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Modification of the existing maximum residue levels for metazachlor in leeks and honey

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant BASF SE submitted a request to the competent national authority in the Netherlands to modify the existing maximum residue levels (MRLs) for the active substance metazachlor in leeks and honey. The data submitted in support of the request were found to be sufficient to derive MRL proposals. Adequate analytical methods for enforcement are available to control the residues of metazachlor metabolites 479 M04, 479 M08 and 479 M16 in plant matrices and honey at the validated limit of quantification (LOQ) of 0.01 and 0.02 mg/kg for each analyte. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of metazachlor according to the reported agricultural practice is unlikely to present a risk to consumer health.

Keywords: metazachlor, leeks, honey, herbicide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance metazachlor in leeks and honey.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the European Food Safety Authority (EFSA) Central Submission System on 11 September 2021. The appointed EMS in the Netherlands assessed the dossier and declared its admissibility on 20 September 2022. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA and a public consultation was launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation ran from 23 March 2023 to 13 April 2023. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded to draft the evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 3 May 2023. To accommodate for the intended uses of metazachlor, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) to 0.3 and to 0.08 mg/kg for leeks and honey, respectively.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points that needed further clarification, which were requested from the EMS. On 11 July 2023, the applicant provided the requested information in an updated IUCLID dossier. The additional information was duly considered by the EMS who submitted a revised evaluation report to EFSA on 12 July 2023 (Netherlands, 2023), which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of metazachlor following foliar application was investigated in cabbages belonging to the group of leafy vegetables, rapeseeds belonging to the group of pulses/oilseeds and in maize belonging to the group of cereals.

Studies investigating the effect of processing on the nature of metazachlor metabolite 479 M16 (hydrolysis studies) demonstrated that this active substance is hydrolytically stable under standard representative conditions. Considering the low expected exposure resulting from the use of metazachlor, an investigation of the effect of processing on the metabolites 479 M04 and 479 M08 is desirable but not essential.

The occurrence of metazachlor residues in rotational crops was investigated in the framework of the peer review and it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed Good Agricultural Practices (GAPs) respecting the restrictions of the implementing Regulation.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological relevance of metabolites the residue definitions for plant products were proposed as 'metazachlor (sum of metabolites 479M04, 479M08 and 479M16, expressed as metazachlor)' for enforcement and 'sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor ('total residues')' for risk assessment. These residue definitions are applicable to primary crops, rotational crops, processed products and honey.

EFSA concluded that for the crops assessed in this application, the metabolism of metazachlor in primary and rotational crops, and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectrometry (HPLC/MS–MS) are available to quantify residues in the commodity under assessment according to the enforcement residue definition. The methods enable quantification of residues at or above LOQs of 0.01 and 0.02 mg/kg in leeks. An adequate liquid chromatography–tandem mass spectrometry detector (LC–MS/MS) enforcement method for monitoring residues in honey was submitted in the framework of this application. The EMS assessed it as sufficiently validated for quantification of residues at or above LOQ of 0.01 mg/kg.

The available southern residue trials are sufficient to derive an MRL proposal of 0.3 mg/kg for leeks based on the SEU GAP. The applicant provided also residue trials for deriving an MRL for honey, where metazachlor was applied to oilseed rape under field conditions. The MRL proposal is based on the highest residue (HR) measured in the oilseed rape inflorescences samples during the flowering. The trials are considered sufficiently representative for the authorised EU uses of metazachlor and are therefore appropriate to propose an MRL for honey (0.08 mg/kg).

Specific studies investigating the magnitude of metazachlor residues in processed commodities are not required, as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI.

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 toxicological profile of metazachlor was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.08 mg/kg bw per day and an acute reference dose (ARfD) of 0.5 mg/kg bw. The metabolites included in the residue definition are of comparable toxicity to the parent active substance.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure assessment was performed only for the commodities assessed in the present MRL application and did not exceed the ARfD for any of the crops assessed. In the framework of the focused MRLs review according to Art. 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 updated this calculation with the relevant supervised trials median residue (STMR) values derived from the residue trials submitted in support of an MRL applications submitted after the focused MRL review and the STMR values derived from the residue trials submitted with the present MRL application. Finally, the crops on which no uses were reported in the MRL review and subsequently published EFSA outputs were excluded from the exposure calculation. The estimated long-term dietary intake accounted for 1% of the ADI (NL toddler diet).

EFSA concluded that the proposed use of metazachlor on leeks and the potential carry-over of residues to honey following the selected critical GAP will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

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

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Metazachlor (Sum of metabolites 479 M04, 479 M08 and 479 M16, expressed as metazachlor)				
0270060	Leeks	0.06*	0.3	The submitted data are sufficient to derive an MRL proposal for the SEU use. Risk for consumers is unlikely. The intended NEU use is not sufficiently supported by data.
1040000	Honey and other apiculture products[(b)]	0.05*	0.08	The submitted data are sufficient to derive an MRL proposal for honey which sufficiently reflects the uses of metazachlor authorised in the EU. Risk for consumers is unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): According to Regulation (EC) No 396/2005 MRLs are not applicable to other apiculture products until individual products have been identified and listed within this group.

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for metazachlor in leeks and honey. A detailed description of the intended uses of metazachlor, which are the basis for the current MRL application, is reported in Appendix A.

Metazachlor is the ISO common name for 2-chloro-2′,6′-dimethyl-*N*-(1*H*-pyrazol-1-ylmethyl) acetanilide (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Metazachlor was evaluated in the framework of Directive 91/414/EEC[1] with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on winter and spring oilseed rape and ornamentals for the control of annual grasses and broad-leaved weeds. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2008). Metazachlor was approved[2] on 1 August 2009 for the use as a herbicide. According to the approval Regulation only uses as herbicide may be authorised. Applications shall be limited to a total dose of not more than 1 kg metazachlor/ha in a three-year period on the same field.

The EU MRLs for metazachlor are established in Annexes II of Regulation (EC) No 396/2005[3]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2014) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for metazachlor. The proposals from these reasoned opinions have been considered in recent MRL regulations.[4]

In accordance with Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381[5], the applicant BASF SE submitted on 11 September 2021 an application to the competent national authority in the Netherlands, alongside the dossier containing the supporting data using the IUCLID format.

