

ADOPTED: 6 December 2017

doi: 10.2903/j.efsa.2018.5127

Modification of the existing maximum residue level for metazachlor in Chinese cabbage

European Food Safety Authority (EFSA),
Alba Brancato, Daniela Brocca, Chloe De Lentdecker, Zoltan Erdos, Lucien Ferreira,
Luna Greco, Samira Jarrah, Dimitra Kardassi, Renata Leuschner, Christopher Lythgo,
Paula Medina, Ileana Miron, Tunde Molnar, Alexandre Nougadere, Ragnor Pedersen,
Hermine Reich, Angela Sacchi, Miguel Santos, Alois Stanek, Juergen Sturma, Jose Tarazona,
Anne Theobald, Benedicte Vagenende, Alessia Verani and Laura Villamar-Bouza

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), France, received an application from BASF SE to modify the existing maximum residue level (MRL) for the active substance metazachlor in Chinese cabbage. To accommodate for the intended use of metazachlor, France proposed to raise the existing MRL from the value of 0.2 mg/kg to 0.6 mg/kg. France drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA. According to EFSA, the data are sufficient to derive a MRL proposal of 0.6 mg/kg for the proposed use on Chinese cabbage. Adequate analytical enforcement methods are available to control the residues of metazachlor on the commodity under consideration. Based on the risk assessment results, EFSA concludes that the proposed use of metazachlor on Chinese cabbage will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

© 2018 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: metazachlor, Chinese cabbage, MRL application, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2016-00382

Correspondence: pesticides.mrl@efsa.europa.eu

Suggested citation: EFSA (European Food Safety Authority), Brancato A, Brocca D, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2018. Reasoned Opinion on the modification of the existing maximum residue level for metazachlor in Chinese cabbage. *EFSA Journal* 2018;16(1):5127, 20 pp. <https://doi.org/10.2903/j.efsa.2018.5127>

ISSN: 1831-4732

© 2018 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the [Creative Commons Attribution-NoDerivs License](https://creativecommons.org/licenses/by/4.0/), which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.



The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.



Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS), France, received an application from BASF SE to modify the existing maximum residue level (MRL) for the active substance metazachlor in Chinese cabbage. To accommodate for the intended use of metazachlor, France proposed to raise the existing MRL from the value of 0.2 mg/kg to 0.6 mg/kg. France drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 6 June 2016.

EFSA bases its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) (and its addendum) prepared under Council Directive 91/414/EEC, the Commission review report on metazachlor, the conclusion on the peer review of the pesticide risk assessment of the active substance metazachlor and the conclusion on the peer review of the pesticide risk assessment for the active substance metazachlor in light of confirmatory data, as well as the conclusions from previous EFSA opinions on metazachlor, including the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of metazachlor was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.08 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.5 mg/kg bw.

The metabolism of metazachlor in primary crops was investigated in the leafy vegetables (cabbage) and pulses/oilseed (rape seed) crop groups following foliar applications and in the cereals (maize) and pulses/oilseed (rape seed) crop groups following soil applications. From these studies, the peer review established the residue definition for enforcement as sum of metabolites 479M04, 479M08 and 479M16, expressed as metazachlor and as sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor for risk assessment. For the use on Chinese cabbage, EFSA concludes that the metabolism of metazachlor in primary crops has been sufficiently addressed and that the residue definitions derived are applicable.

EFSA concludes that the submitted residue trials are sufficient to derive a MRL proposal of 0.6 mg/kg on Chinese cabbage. Adequate analytical enforcement methods are available to monitor the residues of metazachlor (metabolites 479M04, 479M08 and 479M16) in the commodity under consideration at the validated limit of quantification (LOQ) of 0.02 mg/kg for each individual analyte.

Studies investigating the effect of processing on the nature of residues were provided for metabolite 479M16 for the MRL review; under standard hydrolysis conditions, the compound was stable. Based on the available information, it is suggested that for processed commodities, the same residue definition as for raw agricultural commodities (RAC) is applied.

Specific studies investigating the magnitude of metazachlor residues in processed commodities are not required, considering the low dietary exposure.

The occurrence of metazachlor residues in rotational crops was investigated in the framework of the peer review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the compound is used according to the proposed good agricultural practice (GAP).

Residues of metazachlor in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo. The highest chronic intake was calculated to be 0.9% of the ADI (FR, toddler). The contribution of residues in Chinese cabbage to the total consumer exposure accounted for less than 0.1% of the ADI (SE, general population 90th percentile). An acute consumer risk was not identified in relation to the MRL proposal for Chinese cabbage. The highest acute consumer exposure was calculated to be 1.9% of the ARfD for Chinese cabbage.

EFSA concludes that the proposed use of metazachlor on Chinese cabbage will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a health risk to consumers.

EFSA proposes to amend the existing MRL as reported in the summary table below.

