

## **REASONED OPINION OF EFSA**

### **Modification of the existing MRLs for ioxynil in several food commodities of animal origin<sup>1</sup>**

**Prepared by the Pesticides Unit (PRAPeR)**

**(Question No EFSA-Q-2009-00371)**

**Issued on 12 May 2009**

#### **SUMMARY**

The United Kingdom received an application from Oxford Agricultural Consultants to modify the existing MRLs for ioxynil in several food commodities of animal origin (meat, liver, kidney and fat of bovine, sheep, goat and swine). In order to accommodate the new use of ioxynil on rye and triticale, the existing MRLs of 0.05 mg/kg for the foodstuffs of animal origin have to be raised. 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 30 January 2009.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report as well as the Draft Assessment Report prepared by France in the framework of Directive 91/414/EEC.

The metabolism of ioxynil in plant commodities has been investigated in root and tuber vegetables and in cereals and residue definitions for risk assessment and enforcement have been derived for these crop categories as the sum of ioxynil and its esters, expressed as ioxynil. Adequate analytical methods are available for the determination of ioxynil residues in cereals.

The available supervised residues field trials data indicate that there is no need to modify the existing MRL of 0.05 mg/kg for cereals based on the new uses proposed. The residues in rotational crops are not of relevance for the current application, since the DT<sub>90</sub> values for ioxynil residues are expected to be below 100 days.

The livestock dietary burden was calculated with the EFSA livestock dietary burden calculator considering the existing MRLs for ioxynil. The calculated dietary burden exceeds the trigger value of 0.1 mg/kg DM for meat and dairy ruminants. The dietary burden is mainly driven by the high intake of cereal straw for meat ruminants. Since the calculated dietary burden for pigs and poultry is not exceeded, the need for the setting of MRLs for swine and

---

<sup>1</sup> For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRLs for ioxynil in several food commodities of animal origin. *EFSA Scientific Report (2009) 288, 1-28*

poultry meat, fat, kidney and liver was not further investigated in the framework of this application.

The metabolism of ioxynil in livestock was investigated during the peer review in lactating cow, goat and laying hen. A general residue definition for risk assessment and enforcement was proposed for the commodities of animal origin as the sum of ioxynil and its esters, expressed as ioxynil, being the same residue definition as for plant commodities. Adequate analytical methods are available for the enforcement of MRLs in food of animal origin with the LOQ of 0.05 mg/kg and for the milk with the LOQ of 0.01 mg/kg.

A livestock feeding study with lactating cows was performed in the framework of the peer review. For estimating the MRLs in the commodities of animal origin, EFSA took into account the calculated dietary burdens and the results from the livestock feeding study. The MRL proposals are compiled in the table below. Since the maximum dietary burden for dairy ruminants is lower than the lowest feeding level, which resulted in the highest mean residue of 0.01 mg/kg in milk, the existing MRL of 0.01\* mg/kg for milk is confirmed. The processing studies are not necessary with regard to the current MRL application taking into account the low contribution of animal commodities to the total dietary intake.

The consumer intake assessment was performed with revision 2 of the EFSA PRIMo, using the MRLs as established in Annex II and Annex IIIB of Regulation (EC) No 396/2005 as well as the calculated STMR and HR values for ruminant meat, fat, kidney and liver. The chronic dietary intake calculations did not reveal any consumer intake concerns. The calculated total intake values ranged from 10 to 48 % of the ADI. No acute intake concerns were identified for animal commodities under consideration.

EFSA concludes that the proposed uses of ioxynil on rye and triticale will not result in consumer intake concerns.

### Overview of the proposed EC MRL

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Ioxynil including its esters, expressed as ioxynil			
Bovine, goat, sheep meat	0.05*	0.5	The MRL proposal is supported by data and no risk for consumers was identified for the proposed uses on rye and triticale
Bovine, goat, sheep fat	0.05*	1.5	
Bovine, goat, sheep liver	0.05*	1.0	
Bovine, goat, sheep kidney	0.05*	2.5	
Milk	0.01*	0.01*	The existing MRLs are confirmed.
Cereals (rye and triticale)	0.05*	0.05*	

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

**Key words: Ioxynil, rye and triticale, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, ioxynil octanoate, hydroxybenzotrile herbicides**

## TABLE OF CONTENTS

Background .....	4
Terms of reference.....	4
The active substance and its use pattern.....	5
Assessment .....	6
1. Methods of analysis .....	6
1.1. Methods for enforcement of residues in food of plant origin .....	6
1.2. Methods for enforcement of residues in food of animal origin .....	6
2. Mammalian toxicology.....	6
3. Residues.....	6
3.1. Nature and magnitude of residues in plant.....	6
3.1.1. Primary crops.....	6
3.1.1.1. Nature of residues .....	6
3.1.1.2. Magnitude of residues.....	7
3.1.1.3. Effect of industrial processing and/or household preparation .....	9
3.1.2. Rotational crops.....	9
3.1.2.1. Preliminary considerations.....	9
3.2. Nature and magnitude of residues in livestock .....	9
3.2.1. Dietary burden .....	9
3.2.2. Nature of residues.....	10
3.2.3. Magnitude of residues .....	10
4. Consumer risk assessment .....	13
Conclusions and recommendations .....	14
Documentation provided to EFSA .....	15
References .....	15
Appendix A – Good Agricultural Practices (GAPs) .....	16
Appendix B – Existing EC MRLs.....	17
Appendix C – Pesticide Residues Intake Model (PRIMo).....	24
Glossary / Abbreviations.....	27

