Review of the existing maximum residue levels for metobromuron according to Article 12 of Regulation (EC) No 396/2005

European Food Safety Authority (EFSA),
Giulia Bellisai, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Lucien Ferreira,
German Giner, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner,
Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich,
Silvia Ruocco, Miguel Santos, Alessia Pia Scarlato, Anne Theobald, Benedicte Vagenende and
Alessia Verani

Abstract
According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance metobromuron. To assess the occurrence of metobromuron residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EU) No 188/2011 as well as the European authorisations reported by Member States and the United Kingdom (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and all MRL proposals derived by EFSA still require further consideration by risk managers.

© 2021 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: metobromuron, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, herbicide

Requestor: European Commission
Question number: EFSA-Q-2014-00593
Correspondence: pesticides.mrl@efsa.europa.eu
Declarations of interest: The declarations of interest of all scientific experts active in EFSA’s work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Acknowledgement: EFSA wishes to thank the rapporteur Member State, France, for the preparatory work and Stathis Anagnos, Laszlo Bura, Andrea Mioc, Marta Szot, Aikaterini Vlachou for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Giner G, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2021. Reasoned Opinon on the review of the existing maximum residue levels for metobromuron according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2021;19 (9):6841, 42 pp. https://doi.org/10.2903/j.efsa.2021.6841

ISSN: 1831-4732

© 2021 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

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

Metobromuron was approved on 1 January 2015 by means of Commission Implementing Regulation (EU) No 890/2014 in the framework of Regulation (EC) No 1107/2009 as amended by Commission Implementing Regulations (EU) No 540/2011 and 541/2011.

As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation.

As the basis for the MRL review, on 15 May 2020, EFSA initiated the collection of data for this active substance. In a first step, Member States and the UK were invited to submit by 15 June 2020 their national good agricultural practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State, France, to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States and the UK were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 2 October 2020. On the basis of all the data submitted by Member States, the UK and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file, were provided by the RMS to EFSA on 18 December 2020. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States, the UK and the EURLs, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EU) No 188/2011, EFSA prepared in June 2021 a draft reasoned opinion, which was circulated to Member States and EURLs for consultation via a written procedure. Comments received by 07 July 2021 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of metobromuron in plant was investigated in primary and rotational crops. According to the results of the metabolism studies and the available residue trials, the residue definitions for enforcement can be proposed as the 'sum of metobromuron and 4-bromophenylurea, expressed as metobromuron'; and for risk assessment as 'total hydrolysable residues analysed as 4-bromoaniline and expressed as metobromuron'. These residue definitions are limited to soil applications only and are also applicable to rotational crops. A residue definition is not necessary for processed commodities since in all raw commodities, residues were below 0.1 mg/kg except in lamb's lettuce which is expected to be consumed raw and the total theoretical maximum daily intake is not exceeding 10% of the acceptable daily intake (ADI).

Analytical methods are available for the enforcement of the proposed residue definition in high water, high oil, high acid matrices and dry commodities at the combined limit of quantification (LOQ) of 0.01 mg/kg; however, extraction efficiency data are still required. According to the EURLs, a combined LOQ of 0.02 mg/kg is achievable by using the QuEChERS method in routine analyses in all four matrix groups.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. Considering the general data gap on the analytical method identified for matrices with high water, high oil, high acid content and dry commodities, as well as the need for additional trials and storage stability study on lamb's lettuce, all MRLs are tentative. No MRLs are needed for rotational crops provided that Member States will adopt adequate risk mitigation measures to avoid the occurrence of significant residues in rotational crops.

