

REASONED OPINION OF EFSA

Modification of the existing MRL for aminopyralid in bovine kidney¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2008-726)

Issued on 05 June 2009

SUMMARY

According to Article 6(2) of Regulation (EC) No 396/2005, The United Kingdom received an application from the company Dow AgroSciences Limited to modify the existing MRL aminopyralid in bovine kidneys. Based on the use of aminopyralid in pasture, the applicant proposed to raise the existing MRL, which is currently set at the analytical limit of quantification of 0.01 mg/kg, to 0.3 mg/kg. The subsequent evaluation report drafted by The United Kingdom was forwarded to EFSA on 26 September 2008 according to Article 9 of the Regulation. On 04 December 2008 some data requirements were identified, which prevented EFSA to conclude on the consumer risk assessment. An updated evaluation report, addressing those data requirements, was submitted on 14 May 2009. In this updated evaluation report, the supported use for pasture was modified and the subsequent MRL proposal from the company was lowered to 0.1 mg/kg.

Based on the above mentioned evaluation report as well as the Draft Assessment Report (DAR) prepared by the Rapporteur Member State (RMS) The United Kingdom under Directive 91/414/EEC, EFSA derives the following conclusions regarding the application. As the DAR has not yet been fully peer reviewed by EFSA at this stage, conclusions reached in this reasoned opinion are temporary and might be reconsidered after finalization of the peer review.

Metabolism of aminopyralid was investigated for post-emergence applications in grass and cereals, where aminopyralid and its conjugates were demonstrated to be the main components of the residue. Awaiting the peer review to be finalized on this issue, it is proposed in the framework of this application to define the relevant residue in grasses and cereals as the sum of aminopyralid and its conjugates expressed as aminopyralid. An analytical method for enforcement of this residue definition was also validated. Additionally, a sufficient amount of supervised residues trials supporting the authorized use in pasture was made available. These trials allowed EFSA to estimate the expected residue concentrations in grass and to derive a tentative MRL in view of the future need to set MRLs in feed items.

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Considering that the use of aminopyralid in The United Kingdom is restricted to pastures that are not intended for production of hay or silage, the effect of processing was not investigated in the framework of this application. Also the occurrence of residues in rotational crops was not discussed as pastures are not commonly rotated with other crops.

Based on the expected residue concentrations in grass, EFSA identified significant exposure of dairy and meat ruminants to aminopyralid residues. Metabolism in ruminants and poultry was investigated and based on the available studies the relevant residue for all commodities of animal origin was defined as aminopyralid. An analytical method for enforcement of this residue definition was also validated. Considering the expected dietary burden for ruminants and the livestock feeding study that was made available, a higher MRL was proposed for bovine kidneys. There is no need to modify the other existing MRLs for aminopyralid in commodities of animal origin.

Finally, chronic and acute intake calculations were performed considering the new proposed MRL for bovine kidneys as well as all the existing MRLs in plant and animal commodities. The calculations are based on revision 2 of the EFSA PRIMo and no exceedances of the ADI or ARfD were identified. The highest chronic exposure was calculated for Dutch child, representing 0.5% of the ADI. The highest acute exposure was calculated for milk and milk products, representing 1.0% of the ARfD. It is therefore concluded that the proposed use of aminopyralid in grass is not expected to pose any risk with regard to consumer exposure and that the proposed MRL for bovine kidney is acceptable.

EFSA recommendations resulting from the assessment are summarized in the table below. In view of the future need to set MRLs for feed items, a tentative MRL is also derived for grass which might be included in Annex I to Regulation (EC) No 396/2005.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
<i>Residue definition for enforcement: sum of aminopyralid and its conjugates, expressed as aminopyralid</i>			
Grass	-	4	Tentative MRL (in view of future need to set MRLs for feed items) is sufficiently supported by data and no risk for consumers was identified.
<i>Residue definition for enforcement: aminopyralid</i>			
Bovine kidneys	0.01*	0.1	MRL is sufficiently supported by data and no risk for consumers was identified.

(*): Indicates that the MRL is set at the limit of analytical quantification.

Key words: Aminopyralid, bovine kidney, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, picolinic acid herbicides

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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 Dow AgroSciences Limited² to modify the existing MRL for the active substance aminopyralid in bovine kidney. 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 26 September 2008. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2008-726 and the following subject:

Aminopyralid - Application to modify the existing MRL for aminopyralid in bovine kidney from 0.01 mg/kg to 0.3 mg/kg.*

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

On 04 December 2008 some data requirements were identified, which prevented EFSA to conclude on the consumer risk assessment. An updated evaluation report, addressing those data requirements, was submitted by the EMS on 14 May 2009 and taken into consideration by EFSA for finalization of this reasoned opinion.

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.

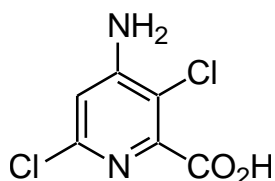
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

In this particular case the calculated deadline for providing the reasoned opinion is 04 June 2009.

² Dow AgroSciences Limited, Latchmore Court, Brand Street, Hitchin, SG5 1NH Hertfordshire, The United Kingdom

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Aminopyralid is the ISO common name for 4-amino-3,6-dichloropyridine-2-carboxylic acid (IUPAC). The acidic form is defined as the active substance but in practice, aminopyralid may be applied as an ester or salt.



Aminopyralid belongs to the class of picolinic acid herbicides. The active substance was developed for control of annual broad-leaf weeds, both after pre- and post-emergence treatment. It mainly inhibits cell division in the target plants.

Aminopyralid is being evaluated in the framework of Directive 91/414/EEC as a new active substance with The United Kingdom being the designated Rapporteur Member State (RMS). The representative use supported for the peer review process is a foliar application on grassland with a PHI of 0 days for grazing and 3 days for mowing. The peer review for this active substance is however not yet finalised by EFSA and a decision on inclusion of the active substance in Annex I of the Directive is not yet taken.

Awaiting the final decision on the Annex I inclusion of the active substance, provisional authorisations for aminopyralid in grasslands have already been issued by some Member States and national MRLs accommodating for these provisional authorisations have been established under the former national MRL legislations. These national MRLs were later on transferred as temporary EC MRLs in Regulation (EC) No 839/2008, which entered into force on 01 September 2008 (see Appendix B). The residue definition at EC levels is currently established as aminopyralid but CXLs are established for the sum of aminopyralid and its conjugates.