## 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 Oxford Agricultural Consultants<sup>2</sup> to modify the existing MRLs for ioxynil in several food commodities of animal origin. 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 30 January 2009. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2009-00371 and the following subject:

*Ioxynil - Application to modify the existing MRLs for ioxynil esters and ioxynil phenol expressed as ioxynil phenol in swine meat from 0.05 mg/kg to 0.1 mg/kg, in bovine meat from 0.05 mg/kg to 0.1 mg/kg, in sheep meat from 0.05 mg/kg to 0.1 mg/kg, in goat meat from 0.05 mg/kg to 0.1 mg/kg, in swine kidney from 0.2 mg/kg to 0.5 mg/kg, in bovine kidney from 0.2 mg/kg to 0.5 mg/kg, in sheep kidney from 0.2 mg/kg to 0.5 mg/kg, in goat kidney from 0.2 mg/kg to 0.5 mg/kg, in swine liver from 0.2 mg/kg to 0.5 mg/kg, in bovine liver from 0.2 mg/kg to 0.5 mg/kg, in sheep liver from 0.2 mg/kg to 0.5 mg/kg, in goat liver from 0.2 mg/kg to 0.5 mg/kg, in swine fat (free of lean meat) from 0.05 mg/kg to 0.1 mg/kg, in bovine fat from 0.05 mg/kg to 0.1 mg/kg, in sheep fat from 0.05 mg/kg to 0.1 mg/kg and in goat fat from 0.05 mg/kg to 0.1 mg/kg, except poultry meat.*

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

## TERMS OF REFERENCE

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

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

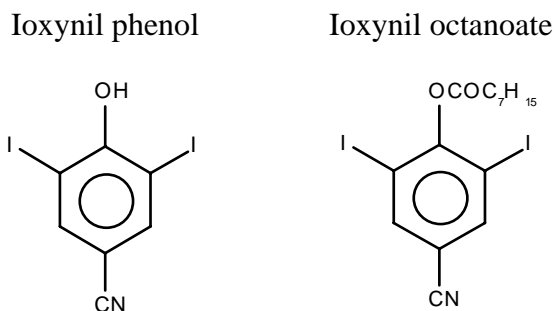
In this particular case the calculated deadline for providing the reasoned opinion was 30 April 2009.

---

<sup>2</sup> Oxford Agricultural Consultants (on behalf of Makhteshim Agan), 3Lower Farm Barns, OX6 9LT, Oxon, Oxfordshire, The United Kingdom

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Ioxynil is the ISO common name for 4-hydroxy-3,5-di-iodobenzonitrile (ioxynil phenol) (IUPAC). The active component is the parent ioxynil phenol, but the octanoate ester (4-cyano-2,6-di-iodophenyl octanoate) is used as the vehicle for the active phenol component.



Ioxynil, its salts and its esters are post-emergence herbicides belonging to the hydroxybenzotrile chemical group. It is used for the control of broadleaf weeds. The active compound acts both as an electron transport inhibitor and as an uncoupling agent. Ioxynil octanoate is considered as a fat soluble residue, but ioxynil phenol is not soluble in fat.

Ioxynil was peer reviewed according to Directive 91/414/EEC with France being the designated Rapporteur Member State. It was included in Annex I to this Directive by Directive 2004/58/EC for use as a herbicide only. The representative uses evaluated in the DAR were treatment of cereals (wheat, barley, oats, rye and triticale), onions, garlic, leeks and shallots.

The current MRLs for ioxynil are set in Annexes II and IIIB of Regulation (EC) No 396/2005 (Appendix B). The MRLs established under Directives 86/362/EEC, 86/363/EEC and 90/642/EEC have been transferred to Annex II of Regulation (EC) No 396/2005. In Annex III temporary MRLs have been established for crops that were not covered by previous Community MRL legislation. For the commodities of animal origin (except edible offal) and cereals the MRLs are set at the LOQ of 0.05 mg/kg.

The applicant has now requested an authorization in the United Kingdom for the new outdoor uses of ioxynil on rye and triticale. The use of ioxynil on rye and triticale will involve one application of the active substance at a rate of 0.240-0.380 kg a.s./ha (the growth stage BBCH 32). The summary of the proposed GAPs is provided in Appendix A.