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Sum of metabolites 479M04, 479M08 and 479M16, expressed as metazachlor				
0243010	Chinese cabbage (Indian or Chinese) mustard, pak choi, Chinese flat cabbage/ai goo choi), choi sum, Peking cabbage/pe-tsai)	0.2	0.6	Supported by SEU trials only (outdoor). The PHI supported by trials for the intended GAP is defined as the time period between application at BBCH growth stages 10–18 and harvest not earlier than BBCH growth stage 49.

MRL: maximum residue level, SEU: southern Europe, GAP: good agricultural practice, BBCH: growth stages of mono- and dicotyledonous plants, PHI: preharvest interval.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

Table of contents

Abstract.....	1
Summary.....	3
Background	6
The active substance and its use pattern	6
Assessment.....	7
1. Method of analysis	7
1.1. Methods for enforcement of residues in food of plant origin	7
1.2. Methods for enforcement of residues in food of animal origin	7
2. Mammalian toxicology	7
3. Residues.....	8
3.1. Nature and magnitude of residues in plant.....	8
3.1.1. Primary crops.....	8
3.1.1.1. Nature of residues.....	8
3.1.1.2. Magnitude of residues	9
3.1.1.3. Effect of industrial processing and/or household preparation	11
3.1.2. Rotational crops	11
3.2. Nature and magnitude of residues in livestock.....	11
4. Consumer risk assessment	11
Conclusions and recommendations	13
References.....	14
Abbreviations	14
Appendix A – Good Agricultural Practice (GAPs).....	16
Appendix B – Used compound codes	17
Appendix C – Pesticide Residue Intake Model (PRIMo)	19

Background

Regulation (EC) No 396/2005¹ (hereinafter referred to as 'the Regulation') establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC², repealed by Regulation (EC) No 1107/2009³, shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of the Regulation.

France, hereafter referred to as the evaluating Member State (EMS), received an application from the company BASF SE⁴ to modify the existing MRL for the active substance metazachlor in Chinese cabbage. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission and to EFSA on 6 June 2016.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00382 and the following subject:

Metazachlor: Application to modify the MRL in Chinese cabbage

France proposed to raise the existing MRL of metazachlor in Chinese cabbage from the value of 0.2 mg/kg to 0.6 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the Regulation. EFSA identified points which needed further clarification which were requested from the EMS. On 20 November 2017, the EMS submitted the requested information and provided an updated evaluation report (France, 2017), which replaced the previously submitted evaluation report.

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

The evaluation report submitted by the EMS and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

The active substance and its use pattern

The Good Agricultural Practice (GAP) for metazachlor in Chinese cabbage for which an authorisation was requested in France and which is the basis of this MRL application is given in Appendix A.

Metazachlor is the ISO common name for 2-chloro-*N*-(pyrazol-1-ylmethyl)acet-2',6'-xylidide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix B. Metazachlor has been approved for the uses as herbicide.

Metazachlor was evaluated in the framework of Directive 91/414/EEC with the United Kingdom designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2008/116/EC⁵ which entered into force on 1 August 2009 for use as a herbicide only. The approval is restricted to uses of maximum 1 kg/ha every third year on the same field. In accordance with Commission Implementing Regulation (EU) No 540/2011⁶ metazachlor is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

The representative uses evaluated in the peer review were as herbicide on winter and spring oilseed rape and ornamentals for the control of annual grasses and broad-leaved weeds. The draft

¹ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.

² Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.

³ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

⁴ BASF SE, Speyerer Strasse 2 67114, Limburgerhof, Germany.

⁵ Commission Directive 2008/116/EC of 15 December 2008 amending Council Directive 91/414/EEC to include aclofenfen, imidacloprid and metazachlor as active substances. OJ L 337, 16.12.2008, p. 86–91.

⁶ Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

assessment report (DAR) has been peer reviewed by EFSA (2008). Confirmatory data regarding the toxicological relevance of groundwater metabolites has been peer reviewed by EFSA (2017).

In 2015, after the MRL review of existing MRLs in the framework of Article 12 of Regulation (EC) No 396/2005 was performed (EFSA 2014), the EU MRLs for metazachlor were amended and transferred to Annex II of Regulation (EC) No 396/2005.

Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (France, 2017), the DAR (and its final addendum) prepared under Directive 91/414/EEC (United Kingdom, 2005, 2007), the Commission review report on metazachlor (European Commission, 2012), the conclusion on the peer review of the pesticide risk assessment of the active substance metazachlor (EFSA, 2008) and the conclusion on the peer review of the pesticide risk assessment for the active substance metazachlor in light of confirmatory data (EFSA, 2017), as well as the conclusions from previous EFSA opinions on metazachlor including the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2009, 2014). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁷ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011).

1. Method of analysis

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

Analytical methods for the determination of metazachlor residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (EFSA, 2008). An analytical method using high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS), confirmed by another analytical method using HPLC–MS/MS, and its independent laboratory validation (ILV) were evaluated and fully validated for the determination of the metabolites 479M04, 479M08 and 479M16 in plant matrices with, for each individual analyte, at a LOQ of 0.02 mg/kg in high water content, high oil content and acidic commodities (carrot, lettuce, rape seed, orange and lemon) (United Kingdom, 2005, 2007).