After having transferred the former national MRLs to the Regulation, The United Kingdom became aware that the national MRL of 0.3 mg/kg for bovine kidney, accommodating the use of aminopyralid in pasture, was omitted in the Regulation. Although uses of aminopyralid are currently suspended in The United Kingdom for reasons of phytotoxicity, a MRL application requesting the rectification of the omission was submitted to EFSA. Initially the authorized use reported by The United Kingdom was the same as the one supported in the framework of the peer review. This GAP was however revised during the process resulting in a lower MRL of 0.1 mg/kg in bovine kidney. The new intended use that served as basis for this assessment is reported in Appendix A. It concerns a foliar outdoor application at a rate of 0.06 kg a.s./ha, at the latest 7 days before re-entry of livestock. The use was also restricted to pastures that are not intended for production of hay or silage. EFSA has no information on other authorized uses of aminopyralid within the European Community.

Besides the evaluation report that was prepared by The United Kingdom in the framework of this application, EFSA also relied for its assessment on the DAR prepared by The United Kingdom under Directive 91/414/EEC. As the peer review of this DAR is not yet finalized conclusions reached in this reasoned opinion should be considered temporary and might be reconsidered after finalization of the peer review.

ASSESSMENT

1. Methods of analysis

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

According to the evaluation performed in the DAR (The United Kingdom, 2006), it was determined that multi-residue methods from Germany and The Netherlands were unsuitable for enforcement of aminopyralid residues. A specific analytical method was therefore validated in dry commodities and commodities with high water content. Additionally, an updated version of this method was submitted in the framework of this application and reported in the updated evaluation report of the EMS. Besides the two aforementioned commodity groups, validation data are now also provided for commodities with high oil content and high acid content. Independent laboratory validations are available for both methods.

According to for both versions of the analytical method, extracts are subject to basic and acidic hydrolytic conditions and subsequently analysed using liquid chromatography with detection by double mass spectrometry. A LOQ of 0.01 mg/kg was derived for all plant commodities. It is noted by EFSA that the methods use an isotopically enriched internal standard, which might not be commonly available for all laboratories. According to the updated evaluation report of The United Kingdom, however, the company is willing to make the internal standard available to qualified laboratories without cost.

Currently, it still needs to be clarified whether the proposed analytical methods analyse for aminopyralid only or for all conjugates of aminopyralid. As described, the methods include acidic and basic hydrolytic steps, which are expected to release free aminopyralid from the conjugates, but the efficacy of the hydrolytic step has not been confirmed by data.

Awaiting the peer review to be finalized on this issue it is concluded that both aminopyralid and its conjugates can be adequately enforced in commodities of plant origin.

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

An analytical method was reported in the DAR (The United Kingdom, 2006) and sufficiently validated for enforcement of aminopyralid residues in milk and bovine tissues. An updated version of this method was then submitted in the framework of this application and reported in the updated evaluation report of the EMS. Besides milk and bovine tissues, validation data are now also provided for eggs and poultry tissues. Independent laboratory validations are available for both methods.

Also the basic principle of the methods is the same as for plant commodities. Extracts are subject to basic and acidic hydrolytic conditions and subsequently analysed using liquid chromatography with detection by double mass spectrometry. A LOQ of 0.01 mg/kg was derived for all commodities of animal origin. Consequently, the same considerations as for plant commodities apply to these methods.

Awaiting the peer review to be finalized it is concluded that both aminopyralid and its conjugates can be adequately enforced in commodities of animal origin.

2. Mammalian toxicology

The toxicological properties of aminopyralid have been evaluated in the DAR prepared under Directive 91/414/EEC (The United Kingdom, 2006) and reference values have been derived. Awaiting the peer review to be finalised by EFSA, it is proposed to rely on the conclusions of the RMS. The reference values derived by The United Kingdom are summarized in the table below.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Aminopyralid					
ADI	DAR	2006	0.26	Rabbit, developmental study	100
ARfD	DAR	2006	0.26	Rabbit, developmental study	100

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Plant metabolism studies in grass and wheat were evaluated in the DAR for aminopyralid (The United Kingdom, 2006). Three varieties of common pasture grasses were treated with a single application of ¹⁴C ring-labelled aminopyralid at 360 g as/ha (6N rate). Spring wheat was treated with a single application of ¹⁴C ring-labelled aminopyralid at 40 g as/ha or 80 g as/ha (0.67 N rate and 1.33 N rate with respect to the GAP in pasture). At various time points over the range 0 – 42 days after treatment (grass) and 0 – 86 days after treatment (wheat) samples of grass, hay, wheat forage, wheat straw and wheat grain were analysed. The principle identified components were parent aminopyralid or conjugates of aminopyralid that were released as parent aminopyralid upon hydrolytic extraction conditions. At 0 days after application the residue mainly consisted of parent aminopyralid but after treatment levels of parent aminopyralid declined while levels of conjugated aminopyralid were increasing. Based on these findings The United Kingdom proposes to define the relevant residue as parent aminopyralid.

EFSA is of the opinion, however, that significant amounts of conjugated compounds were already identified 7 days after treatment, which is the minimum PHI supported for grass. Moreover, longer PHIs might be applied in practice where even higher amounts of conjugated aminopyralid might be expected. The conjugates should therefore be considered relevant for risk assessment. Additionally, the analytical method proposed for enforcement, which was also used in the available residues trials (see section 3.1.1.2), is expected to hydrolyse conjugated compounds to free aminopyralid.

Awaiting the peer review to be finalized on this issue EFSA proposes to temporarily define the relevant residue for enforcement and risk assessment of aminopyralid in cereals and grass as the sum of aminopyralid and its conjugates, expressed as aminopyralid.

3.1.1.2. Magnitude of residues

In the updated evaluation report provided by The United Kingdom in the framework of this application, 8 residues trials complying with the authorized use of aminopyralid were reported (4 trials in NEU and 4 trials in SEU, see Table 3-1). Although 8 trials performed in NEU are normally required, the overall availability of residues trials was considered acceptable because the results of these trials are mainly used for estimating the dietary intake of aminopyralid by livestock. Residue levels in North and South were also found to be similar.