Metobromuron is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for all livestock groups were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues should therefore be assessed in all groups of livestock. However, no studies investigating the behaviour of metobromuron residues were available for this review, and no residue definitions nor MRLs could be derived for animal commodities. It is underlined that the dietary burden calculations showed that potato is the major contributor to the livestock exposure. In case the use of metobromuron on potato would be withdrawn, further investigation in livestock would not be needed.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. For all animal
commodities, where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 10% of the ADI (NL toddler) and the highest acute exposure amounted to 1% of the acute reference dose (ARfD) (potato).
Table of contents

Abstract................................................................................................................................................... 1
Summary................................................................................................................................................. 3
Background ............................................................................................................................................. 6
Terms of Reference .................................................................................................................................. 7
The active substance and its use pattern ............................................................................................... 7
Assessment.............................................................................................................................................. 8
1. Residues in plants .......................................................................................................................... 8
   1.1. Nature of residues and methods of analysis in plants.................................................................... 8
       1.1.1. Nature of residues in primary crops .......................................................................................... 8
       1.1.2. Nature of residues in rotational crops ....................................................................................... 9
       1.1.3. Nature of residues in processed commodities ........................................................................... 9
       1.1.4. Methods of analysis in plants .................................................................................................... 9
       1.1.5. Stability of residues in plants ................................................................................................... 10
       1.1.6. Proposed residue definition ..................................................................................................... 10
   1.2. Magnitude of residues in plants .................................................................................................... 11
       1.2.1. Magnitude of residues in primary crops .................................................................................... 11
       1.2.2. Magnitude of residues in rotational crops ............................................................................... 12
       1.2.3. Magnitude of residues in processed commodities ..................................................................... 12
       1.2.4. Proposed MRLs ....................................................................................................................... 12
2. Residues in livestock ....................................................................................................................... 12
3. Consumer risk assessment .............................................................................................................. 13
Conclusions.............................................................................................................................................. 13
Recommendations.................................................................................................................................... 14
References............................................................................................................................................... 16
Abbreviations ........................................................................................................................................... 17
Appendix A – Summary of authorised uses considered for the review of MRLs ................................ 19
Appendix B – List of end points ............................................................................................................ 24
Appendix C – Pesticide Residue Intake Model (PRIMo) ...................................................................... 35
Appendix D – Input values for the exposure calculations ................................................................. 37
Appendix E – Decision tree for deriving MRL recommendations ...................................................... 39
Appendix F – Used compound codes ................................................................................................. 41
Background

Regulation (EC) No 396/2005¹ (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level.

Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide, within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC² a reasoned opinion on the review of the existing MRLs for that active substance.

As metobromuron was approved on 01 January 2015 by means of Commission Implementing Regulation (EU) No 890/2014³ in the framework of Regulation (EC) No 1107/2009⁴ as amended by Commission Implementing Regulations (EU) No 540/2011⁵ and 541/2011⁶, EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Commission Regulation (EU) No 188/2011⁷, metobromuron was evaluated by France, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2014). Furthermore, according to the provisions of the approval regulation, confirmatory information was requested, among others, as regards the toxicological assessment of the metabolites desmethoxy-metobromuron, 4-bromophenylurea and desmethyl-metobromuron to be submitted by 31 December 2016. Confirmatory data were submitted and assessed by EFSA and it was concluded that properties and reference values of the parent metobromuron are applicable to these metabolites (EFSA, 2019b).

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC repealed by Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Regulation (EC) No 1107/2009 is therefore insufficient for the assessment of all existing MRLs for a given active substance.

To gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;
- the analytical methods for enforcement of the proposed MRLs.

---

¹ Regulation (EC) No 396/2005 of the European 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 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. Repealed by Regulation (EC) No 1107/2009.
³ Commission Implementing Regulation (EU) No 890/2014 of 14 August 2014 approving the active substance metobromuron, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 243, 15.8.2014, p. 42-46.
⁴ 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.
⁵ Commission Implementing Regulation (EU) No 540/2011 of 25 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.
⁶ Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 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. 187-188.
⁷ Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ L 53, 26.2.2011, p. 51-55.
As the basis for the MRL review, on 15 May 2020, EFSA initiated the collection of data for this active substance. In a first step, Member States and the UK8 were invited to submit by 15 June 2020 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation, 19 Member States and the UK provided feedback on their national authorisations of metobromuron. Based on the GAP data submitted, the designated RMS, France, was asked to identify the critical GAPs to be further considered in the assessment, in the format of a specific GAP overview file. Subsequently, in a second step, Member States and the UK were requested to provide residue data supporting the critical GAPs by 2 October 2020.