As the commodity under consideration belongs to high water content commodity group, EFSA concludes that sufficiently validated analytical methods are available for enforcing the proposed MRL for metazachlor in Chinese cabbage.

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

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application since Chinese cabbage is normally not fed to livestock.

2. Mammalian toxicology

The toxicological profile of the active substance metazachlor was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2008). Metazachlor was subsequently classified as suspected of causing cancer (category 2, H351) under Regulation (EC) No 1272/2008⁸, triggering the requirement for submission of further information on the carcinogenic potential of groundwater metabolites 479M04, 479M08, 479M09, 479M11 and 479M12 in accordance with the conditions of approval.⁵ The toxicological profiles of the metabolites were assessed in the framework of the peer review under Regulation (EC) No 1107/2009 on the basis of the confirmatory data submitted (EFSA, 2017). It was concluded that the metabolites 479M04, 479M08 and 479M12 are less toxic than parent metazachlor and toxicological reference values (ADI) were derived (see Table 1). For metabolites 479M09 and 479M11, it cannot be excluded that they share the carcinogenic potential of the parent

⁷ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

⁸ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1–1355.

metazachlor (EFSA, 2017). Thus, taking into account the result of the assessment of the confirmatory data, it is concluded that the previously used conservative approach for the dietary risk assessment (i.e. to use the toxicological reference values for parent metazachlor) is still appropriate. This is also justified since the residue definition for enforcement covers the sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor and does not allow to distinguish between the individual metabolites.

Table 1: Overview of the toxicological reference values

	Source	Year	Value	Study	Uncertainty factor
Metazachlor					
ADI	EFSA	2008	0.08 mg/kg bw per day	Rat, chronic study	100
ARfD	EFSA	2008	0.5 mg/kg bw	Rat, developmental study	100
Metabolites					
479M04					
ADI	EFSA	2017	0.33 mg/kg bw per day	Mouse, 90-day study	1,000 ^(a)
479M08					
ADI	EFSA	2017	0.2 mg/kg bw per day	Rat, developmental study	1,000 ^(a)
479M12					
ADI	EFSA	2017	0.38 mg/kg bw per day	Rat, developmental study	1,000 ^(a)

ADI: acceptable daily intake; ARfD: acute reference dose; bw: body weight.

(a): The toxicological reference values for metabolites 479M04, 479M08 and 479M12 are based on the limited data set and thus an uncertainty factor (UF) of 1,000 is applied.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of metazachlor in primary crops was evaluated in the framework of the peer review under Directive 91/414/EEC (United Kingdom, 2005, 2007, EFSA, 2008) in the leafy vegetables (cabbage), cereals (maize) and pulses/oilseed (rape seed) crop groups. An overview of the available metabolism studies is presented in Table 2.

Table 2: Summary of available metabolism studies in plants

Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comments
Fruit	–	–	–	–
Root	–	–	–	–
Leafy	Cabbage	Foliar spraying: 1 × 1,250 g/ha	34, 147	–
Cereals/grass	Maize	Soil treatment: 1 × 1,000 g/ha	78, 118, 146	–
Pulses/oilseeds	Rape seed	Soil treatment: 1 × 1,250 g/ha	215, 293	–
Pulses/oilseeds	Rape seed	Foliar spraying: 1 × 1,250 g/ha	22, 71	–
Pulses/oilseeds	Rape seed	Foliar spraying: 1 × 750 g/ha	41, 94	–

Based on these metabolism studies, the following residue definitions were derived for plant products (EFSA, 2008):

- Residue definition for monitoring: sum of metabolites 479M04, 479M08 and 479M16, expressed as metazachlor for monitoring;
- Residue definition for risk assessment: sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor.

The above residue definitions for monitoring and for risk assessment were confirmed by the review of the existing MRLs for metazachlor according to Article 12 of Regulation (EC) No 396/2005 (EFSA,

2014). The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review.

For the uses on Chinese cabbage, EFSA concludes that the metabolism of metazachlor is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed during the peer review are applicable.

3.1.1.2. Magnitude of residues

In support of the MRL application, four residue trials on Chinese cabbage in southern Europe (SEU) were submitted. In the four residue trials, one application was made at a rate of 500 g a.s./ha at BBCH growth stage 18, in compliance with the intended GAP. The various preharvest intervals (PHIs) were determined by the time period between application at BBCH growth stage 18 and harvest at BBCH growth stage 49 (26, 45 or 64 days).

According to the EU guidance document on extrapolation (European Commission, 2017), for authorisations of uses in Chinese cabbage in France, residue trials from either the northern or the southern zone are acceptable.

All samples were analysed for 479M04, 479M08 and 479M16; in addition, the samples were analysed with a common moiety method to determine the residue concentration in accordance with the residue definition for risk assessment (i.e. metazachlor and metabolites containing the common moiety 2,6-dimethylaniline, expressed as metazachlor). Residue levels according to the residue definition for monitoring (sum of metabolites 479M04, 479M08 and 479M16, expressed as metazachlor) ranged from 0.026 to 0.260 mg/kg.