Storage stability of aminopyralid in grass was demonstrated at -20°C for a period of 16 months, while grass samples of the above mentioned residues trials were stored under freezer conditions for a maximum period of 7 months. Degradation of aminopyralid residues during storage of these samples is therefore not expected.

The analytical method used in the residues trials is also considered to be sufficiently validated because it is the same as the method referred to in section 1.1.

Consequently, the residues trials presented are acceptable and appropriate risk assessment values for aminopyralid residues in grass can be derived (see Table 3-1). Although MRLs are currently not applicable for grass, a tentative MRL was calculated in view of the future need to set MRLs for feed items.

3.1.1.3. Effect of industrial processing and/or household preparation

According to the updated evaluation report submitted in the framework of this application the use of aminopyralid on pasture for making hay or silage is no longer included in the product label. The effect of processing was therefore not further considered.

3.1.2. Rotational crops

Pasture is not commonly rotated with other crops. Investigation of residues behaviour in succeeding crops is therefore not required in the framework of this application. It is noted that data are reported in the DAR (The United Kingdom, 2006) but these data are rather related to the potential use of aminopyralid in cereals.

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

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement	Risk assessment					
Residue definition for enforcement and risk assessment: <i>sum of aminopyralid and its conjugates, expressed as aminopyralid</i>									
Grass	NEU	Outdoor	1.03; 1.53; 1.81; 2.97	1.03; 1.53; 1.81; 2.97	1.67	2.97	4 ^(e)	1.0	Normally 8 residues trials should have been submitted for NEU only. Considering that for grass residue levels are mainly used to estimate the dietary burden of livestock, the SEU trials were also considered acceptable. Rmax = 3.89 Rber = 4.03
	SEU	Outdoor	0.84; 1.32; 1.96; 2.18	0.84; 1.32; 1.96; 2.18					

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

(e): Tentative MRL proposal in view of the future need to set MRLs for feed items.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

According to the supported GAP, livestock may be exposed to treated pastures 7 days after treatment with aminopyralid. The median and maximum dietary burdens were therefore calculated for the different types of livestock using the agreed European methodology (European Commission, 1996). These calculations should in principle include all feeding items for which the use of aminopyralid is authorised. EFSA is currently not in possession of this information but it is noted that MRLs for cereal grains have been established. Only the residue levels in cereal grains and grass were therefore considered for the calculation of dietary burdens. The input values for grass have been selected according to the latest recommendations of the 2004 JMPR (WHO/FAO, 2005) and are summarized in the table below. For cereal grains the MRLs were used as no information is available regarding the STMRs.

The results of the calculations are reported in Table 3-5, indicating a significant intake for meat and dairy ruminants. No significant intake was identified for poultry and pigs because fresh grass is not commonly fed to these types of livestock.

Table 3-2. Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<i>Residue definition for risk assessment: sum of aminopyralid and its conjugates, expressed as aminopyralid</i>				
Grass (fresh)	1.67	STMR	2.97	HR
Cereal grains	0.1	MRL	0.1	MRL

Table 3-3. Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded ?
<i>Residue definition for risk assessment: sum of aminopyralid and its conjugates, expressed as aminopyralid</i>					
Dairy ruminants	0.540	0.304	Grass (fresh)	14.9	Yes
Meat ruminants	0.636	0.358	Grass (fresh)	14.9	Yes
Poultry	0.005	0.005	Cereal grains	0.08	No
Pigs	0.004	0.004	Cereal grains	0.09	No

3.2.2. Nature of residues

Livestock metabolism studies in ruminants and poultry were evaluated in the DAR of aminopyralid (The United Kingdom, 2006). A lactating goat was dosed for 6 consecutive days

with ^{14}C -labelled aminopyralid at a target dose rate of 15 mg/kg diet as received, which is slightly higher than the calculated dietary burdens for ruminants. Ten laying hens were dosed orally once a day for 7 consecutive days with ^{14}C -Aminopyralid at 11.56 mg/kg in the diet. The dosing rate of this study is not very relevant as currently, poultry is not significantly exposed to aminopyralid residues. In both studies it was clearly demonstrated that radioactive residues were almost entirely recovered in the excreta. Characterization of residues in the excreta of poultry revealed that it is mainly composed of unchanged parent compound. These findings confirm that significant levels of aminopyralid are expected in manure of exposed animals, which might be used as a fertilizer in vegetable crops. In particular, EFSA is aware that phytotoxicity problems with regard to the use of contaminated manure were encountered in The United Kingdom, resulting in the suspension of the authorized uses of aminopyralid (The United Kingdom, 2008). This issue is, however, not further considered in the framework of this reasoned opinion because crops affected by phytotoxicity are normally not consumed.

Characterization of residues in milk, eggs and tissues was poor because total radioactive residue levels in most of these samples were too low to be further analyzed. Only residues in goat kidneys were therefore characterized and parent aminopyralid was identified as the major compound. As the contribution of conjugated compounds to the total residue is expected to be minor, there is no need to include them in the residue definition. The hydrolytic step in the analytical method reported under section 1.2 is therefore also not expected to impact on the results and becomes obsolete. The development of a simplified method might therefore be considered in the framework of the peer review.

Awaiting the peer review to be finalized EFSA proposes to temporarily define the relevant residue for enforcement and risk assessment as aminopyralid in all products of animal origin.

3.2.3. Magnitude of residues

A livestock feeding study on dairy cows was evaluated in the DAR for aminopyralid (The United Kingdom, 2006) where 4 groups of cows were dosed with aminopyralid for 28 consecutive days at 4 different dose levels. A plateau level in the milk was reached after 2 days and residues were not found to accumulate in the fat fraction of the milk. Residues were also found to decline rapidly after cessation of the dosing. Detailed results of the livestock feeding study are summarized in Table 3-4. The highest dose level is however not reported in the table because it was 40 times higher than the dietary burdens calculated in section 3.2.1 and therefore not considered relevant.

Data regarding the storage stability of the samples and regarding the validity of the analytical method used in the livestock feeding study were not reported by the United Kingdom. Awaiting these issues to be clarified during the peer review, it is assumed that the available study is acceptable with regard to these aspects.