EFSA has based its assessment on the evaluation report submitted by the EMS (Netherlands, 2023), the DAR and its final addendum prepared under Directive 91/414/EEC (United Kingdom, 2005, 2007), the Commission review report on metazachlor (European Commission, 2019), the conclusions on the peer review of the pesticide risk assessment of the active substance metazachlor and in relation with the confirmatory data requested under the EU pesticides peer review (EFSA, 2008, 2017) as well as the conclusions from the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2014) and previous EFSA opinions on metazachlor (EFSA, 2017, 2018a, 2019a).

For this application, the data requirements established in Regulation (EU) No 544/2011[6] and the guidance documents applicable at the date of submission of the IUCLID application are applicable (European Commission, 1997a,b,c,d,e,f,g, 2010, 2017, 2018, 2020, 2021; OECD, 2011). 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 546/2011[7].

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, is presented in Appendix B.

[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

[2] Commission Directive 2008/116/EC of 15 December 2008 amending Council Directive 91/414/EEC to include aclonifen, imidacloprid and metazachlor as active substances. No longer in force, Date of end of validity: 13/6/2011. OJ L 337, 16.12.2008, p. 86–91.

[3] 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, 16.3.2005, p. 1–16.

[4] For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as

[5] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

[6] Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

[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.

The evaluation report submitted by the EMS (Netherlands, 2023) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.[8]

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of metazachlor in primary crops belonging to the group of leafy vegetables (cabbages), pulses/oilseeds (rapeseeds) and cereals (maize) was investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2008, 2014).

The metabolic pathway was similar in all crop groups investigated: metazachlor undergoes rapid degradation to several metabolites, the predominant ones being 479 M04, 479 M08 and 479 M16. For the intended use on leeks, EFSA concludes that the metabolic behaviour of metazachlor in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Studies on the nature and magnitude of metazachlor residues in rotational crops were assessed in the framework of the peer review (EFSA, 2008). It was concluded that the residue definitions set for primary crops are also applicable to rotational crops and significant residue levels are unlikely to occur in rotational crops, provided that the substance is used respecting the restriction of Regulation (EU) No 540/2011 to use maximum 1 kg/ha every third year on the same field.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of metazachlor residues was investigated in the framework of the peer review (EFSA, 2008). The standard hydrolysis studies were conducted with the metabolite 479 M16 and it was concluded that the compound is hydrolytically stable under the standard representative conditions of pasteurisation, boiling/brewing/baking and sterilisation. Considering the low expected exposure resulting from the use of metazachlor, the MRL review concluded that investigation of the effect of processing on the metabolites 479 M04 and 479 M08 is desirable but not essential (EFSA, 2014).

The previously derived conclusions are still valid for the current assessment. Considering that the exposure situation did not significantly change, the standard hydrolysis studies with the metabolites 479 M04 and 479 M08 are waived.

1.1.4. Analytical methods for enforcement purposes in plant commodities

Analytical methods for the determination of residues of metazachlor metabolites 479 M04, 479 M08 and 479 M16 in plant commodities were assessed in the context of EU pesticides peer review and confirmatory data following Art. 12 review (EFSA, 2008, 2019a). The HPLC–MS/MS method and its independent laboratory validation (ILV) is sufficiently validated for the determination of the residues of the individual metabolites 479 M04, 479 M08 and 479 M16 in high-water content, high-oil content and high-acidic content commodities. The method allows quantifying residues at or above the LOQ of 0.02 mg/kg for individual analytes.

In the framework of the Art. 12 Confirmatory data application, another sufficiently validated HPLC–MS/MS method was evaluated. This method allows quantification of individual metabolites 479 M04, 479 M08 and 479 M16 in high-water content, high-oil content and high-acidic content commodities, and also in dry matrices at the LOQ of 0.01 mg/kg for each analyte (EFSA, 2019a).

EFSA notes that a study investigating the extraction efficiency of the analytical methods applied for enforcement is provided but was not considered sufficient as indicated according to the requirements of the extraction efficiency Guidance, SANTE 2017/10632 (European Commission, 2017) and the lack of these data introduces additional uncertainty of the present assessment.

[8] Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00586

To satisfy the current criteria of the guidance further investigation on this matter would be required. EFSA would therefore recommend re-assessing the extraction efficiency in the framework of the peer review for the renewal of approval of the active substance.

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

1.1.5. Storage stability of residues in plants

The storage stability of metazachlor and metabolites (M479H04, M479H08 and M479H16) residues in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2008) and MRL review (EFSA, 2014). The storage stability of metazachlor was demonstrated for a period of 24 months at −18°C in high -water content (cabbages, maize forage), high-oil content (rapeseeds) and dry commodities (maize grain).

Under the Article 12 Confirmatory data application, storage stability data on M479H04, M479H08 and M479H16 metabolites were submitted, demonstrating the freezer storage stability of residues for up to 24 months at −20°C in high-water content commodities (cabbages and lettuces).

EFSA concludes that sufficiently validated storage stability studies are available to support the use of metazachlor in leeks (high-water content commodities).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies and the results of hydrolysis studies, the following residue definitions were proposed in the peer review and the MRL review (EFSA, 2008, 2014):

- Residue definition for enforcement: Sum of metabolites 479 M04, 479 M08 and 479 M16, expressed as metazachlor.

It is noted that the above residue definition for enforcement (proposed by the peer review) has been implemented in Regulation (EC) No 396/2005.

- Residue definition for risk assessment: Sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor ('total residues').

The residue definitions apply to primary crops, rotational crops and processed products (EFSA, 2008, 2014).

Taking into account the proposed use assessed in this application, EFSA concluded that these residue definitions are appropriate and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of this MRL application, the applicant submitted the results of 11 independent and GAP-compliant residue trials on leeks (six in the NEU and five in the SEU).

