Evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for metazachlor in various commodities

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Abstract

The applicant BASF SE submitted a request to the competent national authority in the Netherlands to evaluate the confirmatory data that were identified for active substance metazachlor in the framework of the review of maximum residue levels (MRLs) under Article 12 of Regulation (EC) No 396/2005 as not available. The data gaps identified during the MRL review were satisfactorily addressed for brassica, head cabbages, kales and kohlrabies. The applicant no longer supported the uses on radishes, turnips, horseradishes and swedes assessed during the MRL review. In addition, in accordance with Article 6 of Regulation (EC) No 396/2005, the applicant submitted a request to modify the existing MRLs in turnips, swedes, horseradishes and leeks to reflect intended new uses. Nevertheless, the residue data submitted were not fully compliant with the currently applicable data requirements. For turnips, horseradishes and swedes, the applicant and the Netherlands requested EFSA to present the data and the deficiencies identified to allow risk managers to take an informed decision on the appropriate MRLs. A change of the existing MRLs for liver of swine and ruminants resulting from the authorised and intended uses of metazachlor is also proposed. EFSA updated the most recent consumer risk assessment for metazachlor and concluded that the long-term and short-term dietary intake is unlikely to present a risk to consumer health.

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Summary

In 2014, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for metazachlor according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) eight residue trials on oranges or lemons, supporting the southern outdoor Good Agricultural Practice (GAP) for citrus fruit;
2) four residue trials on apples;
3) four trials on a stone fruit supporting the northern outdoor GAP for tree nuts, pome fruits and stone fruits;
4) four residue trials on strawberries and four residue trials on either grape, currant or another type of berries, supporting the northern outdoor GAP for berries and small fruits;
5) eight residue trials supporting the northern outdoor GAP for potatoes;
6) eight residue trials supporting the southern outdoor GAP for potatoes;
7) four residue trials supporting the northern outdoor GAP for radish;
8) four residue trials supporting the indoor GAP for radish;
9) four residue trials on turnips supporting the northern outdoor GAP for turnips, swedes and horseradish;
10) eight residue trials (four on cauliflower and four on broccoli) supporting the northern outdoor GAP for flowering brassica;
11) eight residue trials (four on cauliflower and four on broccoli) supporting the southern outdoor GAP on flowering brassica;
12) eight residue trials supporting the northern outdoor GAP for head cabbage; four residue trials supporting the southern outdoor GAP for head cabbage;
13) four residue trials on kale supporting the northern outdoor GAP for leafy brassica;
14) four residue trials on kale supporting the southern outdoor GAP on leafy brassica;
15) four residue trials supporting the northern outdoor GAP for kohlrabies;
16) four residue trials supporting the northern outdoor GAP for rocket;
17) four residue trials supporting the northern outdoor GAP for asparagus;
18) four residue trials supporting the northern outdoor GAP for rape forage.

Tentative MRLs for radishes, horseradishes, swedes, turnips, flowering brassica, head cabbages, leafy brassica and kohlrabies have been implemented in the EU legislation by Regulation (EU) No 2015/400, including footnotes related to data gaps number 7, 8, 9, 10, 11, 12, 13, 14 and 15, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 14 March 2017.

For citrus fruits, tree nuts, pome fruits, stone fruits, berries and small fruits, potatoes, rocket and asparagus (data gaps 1, 2, 3, 4, 5, 6, 16 and 17), confirmatory data were not requested since a risk management decision was taken to set the MRL at the limit of quantification (LOQ) value. Data gap number 18 has not been implemented in the MRL legislation, since currently MRLs are not established for rape forage which is used for feed purpose only. For Chinese cabbages (data gaps on leafy brassica group number 13 and 14), the tentative MRL was replaced by a new MRL reflecting a new use in Chinese cabbages which was fully supported by data. Thus, the footnote for the group of leafy brassica and Chinese cabbages was deleted by the Regulation (EU) No 2018/832.

To address the data gaps identified by EFSA, the applicant provided residue trials on flowering brassica (broccoli, cauliflowers), head cabbages, kales and kohlrabies performed according to comparable GAPs. Although no data gaps were identified in the MRL review, the applicant submitted residue trials on Brussels sprouts with samples’ analyses according to the residue definition for enforcement. The applicant did not provide residue trials for the uses assessed during the MRL review on radishes (data gaps number 7 and 8) and on turnips, horseradishes and swedes (data gap number 9).

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, the applicant BASF SE submitted a request to the competent national authority in the Netherlands to evaluate the confirmatory data that were identified for metazachlor in the framework of the MRL review.

Together with the confirmatory data, the applicant submitted an MRL application in accordance with Article 6 of Regulation (EC) No 396/2005, requesting to modify the existing MRLs in turnips,
horseradishes, swedes, leeks, rape seeds and mustard seeds for intended new uses. Additional storage stability data and a new method of analysis to enforce residues of metazachlor were also provided.

The Netherlands assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA. EFSA assessed the application and the evaluation report as required by Article 9 and 10 of the MRL regulation and in accordance with the agreed procedure set out in the working document SANTE/10235/2016.

EFSA identified data gaps or points which needed further clarification for both applications, which were requested from the RMS. On 1 April 2019, the RMS submitted the revised evaluation report (Netherlands, 2018), 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 Netherlands in the framework of these applications, the following conclusions are derived.

The residue definition for enforcement is established in Regulation (EC) No 396/2005. For plant products, it covers the 'sum of the metabolites 479M04, 479M08 and 479M16, expressed as metazachlor'. To facilitate the work for analytical enforcement laboratories and to unambiguously identify these compounds, it would be desirable to include their chemical names in the residue definition, as proposed in the summary table below. Considering the complex metabolic pattern of metazachlor, the residue definition for risk assessment comprises the 'sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor'. EFSA concluded that for the crops assessed in the MRL application, the metabolism of metazachlor in primary and in 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 are available to quantify residues of metazachlor according to the enforcement residue definition in the crops under assessment. The methods, which were assessed during the MRL review, allow quantification of residues at or above 0.02 mg (LOQ) for each individual analyte (479M04, 479M08 and 479M16). The applicant submitted an additional method of analysis to enforce residues at a lower LOQ of 0.01 mg/kg per analyte.

The data gaps identified during the MRL review for further residue trials on flowering brassica, head cabbages, kales and kohlrabies were satisfactorily addressed. Based on the results of the new residue trials, for kales and flowering brassica, the lowering of the existing MRL would be possible whereas for head cabbages and kohlrabies, the existing MRLs are confirmed. Although not requested, the applicant provided two new residue trials compliant with the uses assessed in the MRL review which confirmed that quantifiable residues are not expected in Brussels sprouts. The uses on radishes, turnips, horseradishes and swedes assessed during the MRL review are no longer supported by the applicant.

For the intended new uses on turnips, horseradishes and swedes, the applicant submitted a limited number of residue trials on turnips (three northern and three southern European trials) which is not in compliance with the data requirements laid down in Regulation (EU) No 544/2011 and the guidance document SANCO 7525/VI/95 applicable for the current assessment. The applicant and the Netherlands requested EFSA to present the available data to allow an informed risk management decision on the appropriate MRLs on turnips, swedes and horseradishes, considering that, according to Regulation (EU) No 283/2013 (Part A to the Annex, Section 6.3, Test conditions, 5th paragraph), the number of available residue trials would be sufficient to derive a MRL proposal for a minor crop. The applicant did not provide sufficient residue trials to support the intended use on leeks. EFSA did not assessed the intended uses on rape seeds and mustard seeds, which are less critical for residues than the uses assessed in the MRL review, considering that the RMS did not propose a modification of the existing MRLs for these crops. Storage stability of all analytes from residue trials was demonstrated.

Specific studies investigating the magnitude of residues of metazachlor and its metabolites in processed commodities are not required, considering the low dietary exposure expected. Significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed GAPs respecting the restrictions of the implementing Regulation.

The estimated livestock dietary burdens were recalculated in accordance with the currently used methodology, including the crops under consideration to the total livestock exposure. Risk managers shall consider the possibility to modify the existing MRLs for liver of swine and ruminants.

The toxicological profile of metazachlor was assessed in the framework of the EU pesticides peer review 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.

EFSA updated the most recent consumer risk assessment for metazachlor performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). A long-term consumer intake was not identified
for any of the European diets incorporated in the EFSA PRIMo. The highest chronic intake was calculated to be 1.5% of the ADI. An acute consumer risk was not identified in relation to the MRL proposals.

EFSA concluded that the authorised and intended uses of metazachlor assessed in this reasoned opinion will not result in a consumer exposure exceeding the toxicological reference values and therefore are unlikely to pose a risk to consumers’ health. EFSA proposes to amend the existing MRLs as reported in the summary table below.

| Code(a) | Commodity     | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|---------|---------------|------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 0213040 | Horseradishes | 0.15 (ft 1)            | Risk management decision required 0.06* or 0.9 | The data gap identified for the critical NEU GAP assessed in the MRL review with a PHI of 65 days was not addressed. The data submitted in support of a new intended NEU GAP is not fully compliant with the data requirements. The applicant and the RMS proposed an MRL of 0.9 mg/kg derived by extrapolation from three residue trials on turnips compliant with the new, intended GAP on horseradish in the NEU. A risk management decision is required whether the data set, which is not compliant with the data requirements defined in Regulation (EU) No 544/2011, is deemed sufficient to derive an MRL proposal. See also swedes and turnips. Alternatively, the MRL should be lowered to the limit of quantification (LOQ). Risk for consumers unlikely. |
| 0213080 | Radishes      | 0.4 (ft 1)             | 0.06*                   | The data gap identified for the critical NEU and indoor GAP assessed in the MRL review was not addressed. Thus, the MRL should be lowered to the LOQ. |
| 0213100 | Swedes        | 0.15 (ft 1)            | Risk management decision required 0.06* or 0.9 | The data gap identified for the critical NEU GAP assessed in the MRL review was not addressed. The data submitted in support of a new intended GAP is not fully compliant with the data requirements. The applicant and the RMS proposed to derive an MRL of 0.9 mg/kg by extrapolation from three NEU and three SEU residue trials on turnips compliant with the new, intended outdoor GAP on swedes. A risk management decision is required whether the data set, which is not compliant with the data requirements defined in Regulation (EU) No 544/2011, is deemed sufficient to derive an MRL proposal. According to the RMS for the data requirements in Regulation (EU) No 283/2013, the data would be sufficient. Alternatively, the MRL should be lowered to the limit of quantification (LOQ). Risk for consumers unlikely. |
| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|-------------------------|-----------------------|
| 0213110 | Turnips   | 0.15 (ft 1)            | Risk management decision required 0.06* or 0.9 | The data gap identified for the critical NEU GAP assessed in the MRL review with a PHI of 70 days was not addressed. Although the data submitted in support of a new intended GAP are not fully compliant with the data requirements, the applicant and the RMS proposed to derive an MRL of 0.9 mg/kg from three NEU and three SEU trials compliant with a new, intended outdoor GAP on turnips. A risk management decision is required whether the data set, which is not compliant with the data requirements defined in Regulation (EU) No 544/2011, is deemed sufficient to derive a MRL proposal. According to the RMS for the data requirements in Regulation (EU) No 283/2013, the data would be sufficient. Alternatively, the MRL should be lowered to the limit of quantification (LOQ). Risk for consumers unlikely |
| 0241000 | Flowering brassica | 0.4 (ft 1) | 0.06* | The data gap identified for the NEU and the SEU uses assessed in the MRL review has been addressed. The submitted residue data suggest a lower MRL of 0.06 mg/kg (LOQ). Risk for consumers unlikely |
| 0242010 | Brussels sprouts | 0.06* | No new proposal | Although not requested, the applicant provided two new residue trials compliant with the uses assessed in the MRL review which confirmed that quantifiable residues are not expected in Brussels sprouts. MRL is set at the LOQ of the enforcement method. |
| 0242020 | Head cabbages | 0.4 (ft 1) | 0.4 | The data gap identified for the NEU and the SEU uses assessed in the MRL review has been addressed. Tentative MRL is confirmed. Risk for consumers unlikely |
| 0242320 | Kales | 0.2 (ft 1) | 0.15 | The data gap identified for the NEU use assessed in the MRL review has been addressed. The submitted residue data suggest a lower MRL of 0.15 mg/kg. Risk for consumers unlikely |
| 0244000 | Kohlrabies | 0.3 (ft 1) | 0.3 | An adjusted, more critical GAP was proposed which is sufficiently supported by residue data. The data gap identified for the NEU use assessed in the MRL review has been addressed. Tentative MRL is confirmed. Risk for consumers unlikely |
| 0270060 | Leeks | 0.06* | No new proposal | Submitted residue trials are not sufficient to support the intended NEU use on leeks |