Based on the livestock feeding study, residue levels in livestock commodities resulting from the dietary exposure of dairy and meat ruminants could be estimated and MRL proposals were derived (see Table 3-4). These MRLs were calculated according to the latest recommendations of the 2004 JMPR (WHO/FAO, 2005). It is noted that for the calculation of the MRLs The United Kingdom used the median dietary burden rather than the maximum dietary burden. However, this difference didn't affect the outcome of the risk assessment significantly. For poultry and pigs, no MRLs are proposed as a significant intake was not identified for these types of livestock.

Table 3-4. Overview of the values derived from the livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						STMR (mg/kg)	HR (mg/kg)	MRL proposal (mg/kg)	CF for RA
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level ¹ (mg/kg bw/d)	n	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
<u>Residue definition for enforcement and risk assessment: aminopyralid</u>												
Ruminant meat	0.304	0.540	1.193	3	<0.01	<0.01	<0.01	<0.01	0.002	0.005	0.01*	1.0
			2.345	3	<0.01	<0.01	<0.01	<0.01				
			6.600	3	0.024	0.046	0.024	0.046				
Ruminant fat	0.304	0.540	1.193	3	<0.01	0.011	<0.01	0.011	0.002	0.005	0.01*	1.0
			2.345	3	<0.01	<0.01	<0.01	<0.01				
			6.600	3	<0.01	0.013	<0.01	0.013				
Ruminant liver	0.304	0.540	1.193	3	<0.01	<0.01	<0.01	<0.01	0.002	0.005	0.01*	1.0
			2.345	3	<0.01	0.014	<0.01	0.014				
			6.600	3	0.038	0.054	0.038	0.054				
Ruminant kidney	0.304	0.540	1.193	3	0.065	0.102	0.065	0.102	0.02	0.05	0.1	1.0
			2.345	3	0.147	0.202	0.147	0.202				
			6.600	3	0.833	1.537	0.833	1.537				
Milk	0.358	0.636	1.193	3	<0.01	n/a	<0.01	n/a	0.003	0.005	0.01*	1.0
			2.345	3	<0.01	n/a	<0.01	n/a				
			6.600	3	0.019	n/a	0.019	n/a				

¹ Reported in mg/kg DM in the original study, but recalculated to mg/kg bw/d assuming for dairy cows an average body weight of 550 kg and an average DM consumption of 20 kg/d.

(*): Indicates that the MRL is set at the limit of analytical quantification.

n/a: not applicable

4. Consumer risk assessment

Several MRLs for commodities of animal origin have been calculated in section 3.2.3. From these calculated MRLs, the proposed MRL in bovine kidney is the only MRL which is higher than the existing EC MRL. All other MRLs calculated under section 3.2.3 are below or equal to the existing EC MRLs. EFSA is however not able to conclude whether these MRLs should be lowered to the calculated levels because information regarding other authorized uses of aminopyralid in the European Community is lacking. There might be other uses authorized within the EC for which the higher MRLs are required. In order to make sure that all currently authorized uses for aminopyralid are covered by the risk assessment, EFSA decided to perform both chronic and acute consumer intake calculations considering the existing EC MRLs for aminopyralid, except for bovine kidney for which input values are summarized in Table 4-1. These intake calculations are expected to overestimate the exposure but can only be refined if further information on authorized uses within the EC is provided to EFSA. It is noted that such information will be made available to EFSA after the peer review of aminopyralid will be finalized.

Both chronic and acute exposures were calculated using revision 2 of the EFSA PRIMo and detailed results are reported in Appendix C. According to these overestimated intake calculations, no exceedances of the ADI or ARfD were identified. The highest chronic exposure was calculated for Dutch children, representing 0.5% of the ADI. The highest acute exposure was calculated for milk and milk products, representing 1.0% of the ARfD. It is therefore concluded that the proposed use of aminopyralid in grass is not expected to pose any risk with regard to consumer exposure and that the proposed MRL for bovine kidney is acceptable.

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
<i>Residue definition for risk assessment: aminopyralid</i>				
Bovine kidneys	0.02	STMR	0.05	HR
Other commodities of plant and animal origin	See Appendix B	MRL	See Appendix B	MRL

CONCLUSIONS AND RECOMMENDATIONS

According to Article 6(2) of Regulation (EC) No 396/2005, The United Kingdom received an application from the company Dow AgroSciences Limited to modify the existing MRL aminopyralid in bovine kidneys. Based on the use of aminopyralid in pasture, the applicant proposed to raise the existing MRL, which is currently set at the analytical limit of quantification of 0.01 mg/kg, to 0.3 mg/kg. The subsequent evaluation report drafted by The United Kingdom was forwarded to EFSA on 26 September 2008 according to Article 9 of the Regulation. On 04 December 2008 some data requirements were identified, which prevented EFSA to conclude on the consumer risk assessment. An updated evaluation report, addressing those data requirements, was submitted on 14 May 2009. In this updated evaluation report, the supported use for pasture was modified and the subsequent MRL proposal from the company was lowered to 0.1 mg/kg.

Based on the above mentioned evaluation report as well as the Draft Assessment Report (DAR) prepared by the Rapporteur Member State (RMS) The United Kingdom under Directive 91/414/EEC, EFSA derives the following conclusions regarding the application. As the DAR has not yet been fully peer reviewed by EFSA at this stage, conclusions reached in this reasoned opinion are temporary and might be reconsidered after finalization of the peer review.

Metabolism of aminopyralid was investigated for post-emergence applications in grass and cereals, where aminopyralid and its conjugates were demonstrated to be the main components of the residue. Awaiting the peer review to be finalized on this issue, it is proposed in the framework of this application to define the relevant residue in grasses and cereals as the sum of aminopyralid and its conjugates expressed as aminopyralid. An analytical method for enforcement of this residue definition was also validated. Additionally, a sufficient amount of supervised residues trials supporting the authorized use in pasture was made available. These trials allowed EFSA to estimate the expected residue concentrations in grass and to derive a tentative MRL in view of the future need to set MRLs in feed items.

Considering that the use of aminopyralid in The United Kingdom is restricted to pastures that are not intended for production of hay or silage, the effect of processing was not investigated in the framework of this application. Also the occurrence of residues in rotational crops was not discussed as pastures are not commonly rotated with other crops.