The SEU trials were performed in France, Spain and Italy over two seasons (2016 and 2019) and two of them were designed as decline trials. In the five 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 sampling was performed from the treated and the untreated plots at day 0, 22–28 (corresponding to the intended pre-harvest interval, PHI), −32 and 47–52 days after the application. Results indicate that metazachlor and its metabolites (479 M04, 479 M08 and 479 M16) slowly declined in leeks over time.

The samples of the described residue trials were stored under conditions for which the integrity of the samples has been demonstrated. All samples were analysed for 479 M04, 479 M08 and 479 M16, according to the residue definition for enforcement; 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.

The method used for the analysis of residues of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety (L0317/01) is based on gas chromatography with tandem mass spectrometry (GC–MS/MS) and enables quantification of residues at or above the LOQ of 0.05 mg/kg. Whereas the method used for the analysis of residues of metazachlor metabolites (479 M04, 479 M08 and

479 M16) (L0316/01) is based on HPLC–MS/MS and enables quantification of residues at or above the LOQ of 0.01 mg/kg for each analyte in the commodity assessed. According to the assessment of the EMS, the methods used to analyse the reside trial samples were sufficiently validated and fit for purpose (Netherlands, 2023).

EFSA notes that the evaluation of the extraction efficiency of the analytical method L0317/01 applied for residue trials is considered not required. Metazachlor and its metabolites are determined using a common moiety method without a previous separate extraction step, and according to the extraction efficiency Guidance, SANTE 2017/10632 (European Commission, 2017) in these cases an evaluation of the extraction efficiency is not needed.

However, it is to be noted that the extraction efficiency of the method L0316/01 applied for residue trials and used for the determination of the residues of individual metabolites 479 M04, 479 M08 and 479 M16 according to the RD-Mo (residue definition for monitoring) is considered not sufficient as indicated according to the requirements of the extraction efficiency Guidance, SANTE 2017/10632 and the lack of these data introduces additional uncertainty of the present assessment (See Section 1.1.4).

The residue levels in leeks ranged between 0.083 and 0.13 mg/kg according to the residue definition for enforcement and from 0.096 to 0.21 mg/kg according to the residue definition for risk assessment.

In addition, the applicant submitted six independent and GAP compliant NEU trials, which is insufficient to support the northern GAP (leek being a major crop in NEU). Furthermore, decline trials are not available and it is to be noted that the EMS reported deficiencies related to the analytical methods used to analyse some of the samples of those trials.

Nevertheless, in the six available trials, the residue levels in leeks ranged between < 0.03 and 0.05 mg/kg according to the residue definition for enforcement (from < 0.05 to 0.08 mg/kg according to the residue definition for risk assessment), which is much lower than the residues found in the SEU trials (see above). Also considering that a PHI of 56 days is defined for the NEU GAP while a PHI of 28 days is defined for the SEU GAP, there are indications that the SEU GAP is more critical than the NEU GAP. Therefore, the EMS did not consider additional trials for NEU are needed.

Overall, the five submitted trials are sufficient to derive an MRL proposal of 0.3 mg/kg for leeks based on the southern dataset (leek being a minor crop in SEU). The residue data from the supervised residue trials in primary crops are summarised in Appendix B.1.2.1.

1.2.2. Magnitude of residues in rotational crops

The possible transfer of metazachlor residues to crops that are grown in crop rotation has been assessed in EU pesticides peer review (EFSA, 2008). The available studies on the nature and magnitude of metazachlor residues in rotational crops demonstrated 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 kg/ha (EFSA, 2008).

Since according to the proposed GAPs on leeks in this MRL application, the annual application rate is limited to a maximum of 500 g a.s./ha in case of the proposed SEU use and 750 g a.s./ha in case of the proposed NEU use, 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.

1.2.3. Magnitude of residues in processed commodities

Specific studies to assess the magnitude of metazachlor and its metabolites residues in processed commodities were not submitted and are not required according to Regulation (EC) No 544/2011, considering that the contribution of residues in the commodities under consideration to the overall dietary exposure is individually below 10% of the ADI for any European consumer group diet (European Commission, 1997d).

1.2.4. Proposed MRLs

The available southern data are considered sufficient to derive an MRL proposal of 0.3 mg/kg based on the southern GAP (PHI 28 days) as well as risk assessment values for leeks (see Appendix B.1.2.1). In Section 4 EFSA assessed whether residues on this commodity resulting from the intended use are likely to pose a consumer health risk.

2. Residues in livestock

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

3. Residues in honey

3.1. Nature of residues in honey

Honey is produced by bees from sugary secretions of plants (floral nectar mainly) through regurgitation, enzymatic conversion and water evaporation and followed by storage in the bee hives for a certain time period.

In the absence of specific metabolism studies with honey bees, studies investigating the nature of residues in primary crops and rotational crops and studies investigating the degradation during pasteurisation should be considered to determine the nature of residues in honey (European Commission, 2018). It is likely that the nature of residues in pollen and nectar collected from primary and rotational crops, as well as in honey (resulting from the residues in floral nectar), is the same as in primary and rotational crops.

Considering that sufficient data investigating the metabolic profile in primary and rotational crops and the degradation of the active substance under standard hydrolysis conditions are available, no further information is required for the current application according to the guidelines. However, it would be desirable to further investigate whether enzymatic processes involved in the production of honey occurring in the bee gut or during the storage in the beehive have an impact on the nature of residues in honey.

3.1.1. Analytical methods for enforcement in honey

In the framework of the present assessment, the applicant submitted a new method for enforcement of metazachlor residues in honey (Netherlands, 2023). The LC–MS/MS based method is capable to measure metazachlor and the metabolites 479 M04, 479 M08 and 479 M16 in the honey matrix. The LOQ of the method is 0.01 mg/kg for each individual analyte. The confirmatory method and ILV were provided as required (Netherlands, 2023). In conclusion, a sufficiently validated analytical method is available to enforce the proposed MRL of metazachlor in honey and is applicable to be used as a pre-registration well as post-registration method.

Information on the extraction efficiency of the analytical methods applied for enforcement of residues in honey is not available. However, since the existing guidance document on extraction efficiency (European Commission, 2017) cannot be applied for the honey matrix and since no other guidance on how to investigate extraction efficiency in honey is available, demonstration of extraction efficiency in honey matrix is not required for the present assessment.