The results of the residue trials, the related risk assessment input values (highest residue (HR), median residue) and the MRL proposal are summarised in Table 3.

The stability of metazachlor residues in plant matrices under storage conditions prior to analysis was assessed during the peer review under Directive 91/414/EEC (EFSA, 2008). The metabolite 479M16 were found to be stable at $\leq -18^{\circ}\text{C}$ for up to 13 months in high water- and high oil content matrices (United Kingdom, 2007) and metabolites 479M08 and 479M04 were found to be stable at $\leq -18^{\circ}\text{C}$ for up to 18 months in high water content matrices (United Kingdom, 2013). As the trial samples were stored for a maximum period of < 220 days under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical methods used to analyse the residue trial samples have been sufficiently validated and were proven to be fit for the purpose (France, 2017).

EFSA concludes that the data are sufficient to derive the following MRL proposal:

- 0.60 mg/kg Chinese cabbage based on residue trials performed in southern Europe (SEU).

Table 3: Overview of the available residues trials data

Crop (GAPs)	Region/Indoor ^(a)	Residue levels observed in the supervised residue trials ^(b) (mg/kg)	Recommendations/comments ^(c)	MRL proposal (mg/kg)	HR ^(d) (mg/kg)	STMR ^(e) (mg/kg)	CF ^(f)
Chinese cabbage (RD-Mo≠RD-RA)	SEU	Mo: 0.026 ^(PHI 64 d) , 0.107 ^(PHI 26 d) , 0.107 ^(PHI 45 d) , 0.260 ^(PHI 26 d) RA: 0.099 ^(PHI 64 d) , 0.13 ^(PHI 26 d) , 0.14 ^(PHI 45 d) , 0.25 ^(PHI 26 d)	MRL _{OECD} : 0.52/0.60 (unrounded/rounded value)	0.60	0.25 (HR _{Mo} : 0.26)	0.135 (STMR _{Mo} : 0.107)	1.31

GAP: Good Agricultural Practice; MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development; RD: residue definition.

(a): SEU: Outdoor trials conducted in southern Europe.

(b): Individual residue levels considered for MRL calculation are reported in ascending order.

Mo: residue level according to the monitoring/enforcement residue definition.

RA: residue level according to the residue definition for risk assessment.

Residue levels for monitoring/enforcement = $[\sum(\text{Concentration of metabolite } i / \text{MM metabolite } i)] \times \text{MM metazachlor}$.

with MM metazachlor: 277.8 g/mol; MM metabolite 479M04: 273.3 g/mol; MM metabolite 479M08: 323.4 g/mol; MM metabolite 479M16: 379.4 g/mol.

(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values).

(d): HR: Highest residue level according to the residue definition for risk assessment.

HR_{Mo}: Highest residue level according to residue definition for monitoring.

(e): STMR: Median residue level according to residue definition for risk assessment.

STMR_{Mo}: Median residue level according to residue definition for monitoring.

(f): CF: Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

The conversion factor was derived from residue concentrations measured at PHI 64 days; samples with residues at or close to the limit of quantification were disregarded from the calculation.

3.1.1.3. Effect of industrial processing and/or household preparation

Standard hydrolysis studies simulating the effect on the nature of residues of metabolite 479M16 under processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the MRL review (EFSA, 2014) and it was concluded that the compound is hydrolytically stable under the representative conditions. Further investigation on the effect of processing on metabolites 479M04, 479M08 was considered desirable, but due to the low exposure to metazachlor, the information was not considered essential.

Based on the available information, it is suggested that for processed commodities, the same residue definition as for raw agricultural commodities (RAC) is applied.

Specific studies to assess the magnitude of metazachlor residues during the processing of Chinese cabbage are not necessary as the total theoretical maximum daily intake (TMDI) amounts to less than 10% of the ADI (European Commission, 1997d).

3.1.2. Rotational crops

Studies on the nature and magnitude of metazachlor residues in rotational crops were assessed in the framework of the peer review and it was concluded that the residue definitions set for primary crops are also applicable to rotational crops and that significant residues are not expected in rotational crops when the active substance is applied on primary crops up to a total annual dose rate of 1,000 g/ha (EFSA, 2008). Since the annual application rate for the crops under consideration in this MRL application is limited to a maximum of 500 g/ha, EFSA concludes that metazachlor residues are not expected to be present in rotational crops, provided that the active substance is applied according to the proposed GAPs and respecting the restriction of Regulation (EU) No 540/2011 to use maximum 1 kg/ha every third year on the same field.

3.2. Nature and magnitude of residues in livestock

As the crop under consideration is not normally fed to livestock, the nature and magnitude of metazachlor residues in livestock are not assessed in the framework of this application (European Commission, 1996).

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population⁹ (EFSA, 2007).