**Enforcement residue definition** (animal products, except honey): Sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor.
| Code<sup>(a)</sup> | Commodity     | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|---------------|---------------|------------------------|------------------------|---------------------------------------------------------------------------------------|
| 1011030       | Swine, liver  | 0.2                    | Risk management decision required | Based on the updated maximum dietary burden calculations and the results of the feeding study on cattle, the lowering of the current MRL could be considered. Two MRL proposals are derived, reflecting the scenario including turnips, swedes and turnip leaves in the dietary burden (scenario 1, see also comments on swedes and turnips, codes 0213100 and 0213110); the second MRL proposal was derived based on existing uses fully supported by data. Risk for consumers unlikely |
| 1012030       | Bovine, liver | 0.3                    | Risk management decision required | Based on the updated maximum dietary burden calculations and the results of the feeding study on cattle, the change of the current MRL could be considered. Two MRL proposals are derived, reflecting the scenario including turnips, swedes and turnip leaves in the dietary burden (scenario 1, see also comments on swedes and turnips, codes 0213100 and 0213110); the second MRL proposal was derived based on existing uses fully supported by data. Risk for consumers unlikely |
| 1013030       | Sheep, liver  | 0.3                    | Risk management decision required | Based on the updated maximum dietary burden calculations and the results of the feeding study on cattle, the existing MRL should be maintained (scenario 1, see also comments on swedes and turnips, codes 0213100 and 0213110). The MRL proposal derived in scenario 2 is based on the existing uses fully supported by data. Risk for consumers unlikely |
| 1014030       | Goat, liver   | 0.3                    | Risk management decision required |                                                                                       |

*: 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): The residue definition implemented in the EU legislation reference only the codes for the three metabolites of metazachlor. To facilitate the work for analytical enforcement laboratories and to unambiguously identify the compounds, it would be desirable to include the chemical names of the metabolites in the residue definition.
(ft 1): The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 14 March 2017, or, if that information is not submitted by that date, the lack of it (Footnote related to data gaps No 7, 8, 9, 10, 11, 12 and 15).
# Evaluation of confirmatory data and modification of MRLs for metazachlor in various crops

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Assessment

The EU MRLs for metazachlor are established in Annex II of Regulation (EC) No 396/2005. The review of existing MRLs for the active substance metazachlor according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed in 2014 (EFSA, 2014). The European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified.

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) No 2015/400, including footnotes for tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 17 March 2017.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2016) the applicant, BASF SE, submitted an application to the competent national authority in the Netherlands (designated rapporteur Member State, RMS) to evaluate the confirmatory data identified during the MRL review. To address the data gaps identified by EFSA, the applicant provided new residue trials on turnips, broccoli, cauliflower, kohlrabies, kales and horseradishes representative for the previously assessed or for adjusted Good Agricultural Practices (GAPs) (see Appendix A).

Furthermore, under the same application, BASF SE submitted a request to modify the existing maximum residue levels (MRLs) in turnips, horseradishes, swedes, rape seeds and mustard seeds for intended new uses in accordance with Article 6 of Regulation (EC) No 396/2005. The RMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005 and with the agreed procedure set out in the working document SANTE/10235/2016, which was submitted to the European Commission and forwarded to the EFSA on 11 July 2018. The detailed description of the uses of metazachlor assessed in the framework of the MRL review, the adjusted GAPs and the new intended uses of metazachlor, which are the basis for the MRL application, is reported in Appendix A.

Metazachlor is the ISO common name for 2-chloro-N-(pyrazol-1-ylmethyl)acet-2,6'-xylidide or 2-chloro-2',6'-dimethyl-N-(1H-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 with the United Kingdom being the designated rapporteur Member State (RMS). The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2008). Metazachlor was approved on 1 August 2009 for the use as herbicide. In accordance with Commission Implementing Regulation (EU) No 540/2011, metazachlor is approved under Regulation (EC) No 1107/2009, repealing Directive 91/414/EEC. The process of renewal of the first approval is ongoing; however, the peer review process has not initiated yet.

EFSA assessed the applications and the evaluation report as required by Article 9 and 10 of the MRL regulation and in accordance with the agreed procedure set out in the working document SANTE/10235/2016.

EFSA has based its assessment on the evaluation report submitted by the RMS (Netherlands, 2018), 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 conclusions on the peer review of the pesticide risk assessment of the active substance metazachlor and in relation to the designated Member State (RMS).

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, 16.3.2005, p. 1–16.
2 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, 14.3.2015, p. 56–113.
3 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eur-pesticides-database/public/?event=pesticide.residue.selection&language=EN
4 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.
5 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: 13/06/2011. 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.
7 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.
with the confirmatory data requested under the EU pesticides peer review (EFSA, 2008) 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 a previous EFSA opinion on metazachlor (EFSA, 2018).

For the current applications, the data requirements established in Regulation (EU) No 544/2011 and the guidance documents applicable at the date of submission of the MRL application to the RMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). 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.

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

The evaluation report submitted by the RMS (Netherlands, 2018) 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 as background documents to this reasoned opinion.

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 crops, pulses/oilseeds and cereals 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 metabolisation to several metabolites, the predominant ones being 479M04, 479M08 and 479M16.

1.1.2. Nature of residues in rotational crops

The nature of residues in succeeding crops resulting from the use of metazachlor was evaluated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2008, 2014). The metabolic pathway in rotational crops was similar to that in primary crops.

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 MRL review (EFSA, 2014). The studies were conducted with the metabolite 479M16 and it was concluded that the compound is hydrolytically stable under the standard representative conditions. Due to the low expected exposure resulting from the use of metazachlor, the MRL review considered desirable but not essential to investigate the effect of processing on the metabolites 479M04 and 479M08.

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 479M04 and 479M08 are waived.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of residues related to the use of metazachlor in plant commodities were assessed during the EU pesticides peer review and the MRL review (EFSA, 2008, 2014). The high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) was considered as fully validated for the determination of the individual metabolites 479M04, 479M08 and 479M16 in plant matrices with high water content, high oil content and high acidic content commodities. The limit of quantification (LOQ) was 0.02 mg/kg for each individual analyte.

Under the current MRL application, a sufficiently validated analytical method was provided. The HPLC-MS/MS method is capable to measure the metabolites 479M04, 479M08 and 479M16 in high

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8 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.
9 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.
water content (head cabbages), high oil content (rape seeds), high acid content (lemon) and dry matrices (wheat grain). The LOQ of the method was 0.01 mg/kg for each individual analyte (Netherlands, 2018).

Overall, sufficiently validated analytical methods are available to enforce the proposed MRLs of metazachlor in plants.

1.1.5. Storage stability of residues in plants

Storage stability of metazachlor residues was assessed in the framework of the EU pesticides peer review and the MRL review (EFSA, 2008, 2014). Under the current MRL application, further storage stability data on 479M04, 479M08 and 479M16 stored at ≤ −20°C were provided (Netherlands, 2018). For the three metabolites, freezer storage stability was demonstrated for up to 24 months in high water content commodities.

1.1.6. Proposed residue definitions

Based on the results of the metabolism studies and the hydrolysis studies, the following residue definitions for plants were suggested in the peer review and the MRL review:

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

This residue definition has been implemented in Regulation (EC) No 396/2005. To facilitate the work for analytical enforcement laboratories and to unambiguously identify the compounds, it would be desirable to include the chemical names of the metabolites in the residue definition for enforcement as follows:

Proposed residue definition for enforcement: Sum of metabolites 479M04 ([(2,6-dimethylphenyl)(1H-pyrazol-1-ylmethyl)amino](oxo)acetic acid), 479M08 (2-[(2,6-dimethylphenyl)(1H-pyrazol-1-ylmethyl) amino]-2-oxoethanesulfonic acid) and 479M16 (3-(2-[(2,6-dimethylphenyl)(1H-pyrazol-1-ylmethyl) amino]-2-oxoethyl)sulfinyl)-2-hydroxypropanoic acid), expressed as metazachlor

- 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).

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

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To address the data gaps identified by EFSA in the framework of the MRL review, the applicant provided new residue trials on flowering brassica (broccoli, cauliflowers), head cabbages, brussels sprouts and kales representative for the existing GAPs previously assessed in the framework of the MRL review. For kohlrabies, residue trials were provided for an adjusted GAP (a PHI of 21 days has been specified in the adjusted GAP).

Additionally, residue trials on turnips, for extrapolation to horseradishes and swedes, and on leeks according to new, intended GAPs were provided. Furthermore, residue trials for rape seeds were submitted reflecting a new GAP in rape seeds and mustard seeds. EFSA did not assess the intended uses on rape seeds and mustard seeds, which are less critical for residues than the uses assessed in the MRL review, considering that the RMS did not propose a modification of the existing MRLs for these crops.

In the residue trials submitted to support the intended new uses and to address the data gaps identified in the MRL review, all samples were analysed for the individual metabolites 479M04 (N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)oxalamide), 479M08 (N-(2,6-dimethylphenyl)-N-(1H-pyrazol-1-ylmethyl)aminocarbonylmethylsulfonic acid) and 479M16 (3-(2-[(2,6-dimethylphenyl)(1H-pyrazol-1-ylmethyl)]

10 The application rate of the GAP assessed in the MRL review is higher (1 kg/ha) compared to the application rate of the new intended GAP (0.75 kg/ha). The other parameters of the GAP are comparable.
pyrazol-1-ylmethyl\(\text{[amino]}\)-2-oxoethyl sulfanyl)-2-hydroxypropanoic acid). In addition, the results for the common moiety method were reported as total 2,6-dimethylaniline, expressed as metazachlor residues (residue definition for risk assessment).

According to the assessment of the RMS, the methods of analysis used in the residue trials were sufficiently validated and fit for purpose. The samples of the residue trials assessed were stored under conditions for which integrity of the samples was demonstrated. The detailed residue trials data are reported in the Section B.1.2.1.

- Radishes

NEU use/Indoor use (existing GAP assessed in the MRL review): The applicant did not provide residue trials to address the data gap number 7 and 8.\(^{11}\)

- Turnips

NEU use (existing GAP assessed in the MRL review): The applicant did not provide residue trials to address the data gap number 9.\(^{12}\)

NEU/SEU use (intended new use): The applicant provided in total six trials on turnips, three conducted in the northern Europe (NEU) and three conducted in the southern Europe (SEU). The trials are compliant with the intended new GAP (see Appendix A, Table A.2). According to the data requirements laid down in Regulation (EU) No 544/2011, which is the relevant legal framework for the current application, at least four trials for each residue zone are required for turnips, since turnips is a minor crop in both geographical zones. Therefore, the data are insufficient to derive an MRL proposal.

The applicant and the RMS proposed to accept a reduced number of trials and derived an MRL proposal for turnips from the combined NEU and SEU residue trials in line with the data requirements of Regulation (EU) No 283/2013. For applications assessed under Regulation (EU) No 283/2013, the reduced data set would be sufficient, since the GAPs in both geographical zones are identical and the six residue trials were equally distributed.

Considering that for the current application the old data requirements established by Regulation (EU) No 544/2011 are applicable, a risk management decision has to be taken whether other legitimate factors justify the setting of an MRL despite the deficiency of the data set submitted by the applicant. The tentatively calculated MRL and risk assessment values derived from the combined data set are reported in Appendix B, Section B.1.2.1.

