

## REASONED OPINION OF EFSA

### Modification of the existing MRL for cyflufenamid in oats<sup>1</sup>

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2008-728)

Issued on 19 May 2009

#### SUMMARY

The United Kingdom received an application from Nisso Chemical Europe GmbH to modify the existing MRL for cyflufenamid in oats. In order to accommodate the new use of cyflufenamid on oats, the applicant proposes to raise the existing MRL of 0.02 mg/kg to 0.1 mg/kg. The United Kingdom as the Evaluating Member State (EMS) drafted an Evaluation Report according to Article 9 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 26 September 2008.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report, the Draft Assessment Report prepared by The United Kingdom and EFSA conclusion prepared in the framework of the peer review.

The metabolism of cyflufenamid was investigated in cereals in the peer review and it was concluded that the residue definition for risk assessment and enforcement in cereals should be set as the sum of cyflufenamid (*Z*-isomer) and its *E*-isomer. The MRL application for oats does not require additional metabolism studies. Currently in the Regulation (EC) No 396/2005 the enforcement residue definition for cyflufenamid is set as parent cyflufenamid (*Z*-isomer) only. Taking into account the new metabolism data, EFSA proposes to change the enforcement residue definition as proposed in the peer review. It should be noted, that all proposals made in this reasoned opinion are in accordance with the new residue definition. Adequate analytical methods are available to enforce the proposed MRL in oats.

Submitted supervised field trials indicate that the current MRL of 0.02 mg/kg does not accommodate the intended GAP in the United Kingdom and a higher MRL of 0.1 mg/kg would be necessary.

The processing studies are not necessary with regard to the current MRL application, since contribution of oats to the total dietary intake is very low. The occurrence of cyflufenamid residues in rotational crops was also investigated. EFSA concludes that significant residue levels in rotational crops are not expected provided that cyflufenamid is applied according to the proposed GAP.

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The livestock dietary burden was calculated considering the expected residue levels in oat grain and oat straw. The calculated dietary burden exceeds the trigger value of 0.1 mg/kg DM for meat ruminants, but significant residues are not expected in the food of animal origin taking into account the results of the livestock metabolism study. However, in the peer review it was concluded that the MRLs for food of animal origin should be set at the LOQ when an enforcement analytical method is available. In April 2009 the RMS submitted supplementary information regarding the analytical method (enforcement) for the determination of cyflufenamid residues in animal matrices. The analytical method is sufficiently validated at the LOQ of 0.03 mg/kg for the determination of cyflufenamid residues in food of animal origin according to the new residue definition which was proposed in the peer review as the sum of cyflufenamid, the *E*-isomer and metabolite 149-F1, expressed as cyflufenamid. Consequently, EFSA proposes to set the enforcement residue definition as proposed in the peer review and concludes that the MRLs at the LOQ of 0.03 mg/kg for products of animal origin should be included in Annex III of Regulation 396/2005.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo, using the MRLs as established in Annex IIIA, the STMR and HR values as derived for the intended use on oats and the proposed MRLs for products of animal origin. In addition, for ruminant (bovine, sheep and goat) liver and fat EFSA followed the proposal of the peer review and included in chronic consumer intake calculations the respective values from livestock metabolism study. The chronic dietary intake calculations did not reveal any consumer intake concerns. The contribution of oats to the total dietary intake is insignificant, being not higher than 0.01% of the ADI (UK infant diet). The calculated total dietary intake values ranged between 0.5 and 4.7 % of the ADI. No acute intake concerns were identified with regard to oats.

EFSA concludes that the proposed use of cyflufenamid on oats is sufficiently supported by data and no risk for consumer health was identified.

### Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer			
Oats	0.02*	0.1	The MRL proposal is fully supported by data and no risk for consumers was identified for the intended uses.
Sum of cyflufenamid, the <i>E</i> -isomer and metabolite 149-F1 (2,3-difluoro-6-(trifluoromethyl)benzamidine), expressed as cyflufenamid			
Products of animal origin:	-	0.03*	The MRL proposal is based on the conclusions taken in the peer review.

\* - indicates that the MRL is set at the limit of analytical quantification

<sup>a</sup> - only commodities that fall under codes 1010000, 1020000 and 1030000 according to Annex I of Regulation (EC) No 396/2005

**Key words:** Cyflufenamid, oats, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, Z/E isomers, amidoxime 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 Nisso Chemical Europe GmbH<sup>2</sup> to modify the existing MRL for cyflufenamid in oats. 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-2008-728 and the following subject:

*Cyflufenamid – Application to modify the existing MRL for cyflufenamid in oats grain from 0.02\* mg/kg to 0.1 mg/kg.*

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

On 18 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 23 April 2009 and was 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.

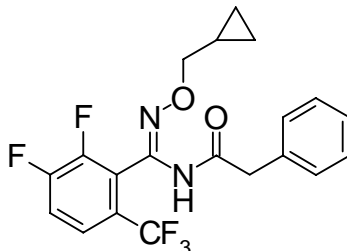
In this particular case the calculated deadline for providing the reasoned opinion was 1 May 2009.

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<sup>2</sup> Nisso Chemical Europe GmbH, Stein Straße 27, 40210, Düsseldorf, Germany

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Cyflufenamid is the ISO common name for (Z)-N-[ $\alpha$ -(cyclopropylmethoxyimino)-2,3-difluoro-6-(trifluoromethyl)benzyl]-2-phenylacetamide.



The active substance cyflufenamid (Z-isomer) is a novel fungicide belonging to the amidoxime chemical group. It is used to control powdery mildew in winter and spring wheat, winter and spring barley, durum wheat, winter rye and triticale. It is considered as fat soluble since it has a  $\log P_{ow}$  of 4.7.