Based on the expected residue concentrations in grass, EFSA identified significant exposure of dairy and meat ruminants to aminopyralid residues. Metabolism in ruminants and poultry was investigated and based on the available studies the relevant residue for all commodities of animal origin was defined as aminopyralid. An analytical method for enforcement of this residue definition was also validated. Considering the expected dietary burden for ruminants and the livestock feeding study that was made available, a higher MRL was proposed for bovine kidneys. There is no need to modify the other existing MRLs for aminopyralid in commodities of animal origin.

Finally, chronic and acute intake calculations were performed considering the new proposed MRL for bovine kidneys as well as all the existing MRLs in plant and animal commodities. The calculations are based on revision 2 of the EFSA PRIMo and no exceedances of the ADI or ARfD were identified. The highest chronic exposure was calculated for Dutch child, representing 0.5% of the ADI. The highest acute exposure was calculated for milk and milk products, representing 1.0% of the ARfD. It is therefore concluded that the proposed use of

aminopyralid in grass is not expected to pose any risk with regard to consumer exposure and that the proposed MRL for bovine kidney is acceptable.

EFSA recommendations resulting from the assessment are summarized in the table below. In view of the future need to set MRLs for feed items, a tentative MRL is also derived for grass which might be included in Annex I to Regulation (EC) No 396/2005.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
<i>Residue definition for enforcement: sum of aminopyralid and its conjugates, expressed as aminopyralid</i>			
Grass	-	4	Tentative MRL (in view of future need to set MRLs for feed items) is sufficiently supported by data and no risk for consumers was identified.
<i>Residue definition for enforcement: aminopyralid</i>			
Bovine kidneys	0.01*	0.1	MRL is sufficiently supported by data and no risk for consumers was identified.

(*): Indicates that the MRL is set at the limit of analytical quantification.

DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the modification of the existing MRL for aminopyralid in bovine kidneys prepared by The United Kingdom under Regulation (EC) No 396/2005. Submitted to EFSA on 26 September 2008.
2. Updated evaluation report on the modification of the existing MRL for aminopyralid in bovine kidneys prepared by The United Kingdom under Regulation (EC) No 396/2005. Submitted to EFSA on 14 May 2009.

REFERENCES

- European Commission, 1996. Livestock Feeding Studies. 7031/VI/95 rev.4, 22 July 1996.
- The United Kingdom, 2006. Draft Assessment Report on aminopyralid prepared by The United Kingdom under Directive 91/414/EEC. August 2006.
- The United Kingdom, 2008. Aminopyralid – Results of Analysis of Contaminated Manure, Soil and Damaged Crops. www.pesticides.gov.uk, Regulatory Update 30/2008, 11 September 2008.
- WHO/FAO, 2005. Pesticide residues in food – 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. FAO Plant Production and Protection Paper 178, 2005.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Pesticide(s) (common name(s)):	Aminopyralid	Responsible body for reporting (name, address):	PSD
Trade name(s):	Pro-Banish	Reporting Country:	UK
Main uses:	Herbicide	Date application submitted:	10/07/2007

Crop and/or situation (a)	F or G (b)	Pest or group of pests controlled (c)	Formulation rate per treatment		Application			Application rate per treatment			PHI (days) (k)	Remarks: (l) e.g. minimum realistic PHI
			Type (d-f)	Conc. of a.s. (i)	method, kind, if other than spray (f-h)	growth stage (j)	number (range)	kg a.s./ha, where appropriate	water L/ha	kg a.s./hL, where appropriate		
Grassland including rotational grass, established grass, paddocks, small holdings and grassy areas around farms including green cover	F	Broad-leaf weeds.	SC	30 g/L	Tractor mounted hydraulic sprayer	None specified	1 treatment per crop per year.	0.06 kg as/ha	200 – 400 L water/ha	0.015 – 0.030 kg as/hL	7-day re-entry period before grazing.	Keep livestock out of treated areas for at least 7 days or until foliage of any poisonous weeds such as ragwort has died and become unpalatable

- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure).
- (b) Outdoor or field use (F), glasshouse application (G) or indoor application.
- (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds.
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR).
- (e) GCPF Codes – GIFAP Technical Monograph No 2, 1989.
- (f) All abbreviations used must be explained.
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated.
- (i) g/kg or g/L.
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application.
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use.
- (l) PHI – minimum pre-harvest interval.
- (m) Remarks may include: extent of use/economic importance/restrictions.

All active substance concentrations are expressed as acid equivalents.

APPENDIX B – EXISTING EC MRLs

Pesticides - Web Version - EU MRLs (File created on 27/05/2009 16:56)		
Code number	Groups and examples of individual products to which the MRLs apply (a)	Aminopyralid
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,01*
110000	(i) Citrus fruit	0,01*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,01*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,01*
110030	Lemons (Citron, lemon)	0,01*
110040	Limes	0,01*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,01*
110990	Others	0,01*
120000	(ii) Tree nuts (shelled or unshelled)	0,01*
120010	Almonds	0,01*
120020	Brazil nuts	0,01*
120030	Cashew nuts	0,01*
120040	Chestnuts	0,01*
120050	Coconuts	0,01*
120060	Hazelnuts (Filbert)	0,01*
120070	Macadamia	0,01*
120080	Pecans	0,01*
120090	Pine nuts	0,01*
120100	Pistachios	0,01*
120110	Walnuts	0,01*
120990	Others	0,01*
130000	(iii) Pome fruit	0,01*
130010	Apples (Crab apple)	0,01*
130020	Pears (Oriental pear)	0,01*
130030	Quinces	0,01*
130040	Medlar	0,01*
130050	Loquat	0,01*
130990	Others	0,01*
140000	(iv) Stone fruit	0,01*
140010	Apricots	0,01*
140020	Cherries (sweet cherries, sour cherries)	0,01*
140030	Peaches (Nectarines and similar hybrids)	0,01*