On the basis of all the data submitted by Member States, the UK and the EU Reference Laboratories for Pesticides Residues (EURLs), EFSA asked France to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file, were submitted to EFSA on 18 December 2020. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information, EFSA prepared in June 2021 a draft reasoned opinion, which was circulated to Member States and EURLs for commenting via a written procedure. All comments received by 07 July 2021 considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (France, 2020), taking into account also the information provided by Member States and the UK during the collection of data, and the EURLs report on analytical methods (EURLs, 2020) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 2021a) and the Member States consultation report (EFSA, 2021b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) and the PROFile as well as the GAP overview file listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo is presented in Appendix C.

Terms of Reference

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

The active substance and its use pattern

Metobromuron is the ISO common name for 3-(4-bromophenyl)-1-methoxy-1-methylurea (IUPAC). The chemical structure of the active substance and its main metabolites are reported in Appendix F. For metobromuron default MRL of 0.01 mg/kg is established according to Art 18(1)(b) of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for metobromuron are not available. There are no MRL changes occurred since the entry into force of the Regulation mentioned above.

For the purpose of this MRL review, all the uses of metobromuron currently authorised within the EU as submitted by the Member States and the UK during the GAP collection have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAPs for metobromuron are given in Appendix A.

8 The United Kingdom withdrew from EU on 1 February 2020. In accordance with the Agreement on the Withdrawal of the United Kingdom from the EU, and with the established transition period, the EU requirements on data reporting also apply to the United Kingdom data collected until 31 December 2020.
Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (France, 2020);
- the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (France, 2013a,b);
- the conclusion on the peer review of the pesticide risk assessment of the active substance metobromuron (EFSA, 2014);
- the technical report on the outcome of the consultation on the pesticide risk assessment for metobromuron in light of confirmatory data (EFSA, 2019b);
- the review report on metobromuron (European Commission, 2014).

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

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 metobromuron was investigated after one pre-emergence soil application of 2.5 kg a.s./ha on potato, representative of root and tuber vegetable group (France, 2013a,b) and assessed in the framework of the peer review (EFSA, 2014). In this study, metobromuron was radiolabelled in the phenyl ring of the molecule.

At harvest, metobromuron was neither detected in tubers nor in foliage. The total radioactive residues (TRRs) of the most relevant metabolite, 4-bromophenylurea in tubers amounted up to 18.2% (0.017 mg eq/kg) and in foliage up to 10.3% (0.018 mg eq/kg). In foliage also desmethyl-metobromuron was detected at 13.8% TRR (0.024 mg eq/kg) together with a minor metabolite, desmethoxy-metobromuron at 7.1% TRR (0.012 mg eq/kg).

Additional metabolism studies with soil application of metobromuron labelled in the phenyl ring on leafy vegetables and pulses and oilseeds were evaluated and submitted in the framework of this MRL review (France, 2020).

After one pre-emergence soil application of 750 g a.s./ha on lamb’s lettuce, parent metobromuron was not found in any sample of immature or mature lamb’s lettuce. Both in mature and immature leaves, the most relevant metabolites were the glucoside conjugates of 4-bromophenylurea (HHAC-073), which amounted to 17.4% TRR (0.42 mg eq/kg) and 24.7% TRR (0.006 mg eq/kg), respectively. The glucoside conjugate of desmethyl-metobromuron (HHAC-079) was identified as the second major metabolite accounting for 9% TRR (0.219 mg/kg) in immature leaves. Other metabolites were identified, however, at lower levels; among these also 4-bromophenylurea was detected in mature leaves at 7.8% TRR (0.019 mg eq/kg).