Cyflufenamid is considered as a new active substance according to the definition of Directive 91/414/EEC. The United Kingdom is the designated Rapporteur Member State. The peer review of cyflufenamid was finalized and an EFSA conclusion was issued on 8 April 2009. The representative uses evaluated under the peer review of Directive 91/414/EEC were foliar spraying to winter and spring cereals (wheat, barley, triticale, rye) against powdery mildew at an application rate of 0.025 kg a.s./ha per application.

The GAP for which now an authorisation is requested in The United Kingdom refers to the use of cyflufenamid on oats. The EW formulation should be applied twice at an application rate of 0.025 kg a.s./ha. The GAP is summarized in Appendix A.

In the European Community currently temporary MRLs are established for cyflufenamid in the Annex IIIA of Regulation (EC) No 396/2005 (Appendix B). These temporary MRLs have been derived from MRLs that have been set at national level before Regulation (EC) No 396/2005 entered into force. The residue definition for cyflufenamid in the Regulation (EC) No 396/2005 currently is set as parent cyflufenamid (Z-isomer). The only MRLs established above the LOQ are the MRLs for barley (0.1 mg/kg), wheat and rye (0.05 mg/kg). The current MRL for oats is set at the LOQ of 0.02 mg/kg. For commodities of animal origin no EU MRLs are established. Codex Alimentarius Commission has not set CXLs for cyflufenamid.

## ASSESSMENT

### 1. Methods of analysis

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

The analytical methods for the determination of cyflufenamid in the foodstuffs of plant origin were evaluated in the framework of the peer review (The United Kingdom, 2006). The GC-MS method was sufficiently validated for the determination of cyflufenamid residues in dry commodities (cereals) with the LOQ of 0.01 mg/kg. In the peer review the data requirement was identified for the analytical method since it was not clear whether the analytical method can distinguish *E*- and *Z*-isomers. The RMS confirmed in April 2009 that the method covers both isomers and therefore is considered appropriate for enforcement of the new proposed residue definition which now includes *Z*- and *E*-isomers (The United Kingdom, 2009).

With regard to that EFSA concludes that there is adequate analytical method available to enforce the proposed MRL in oats.

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

In the peer review it was decided to set a new residue definition for risk assessment and enforcement for the commodities of animal origin as the sum of cyflufenamid, *E*-isomer<sup>3</sup> and metabolite 149-F1<sup>4</sup>, expressed as cyflufenamid (EFSA, 2009). The RMS in April 2009 confirmed the availability of LC/MS/MS analytical method which was sufficiently validated at the LOQ of 0.03 mg/kg (parent cyflufenamid 0.01 mg/kg, *E*-isomer 0.01 mg/kg and 149-F1 0.01 mg/kg) for the determination of cyflufenamid residues in the commodities of animal origin (The United Kingdom, 2009). Consequently, EFSA concludes that an adequate analytical method is available to enforce the proposed MRLs in products of animal origin. It should be noted, that no ILV data were submitted.

### 2. Mammalian toxicology

The toxicological reference values for cyflufenamid were derived during the peer review and are compiled in the Table 2-1 (EFSA, 2009).

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Cyflufenamid					
ADI	EFSA	2009	0.04	2 yr rat 1 yr dog	100
ARfD	EFSA	2009	0.05	Rabbit developmental toxicity	100

<sup>3</sup> 149-(*E*)-FB: (E)-N-[ $\alpha$ -(cyclopropylmethoxyimino)-2,3-difluoro-6-(trifluoromethyl)benzyl]-2-phenylacetamide

<sup>4</sup> 149-F1: 2,3-difluoro-6-(trifluoromethyl)benzimidine

### 3. Residues

#### 3.1. Nature and magnitude of residues in plant

##### 3.1.1. Primary crops

###### 3.1.1.1. Nature of residues

The metabolism of cyflufenamid in plant commodities was investigated under the peer review of Directive 91/414/EEC in wheat (The United Kingdom, 2006). Cyflufenamid (*Z*-isomer), radiolabelled either in 2,3-difluoro-6-(trifluoromethyl) phenyl or the cyclopropyl ring was applied two times at 25 g a.s./ha and two times at 100 g a.s./ha, respectively.

The major component of TRR in all crop samples was cyflufenamid at levels of up to 99% of the TRR in forage, 37% of the TRR in straw and 7% in grain. 149-(*E*)-FB, the *E*-isomer of cyflufenamid, was found in forage and parts of mature crops at levels of up to 4% of the TRR (up to approximately 10% of the level of cyflufenamid). In samples from mature plants also low concentrations (all < 5%) of the following metabolites were identified: 149-F-2-OH-B<sup>5</sup>, 149-F-4-OH-B<sup>6</sup>, 149-F- $\alpha$ -OH-B<sup>7</sup>, 149-F<sup>8</sup> and 149-F4B-Glu<sup>9</sup>.

In the peer review the expert meeting concluded that toxicological potential of *E*-isomer should be addressed in the consumer risk assessment even though the stereoisomer is not reported to be of greater toxicity than the parent compound. Consequently, it was concluded that the residue definition for risk assessment and enforcement in cereals should be set as the sum of cyflufenamid (*Z*-isomer) and its *E*-isomer.

Currently in the Regulation (EC) No 396/2005 the residue definition for cyflufenamid is set as parent cyflufenamid (*Z*-isomer) only. Taking into account the metabolism data and the conclusion reached in the peer review, EFSA proposes to change the enforcement residue definition to be in line with the residue definition derived in the peer review. It should be noted, that all proposals made in this reasoned opinion are in accordance with the new residue definition.