140040	Plums (Damson, greengage, mirabelle)	0,01*
140990	Others	0,01*
150000	(v) Berries & small fruit	0,01*
151000	(a) Table and wine grapes	0,01*
151010	Table grapes	0,01*
151020	Wine grapes	0,01*
152000	(b) Strawberries	0,01*
153000	(c) Cane fruit	0,01*
153010	Blackberries	0,01*
153020	Dewberries (Loganberries, Boysenberries, and doudbberries)	0,01*
153030	Raspberries (Wineberries)	0,01*
153990	Others	0,01*
154000	(d) Other small fruit & berries	0,01*
154010	Blueberries (Bilberries, cowberries (red bilberries))	0,01*
154020	Cranberries	0,01*
154030	Currants (red, black and white)	0,01*
154040	Gooseberries (including hybrids with other berries species)	0,01*
154050	Rose hips	0,01*
154060	Nubberries (arbutus berry)	0,01*
154070	Azarole (Mediterranean medlar)	0,01*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea-sallowthorn), hawthorn, service berries, and other treeberries)	0,01*
154990	Others	0,01*
160000	(vi) Miscellaneous fruit	0,01*
161000	(a) Edible peel	0,01*
161010	Dates	0,01*
161020	Figs	0,01*
161030	Table olives	0,01*
161040	Kumquats (Marumikumquats, nagamikumquats)	0,01*
161050	Carambola (Bilimbi)	0,01*
161060	Persimmon	0,01*
161070	Jambolan (Java plum) (Java apple (water apple), pomeraç, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,01*
161990	Others	0,01*
162000	(b) Inedible peel, small	0,01*
162010	Kiwi	0,01*
162020	Lychee (Litchi) (Pulasan, rambutan)	0,01*

	(hairy litchi)	
162030	Passion fruit	0,01*
162040	Prickly pear (cactus fruit)	0,01*
162050	Star apple	0,01*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, caristel (yellow sapote), and mammy sapote)	0,01*
162990	Others	0,01*
163000	(c) Inedible peel, large	0,01*
163010	Avocados	0,01*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,01*
163030	Mangoes	0,01*
163040	Papaya	0,01*
163050	Pomegranate	0,01*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,01*
163070	Guava	0,01*
163080	Pineapples	0,01*
163090	Breadfruit (Jackfruit)	0,01*
163100	Durian	0,01*
163110	Soursop (guanabana)	0,01*
163990	Others	0,01*
200000	2. VEGETABLES FRESH OR FROZEN	0,01*
210000	(i) Root and tuber vegetables	0,01*
211000	(a) Potatoes	0,01*
212000	(b) Tropical root and tuber vegetables	0,01*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,01*
212020	Sweet potatoes	0,01*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,01*
212040	Arrowroot	0,01*
212990	Others	0,01*
213000	(c) Other root and tuber vegetables except sugar beet	0,01*
213010	Beetroot	0,01*
213020	Carrots	0,01*
213030	Celeriac	0,01*
213040	Horseradish	0,01*
213050	Jerusalem artichokes	0,01*
213060	Parsnips	0,01*
213070	Parsley root	0,01*
213080	Radishes (Black radish, Japanese)	0,01*

	radish, small radish and similar varieties)	
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oyster plant))	0,01*
213100	Swedes	0,01*
213110	Turnips	0,01*
213990	Others	0,01*
220000	(ii) Bulb vegetables	0,01*
220010	Garlic	0,01*
220020	Onions (Silver skin onions)	0,01*
220030	Shallots	0,01*
220040	Spring onions (Welsh onion and similar varieties)	0,01*
220990	Others	0,01*
230000	(iii) Fruiting vegetables	0,01*
231000	(a) Solanacea	0,01*
231010	Tomatoes (Cherry tomatoes,)	0,01*
231020	Peppers (Chili peppers)	0,01*
231030	Aubergines (egg plants) (Pepino)	0,01*
231040	Okra, ladyfingers	0,01*
231990	Others	0,01*
232000	(b) Cucurbits - edible peel	0,01*
232010	Cucumbers	0,01*
232020	Gherkins	0,01*
232030	Courgettes (Summer squash, marrow (patisson))	0,01*
232990	Others	0,01*
233000	(c) Cucurbits - inedible peel	0,01*
233010	Melons (Kiwano)	0,01*
233020	Pumpkins (Winter squash)	0,01*
233030	Watermelons	0,01*
233990	Others	0,01*
234000	(d) Sweet corn	0,01*
239000	(e) Other fruiting vegetables	0,01*
240000	(iv) Brassica vegetables	0,01*
241000	(a) Flowering brassica	0,01*
241010	Broccoli (Calabrese, Chinese broccoli,	0,01*
241020	Broccoli raab)	0,01*
241020	Cauliflower	0,01*
241990	Others	0,01*
242000	(b) Head brassica	0,01*
242010	Brussels sprouts	0,01*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,01*
242990	Others	0,01*
243000	(c) Leafy brassica	0,01*

243010	Chinese cabbage (Indian (Chinese) mustard, pak choy, Chinese flat cabbage (tai goo choy), peking cabbage (petsai), cow cabbage)	0,01*
243020	Kale (Borecole (curly kale), collards)	0,01*
243990	Others	0,01*
244000	(d) Kohlrabi	0,01*
250000	(v) Leaf vegetables & fresh herbs	0,01*
251000	(a) Lettuce and other salad plants including Brassicaceae	0,01*
251010	Lamb's lettuce (Italian corn salad)	0,01*
251020	Lettuce (Head lettuce, lol rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,01*
251030	Scarole (broad leaf endive) (Wild chicory, red leaved chicory, radicchio, curd leave endive, sugar loaf)	0,01*
251040	Cress	0,01*
251050	Land cress	0,01*
251060	Rocket, Rucola (Wild rocket)	0,01*
251070	Red mustard	0,01*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,01*
251990	Others	0,01*
252000	(b) Spinach & similar (leaves)	0,01*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,01*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,01*
252030	Beet leaves (chard) (Leaves of beetroot)	0,01*
252990	Others	0,01*
253000	(c) Vine leaves (grape leaves)	0,01*
254000	(d) Water cress	0,01*
255000	(e) Willow	0,01*
256000	(f) Herbs	0,01*
256010	Chervil	0,01*
256020	Chives	0,01*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,01*
256040	Parsley	0,01*
256050	Sage (Winter savory, summer savory,)	0,01*
256060	Rosemary	0,01*
256070	Thyme (marjoram, oregano)	0,01*
256080	Basil (Balm leaves, mint, peppermint)	0,01*