3.1.2. Storage stability of residues in honey

No new storage stability data of residues of metazachlor and its metabolites in honey or flower parts were submitted in the framework of this application.

Samples of these residue trials were stored for a maximum storage interval of 136 days at −18°C prior to analyses. It is noted that inflorescence samples were stored for a period exceeding 30 days. However, considering that inflorescences are a high-water commodity matrix, for which storage stability is demonstrated, it is concluded that the residue data are valid with regard to storage stability.

3.1.3. Proposed residue definitions

In the absence of specific metabolism studies on honey, the studies investigating the nature of residues in primary and rotational crops and studies investigating the degradation of the active substance during pasteurisation are considered to derive the residue definitions for honey; the same residue definitions as mentioned for plant commodities are therefore proposed.

3.2. Magnitude of residues in honey

In support of the MRL application in honey, the applicant submitted four independent residue trials where metazachlor was applied to oilseed rape under field conditions during the growing season of

2020 in Germany, the Netherlands, Poland and Belgium. Each trial consisted of two control plots and one treatment plot. The active substance was applied on oilseed rape as one foliar application under field conditions, at BBCH 16 – 18 and a target rate of 750 g a.s./ha. Since two of the metazachlor metabolites 479 M04 and 479 M08 are characterised as having medium to high persistence in soil (DT50s of 175–461 days and 198–568 days respectively, EFSA, 2008), the application performed before the flowering contributes to the residues carry-over from the plant to honey.

The application rate tested in the residue trials is compliant with the critical GAP selected by the Applicant (GAP: 1 × 750 mg/kg). EFSA considered this GAP as sufficiently representative of the worst-case GAP with respect to residues in honey.

The residue data were measured in inflorescences samples collected 18–29 days after the application at full flowering BBCH 65 and were taken on the whole sample (no single blossoms were collected). The minimum reported weight sample was at least 100 g. The samples of the residue trials were stored under conditions for which integrity of the samples has been demonstrated (Netherlands, 2023).

Residue levels of metazachlor and its metabolites M479H04, M479H08 and M479H16 were measured in inflorescences samples according to the same analytical methods (L0316/01 and L0317/01) as previously described for leeks. Therefore, considered valid (Netherlands, 2023). Information on extraction the efficiency of the analytical method used for data generation from honey samples is not available. However, since the existing guidance document on extraction efficiency (European Commission, 2017) cannot be applied for the honey matrix and since no other guidance on how to investigate extraction efficiency in honey is available, demonstration of extraction efficiency in honey matrix is not required for the present assessment.

The residue levels in inflorescences samples ranged between 0.045 and 0.076 mg/kg according to the residue definition for enforcement and from 0.089 to 1.0 mg/kg according to the residue definition for risk assessment. No residues of metazachlor and its metabolites were found at or above the LOQ in inflorescences samples collected from untreated plots.

As the highest residue level in aerial parts of plants is above the threshold value of 0.05 mg/kg but below 0.5 mg/kg, an MRL proposal for honey can be made based on the highest residue (HR) and on the hypothesis of a transfer factor of 1 from aerial parts following the decision-making scheme for MRL-setting in honey (European Commission, 2018).

3.2.1. Proposed MRLs

The available data are considered sufficient to derive an MRL proposal of 0.08 mg/kg as well as risk assessment values for honey (see Appendix B.3.2.1). In Section 4, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

It should be noted that currently, MRLs set for honey are not applicable to other apicultural products following Commission Regulation (EU) 2018/62[9].

4. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018b, 2019b). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for metazachlor used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (European Commission, 2019). The metabolites included in the risk assessment residue definition were considered to be of comparable toxicity to the parent compound.

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for the commodities assessed in this application in accordance with the internationally agreed methodology (FAO, 2016). The calculations were based on the HR (expressed according to the residue definition for risk assessment) derived from supervised field trials and the complete list of input values can be found in Appendix D.1. The short-term exposure did not exceed the ARfD for any of the commodities assessed in this application.

[9] Commission Regulation (EU) 2018/62 of 17 January 2018 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council. C/2018/0138. OJ L 18, 23.1.2018, p. 1–73.

Long-term (chronic) dietary risk assessment

In the framework of the MRL review a comprehensive long-term exposure assessment was performed, taking into account the existing uses at the EU level (EFSA, 2014). EFSA updated the calculation with the relevant STMR values derived from the residue trials submitted in support of this MRL application for leeks and honey; in addition, STMRs derived in the two EFSA opinions published after the MRL review on modification of the existing MRLs in Chinese cabbage (EFSA, 2018a) and on the evaluation of confirmatory data following the Article 12 MRL review and modification of the existing MRLs in various commodities (EFSA, 2019a). The crops on which no uses were reported in those outputs were excluded from the exposure calculation. The input values used in the exposure calculations are summarised in Appendix D.1.

The highest estimated long-term dietary intake accounted for 1% of the ADI (NL toddler diet). The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix B.4. EFSA concluded that the long-term intake of residues of metazachlor resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

5. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for leeks and honey. For leeks, the MRL proposal is derived from the SEU GAP (fully supported by data) while the NEU GAP is not fully supported by the data.