## ASSESSMENT

### 1. Methods of analysis

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

The analytical methods for the determination of ioxynil residues in the foodstuffs of plant origin were evaluated in the framework of the peer review of Directive 91/414/EEC (France, 2002). For the determination of ioxynil and its residues in cereal (grain and straw) and cotton seed the CC-ECD method is sufficiently validated at the LOQ of 0.01 mg/kg.

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

The analytical methods for the determination of ioxynil residues in food of animal origin were evaluated in the framework of the peer review of Directive 91/414/EEC (France, 2001). The analytical method where ioxynil residues were determined with GC-ECD was sufficiently validated at the LOQ of 0.01 mg/kg in milk and 0.05 mg/kg in meat, liver, fat, kidney and eggs. A confirmatory method with GC-MS/MS is also available. It is concluded that there are adequate analytical methods available for the enforcement of the proposed MRLs.

### 2. Mammalian toxicology

The toxicological reference values for ioxynil were derived at Community level during the peer review of Directive 91/414/EEC (European Commission, 2004) and are compiled in Table 2-1.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Ioxynil					
ADI	COM	2004	0.005	2 yr rat	100
ARfD	COM	2004	0.04	Rat developmental	100

### 3. Residues

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

##### 3.1.1. Primary crops

##### 3.1.1.1. Nature of residues

During the peer review the metabolism of ioxynil was investigated in plants for the following crops (France, 2002):

- cereals: wheat – post-emergence application of ioxynil octanoate at a rate of 0.400 kg a.s./ha (i.e., 0.300 kg ioxynil phenol equiv./ha)
- foot and tuber vegetables: onions- application of ioxynil octanoate at a rate of 0.942 kg a.s./ha (i.e., 0.703 kg ioxynil phenol equiv./ha)

Metabolism studies were performed with  $^{14}\text{C}$  labelled ioxynil octanoate. In onions the major component of the TRR was polar material. The nature of it was assumed to be  $^{14}\text{C}$  glucose. In cereals the TRR was determined in grain, straw, leaves and stubble. The TRR in grain (0.036 mg/kg) was significantly lower than that for the straw (0.319 mg/kg) and the stubble (3.089 mg/kg). After characterization, the major component of the TRR was identified to be polar material (45.2% and 50% in grain and straw respectively). The polar material was characterized by performing deconjugation, which resulted in the release of material with chromatographic properties similar to ioxynil phenol, ioxynil octanoate, 3-iodo-4-hydroxybenzamide, 4-hydroxybenzoxitrile and 3,5-diiodo-4-hydroxybenzamide. In general, the metabolic pathway proceeds by ester hydrolysis of ioxynil octanoate to produce ioxynil phenol, followed by mono and di-deiodination to form 3-iodo-4-hydroxybenzoxitrile and 3,5-diiodo-4-hydroxybenzamide.

In the peer review it was concluded that none of the metabolites observed in the metabolism study was present at a significant level to constitute a relevant metabolite for the residue definition. Therefore it was proposed to set the residue definition for risk assessment and enforcement for the considered crop categories as the sum of ioxynil and its esters, expressed as ioxynil.

#### 3.1.1.2. Magnitude of residues

In support of the proposed GAPs, the applicant refers to the supervised residue field trials data that are reported in the DAR for the representative uses evaluated at that time on cereals. The applicant refers to the extrapolation of available data on wheat and barley to rye and triticale. Since ioxynil is applied on the crop at the early growth stage, such extrapolation is possible. For addressing this issue, EFSA consulted the DAR and available data on supervised residue field trials (Table 3-1). EFSA considered only those field trials data that were obtained following the application rate within  $\pm 25\%$  of the proposed GAPs. Finally, the data on wheat and barley were combined. In total, eight residue trials were used for extrapolating residues data from wheat and barley to rye and triticale. For straw, in total 24 residue trials were available and the respective STMR and HR values were derived.

The storage stability data of ioxynil residues was investigated in the peer review of Directive 91/414/EEC (France, 2002). Studies demonstrated that residues of ioxynil are stable in dry commodities and commodities with high oil content for up to 2 years when stored at  $-18^\circ\text{C}$ . Since the supervised residue field trials data were evaluated under the peer review, EFSA concludes that residue data can be considered valid both in the means of analytical performance and storage stability.

From the available data it is concluded that there is no need to modify the existing MRLs for cereal grains which are currently set at the LOQ of 0.05 mg/kg. The MRL for cereal straw is not proposed since no MRLs are currently set for feed items.



