REASONED OPINION OF EFSA

Modification of the existing MRLs of metazachlor for certain products of animal origin[1]

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00215)

Issued on 26 June 2009

SUMMARY

According to Article 6(2) of Regulation (EC) No 396/2005, Germany has made an application to modify the existing MRLs for bovine, sheep, goat and pig liver. The applicant proposes to raise the existing MRLs, which are currently set at the analytical limit of quantification of 0.05 mg/kg, to 0.2 mg/kg for bovine, sheep and goat liver and to 0.1 mg/kg for pig liver. The changes are necessary because residues on feed treated with metazachlor (rape forage, rape seeds, kale, cabbage, swedes and turnips) can lead to residues in certain food commodities of animal origin. Also residues on rotational crops, in particular cereal straw and cereal grain, grown in crop rotation after primary crops which were treated with metazachlor, contribute to the dietary burden of metazachlor in livestock resulting in residues in liver.

Based on the evaluation report of Germany, supporting documents provided by Germany, the EFSA conclusion, the Draft assessment Report (DAR) and Addendum 2 to the DAR prepared by the United Kingdom in the framework of the peer review under Directive 91/414/EEC, EFSA derives the following conclusion regarding the application:

The metabolism of metazachlor in primary crops was investigated in cabbage, rape and maize after pre- and post-emergence applications of metazachlor. Three crop groups (leafy crops, oilseeds and cereals) are covered by the available studies. Metazachlor is metabolised quickly and the metabolic pattern is complex. Confined rotational crop studies showed that metabolism in rotational crops is similar to primary crops. The main metabolites in primary crops and rotational crops have similar toxicological potential as metazachlor. Therefore, the following risk assessment residue definition for plant matrices was proposed: metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor. Fo enforcement purposes the experts involved in the peer review agreed on the following residue definition: sum of metabolites 479-M04 (*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)oxalamide), 479-M08 (*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonic acid) and 479-M16 (3-[*N*-(2,6-

[1] For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the Modification of the existing MRLs of metazachlor for certain products of animal origin. *EFSA Scientific Report* (2009) 320, 1-32

dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl]-2-hydroxypropanoic acid), expressed as metazachlor.

The metabolism of metazachlor was investigated in lactating goats and laying hens. Metazachlor was metabolised extensively leading to a complex pattern of metabolites. The metabolism in ruminants and poultry is similar to the metabolism in rats. The following residue definition is proposed for food of animal origin for enforcement and risk assessment: metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor. Analytical methods for enforcement of this residue definition are available.

A sufficient amount of supervised field trials on rape forage and turnips as well as field trials for rotational crops are available to estimate the expected residue levels in feed and to calculate the dietary burden for ruminants, poultry and pigs.

Feeding studies on dairy cows are available which allow to predict the expected residues in animal commodities under the assumption that livestock is exposed to residues of metazachlor in primary and rotational corps. Considering the expected dietary burden for ruminants and the livestock feeding studies, the need to raise the MRL for liver was confirmed. The residues expected in other ruminants and pigs were extrapolated from dairy cows. Also for poultry the dietary intake exceeded the trigger value slightly and therefore feeding studies would be required. Lacking these feeding studies no conclusion could be derived regarding the possible need to change MRLs for poultry. However, in the MRL review under Article 12(1) of Regulation 396/2005 this issue will be further discussed.

Chronic and acute intake calculations were performed using revision 2 of the EFSA PRIMo. The chronic intake calculations considered medium residue values for liver of ruminants and pigs as well as all existing MRLs established for plant commodities. No chronic intake concerns were identified for the European consumers. The potential chronic exposure was not higher than 10% of the ADI; the consumption of liver does not lead to a significant contribution. The acute intake of metazachlor liver is calculated to be maximum 0.4% of the ARfD for children and 0.1% of the ARfD for adults for bovine liver

EFSA recommendations resulting from the assessment are summarized below. It should be noted that in order to be in line with the conclusions of the peer review under Directive 91/414/EEC the residue definition for products of animal origin needs to be modified. The current residue definition for animal products contains only the parent compound which is not expected as a terminal residue in products of animal origin.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor			
Bovine live	0.05*	0.3	The proposed MRLs are supported by the data provided and no risk for consumers was identified.
Sheep liver	0.05*	0.3	
Goat liver	0.05*	0.3	
Pig liver	0.05*	0.2	

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

Key words: **Metazachlor, bovine liver, goat liver, sheep liver, swine liver, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, chloroacetanilide and pyrazole herbicide**

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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 where a Member State considers that the modification of an MRL is necessary, that Member State may compile and evaluate an application to modify the MRL in accordance with the provisions of Article 7 of that regulation.

In particular, Germany, hereafter referred to as the Evaluating Member State (EMS)[2], compiled an application to modify the existing MRL of 0.05 mg/kg for the active substance metazachlor in food of animal origin for swine liver to 0.1 mg/kg and for ruminant liver to 0.2 mg/kg. This application was notified to the European Commission and EFSA and subsequently evaluated 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 14/01/2009. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2009-215 and the following subject:

- *Metazachlor - Application to modify the existing MRLs for metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor in bovine liver from 0.05 mg/kg to 0.2 mg/kg, in goat liver from 0.05 mg/kg to 0.2 mg/kg, in sheep liver from 0.05 mg/kg to 0.2 mg/kg and in swine liver from 0.05 mg/kg to 0.1 mg/kg.*

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

TERMS OF REFERENCE

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

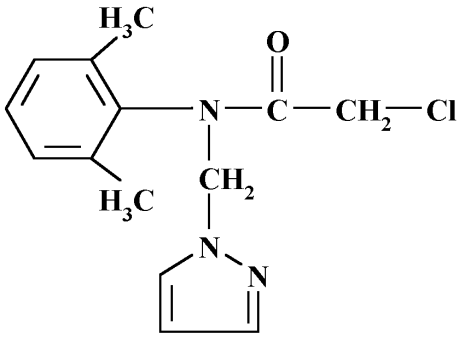
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the data of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

In this particular case the calculated deadline for providing the reasoned opinion is 14 April 2009.

[2] Federal Office of Consumer Protection and Food Safety - Unit 2, Messeweg 11/12, 38104 Braunschweig, Germany

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Metazachlor is the ISO common name for 2-chloro-*N*-(pyrazol-1-ylmethyl)acet-2',6'-xylidide (IUPAC).