EFSA concluded that the proposed use of metazachlor on leeks and the potential carry-over of residues to honey following the selected critical GAP will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.5.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
EC	emulsifiable concentrate
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice

GC–MS/MS	gas chromatography with tandem mass spectrometry
HPLC–MS/MS	high performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern Europe
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SC	suspension concentrate
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Crop and/or situation	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. (g/kg)	Method kind	Range of growth stages and season[c]	Number min-max	Interval between application (days) min-max	g a.s./hL min–max	Water (L/ha) min–max	Rate min-max	Unit		
Leeks	NEU	F	Annual monocotyl and dicotyl weeds	SC	500	Foliar spray	12 – 18	1	–	1.5	100–400	0.75	kg a.i./ha	56	
Leeks	SEU	F	Annual monocotyl and dicotyl weeds	EC	200	Foliar spray	10–18	1	–	2.5	100–400	0.5	kg a.i./ha	28	

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: suspension concentrate; EC: Emulsifiable Concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(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 pre-harvest interval.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and analytical methods for enforcement purposes in plant commodities

B.1.1.1. Metabolism studies, analytical methods and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling**	**Comment/Source**
	Leafy crops	Cabbages	Foliar, 1 × 1.25 kg/ha, BBCH 14–16	34, 147 DAT	[phenyl-UL-^{14}C]-metazachlor (EFSA, 2008)
	Cereals/grasses	Maize	Foliar, 1 × 1 kg/ha, pre-emergence	78, 118, 146 DALA	
	Pulses/oilseeds	Oilseed rape	Foliar, 1 × 1.25 kg/ha, BBCH 14–16	22, 71 DAT	
			Soil, 1 × 1.25 kg/ha	215, 293 DAT	
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Radishes	Soil application, 1 × 1.25 kg/ha	30, 120, 366	[phenyl-UL-^{14}C]-metazachlor (EFSA, 2008)
		Carrots	Soil application, 1 × 0.75 kg/ha	30	
	Leafy crops	Lettuces	Soil application, 1 × 1.25 kg/ha	30, 120, 366	
		Cabbages	Soil application, 1 × 0.75 kg/ha	30	
		Spinaches	Soil application, 1 × 0.75 kg/ha	30	
	Cereal (small grain)	Wheat	Soil application, 1 × 1.25 kg/ha	30, 120, 366	
			Soil application, 1 × 0.75 kg/ha	30	
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		479 M16	Yes	[phenyl-UL-^{14}C]-479 M16 (EFSA, 2008)
	Baking/brewing/boiling (60 min, 100°C, pH 5)		479 M16	Yes	
	Sterilisation (20 min, 120°C, pH 6)		479 M16	Yes	
	Parent metazachlor, 479H04 and 479H08: not investigated (not essential) (EFSA, 2014)				

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2008)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2008)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2014)
Plant residue definition for monitoring (RD-Mo)	Metazachlor (Sum of metabolites 479M04, 479M08 and 479M16, expressed as metazachlor)	
Plant residue definition for risk assessment (RD-RA)	Sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Matrices with high water content, high oil content, high acid content: Metabolite: 479M04, 479M08 and 479M16 HPLC-MS/MS, LOQ 0.02 mg/kg (per analyte) Confirmatory method and ILV available (EFSA, 2008) Matrices with high water content (head cabbages), high oil content (rape seed), high acid content (lemon), and dry matrices (wheat grain) Metabolite: 479M04, 479M08 and 479M16 HPLC-MS/MS, LOQ 0.01 mg/kg (per analyte) ILV available (EFSA, 2019a)	

DAT: days after treatment; PBI: plant-back interval; a.s.: active substance; MRL: maximum residue level; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/Source
				Value	Unit		
	High-water content	Cabbages, maize forage	−18	24	Months	Total residues[(a)]	EFSA (2014)
		Rapeseeds forage	−18	13	Months	479 M16	EFSA (2014)
		Cabbages	−20	24	Months	479 M16	EFSA (2019a)
		Lettuces	−20	24	Months	479 M04	EFSA (2019a)
		Lettuces	−20	24	Months	479 M08	EFSA (2019a)
	High-oil content	Rapeseeds	−18	24	Months	Total residues[(a)]	EFSA (2014)
		Rapeseeds	−18	13	Months	479 M16	EFSA (2014)
	Dry/High starch	Maize grain	−18	24	Months	Total residues[(a)]	EFSA (2014)

(a): Parent and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor.

B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

Commodity	Region[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Leeks	SEU	**Mo:** 0.083; 0.091; 0.092; 0.102; 0.13 **RA:** 0.096; 0.14; 0.15, 0.17; 0.21	Residue trials on leeks compliant with a new intended GAP.	**0.3**	**Mo:** 0.13 **RA:** 0.21	**Mo:** 0.09 **RA:** 0.15	
Leeks	NEU	**Mo:** < 0.03, 3 × 0.03; 0.04; 0.05 **RA:** 4 × < 0.05; 0.053; 0.08	Residue trials on leeks compliant with a new intended GAP. Number of trials is not sufficient to derive an MRL proposal and risk assessment values.	–	–	–	

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Yes	A potential transfer of soil residues to rotational crops has been identified (EFSA, 2008)
Residues in rotational and succeeding crops expected based on field rotational crop study?	Risk mitigation measures	Residues are not expected to be present in rotational crops, provided that the active substance is applied respecting the restrictions laid down in Regulation (EU) No 540/2011 (maximum use of 1 kg/ha every third year).

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Not relevant

B.3. Residues in honey

B.3.1. Nature of residues and analytical methods for enforcement purposes in honey

B.3.1.1. Metabolism studies, analytical methods and residue definitions in honey

Metabolism studies in honey	Metabolism studies in honey are not available. The nature of the residues in honey is based on the major components of the residue detected in primary crops, rotational crops and processed commodities.
Honey residue definition for monitoring (RD-Mo)	Metazachlor (Sum of metabolites 479M04, 479M08 and 479M16, expressed as metazachlor)
Honey residue definition for risk assessment (RD-RA)	Sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Honey matrix Parent and metabolites: 479M04, 479M08 and 479M16 LC-MS/MS, LOQ 0.010 mg/kg (per analyte) Confirmatory method and ILV available (Netherlands, 2023)

LC-MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.3.1.2. Storage stability of residues in honey

New studies were not submitted and were not requested.

