intake assessment was performed with revision 2 of EFSA PRIMo to estimate the consumer exposure to amisulbrom residues. For the chronic intake assessment the STMR as derived from the supervised field trials was used as an input value for table and wine grapes. For the acute intake assessment, the HR value from the supervised residue field trials was used as an input value. Currently no MRLs are set for amisulbrom at the Community level and therefore the consumer intake assessment was performed only with regard to the intake of grapes treated with amisulbrom.

No long-term intake concerns were identified for any of the European diets. The total calculated intake values for grapes accounted for a maximum of 0.12% of the ADI.

No acute intake concerns were identified as the estimated intake of amisulbrom residues from the table grapes accounted for a maximum of 5% of the ARfD. The short-term adult consumer exposure to amisulbrom residues from wine grapes accounted for 0.0127% of the ARfD.

Provisionally EFSA concludes that the intended use of amisulbrom on grapes is acceptable with regard to consumer safety.

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Amisulbrom			
Table and wine grapes	Not set. Default MRL of 0.01 mg/kg is applicable.	Provisional 0.3	Provisional risk assessment did not identify consumer health concerns with regard to the intended use.

As the DAR has not yet been peer reviewed by EFSA, the conclusions reached in this reasoned opinion have to be considered as provisional and might be reconsidered in the light of the outcome of the peer review.

REFERENCES

The United Kingdom, 2009. Evaluation report on the setting of new MRLs for amisulbrom in table and wine grape prepared by the evaluating Member State The United Kingdom under Article 8 of Regulation (EC) No 396/2005, July, 2009.

The United Kingdom, 2008. Draft Assessment Report (DAR) on the active substance amisulbrom prepared by the rapporteur Member State The United Kingdom in the framework of Directive 91/414/EEC, July, 2008.

European Commission, 1997. Appendix E - Processing studies. 7035/VI/95 rev.5., 22 July 1997

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Crop and/or situation	Member State or Country	F G or I	Pests or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)
				Type	Conc. of as	method kind	growth stage & season	No. min/ max	kg as/hL	water l/ha	kg as/ha min max	
Grapes	NEU: Austria Germany SEU: Italy Spain Portugal	F	Downy mildew (*Plasomopara viticola)*	SC	200 g/L	Tractor mounted/ trailed vineyard air blast sprayer	BBCH 12-83 (spring-summer)	4	0.0075-0.05	150-1000	max. 0.075	28

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Amisulbrom			
Status of the active substance:	NAS	Code no.	#N/A
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.098	ARfD (mg/kg bw):	0.3
Source of ADI:	DAR	Source of ARfD:	DAR
Year of evaluation:	2008	Year of evaluation:	2008

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum

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)
0.12	DE child	0.12	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.07	NL child	0.07	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.03	WHO Cluster diet B	0.03	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.03	PL general population	0.03	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.03	PT General population	0.03	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.03	IE adult	0.03	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.02	UK Toddler	0.02	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.02	NL general	0.02	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.02	FR toddler	0.02	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.02	WHO cluster diet D	0.02	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.02	DK child	0.02	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.02	WHO cluster diet E	0.01	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.02	WHO regional European diet	0.01	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.01	FR all population	0.01	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.01	IT adult	0.01	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.01	WHO Cluster diet F	0.01	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.01	IT kids/toddler	0.01	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.01	DK adult	0.01	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.01	UK vegetarian	0.01	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.01	FR infant	0.01	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.01	UK Adult	0.00	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.00	ES adult	0.00	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.00	ES child	0.00	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.00	UK Infant	0.00	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.00	FI adult	0.00	Table grapes	0.00	Wine grapes		FRUIT (FRESH OR FROZEN)	
0.00	LT adult	0.00	Table grapes		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	SE general population 90th percentile		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

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

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

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

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

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
5.0	Table grapes	0.23 / -	5.0	Table grapes	0.23 / -	2.4	Table grapes	0.23 / -	2.4	Table grapes	0.23 / -
0.0042	Wine grapes	0.00161 / -	0.0042	Wine grapes	0.00161 / -	0.0127	Wine grapes	0.00161 / -	0.0127	Wine grapes	0.00161 / -
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)			
0.104	Grape juice	0.0095 / -				0.030	Raisins	0.2185 / -			
0.030	Grapes (raisins)	0.2185 / -				0.001	Wine	0.000665 / -			
0.000	Wine	0.000665 / -									

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

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

APPENDIX C – EXISTING EC MRLS

European Community MRLs for amisulbrom are currently not established.

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
Bw	body weight
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
dw	dry weight
EC	European Community
EDI	estimated daily intake
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre
LC	liquid chromatography
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level

LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10^{-6})
PRIMo	Pesticide Residues Intake Model
RMS	rapporteur Member State
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organisation