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Metazachlor belongs to the class of chloroacetanilide and pyrazole herbicides. Metazachlor acts as an inhibitor in the lipid biosynthesis, having effect on cell division and tissue differentiation. Metazachlor is mainly taken up via the roots, the hypocotyl and the cotyledons of the germinating and emerging weeds.

Metazachlor has been evaluated in the framework of Directive 91/414/EEC (stage 3A) with the United Kingdom being the designated Rapporteur Member State (RMS). The representative uses supported for the peer review process were pre- and early post-emergence applications on spring and winter rape and early post-emergence applications on diverse ornamental shrubs. The peer review for this active substance has been finalised and it has been decided to include metazachlor in Annex I of Directive 91/414/EEC. Commission Directive 2008/116/EC amending the Directive accordingly will enter into force on 1 August 2009. Only uses as herbicide may be authorised and application shall be restricted to maximum 1.0 kg a.i./ha only every third year on the same field.

In the European Community temporary MRLs are currently established for metazachlor (see Annex B). These temporary MRLs have been derived from the MRLs established at national level before Regulation EC (No) 396/2005 entered into force. The MRLs for bovine, sheep, goat and pig liver were established at the level of 0.05*mg/kg. It should be noted that the residue definition in Regulation 396/2005 is parent metazachlor only. Currently temporary MRLs are set at levels above the LOQ also for some commodities which can also be used as animal feed (i.e. kale, cabbage, potatoes, swedes, turnips and rape seed). No MRLs for metazachlor have been set so far by the Codex Alimentarius Commission.

Germany received a request for authorisation of a plant protection product containing the active substance metazachlor in oilseed rape. The evaluation of the residue behaviour in rotational crops led to the conclusion that detectable residues in straw of succeeding cereals are expected which lead to higher residues in liver of domestic animals. Therefore, Germany proposed to amend the existing MRLs for swine liver and ruminant liver.

A detailed overview of the critical German authorised and pending GAPs of metazachlor is available in Appendix A to this document (only those crops are reported that may be used as feed). For all authorised plant protection products Germany has set a restriction regarding the

feeding of cereal straw from succeeding cereal crops awaiting the amending of the MRL for liver.

No information is provided regarding the authorisations of metazachlor on feed commodities in other Member States.

In support of the MRL application an evaluation report (10 September 2009) and additional information and supporting documents have been submitted (12 March 2009 and 15 April 2009).

In addition to the documents provided by Germany, EFSA also relied on the DAR (2005), Addendum 2 (2007) to the DAR prepared by the United Kingdom under Directive 91/414/EEC and the EFSA conclusion (2008).

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ASSESSMENT

1. Methods of analysis

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

The available analytical methods have been evaluated in the framework of the peer review under Directive 91/414/EEC. It was concluded that adequate analytical methods are available to determine residues of metazachlor according to the residue definition proposed in the peer review (proposed residue definition for enforcement for plants: sum of metabolites 479-M04[3], 479-M08[4] and 479-M16[5], expressed as metazachlor) (EFSA, 2008). The LOQs range from 0.01 to 0.05 mg/kg, depending on the method and the commodities.

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

Analytical method for enforcement of metazachlor residues in animal matrices were evaluated in the peer review. Methods based on HPLC-MS/MS, LC-MS or GC-PND are available to monitor residues of metazachlor in food of animal origin (milk, liver) according to the proposed residue definition (metazachlor including degradation and reaction products which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor). The LOQ achievable for liver is 0.05 mg/kg.

[3] 479M04/BH 479-4: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)oxalamide
[4] 479M08/BH 479-8/BH 479-18: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonic acid
[5] 479M16/BH 479-21: 3-[*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl]-2-hydroxypropanoic acid

2. Mammalian toxicology

The toxicological properties of metazachlor have been evaluated in the DAR prepared under Directive 91/414/EEC (United Kingdom, 2005). The peer review of the evaluation has been finalised and EFSA has provided a conclusion (EFSA, 2008). The reference values derived in the peer review and included in the EFSA conclusion are summarised in the table below.

Table 2-1 **Overview of the toxicological reference values**

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Parent compound metazachlor					
ADI	EFSA	2008	0.08	Rat, chronic study	100
ARfD	EFSA	2008	0.5	Rat, developmental study	100

3. Residues

3.1. Nature and magnitude of residues in plant

The application under evaluation concerns MRLs for liver of ruminants and pigs. The evaluation report (Germany 2008) states that the main contributors to the dietary burden are forage rape and turnips (roots) from the crops with registered or pending uses of metazachlor on feed crops in Germany (Appendix A). Furthermore, residues in straw from cereal grown in rotation after the application of metazachlor should be taken into consideration as major source of dietary intake of livestock. Therefore, the residue situation of metazachlor in plants is discussed only insofar as relevant for these feeding stuffs and their intake by livestock.

3.1.1. Primary crops

3.1.1.1. Nature of residues

Plant metabolism studies have been provided with pre- and/or post-emergence applications of metazachlor in cabbage, rape and maize (United Kingdom, 2005). The test substance has been labelled with a radioactive marker in the phenyl-ring. Application rates were of the same order or higher than the registered uses in Germany.

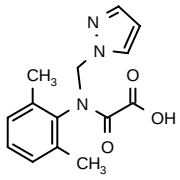
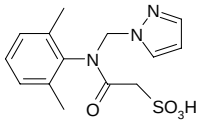
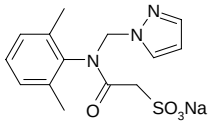
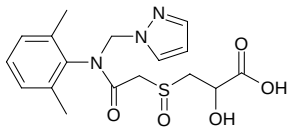
Metazachlor was shown to metabolise quickly in plants. The main degradation pathway proceeds through initial formation of a glutathione conjugate. The conjugate is subsequently metabolised to a wide range of compounds, e.g. to 479M16[6] which was identified as a main metabolite in all primary crops. In a further metabolism route oxidation of metazachlor leads to metabolite 479M04[7] which was only found in maize and cabbage.

The metabolic pattern in plants is considered to be covered by the toxicological dossier. Although the metabolism routes in plants and the rat show some differences, the toxicological information provided on several plant metabolites (including the main metabolites in primary and rotational crops 479M04, 479M08[8] and 479M16) suggests that these metabolites may be considered for risk assessment of comparable toxicity to the parent compound.