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

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) <sup>(b)</sup>	HR (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement	Risk assessment					
Ioxynil, including its esters, expressed as ioxynil									
Rye grain Triticale grain	NEU	Outdoor	2 x < 0.01; 4 x 0.02; 2 x < 0.05	2 x < 0.01; 4 x < 0.02; 2 x < 0.05	0.02	< 0.05	0.05*	1.00	Combined data set on wheat (4), barley (2) and oats (2) with application rates of 0.25-0.450 kg a.s./ha. It should be mentioned, that EFSA did not consider residue values below the LOQ of 0.1 mg/kg considering insufficient sensitivity of the analytical method.
Rye straw Triticale straw	NEU	Outdoor	0.01; 4 x < 0.02; 0.02; 0.04; 2 x 0.05; 0.1; 0.12; 0.13; 0.15; 0.2; 2 x 0.22; 0.24; 0.26; 0.32; 0.35; 0.54; 0.73; 1.3; 1.47	0.01; 4 x < 0.02; 0.02; 0.04; 2 x 0.05; 0.1; 0.12; 0.13; 0.15; 0.2; 2 x 0.22; 0.24; 0.26; 0.32; 0.35; 0.54; 0.73; 1.3; 1.47	0.14	1.47	n/a	1.0	Combined data set on wheat (10), barley (12) and oats (2) with application rates 0.25-0.450 kg a.s./ha. It should be mentioned, that EFSA did not consider residue values below the LOQ of 0.1 mg/kg considering insufficient sensitivity of the analytical method.

(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

In the peer review the effect of processing on the nature or magnitude of ioxynil residues was not investigated (France, 2002). In the framework of the current application no processing studies have been submitted but are not considered necessary, taking into account the low contribution of animal commodities to the total dietary intake.

## 3.1.2. Rotational crops

### 3.1.2.1. Preliminary considerations

Cereals can be grown in rotation. According to the soil degradation studies performed in the framework of the peer review, the DT<sub>50</sub> values were determined for ioxynil octanoate and ioxynil phenol and both were below 10 days (France, 2002). Di-iodo-4-OH-benzamide and di-iodo-4-OH-benzoic acid have been reported as relevant soil metabolites, but for none of them the DT<sub>50</sub> value exceeds 10 days. The DT<sub>90</sub> values are not available, but taking into account the low DT<sub>50</sub> values, it is not expected that the trigger value of 100 days for DT<sub>90</sub> will be exceeded. With regard to that, EFSA concludes that ioxynil residues in rotational crops are not of relevance for the current application.

## 3.2. Nature and magnitude of residues in livestock

### 3.2.1. Dietary burden

According to the EU Guidance document on livestock feeding studies Appendix G (Document 7031/VI/95 rev.4) cereals are a potential feed item for dairy and meat ruminants, pigs and chicken. The dietary burden for different types of livestock was calculated using the EFSA livestock dietary burden calculator. The input values for cereals are summarized in Table 3-2. The results of the calculations are reported 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
Ioxynil, including its esters, expressed as ioxynil				
Cereal grain	0.02	STMR	0.02	STMR
Cereal straw	0.14	STMR	1.47	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	Dietary burden triggered?
Ioxynil and its esters, expressed as ioxynil				
Dairy ruminants	0.012770	0.001522	Wheat straw	Yes
Meat ruminants	0.037126	0.003987	Wheat straw	Yes

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Dietary burden triggered?
Poultry	0.001028	0.001028	Wheat grain	No
Pigs	0.000744	0.000744	Wheat grain	No

The calculated dietary burdens exceed the trigger value of 0.1 mg/kg DM for dairy and meat ruminants only. The highest contributing commodity for both livestock species is wheat straw and the highest exceedance of dietary burden is identified for meat ruminants.

### 3.2.2. Nature of residues

The nature of ioxynil and its residues was investigated during the peer review of Directive 91/414/EEC (France, 2002). The metabolism of ioxynil in livestock was studied in dairy cows using unlabelled ioxynil phenol and in lactating goats and laying hens with <sup>14</sup>C-phenyl ioxynil octanoate. In goat and hen, a significant proportion of ioxynil octanoate was eliminated via excreta. Elimination via milk or eggs was minor. According to the results of goat metabolism study, residues in milk and tissues consist mainly of ioxynil phenol (66 to 99% TRR), accompanied in certain cases by residues of ioxynil octanoate (9% in milk) or 3-iodo-4-hydroxybenzotrile (24% in liver, 0,5% in kidney). The highest concentration of radioactivity in goat milk was 0.028 mg equiv./kg following the high administered dose (10 mg/kg). Fat and muscle contained the lowest residues, but kidney and liver were found to contain the highest residues. The metabolic mechanisms found for both the goat and hen were consistent with those found in the rat. The ioxynil phenol was found to be the major component in the tissue residues of goat; in hen tissues in addition 3-iodo-4-hydroxybenzotrile and 4-hydroxybenzotrile were identified.

The residue definition for risk assessment and enforcement in commodities of animal origin was set as the sum of ioxynil and its esters, expressed as ioxynil.