256090	Bay leaves (laurel)	0,01*
256100	Tarragon (Hyssop)	0,01*
256990	Others	0,01*
260000	(vi) Legume vegetables (fresh)	0,01*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,01*
260020	Beans (without pods) (Broad beans, Figeolets, jack bean, lima bean, cow pea)	0,01*
260030	Peas (with pods) (Mangetout (sugar peas))	0,01*
260040	Peas (without pods) (Garden pea, green pea, chick pea)	0,01*
260050	Lentils	0,01*
260990	Others	0,01*
270000	(vii) Stem vegetables (fresh)	0,01*
270010	Asparagus	0,01*
270020	Cardoons	0,01*
270030	Celery	0,01*
270040	Fennel	0,01*
270050	Globe artichokes	0,01*
270060	Leek	0,01*
270070	Rhubarb	0,01*
270080	Bamboo shoots	0,01*
270090	Palm hearts	0,01*
270990	Others	0,01*
280000	(viii) Fungi	0,01*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi take)	0,01*
280020	Wild (Chanterelle, Truffle, Morel,)	0,01*
280990	Others	0,01*
290000	(ix) Sea weeds	0,01*
300000	3. PULSES, DRY	0,01*
300010	Beans (Broad beans, navy beans, figeolets, jack beans, lima beans, field beans, cow peas)	0,01*
300020	Lentils	0,01*
300030	Peas (Chick peas, field peas, chickling vetch)	0,01*
300040	Lupins	0,01*
300990	Others	0,01*
400000	4. OILSEEDS AND OILFRUITS	0,01*
401000	(i) Oilseeds	0,01*
401010	Linseed	0,01*
401020	Peanuts	0,01*
401030	Poppy seed	0,01*

401040	Sesameseed	0,01*
401050	Sunflowerseed	0,01*
401060	Rapeseed (Bird rapeseed, turnip rape)	0,01*
401070	Soya bean	0,01*
401080	Mustard seed	0,01*
401090	Cottonseed	0,01*
401100	Pumpkin seeds	0,01*
401110	Safflower	0,01*
401120	Borage	0,01*
401130	Gold of pleasure	0,01*
401140	Hempseed	0,01*
401150	Castor bean	0,01*
401990	Others	0,01*
402000	(ii) Oilfruits	0,01*
402010	Olives for oil production	0,01*
402020	Palm nuts (palm oil kernels)	0,01*
402030	Palm fruit	0,01*
402040	Kapok	0,01*
402990	Others	0,01*
500000	5. CEREALS	0,1
500010	Barley	0,1
500020	Buckwheat	0,01*
500030	Maize	0,01*
500040	Millet (Foxtail millet, teff)	0,01*
500050	Oats	0,1
500060	Rice	0,01*
500070	Rye	0,1
500080	Sorghum	0,01*
500090	Wheat (Spelt, Triticale)	0,1
500990	Others	0,01*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,02*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,02*
620000	(ii) Coffee beans	0,02*
630000	(iii) Herbal infusions (dried)	0,02*
631000	(a) Flowers	0,02*
631010	Camomille flowers	0,02*
631020	Hybiscus flowers	0,02*
631030	Rose petals	0,02*
631040	Jasmine flowers	0,02*
631050	Lime (Linden)	0,02*
631990	Others	0,02*
632000	(b) Leaves	0,02*
632010	Strawberry leaves	0,02*

632020	Rooibos leaves	0,02*
632030	Maté	0,02*
632990	Others	0,02*
633000	(c) Roots	0,02*
633010	Valerian root	0,02*
633020	Ginseng root	0,02*
633990	Others	0,02*
639000	(d) Other herbal infusions	0,02*
640000	(iv) Cocoa (fermented beans)	0,02*
650000	(v) Carob (stjohns bread)	0,02*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,02*
800000	8. SPICES	0,02*
810000	(i) Seeds	0,02*
810010	Anise	0,02*
810020	Black caraway	0,02*
810030	Celery seed (Lovage seed)	0,02*
810040	Coriander seed	0,02*
810050	Cumin seed	0,02*
810060	Dill seed	0,02*
810070	Fennel seed	0,02*
810080	Fenugreek	0,02*
810090	Nutmeg	0,02*
810990	Others	0,02*
820000	(ii) Fruits and berries	0,02*
820010	Allspice	0,02*
820020	Anise pepper (Japan pepper)	0,02*
820030	Caraway	0,02*
820040	Cardamom	0,02*
820050	Juniper berries	0,02*
820060	Pepper, black and white (Long pepper, pink pepper)	0,02*
820070	Vanilla pods	0,02*
820080	Tamarind	0,02*
820990	Others	0,02*
830000	(iii) Bark	0,02*
830010	Cinnamon (Cassia)	0,02*
830990	Others	0,02*
840000	(iv) Roots or rhizome	0,02*
840010	Liquorice	0,02*
840020	Ginger	0,02*
840030	Turmeric (Curcuma)	0,02*
840040	Horse radish	0,02*
840990	Others	0,02*
850000	(v) Buds	0,02*
850010	Cloves	0,02*

850020	Capers	0,02*
850990	Others	0,02*
860000	(M) Flower stigma	0,02*
860010	Saffron	0,02*
860990	Others	0,02*
870000	(M) Artichoke	0,02*
870010	Mace	0,02*
870990	Others	0,02*
900000	9. SUGAR PLANTS	0,01*
900010	Sugar beet (root)	0,01*
900020	Sugarcane	0,01*
900030	Chicory roots	0,01*
900990	Others	0,01*
100000	10. PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS	
101000	(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	
101100	(a) Swine	
101101	Meat	0,01*
101102	Fat free of lean meat	0,02
101103	Liver	0,02
101104	Kidney	0,3
101105	Edible offal	0,01*
101199	Others	0,01*
101200	(b) Bovine	
101201	Meat	0,01*
101202	Fat	0,02
101203	Liver	0,02
101204	Kidney	0,01*
101205	Edible offal	0,01*

101299	Others	0,01*
101300	(c) Sheep	
101301	Meat	0,01*
101302	Fat	0,02
101303	Liver	0,02
101304	Kidney	0,3
101305	Edible offal	0,01*
101399	Others	0,01*
101400	(d) Goat	
101401	Meat	0,01*
101402	Fat	0,02
101403	Liver	0,02
101404	Kidney	0,3
101405	Edible offal	0,01*
101499	Others	0,01*
101500	(e) Horses, asses, mules or hinnies	
101501	Meat	0,01*
101502	Fat	0,02
101503	Liver	0,02
101504	Kidney	0,3
101505	Edible offal	0,01*
101599	Others	0,01*
101600	(f) Poultry: chicken, geese, duck, turkey and Guinea fowl, ostrich, pigeon	
101601	Meat	0,01*