In the framework of the review of the existing MRLs for metazachlor according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses at the EU level (EFSA, 2014). EFSA updated this risk assessment with the median residue levels (STMR) derived from the residue trials conducted on the crop under consideration in this MRL application (Table 4). The food commodities, for which no uses were reported in the framework of the Article 12 review, were excluded from the exposure calculation, assuming that there is no use of metazachlor on these crops.

The acute exposure assessment was performed only with regard to the commodity under consideration assuming the consumption of a large portion of the food item as reported in the national food surveys and that these items contained residues at the HR level as observed in supervised field trials (Table 4). A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

The input values used for the dietary exposure calculation are summarised in Table 4.

⁹ The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment, the most critical large portion consumption data from 19 national diets collected from Member States surveys are used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

Table 4: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment residue definition: Sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor				
Oranges, Lemons	–	See note ^(a)	0.25	HR
Tree nuts, Pome fruits, Stone fruits, berries and small fruits	–	See note ^(a)		
Potatoes	–	See note ^(a)		
Radishes	0.09	Median residue (tentative) (EFSA, 2014) ^(b)		
Turnips, Swedes, Horseradish	0.05	Median residue (tentative) (EFSA, 2014) ^(b)		
Garlic	0.05	Median residue (EFSA, 2014)		
Cauliflower, Broccoli	0.05	Median residue (tentative) (EFSA, 2014) ^(b)		
Brussels sprouts	0.05	Median residue (EFSA, 2014)		
Head cabbage	0.05	Median residue (tentative) (EFSA, 2014) ^(b)		
Chinese cabbage	0.135	STMR		
Kale	0.05	Median residue (tentative) (EFSA, 2014) ^(b)	0.25	HR
Kohlrabi	0.08	Median residue (tentative) (EFSA, 2014) ^(b)		
Rocket, Rucola	–	See note ^(a)		
Asparagus	–	See note ^(a)		
Globe artichokes	0.05	Median residue (EFSA, 2014)		
Leek	0.05	Median residue (EFSA, 2014)		
Linseed, Rape seed, Sunflower seed, Mustard seed, Borage, Gold of pleasure	0.05	Median residue (EFSA, 2014)		
Swine meat	0.05*	Median muscle (EFSA, 2014)		
Swine fat (free of lean meat)	0.05*	Median residue (EFSA, 2014)		
Swine liver	0.07	Median residue (EFSA, 2014)		
Swine kidney	0.05*	Median residue (EFSA, 2014)		
Swine: Edible offal	0.05*	MRL		
Other swine products				
Ruminant meat	0.05 ^(*)	Median muscle (EFSA, 2014)		
Ruminant fat	0.05*	Median residue (EFSA, 2014)		
Ruminant liver	0.11	Median residue (EFSA, 2014)		
Ruminant kidney	0.05*	Median residue (EFSA, 2014)		
Ruminant: Edible offal	0.05*	MRL		
Other ruminant products				
Horse meat, fat	0.05 ^(*)	MRL		
Horse liver	0.3	MRL		
Horse: Edible offal	0.05*	MRL		
Other horse products				
Poultry products	0.05*	MRL		
Other farm animals: muscle, fat	0.05*	MRL		
Other farm animals: liver	0.3	MRL		

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Other farm animals: kidney, edible offal, others	0.05*	MRL		
Milk	0.01*	MRL		
Birds' eggs	0.05*	Median residue (EFSA, 2014)		
Honey	0.05*	MRL		

HR: highest residue; MRL: maximum residue level.

*: Indicates that the input value is proposed at the limit of analytical quantification.

(a): The STMR values reported in the EFSA reasoned opinion in accordance with Article 12(1) of Regulation (EC) No 396/2005 (EFSA, 2014) have not been included for oranges, lemons, tree nuts, pome fruits, stone fruits, berries and small fruits, potatoes, rocket and asparagus, since the MRL was set at the LOQ or default value in Commission Regulation (EU) 2015/400. (Commission Regulation (EU) 2015/400 of 25 February 2015 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bone oil, carbon monoxide, cyprodinil, dodemorph, iprodione, metaldehyde, metazachlor, paraffin oil (CAS 64742-54-7), petroleum oils (CAS 92062-35-6) and propargite in or on certain products. OJ L 71/56, 14.3.2015, 58 pp.)

(b): The risk assessment values derived in EFSA reasoned opinion in accordance with Article 12(1) of Regulation (EC) No 396/2005 (EFSA, 2014) are used for indicative exposure calculations, but the use reported by the RMS is not fully supported by data.

The estimated exposure was then compared with the toxicological reference values derived for metazachlor (Table 2). The results of the intake calculation using the EFSA PRIMo is a key supporting document and is made publicly available as a background document to this reasoned opinion.

A long-term consumer intake concern was not identified for any of the European diets incorporated in the EFSA PRIMo. The highest chronic intake was calculated to be 0.9% of the ADI (FR, toddler). The contribution of residues in Chinese cabbage to the total consumer exposure accounted for less than 0.1% of the ADI (SE, general population 90th percentile).