### 3.2.3. Magnitude of residues

During the peer review of Directive 91/414/EEC the magnitude of ioxynil residues in livestock was investigated in the feeding study with lactating cows (France, 2003). The groups of lactating cows were dosed with ioxynil octanoate. The dose levels were 1N (0.014 mg ioxynil/kg bw/day), 3N (0.041 mg ioxynil/kg bw/day) and 10N (0.136 mg ioxynil/kg bw/day) of the calculated dietary burden. The analytical method which was used for the determination of ioxynil residues had the LOQ of 0.0075 mg/kg and the LOD of 0.0015 mg/kg expressed as ioxynil equivalent. The mean concentrations of ioxynil residues in whole milk reached a maximum for the low dose group at day 7 (0.01 mg/kg), for the medium dose group at day 41 (0.04 mg/kg) and for the high dose group at day 30 (0.13 mg/kg).

For estimating the MRLs in the commodities of animal origin, EFSA took into account the calculated dietary burdens for ruminants and results from the livestock feeding study. The overview of the results from the livestock feeding study and the proposed MRLs are summarized in Table 3-4. It should be noted, that since only for ruminants the dietary burden is exceeded, MRLs are estimated and proposed only for ruminant meat, kidney, liver and fat. For poultry and pigs therefore EFSA did not consider the setting of MRLs for the corresponding food commodities.

The maximum calculated dietary burden for dairy ruminants and the results of a feeding study confirm the existing MRL of 0.01 mg/kg for milk.

It should be noted, that the existing ioxynil MRLs for animal commodities were set according to an internationally agreed approach where the calculated median dietary burden was used for deriving the MRLs. In the case of ioxynil it resulted in MRLs below the LOQ. Nowadays, maximum calculated dietary burden is used for deriving the MRL proposals resulting in higher MRL values.

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

Livestock	Dietary burden		Commodity	Results of livestock feeding study						STMR (mg/kg)	HR (mg/kg)	MRL proposal	CF
	Median (mg/kg bw/d)	Max (mg/kg bw/d)		Dose level (mg/kg bw/d)	No of samples	Result for enforcement		Result for risk assessment					
						Mean (mg/kg)	Max (mg/kg)	Mean (mg/kg)	Max (mg/kg)				
Ioxynil, including its esters, expressed as ioxynil													
Meat ruminants	0.003987	0.037126	Ruminant kidney	0.014	3	0.75	0.81	0.75	0.81	0.2	2.2	2.5	1.0
				0.041		1.66	2.21	1.66	2.21				
				0.136		5.63	6.30	5.63	6.30				
			Ruminant liver	0.014	3	0.34	0.375	0.34	0.375	0.1	0.9	1.0	1.0
				0.041		0.82	0.89	0.82	0.89				
				0.136		2.17	2.42	2.17	2.42				
			Ruminant muscle	0.014	3	0.15	0.17	0.15	0.17	0.04 (<LOQ)	0.33	0.5	1.0
				0.041		0.32	0.33	0.32	0.33				
				0.136		1.01	1.15	1.01	1.15				
			Ruminant fat	0.014	6	0.14	0.22	0.14	0.22	0.06	1.1	1.5	1.0
				0.041		0.53	1.1	0.53	1.1				
				0.136		2.77	5.15	2.77	5.15				
Dairy ruminants	0.001522	0.012770	Milk	0.014	3	0.01	0.011	0.01	0.011	0.01	0.011	0.01	1.0

#### 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 II and Annex IIIB of Regulation (EC) No 396/2005 as well as the derived STMR and HR values for ruminant meat, fat, kidney and liver. 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
Ioxynil including its esters, expressed as ioxynil				
Ruminant meat	0.04	STMR	0.33	HR
Ruminant fat	0.06	STMR	1.1	HR
Ruminant liver	0.1	STMR	0.9	HR
Ruminant kidney	0.2	STMR	2.2	HR

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 calculated total intake values ranged from 10 to 48 % of the ADI. No acute intake concerns were identified for the considered animal commodities and the highest contribution was identified for bovine kidney amounting for up to 21% of the ARfD.

EFSA concludes that the proposed uses of ioxynil on rye and triticale will not result in the consumer intake concerns.

## CONCLUSIONS AND RECOMMENDATIONS

The United Kingdom received an application from Oxford Agricultural Consultants to modify the existing MRLs for ioxynil in several food commodities of animal origin (meat, liver, kidney and fat of bovine, sheep, goat and swine). In order to accommodate the new use of ioxynil on rye and triticale, the existing MRLs of 0.05 mg/kg for the foodstuffs of animal origin have to be raised. 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 30 January 2009.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report as well as the Draft Assessment Report prepared by France in the framework of Directive 91/414/EEC.

The metabolism of ioxynil in plant commodities has been investigated in root and tuber vegetables and in cereals and residue definitions for risk assessment and enforcement have been derived for these crop categories as the sum of ioxynil and its esters, expressed as ioxynil. Adequate analytical methods are available for the determination of ioxynil residues in cereals.

The available supervised residues field trials data indicate that there is no need to modify the existing MRL of 0.05 mg/kg for cereals based on the new uses proposed. The residues in rotational crops are not of relevance for the current application, since the DT<sub>90</sub> values for ioxynil residues are expected to be below 100 days.