- Swedes

NEU use (existing GAP assessed in the MRL review): The applicant did not provide residue trials to address the data gap number 9.\(^{12}\)

NEU/SEU use (intended new use): The applicant proposed the three northern European and the three southern European residue trials on turnips for extrapolation to swedes. These trials are compliant with the intended GAP on swedes. In principle, extrapolation from turnips to swedes is possible, provided that the number of trials is compliant with the legal data requirements. According to the guidance document SANCO 7525/VI/95, at least four residue trials on turnips per residue zone are required to establish an MRL for swedes by extrapolation. The applicant and the RMS suggested to accept a reduced number of trials, making reference to the data requirements set by Regulation (EU) No 283/2013.

Although EFSA did not agree with the interpretation of the new data requirements and requested an additional residue trial, EFSA agreed with the RMS to present the data and the deficiencies in the current assessment for further considerations by risk managers, allowing to take an informed risk management decision.

- Horseradishes

NEU use (existing use assessed in the MRL review): The applicant did not provide residue trials to address the data gap number 9.\(^{12}\)

NEU use (intended new use): The applicant proposed to derive an MRL by extrapolation from the three residue trials on turnips conducted in the NEU and compliant with the intended GAP on horseradishes. In principle, extrapolation from turnips to horseradishes is possible, provided that the number of trials is compliant with the legal data requirements. According to the guidance document

\(^{11}\) Data gap number 7: four residue trials supporting the northern outdoor GAP for radish; data gap number 8: 4 residue trials supporting the indoor GAP for radish.

\(^{12}\) Data gap number 9: four residue trials on turnips supporting the northern outdoor GAP for turnips, swedes and horseradish.
SANCO 7525/VI/95, at least four NEU residue trials on turnips are required to derive an MRL in horseradishes by extrapolation. The applicant and the RMS requested EFSA to present the available data for risk management consideration (see swedes).

- Flowering brassica (broccoli, cauliflower)

  **NEU use (existing GAP assessed in the MRL review):** The applicant provided four residue trials on cauliflowers and four residue trials on broccoli conducted according to the authorised use in the NEU to address the data gap number 10.\(^\text{13}\) The new set of residue trials allows deriving an MRL proposal for the group of flowering brassica.

  **SEU use (existing GAP assessed in the MRL review):** The applicant provided four residue trials on cauliflowers and four residue trials on broccoli conducted according to the authorised use in the SEU to address the data gap number 11.\(^\text{14}\) The new set of residue trials allows deriving an MRL proposal for the group of flowering brassica.

- Head cabbages

  **NEU/SEU use (existing GAP assessed in the MRL review):** The applicant provided eight residue trials conducted in the NEU and four residue trials conducted in the SEU according to the authorised use in the EU to address data gap number 12.\(^\text{15}\) The new residue trials support the NEU and SEU uses and allow to derive MRL proposals.

- Brussels sprouts

  **NEU/SEU use (existing GAP assessed in the MRL review):** The applicant provided two residue trials conducted in the NEU and two residue trials conducted in the SEU according to the authorised use on Brussels sprouts. The new data confirmed that quantifiable residues of metazachlor metabolites are not expected when the active substance is applied according to the existing GAP.

- Kales

  **NEU use (existing GAP assessed in the MRL review):** The applicant provided four residue trials on kales conducted according to the authorised use in the NEU to address the data gap number 13.\(^\text{16}\) The data are considered sufficient to derive an MRL proposal.

  **SEU use (existing GAP assessed in the MRL review):** The applicant did not provide residue trials to address data gap number 14.\(^\text{17}\)

- Kohlrabies

  **NEU use (adjusted GAP):** The applicant provided five residue trials conducted in the NEU to address the data gap number 15.\(^\text{18}\) These trials are compliant with an adjusted GAP in which a PHI of 21 days was specified. Kohlrabi samples (whole product after removal of roots and tops) were analysed according to the residue definitions for enforcement and risk assessment.\(^\text{19}\) The data are sufficient to derive a MRL proposal for the adjusted GAP.

  **SEU use (intended new use):** No residue trials supporting the intended use were provided.

- Leeks

  **NEU use (intended new use):** The applicant provided two residue trials on leeks conducted according to the intended GAP with PHI 35 days. The number of trials is, however, insufficient to derive a MRL proposal. According to the EU data requirements (Regulation (EU) 544/2011), at least four residue trials are required.

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\(^\text{13}\) Data gap number 10: eight residue trials (four on cauliflower and four on broccoli) supporting the northern outdoor GAP for flowering brassica.

\(^\text{14}\) Data gap number 11: eight residue trials (four on cauliflower and four on broccoli) supporting the southern outdoor GAP on flowering brassica.

\(^\text{15}\) Data gap number 12: eight residue trials supporting the northern outdoor GAP for head cabbage; four residue trials supporting the southern outdoor GAP for head cabbage.

\(^\text{16}\) Data gap number 13: four residue trials on kale supporting the northern outdoor GAP for leafy brassica.

\(^\text{17}\) Data gap number 14: four residue trials on kale supporting the southern outdoor GAP on leafy brassica.

\(^\text{18}\) Data gap number 14: four residue trials supporting the northern outdoor GAP for kohlrabies.

\(^\text{19}\) It is noted that results were also reported for kohlrabi leaves. Kohlrabi leaves are a commodity classified in Annex I Part B to Regulation (EC) No 396/2005 as a product to which the same MRL applies as to kales (commodity code 0243020-004). Since the applicant did not request a modification of the MRL based on the results on kohlrabi leaves, EFSA did not perform a detailed assessment of these data.
• Turnip leaves (feed item)

NEU/SEU use (intended new use): Since turnip leaves may be used as feed item, an assessment of the expected residues is required, if a GAP on turnip roots is proposed. The applicant provided three NEU and three SEU trials that allow to estimate the total residue of metazachlor in turnip leaves according to the intended GAP on turnips. NEU and SEU residues were combined to derive the input value to be used in the dietary burden calculation. Because the MRL proposed for the intended use on turnip roots is tentative, the risk assessment value for turnip leaves to be used in the dietary burden calculation is tentative as well.

1.2.2. Magnitude of residues in rotational crops

Significant residues are not expected 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) (EFSA, 2014). Since GAPs assessed in this application comply with the restrictions, the previously derived conclusion is still valid.

1.2.3. Magnitude of residues in processed commodities

Specific studies to assess the magnitude of metazachlor and its metabolites residues during processing of the crops under consideration in the MRL application are not necessary, due to the low dietary exposure (European Commission, 1997d).

1.2.4. Proposed MRLs

EFSA concluded that sufficient information was provided to confirm the tentative MRLs of metazachlor for head cabbages and kohlrabies. Based on the results from the residue trials submitted, risk managers may consider lowering the existing MRLs for flowering brassica and kales or maintain the values tentatively set in the legislation. For Brussels sprouts, EFSA proposes to maintain the existing MRL set at the LOQ of the peer-reviewed enforcement method. The uses on radishes, turnips, horseradishes and swedes assessed during the MRL review are no longer supported.

For the intended new uses on turnips, horseradishes and swedes, the applicant submitted a limited number of residue trials on turnips (three NEU and three SEU) which is not in compliance with the data requirements laid down in Regulation (EU) No 544/2011 and the guidance document SANCO 7525/VI/95 applicable for the current assessment. The applicant and the RMS requested EFSA to present the available data to allow an informed risk management decision on the appropriate MRLs on turnips, swedes and horseradishes, considering that, according to Regulation (EU) No 283/2013 (Part A to the Annex, Section 6.3, Test conditions, 5th paragraph), the number of available residue trials would be sufficient to derive an MRL proposal for a minor crop. The intended use on leeks is not sufficiently supported by data.

In Section 3, EFSA assessed whether the metazachlor total residues expected on these crops are likely to pose a consumer health risk.

2. Residues in livestock

The most recent livestock dietary burden calculation was conducted in the framework of the MRL review. In that calculation, EFSA took into account the tentative MRLs for turnips, swedes, cabbages, kales and oilseed rape forage (EFSA, 2014). The calculation was performed according to the methodology described in the previously used European guidance document (European Commission, 1996).

In the framework of the current applications, the dietary burden was recalculated in accordance with the OECD guidance document (OECD, 2013) which is the methodology applicable at the date of submission of the MRL application; the residue concentrations expected in the feed items were derived from the new residue trials submitted under the MRL application.

Pending a final risk management decision whether the data submitted for swedes and turnips are sufficient, EFSA calculated the dietary burden for livestock in two scenarios: scenario 1 (Table B.2.1) includes swedes, turnips and turnip leaves, while in scenario 2 (Table B.2.2), these products were excluded, assuming that the intended use will be not authorised. Rape forage was excluded from both scenarios, because the applicant confirmed that this use is no longer supported. The input values are summarised in Appendix D.1. The results of the calculations are presented in Appendix B.2.2.
Comparing the results obtained with the new methodology and the results reported in the previous EFSA opinion (EFSA, 2014), it becomes evident that the different methodology and the exclusion of oilseed rape forage have an impact on the calculations. Furthermore, the inclusion/exclusion of the residues tentatively derived for the intended new use in turnips and swedes impacted the livestock intakes as well.

Based on the results of the updated dietary burden calculations and the feeding study performed with metazachlor on cattle, EFSA derived MRL proposals reflecting scenario 1 and scenario 2 for further risk management consideration. A modification of the existing MRLs for liver of swine and bovine is suggested for scenario 1 and 2. For liver of sheep and goat, the existing MRL would be appropriate for scenario 1, whereas for scenario 2, a lower MRL would be required.

The updated dietary burden calculations confirmed that residue levels in poultry tissues and eggs are expected to remain below the enforcement LOQ of 0.05 mg/kg.

In Section 3, EFSA assessed whether the metazachlor total residues expected on products of animal origin are likely to pose a consumer health risk.

3. Consumer risk assessment

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

The estimated exposure was then compared with the toxicological reference values derived during the EU pesticides peer review (European Commission, 2012).

The most recent long-term exposure assessment performed by EFSA (EFSA, 2018) was updated with the median residue value (STMR) derived for the commodities under assessment. For the uses on turnips, swedes and horseradishes, the tentative STMR values were included in the calculations. For animal products, EFSA included the input values derived according to the highest maximum dietary burden, which was calculated including the intended use on turnips and swedes. Thus, regardless to the final decision on the tentatively proposed MRLs. The acute exposure assessment was performed only with regard to the uses of metazachlor under consideration and for liver of swine and ruminants. The input values used for the dietary exposure calculation are summarised in Appendix D.2.

No long-term consumer intake concerns were identified for the authorised and the intended uses of metazachlor. The estimated maximum long-term dietary intake accounted for 1.5% of the acceptable daily intake (ADI) (French toddler diet). The maximum short-term exposure was calculated for swedes (4.7% of the acute reference dose (ARfD)).

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

4. Conclusion and Recommendations

The data gaps identified during the MRL review for further residue trials on flowering brassica, head cabbages, kales and kohlrabies were satisfactorily addressed. Based on the results of the new residue trials, for kales and flowering brassica, the lowering of the existing MRL would be possible whereas for head cabbages and kohlrabies, the existing MRLs are confirmed. Although not requested, the applicant provided two new residue trials compliant with the uses assessed in the MRL review which confirmed that quantifiable residues are not expected in Brussels sprouts. The uses on radishes, turnips, horseradishes and swedes assessed during the MRL review are no longer supported.

For the intended new uses on turnips, horseradishes and swedes, the applicant submitted a limited number of residue trials on turnips (three northern and three southern European trials) which is not in compliance with the data requirements laid down in Regulation (EU) No 544/2011 and the guidance document SANCO 7525/VI/95 applicable for the current assessment. The applicant and the competent national authority in the Netherlands requested EFSA to present the available data to allow an informed risk management decision on the appropriate MRLs on turnips, swedes and horseradishes, considering that, according to Regulation (EU) No 283/2013 (Part A to the Annex, Section 6.3, Test conditions, 5th paragraph), the number of available residue trials would be sufficient to derive an MRL proposal for a minor crop. The applicant did not provide sufficient residue trials to support the intended use on leeks.

A change of the existing MRLs for liver of swine and ruminants resulting from the authorised and intended uses of metazachlor is also proposed.
EFSA concluded that the use of metazachlor on the crops under consideration 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.4.