After one pre-emergence soil application of 1.5 kg a.s./ha on sunflowers, the major component identified in seeds was 4-bromophenylurea, representing 17.3% TRR (0.005 mg eq/kg), HHAC-073 also was predominant (14% TRR; 0.006 mg eq/kg). 4-bromophenylurea was present at 43.7% TRR (0.02 mg eg/kg) in heads, 13.3% TRR (0.0825 mg eq/kg) in stalks and at 3.8% TRR (0.008 mg eq/kg) in immature plants. The main metabolites identified in significant proportions in immature plant are the glucose conjugates of metobromuron; metabolites HHAC-090, HHAC-073, HHAC-091 but not detected anymore at harvest in the edible part of the plant. Parent metobromuron was not found in any samples (France, 2020).

The metabolic pathway of metobromuron was similar in leafy vegetables, roots and oilseeds.

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.
1.1.2. Nature of residues in rotational crops

Metobromuron is authorised on crops that may be grown in rotation. The field DT$_{90}$ for metobromuron reported in the soil degradation studies evaluated in the framework of the peer review was 243.6 days (EFSA, 2014). Therefore, further investigation on the nature of the residue in rotational crops is required.

One confined rotational crop study with metobromuron radiolabelled on the phenyl ring was available for this review and assessed during the peer review for approval (France, 2013a,b; EFSA, 2014). Metobromuron was applied at a rate of 2.5 kg a.s./ha onto bare soil. The nature of residues in rotated crops was determined in lettuce, wheat, sugar beet and corn. The study was not fully compliant with EU guidelines because of lack of data for all crop/plant back interval combinations (lettuce was planted 30 days and 1 year after application, wheat was sown 6 months after application, sugar beet and corn 1 year after treatment); therefore, it was not considered further in the assessment. A new confined rotational crop study has been submitted for the current MRL review (France, 2020).

In this study, bare soil was treated once with [phenyl-14C]-metobromuron at a nominal application rate of 2 kg a.s./ha. Crops were planted at plant back intervals (PBI) of 30 and 120 days after treatment (DAT). Crops planted at each interval consisted of leafy vegetable (spinach), roots (carrot) and cereals (wheat).

Residues in all three crops declined over time. In the mature spinach, the most relevant metabolite was 4-bromophenylurea, identified at 0.013 mg/kg (7.4% of TRR) at 30-day PBI and declined to 0.001 mg/kg (2.4% of TRR) at 120 PBI. HHAC-091 was the main metabolite in all the wheat plant parts with values from 10.9% TRR (0.044 mg/kg) in mature straw to 36.1% TRR (0.183 mg/kg) in immature forage. For wheat, 4-bromophenylurea was the highest metabolite only in immature grain with 1.8% TRR (0.002 mg/kg). In straw, 4-bromophenylurea was identified as the second major metabolite and it declined from 0.201 mg/kg (11.7% TRR) to 0.027 mg/kg (6.7% TRR) at 30 and 120 days, respectively. At 120 days PBI, metabolite HHAC-091 was above 0.01 mg/kg (0.019 mg/kg – 21.5% TRR) in carrot foliage.

Based on these results, it is concluded that the metabolism and distribution of metobromuron in rotational crops are similar to the metabolic pathway observed in primary crops.

1.1.3. Nature of residues in processed commodities

There were no studies investigating the nature of residues of metobromuron in processed commodities available for this review. Nevertheless, in all raw commodities, residues were below 0.1 mg/kg except in lamb’s lettuce which is expected to be consumed raw (see Appendix B.1.2.1) and the total theoretical maximum daily intake is not exceeding 10% of the acceptable daily intake (ADI). Therefore, the investigation of the nature of residues in processed commodities is not required.

1.1.4. Methods of analysis in plants

During the peer review (France, 2013a,b; EFSA, 2014), a hyphenated analytical method based on high-performance liquid chromatography (HPLC) coupled to MS/MS detection (QuEChERS multiresidue method) was validated in high water content matrices (potato and lamb’s lettuce), with individual LOQs of 0.005 mg/kg for each analyte (metobromuron, desmethyl-metobromuron, desmethoxy-metobromuron and 4-bromophenylurea).