B.3.2. Magnitude of residues in honey

B.3.2.1. Summary of residues data from the supervised residue trials

Commodity	Region[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CF[d]
Rapeseeds inflorescences	NEU/SEU	**Mo:** 0.045; 0.048; 0.060; 0.076 **RA:** 0.09; 0.10; 0.82; 1.0	Data are available for the aerial parts of oilseed rape samples during flowering (GAP: 1 × 750 mg/kg). As the highest residue level in aerial parts of plants is above the threshold value of 0.05 mg/kg but below 0.5 mg/kg, an MRL proposal for honey is based on the HR and on the hypothesis of a transfer factor of 1 from aerial parts (European Commission, 2018). The number of trials is sufficient to derive an MRL in honey.	**0.08**	**Mo:** 0.076 **RA:** 1.0	**Mo:** 0.05 **RA:** 0.460	–

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

B.4. Consumer risk assessment

ARfD	0.5 mg/kg bw (European Commission, 2019)
Highest IESTI, according to EFSA PRIMo	Leeks: 2.5% of ARfD (children) Honey and other apiculture products: 0.7% of ARfD (children)
Assumptions made for the calculations	Calculations performed with PRIMo revision 3.1. The calculation is based on the highest residue levels (HR values expressed according to the residue definition for risk assessment) expected in raw agricultural commodities under assessment.

ADI	0.08 mg/kg bw per day (European Commission, 2019)
Highest IEDI, according to EFSA PRIMo	1% ADI (NL toddler diet) Contribution of crops assessed: Leeks: 0.05% of ADI (GEMS/Food G11 diet) Honey and other apiculture products: 0.06% of ADI (DE child diet)
Assumptions made for the calculations	Calculations performed with PRIMo revision 3.1. The calculation is based on the median residue levels (STMR values expressed according to the residue definition for risk assessment) derived for the intended use on leek and STMR value derived from residue trials in oilseed rape.

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; HR: highest residue from the supervised trials; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; STMR: supervised trials median residue.

B.5. Recommended MRLs

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Metazachlor (Sum of metabolites 479 M04, 479 M08 and 479 M16, expressed as metazachlor)				
0270060	Leeks	0.06*	0.3	The submitted data are sufficient to derive an MRL proposal for the SEU use. Risk for consumers is unlikely. The intended NEU use is not sufficiently supported by data.
1040000	Honey and other apiculture products[(b)]	0.05*	0.08	The submitted data are sufficient to derive an MRL proposal for honey which sufficiently reflects the uses of metazachlor authorised in the EU. Risk for consumers is unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): According to Regulation (EC) No 396/2005 MRLs are not applicable to other apiculture products until individual products have been identified and listed within this group.

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Metazachlor			
LOQs (mg/kg) range from:	0.01	to:	0.10
Toxicological reference values			
ADI (mg/kg bw per day):	0.08	ARfD (mg/kg bw):	0.5
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2019	Year of evaluation:	2019

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk | Details – acute risk

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	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	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
1%	NL toddler	0.94	0.7%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Rapeseeds/canola seeds		1%
0.8%	UK infant	0.64	0.5%	Milk: Cattle	0.1%	Eggs: Chicken	0.1%	Bovine: Muscle/meat		0.8%
0.8%	FR toddler 2 3 yr	0.61	0.4%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Swine: Muscle/meat		0.8%
0.8%	FR child 3 15 yr	0.61	0.3%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Swine: Muscle/meat		0.8%
0.7%	SE general	0.53	0.3%	Bovine: Muscle/meat	0.2%	Milk: Cattle	0.1%	Eggs: Chicken		0.7%
0.6%	NL child	0.52	0.3%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat		0.6%
0.5%	DE child	0.42	0.2%	Milk: Cattle	0.1%	Eggs: Chicken	0.1%	Honey and other apiculture products		0.5%
0.5%	GEMS/Food G07	0.42	0.1%	Milk: Cattle	0.1%	Poultry: Muscle/meat	0.1%	Swine: Muscle/meat		0.5%
0.5%	GEMS/Food G08	0.42	0.1%	Swine: Muscle/meat	0.1%	Turnips	0.1%	Milk: Cattle		0.5%
0.5%	GEMS/Food G15	0.41	0.1%	Swine: Muscle/meat	0.1%	Milk: Cattle	0.1%	Poultry: Muscle/meat		0.5%
0.5%	ES child	0.41	0.2%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Poultry: Muscle/meat		0.5%
0.5%	DK child	0.40	0.2%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Bovine: Muscle/meat		0.5%
0.5%	UK toddler	0.40	0.3%	Milk: Cattle	0.1%	Bovine: Muscle/meat	0.1%	Eggs: Chicken		0.5%
0.5%	RO general	0.38	0.1%	Milk: Cattle	0.1%	Head cabbages	0.1%	Swine: Muscle/meat		0.5%
0.4%	IE adult	0.35	0.1%	Swedes/rutabagas	0.1%	Milk: Cattle	0.0%	Sheep: Liver		0.4%
0.4%	GEMS/Food G10	0.34	0.1%	Poultry: Muscle/meat	0.1%	Milk: Cattle	0.1%	Bovine: Muscle/meat		0.4%
0.4%	GEMS/Food G11	0.34	0.1%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.1%	Poultry: Muscle/meat		0.4%
0.4%	FR infant	0.34	0.2%	Milk: Cattle	0.1%	Turnips	0.0%	Leeks		0.4%
0.4%	NL general	0.29	0.1%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		0.4%
0.4%	DE general	0.29	0.2%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		0.4%
0.3%	DE women 14-50 yr	0.28	0.2%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		0.3%
0.3%	FR adult	0.23	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		0.3%
0.3%	ES adult	0.22	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat	0.0%	Swine: Muscle/meat		0.3%
0.2%	DK adult	0.19	0.1%	Milk: Cattle	0.1%	Swine: Muscle/meat	0.0%	Bovine: Muscle/meat		0.2%
0.2%	LT adult	0.17	0.1%	Swine: Muscle/meat	0.0%	Milk: Cattle	0.0%	Head cabbages		0.2%
0.2%	GEMS/Food G06	0.17	0.0%	Poultry: Muscle/meat	0.0%	Milk: Cattle	0.0%	Turnips		0.2%
0.2%	UK adult	0.13	0.0%	Bovine: Muscle/meat	0.0%	Milk: Cattle	0.0%	Poultry: Muscle/meat		0.2%
0.1%	IE child	0.09	0.0%	Milk: Cattle	0.0%	Swine: Muscle/meat	0.0%	Eggs: Chicken		0.1%
0.1%	UK vegetarian	0.08	0.0%	Milk: Cattle	0.0%	Eggs: Chicken	0.0%	Cauliflowers		0.1%
0.0%	FI 3 yr	0.04	0.0%	Swedes/rutabagas	0.0%	Leeks	0.0%	Honey and other apiculture products		0.0%
0.0%	PL general	0.03	0.0%	Head cabbages	0.0%	Leeks	0.0%	Cauliflowers		0.0%
0.0%	FI 6 yr	0.03	0.0%	Swedes/rutabagas	0.0%	Chinese cabbages/pe-tsai	0.0%	Head cabbages		0.0%
0.0%	PT general	0.03	0.0%	Sunflower seeds	0.0%	Kales	0.0%	Turnips		0.0%
0.0%	FI adult	0.02	0.0%	Swedes/rutabagas	0.0%	Head cabbages	0.0%	Chinese cabbages/pe-tsai		0.0%
0.0%	IT adult	0.01	0.0%	Cauliflowers	0.0%	Globe artichokes	0.0%	Other leafy brassica		0.0%
0.0%	IT toddler	0.01	0.0%	Cauliflowers	0.0%	Turnips	0.0%	Other leafy brassica		0.0%