An acute consumer risk was not identified in relation to the MRL proposal for Chinese cabbage. The highest acute consumer exposure was calculated to be 1.9% of the ARfD for Chinese cabbage.

EFSA concludes that the intended use of metazachlor on Chinese cabbage will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a concern for public health.

It is noted that in case the approval conditions for metazachlor are modified, taking into account the conclusions of the assessment of confirmatory data (EFSA, 2017), the dietary risk assessment might have to be reconsidered.

Conclusions and recommendations

The information submitted was sufficient to propose the MRL summarised in the table below:

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Sum of metabolites 479M04, 479M08 and 479M16, expressed as metazachlor				
0243010	Chinese cabbage (Indian or Chinese) mustard, pak choi, Chinese flat cabbage/ai goo choi), choi sum, Peking cabbage/pe-tsai)	0.2	0.6	Supported by SEU trials only (outdoor). The PHI supported by trials for the intended GAP is defined as the time period between application at BBCH growth stages 10–18 and harvest not earlier than BBCH growth stage 49.

MRL: maximum residue level, SEU: Southern Europe, GAP: good agricultural practice, BBCH: growth stages of mono- and dicotyledonous plants, PHI: preharvest interval.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

References

- EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers health arising from proposed temporary EU MRLs. EFSA Journal 2007;5(3):32r, 1141 pp. <https://doi.org/10.2903/j.efsa.2007.32r>
- EFSA (European Food Safety Authority), 2008. Conclusion on the peer review of the pesticide risk assessment of the active substance metazachlor. EFSA Journal 2008;6(7):145r, 132 pp. <https://doi.org/10.2903/j.efsa.2008.145r>
- EFSA (European Food Safety Authority), 2009. Reasoned opinion on the modification of the existing MRLs for metazachlor for certain products of animal origin. EFSA Journal 2009;7(7):320r, 132 pp. <https://doi.org/10.2903/j.efsa.2009.320r>
- EFSA (European Food Safety Authority), 2014. Review of the existing maximum residue levels for metazachlor according to Article 12 of Regulation (EC) No 396/2005, 7 April 2014 revised 20 June 2014. Available online: www.efsa.europa.eu
- EFSA (European Food Safety Authority), Brancato A, Brocca D, Bura L, Byers H, Chiusolo A, Court Marques D, Crivellente F, De Lentdecker C, De Maglie M, Egsmose M, Erdos Z, Fait G, Ferreira L, Goumenou M, Greco L, Istace F, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Magrans JO, Medina P, Miron I, Molnar T, Nougadere A, Padovani L, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Serafimova R, Stanek A, Sturma J, Tarazona J, Terron A, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2017. Conclusion on the peer review of the pesticide risk assessment for the active substance metazachlor in light of confirmatory data. EFSA Journal 2017;15(6):4833, 55 pp. <https://doi.org/10.2903/j.efsa.2017.4833>
- European Commission, 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95-rev.4.
- European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3.
- European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realisation of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6.
- European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2.
- European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5.
- European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3.
- European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5.
- European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95.
- European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414). SANCO/3029/99-rev.4.
- European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
- European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev.8.1.
- European Commission, 2012. Review report for the active substance metazachlor. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 26 September 2008 in view of the inclusion of metazachlor in Annex I of Council Directive 91/414/EEC. SANCO/140/08 – final rev. 2, 24 January 2012, 9 pp.
- European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.3, 13 June 2017.
- France, 2017. Evaluation report on the modification of MRL for metazachlor in Chinese cabbage prepared by the evaluating Member State France under Article 8 of Regulation (EC) No 396/2005, October 2016 revised in November 2017, 41 pp.
- OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: <http://www.oecd.org>
- United Kingdom, 2005. Draft assessment report on the active substance metazachlor prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, June 2005.
- United Kingdom, 2007. Final addendum to the draft assessment report on the active substance metazachlor prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, compiled by EFSA, September 2007.
- United Kingdom, 2013. Evaluation Report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing MRLs for metazachlor, December 2013.

Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
Bw	body weight
CAS	Chemical Abstract Service

CF	conversion factor for enforcement to risk assessment residue definition
DAR	draft assessment report
DAT	days after treatment
EC	emulsifiable concentrate
EMS	Evaluating Member State
GAP	Good Agricultural Practice
HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
Mo	monitoring
MRL	maximum residue level
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SEU	southern Europe
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake

Appendix A – Good Agricultural Practice (GAPs)

Crop	NEU, SEU, MS or country	F G or I (a)	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days) ^(d)	Remarks
				Type ^(b)	Conc. a.s.	Method kind	Range of growth stages & season ^(c)	Number min-max	Interval between application	g/hL min-max	Water L/ha min-max	g/ha min-max		
Leafy cabbage (Chinese cabbage) transplanted	SEU (FR)	F	Weeds (general)	EC	200 g/L metazachlor (1)	Spraying	BBCH 10–18	1	n/a	0.1–0.5 (1)	100–500	0.5 (1)	F*	Post-transplanting, not earlier than 5–7 days after transplanting. F = PHI is covered by the time remaining between application and harvest. *Harvest not earlier than BBCH growth stage 49.
					200 g/L dimethenamid-p (2)					0.1–0.5 (2)		0.5 (2)		

NEU: northern Europe; SEU: southern Europe; MS: Member State; EC: emulsifiable concentrate; a.s.: active substance.