The livestock dietary burden was calculated with the EFSA livestock dietary burden calculator considering the existing MRLs for ioxynil. The calculated dietary burden exceeds the trigger value of 0.1 mg/kg DM for meat and dairy ruminants. The dietary burden is mainly driven by the high intake of cereal straw for meat ruminants. Since the calculated dietary burden for pigs and poultry is not exceeded, the need for the setting of MRLs for swine and poultry meat, fat, kidney and liver was not further investigated in the framework of this application.

The metabolism of ioxynil in livestock was investigated during the peer review in lactating cow, goat and laying hen. A general residue definition for risk assessment and enforcement was proposed for the commodities of animal origin as the sum of ioxynil and its esters, expressed as ioxynil, being the same residue definition as for plant commodities. Adequate analytical methods are available for the enforcement of MRLs in food of animal origin with the LOQ of 0.05 mg/kg and for the milk with the LOQ of 0.01 mg/kg.

A livestock feeding study with lactating cows was performed in the framework of the peer review. For estimating the MRLs in the commodities of animal origin, EFSA took into account the calculated dietary burdens and the results from the livestock feeding study. The MRL proposals are compiled in the table below. Since the maximum dietary burden for dairy ruminants is lower than the lowest feeding level, which resulted in the highest mean residue of 0.01 mg/kg in milk, the existing MRL of 0.01\* mg/kg for milk is confirmed. The processing studies are not necessary with regard to the current MRL application taking into account the low contribution of animal commodities to the total dietary intake.

The consumer intake assessment was performed with revision 2 of the EFSA PRIMo, using the MRLs as established in Annex II and Annex IIIB of Regulation (EC) No 396/2005 as well as the calculated STMR and HR values for ruminant meat, fat, kidney and liver. The chronic dietary intake calculations did not reveal any consumer intake concerns. The calculated total

intake values ranged from 10 to 48 % of the ADI. No acute intake concerns were identified for animal commodities under consideration.

EFSA concludes that the proposed uses of ioxynil on rye and triticale will not result in consumer intake concerns.

Table 5-1. Overview of the proposed EC MRL

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Ioxynil including its esters, expressed as ioxynil			
Bovine, goat, sheep meat	0.05*	0.5	The MRL proposal is supported by data and no risk for consumers was identified for the proposed uses on rye and triticale
Bovine, goat, sheep fat	0.05*	1.5	
Bovine, goat, sheep liver	0.05*	1.0	
Bovine, goat, sheep kidney	0.05*	2.5	
Milk	0.01*	0.01*	The existing MRLs are confirmed.
Cereals (rye and triticale)	0.05*	0.05*	

\* 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 ioxynil in several food commodities of animal origin under Regulation (EC) No 396/2005. Submitted to EFSA on 30 January 2009. Prepared by the Pesticide Safety Directorate, UK.

#### REFERENCES

- France, 2002. Draft Assessment Report on ioxynil prepared by France under Directive 91/414/EEC. June 2006. Addendum to the DAR. B-7.- Residue data. November, 2002
- France, 2003. Addendum to the DAR, prepared by France under Directive 91/414/EEC. April, 2003.
- European Commission, 2004. Review report for the active substance ioxynil. February, 2004.



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

Crop and/or situation (a)	Member State or Country	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks:
				Type (d-f)	Conc. of a.s. g/L * (i)	method, kind (f-h)	growth stage & season (j)	number (range) (k)	interval between appl. (min.)	kg a.s./hl (range)	water l/ha (range)	kg a.s./ha (range)		
Winter and spring rye and triticale	UK	F	Annual broad leaved weeds	EC	160-190	spraying	BBCH 32	1	-	120-190	Min.250	0.240-0.380	-	The application rates are expressed as ioxynil equivalents.