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Metazachlor is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Swedes/rutabagas	0.9/0.45	23
3%	Head cabbages	0.4/0.38	17
3%	Turnips	0.9/0.45	16
2%	Kohlrabies	0.3/0.24	12
2%	Leeks	0.3/0.21	12
2%	Cauliflowers	0.06/0.21	12
2%	Broccoli	0.06/0.21	8.7
2%	Chinese cabbages/pe-tsai	0.6/0.25	8.0
1%	Kales	0.15/0.14	6.2
0.7%	Honey and other apiculture	0.08/1	3.6
0.5%	Bovine: Liver	0.4/0.34	2.7
0.2%	Milk: Cattle	0.01/0.01	1.2
0.2%	Globe artichokes	0.06/0.05	0.88
0.2%	Poultry: Muscle/meat	0.05/0.05	0.85
0.1%	Eggs: Chicken	0.05/0.05	0.62

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
3%	Head cabbages	0.4/0.38	16
3%	Swedes/rutabagas	0.9/0.45	15
1%	Chinese cabbages/pe-tsai	0.6/0.25	6.3
1%	Turnips	0.9/0.45	5.0
1%	Broccoli	0.06/0.21	5.0
1.0%	Cauliflowers	0.06/0.21	4.9
0.7%	Kohlrabies	0.3/0.24	3.4
0.7%	Horseradishes	0.9/0.45	3.3
0.6%	Leeks	0.3/0.21	2.8
0.5%	Kales	0.15/0.14	2.7
0.3%	Honey and other apiculture	0.08/1	1.4
0.3%	Bovine: Liver	0.4/0.34	1.4
0.1%	Sheep: Liver	0.3/0.26	0.73
0.1%	Globe artichokes	0.06/0.05	0.65
0.1%	Poultry: Muscle	0.05/0.05	0.59

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Turnips/boiled	0.9/0.45	23
3%	Broccoli/boiled	0.06/0.21	17
3%	Cauliflowers/boiled	0.06/0.21	15
2%	Leeks/boiled	0.3/0.21	12
0.8%	Kales/boiled	0.15/0.14	3.9
0.1%	Brussels sprouts/boiled	0.06/0.05	0.51
0.1%	Head cabbages/canned	0.4/0.05	0.29
0.0%	Sunflower seeds/oils	0.06/0.1	0.12
0.0%	Rapeseeds/oils	0.06/0.1	0.03

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Cauliflowers/boiled	0.06/0.21	8.7
2%	Turnips/boiled	0.9/0.45	8.6
1%	Kohlrabies/boiled	0.3/0.24	5.1
1%	Broccoli/boiled	0.06/0.21	5.1
0.7%	Leeks/boiled	0.3/0.21	3.7
0.09%	Head cabbages/canned	0.4/0.05	0.47