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**Abbreviations**

| Abbreviation | Definition |
|--------------|------------|
| 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 |
| DAR | draft assessment report |
| DAT | days after treatment |
| DM | dry matter |
| eq | residue expressed as a.s. equivalent |
| GAP | Good Agricultural Practice |
| 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 Organisation for Standardisation |
| IUPAC | International Union of Pure and Applied Chemistry |
| LC-MS/MS | liquid chromatography tandem mass spectrometry detector |
| LOQ | limit of quantification |
| MRL | maximum residue level |
| NEU | northern Europe |
| OECD | Organisation for Economic Co-operation and Development |
| PBI | plant back interval |
| PF | processing factor |
| PHI | preharvest interval |
| PRIMo | (EFSA) Pesticide Residues Intake Model |
| RA | risk assessment |
| RAC | raw agricultural commodity |
| RD | residue definition |
| RD-Mo | residue definition for monitoring |
| RMS | rapporteur Member State |
| RPF | relative potency factor |
| SC | suspension concentrate |
| SEU | southern Europe |
| STMR | supervised trials median residue |
### Appendix A – Summary of GAPs assessed in the current Reasoned opinion

#### A.1. Summary of the authorised/adjusted GAPs relevant for the assessment of confirmatory data

| Crop and/or situation | Preparation | Application | Application rate per treatment | PHI days<sup>(a)</sup> | Remarks |
|-----------------------|-------------|-------------|---------------------------------|-------------------------|---------|
|                       | Type<sup>(b)</sup> | Conc. a.s. g/L | Method kind | Range of growth stages & season<sup>(c)</sup> | Number min–max | Interval between application (min) | Rate g a.s./ha min–max | Water L/ha min–max | Rate Unit | PH (days)<sup>(a)</sup> | Remarks |
| **Critical Outdoor GAPs for Northern Europe (EFSA, 2014)** | | | | | | | | | | | |
| Horseradishes NEU F | Foliar treatment – spraying | 1 | | | | | | | | 1.00 kg a.i./ha | 65 | Use on black radish |
| Radishes NEU F | Soil treatment – general (see also comment field) | 0–9 | 1 | | | | | | | 0.75 kg a.i./ha | 70 | |
| Swedes NEU F | Foliar treatment – spraying | 1–18 | 1 | | | | | | | 1.00 kg a.i./ha | n.a. | Max. 1,000 g metazachlor/ha/3 years, max 1 application of metazachlor/3 years |
| Turnips NEU F | Soil treatment – general (see also comment field) | 1–9 | 1 | | | | | | | 75.00* kg a.i./ha | 70 | |
| Broccoli NEU F | Foliar treatment – spraying | n.a.–16 | 1 | | | | | | | 1.00 kg a.i./ha | n.a. | |
| Crop and/or situation | NEU, SEU, MS or country | FG or T<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|-------------------------|----------------------|----------------------------------|-------------|----------------|-------------------------------|----------------|---------|
| Cauliflower           | NEU                     | F                    | Weeds                            | SC          | 500.0 Foliar treatment – spraying | n.a.–16 | 1 | 1.00 kg a.i./ha | n.a. |
| Brussels sprouts      | NEU                     | F                    | Weeds                            | SC          | 500.0 Foliar treatment – spraying | n.a.–16 | 1 | 1.00 kg a.i./ha | n.a. After planting when crop begins to grow |
| Head cabbages         | NEU                     | F                    | Weeds                            | SC          | 500.0 Foliar treatment – spraying | n.a.–16 | 1 | 1.00 kg a.i./ha | n.a. After planting when crop begins to grow |
| Kale                  | NEU                     | F                    | Weeds                            | SC          | 500.0 Foliar treatment – spraying | n.a.–16 | 1 | 1.00 kg a.i./ha | n.a. application rate of 1.25 in GAP notified by DE and evaluated by EFSA |
| Kohlrabies            | NEU                     | F                    | Weeds                            | SC          | 500.0 Foliar treatment – spraying | n.a.–16 | 1 | 1.00 kg a.i./ha | n.a. 6–8 days after planting |
| Kohlrabies            | NEU                     | F                    | Weeds                            | SC          | 500.0 Foliar treatment – spraying | 10–16   | 1 | 0.75 kg a.i./ha | 21 Adjusted GAP |

**Critical Outdoor GAPs for Southern Europe (EFSA, 2014)**

| Crop | SEU | F | Weeds | SC | 500.0 Foliar treatment – spraying | n.a.–18 | 1 | 0.40–1.00 kg a.i./ha | n.a. Pre- and early post-emergence |
|------|-----|---|-------|----|----------------------------------|---------|---|----------------|-----------------|
| Broccoli | SEU | F | Weeds | SC | 500.0 Foliar treatment – spraying | n.a.–18 | 1 | 1.00 kg a.i./ha | n.a. 5–6 days after transplanting |
| Crop and/or situation | NEU, SEU, MS or country | F G or I<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Conc. a.s. g/L<sup>(b)</sup> | Method kind | Range of growth stages & season<sup>(c)</sup> | PHI (days)<sup>(d)</sup> | Interval between application (min) | Application rate per treatment | Remarks |
|----------------------|-------------------------|-----------------|---------------------------------|-------------|----------------|-------------|---------------------------------|-----------------|-------------------------------|------------------------|---------|
| Brussels sprouts     | SEU                     | F               | Weeds                           | SC          | 500.0          | Foliar treatment – spraying | n.a.–18          | 1                             | 0.40–1.00 kg a.i./ha     | n.a.   | Pre- and early post-emergence |
| Head cabbages        | SEU                     | F               | Weeds                           | SC          | 500.0          | Foliar treatment – spraying | n.a.–18          | 1                             | 0.40–1.00 kg a.i./ha     | n.a.   | Pre- and early post-emergence |
| Kale                 | SEU                     | F               | Weeds                           | SC          | 500.0          | Foliar treatment – spraying | 12–16            | 1                             | 1.00 kg a.i./ha          | n.a.   |                        |

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments) (EFSA, 2014)

| Crop and/or situation | NEU/SEU | F | Weeds | Preparation | Conc. a.s. g/L | Method kind | Range of growth stages & season | PHI (days) | Interval between application | Application rate per treatment | Remarks |
|-----------------------|---------|---|-------|-------------|----------------|-------------|--------------------------------|------------|-----------------------------|-------------------------------|---------|
| Radishes              | NEU/SEU | F | Weeds | SC          | 500.0          | Soil treatment – general   | 0–9            | 1                             | 0.40 kg a.i./ha               | n.a.   |

NEU: northern European Union; SEU: southern European Union; MS: Member State.

*: The application rate for turnips (NEU use) in the Reasoned opinion on the review of the existing maximum residue levels for metazachlor according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2014) may be mistyped (75 mg/ha or 0.75 kg/ha instead of 75 kg/ha as reported). Since the GAP was not supported any longer by the applicant, the typo is of no practical relevance.

(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 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 preharvest interval.
## A.2. Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | Pest(s) controlled | Preparation | Application Method | Range of growth stages & season | Number min–max | Interval between application (min) | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|-------------------|-------------|-------------------|-------------------------------|----------------|----------------------------------|--------------------------------|-----------|---------|
| **Swedes**            | NEU                     | Weeds             | SC          | Foliar spraying    | BBCH 12–18                    | 1              | –                                | 100–400                         | 750       | n.a.    |
|                       | SEU                     | Weeds             | SC          | Foliar spraying    | BBCH 12–18                    | 1              | –                                | 100–400                         | 750       | n.a.    |
| **Turnip**            | NEU                     | Weeds             | SC          | Foliar spraying    | BBCH 12–18                    | 1              | –                                | 100–400                         | 750       | n.a.    |
|                       | SEU                     | Weeds             | SC          | Foliar spraying    | BBCH 12–18                    | 1              | –                                | 100–400                         | 750       | n.a.    |
| **Kohlrabies**        | SEU                     | Weeds             | SC          | Foliar spraying    | BBCH 00–09                    | 1              | –                                | 100–400                         | 750       | n.a.    |
| **Leek**              | NEU                     | Weeds             | SC          | Foliar spraying    | BBCH 12–18                    | 1              |                                  | 100–400                         | 750       | 35      |
| **Rape seeds**        | NEU                     | Weeds             | SC          | Foliar spraying    | BBCH 10–18                    | 1              |                                  | 100–400                         | 750       | n.a.    |
|                       | SEU                     | Weeds             | SC          | Foliar spraying    | BBCH 10–18                    | 1              |                                  | 100–400                         | 750       | n.a.    |
| **Mustard seeds**     | NEU                     | Weeds             | SC          | Foliar spraying    | BBCH 10–18                    | 1              |                                  | 100–400                         | 750       | n.a.    |
|                       | SEU                     | Weeds             | SC          | Foliar spraying    | BBCH 10–18                    | 1              |                                  | 100–400                         | 750       | n.a.    |

**NEU:** northern European Union; **SEU:** southern European Union; **MS:** Member State.

(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 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 preharvest interval.
### Appendix B – List of end points

#### B.1. Residues in plants

#### B.1.1. Nature of residues and methods of analysis in plants

#### B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling | Comment/source |
|-----------------------------------|-------------|---------|----------------|----------|---------------|
| Leafy crops                       | Cabbage     | Foliar, 1 x 1.25 kg/ha, BBCH 14-16 | 34, 147 DAT | [phenyl-UL-\(^{14}\)C]-metazachlor (EFSA, 2008) |
| Cereals/grasses                   | Maize       | Foliar, 1 x 1 kg/ha, pre-emergence | 78, 118, 146 DALA | [phenyl-UL-\(^{14}\)C]-metazachlor (EFSA, 2008) |
| Pulses/oilseeds                   | Oilseed rape| Foliar, 1 x 1.25 kg/ha, BBCH 14-16 | 22, 71 DAT | [phenyl-UL-\(^{14}\)C]-metazachlor (EFSA, 2008) |
|                                   |             | Soil, 1 x 1.25 kg/ha               | 215, 293 DAT | [phenyl-UL-\(^{14}\)C]-metazachlor (EFSA, 2008) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|--------------------------------------|-------------|---------|----------------|-----------|---------------|
| Root/tuber crops                     | radishes    | soil application, 1 x 1.25 kg/ha | 30, 120, 366 | [phenyl-UL-\(^{14}\)C]-metazachlor (EFSA, 2008) |
|                                      | carrots     | Soil application, 1 x 0.75 kg/ha | 30         |              |
| Leafy crops                          | Lettuce     | Soil application, 1 x 1.25 kg/ha | 30, 120, 366 | [phenyl-UL-\(^{14}\)C]-metazachlor (EFSA, 2008) |
|                                      | Cabbage     | Soil application, 1 x 0.75 kg/ha | 30         |              |
|                                      | Spinach     | Soil application, 1 x 0.75 kg/ha | 30         |              |
| Cereal (small grain)                 | Wheat       | Soil application, 1 x 1.25 kg/ha | 30, 120, 366 | [phenyl-UL-\(^{14}\)C]-metazachlor (EFSA, 2008) |
|                                      |             | Soil application, 1 x 0.75 kg/ha | 30         |              |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/source |
|------------------------------------------|------------|--------|----------------|
|                                         | Pasteurisation (20 min, 90°C, pH 4) | 479M16 | Yes [phenyl-UL-\(^{14}\)C]- 479M16 (EFSA, 2008) |
|                                         | Baking/brewing/boiling (60 min, 100°C, pH 5) | 479M16 | Yes [phenyl-UL-\(^{14}\)C]- 479M16 (EFSA, 2008) |
|                                         | Sterilisation (20 min, 120°C, pH 6) | 479M16 | Yes [phenyl-UL-\(^{14}\)C]- 479M16 (EFSA, 2008) |
|                                         | Parent metazachlor, 479H04 and 479H08: not investigated (not essential) (EFSA, 2014) |        | |

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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)

Plant residue definition for risk assessment (RD-RA)

Metazachlor (Sum of metabolites 479M04, 479M08 and 479M16, expressed as metazachlor)

Sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor

Metabolite: 479M04, 479M08 and 479M16

LC–MS/MS, LOQ 0.02 mg/kg (per analyte)

Confirmatory method and ILV available (EFSA, 2008)