- (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)	Ioxylin, including its esters expressed as ioxylin (F)
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,05*
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*
110030	Lemons (Citron, lemon )	0,05*
110040	Limes	0,05*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,05*
110990	Others	0,05*
120000	(ii) Tree nuts (shelled or unshelled)	0,05*
120010	Almonds	0,05*
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	0,05*
120050	Coconuts	0,05*
120060	Hazelnuts (Filbert)	0,05*
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	0,05*
120110	Walnuts	0,05*
120990	Others	0,05*
130000	(iii) Pome fruit	0,05*
130010	Apples (Crab apple)	0,05*
130020	Pears (Oriental pear)	0,05*
130030	Quinces	0,05*
130040	Medlar	0,05*
130050	Loquat	0,05*
130990	Others	0,05*
140000	(iv) Stone fruit	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ioxylin, including its esters expressed as ioxylin (F)
140010	Apricots	0,05*
140020	Cherries (sweet cherries, sour cherries)	0,05*
140030	Peaches (Nectarines and similar hybrids)	0,05*
140040	Plums (Damson, greengage, mirabelle)	0,05*
140990	Others	0,05*
150000	(v) Berries & small fruit	0,05*
151000	(a) Table and wine grapes	0,05*
151010	Table grapes	0,05*
151020	Wine grapes	0,05*
152000	(b) Strawberries	0,05*
153000	(c ) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberrries)	0,05*
153030	Raspberries (Wineberries )	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,05*
154020	Cranberries	0,05*
154030	Currants (red, black and white)	0,05*
154040	Gooseberries (Including hybrids with other ribes species)	0,05*
154050	Rose hips	0,05*
154060	Mulberries (arbutus berry)	0,05*
154070	Azarole (mediterranean medlar)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ioxynil, including its esters expressed as ioxynil (F)
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	0,05*
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	0,05*
163010	Avocados	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ioxynil, including its esters expressed as ioxynil (F)
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,05*
163070	Guava	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,05*
213020	Carrots	0,2
213030	Celeriac	0,05*
213040	Horseradish	0,05*
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,2
213070	Parsley root	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ioxynil, including its esters expressed as ioxynil (F)
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	0,05*
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	
220010	Garlic	0,2
220020	Onions (Silverskin onions)	0,2
220030	Shallots	0,2
220040	Spring onions (Welsh onion and similar varieties)	3
220990	Others	0,05*
230000	(iii) Fruiting vegetables	0,05*
231000	(a) Solanaceae	0,05*
231010	Tomatoes (Cherry tomatoes, )	0,05*
231020	Peppers (Chilli peppers)	0,05*
231030	Aubergines (egg plants) (Pepino)	0,05*
231040	Okra, lady's fingers	0,05*
231990	Others	0,05*
232000	(b) Cucurbits – edible peel	0,05*
232010	Cucumbers	0,05*
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson))	0,05*
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano )	0,05*
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ioxynil, including its esters expressed as ioxynil (F)
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choy, Chinese flat cabbage (tai goo choy), peking cabbage (pe-tsai), cow cabbage)	0,05*
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	0,05*
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*
251010	Lamb's lettuce (Italian cornsalad)	0,05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ioxynil, including its esters expressed as ioxynil (F)
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,05*
251040	Cress	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,05*
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory, )	0,05*
256060	Rosemary	0,05*
256070	Thyme ( marjoram, oregano)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ioxynil, including its esters expressed as ioxynil (F)
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	3
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	
300000	3. PULSES, DRY	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ioxynil, including its esters expressed as ioxynil (F)
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	0,1*
401010	Linseed	0,1*
401020	Peanuts	0,1*
401030	Poppy seed	0,1*
401040	Sesame seed	0,1*
401050	Sunflower seed	0,1*
401060	Rape seed (Bird rapeseed, turnip rape)	0,1*
401070	Soya bean	0,1*
401080	Mustard seed	0,1*
401090	Cotton seed	0,1*
401100	Pumpkin seeds	0,1*
401110	Safflower	0,1*
401120	Borage	0,1*
401130	Gold of pleasure	0,1*
401140	Hempseed	0,1*
401150	Castor bean	0,1*
401990	Others	0,1*
402000	(ii) Oilfruits	
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,1*
402030	Palmfruit	0,1*
402040	Kapok	0,1*
402990	Others	0,1*
500000	5. CEREALS	0,05*
500010	Barley	0,05*
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ioxynil, including its esters expressed as ioxynil (F)
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	0,05*
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i> )	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,1*
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ioxynil, including its esters expressed as ioxynil (F)
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia )	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Aril	0,1*
870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	0,05*
900010	Sugar beet (root)	0,05*
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ioxynil, including its esters expressed as ioxynil (F)
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	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,2
1011990	Others	0,05*
1012000	(b) Bovine	
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,2
1012990	Others	0,05*
1013000	(c) Sheep	
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,2
1013990	Others	0,05*
1014000	(d) Goat	
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,2
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	



Code number	Groups and examples of individual products to which the MRLs apply (a)	Ioxynil, including its esters expressed as ioxynil (F)
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,2
1015990	Others	0,05*
1016000	(f) Poultry – chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,2
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,2
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,01*
1020010	Cattle	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ioxynil, including its esters expressed as ioxynil (F)
1020020	Sheep	0,01*
1020030	Goat	0,01*
1020040	Horse	0,01*
1020990	Others	0,01*
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>ioxynil</b>			
Status of the active substance:	<b>Included</b>	Code no.:	<b>#N/A</b>
LOQ (mg/kg bw):		proposed LOQ:	
<b>Toxicological end points</b>			
ADI (mg/kg bw/day):	<b>0.005</b>	ARfD (mg/kg bw):	<b>0.04</b>
Source of ADI:	<b>COM</b>	Source of ARfD:	<b>COM</b>
Year of evaluation:	<b>2004</b>	Year of evaluation:	<b>2004</b>