Considering the complex metabolic pattern in plant commodities, it was concluded in the peer review that the residue definition for risk assessment should be established as metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline (in the following referred to as 'total residues'), calculated in total as metazachlor (EFSA, 2008). The residue definition for risk assessment in plant matrices is also relevant for the dietary burden calculation in livestock. For enforcement purposes the parent compound and the major metabolites 479M04, 479M08 and 479M16 were deemed sufficient.

It should be highlighted that the currently established residue definition in Regulation (EC) No. 396/2005 is parent compound only. An amendment of the current residue definition should therefore be considered.

[6] 3-[*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl]-2-hydroxypropanoic acid
[7] *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)hydroxyacetamide
[8] *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonic acid

Code/Trivial name	Chemical name	Structural formula
479M04	*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)oxalamide	
479M08	*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonic acid	
	sodium *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonate	
479M16	3-[*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl]-2-hydroxypropanoic acid	

3.1.1.2. Magnitude of residues

In the evaluation report (Germany, 2008), the results of supervised field trials in summer and winter rape are reported. In 25 trials with application rates of 0.75 to 1.25 kg/ha no detectable residues were found in rape seeds. In nine trials with application rate of 1.17 kg/ha residues were also measured in rape forage. 49 to 65 days after the treatment the residues ranged between 0.15 to 1.24 mg/kg. Although the application rate was significantly higher than the intended GAP, the trial results are used to estimate the expected residues in feed, knowing that these data may overestimate the real dietary exposure situation. Germany proposed to re-calculate the trials to correct for the higher application rate, but EFSA prefers to use the uncorrected values because it can not be taken as granted that there is a linear correlation between application rate and final residues in the commodity harvested. Three additional residue trials on rape forage which were carried out in accordance with the intended GAP have been submitted by Germany on 12 March 2009. In these trials the residues were in the same range as the overdosed trials. The results of all the acceptable residue trials and the derived input values for the dietary burden calculation are reported in table 3-1.

Germany performed also an evaluation of turnips because this crop is expected to be of relevance for feed. Nine trials were carried out at the critical application rate of 1 kg/ha. This application rate is the maximum application rate as defined in the restrictions for Annex I inclusion (see section "The active substance and its use pattern", page 5). Although the growth stages at the time of application in the residue trials pre emergence were slightly earlier than the growth stage in the registered critical GAP (up to 7 days after planting), the trials can be regarded as acceptable (table 3-1).

Three trials on kale and one trial on stem kale were also included in the evaluation report prepared by Germany. As kale is a potential feed item EFSA included the results in table 3-1. This information is also relevant for calculating the dietary burden for livestock.

In addition to these crops, Germany also presented supervised field trials for other crops (e.g. small radishes and St. Johnswort) which are not considered relevant in the context of this application.

It is assumed that the samples of the supervised field trials trials were analysed for 'total residues' of metazachlor, which is in accordance with the residue definition for risk assessment in plant matrices. Information if the analytical methods used in the residue trials were demonstrated to be valid is not available to EFSA.

The studies are acceptable to support the request to change the MRLs for liver. However, considering the results for rape seed and turnips, the lowering of the existing MRLs might be considered. This review will be performed in the framework of Article 12(1) where the existing MRLs will be critically scrutinised.

According to the DAR (United Kingdom, 2005) storage stability of 'total residues' of metazachlor has been demonstrated for a period of two years at -20 °C in commodities with high content of oil (rape seed), high content of water (cabbage, cereal forage) and low content of water (cereal grain and straw). It was concluded in the DAR that the relevance of the stability study was unclear, as metazachlor residues in plants consist only of metabolites. Therefore, an additional stability study on 479M16, the main metabolite in primary crops was submitted. The metabolite was shown to be stable at - 17 to - 32 °C in rape seeds and forage for 13 months (United Kingdom, 2007).

Information concerning the duration of storage of samples before analysis is not available to EFSA. The evaluation report of the EMS (2008) does not include an evaluation if these storage stability studies are sufficient to support the residue trials on rape and turnips. However, since the studies were accepted as supporting documents for registrations, EFSA assumes that the EMS has checked the validity of the supervised trials.

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

Commodity	Region (a)	Outdoor/Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement	Risk assessment					
Residue definition for risk assessment: metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor Residue definition for enforcement: sum of metabolites 479-M04[9], 479-M08[10] and 479-M16[11], expressed as metazachlor									
Rape seed	NEU	Outdoor		25 x <0.05	0.05	0.05	0.05	1(2)	
Rape forage	NEU	Outdoor		0.15(1); 2 x 0.23(1); 0.30(1); 0.32(1); 0.49(1); 0.51; 0.56(1); 0.82; 0.97; 1.05(1); 1.24(1)	0.5	1.24	2	1(2)	
Turnips	NEU	Outdoor		6 x <0.05; 2 x 0.06; 0.08	0.05	0.08	0.1	1(2)	
Kale	NEU	Outdoor		<0.01; 2 x <0,02	0,02	0.02	0.05	1(2)	

(1) Trial was carried out at an application rate of 1.17 kg a.s./ha.
(2) Although no data are available to derive a conversion factor, a factor of 1 is assumed.

(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.

[9] 479M04/BH 479-4: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)oxalamide
[10] 479M08/BH 479-8/BH 479-18: *N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonic acid
[11] 479M16/BH 479-21: 3-[*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl]-2-hydroxypropanoic acid

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of industrial processing on the residues of metazachlor was not further considered in the framework of this application. Heat treatment or other processing steps which may have an effect on the nature or level of residues are normally not used for processing of rape forage, straw and turnips used as feed.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Metazachlor quickly metabolises in soil with a DT_{90} shorter than 100 days in all field trials. However, metabolites of metazachlor have been shown to be more stable in soil. Therefore, the possible uptake of soil metabolites and especially of the main metabolites 479M04 and 479M08 has to be taken into consideration.

In the EFSA conclusion (EFSA, 2008) cereal straw has been identified as a feed commodity where significant residue levels might be expected when crops are grown following rape which has been treated with metazachlor.

3.1.2.2. Nature of residues

Confined rotational crop studies are reported in the DAR (United Kingdom, 2005) and in Addendum 2 to the DAR (United Kingdom, 2007). Metazachlor was applied to bare soil at a rate of 1.25 kg a.i./ha which is 1.7 times the critical application rate on rape. Leafy, root and cereal crops were planted at plant back intervals of 30, 120 and 366 days. Studies were performed using metazachlor radio labelled in the phenyl ring.