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Metazachlor is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Risk assessment residue definition: Sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor						
Horseradishes	0.9	EFSA (2019a)	0.26	STMR-RAC	0.45	HR-RAC
Swedes/rutabagas	0.9	EFSA (2019a)	0.26	STMR-RAC	0.45	HR-RAC
Turnips	0.9	EFSA (2019a)	0.26	STMR-RAC	0.45	HR-RAC
Garlic	0.06	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Broccoli	0.06	EFSA (2019a)	0.05	STMR-RAC	0.21	HR-RAC
Cauliflowers	0.06	EFSA (2019a)	0.05	STMR-RAC	0.21	HR-RAC
Other flowering brassica	0.06	EFSA (2019a)	0.05	STMR-RAC		
Brussels sprouts	0.06	EFSA (2019a)	0.05	STMR-RAC	0.05	HR-RAC
Head cabbages	0.4	EFSA (2019a)	0.05	STMR-RAC	0.38	HR-RAC
Chinese cabbages/pe-tsai	0.6	EFSA (2018a)	0.135	STMR-RAC	0.25	HR-RAC
Kales	0.15	EFSA (2019a)	0.06	STMR-RAC	0.14	HR-RAC
Other leafy brassica	0.2	EFSA (2014)	0.05	STMR-RAC		
Kohlrabies	0.3	EFSA (2019a)	0.1	STMR-RAC	0.24	HR-RAC
Globe artichokes	0.06	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Leeks	0.3	MRL proposal	0.15	STMR-RAC	0.21	HR-RAC
Linseeds	0.06	EFSA (2014)	0.05	STMR-RAC	0.05	STMR-RAC
Sunflower seeds	0.06	EFSA (2014)	0.05	STMR-RAC	0.05	STMR-RAC
Rapeseeds/canola seeds	0.06	EFSA (2014)	0.05	STMR-RAC	0.05	STMR-RAC
Mustard seeds	0.06	EFSA (2014)	0.05	STMR-RAC	0.05	STMR-RAC
Borage seeds	0.06	EFSA (2014)	0.05	STMR-RAC	0.05	STMR-RAC
Gold of pleasure seeds	0.06	EFSA (2014)	0.05	STMR-RAC	0.05	STMR-RAC
Swine: Muscle/meat	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Swine: Fat tissue	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Swine: Liver	0.15	EFSA (2019a)	0.07	STMR-RAC	0.13	HR-RAC
Swine: Kidney	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Swine: Edible offals (other than liver and kidney)	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Swine: Other products	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Bovine: Muscle/meat	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Bovine: Fat tissue	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Bovine: Liver	0.4	EFSA (2019a)	0.14	STMR-RAC	0.34	HR-RAC
Bovine: Kidney	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Bovine: Edible offals (other than liver and kidney)	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Bovine: Other products	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Sheep: Muscle/meat	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Sheep: Fat tissue	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Sheep: Liver	0.3	EFSA (2019a)	0.11	STMR-RAC	0.26	HR-RAC
Sheep: Kidney	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment[(b)]
Sheep: Edible offals (other than liver and kidney)	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Sheep: other products	0.05	EFSA (2014)	0.05	STMR-RAC		
Goat: Muscle/meat	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Goat: Fat tissue	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Goat: Liver	0.3	EFSA (2019a)	0.11	STMR-RAC	0.26	HR-RAC
Goat: Kidney	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Goat: Edible offals (other than liver and kidney)	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Goat: other products	0.05	EFSA (2014)	0.05	STMR-RAC		
Equine: Muscle/meat	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Equine: Fat tissue	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Equine: Liver	0.3	EFSA (2019a)	0.4	STMR-RAC	0.4	HR-RAC
Equine: Kidney	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Equine: Edible offals (other than liver and kidney)	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Equine: Other products	0.05	EFSA (2014)	0.05	STMR-RAC		
Poultry: Muscle/meat	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Poultry: Fat tissue	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Poultry: Liver	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Poultry: Kidney	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Poultry: Edible offals (other than liver and kidney)	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Poultry: Other products	0.05	EFSA (2014)	0.05	STMR-RAC		
Other farmed animals: Muscle/meat	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Other farmed animals: Fat tissue	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Other farmed animals: Liver	0.3	EFSA (2019a)	0.4	STMR-RAC	0.4	HR-RAC
Other farmed animals: Kidney	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Other farmed animals: Edible offals (other than liver and kidney)	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Other farmed animals: Other products	0.05	EFSA (2014)	0.05	STMR-RAC		
Milk: Cattle	0.01	EFSA (2014)	0.01	STMR-RAC	0.01	STMR-RAC
Milk: Sheep	0.01	EFSA (2014)	0.01	STMR-RAC	0.01	STMR-RAC
Milk: Goat	0.01	EFSA (2014)	0.01	STMR-RAC	0.01	STMR-RAC
Milk: Horse	0.01	EFSA (2014)	0.01	STMR-RAC	0.01	STMR-RAC
Milk: Others	0.01	EFSA (2014)	0.01	STMR-RAC	0.01	STMR-RAC
Eggs: Chicken	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Eggs: Duck	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Eggs: Goose	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC

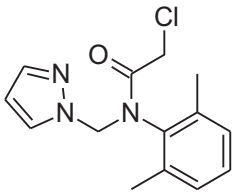
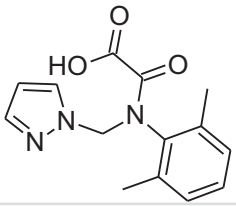
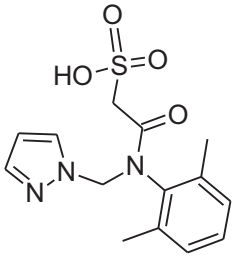
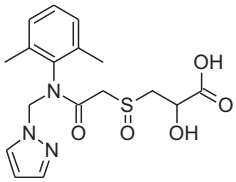
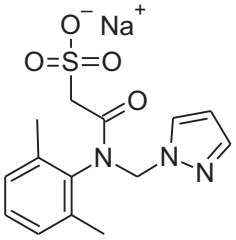
Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[(a)] (mg/kg)	Comment	Input value[(a)] (mg/kg)	Comment[(b)]
Eggs: Quail	0.05	EFSA (2014)	0.05	STMR-RAC	0.05	HR-RAC
Eggs: Others	0.05	EFSA (2014)	0.05	STMR-RAC		
Honey and other apiculture products	0.08	MRL proposal	0.46	STMR-RAC	1	HR-RAC

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor.

(a): Figures in the table are rounded to two digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

(b): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
metazachlor	2-chloro-2′,6′-dimethyl-*N*-(1*H*-pyrazol-1-ylmethyl)acetanilide O=C(CCl)N(Cn1cccn1)c1c(C)cccc1C STEPQTYSZVCJPV-UHFFFAOYSA-N	
479 M04 (M479H004)	{(2,6-dimethylphenyl)[(1*H*-pyrazol-1-yl)methyl]amino}(oxo) acetic acid O=C(N(Cn1cccn1)c1c(C)cccc1C)C(=O)O PHMHHVKFXZNTKU-UHFFFAOYSA-N	
479 M08 (M479H008)	2-[(2,6-dimethylphenyl)(1*H*-pyrazol-1-ylmethyl)amino]-2-oxoethanesulfonic acid O=C(CS(=O)(=O)O)N(Cn1cccn1)c1c(C)cccc1C IPVCSECPEVHQOV-UHFFFAOYSA-N sodium 2-[(2,6-dimethylphenyl)(1*H*-pyrazol-1-ylmethyl)amino]-2-oxoethanesulfonate [Na+].O=C(CS([O-])(=O)=O)N(Cn1cccn1)c1c(C)cccc1C PCVFIVBODVWPQX-UHFFFAOYSA-M	 
479 M16 (M479H016)	3-({2-[(2,6-dimethylphenyl)(1*H*-pyrazol-1-ylmethyl)amino]-2-oxoethyl}sulfinyl)-2-hydroxypropanoic acid O=C(CS(=O)CC(O)C(=O)O)N(Cn1cccn1)c1c(C)cccc1C RTFJGJZKLFURCR-UHFFFAOYSA-N	

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).