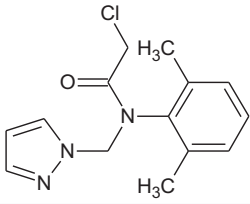
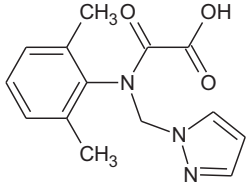
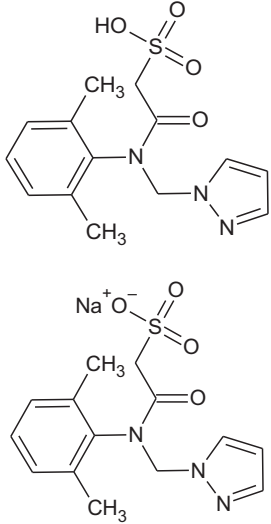
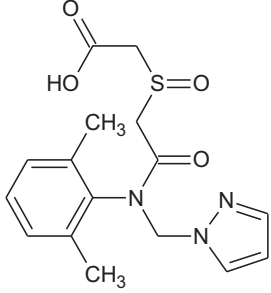
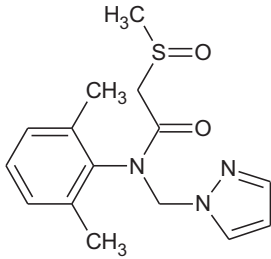
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

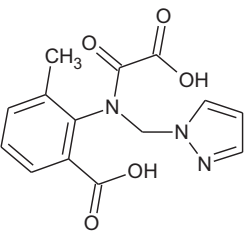
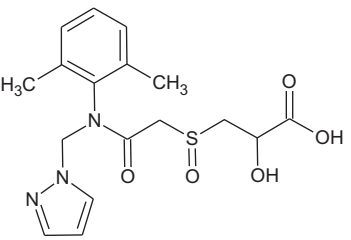
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.

Appendix B – Used compound codes

Code/Trivial name	Chemical name	Structural formula
Metazachlor	2-chloro- <i>N</i> -(pyrazol-1-ylmethyl)acet-2',6'-xylylide <chem>O=C(Cl)N(Cn1cccn1)c2c(C)cccc2C</chem>	
479M04 BH 479-4	[(2,6-dimethylphenyl)(1 <i>H</i> -pyrazol-1-ylmethyl)amino](oxo)acetic acid <chem>O=C(N(Cn1cccn1)c2c(C)cccc2C)C(=O)O</chem>	
479M08 BH 479-8 BH 479-18 479M18	2-[(2,6-dimethylphenyl)(1 <i>H</i> -pyrazol-1-ylmethyl)amino]-2-oxoethanesulfonic acid <chem>O=C(CS(=O)(=O)O)N(Cn1cccn1)c2c(C)cccc2C</chem> sodium 2-[(2,6-dimethylphenyl)(1 <i>H</i> -pyrazol-1-ylmethyl)amino]-2-oxoethanesulfonate <chem>[Na+].O=C(CS([O-])(=O)=O)N(Cn1cccn1)c2c(C)cccc2C</chem>	
479M09 BH 479-9	({2-[(2,6-dimethylphenyl)(1 <i>H</i> -pyrazol-1-ylmethyl)amino]-2-oxoethyl}sulfinyl)acetic acid <chem>O=C(CS(=O)CC(=O)O)N(Cn1cccn1)c2c(C)cccc2C</chem>	
479M11 BH 479-11	<i>N</i> -(2,6-dimethylphenyl)-2-(methylsulfinyl)- <i>N</i> -(1 <i>H</i> -pyrazol-1-ylmethyl)acetamide <chem>O=C(CS(C)=O)N(Cn1cccn1)c2c(C)cccc2C</chem>	

Code/Trivial name	Chemical name	Structural formula
479M12 BH 479-12	3-methyl-2-[oxalo(1 <i>H</i> -pyrazol-1-ylmethyl)amino]benzoic acid <chem>O=C(N(Cn1cccn1)c2c(C)cccc2C(=O)O)C(=O)O</chem>	
479M16 M16	3-({ 2-[(2,6-dimethylphenyl)(1 <i>H</i> -pyrazol-1-ylmethyl)amino]-2-oxoethyl} sulfinyl)-2-hydroxypropanoic acid <chem>O=C(CS(=O)CC(O)C(=O)O)N(Cn1cccn1)c2c(C)cccc2C</chem>	

Appendix C – Pesticide Residue Intake Model (PRIMO)

Metazachlor			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.01	Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	0.08	ARfD (mg/kg bw):	0.5
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2008	Year of evaluation:	2008

EFSA-Q-2016-00382 Art. 10 Chinese cabbage/MRLs as set in Reg. (EU) 2015.400/.