In the framework of the current review (France, 2020), additional validation data were provided. The QuEChERS method based on HPLC-MS/MS technique was validated in high oil content matrices (sunflower seeds), in high acid content matrices (oranges) and in dry commodities (wheat straw), with individual LOQs of 0.005 mg/kg for each analyte (metobromuron, desmethyl-metobromuron, desmethoxy-metobromuron and 4-bromophenylurea).

This method is supported by independent laboratory validations (ILV) performed in high water (potato and lamb’s lettuce) and in high oil content commodities (sunflower seeds). However, in line with the EFSA conclusion on the peer review (EFSA, 2014), data to address the extraction efficiency of the enforcement method provided are required (data gap).

During the completeness check, the EURLs provided QuEChERS multiresidue analytical methods for the routine analysis of metobromuron and metabolite 4-bromophenylurea in high water content, high acid content, high oil content and dry matrices. According to the EURLs, for metobromuron and 4-
bromophenylurea, the default LOQ of 0.01 mg/kg is achievable in the four matrix groups and even lower levels were successfully validated (down to 0.005 and 0.002 mg/kg) (EURLs, 2020).

1.1.5. Stability of residues in plants

The storage stability of parent metobromuron and its metabolites desmethyl-metobromuron, desmethoxy-metobromuron, 4-bromophenylurea was investigated in high water content commodities (potatoes and lamb’s lettuce) in the framework of the peer review (France, 2013a,b; EFSA, 2014). According to the conclusion, they have been shown to be stable for at least 12 months in samples stored at -18°C.

In the framework of this MRL review, the storage stability of metobromuron and its three metabolites (desmethyl-metobromuron, desmethoxy-metobromuron and 4-bromophenylurea) was further investigated in carrot, grape, green bean (high water content commodities) and dry bean (dry commodities). It has been demonstrated that all four compounds are stable for up to 36 months when samples are stored at or below -18°C in carrot, grape and dry bean. In green bean, however, only the parent and desmethoxy-metobromuron were stable for 36 months, while a significant degradation was observed after 12 months for 4-bromophenylurea and desmethyl-metobromuron (France, 2020).

Additional storage stability studies were also submitted for high oil content commodities (sunflower seed). In this commodity, storage stability for metobromuron, desmethyl-metobromuron, desmethoxy-metobromuron was demonstrated for up to 24 months; while for 4-bromophenylurea, a significant degradation was observed after 12 months (France, 2020).

1.1.6. Proposed residue definition

The metabolism of metobromuron was similar in all crops assessed. A similar metabolic pathway was observed in primary crops and rotational crops. The effect of processing on the nature of residues was not investigated; however, a specific residue definition in processed commodities is not required since in all raw commodities residues were below 0.1 mg/kg (except in lamb’s lettuce which is expected to be consumed raw) and the total theoretical maximum daily intake is not exceeding 10% of the acceptable daily intake (ADI).

During the peer review, metabolite 4-bromophenylurea was found to be the only relevant compound to be included in the enforcement residue definition for the representative use on potatoes, as the parent compound was not detected in roots (EFSA, 2014). The new metabolism studies assessed under this review confirmed that parent metobromuron is not a sufficient marker, as it is not detected neither in lamb’s lettuce (leafy vegetables) nor in sunflower seeds (oilseeds). Nevertheless, in the metabolism study on lamb’s lettuce (which has a shorter crop cycle compared to sunflowers seeds and potatoes), 4-bromophenylurea was not the predominant compound while the glucoside conjugates of 4-bromophenylurea (HHAC-073) and of desmethyl-metobromuron (HHAC-079) were the main identified metabolites. Moreover, metobromuron parent was measured in significant levels (up to 0.2 mg/kg) in residue trials on lamb’s lettuce (France, 2020). Therefore, the residue definition for enforcement is proposed as the sum of metobromuron and 4-bromophenylurea, expressed as metobromuron. This residue definition is limited to soil treatments only and is also applicable to rotational crops.