0		
101602	Fat	0,02
101603	Liver	0,02
101604	Kidney	0,3
101605	Edible offal	0,01*
101699	Others	0,01*
101700	(g) Other farm animals (Rabbit, Kangaroo)	
101701	Meat	0,01*
101702	Fat	0,02
101703	Liver	0,02
101704	Kidney	0,3
101705	Edible offal	0,01*
101799	Others	0,01*
102000	(i) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,02
102001	Cattle	0,02
102002	Sheep	0,02
102003	Goat	0,02
102004	Horse	0,02
102099	Others	0,02
103000	(ii) Birds' eggs, fresh preserved or cooked. Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,01*
103001	Chicken	0,01*

103002	Duck	0,01*
103003	Goose	0,01*
103004	Quail	0,01*
103099	Others	0,01*
104000	(iv) Honey (Royal jelly, pollen)	0,01*
105000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,01*
106000	(vi) Snails	0,01*
107000	(vii) Other terrestrial animal products	0,01*

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Aminopyralid			
Status of the active substance:	Pending	Code no.	
LOQ (mg/kg bw):	0.01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.26	ARfD (mg/kg bw):	0.26
Source of ADI:	DAR	Source of ARfD:	DAR
Year of evaluation:	2006	Year of evaluation:	2006

Explain choice of toxicological reference values.

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

Chronic risk assessment - refined calculations								
		TMDI (range) in % of ADI minimum - maximum						
		1						
		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)
0.5	NL child	0.2	Milk and cream,	0.2	Wheat	0.0	Apples	0.1
0.5	DK child	0.2	Wheat	0.2	Rye	0.1	Milk and cream,	0.1
0.5	UK infant	0.3	Milk and cream,	0.1	Wheat	0.0	Sugar beet (root)	0.1
0.5	FR toddler	0.3	Milk and cream,	0.1	Wheat	0.0	Potatoes	0.1
0.5	WHO Cluster diet B	0.3	Wheat	0.0	Milk and cream,	0.0	Tomatoes	0.1
0.5	UK Toddler	0.2	Milk and cream,	0.2	Wheat	0.1	Sugar beet (root)	0.1
0.4	DE child	0.2	Wheat	0.1	Milk and cream,	0.0	Apples	0.1
0.4	WHO cluster diet D	0.3	Wheat	0.0	Milk and cream,	0.0	Potatoes	0.1
0.3	ES child	0.2	Wheat	0.1	Milk and cream,	0.0	Oranges	0.1
0.3	WHO cluster diet E	0.2	Wheat	0.0	Barley	0.0	Milk and cream,	0.1
0.3	FR infant	0.2	Milk and cream,	0.0	Wheat	0.0	Potatoes	0.1
0.3	IT kids/toddler	0.3	Wheat	0.0	Other cereal	0.0	Tomatoes	0.0
0.3	SE general population 90th percentile	0.1	Wheat	0.1	Milk and cream,	0.0	Potatoes	0.1
0.3	WHO Cluster diet F	0.1	Wheat	0.0	Milk and cream,	0.0	Rye	0.1
0.3	IE adult	0.1	Wheat	0.0	Barley	0.0	Milk and cream,	0.1
0.2	WHO regional European diet	0.1	Wheat	0.0	Milk and cream,	0.0	Potatoes	0.1
0.2	PT General population	0.2	Wheat	0.0	Potatoes	0.0	Wine grapes	0.1
0.2	NL general	0.1	Wheat	0.1	Milk and cream,	0.0	Barley	0.1
0.2	FR all population	0.1	Wheat	0.0	Milk and cream,	0.0	Wine grapes	0.0
0.2	ES adult	0.1	Wheat	0.0	Milk and cream,	0.0	Barley	0.0
0.2	IT adult	0.2	Wheat	0.0	Tomatoes	0.0	Apples	0.0
0.2	DK adult	0.1	Wheat	0.0	Milk and cream,	0.0	Rye	0.0
0.2	LT adult	0.0	Rye	0.0	Wheat	0.0	Milk and cream,	0.0
0.2	UK vegetarian	0.1	Wheat	0.0	Milk and cream,	0.0	Sugar beet (root)	0.0
0.1	FI adult	0.0	Milk and cream,	0.0	Wheat	0.0	Rye	0.0
0.1	UK Adult	0.1	Wheat	0.0	Milk and cream,	0.0	Sugar beet (root)	0.0
0.0	PL general population	0.0	Potatoes	0.0	Apples	0.0	Tomatoes	0.0

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

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations
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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 variability 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)	
1.0	Milk and milk products:	0.02 / -	1.0	Milk and milk	0.02 / -	0.3	Wheat	0.1 / -	0.3	Wheat	0.1 / -	
0.6	Potatoes	0.01 / -	0.6	Melons	0.01 / -	0.3	Barley	0.1 / -	0.3	Barley	0.1 / -	
0.6	Melons	0.01 / -	0.6	Wheat	0.1 / -	0.2	Pumpkins	0.01 / -	0.2	Pumpkins	0.01 / -	
0.6	Wheat	0.1 / -	0.5	Watermelons	0.01 / -	0.2	Rye	0.1 / -	0.2	Rye	0.1 / -	
0.5	Oranges	0.01 / -	0.4	Potatoes	0.01 / -	0.2	Swine: Kidney	0.3 / -	0.2	Swine: Kidney	0.3 / -	
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)
0.5	Wheat flour	0.1 / -	0.2	Bread/pizza	0.1 / -	
0.2	Apple juice	0.01 / -	0.0	Orange juice	0.01 / -	
0.2	Orange juice	0.01 / -	0.0	Apple juice	0.01 / -	
0.2	Carrot, juice	0.01 / -	0.0	Wine	0.01 / -	
0.1	Grape juice	0.01 / -	0.0	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 Aminopyralid 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.

GLOSSARY / 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
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CS	capsule suspension
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DM	dry matter
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
ha	hectare
hL	hectolitre
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State

SEU	Southern European Union
STMR	supervised trials median residue
TRR	total radioactive residue
WHO	World Health Organisation