Matrices with high water content, high oil content, high acid content:

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

LC–MS/MS (method No L0316/01), LOQ 0.01 mg/kg (per analyte)

ILV available (Netherlands, 2018)

B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category                  | Commodity                        | T (°C) | Stability period | Compounds covered | Comment/source |
|-----------------------------------|---------------------------|----------------------------------|--------|-----------------|-------------------|---------------|
| Cabbage, maize forage             | High water content        | −18                               | 24     | Months          | Total residues(a) | EFSA (2014)   |
| Rape seed forage                 | High water content        | −18                               | 13     | Months          | 479M16            | EFSA (2014)   |
| Cabbage                           | High oil content          | −20                               | 24     | Months          | 479M16            | Netherlands (2018) |
| Lettuce                           | High oil content          | −20                               | 24     | Months          | 479M04            | Netherlands (2018) |
| Lettuce                           | Dry/high starch           | −20                               | 24     | Months          | Total residues(a) | EFSA (2014)   |
| Rape seed                        | Dry/high starch           | −18                               | 24     | Months          | Total residues(a) | EFSA (2014)   |
| Rape seed                        | Dry/high starch           | −18                               | 13     | Months          | 479M16            | EFSA (2014)   |

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

DAT: days after treatment; BBCH: growth stages of mono- and dicotyledonous plants; DALA: days after last application; a.s: active substance; PBI: plant-back interval; LOQ: limit of quantification; LC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; ILV: independent laboratory validation.
B.1.2. Magnitude of residues in plants

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

| Commodity                      | Region/indoor(a) | Residue levels observed in the supervised residue trials(b) (mg/kg) | Comments/source                                                                 | Calculated MRL (mg/kg) | HR(c) (mg/kg) | STMR(d) (mg/kg) | CF(e) |
|--------------------------------|------------------|--------------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|---------------|----------------|-------|
| Radishes                       | NEU              | EFSA (2014): no data                                              | No residue trials are available for the GAP assessed in the MRL review         | –                      | –             | –              | –     |
| Indoor                         | EFSA (2014)      | Mo: –; RA: 0.04; 0.05; 0.12; 0.14                                  | No new data were submitted for the GAP assessed in the MRL review             | –                      | –             | –              | –     |
| Turnips, swedes, horseradishes | NEU              | EFSA (2014)                                                       | Data on turnips are insufficient to derive MRL proposal for turnips and, by extrapolation, for swedes and horseradishes | –                      | –             | –              | –     |
| Turnips, swedes, horseradishes | NEU              | Netherlands (2018)                                                | Residue trials on turnips compliant with the intended NEU GAP with samples harvested between 27 and 50 days | –                      | –             | –              | 1.14  |
| Turnips, swedes                | SEU              | Netherlands (2018)                                                | Residue trials on turnips compliant with the intended SEU GAP with samples harvested between 27 and 78 days | –                      | –             | –              | 0.96  |
| Commodity                          | Region/indoor(a) | Residue levels observed in the supervised residue trials(b) (mg/kg) | Comments/source                                                                                                                                                                                                                                                                                                                                                     | Calculated MRL (mg/kg) | HR(c) (mg/kg) | STMR(d) (mg/kg) | CF(e)  |
|-----------------------------------|------------------|--------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|----------------|--------|
| Turnips, swedes (both NEU and SEU), horseradishes (only NEU) | NEU/SEU          | NEU/SEU Netherlands (2018) Mo: 0.12, 0.14, 0.24, 0.31, 0.37; 0.45 RA: 0.10; 0.16, 0.23, 0.29, 0.42; 0.45 | Combined NEU and SEU data set of residue trials on turnips compliant with the intended NEU/SEU GAP Applicant/RMS proposed to derive an MRL proposal using the combined data set for further risk management consideration The approach to derive an MRL proposal for a minor crop from a data set with less than four trials is not in line with the data requirements of Regulation (EU) No 544/2011, which is the relevant legal framework for the current application For applications assessed under Regulation (EU) No 283/2013, the reduced data set would be an acceptable deviation for a minor crop In principle, extrapolation from turnips to swedes (NEU and SEU) and horseradishes (only NEU) is possible, provided that the number of trials is compliant with the legal data requirements Due to the non-compliance with the legal data requirements, the MRL proposal for turnips and the risk assessment values are considered as tentative | 0.9 (tentative) | 0.45 (tentative) | 0.26 (tentative) | 0.98   |
| Flowering brassica               | NEU              | EFSA (2014) Mo: – RA: 2 × < 0.03; 2 × < 0.05; 0.06; 0.21 Netherland, 2018 Mo: 4 × < 0.03; 4 × 0.03 RA: 7 × < 0.05; 0.07 | New residue trials on cauliflowers (4) and broccoli (4) compliant with the GAP assessed in the MRL review (± 25% tolerance for application rate) Data are sufficient to derive a group MRL proposal for flowering brassica | 0.06 | 0.21 | 0.05 | 1.62   |
| Commodity       | Region/indoor(a) | Residue levels observed in the supervised residue trials(b) (mg/kg) | Comments/source                                                                 | Calculated MRL (mg/kg) | HR(c) (mg/kg) | STMR(d) (mg/kg) | CF(e)  |
|-----------------|------------------|------------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------|-----------------|--------|
| Flowering brassica | SEU               | EFSA (2014)                                                       | New set of residue trials on cauliflowers (4) and broccoli (4) compliant with the GAP assessed in the MRL review (± 25% tolerance for application rate) Data are sufficient to derive group MRL proposal for flowering brassica | 0.06                   | 0.21         | 0.05            | 1.64   |
| Head cabbages   | NEU               | EFSA (2014)                                                       | New residue trials compliant with the GAP assessed in the MRL review (± 25% tolerance for application rate) Data are sufficient to derive MRL proposal | 0.4                    | 0.38         | 0.05            | 3.54   |
| Head cabbages   | SEU               | EFSA (2014)                                                       | New residue trials compliant with the GAP assessed in the MRL review (± 25% tolerance for application rate) Data are sufficient to derive MRL proposal | 0.05                   | 0.14         | 0.05            | 3.14   |
| Brussels sprouts| NEU               | EFSA (2014)                                                       | Residue trials assessed during the MRL review were sufficient to conclude that no quantifiable residues are expected for the authorised critical use New residue trials compliant with GAP (± 25% tolerance for application rate) were submitted; samples were analysed also according to residue definition for risk assessment It is proposed to maintain the enforcement LOQ of 0.06 mg/kg | 0.03*                  | 0.05         | 0.05            | –      |
| Commodity      | Region/ indoor | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source                                                                                                                                                                                                 | Calculated MRL (mg/kg) | HR<sup>(c)</sup> (mg/kg) | STMR<sup>(d)</sup> (mg/kg) | CF<sup>(e)</sup> |
|---------------|----------------|-----------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|------------------------|------------------------|-------------|
| Brussels sprouts | SEU            | EFSA (2014)  
Mo: –  
RA: 2 × < 0.05  
Netherlands (2018) Mo: 2 × < 0.03  
RA: 2 × < 0.05 | Residue trials assessed during the MRL review were sufficient to conclude that no quantifiable residues are expected for the authorised critical use. New residue trials compliant with GAP (± 25% tolerance application rate) were submitted; samples were analysed also according to residue definition for risk assessment. It is proposed to maintain the enforcement LOQ of 0.06 mg/kg | 0.03*                  | 0.05                   | 0.05                   | –           |
| Kales         | NEU            | EFSA (2014)  
Mo: –  
RA: 4 × < 0.05; 0.06; 0.14  
Netherlands (2018) Mo: 2 × 0.04; 0.05; 0.07  
RA: 0.06; 0.08; 0.11; 0.14 | New residue trials compliant with GAP assessed in the MRL review (± 25% tolerance for application rate) Data are sufficient to derive MRL proposal | 0.2                    | 0.14                   | 0.06                   | 1.55         |
| Kales         | SEU            | EFSA (2014)  
Mo: –  
RA: 0.06; 0.08  
Netherlands (2018): no data | No new data submitted for the GAP assessed in the MRL review Data insufficient to derive MRL proposal | –                      | –                      | –                      | –            |
| Kohlrabies    | NEU            | EFSA (2014)  
Mo: –  
RA: 2 × < 0.05; 0.08; 0.09; 0.14  
Netherlands, (2018): no data | No new data submitted for the GAP assessed in the MRL review Data not sufficient to derive MRL proposal | –                      | –                      | –                      | –            |
| Kohlrabies    | NEU            | Mo: 0.05, 0.06, 0.10, 0.11, 0.14  
RA: 0.06, 0.07, 0.10, 2 × 0.24 | New residue trials compliant with an adjusted GAP with 21 days PHI Data are sufficient to derive MRL proposal | 0.3                    | 0.24                   | 0.10                   | 1.30         |
| Commodity         | Region/indoor(a) | Residue levels observed in the supervised residue trials(b) (mg/kg) | Comments/source                                                                 | Calculated MRL (mg/kg) | HR(c) (mg/kg) | STMR(d) (mg/kg) | CF(e) |
|------------------|------------------|-------------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| Leeks            | NEU              | **Mo:** 0.03; 0.08  
**RA:** < 0.05; 0.05                                               | Residue trials compliant with a new intended GAP with 35 days PHI  
Number of trials not sufficient to derive an MRL proposal and risk assessment values | –                     | –            | –             | –     |
| Turnip leaves    | NEU/SEU          | **RA:** 0.19; 0.98; 2 × 1.2; 1.8; 2.8                              | Turnip leaves are feed items  
Combined data set of residue trials on turnips compliant with the intended GAP (see turnips roots) | 2.8 (tentative)        | –            | 1.2 (tentative) | –     |

Mo: monitoring; RA: risk assessment.
In bold, values used for the MRL proposal and the consumer risk assessment.
*: Indicates that the MRL is proposed at the limit of quantification. In bold, the MRL and the input values selected for the risk assessment of the crop, since more critical for residues.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Before summing up, the individual residue levels of 479-M04, 479-M08 and 479-M16 above the LOQ of 0.01 mg/kg were recalculated to express them as metazachlor equivalents by using the molecular conversion factors of 1.02, 0.86 and 0.73, respectively.
(c): Highest residue according to the residue definition for risk assessment. The highest residue for risk assessment refers to the whole commodity.
(d): Supervised trials median residue according to the residue definition for risk assessment. The median residue for risk assessment refers to the whole commodity.
(e): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment (median of CF derived from individual trials). The CF was not calculated when residues in the residue trial were below the LOQ according to both the residue definition for monitoring (Mo) and for risk assessment (RA).
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 MRL application.
### B.2. Residues in livestock

#### B.2.1. Scenario 1: Dietary burden calculation, including intended uses on turnips and swedes

| Relevant groups          | Dietary burden expressed in | Most critical diet (a) | Most critical commodity (b) | Trigger exceeded (yes/no) | Max burden previous assessment (EFSA, 2014) |
|--------------------------|----------------------------|------------------------|-----------------------------|----------------------------|---------------------------------------------|
|                          | mg/kg bw per day           | mg/kg DM               | mg/kg DM                    | 0.10                       | mg/kg DM                                   |
|                          | Median | Maximum | Median | Maximum |                        |                                           |
| Cattle (all diets)       | 0.064  | 0.133   | 2.65  | 5.54    | Beef cattle             | Turnip tops (leaves)                     | Yes                                         | 3.57                                       |
| Cattle (dairy only)      | 0.051  | 0.107   | 1.33  | 2.78    | Dairy cattle            | Turnip TOPS (LEAVES)                     | Yes                                         | 0.66                                       |
| Sheep (all diets)        | 0.085  | 0.177   | 1.99  | 4.16    | Lamb                    | Turnip Tops (leaves)                     | Yes                                         | –                                          |
| Sheep (ewe only)         | 0.066  | 0.139   | 1.99  | 4.16    | Ram/Ewe                 | Turnip Tops (leaves)                     | Yes                                         | –                                          |
| Swine (all diets)        | 0.032  | 0.054   | 1.09  | 2.06    | Swine (finishing)       | Cabbage, heads                          | Leaves                                     | Yes                                        | 1.82                                       |
| Poultry (all diets)      | 0.019  | 0.040   | 0.28  | 0.58    | Poultry layer           | Cabbage, heads                          | Leaves                                     | Yes                                        | 0.22                                       |
| Poultry (layer only)     | 0.019  | 0.040   | 0.28  | 0.58    | Poultry layer           | Cabbage, heads                          | Leaves                                     | Yes                                        | 0.22                                       |