Metabolism in rotational crops is similar as in primary crops and in soil. It includes the glutathione pathway and also the oxidative formation of 479M04. Metazachlor was not identified in samples of rotational crops. The main compounds found in succeeding crops were the soil metabolites 479M04 and 479M08.

3.1.2.3. Magnitude of residues

A total of 25 field trials on rotational crops have been evaluated (United Kingdom 2005 and 2007). The studies in root and oilseed/pulse crops indicated that significant residues in these crop groups are unlikely if grown in crop rotation after rape seed treated with up to 1.25 kg/ha. Six results for field rotational crop studies for cereals, simulating a crop failure scenario (re-plant interval of 30 days), are available. In these trials metazachlor was applied to bare soil at an application rate of 1.25 kg a.i./ha and wheat was sown at plant back intervals between 29 and 51 days. In cereal grain no residues were measurable (>0.05 mg/kg). The straw samples were analysed for 'total residues' of metazachlor and residue levels between 0.06 mg/kg and 0.39 were found (STMR = 0.25 mg/kg, HR= 0.39 mg/kg). EFSA does not follow the German proposal to correct the results for the difference in the application rate for the same reasons as explained in section 3.1.1.2.

In the DAR it is not clearly stated if the analytical methods used have been fully validated.

The samples were stored frozen for up to 15 months prior to analysis. Storage stability study in cereal straw with metazachlor fortification have been submitted and 'total residues' have been shown as stable for two years. As metazachlor was not found in rotational crops, the relevance of these results is disputed. Ideally the results should be supported by stability studies on the main metabolites in rotational crops.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden

The dietary burden calculation is based on the residue values found in supervised residue trials on rape forage, rape seed, kale and turnips, respectively and in field studies on rotational crops for cereal grain and wheat straw. The STMR and HR values for these commodities were derived in sections 3.1.1.2 (table 3-1) and section 3.1.2.3. The input values and the results of this dietary burden calculation are summarized in table 3-2 and 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: metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor				
Rape forage	0.5	STMR	1.24	HR
Rape seed	0.05	STMR	0.05	HR
Kale/cabbage	0.02	STMR	0.02	HR
Turnips/Swedes (roots)	0.05	STMR	0.08	HR
Cereal straw (a)	0.25	STMR from rotational crop study	0.39	HR from rotational crop study
Cereal grain (a)	0.05	STMR from rotational crop study	0.05	HR from rotational crop study

(a) Grown as rotational crop (after rape)

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	Maximum dietary burden (mg/kg DM)	Trigger exceeded?
Risk assessment residue definition: metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor					
Dairy ruminants	0.014	0.01	Turnips	0.39	yes

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Maximum dietary burden (mg/kg DM)	Trigger exceeded?
Meat ruminants	0.154	0.067	Rape forage	3.5	yes
Poultry	0.013	0.01	Turnips	0.21	yes
Pigs	0.073	0.034	Rape forage	1.83	yes

The calculations above reflect only residues in the feed commodities mentioned above. It should be mentioned that also potatoes might be fed to livestock and should therefore be included in the dietary burden calculation. However, it is expected that the potatoes will not significantly change the result of these calculations because they belong to the same feed category as turnips. EFSA is of the opinion that a more accurate estimation of the dietary burden could be derived on the basis of the STMR and HR of turnips instead of using the MRL for potatoes.

From the dietary intake calculations it is concluded that significant intake might be expected for all animal species (dairy and meat ruminants, poultry and pigs) under the hypothetical assumption that livestock is exposed to feed treated with metazachlor (primary crop treatment of rape forage, rape seed, kale, cabbage, Swedes or turnips) and to feed (cereal grain or cereal straw) that is grown in crop rotation after crops treated with metazachlor.

3.2.2. Nature of residues

Livestock metabolism studies were carried out on lactating goats and laying hens (United Kingdom, 2005). In both species metazachlor was metabolised mainly through conjugation with glutathione followed by further cleavage, oxidative and glucuronide conjugation processes. Additionally, hydroxylation of both the pyrazole and the dimethyl-phenyl ring was observed. The metabolic pattern in milk, eggs and edible tissues was found to be very complex. The metabolism in ruminants and poultries is similar to the metabolism in rats.

Due to the complex metabolic pattern, the proposed residue definition for monitoring and risk assessment in animal commodities is metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor.

The metabolism studies showed that the highest TRR concentrations were expected in liver.

An analytical method in line with the residue definition is available for the enforcement of metazachlor residues in animal commodities (see section 1.2.).

3.2.3. Magnitude of residues

Feeding studies on dairy cows are available and have been evaluated in the DAR (United Kingdom, 2005). The animals were dosed for 28 consecutive days at rates of 0.024, 0.077 and 0.261 mg/kg bw/day (0.8, 2.4 and 8.0 mg/ kg feed (DM). Samples were analysed for 'total residue' of metazachlor. No residues were found above the LOQ in any of the milk, cream, muscle, kidney or fat samples from the three dosing levels. The LOQ for milk and cream was

0.01 mg/kg, for the other commodities 0.05 mg/kg were reported as LOQ. Residues in liver are presented in table 3-4. The residue levels in liver show linear relationship to the dose rate and therefore can be used for extrapolation to the calculated intake for beef cattle. The MRL derived for bovine liver is also suggested for sheep and goat liver. As no feeding study on pigs is available, the results of the dairy cow study were used also for extrapolation to residue levels in pig liver.

The analytical method for enforcement (section 1.2) was also used in the feeding studies and has been fully validated.

Storage stability test of 'total residues' of metazachlor are available (United Kingdom, 2005). After fortification with metazachlor, 'total residues' of metazachlor were shown to be stable at ≤- 18 °C for 169 days. Samples of the feeding study were stored frozen for a maximum of 197 days. However, as metazachlor was not found in rotational crops, the relevance of these results is not clear.

The calculation carried out by EFSA leads to the conclusion that an MRL of 0.3 mg/kg for bovine, sheep and goat liver and an MRL of 0.2 mg/kg for pig liver would be required to accommodate the registered and pending uses in Germany.

Feeding studies in poultry are not available. Therefore no MRL proposal can be derived for poultry.