**Chronic risk assessment - refined calculations**

		TMDI (range) in % of ADI minimum - maximum							
		10      48							
		<b>No of diets exceeding ADI:</b>		---					
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	pTMRs at LOQ (in % of ADI)	
47.8	WHO Cluster diet B	8.5	Wheat	3.1	Onions	3.1	Tomatoes		
47.3	UK Toddler	22.9	Sugar beet (root)	4.1	Milk and cream,	3.9	Wheat		
44.0	DE child	12.1	Apples	4.1	Carrots	4.1	Carrots		
43.1	NL child	6.3	Apples	5.9	Potatoes	5.9	Milk and cream,		
41.0	FR toddler	9.8	Carrots	7.9	Milk and cream,	5.1	Potatoes		
40.3	IE adult	3.5	Sweet potatoes	2.8	Spring onions	2.5	Parsnips		
40.0	UK Infant	10.1	Sugar beet (root)	7.7	Milk and cream,	5.3	Carrots		
30.8	FR infant	10.6	Carrots	5.1	Milk and cream,	4.1	Potatoes		
30.6	DK child	5.5	Wheat	5.5	Carrots	4.4	Rye		
28.9	WHO cluster diet E	3.9	Wheat	3.8	Potatoes	1.8	Carrots		
26.8	WHO cluster diet D	6.5	Wheat	4.1	Potatoes	2.0	Onions		
25.9	SE general population 90th percentile	4.2	Potatoes	3.4	Carrots	3.2	Wheat		
24.6	WHO Cluster diet F	3.6	Wheat	3.4	Potatoes	1.9	Carrots		
24.3	PT General population	5.3	Potatoes	3.9	Wheat	2.7	Carrots		
23.7	WHO regional European diet	4.0	Potatoes	3.0	Wheat	1.7	Onions		
23.2	ES child	4.4	Wheat	2.5	Milk and cream,	2.2	Oranges		
18.2	NL general	2.7	Potatoes	2.1	Wheat	1.5	Oranges		
17.8	IT kids/toddler	6.6	Wheat	1.5	Other cereal	1.4	Tomatoes		
17.2	UK vegetarian	3.8	Sugar beet (root)	2.0	Wheat	1.4	Potatoes		
16.7	FR all population	4.0	Wine grapes	3.3	Wheat	1.2	Carrots		
15.1	ES adult	2.3	Wheat	1.3	Oranges	1.0	Milk and cream,		
14.7	UK Adult	4.0	Sugar beet (root)	1.7	Wheat	1.4	Potatoes		
13.2	DK adult	2.0	Wheat	1.8	Carrots	1.5	Potatoes		
13.1	IT adult	4.1	Wheat	1.2	Tomatoes	0.8	Apples		
11.8	LT adult	3.2	Potatoes	1.9	Apples	1.1	Rye		
11.6	PL general population	3.4	Potatoes	2.0	Apples	1.3	Onions		
9.8	FI adult	1.2	Potatoes	1.1	Milk and cream,	1.0	Wheat		

**Conclusion:**  
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI.  
A long-term intake of residues of ioxynil 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>
---	---

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)
	20.7	Bovine: Kidney	2.2 / -	20.7	Bovine: Kidney	2.2 / -	9.4	Bovine: Kidney	2.2 / -	9.4	Bovine: Kidney	2.2 / -
	18.2	Bovine: Liver	0.9 / -	18.2	Bovine: Liver	0.9 / -	6.1	Bovine: Liver	0.9 / -	6.1	Bovine: Liver	0.9 / -
	10.5	Bovine: Meat	0.33 / -	10.5	Bovine: Meat	0.33 / -	4.9	Bovine: Meat	0.33 / -	4.9	Bovine: Meat	0.33 / -
	8.5	Sheep: Meat	0.33 / -	8.5	Sheep: Meat	0.33 / -	3.9	Sheep: Meat	0.33 / -	3.9	Sheep: Meat	0.33 / -
	5.7	Bovine: Fat	1.1 / -	5.7	Bovine: Fat	1.1 / -	1.8	Bovine: Fat	1.1 / -	1.8	Bovine: Fat	1.1 / -
	<b>No of critical MRLs (IESTI 1)</b>			<b>No of critical MRLs (IESTI 2)</b>			<b>No of critical MRLs (IESTI 1)</b>			<b>No of critical MRLs (IESTI 2)</b>		

Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	IESTI 1			IESTI 2		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	21.4	Carrot, juice	0.2 / -	1.3	Orange juice	0.05 / -
	6.4	Apple juice	0.05 / -	0.8	Apple juice	0.05 / -
	6.2	Orange juice	0.05 / -	0.5	Bread/pizza	0.05 / -
	4.1	Grape juice	0.05 / -	0.5	Wine	0.05 / -
	2.2	Peach juice	0.05 / -	0.3	Pineapples preserved	0.05 / -

\*) 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 ioxynil 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
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
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	emulsifiable concentrate
ECD	electron capture detection
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
GC	gas chromatography
GS-MS	gas chromatography with tandem mass spectrometry
GS	growth stage
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
LC	liquid chromatography
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
TMDI	theoretical maximum daily intake
TRR	total radioactive residue