###### 3.1.1.2. Magnitude of residues

In support of the proposed GAP the applicant submitted ten supervised residue field trials on barley (NEU use). The data set is sufficient to extrapolate residues data from barley to oats. The overview of the available residue trials data is presented in Table 3-1. The applicant also provided residue data in straw and EFSA obtained the respective STMR and HR values necessary for calculating the livestock dietary burden. EFSA also calculated an MRL for straw, which should be considered if MRLs will be set in the future for feed items.

The storage stability of cyflufenamid in treated crops was evaluated under the peer review of Directive 91/414/EEC (The United Kingdom, 2006). Studies demonstrated that cyflufenamid

<sup>5</sup> 149-F-2-OH-B-*N*-{(Z)-[(cyclopropylmethoxy)imino][2,3-difluoro-6-(trifluoromethyl)phenyl]methyl}-2-(3-hydroxyphenyl)acetamide

<sup>6</sup> 149-F-4-OH-B-*N*-{(Z)-[(cyclopropylmethoxy)imino][2,3-difluoro-6-(trifluoromethyl)phenyl]methyl}-2-(4-hydroxyphenyl)acetamide

<sup>7</sup> 149-F- $\alpha$ -OH-B-*N*-{(Z)-[(cyclopropylmethoxy)imino][2,3-difluoro-6-(trifluoromethyl)phenyl]methyl}-2-hydroxy-2-phenylacetamide

<sup>8</sup> 149-F: N<sup>2</sup>-cyclopropylmethoxy-2,3-difluoro-6-(trifluoromethyl) benzamidine

<sup>9</sup> 149-F4B-Glu-*N*-{(Z)-[2,3-difluoro-6-trifluoromethyl  $\alpha$ -( $\beta$ -glucopyranosylimino)benzyl]}-2-phenylacetamide

is stable under frozen storage conditions in barley straw and shoots for at least 25 months and in barley grain for at least 22 months.

According to the evaluation of the EMS, the supervised residues field trials data are considered valid both with regard to analytical methods and storage stability.



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					
Enforcement residue definition: sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer									
Oats grain	NEU	Outdoor	3 x <0.02; 4 x 0.02; 2 x 0.03; 0.05	3 x <0.02; 4 x 0.02; 2 x 0.03; 0.05	0.02	0.05	0.1	1.0	The residues trials were performed on barley but can be extrapolated to oats.  It should be noted, that all results presented are expressed as parent cyflufenamid ( <i>Z</i> -isomer) therefore not being in line with the new proposed residue definition. According to the information submitted by the RMS on April 2009, results can be considered acceptable since <i>E</i> -isomer is not expected to have impact to the residue levels in oat grains and straw (The United Kingdom, 2009). R <sub>ber(grain)</sub> =0.06 mg/kg R <sub>max(grain)</sub> = 0.05 mg/kg R <sub>ber (straw)</sub> =0.26 mg/kg R <sub>max(straw)</sub> =0.255 mg/kg
Oats straw	NEU	Outdoor	4 x <0.1; 0.1; 0.11; 2 x 0.12; 0.16; 0.24	4 x <0.1; 0.1; 0.11; 2 x 0.12; 0.16; 0.24	0.11	0.24	0.3	1.0	

(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.

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

n/a: not applicable

### 3.1.1.3. Effect of industrial processing and/or household preparation

Under the peer review of Directive 91/414/EEC the effect of processing on the nature and magnitude of cyflufenamid was not investigated (The United Kingdom, 2006). With regard to the current application no additional processing studies were submitted. However, such studies are not considered necessary taking into account the low levels of cyflufenamid residues in oat grain and the expected low dietary exposure of consumers.

## 3.1.2. Rotational crops

### 3.1.2.1. Preliminary considerations

Cereals are crops grown in rotation. According to the soil degradation studies performed in the framework of the peer review, the DT<sub>90</sub> values were derived for cyflufenamid and its relevant soil metabolites. Under aerobic soil conditions cyflufenamid exhibits low to high persistence and forms its relevant soil metabolites: 149-F, 149-F11<sup>10</sup>, 149-F1 and 149-F6<sup>11</sup> (The United Kingdom, 2006). The DT<sub>90</sub> values for cyflufenamid and its metabolites 149-F1 and 149-F6, exceed 100 days, therefore rotational crop studies are necessary.

### 3.1.2.2. Nature of residues

Confined rotational crop studies were performed in the framework of the peer review of Directive 91/414/EEC by applying <sup>14</sup>C-cyflufenamid to bare soil at an application rate of 0.05 kg a.s./ha (The United Kingdom, 2006). Spring wheat was sown 30, 120 and 270 DAT, carrots 30 and 120 DAT, and lettuce 30 DAT. Translocation of radioactive residues was low. TRR found in crop parts intended for human consumption was maximum 0.006 mg/kg. Highest levels of TRR were found in wheat straw (maximum 0.09 mg/kg). Cyflufenamid is extensively metabolised in soil to 149-F11, 149-F, 149-F1 and 149-F6. Metabolites in rotational crops were not identified apart from a single compound in carrot foliage identified as 149-F6.

In the peer review it was concluded that field studies on rotational crops are not necessary, as based on the results of the submitted confined metabolism study, residues of cyflufenamid in parts of rotational crops intended for human consumption are expected below the LOQ.

### 3.1.2.3. Magnitude of residues

With regard to the current application EFSA concludes that significant residue levels (exceeding 0.01 mg/kg) in rotational crops will not occur provided that cyflufenamid is applied according to the proposed GAP.