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

Commodity	Dietary burden		Results of the livestock feeding study						STMR (mg/kg)	HR (mg/kg)	MRL proposal (mg/kg)	CF for RA
	Median (mg/kg bw/d)	Maximum (mg/kg bw/d)	Dose Level (mg/kg bw/d)	n	Result for enforcement		Result for risk assessment					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Residue definition (enforcement and risk assessment): metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor												
Ruminant liver	0.067	0.154	0.024	3	<0.05	0.06	<0.05	0.06	0.11	0.28	0.3	1
			0.077	3	0.13	0.15	0.13	0.15				
			0.261	3	0.32	0.49	0.32	0.49				
Pig liver	0.034	0.073	Extrapolation from results of feeding studies on dairy cows						0.065	0.14	0.2	1

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

4. Consumer risk assessment

Chronic and acute intake calculations were carried out using revision 2 of the EFSA PRIMo. The input values for ruminant and pig liver are summarised in Table 4-1. For all remaining commodities the existing MRLs (Appendix B) have been used as input values for the chronic risk assessment. Because of the low intake no refined calculations replacing the MRL values with the respective STMR values were necessary.

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
Risk assessment residue definition: metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor				
Bovine live	0.11	STMR	0.28	HR
Sheep liver	0.11	STMR	0.28	HR
Goat liver	0.11	STMR	0.28	HR
Pig liver	0.065	STMR	0.14	HR
Other commodities of plant or animal origin	MRLs	See Appendix B	Not relevant	

The results of the intake calculations are reported in Appendix C to this document. Intake calculations for all European diets resulted in a chronic exposure not higher than 10% of the ADI. The consumption of liver does not lead to a significant contribution. The acute intake of metazachlor in liver is calculated to be maximum 0.5% of the ARfD for children and 0.2% of the ARfD for adults for bovine liver.

It is therefore concluded that the proposed amendment of the MRLs for bovine liver, sheep liver, goat liver and pig liver does not cause a consumer intake risk.

Lacking feeding studies, possible residues in poultry liver could not be estimated.

CONCLUSIONS AND RECOMMENDATIONS

The metabolism of metazachlor in primary crops was investigated in cabbage, rape and maize after pre- and post-emergence applications of metazachlor. Three crop groups (leafy crops, oilseeds and cereals) are covered by the available studies. Metazachlor is metabolised quickly and the metabolic pattern is complex. Confined rotational crop studies showed that metabolism in rotational crops is similar to primary crops. The main metabolites in primary crops and rotational crops have similar toxicological potential as metazachlor. Therefore, the following risk assessment residue definition for plant matrices was proposed: metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor. Fo enforcement purposes the experts involved in the peer review agreed on the following residue definition: sum of metabolites 479-M04 (*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)oxalamide), 479-M08 (*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonic acid) and 479-M16 (3-[*N*-(2,6-dimethylphenyl)-*N*-(1*H*-pyrazol-1-ylmethyl)aminocarbonylmethylsulfinyl]-2-hydroxypropanoic acid), expressed as metazachlor.

The metabolism of metazachlor was investigated in lactating goats and laying hens. Metazachlor was metabolised extensively leading to a complex pattern of metabolites. The metabolism in ruminants and poultry is similar to the metabolism in rats. The following residue definition is proposed for food of animal origin for enforcement and risk assessment: metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor. Analytical methods for enforcement of this residue definition are available.

A sufficient amount of supervised field trials on rape forage and turnips as well as field trials for rotational crops are available to estimate the expected residue levels in feed and to calculate the dietary burden for ruminants, poultry and pigs.

Feeding studies on dairy cows are available which allow to predict the expected residues in animal commodities under the assumption that livestock is exposed to residues of metazachlor in primary and rotational corps. Considering the expected dietary burden for ruminants and the livestock feeding studies, the need to raise the MRL for liver was confirmed. The residues expected in other ruminants and pigs were extrapolated from dairy cows. Also for poultry the dietary intake exceeded the trigger value slightly and therefore feeding studies would be required. Lacking these feeding studies no conclusion could be derived regarding the possible need to change MRLs for poultry. However, in the MRL review under Article 12(1) of Regulation 396/2005 this issue will be further discussed.

Chronic and acute intake calculations were performed using revision 2 of the EFSA PRIMo. The chronic intake calculations considered medium residue values for liver of ruminants and pigs as well as all existing MRLs established for plant commodities. No chronic intake concerns were identified for the European consumers. The potential chronic exposure was not higher than 10% of the ADI; the consumption of liver does not lead to a significant contribution. The acute intake of metazachlor liver is calculated to be maximum 0.4% of the ARfD for children and 0.1% of the ARfD for adults for bovine liver

EFSA recommendations resulting from thee the assessment are summarized below. It should be noted that in order to be in line with the conclusions of the peer review under Directive 91/414/EEC the residue definition for products of animal origin needs to be modified. The

current residue definition for animal products contains only the parent compound which is not expected as a terminal residue in products of animal origin.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: metazachlor including degradation and reaction products, which can be determined as 2,6-dimethylaniline, calculated in total as metazachlor			
Bovine live	0.05*	0.3	The proposed MRLs are supported by the data provided and no risk for consumers was identified.
Sheep liver	0.05*	0.3	
Goat liver	0.05*	0.3	
Pig liver	0.05*	0.2	

(*): 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 metazachlor in ruminant and pig livers under Regulation (EC) No 396/2005. 10 September 2008. Prepared by the Federal Office of Consumer Protection and Food Safety.
2. Additional information and supporting documents for the modification of the existing MRL for metazachlor in ruminant and pig livers under Regulation (EC) No 396/2005. 12 March 2009 and 15 April 2009. Prepared by the Federal Office of Consumer Protection and Food Safety.

REFERENCES

EFSA (European Food Safety Agency), 2008. Conclusion regarding the peer review of the pesticide risk assessment of the active substance metazachlor. April 2008.

The United Kingdom, 2005. Draft Assessment Report on metazachlor prepared by the PSD under Directive 91/414/EEC. June 2005.