Chronic risk assessment – refined calculations								
		TMDI (range) in % of ADI minimum – maximum						
		No of diets exceeding ADI:		---		1		
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)
0.9	FR toddler	0.5	Milk and cream	0.1	Bovine: Meat	0.1	Birds' eggs	0.5
0.7	NL child	0.4	Milk and cream	0.1	Swine: Meat	0.1	Bovine: Meat	0.4
0.6	UK Infant	0.5	Milk and cream	0.1	Birds' eggs	0.0	Poultry – chicken, geese, duck	0.5
0.5	FR infant	0.3	Milk and cream	0.0	Bovine: Meat	0.0	Poultry – chicken, geese, duck	0.3
0.5	ES child	0.2	Milk and cream	0.1	Bovine: Meat	0.1	Poultry – chicken, geese, duck	0.2
0.4	WHO regional European diet	0.1	Swine: Meat	0.1	Bovine: Meat	0.1	Poultry – chicken, geese, duck	0.1
0.4	WHO Cluster diet B	0.1	Poultry – chicken, geese, duck	0.1	Bovine: Meat	0.0	Swine: Meat	0.0
0.4	DE child	0.2	Milk and cream	0.1	Birds' eggs	0.0	Poultry – chicken, geese, duck	0.2
0.4	WHO cluster diet E	0.1	Poultry – chicken, geese, duck	0.0	Bovine: Meat	0.0	Birds' eggs	0.0
0.4	UK Toddler	0.3	Milk and cream	0.1	Birds' eggs	0.0	Poultry – chicken, geese, duck	0.3
0.4	IE adult	0.0	Other swine products	0.0	Milk and cream	0.0	Sheep: Liver	0.0
0.4	WHO Cluster diet F	0.1	Swine: Meat	0.1	Bovine: Meat	0.0	Milk and cream	0.0
0.3	SE general population 90th percentile	0.2	Milk and cream	0.1	Birds' eggs	0.0	Head cabbage	0.2
0.3	WHO cluster diet D	0.1	Milk and cream	0.0	Bovine: Meat	0.0	Chinese cabbage	0.1
0.3	NL general	0.1	Milk and cream	0.1	Swine: Meat	0.0	Bovine: Meat	0.1
0.3	DK child	0.2	Milk and cream	0.1	Birds' eggs	0.0	Poultry – chicken, geese, duck	0.2
0.3	ES adult	0.1	Milk and cream	0.0	Bovine: Meat	0.0	Swine: Meat	0.1
0.2	LT adult	0.1	Swine: Meat	0.0	Milk and cream	0.0	Head cabbage	0.0
0.2	FR all population	0.0	Poultry – chicken, geese, duck	0.0	Milk and cream	0.0	Bovine: Meat	0.0
0.2	DK adult	0.1	Milk and cream	0.0	Bovine: Meat	0.0	Birds' eggs	0.1
0.1	FI adult	0.1	Milk and cream	0.0	Poultry – chicken, geese, duck	0.0	Birds' eggs	0.1
0.1	UK Adult	0.0	Milk and cream	0.0	Poultry – chicken, geese, duck	0.0	Birds' eggs	0.0
0.1	UK vegetarian	0.0	Milk and cream	0.0	Birds' eggs	0.0	Cauliflower	0.0
0.0	PL general population	0.0	Head cabbage	0.0	Cauliflower	0.0	Chinese cabbage	
0.0	PT General population	0.0	Sunflower seed	0.0	Turnips	0.0	Garlic	
0.0	IT adult	0.0	Cauliflower	0.0	Globe artichokes	0.0	Head cabbage	
0.0	IT kids/toddler	0.0	Cauliflower	0.0	Globe artichokes	0.0	Sunflower seed	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs 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 variability factor of 3.
Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
	IESTI 1 *) **)			IESTI 2 *) **)			IESTI 1 *) **)			IESTI 2 *) **)		
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	1.9	Chinese cabbage	0.25/-	1.9	Chinese cabbage	0.25/-	1.8	Chinese cabbage	0.25/-	1.8	Chinese cabbage	0.25/-
No of critical MRLs (IESTI 1)			---			No of critical MRLs (IESTI 2)			---			

Processed commodities	No of commodities for which ARfD/ADI is exceeded: ---			No of commodities for which ARfD/ADI is exceeded: ---		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	0.2	Apple juice	0.02/-	0.0	Orange juice	0.02/-
0.2	Orange juice	0.02/-	0.0	Apple juice	0.02/-	
0.2	Carrot, juice	0.02/-	0.0	Bread/pizza	0.02/-	
0.1	Grape juice	0.02/-	0.0	Wine	0.02/-	
0.1	Peach juice	0.02/-	0.0	Pineapples preserved	0.02/-	

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
 **) pTMRL: provisional temporary MRL.
 ***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:
 For 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.