An analytical method for the enforcement of the proposed residue definition at the combined LOQ of 0.01 mg/kg in high water, high acid, high oil content matrices and dry commodities is available although data to address the extraction efficiency of this method is still required (EFSA, 2014; France, 2020). According to the EURLs, a default combined LOQ of 0.02 mg/kg is achievable by using the QuEChERS method in routine analyses in all matrix groups (EURLs, 2020).

For risk assessment, during the peer review, a residue definition was proposed as total hydrolysable residues analysed as 4-bromoaniline and expressed as parent metobromuron (EFSA, 2014). This residue definition will include the parent and the metabolites with 4-bromoaniline moiety that might be present at significant levels in the edible crops according to the metabolism studies and the residue trials: desmethoxy-metobromuron, desmethyl-metobromuron, 4-bromophenylurea, the glucoside conjugates of 4-bromophenylurea (HHAC-073) and of desmethyl-metobromuron (HHAC-079). This residue definition is limited to soil treatments only and is also applicable to rotational crops. In light of

\[10\] Although based on the different molecular weights of metobromuron and 4-bromophenylurea the calculated combined LOQ for enforcement of the residue proposed definition would be 0.011 mg/kg, it is proposed to consider the default LOQ of 0.01 mg/kg.
the confirmatory data provided on the toxicological profile of several metabolites, it was concluded that the toxicological properties and reference values of the parent metobromuron are applicable to metabolites desmethoxy-metobromuron, desmethyl-metobromuron and 4-bromophenylurea (EFSA, 2019b). In addition, the new toxicological studies provided under this review also concluded that metabolite HHAC-073, predominant in mature leaves of lamb’s lettuce (see Section 1.1.1), shares the same profile as parent metobromuron (France, 2020).

Thus, it is concluded that the proposed residue definition ‘total hydrolysable residues analysed as 4-bromoaniline and expressed as parent metobromuron’ is still applicable under the current review (both for primary and rotational crops) and would allow to consider all relevant metabolites identified in the metabolism studies or that are significant in the residue trials.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of metobromuron residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (France, 2020) as well as the residue trials evaluated in the framework of the peer review (France, 2013a,b; EFSA, 2014). All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated, except for two trials on lamb’s lettuce for which samples were stored for 16 months. According to the RMS, as no decline in recovery of residues of metobromuron and its three metabolites was observed for a storage period up to 12 months and a reduction of 30% in recovery is not expected in four additional months (storage period up to 16 months), lamb’s lettuce samples of field trials stored for up to 16 months could be considered to support the MRL proposal (France, 2020). Nevertheless, considering that results from these trials are the lowest values and that a degradation of 4-bromophenylurea was observed after 12 months in another high-water content commodity (green beans, see Section 1.1.5), an additional storage stability study on lamb’s lettuce covering a longer storage period is still required to confirm the results from these two trials (data gap).

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

Residue trials are not available to support the authorisations on strawberries, carrots, parsnips, celery leaves, spinach, watercress, dry peas, dry beans, parsley, sage, thyme, basil, Florence fennel and asparagus. Nevertheless, for all these crops, no residue trials are considered necessary, since no residues are expected in the edible part of the crops at harvest, taking note of the following considerations:

- Strawberries: following the current GAP, metobromuron is authorised for pre-emergence application only the year strawberry plants are planted, and strawberries are not intended for human consumption the first year after planting.
- Asparagus: following the current GAP, metobromuron is only applied once the edible part of the crop is harvested and long before the next harvest.
- All other crops of the list mentioned above: following the GAPs, the use of metobromuron is authorised for pre-emergence application for seed production only.