(a): When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

#### B.2.2. Scenario 2: Dietary burden calculation, excluding intended uses on turnips and swedes

| Relevant groups          | Dietary burden expressed in | Most critical diet (a) | Most critical commodity (b) | Trigger exceeded (Yes/No) | Max burden previous assessment (EFSA, 2014) |
|--------------------------|----------------------------|------------------------|-----------------------------|----------------------------|---------------------------------------------|
|                          | mg/kg bw per day           | mg/kg DM               | mg/kg DM                    | 0.10                       | mg/kg DM                                   |
|                          | Median | Maximum | Median | Maximum |                        |                                           |
| Cattle (all diets)       | 0.003  | 0.020   | 0.09  | 0.52    | Dairy cattle            | Cabbage, heads                          | Leaves                                     | Yes                                        |
| Cattle (dairy only)      | 0.003  | 0.020   | 0.09  | 0.52    | Dairy cattle            | Cabbage, heads                          | Leaves                                     | Yes                                        |
| Sheep (all diets)        | 0.002  | 0.011   | 0.05  | 0.26    | Lamb                    | Cabbage, heads                          | Leaves                                     | Yes                                        |
| Sheep (ewe only)         | 0.002  | 0.009   | 0.05  | 0.26    | Ram/Ewe                 | Cabbage, heads                          | Leaves                                     | Yes                                        |
| Swine (all diets)        | 0.001  | 0.006   | 0.05  | 0.26    | Swine (breeding)        | Cabbage, heads                          | Leaves                                     | Yes                                        |
| Poultry (all diets)      | 0.002  | 0.009   | 0.02  | 0.13    | Poultry layer           | Cabbage, heads                          | Leaves                                     | Yes                                        |
| Poultry (layer only)     | 0.002  | 0.009   | 0.02  | 0.13    | Poultry layer           | Cabbage, heads                          | Leaves                                     | Yes                                        |

(a): When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.

(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.
B.2.3. Metabolism studies, methods of analysis and residue definitions in livestock

Not relevant. No new information provided.

Animal residue definition for monitoring (RD-Mo)

Sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor (EFSA, 2014)

Animal residue definition for risk assessment (RD-RA)

Sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor (EFSA, 2014)

Fat soluble residues

No EFSA (2018)

B.2.4. Magnitude of residues in livestock

B.2.4.1. Summary of the residue data from livestock feeding studies

B.2.4.1.1. Scenario 1: Including intended uses on turnips and swedes

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N level | MRL proposal (mg/kg) |
|------------------|---------------------------------------------|-----------------------------|----------------------|
|                  | Mean | Highest | STMR<sub>Mo</sub> (mg/kg) | HR<sub>Mo</sub> (mg/kg) |
| Cattle (all diets) | 8 | 1.4 | N Beef cattle (highest diet) |
| Muscle           | 0.05 | 0.05 | 0.05 | 0.05 | 0.05* |
| Fat              | 0.05 | 0.05 | 0.05 | 0.05 | 0.05* |
| Liver            | 0.32 | 0.49 | 0.14 | 0.34 | 0.4 |
| Kidney           | 0.05 | 0.05 | 0.05 | 0.05 | 0.05* |
| Cattle (dairy only) | 8 | 2.9 | N Dairy cattle |
| Milk             | 0.01 | 0.01 | 0.01 | 0.01 | 0.01* |
| Sheep (all diets) | 2.4 | 0.6 | N Ram/Ewe (highest diet) |
| Muscle           | 0.05 | 0.05 | 0.05 | 0.050 | 0.05* |
| Fat              | 0.05 | 0.05 | 0.05 | 0.050 | 0.05* |
| Liver            | 0.13 | 0.15 | 0.11 | 0.260 | 0.3 |
| Kidney           | 0.05 | 0.05 | 0.05 | 0.050 | 0.05* |
| Sheep (dairy only) | 2.4 | 0.6 | N Ewe |
| Milk             | 0.01 | 0.01 | 0.01 | 0.01 | 0.01* |
| Swine            | 2.4 | 1.2 | N Breeding (highest diet) |
| Muscle           | 0.05 | 0.05 | 0.05 | 0.050 | 0.05* |
| Fat              | 0.05 | 0.05 | 0.05 | 0.050 | 0.05* |
| Liver            | 0.13 | 0.15 | 0.07 | 0.133 | 0.15 |
| Kidney           | 0.05 | 0.05 | 0.05 | 0.050 | 0.05* |
| Poultry (all diets) | 11 | 18.9 | N Layer (highest diet) |
| Muscle           | 0.02 | 0.02 | 0.05 | 0.001 | 0.05* |
| Fat              | 0.01 | 0.01 | 0.05 | 0.000 | 0.05* |
| Liver            | 0.29 | 0.29 | 0.05 | 0.015 | 0.05* |
### Animal commodity

| Animal commodity | Residues at the closet feeding level (mg/kg) | Estimated value at 1N level | MRL proposal (mg/kg) |
|------------------|---------------------------------------------|----------------------------|----------------------|
|                  | Mean | Highest | STMR<sub>Mo</sub> (mg/kg) | HR<sub>Mo</sub> (mg/kg) |
| Poultry (layer only) |      |         |                         |                       |
| Closest feeding level<sup>c</sup>: | 11 mg/kg DM | 18.9 | N Layer | 0.05 | 0.003 | 0.05* |
| Eggs<sup>d</sup> | 0.06 | 0.06 | 0.05 | 0.003 | 0.05* |        |

*: Indicates that the input value is proposed at the limit of analytical quantification.
(a): Closest feeding level and N dose rate related to the maximum dietary burden including intended uses on turnips and swedes.
(b): Highest residue level (LOQ) from day D1 to day D28 (daily mean of three cows per group).
(c): Based on the results of the metabolism study in laying hens. No poultry feeding study is available.
(d): Highest residue level (LOQ) from day D1 to D6 (daily mean of 10 laying hens).

### B.2.4.1.2. Scenario 2: Excluding intended uses on turnips and swedes

| Animal commodity | Residues at the closet feeding level (mg/kg) | Estimated value at 1N level | MRL proposal (mg/kg) |
|------------------|---------------------------------------------|----------------------------|----------------------|
|                  | Mean | Highest | STMR<sub>Mo</sub> (mg/kg) | HR<sub>Mo</sub> (mg/kg) |
| Cattle (all diets) | 0.8 mg/kg DM | 1.5 | N Beef cattle (highest diet) | 0.05* |
| Muscle | 0.05 | 0.05 | 0.050 | 0.050 | 0.05* |
| Fat | 0.05 | 0.05 | 0.050 | 0.050 | 0.05* |
| Liver | 0.05 | 0.06 | 0.006 | 0.039 | 0.05* |
| Kidney | 0.05 | 0.05 | 0.050 | 0.050 | 0.05* |
| Cattle (dairy only) | 0.8 mg/kg DM | 1.6 | N Dairy cattle | 0.01* |
| Milk<sup>b</sup> | 0.01 | 0.01 | 0.01 | 0.01 | 0.01* |
| Sheep (all diets) | 0.8 mg/kg DM | 3.0 | N Ram/Ewe (highest diet) | 0.05* |
| Muscle | 0.05 | 0.05 | 0.050 | 0.050 | 0.05* |
| Fat | 0.05 | 0.05 | 0.050 | 0.050 | 0.05* |
| Liver | 0.05 | 0.06 | 0.003 | 0.020 | 0.05* |
| Kidney | 0.05 | 0.05 | 0.050 | 0.050 | 0.05* |
| Sheep (dairy only) | 0.8 mg/kg DM | 3.0 | N Ewe | 0.01* |
| Milk<sup>b</sup> | 0.01 | 0.01 | 0.01 | 0.01 | 0.01* |
| Swine | 0.8 mg/kg DM | 3.0 | N Breeding (highest diet) | 0.05* |
| Muscle | 0.05 | 0.05 | 0.050 | 0.050 | 0.05* |
| Fat | 0.05 | 0.05 | 0.050 | 0.050 | 0.05* |
| Liver | 0.05 | 0.06 | 0.003 | 0.020 | 0.05* |
| Kidney | 0.05 | 0.05 | 0.050 | 0.050 | 0.05* |
| Poultry (all diets) | 11 mg/kg DM | 83.1 | N Layer (highest diet) | 0.05* |
| Muscle | 0.02 | 0.02 | 0.00004 | 0.00020 | 0.05* |
| Fat | 0.01 | 0.01 | 0.00002 | 0.00010 | 0.05* |
| Liver | 0.29 | 0.29 | 0.00100 | 0.00300 | 0.05* |
| Poultry (layer only) | 11 mg/kg DM | 83.1 | N Layer | 0.05* |
| Eggs<sup>d</sup> | 0.06 | 0.06 | 0.0001 | 0.0010 | 0.05* |

*: Indicates that the input value is proposed at the limit of analytical quantification.
(a): Closest feeding level and N dose rate related to the maximum dietary burden excluding intended uses on turnips and swedes.
(b): Highest residue level (LOQ) from day D1 to day D28 (daily mean of three cows per group).

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B.3. Consumer risk assessment

| ARfD | 0.5 mg/kg bw (European Commission, 2012) |
|------|---------------------------------|
| Highest IESTI, according to EFSA PRIMo |
| Horseradishes: | 0.02% of ARfD (tentative) |
| Turnips: | 3.2% of ARfD (tentative) |
| Swedes: | 4.7% of ARfD (tentative) |
| Broccoli: | 2.4% of ARfD |
| Cauliflowers: | 2.8% of ARfD |
| Head cabbages: | 4.0% of ARfD |
| Brussels sprouts: | 0.1% of ARfD |
| Kales: | 1.9% of ARfD |
| Kohlrabies: | 2.4% of ARfD |
| Bovine, liver: | 0.5% of ARfD |
| Swine, liver: | 0.03% of ARfD |

Assumptions made for the calculations

The calculation was performed with PRIMo rev. 2. It is based on the highest residue levels expected in the raw agricultural commodities under consideration. For horseradishes, turnips and swedes and liver of swine and ruminants the tentative highest residue was used, pending risk management decision.

| ADI | 0.08 mg/kg bw per day (European Commission, 2012) |
|------|---------------------------------|
| Highest IEDI, according to EFSA PRIMo |
| Horseradishes: | 0.01% of ADI |
| Turnips: | 0.09% of ADI |
| Broccoli: | 0.02% of ADI |
| Cauliflower: | 0.03% of ADI |
| Brussels sprouts: | 0.01% of ADI |
| Head cabbages: | 0.04% of ADI |
| Kales: | 0.01% of ADI |
| Kohlrabies: | 0.03% of ADI |
| Bovine, liver: | 0.02% of ADI |
| Sheep, liver: | 0.03% of ADI |
| Swine, liver: | 0.01% of ADI |

Assumptions made for the calculations

The calculation was performed with PRIMo rev. 2. The calculation is based on the median residue levels expected in raw agricultural commodities, for which the authorised uses were fully supported by data either in the framework of MRL review or of the MRL confirmatory data. For horseradishes, turnips and swedes and liver of swine and ruminants the tentative risk assessment value was included, pending risk management decision. The contributions of commodities where no existing or intended GAP was reported in the framework of the MRL review and in the previous EFSA opinion on Chinese cabbages were not included in the calculation.