The United Kingdom 2007. Addendum 2 to the Draft Assessment Report on metazachlor prepared by the PSD under Directive 91/414/EEC. September 2007.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

SUMMARY OF GOOD AGRICULTURAL PRACTICES FOR PESTICIDE USES

(Application on agricultural and horticultural crops)

Use Pattern

1	2	3	4	5	6			7			8	9
Crop and / or situation	F, G or I	Pest or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks:
			Type	Conc. of a.i.	method, kind	growth stage	number (range)	kg a.i./hl	water l/ha	kg a.i./ha		
(a)	(b)	(c)	(d - f)	(i)	(f - h)	(j)					(k)	(l)
Winter rape	F	Slender foxtail, Windgrass, Annual bluegrass, Dicotyledonous grain weeds	CS, SC,	250 33,3) g/l	spraying	10-12 After emergence, autumn	1 ; 1	0,188 - 0,375	200 - 400	0,75	XF	**VZ456**
Spring rape	F	Slender foxtail, Windgrass, Annual bluegrass, Dicotyledonous grain weeds	SC	375 125) g/l	spraying	10 - 18; After emergence	1 ; 1	0,188 - 0,375	200 - 400	0,75	XF	**VZ456**
Turnip, edible	F	Monocotyledonous grain weeds, Dicotyledonous grain weeds	SC	500 g/l	spraying	for feeding purpose; Before emergence	1 ; 1	0,25 - 0,5	200 - 400	1	70	**VZ456**
Kale	F	Monocotyledonous grain weeds, Dicotyledonous grain weeds	SC	500 g/l	spraying	crop culture; 6-8 days after planting	1 ; 1	0,313 - 0,625	200 - 400	1,25	XF	**VZ456**

1	2	3	4	5	6			7			8	9
Crop and / or situation	F, G or I	Pest or group of pests controlled	Formulation		Application			Application rate per treatment			PHI (days)	Remarks:
			Type	Conc. of a.i.	method, kind	growth stage	number (range)	kg a.i./hl	water l/ha	kg a.i./ha		
(a)	(b)	(c)	(d - f)	(i)	(f - h)	(j)					(k)	(l)
Swedes, turnips	F	Annual bluegrass, Dicotyledonous grain weeds (except Catchweed bedstraw)	SC	500 g/l	spraying	crop culture; Up to 7 days after planting on medium or heavy soils	1 ; 1	0,25 - 0,5	200 - 400	1	XF	**VZ456**

VZ456 Do not apply products containing the active substance metazachlor more than once a year on the same area.

For all authorised plant protection products the following restriction is set, awaiting the amending of the MRL for liver:

Do not feed straw from succeeding cereal crops.

In addition to the GAPs reported in the table above, Germany notified uses for the following crops:

Mustard spices, Savoy cabbage, red cabbage, white cabbage, kohlrabi, cauliflower, Brussels sprouts, broccoli, small radish, gold-of-pleasure, St. Johnswort,Pak choi, Chinese cabbage, crambe, stem kale, horse radish.

Since these GAPs are of no relevance for the application to amend the MRL for liver, they are not further considered.

APPENDIX B – LIST OF EXISTING EC MRLS

Pesticides - Web Version - EU MRLs (File created on 04/03/2009 18:27)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg. (EC) No 839/2008
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,1*
110000	(i) Citrus fruit	0,1*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,1*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,1*
110030	Lemons (Citron, lemon)	0,1*
110040	Limes	0,1*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,1*
110990	Others	0,1*
120000	(ii) Tree nuts (shelled or unshelled)	0,1*
120010	Almonds	0,1*
120020	Brazil nuts	0,1*
120030	Cashew nuts	0,1*
120040	Chestnuts	0,1*
120050	Coconuts	0,1*
120060	Hazelnuts (Filbert)	0,1*
120070	Macadamia	0,1*
120080	Pecans	0,1*
120090	Pine nuts	0,1*
120100	Pistachios	0,1*
120110	Walnuts	0,1*
120990	Others	0,1*
130000	(iii) Pome fruit	0,1*
130010	Apples (Crab apple)	0,1*
130020	Pears (Oriental pear)	0,1*
130030	Quinces	0,1*
130040	Medlar	0,1*
130050	Loquat	0,1*
130990	Others	0,1*
140000	(iv) Stone fruit	0,1*
140010	Apricots	0,1*
140020	Cherries (sweet cherries, sour cherries)	0,1*
140030	Peaches (Nectarines and similar hybrids)	0,1*
140040	Plums (Damson, greengage, mirabelle)	0,1*
140990	Others	0,1*
150000	(v) Berries & small fruit	0,1*
151000	(a) Table and wine grapes	0,1*
151010	Table grapes	0,1*
151020	Wine grapes	0,1*
152000	(b) Strawberries	0,1*
153000	(c) Cane fruit	0,1*
153010	Blackberries	0,1*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,1*
153030	Raspberries (Wineberries)	0,1*
153990	Others	0,1*
154000	(d) Other small fruit & berries	0,1*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,1*
154020	Cranberries	0,1*
154030	Currants (red, black and white)	0,1*
154040	Gooseberries (Including hybrids with other ribes species)	0,1*
154050	Rose hips	0,1*
154060	Mulberries (arbutus berry)	0,1*
154070	Azarole (mediteranean medlar)	0,1*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,1*
154990	Others	0,1*
160000	(vi) Miscellaneous fruit	0,1*
161000	(a) Edible peel	0,1*
161010	Dates	0,1*
161020	Figs	0,1*
161030	Table olives	0,1*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,1*
161050	Carambola (Bilimbi)	0,1*
161060	Persimmon	0,1*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,1*
161990	Others	0,1*
162000	(b) Inedible peel, small	0,1*
162010	Kiwi	0,1*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,1*
162030	Passion fruit	0,1*
162040	Prickly pear (cactus fruit)	0,1*
162050	Star apple	0,1*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,1*
162990	Others	0,1*
163000	(c) Inedible peel, large	0,1*
163010	Avocados	0,1*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,1*
163030	Mangoes	0,1*
163040	Papaya	0,1*
163050	Pomegranate	0,1*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,1*
163070	Guava	0,1*
163080	Pineapples	0,1*
163090	Bread fruit (Jackfruit)	0,1*
163100	Durian	0,1*
163110	Soursop (guanabana)	0,1*
163990	Others	0,1*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,3
211000	(a) Potatoes	0,3
212000	(b) Tropical root and tuber vegetables	0,3
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,3
212020	Sweet potatoes	0,3
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,3
212040	Arrowroot	0,3
212990	Others	0,3
213000	(c) Other root and tuber vegetables except sugar beet	0,3
213010	Beetroot	0,3
213020	Carrots	0,3
213030	Celeriac	0,3
213040	Horseradish	0,3
213050	Jerusalem artichokes	0,3
213060	Parsnips	0,3
213070	Parsley root	0,3
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,3
213090	Salsify (Scorzonera, Spanish salsify (Spanish	0,3