For all other crops, available residue trials are sufficient to derive tentative MRL and risk assessment values, taking note of the following considerations:

- Potato: The number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop. However, in line with the conclusion of the peer review (EFSA, 2014), no additional trials are required to support the northern GAP.
- Lamb’s lettuce: Two additional trials on lamb’s lettuce compliant with the northern outdoor GAP and one additional trial on lamb’s lettuce compliant with the indoor GAP are required. Furthermore, it is noted that according to the metabolism studies, the glucoside conjugates of 4-bromophenylurea (HHAC-073) and of desmethyl-metobromuron (HHAC-079) can be present at significant levels in leafy crops. Therefore, samples from residue trials should be analysed by using an analytical method including a hydrolysis step to release the conjugates. Additional information on the suitability of the analytical method used is also needed to confirm the results of the trials available for this review.
Sunflower seeds: Although MRL and risk assessment values can be derived from the northern data, six additional trials compliant with the southern GAP are still required.

Soyabean: Although MRL and risk assessment values can be derived from the northern data extrapolated from sunflower seeds, eight trials compliant with the southern GAP are still required.

1.2.2. Magnitude of residues in rotational crops

There were no studies investigating the magnitude of residues in rotational crops available for this review.

Nevertheless, the occurrence of residue levels in rotational crops can be estimated based on the rotational confined crop study. In the available confined rotational crop study performed at IN the maximum application rate assessed in this review (2 kg a.s./ha, potato), significant total radioactive residues were measured in all rotated crops and at all plant back intervals. At the shortest PBI (30 DAT), residue levels ranged from 0.09 mg eq/kg in carrot root to 1.71 mg eq/kg in wheat straw. Although residues in rotated crops decreased with soil age, TRR after the 120-day rotation were still significant, ranging from 0.02 mg eq/kg in carrot root to 0.40 mg eq/kg in wheat straw (France, 2020). These results suggest possible soil uptake, even at long plant back intervals.

Residue levels of identified metabolites were measured above 0.01 mg eq/kg in spinach and above 0.05 mg eq/kg in feed commodities (root foliage, wheat forage, hay and straw) only at 30-day PBI. At 120-day PBI, residue levels did not exceed 0.01 mg eq/kg in edible part of the crops nor 0.05 mg eq/kg in feed items (except straw).

Based on the study results, EFSA concludes that, in case of a crop failure, residues of parent metobromuron, 4-bromophenylurea or desmethoxy-metobromuron above 0.01 mg/kg cannot be excluded in rotational crops. Risk mitigation measures were thus proposed by the RMS: 120-day PBI should be respected for cereals and leafy crops, and tops of root crops planted before a PBI of 120 days should not be fed to livestock. Member States granting authorisations for metobromuron should take these risk mitigation measures in order to avoid the presence of significant residues in rotational crops.

1.2.3. Magnitude of residues in processed commodities

No studies investigating the effect of industrial processing and/or household preparation were available and are not required under this review (see also Section 1.1.3).

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. Considering the general data gap identified for the analytical method for high water, high oil, high acid content matrices and dry commodities, as well as the required additional trials and storage stability study on lamb's lettuce, all MRLs are tentative.

Specific MRLs for rotational crops are not needed, provided that Member States will take adequate risk mitigation measures (120-day PBI for cereals and leafy crops; do not feed to livestock with tops of root crops planted before a PBI of 120 days) in order to avoid significant residues to occur in rotational crops.

2. Residues in livestock

Metobromuron is authorised for use on crops (potatoes, sunflower seeds, soyabean) that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Therefore, behaviour of residues should be assessed in all groups of livestock.

No metabolism nor feeding studies are available for this review. Therefore, the behaviour of metobromuron residues in livestock could not be investigated and no residue definition nor MRLs could be proposed.

Metabolism studies in ruminants and poultry are required, as well as the relevant analytical enforcement methods and feeding studies to propose a residue definition and set appropriate MRLs.
Depending on the results of the metabolism studies, livestock feeding studies and storage stability studies might also be required. The dietary burden calculations showed that potato is the major contributor to the livestock exposure (see Appendix B.2).