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; GAP: Good Agricultural Practice; MRL: maximum residue level.
### B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|-------------------------|-------------------------|-----------------------|
| **Enforcement residue definition** (plant products): Metazachlor (Sum of metabolites 479M04, 479M08 and 479M16, expressed as metazachlor) | **Proposed enforcement residue definition** (plant products): Metazachlor (Sum of metabolites 479M04 ([(2,6-dimethylphenyl)(1H-pyrazol-1-ylmethyl)amino](oxo)acetic acid), 479M08 (2-[(2,6-dimethylphenyl)(1H-pyrazol-1-ylmethyl)amino]-2-oxoethanesulfonic acid) and 479M16 (3-[(2,6-dimethylphenyl)(1H-pyrazol-1-ylmethyl) amino]-2-oxoethyl)sulfanyl)-2-hydroxypropanoic acid), expressed as metazachlor(b) | 0213040 Horseradishes | 0.15 (ft 1) | Risk management decision required 0.06* or 0.9 | The data gap identified for the critical NEU GAP assessed in the MRL review with a PHI of 65 days was not addressed. The data submitted in support of a new intended NEU GAP is not fully compliant with the data requirements. The applicant and the RMS proposed an MRL of 0.9 mg/kg derived by extrapolation from three residue trials on turnips compliant with the new, intended GAP on horseradish in the NEU. A risk management decision is required whether the data set, which is not compliant with the data requirements defined in Regulation (EU) No 544/2011, is deemed sufficient to derive an MRL proposal. See also swedes and turnips. Alternatively, the MRL should be lowered to the limit of quantification (LOQ). Risk for consumers unlikely. |
| 0213080 Radishes | 0.4 (ft 1) | 0.06* | The data gap identified for the critical NEU and indoor GAP assessed in the MRL review was not addressed. Thus, the MRL should be lowered to the LOQ. |
| 0213100 Swedes | 0.15 (ft 1) | Risk management decision required 0.06* or 0.9 | The data gap identified for the critical NEU GAP assessed in the MRL review was not addressed. The data submitted in support of a new intended GAP is not fully compliant with the data requirements. The applicant and the RMS proposed to derive an MRL of 0.9 mg/kg by extrapolation from three NEU and three SEU residue trials on turnips compliant with the new, intended outdoor GAP on swedes. A risk management decision is required whether the data set, which is not compliant with the data requirements defined in Regulation (EU) No 544/2011, is deemed sufficient to derive an MRL proposal. According to the RMS for the data requirements in Regulation (EU) No 283/2013, the data would be sufficient. Alternatively, the MRL should be lowered to the limit of quantification (LOQ). Risk for consumers unlikely. |
| Code   | Commodity       | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                                                                                                                                                 |
|--------|-----------------|------------------------|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0213110| Turnips         | 0.15 (ft 1)            | Risk management decision required 0.06* or 0.9 | The data gap identified for the critical NEU GAP assessed in the MRL review with a PHI of 70 days was not addressed. Although the data submitted in support of a new intended GAP is not fully compliant with the data requirements, the applicant and the RMS proposed to derive an MRL of 0.9 mg/kg from three NEU and three SEU trials compliant with a new, intended outdoor GAP on turnips. A risk management decision is required whether the data set, which is not compliant with the data requirements defined in Regulation (EU) No 544/2011, is deemed sufficient to derive an MRL proposal. According to the RMS for the data requirements in Regulation (EU) No 283/2013, the data would be sufficient. Alternatively, the MRL should be lowered to the limit of quantification (LOQ). Risk for consumers unlikely. |
| 0241000| Flowering brassica | 0.4 (ft 1)            | 0.06*                   | The data gap identified for the NEU and the SEU uses assessed in the MRL review has been addressed. The submitted residue data suggest a lower MRL of 0.06 mg/kg (LOQ). Risk for consumers unlikely. |
| 0242010| Brussels sprouts | 0.06*                  | No new proposal         | Although not requested, the applicant provided two new residue trials compliant with the uses assessed in the MRL review which confirmed that quantifiable residues are not expected in Brussels sprouts. MRL is set at the LOQ of the enforcement method. |
| 0242020| Head cabbages   | 0.4 (ft 1)            | 0.4                     | The data gap identified for the NEU and the SEU uses assessed in the MRL review has been addressed. Tentative MRL is confirmed. Risk for consumers unlikely. |
| 0242320| Kales           | 0.2 (ft 1)            | 0.15                    | The data gap identified for the NEU use assessed in the MRL review has been addressed. The submitted residue data suggest a lower MRL of 0.15 mg/kg. Risk for consumers unlikely. |
| 0244000| Kohlrabies      | 0.3 (ft 1)            | 0.3                     | An adjusted, more critical GAP was proposed which is sufficiently supported by residue data. The data gap identified for the NEU use assessed in the MRL review has been addressed. Tentative MRL is confirmed. Risk for consumers unlikely. |
| 0270060| Leeks           | 0.06*                  | No new proposal         | Submitted residue trials are not sufficient to support the intended NEU use on leeks. |

**Enforcement residue definition** (animal products, except honey): Sum of metazachlor and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metazachlor.
| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---|---|---|---|---|
| 1011030 | Swine, liver | 0.2 | Risk management decision required Scenario 1: 0.15 Scenario 2: 0.05* | Based on the updated maximum dietary burden calculations and the results of the feeding study on cattle, the lowering of the current MRL could be considered. Two MRL proposals are derived, reflecting the scenario including turnips, swedes and turnip leaves in the dietary burden (scenario 1, see also comments on swedes and turnips, codes 0213100 and 0213110); the second MRL proposal was derived based on existing uses fully supported by data. Risk for consumers unlikely |
| 1012030 | Bovine, liver | 0.3 | Risk management decision required Scenario 1: 0.4 Scenario 2: 0.05* | Based on the updated maximum dietary burden calculations and the results of the feeding study on cattle, the change of the current MRL could be considered. Two MRL proposals are derived, reflecting the scenario including turnips, swedes and turnip leaves in the dietary burden (scenario 1, see also comments on swedes and turnips, codes 0213100 and 0213110); the second MRL proposal was derived based on existing uses fully supported by data. Risk for consumers unlikely |
| 1013030 | Sheep, liver | 0.3 | Risk management decision required Scenario 1: 0.3 Scenario 2: 0.05* | Based on the updated maximum dietary burden calculations and the results of the feeding study on cattle, the existing MRL should be maintained (scenario 1, see also comments on swedes and turnips, codes 0213100 and 0213110)). The MRL proposal derived in scenario 2 is based on the existing uses fully supported by data. Risk for consumers unlikely |
| 1014030 | Goat, liver | 0.3 | Risk management decision required Scenario 1: 0.3 Scenario 2: 0.05* | |

<sup>*</sup>: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

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

<sup>(b)</sup>: The residue definition implemented in the EU legislation reference only the codes for the three metabolites of metazachlor. To facilitate the work for analytical enforcement laboratories and to unambiguously identify the compounds, it would be desirable to include the chemical names of the metabolites in the residue definition.

<sup>(ft 1)</sup>: The European Food Safety Authority identified some information on residue trials as unavailable. When re-reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 14 March 2017, or, if that information is not submitted by that date, the lack of it (Footnote related to data gaps No 7, 8, 9, 10, 11, 12 and 15).
### Appendix C – Pesticide Residue Intake Model (PRIMo)

#### Metazachlor

**Status of the active substance:** Approved  
**Code no.:**  
**LOQ (mg/kg bw):** Proposed LOQ:  
**ADI (mg/kg bw per day):** 0.08  
**ARfD (mg/kg bw):** 0.5  
**Source of ADI:** COM  
**Source of ARfD:** COM  
**Year of evaluation:** 2012  
**No of diets exceeding ADI:** ---

#### Highest calculated TMDI values in % of ADI

| MS Diet            | Commodity/ group of commodities | TMDI (range) in % of ADI | No of diets exceeding ADI |
|--------------------|---------------------------------|--------------------------|---------------------------|
| FR toddler         | Milk and cream                  | 0.5                      | 0.5 Milk and cream        |
| NL child           | Milk and cream                  | 0.2                      | 0.1 Swine: Meat           |
| UK infant          | Milk and cream                  | 0.2                      | 0.1 Birds’ eggs           |
| DE child           | Milk and cream                  | 0.2                      | 0.1 Turnips               |
| UK Toddler         | Milk and cream                  | 0.2                      | 0.1 Swine: Meat           |
| SE general population 90th percentile | Milk and cream | 0.2                      | 0.1 Swine: Meat           |
| YHCHO Cluster diet F | Milk and cream          | 0.1                      | 0.1 Turnips               |
| IE adult           | Milk and cream                  | 0.1                      | 0.1 Swine: Meat           |
| WHO regional European diet | Milk and cream | 0.1                      | 0.1 Birds’ eggs           |
| WHO Cluster diet B | Milk and cream                  | 0.1                      | 0.1 Swine: Meat           |
| WHO Cluster diet E | Milk and cream                  | 0.1                      | 0.1 Birds’ eggs           |
| WHO Cluster diet D | Milk and cream                  | 0.1                      | 0.1 Birds’ eggs           |
| DK child           | Milk and cream                  | 0.2                      | 0.1 Birds’ eggs           |
| NL general         | Milk and cream                  | 0.1                      | 0.1 Swine: Meat           |
| ES adult           | Milk and cream                  | 0.1                      | 0.1 Birds’ eggs           |
| LT adult           | Milk and cream                  | 0.2                      | 0.1 Birds’ eggs           |
| FR all population  | Milk and cream                  | 0.2                      | 0.1 Birds’ eggs           |
| DK adult           | Milk and cream                  | 0.1                      | 0.1 Birds’ eggs           |
| FI adult           | Milk and cream                  | 0.1                      | 0.1 Birds’ eggs           |
| UK vegetarian      | Milk and cream                  | 0.1                      | 0.1 Birds’ eggs           |
| UK Adult           | Milk and cream                  | 0.1                      | 0.1 Birds’ eggs           |
| PL general population | Head cabbage                  | 0.1                      | 0.1 Birds’ eggs           |
| PT General population | Sunflower seed              | 0.1                      | 0.1 Birds’ eggs           |
| IT adult           | Milk and cream                  | 0.1                      | 0.1 Birds’ eggs           |
| IT kid/toddler     | Milk and cream                  | 0.1                      | 0.1 Birds’ eggs           |

#### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Metazachlor (Sum of metabolites 479M04, 479M08 and 479M16, expressed as metazachlor) is unlikely to present a public health concern.
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.