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg. (EC) No 839/2008
	oysterplant))	
213100	Swedes	0,3
213110	Turnips	0,3
213990	Others	0,3
220000	(ii) Bulb vegetables	0,3
220010	Garlic	0,3
220020	Onions (Silverskin onions)	0,3
220030	Shallots	0,3
220040	Spring onions (Welsh onion and similar varieties)	0,3
220990	Others	0,3
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	0,3
231020	Peppers (Chilli peppers)	0,3
231030	Aubergines (egg plants) (Pepino)	0,3
231040	Okra, lady' s fingers	30
231990	Others	0,3
232000	(b) Cucurbits - edible peel	0,3
232010	Cucumbers	0,3
232020	Gherkins	0,3
232030	Courgettes (Summer squash, marrow (patisson))	0,3
232990	Others	0,3
233000	(c) Cucurbits-inedible peel	0,3
233010	Melons (Kiwano)	0,3
233020	Pumpkins (Winter squash)	0,3
233030	Watermelons	0,3
233990	Others	0,3
234000	(d) Sweet corn	0,3
239000	(e) Other fruiting vegetables	30
240000	(iv) Brassica vegetables	0,3
241000	(a) Flowering brassica	0,3
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,3
241020	Cauliflower	0,3
241990	Others	0,3
242000	(b) Head brassica	0,3
242010	Brussels sprouts	0,3
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,3
242990	Others	0,3
243000	(c) Leafy brassica	0,3
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,3
243020	Kale (Borecole (curly kale), collards)	0,3
243990	Others	0,3
244000	(d) Kohlrabi	0,3
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb´s lettuce (Italian cornsalad)	0,3
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,5
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,3
251040	Cress	0,3
251050	Land cress	0,3
251060	Rocket, Rucola (Wild rocket)	0,3
251070	Red mustard	0,3
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,3
251990	Others	0,3
252000	(b) Spinach & similar (leaves)	0,3
252010	Spinach (New Zealand spinach, turnip greens	0,3
	(turnip tops))	
252020	Purslane (Winter purslane (miner' s lettuce), garden purslane, common purslane, sorrel, glassworth)	0,3
252030	Beet leaves (chard) (Leaves of beetroot)	0,3
252990	Others	0,3
253000	(c) Vine leaves (grape leaves)	0,3
254000	(d) Water cress	0,3
255000	(e) Witloof	0,3
256000	(f) Herbs	0,3
256010	Chervil	0,3
256020	Chives	0,3
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,3
256040	Parsley	0,3
256050	Sage (Winter savory, summer savory,)	0,3
256060	Rosemary	0,3
256070	Thyme (marjoram, oregano)	0,3
256080	Basil (Balm leaves, mint, peppermint)	0,3
256090	Bay leaves (laurel)	0,3
256100	Tarragon (Hyssop)	0,3
256990	Others	0,3
260000	(vi) Legume vegetables (fresh)	0,3
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,3
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,3
260030	Peas (with pods) (Mangetout (sugar peas))	0,3
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,3
260050	Lentils	0,3
260990	Others	0,3
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,3
270020	Cardoons	0,3
270030	Celery	0,3
270040	Fennel	0,3
270050	Globe artichokes	0,3
270060	Leek	0,3
270070	Rhubarb	0,3
270080	Bamboo shoots	30
270090	Palm hearts	30
270990	Others	0,3
280000	(viii) Fungi	0,3
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,3
280020	Wild (Chanterelle, Truffle, Morel ,)	0,3
280990	Others	0,3
290000	(ix) Sea weeds	0,1*
300000	3. PULSES, DRY	0,1*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,1*
300020	Lentils	0,1*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,1*
300040	Lupins	0,1*
300990	Others	0,1*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
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)	1
401070	Soya bean	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg. (EC) No 839/2008
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	0,1*
402010	Olives for oil production	0,1*
402020	Palm nuts (palmoil kernels)	0,1*
402030	Palmfruit	0,1*
402040	Kapok	0,1*
402990	Others	0,1*
500000	5. CEREALS	0,1*
500010	Barley	0,1*
500020	Buckwheat	0,1*
500030	Maize	0,1*
500040	Millet (Foxtail millet, teff)	0,1*
500050	Oats	0,1*
500060	Rice	0,1*
500070	Rye	0,1*
500080	Sorghum	0,1*
500090	Wheat (Spelt Triticale)	0,1*
500990	Others	0,1*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	**0,2***
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	**0,2***
620000	(ii) Coffee beans	**0,2***
630000	(iii) Herbal infusions (dried)	**0,2***
631000	(a) Flowers	**0,2***
631010	Camomille flowers	**0,2***
631020	Hybiscus flowers	**0,2***
631030	Rose petals	**0,2***
631040	Jasmine flowers	**0,2***
631050	Lime (linden)	**0,2***
631990	Others	**0,2***
632000	(b) Leaves	**0,2***
632010	Strawberry leaves	**0,2***
632020	Rooibos leaves	**0,2***
632030	Maté	**0,2***
632990	Others	**0,2***
633000	(c) Roots	**0,2***
633010	Valerian root	**0,2***
633020	Ginseng root	**0,2***
633990	Others	**0,2***
639000	(d) Other herbal infusions	**0,2***
640000	(iv) Cocoa (fermented beans)	**0,2***
650000	(v) Carob (st johns bread)	**0,2***
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	**0,2***
800000	8. SPICES	**0,2***
810000	(i) Seeds	**0,2***
810010	Anise	**0,2***
810020	Black caraway	**0,2***
810030	Celery seed (Lovage seed)	**0,2***
810040	Coriander seed	**0,2***
810050	Cumin seed	**0,2***
810060	Dill seed	**0,2***
810070	Fennel seed	**0,2***
810080	Fenugreek	**0,2***
810090	Nutmeg	**0,2***
810990	Others	**0,2***
820000	(ii) Fruits and berries	**0,2***