## 3.2. Nature and magnitude of residues in livestock

### 3.2.1. Dietary burden

According to the EU Guidance document on livestock feeding studies (Document 7031/VI/95 rev.4) oats is a potential feed item for dairy and meat ruminants, pigs and chicken. The dietary

<sup>10</sup> 149-F11: (Z)-N-[α-(cyclopropylmethoxyimino)-2,3-difluoro-6-(trifluoromethyl)benzyl]malonamic acid

<sup>11</sup> 149-F6: 2,3-difluoro-6-(trifluoromethyl)benzamide

burden for different types of livestock was calculated with the EFSA livestock dietary burden calculator using the derived STMR values for oat grain and the STMR and HR values for oat straw. Input values are summarized in Table 3-2. The results of dietary burden calculations are summarized in Table 3-3.

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
Risk assessment residue definition: sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer				
Oat grain	0.02	STMR	0.02	STMR
Oat straw	0.11	STMR	0.24	HR

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	Intake (mg/kg DM)	Dietary burden triggered?
Risk assessment residue definition: sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer					
Dairy ruminants	0.00237	0.00127	Oat straw	0.07	No
Meat ruminants	0.00648	0.00324	Oat straw	0.15	Yes
Poultry	0.00103	0.00103	Oat grain	0.03	No
Pigs	0.00074	0.00074	Oat grain	0.01	No

The calculated dietary burdens, based on the expected residues in oats, exceed the trigger value of 0.1 mg/kg DM for meat ruminants only, meaning that the intake of cyflufenamid residues with feed is significant and the need for the setting of MRLs for commodities of animal origin should be assessed. The need for the setting of MRLs for food of animal origin was considered also in the peer review, since the calculated livestock dietary burdens exceeded the trigger value of 0.1 mg/kg DM for meat and dairy ruminants following the intake of cereal grain and straw.

### 3.2.2. Nature of residues

Study on the nature of cyflufenamid residues in livestock is reported in the DAR (The United Kingdom, 2006). The study was performed with lactating goats, which were dosed with <sup>14</sup>C-cyflufenamid at 1.2 mg/kg feed/cattle and 13.3 mg/kg feed/cattle (representing approximately 8N and 90N of the calculated maximum dietary burdens for meat ruminants from the intake of oat straw (see Table 3-3.) and 3N and 36N of the calculated maximum dietary burdens for meat ruminants as considered in the peer review).

The major component of TRR in fat was parent cyflufenamid (80% of the TRR) besides low levels (<2% of TRR) of 149-F, 149-F-4-OH-B, 149-(*E*)-FB and 149-F- $\alpha$ -OH-B. In the other tissue samples and milk, the main radioactive compound was 149-F1 (31-62% of TRR) besides low levels of 149-F6 (3-30% of TRR). Cyflufenamid (22% of TRR) and 149-F (15%

of TRR) were additionally found in muscle and liver respectively. Transfer of radioactivity into milk and tissues was low. A residue plateau in milk of 0.3 mg/kg was reached after 2-3 days in high dose group. In the low dose group total residues in milk were maximum 0.008 mg/kg, in muscle 0.003 mg/kg, in kidney 0.015 mg/kg, in liver 0.113 mg/kg and in fat 0.014 mg/kg.

In the peer review a new risk assessment and enforcement residue definition was proposed for animal matrices as the sum of cyflufenamid, the *E*-isomer and metabolite 149-F1, expressed as cyflufenamid.

### 3.2.3. Magnitude of residues

No livestock feeding studies have been submitted in the framework of the peer review, since from the available metabolism study it was concluded that significant cyflufenamid residues are not expected in food of animal origin after feeding with cereal grain and straw treated according to the proposed GAPs. However, in the peer review it was stated that the estimated residue levels of cyflufenamid plus 149-F1 in liver (0.011 mg/kg estimated value at 1N dose) and fat (0.004 mg/kg estimated value at 1 N dose) should be considered for the consumer risk assessment (EFSA, 2009).

Finally in the peer review it was concluded that the MRLs for food of animal origin should be set at the LOQ when an enforcement analytical method is available (EFSA, 2009). The RMS on April 2009 submitted enforcement analytical method with the LOQ of 0.03 mg/kg for the determination of cyflufenamid residues in animal matrices (see section 1.2) according to the residue definition for risk assessment and enforcement as proposed in the peer review (The United Kingdom, 2009).

Consequently EFSA concludes that the MRLs for food of animal origin should be set at the LOQ of 0.03 mg/kg.

## 4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model), using the MRLs as established in Annex IIIA, the proposed MRL for products of animal origin as well as the STMR and HR values derived for the intended use on oats. For refined consumer intake calculations EFSA took into account the decision of the peer review (see section 3.2.3.) and included the respective values from the livestock metabolism study for ruminant (bovine, sheep and goat) liver and fat in the consumer intake calculations. EFSA did not apply the proposed MRL and risk assessment values for wheat (triticale) and rye as reported in the DAR, since the existing MRLs of 0.05 mg/kg for these crops are set higher and EFSA does not have additional information on the GAPs in support of which these values were set.