### Acute risk assessment/children – refined calculations

**Acute risk assessment/adults/general population – refined calculations**

| 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: |
|---|---|---|
| Highest % of ARfD/ADI | Highest % of ARfD/ADI | Highest % of ARfD/ADI |
| Commodity | pTMRL/ threshold MRL (mg/kg) | Commodity | pTMRL/ threshold MRL (mg/kg) | Commodity | pTMRL/ threshold MRL (mg/kg) |
| 4.7 Swedes 0.45/- | 4.7 Swedes 0.45/- | 4.7 Swedes 0.38/- | 2.4 Head cabbage 0.25/- | 2.4 Head cabbage 0.25/- | 2.4 Head cabbage 0.38/- |
| 4.0 Head cabbage 0.38/- | 4.0 Head cabbage 0.38/- | 2.8 Cauliflower 0.21/- | 2.8 Cauliflower 0.21/- | 2.8 Cauliflower 0.21/- | 2.8 Cauliflower 0.24/- |
| 3.2 Tumbs 0.45/- | 3.2 Tumbs 0.45/- | 2.4 Kohlrabi 0.24/- | 2.4 Kohlrabi 0.24/- | 2.4 Kohlrabi 0.24/- | 2.4 Kohlrabi 0.24/- |
| 2.8 Cauliflower 0.21/- | 2.8 Cauliflower 0.21/- | 1.7 Broccoli 0.21/- | 1.7 Broccoli 0.21/- | 1.7 Broccoli 0.21/- | 1.7 Broccoli 0.21/- |
| 2.4 Kohlrabi 0.24/- | 2.4 Kohlrabi 0.24/- | 1.4 Kale 0.14/- | 1.4 Kale 0.14/- | 1.4 Kale 0.14/- | 1.4 Kale 0.14/- |
| 1.9 Kale 0.14/- | 1.9 Kale 0.14/- | 0.5 Bovine: Liver 0.34/- | 0.5 Bovine: Liver 0.34/- | 0.5 Bovine: Liver 0.34/- | 0.5 Bovine: Liver 0.34/- |
| 0.5 Bovine: Liver 0.34/- | 0.5 Bovine: Liver 0.34/- | 0.09 Brussels sprouts 0.05/- | 0.09 Brussels sprouts 0.05/- | 0.09 Brussels sprouts 0.05/- | 0.09 Brussels sprouts 0.05/- |
| 0.03 Swine: Liver 0.13/- | 0.03 Swine: Liver 0.13/- | 0.02 Horseradish 0.45/- | 0.02 Horseradish 0.45/- | 0.02 Horseradish 0.45/- | 0.02 Horseradish 0.45/- |
| 0.02 Horseradish 0.45/- | 0.02 Horseradish 0.45/- | 0.4 Apple juice 0.02/- | 0.4 Apple juice 0.02/- | 0.4 Apple juice 0.02/- | 0.4 Apple juice 0.02/- |
| 0.4 Apple juice 0.02/- | 0.4 Apple juice 0.02/- | 0.4 Orange juice 0.02/- | 0.4 Orange juice 0.02/- | 0.4 Orange juice 0.02/- | 0.4 Orange juice 0.02/- |
| 0.2 Orange juice 0.02/- | 0.2 Orange juice 0.02/- | 0.2 Orange juice 0.02/- | 0.2 Orange juice 0.02/- | 0.2 Orange juice 0.02/- | 0.2 Orange juice 0.02/- |
| 0.2 Carrot, juice 0.02/- | 0.2 Carrot, juice 0.02/- | 0.2 Carrot, juice 0.02/- | 0.2 Carrot, juice 0.02/- | 0.2 Carrot, juice 0.02/- | 0.2 Carrot, juice 0.02/- |
| 0.1 Grape juice 0.02/- | 0.1 Grape juice 0.02/- | 0.01 Pineapplle preserves 0.02/- | 0.01 Pineapplle preserves 0.02/- | 0.01 Pineapplle preserves 0.02/- | 0.01 Pineapplle preserves 0.02/- |
| 0.1 Peach juice 0.02/- | 0.1 Peach juice 0.02/- | 0.01 Peach preserves with syrup 0.02/- | 0.01 Peach preserves with syrup 0.02/- | 0.01 Peach preserves with syrup 0.02/- | 0.01 Peach preserves with syrup 0.02/- |
| 0.1 Pear juice 0.02/- | 0.1 Pear juice 0.02/- | 0.01 Tomato juice (pressed) 0.02/- | 0.01 Tomato juice (pressed) 0.02/- | 0.01 Tomato juice (pressed) 0.02/- | 0.01 Tomato juice (pressed) 0.02/- |
| 0.1 Tomato juice 0.02/- | 0.1 Tomato juice 0.02/- | 0.01 Elderberry juice 0.02/- | 0.01 Elderberry juice 0.02/- | 0.01 Elderberry juice 0.02/- | 0.01 Elderberry juice 0.02/- |
| 0.1 Elderberry juice 0.02/- | 0.1 Elderberry juice 0.02/- | 0.01 Kiwi juice 0.02/- | 0.01 Kiwi juice 0.02/- | 0.01 Kiwi juice 0.02/- | 0.01 Kiwi juice 0.02/- |
| 0.1 Kiwi juice 0.02/- | 0.1 Kiwi juice 0.02/- | 0.01 Plum preserves 0.02/- | 0.01 Plum preserves 0.02/- | 0.01 Plum preserves 0.02/- | 0.01 Plum preserves 0.02/- |
| 0.1 Plums juice 0.02/- | 0.1 Plums juice 0.02/- | 0.01 Quince jelly 0.02/- | 0.01 Quince jelly 0.02/- | 0.01 Quince jelly 0.02/- | 0.01 Quince jelly 0.02/- |
| 0.1 Quince jelly 0.02/- | 0.1 Quince jelly 0.02/- | 0.01 Potato uree (flakes) 0.02/- | 0.01 Potato uree (flakes) 0.02/- | 0.01 Potato uree (flakes) 0.02/- | 0.01 Potato uree (flakes) 0.02/- |
| 0.05 Potato uree (flakes) 0.02/- | 0.05 Potato uree (flakes) 0.02/- | 0.03 Fried potatoes 0.02/- | 0.03 Fried potatoes 0.02/- | 0.03 Fried potatoes 0.02/- | 0.03 Fried potatoes 0.02/- |

**Summary:**

- 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 (Sum of metabolites 479M04, 479M08 and 479M16, expressed as 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.

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### Appendix D – Input values for the exposure calculations

#### D.1. Livestock dietary burden calculations

| Feed commodity                  | Median dietary burden | Maximum dietary burden |
|---------------------------------|-----------------------|------------------------|
|                                 | Input value (mg/kg)   | Comment                |
| **Feed items included in dietary burden calculation scenario 1 and 2** |                       |                        |
| Cabbage heads, leaves           | 0.05                   | STMR (old + new data)  |
| Kale leaves (forage)           | 0.06                   | STMR (old + new data)  |
| Linseed meal                  | 0.05                   | $\times \text{PF}(a)$ (EFSA, 2014) |
| Sunflower meal               | 0.05                   | $\times \text{PF}(a)$ (EFSA, 2014) |
| Rape seed meal               | 0.05                   | $\times \text{PF}(a)$ (EFSA, 2014) |
| **Feed items included only in dietary burden calculation scenario 1** |                       |                        |
| Turnip, tops (leaves)         | 1.20                   | STMR (tentative)       |
| Swede roots                 | 0.26                   | STMR (tentative)       |
| Turnip roots                 | 0.26                   | STMR (tentative)       |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

(a): For oilseed meals, in the absence of processing factors supported by data, a processing factor of 1 was applied in the framework of the MRL review (EFSA, 2014). Residues are expected to be below the LOQ and their concentration in meal is therefore not expected.

#### D.2. Consumer risk assessment

| Commodity                       | Chronic risk assessment | Acute risk assessment |
|---------------------------------|-------------------------|-----------------------|
|                                 | Input value (mg/kg)     | Comment               |
|                                 |                         | Input value (mg/kg)   | Comment               |
| Radishes                        | (a)                     | (a)                   |
| Horseradishes                   | 0.26                    | STMR (tentative)(b)   | 0.45                  | HR (tentative)(b)    |
| Turnips                         | 0.26                    | STMR (tentative)(b)   | 0.45                  | HR (tentative)(b)    |
| Swedes                          | 0.26                    | STMR (tentative)(b)   | 0.45                  | HR (tentative)(b)    |
| Garlic                          | 0.05                    | STMR (EFSA, 2014)     |
| Flowering brassica             | 0.05                    | STMR                  | 0.21                  | HR                    |
| Brussels sprouts               | 0.05                    | STMR                  | 0.05                  | HR                    |
| Head cabbages                  | 0.05                    | STMR                  | 0.38                  | HR                    |
| Chinese cabbages               | 0.135                   | STMR (EFSA, 2018)     |
| Kales                           | 0.06                    | STMR                  | 0.14                  | HR                    |
| Kohlrabies                      | 0.10                    | STMR                  | 0.24                  | HR                    |
| Globe artichokes               | 0.05                    | STMR (EFSA, 2014)     | Acute risk assessment undertaken only with regard to the crops under consideration |
| Leek                            | 0.05                    | STMR (EFSA, 2014)     |
| Linseed, Rape seed             | 0.05                    | STMR (EFSA, 2014)     |
| Sunflower seed                 | 0.05                    | STMR (EFSA, 2014)     |
| Mustard seed, Borage           | 0.05                    | STMR (EFSA, 2014)     |
| Gold of pleasure               | 0.05                    | STMR (EFSA, 2014)     |
| Swine meat                      | 0.05                    | MRL (LOQ) (EFSA, 2014) |
| Swine fat                       | 0.05                    | MRL (LOQ) (EFSA, 2014) |
| Swine liver                     | 0.07                    | STMR (incl. tentative use) | 0.13 | HR (incl. tentative use) |
| Commodity                        | Chronic risk assessment | Acute risk assessment |
|---------------------------------|-------------------------|-----------------------|
|                                 | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment            |
| Swine kidney                    | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Swine edible offal              | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Swine, other products          | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Ruminant meat                  | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Ruminant fat                   | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Bovine, liver                  | 0.14                    | STMR (inc. tentative use) | 0.34          | HR (incl. tentative use) |
| Sheep, goat, liver             | 0.11                    | STMR (inc. tentative use) | 0.26          | HR (incl. tentative use) |
| Ruminant kidney                | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Ruminant edible offal          | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Ruminant other products        | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Horse meat, fat                | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Horse liver                    | 0.4                     | Proposed MRL (incl. tentative use) | 0.4          | Proposed MRL (incl. tentative use) |
| Horse edible offal             | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Horse other products           | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Poultry products               | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Other farm animals’ muscle     | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Other farm animals’ fat        | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Other farm animals’ liver      | 0.4                     | Proposed MRL (incl. tentative use) | 0.4          | Proposed MRL (incl. tentative use) |
| Other farm animals’ kidney     | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Other farm animals’ edible offal | 0.05                  | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Other farm animals’ other products | 0.05               | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Milk                           | 0.01                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Birds’ eggs                    | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |
| Honey                          | 0.05                    | MRL (LOQ) (EFSA, 2014)|                      |                    |

(a): The use on radishes assessed in the framework of the Article 12 of Regulation (EC) No 396/2005 (EFSA, 2014) is no longer supported by the applicant.

(b): Tentative as the intended uses on horseradishes, turnips and swedes are not fully supported according to currently applicable data requirements and applicable guidance documents.
### Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|-----------------------------------------------|---------------------------------|
| metazachlor                     | 2-chloro-N-(pyrazol-1-ylmethyl)acet-2',6'-xylidide | ![Structural formula](image1) |
|                                 | O=C(CCl)(N(Cn1ccc1)c2c(C)ccc2C)               | ![Structural formula](image2) |
|                                 | STEPQTYSZVCJPV-UHFFFAOYSA-N                  | ![Structural formula](image3) |
| 479M04 (M479H004)               | [(2,6-dimethylphenyl)(1H-pyrazol-1-ylmethyl)amino] | ![Structural formula](image4) |
|                                 | (oxo)acetic acid                             | ![Structural formula](image5) |
|                                 | O=C(N(Cn1ccc1)c2c(C)ccc2C)(-O)O               | ![Structural formula](image6) |
|                                 | PHMHVVKFXZNTKU-UHFFFAOYSA-N                  | ![Structural formula](image7) |
| 479M08 (M479H008)               | 2-[(2,6-dimethylphenyl)(1H-pyrazol-1-ylmethyl)amino]-2-oxoethanesulfonic acid | ![Structural formula](image8) |
|                                 | O=C(CS(-O)(-O)O)(N(Cn1ccc1)c2c(C)ccc2C)       | ![Structural formula](image9) |
|                                 | IPVCSECPEVHQOV-UHFFFAOYSA-N                  | ![Structural formula](image10) |
|                                 | sodium 2-[(2,6-dimethylphenyl)(1H-pyrazol-1-ylmethyl)amino]-2-oxoethanesulfonate | ![Structural formula](image11) |
|                                 | [Na+].O=C(CS([-O-])(-O)=O)(N(Cn1ccc1)c2c(C)ccc2C) | ![Structural formula](image12) |
|                                 | PCVFIVBODVWPQX-UHFFFAOYSA-M                  | ![Structural formula](image13) |
| 479M16 (M479H016)               | 3-[(2,6-dimethylphenyl)(1H-pyrazol-1-ylmethyl)amino]-2-oxoethyl sulfanyl]-2-hydroxypropanoic acid | ![Structural formula](image14) |
|                                 | O=C(CS(-O)CC(O)(-O)O)(N(Cn1ccc1)c2c(C)ccc2C)   | ![Structural formula](image15) |
|                                 | RTFJGJZKLFURCR-UHFFFAOYSA-N                  | ![Structural formula](image16) |

<sup>(a)</sup>: The metabolite name in bold is the name used in the conclusion.

<sup>(b)</sup>: ACD/Name 2018.2.2 ACD/Labs 2018 Release (File version N50E41, Build 103230, 21 Jul 2018).

<sup>(c)</sup>: ACD/ChemSketch 2018.2.2 ACD/Labs 2018 Release (File version C60H41, Build 106041, 7 Dec 2018).