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg. (EC) No 839/2008
820010	Allspice	**0,2***
820020	Anise pepper (Japan pepper)	**0,2***
820030	Caraway	**0,2***
820040	Cardamom	**0,2***
820050	Juniper berries	**0,2***
820060	Pepper, black and white (Long pepper, pink pepper)	**0,2***
820070	Vanilla pods	**0,2***
820080	Tamarind	**0,2***
820990	Others	**0,2***
830000	(iii) Bark	**0,2***
830010	Cinnamon (Cassia)	**0,2***
830990	Others	**0,2***
840000	(iv) Roots or rhizome	**0,2***
840010	Liquorice	**0,2***
840020	Ginger	**0,2***
840030	Turmeric (Curcuma)	**0,2***
840040	Horseradish	**0,2***
840990	Others	**0,2***
850000	(v) Buds	**0,2***
850010	Cloves	**0,2***
850020	Capers	**0,2***
850990	Others	**0,2***
860000	(vi) Flower stigma	**0,2***
860010	Saffron	**0,2***
860990	Others	**0,2***
870000	(vii) Aril	**0,2***
870010	Mace	**0,2***
870990	Others	**0,2***
900000	9. SUGAR PLANTS	0,1*
900010	Sugar beet (root)	0,1*
900020	Sugar cane	0,1*
900030	Chicory roots	0,1*
900990	Others	0,1*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	0,05*
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	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg. (EC) No 839/2008
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
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	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
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	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	**0,05***
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	**0,05***
1060000	(vi) Snails	**0,05***
1070000	(vii) Other terrestrial animal products	**0,05***

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Metazachlor			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,08**	ARfD (mg/kg bw):	**0,5**
Source of ADI: Year of evaluation:		Source of ARfD: Year of evaluation:	

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
2	9
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)
9,4	WHO Cluster diet B	1,2	Tomatoes	1,1	Wheat	1,0	Potatoes	
9,0	NL child	2,2	Potatoes	1,8	Milk and cream,	0,8	Apples	
9,0	FR toddler	2,5	Milk and cream,	1,9	Potatoes	0,9	Carrots	
8,0	UK Toddler	2,9	Sugar beet (root)	1,3	Potatoes	1,3	Milk and cream,	
7,7	DE child	1,5	Apples	1,0	Potatoes	0,9	Milk and cream,	
7,6	UK Infant	2,4	Milk and cream,	1,3	Sugar beet (root)	1,2	Potatoes	
7,5	IE adult	1,3	Sweet potatoes	0,9	Potatoes	0,3	Melons	
6,5	FR infant	1,6	Milk and cream,	1,6	Potatoes	1,0	Carrots	
6,1	WHO cluster diet E	1,4	Potatoes	0,7	Rape seed	0,5	Wheat	
5,6	SE general population 90th percentile	1,6	Potatoes	0,8	Milk and cream,	0,4	Wheat	
5,6	DK child	0,9	Potatoes	0,8	Milk and cream,	0,7	Wheat	
5,3	WHO cluster diet D	1,5	Potatoes	0,8	Wheat	0,4	Tomatoes	
5,2	WHO regional European diet	1,5	Potatoes	0,4	Tomatoes	0,4	Wheat	
4,8	WHO Cluster diet F	1,3	Potatoes	0,5	Wheat	0,4	Rape seed	
4,6	PT General population	2,0	Potatoes	0,5	Wheat	0,3	Tomatoes	
4,5	ES child	0,8	Milk and cream,	0,7	Potatoes	0,6	Wheat	
3,9	NL general	1,0	Potatoes	0,4	Milk and cream,	0,3	Wheat	
3,2	IT kids/toddler	0,8	Wheat	0,5	Tomatoes	0,3	Potatoes	
3,1	UK vegetarian	0,5	Potatoes	0,5	Sugar beet (root)	0,3	Wheat	
3,0	ES adult	0,3	Potatoes	0,3	Lettuce	0,3	Milk and cream,	
2,9	FR all population	0,5	Wine grapes	0,4	Potatoes	0,4	Wheat	
2,9	LT adult	1,2	Potatoes	0,2	Milk and cream,	0,2	Apples	
2,8	PL general population	1,3	Potatoes	0,3	Tomatoes	0,3	Apples	
2,7	UK Adult	0,5	Potatoes	0,5	Sugar beet (root)	0,2	Wheat	
2,6	IT adult	0,5	Wheat	0,4	Tomatoes	0,2	Lettuce	
2,4	DK adult	0,5	Potatoes	0,3	Milk and cream,	0,3	Wheat	
2,0	FI adult	0,5	Potatoes	0,4	Milk and cream,	0,2	Tomatoes	

Conclusion:

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

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

The acute risk assessment is based on the ARfD.
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.
In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
0,5	Bovine: Liver	0,28 / -	0,5	Bovine: Liver	0,28 / -	0,2	Bovine: Liver	0,28 / -	0,2	Bovine: Liver	0,28 / -
0,0	Swine: Liver	0,14 / -	0,0	Swine: Liver	0,14 / -	0,0	Sheep: Liver	0,28 / -	0,0	Sheep: Liver	0,28 / -
						0,0	Swine: Liver	0,14 / -	0,0	Swine: Liver	0,14 / -
No of critical MRLs (IESTI 1)		---				**No of critical MRLs (IESTI 2)**		---			

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		---				**No of commodities for which ARfD/ADI is exceeded:**		---			
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
2,6	Carrot, juice	0,3 / -				0,2	Orange juice	0,1 / -			
1,0	Tomato juice	0,3 / -				0,1	Apple juice	0,1 / -			
1,0	Apple juice	0,1 / -				0,1	Tomato (preserved-	0,3 / -			
1,0	Orange juice	0,1 / -				0,1	Bread/pizza	0,1 / -			
0,8	Potato puree (flakes)	0,3 / -				0,1	Wine	0,1 / -			

*) 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 Metazachlor 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)
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany
Bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
CS	capsule suspension
CXL	codex maximum residue limit
D	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DP	dustable powder
DT_{90}	period required for 90 percent dissipation (define method of estimation)
DTU	Danish Technical University
dw	dry weight
EC	European Community
EC	emulsifiable concentrate
ECD	electron capture detection
EDI	estimated daily intake
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	european union
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionization detection
GAP	good agricultural practice
GAP	good agricultural practice
GC	gas chromatography
GR	granule
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation

ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10^{-6})
PRIMo	Pesticide Residues Intake Model
PSD	Pesticide Safety Directorate, United Kingdom
RMS	Rapporteur Member State
SC	suspension concentrate
SEU	Southern European Union
SG	water soluble granule
SL	soluble concentrate
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection
WG	water dispersible granule
WHO	World Health Organisation
WP	wettable powder