The input values are summarized in 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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition for commodities of plant origin: sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer Risk assessment definition for commodities of animal origin: sum of cyflufenamid, the <i>E</i> -isomer and metabolite 149-F1, expressed as cyflufenamid				
Oats	0.02	STMR	0.05	HR
Wheat, rye, triticale	0.05	MRL	The acute risk assessment was performed only with regard to oats.	
Barley	0.02	MRL (EFSA, 2009)		
Products of animal origin (except fat and liver of bovine, sheep and goat; except honey, amphibians and reptiles, snails)	0.03	MRL (EFSA, 2009)		
Liver of bovine, sheep and goat	0.011	EFSA (2009)*		
Fat of bovine, sheep and goat	0.004	EFSA (2009)*		

\* -residue values from the livestock feeding study

The summary of the intake calculations can be found in Appendix C. The chronic dietary intake calculations did not reveal any consumer intake concerns. The total calculated intake values range between 0.5 and 4.7 % of the ADI. The contribution of oats to the total dietary intake is insignificant, being not higher than 0.01% of the ADI (UK infant). No acute intake concerns were identified with regard to oats (0.4% of the ARfD).

EFSA concludes that the proposed use of cyflufenamid on oats is sufficiently supported by data and no risk for consumer health was identified.

## CONCLUSIONS AND RECOMMENDATIONS

The United Kingdom received an application from Nisso Chemical Europe GmbH to modify the existing MRL for cyflufenamid in oats. In order to accommodate the new use of cyflufenamid on oats, the applicant proposes to raise the existing MRL of 0.02 mg/kg to 0.1 mg/kg. The United Kingdom as the Evaluating Member State (EMS) drafted an Evaluation Report according to Article 9 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 26 September 2008.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report, the Draft Assessment Report prepared by The United Kingdom and EFSA conclusion prepared in the framework of the peer review.

The metabolism of cyflufenamid was investigated in cereals in the peer review and it was concluded that the residue definition for risk assessment and enforcement in cereals should be set as the sum of cyflufenamid (*Z*-isomer) and its *E*-isomer. The MRL application for oats does not require additional metabolism studies. Currently in the Regulation (EC) No 396/2005 the enforcement residue definition for cyflufenamid is set as parent cyflufenamid (*Z*-isomer) only. Taking into account the new metabolism data, EFSA proposes to change the enforcement residue definition as proposed in the peer review. It should be noted, that all proposals made in this reasoned opinion are in accordance with the new residue definition. Adequate analytical methods are available to enforce the proposed MRL in oats.

Submitted supervised field trials indicate that the current MRL of 0.02 mg/kg does not accommodate the intended GAP in the United Kingdom and a higher MRL of 0.1 mg/kg would be necessary.

The processing studies are not necessary with regard to the current MRL application, since contribution of oats to the total dietary intake is very low. The occurrence of cyflufenamid residues in rotational crops was also investigated. EFSA concludes that significant residue levels in rotational crops are not expected provided that cyflufenamid is applied according to the proposed GAP.

The livestock dietary burden was calculated considering the expected residue levels in oat grain and oat straw. The calculated dietary burden exceeds the trigger value of 0.1 mg/kg DM for meat ruminants, but significant residues are not expected in the food of animal origin taking into account the results of the livestock metabolism study. However, in the peer review it was concluded that the MRLs for food of animal origin should be set at the LOQ when an enforcement analytical method is available. In April 2009 the RMS submitted supplementary information regarding the analytical method (enforcement) for the determination of cyflufenamid residues in animal matrices. The analytical method is sufficiently validated at the LOQ of 0.03 mg/kg for the determination of cyflufenamid residues in food of animal origin according to the new residue definition which was proposed in the peer review as the sum of cyflufenamid, the *E*-isomer and metabolite 149-F1, expressed as cyflufenamid. Consequently, EFSA proposes to set the enforcement residue definition as proposed in the peer review and concludes that the MRLs at the LOQ of 0.03 mg/kg for products of animal origin should be included in Annex III of Regulation 396/2005.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo, using the MRLs as established in Annex IIIA, the STMR and HR values as derived for the intended use on oats and the proposed MRLs for products of animal origin. In addition, for ruminant (bovine, sheep and goat) liver and fat EFSA followed the proposal of the peer review and

included in chronic consumer intake calculations the respective values from livestock metabolism study. The chronic dietary intake calculations did not reveal any consumer intake concerns. The contribution of oats to the total dietary intake is insignificant, being not higher than 0.01% of the ADI (UK infant diet). The calculated total dietary intake values ranged between 0.5 and 4.7 % of the ADI. No acute intake concerns were identified with regard to oats.

EFSA concludes that the proposed use of cyflufenamid on oats is sufficiently supported by data and no risk for consumer health was identified.

### Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Sum of cyflufenamid ( <i>Z</i> -isomer) and its <i>E</i> -isomer			
Oats	0.02*	0.1	The MRL proposal is fully supported by data and no risk for consumers was identified for the intended uses.
Sum of cyflufenamid, the <i>E</i> -isomer and metabolite 149-F1 (2,3-difluoro-6-(trifluoromethyl)benzamidine), expressed as cyflufenamid			
Products of animal origin:	-	0.03*	The MRL proposal is based on the conclusions taken in the peer review.

\* - indicates that the MRL is set at the limit of analytical quantification

<sup>a</sup> - only commodities that fall under codes 1010000, 1020000 and 1030000 according to Annex I of Regulation (EC) No 396/2005

### DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the modification of the existing MRL for cyflufenamid in oats under Regulation (EC) No 396/2005. Submitted to EFSA in 26 September, 2008. Updated on 23 April, 2009. Prepared by the Pesticide Safety Directorate, UK.

### REFERENCES

- EFSA, 2009. Conclusion on pesticide peer review regarding the risk assessment of the active substance cyflufenamid. *EFSA Scientific Report (2009) 258, 1-99*.
- The United Kingdom, 2006. Draft Assessment Report on cyflufenamid prepared by the PSD under Directive 91/414/EEC. January 2006.
- The United Kingdom, 2009. Addendum 5 to the Draft Assessment Report on cyflufenamid prepared by the PSD under Directive 91/414/EEC. April, 2009.

**APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)**

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. min'm realistic PHI
			Type (d-f)	Conc. of a.i. (i)	method, kind, if other than spray (f-h)	growth stage (j)	number (range)	kg ai/hl, where appropriate	water l/ha	kg ai/ha, where appropriate		
Oats	F	Powdery mildews	EW	50 g/l	Tractor boom	Before start of flowering (BBCH 60)	1-2	0.00625 (min) 0.0125 (max)	200 (min) 400 (max)	0.025	49-70	

(a) The EU and Codex classification (both) should be used

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(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) GIFAP 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 plants

(i) g/kg or g/l

(j) Growth stage at last treatment

(k) PHI - Pre-Harvest Interval

(l) Remarks may include: Intent of use/economic importance/restrictions (e.g. feeding/grazing/minimal intervals between applications)



**APPENDIX B – EXISTING EC MRLS**

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyflufenamid
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,02*
110000	(i) Citrus fruit	0,02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*
110030	Lemons (Citron, lemon )	0,02*
110040	Limes	0,02*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,02*
110990	Others	0,02*
120000	(ii) Tree nuts (shelled or unshelled)	0,02*
120010	Almonds	0,02*
120020	Brazil nuts	0,02*
120030	Cashew nuts	0,02*
120040	Chestnuts	0,02*
120050	Coconuts	0,02*
120060	Hazelnuts (Filbert)	0,02*
120070	Macadamia	0,02*
120080	Pecans	0,02*
120090	Pine nuts	0,02*
120100	Pistachios	0,02*
120110	Walnuts	0,02*
120990	Others	0,02*
130000	(iii) Pome fruit	0,02*
130010	Apples (Crab apple)	0,02*
130020	Pears (Oriental pear)	0,02*
130030	Quinces	0,02*
130040	Medlar	0,02*
130050	Loquat	0,02*
130990	Others	0,02*
140000	(iv) Stone fruit	0,02*
140010	Apricots	0,02*
140020	Cherries (sweet cherries, sour cherries)	0,02*
140030	Peaches (Nectarines and similar hybrids)	0,02*
140040	Plums (Damson, greengage, mirabelle)	0,02*
140990	Others	0,02*
150000	(v) Berries & small fruit	0,02*
151000	(a) Table and wine grapes	0,02*
151010	Table grapes	0,02*
151020	Wine grapes	0,02*
152000	(b) Strawberries	0,02*
153000	(c) Cane fruit	0,02*
153010	Blackberries	0,02*
153020	Dewberries (Loganberries, Boysenberries, and cloudberry)	0,02*
153030	Raspberries (Wineberries )	0,02*
153990	Others	0,02*
154000	(d) Other small fruit & berries	0,02*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,02*
154020	Cranberries	0,02*
154030	Currants (red, black and white)	0,02*
154040	Gooseberries (Including hybrids)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyflufenamid
	with other ribes species)	
154050	Rose hips	0,02*
154060	Mulberries (arbutus berry)	0,02*
154070	Azarole (mediteranean medlar)	0,02*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea salallowthorn), hawthorn, service berries, and other treeberries)	0,02*
154990	Others	0,02*
160000	(vi) Miscellaneous fruit	0,02*
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) (Java apple (water apple), pomeac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,02*
161990	Others	0,02*
162000	(b) Inedible peel, small	0,02*
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*
162030	Passion fruit	0,02*
162040	Prickly pear (cactus fruit)	0,02*
162050	Star apple	0,02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,02*
162990	Others	0,02*
163000	(c) Inedible peel, large	0,02*
163010	Avocados	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,02*
163030	Mangoes	0,02*
163040	Papaya	0,02*
163050	Pomegranate	0,02*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,02*
163070	Guava	0,02*
163080	Pineapples	0,02*
163090	Bread fruit (Jackfruit)	0,02*
163100	Durian	0,02*
163110	Soursop (guanabana)	0,02*
163990	Others	0,02*
200000	2. VEGETABLES FRESH OR FROZEN	0,02*
210000	(i) Root and tuber vegetables	0,02*
211000	(a) Potatoes	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*
212020	Sweet potatoes	0,02*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*
212040	Arrowroot	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyflufenamid
212990	Others	0,02*
213000	(c) Other root and tuber vegetables except sugar beet	0,02*
213010	Beetroot	0,02*
213020	Carrots	0,02*
213030	Celeriac	0,02*
213040	Horseradish	0,02*
213050	Jerusalem artichokes	0,02*
213060	Parsnips	0,02*
213070	Parsley root	0,02*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,02*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,02*
213100	Swedes	0,02*
213110	Tumips	0,02*
213990	Others	0,02*
220000	(ii) Bulb vegetables	0,02*
220010	Garlic	0,02*
220020	Onions (Silverskin onions)	0,02*
220030	Shallots	0,02*
220040	Spring onions (Welsh onion and similar varieties)	0,02*
220990	Others	0,02*
230000	(iii) Fruiting vegetables	0,02*
231000	(a) Solanacea	0,02*
231010	Tomatoes (Cherry tomatoes, )	0,02*
231020	Peppers (Chilli peppers)	0,02*
231030	Aubergines (egg plants) (Pepino)	0,02*
231040	Okra, lady's fingers	0,02*
231990	Others	0,02*
232000	(b) Cucurbits - edible peel	0,02*
232010	Cucumbers	0,02*
232020	Gherkins	0,02*
232030	Courgettes (Summer squash, marrow (patisson))	0,02*
232990	Others	0,02*
233000	(c) Cucurbits-inedible peel	0,02*
233010	Melons (Kiwano )	0,02*
233020	Pumpkins (Winter squash)	0,02*
233030	Watermelons	0,02*
233990	Others	0,02*
234000	(d) Sweet corn	0,02*
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	0,02*
241000	(a) Flowering brassica	0,02*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,02*
241020	Cauliflower	0,02*
241990	Others	0,02*
242000	(b) Head brassica	0,02*
242010	Brussels sprouts	0,02*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,02*
242990	Others	0,02*
243000	(c) Leafy brassica	0,02*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,02*
243020	Kale (Borecole (curly	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyflufenamid
	kale), collards)	
243990	Others ( )	0,02*
244000	(d) Kohlrabi	0,02*
250000	(v) Leaf vegetables & fresh herbs	0,02*
251000	(a) Lettuce and other salad plants including Brassicacea	0,02*
251010	Lamb's lettuce (Italian comsalad)	0,02*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,02*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,02*
251040	Cress	0,02*
251050	Land cress	0,02*
251060	Rocket, Rucola (Wild rocket)	0,02*
251070	Red mustard	0,02*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,02*
251990	Others	0,02*
252000	(b) Spinach & similar (leaves)	0,02*
252010	Spinach (New Zealand spinach, tumip greens (tumip tops))	0,02*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,02*
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves)	0,02*
254000	(d) Water cress	0,02*
255000	(e) Witloof	0,02*
256000	(f) Herbs	0,02*
256010	Chervil	0,02*
256020	Chives	0,02*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,02*
256040	Parsley	0,02*
256050	Sage (Winter savory, summer savory, )	0,02*
256060	Rosemary	0,02*
256070	Thyme ( marjoram, oregano)	0,02*
256080	Basil (Balm leaves, mint, peppermint)	0,02*
256090	Bay leaves (laurel)	0,02*
256100	Tarragon (Hyssop)	0,02*
256990	Others	0,02*
260000	(vi) Legume vegetables (fresh)	0,02*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,02*
260020	Beans (without pods)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyflufenamid
	(Broad beans, Flageolets, jack bean, lima bean, cowpea)	
260030	Peas (with pods) (Mangetout (sugar peas))	0,02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,02*
260050	Lentils	0,02*
260990	Others	0,02*
270000	(vii) Stem vegetables (fresh)	0,02*
270010	Asparagus	0,02*
270020	Cardoons	0,02*
270030	Celery	0,02*
270040	Fennel	0,02*
270050	Globe artichokes	0,02*
270060	Leek	0,02*
270070	Rhubarb	0,02*
270080	Bamboo shoots	0,02*
270090	Palm hearts	0,02*
270990	Others	0,02*
280000	(viii) Fungi	0,02*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*
280020	Wild (Chanterelle, Truffle, Morel, )	0,02*
280990	Others	0,02*
290000	(ix). Sea weeds	0,02*
300000	3. PULSES, DRY	0,02*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,02*
300020	Lentils	0,02*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,02*
300040	Lupins	0,02*
300990	Others	0,02*
400000	4. OILSEEDS AND OILFRUITS	0,02*
401000	(i) Oilseeds	0,02*
401010	Linseed	0,02*
401020	Peanuts	0,02*
401030	Poppy seed	0,02*
401040	Sesame seed	0,02*
401050	Sunflower seed	0,02*
401060	Rape seed (Bird rapeseed, turnip rape)	0,02*
401070	Soya bean	0,02*
401080	Mustard seed	0,02*
401090	Cotton seed	0,02*
401100	Pumpkin seeds	0,02*
401110	Safflower	0,02*
401120	Borage	0,02*
401130	Gold of pleasure	0,02*
401140	Hempseed	0,02*
401150	Castor bean	0,02*
401990	Others	0,02*
402000	(ii) Oilfruits	0,02*
402010	Olives for oil production	0,02*
402020	Palm nuts (palmoil kernels)	0,02*
402030	Palmfruit	0,02*
402040	Kapok	0,02*
402990	Others	0,02*
500000	5. CEREALS	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyflufenamid
500010	Barley	0,1
500020	Buckwheat	0,02*
500030	Maize	0,02*
500040	Millet (Foxtail millet, teff)	0,02*
500050	Oats	0,02*
500060	Rice	0,02*
500070	Rye	0,05
500080	Sorghum	0,02*
500090	Wheat (Spelt Triticale)	0,05
500990	Others	0,02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i> )	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) Roots	0,05*
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
633990	Others	0,05*
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,05*
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyflufenamid
830010	Cinnamon (Cassia )	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horse-radish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	0,02*
900010	Sugar beet (root)	0,02*
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
1011000	(a) Swine	
1011010	Meat	
1011020	Fat free of lean meat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offal	
1011990	Others	
1012000	(b) Bovine	
1012010	Meat	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offal	
1012990	Others	
1013000	(c) Sheep	
1013010	Meat	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offal	
1013990	Others	
1014000	(d) Goat	
1014010	Meat	
1014020	Fat	
1014030	Liver	
1014040	Kidney	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyflufenamid
1014050	Edible offal	
1014990	Others	
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offal	
1015990	Others	
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Meat	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offal	
1016990	Others	
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offal	
1017990	Others	
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others	
1030000	(iii) 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	
1030010	Chicken	
1030020	Duck	
1030030	Goose	
1030040	Quail	
1030990	Others	
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

## APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

<b>Cyflufenamid</b>			
Status of the active substance:	<b>NAS</b>	Code no.:	<b>#N/A</b>
LOQ (mg/kg bw):		proposed LOQ:	
<b>Toxicological end points</b>			
ADI (mg/kg bw/day):	<b>0.04</b>	ARfD (mg/kg bw):	<b>0.05</b>
Source of ADI:	<b>EFSA</b>	Source of ARfD:	<b>EFSA</b>
Year of evaluation:	<b>2009</b>	Year of evaluation:	<b>2009</b>

**Chronic risk assessment - refined calculations**

		TMDI (range) in % of ADI minimum - maximum 1 - 5							
		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)	
4.7	FR toddler	3.0	Milk and cream,	0.3	Wheat	0.3	Potatoes		
4.6	UK Infant	2.9	Milk and cream,	0.5	Sugar beet (root)	0.3	Wheat		
4.6	NL child	2.2	Milk and cream,	0.6	Wheat	0.3	Apples		
4.0	UK Toddler	1.5	Milk and cream,	1.1	Sugar beet (root)	0.5	Wheat		
3.5	DE child	1.1	Milk and cream,	0.6	Apples	0.5	Wheat		
3.2	WHO Cluster diet B	1.1	Wheat	0.2	Milk and cream,	0.2	Tomatoes		
3.1	DK child	0.9	Milk and cream,	0.7	Wheat	0.6	Rye		
3.0	FR infant	1.9	Milk and cream,	0.2	Potatoes	0.1	Carrots		
2.6	ES child	0.9	Milk and cream,	0.6	Wheat	0.1	Oranges		
2.3	IE adult	0.3	Wheat	0.2	Milk and cream,	0.2	Sweet potatoes		
2.2	SE general population 90th percentile	0.9	Milk and cream,	0.4	Wheat	0.2	Potatoes		
2.1	WHO cluster diet D	0.8	Wheat	0.4	Milk and cream,	0.2	Potatoes		
2.0	WHO cluster diet E	0.5	Wheat	0.2	Milk and cream,	0.2	Potatoes		
1.8	WHO regional European diet	0.4	Wheat	0.4	Milk and cream,	0.2	Potatoes		
1.8	WHO Cluster diet F	0.5	Wheat	0.3	Milk and cream,	0.2	Potatoes		
1.6	NL general	0.5	Milk and cream,	0.3	Wheat	0.1	Potatoes		
1.4	ES adult	0.4	Milk and cream,	0.3	Wheat	0.1	Oranges		
1.3	PT General population	0.5	Wheat	0.3	Potatoes	0.1	Wine grapes		
1.3	IT kids/toddler	0.8	Wheat	0.1	Other cereal	0.1	Tomatoes		
1.3	FR all population	0.4	Wheat	0.2	Milk and cream,	0.2	Wine grapes		
1.3	DK adult	0.4	Milk and cream,	0.3	Wheat	0.1	Rye		
1.1	UK vegetarian	0.3	Wheat	0.2	Milk and cream,	0.2	Sugar beet (root)		
1.1	LT adult	0.3	Milk and cream,	0.2	Potatoes	0.1	Rye		
1.0	UK Adult	0.2	Milk and cream,	0.2	Wheat	0.2	Sugar beet (root)		
1.0	FI adult	0.4	Milk and cream,	0.1	Wheat	0.1	Rye		
0.9	IT adult	0.5	Wheat	0.1	Tomatoes	0.0	Apples		
0.5	PL general population	0.2	Potatoes	0.1	Apples	0.0	Tomatoes		

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

<b>Acute risk assessment /children - refined calculations</b>	<b>Acute risk assessment / adults / general population - refined calculations</b>
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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.

<b>Unprocessed commodities</b>	<b>No of commodities for which ARfD/ADI is exceeded (IESTI 1):</b> ---			<b>No of commodities for which ARfD/ADI is exceeded (IESTI 2):</b> ---			<b>No of commodities for which ARfD/ADI is exceeded (IESTI 1):</b> ---			<b>No of commodities for which ARfD/ADI is exceeded (IESTI 2):</b> ---		
	*) **)			*) **)			*) **)			*) **)		
	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)
	0.4	Oats	0.05 / -	0.4	Oats	0.05 / -	0.1	Oats	0.05 / -	0.1	Oats	0.05 / -
<b>No of critical MRLs (IESTI 1)</b>			---			<b>No of critical MRLs (IESTI 2)</b>			---			

<b>Processed commodities</b>	<b>No of commodities for which ARfD/ADI is exceeded:</b> ---			<b>No of commodities for which ARfD/ADI is exceeded:</b> ---		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	2.0	Apple juice	0.02 / -	0.4	Bread/pizza	0.05 / -
2.0	Orange juice	0.02 / -	0.4	Orange juice	0.02 / -	
1.7	Carrot, juice	0.02 / -	0.3	Apple juice	0.02 / -	
1.3	Grape juice	0.02 / -	0.2	Wine	0.02 / -	
1.2	Wheat flour	0.05 / -	0.1	Pineapples preserved	0.02 / -	

\*) 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 Cyflufenamid 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
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement residue definition to risk assessment residue definition
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eeC)
DAT	days after treatment
DM	dry matter
DT <sub>90</sub>	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European Union
EW	oil in water emulsion
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ISO	International Organization for Standardization
ILV	independent laboratory validation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K <sub>oc</sub>	organic carbon adsorption coefficient
L	litre
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
PF	processing factor
PHI	pre harvest interval
ppm	parts per million ( $10^{-6}$ )
PRIMo	Pesticide Residues Intake Model
PSD	Pesticide Safety Directorate, United Kingdom
RMS	Rapporteur Member State
SEU	Southern European Union
STMR	supervised trials median residue
TRR	total radioactive residue
UVD	ultra-violet detection