It should be noted that in case the use of metobromuron on potato would be withdrawn, the dietary burdens would not exceed the trigger value anymore for any of the groups and further investigation in livestock would not be needed (see also France, 2020).

3. Consumer risk assessment

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019a). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a tentative MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). For those commodities where data were insufficient to derive an MRL (all livestock commodities), EFSA considered the existing EU MRL for an indicative calculation. All input values included in the exposure calculations are summarised in Appendix D.

The exposure values calculated were compared with the toxicological reference values derived for metobromuron (European Commission, 2014). The highest chronic exposure was calculated for the Dutch toddler, representing 10% of the ADI, and the highest acute exposure was calculated for potato, representing 1% of the acute reference dose (ARfD). These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference values. Although major uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not demonstrate a risk to consumer’s health.

Conclusions

The metabolism of metobromuron in plant was investigated in primary and rotational crops. According to the results of the metabolism studies and the available residue trials, the residue definitions for enforcement can be proposed as the ‘sum of metobromuron and 4-bromophenylurea, expressed as metobromuron’; and for risk assessment as ‘total hydrolysable residues analysed as 4-bromoaniline and expressed as metobromuron’. These residue definitions are limited to soil applications only and are also applicable to rotational crops. A residue definition is not necessary for processed commodities since in all raw commodities, residues were below 0.1 mg/kg except in lamb’s lettuce which is expected to be consumed raw and the total theoretical maximum daily intake is not exceeding 10% of the acceptable daily intake (ADI).

Analytical methods are available for the enforcement of the proposed residue definition in high water, high oil, high acid matrices and dry commodities at the combined LOQ of 0.01 mg/kg; however, extraction efficiency data are still required. According to the EURs, a combined LOQ of 0.02 mg/kg is achievable by using the QuEChERS method in routine analyses in all four matrix groups.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. Considering the general data gap on the analytical method identified for matrices with high water, high oil, high acid content and dry commodities, as well as the need for additional trials and storage stability study on lamb’s lettuce, all MRLs are tentative. No MRLs are needed for rotational crops provided that Member States will adopt adequate risk mitigation measures to avoid the occurrence of significant residues in rotational crops.

Metobromuron is authorised for use on crops that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. The dietary burdens calculated for all livestock groups were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues should therefore be assessed in all groups of livestock. However, no studies investigating the behaviour of metobromuron residues were available for this review, and no residue definitions nor MRLs could be derived for animal commodities. It is underlined that the dietary burden calculations showed that potato is the major contributor to the livestock exposure. In case the use of metobromuron on potato would be withdrawn, further investigation in livestock would not be needed.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. For all animal...
commodities, where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 10% of the ADI (NL toddler) and the highest acute exposure amounted to 1% of the ARfD (potato).

**Recommendations**

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 1). None of the MRL values listed in the table are recommended for inclusion in Annex II to the Regulation as they are not sufficiently supported by data and require further consideration by risk managers. In particular, all tentative MRLs and existing EU MRLs need to be confirmed by the following data:

1) Data on the extraction efficiency of the enforcement method provided for high water, high oil and high acid content matrices and dry commodities.

2) Metabolism studies on livestock performed at dose rates covering the dietary burdens and relevant analytical methods for enforcement. Depending on the results of the metabolism studies, livestock feeding studies and storage stability studies might also be required. It should be noted that in the absence of these data, it was not possible to derive residue definitions and MRLs for livestock and that the existing MRL for these commodities considered for an indicative calculation of the risk assessment might not be sufficient to cover the residues expected in livestock from the most critical GAP on potatoes. Therefore, this data gap is considered relevant for the derived MRL on potatoes and, in the absence of the data on the nature and magnitude of the residues in livestock, risk managers can consider withdrawing the most critical GAPs on potatoes and lowering the MRL for this commodity to the LOQ;

3) Additional residue trials on lamb’s lettuce with residues analysed by using an analytical method including a hydrolysis step to release the conjugates and additional information on the suitability of the analytical method used in the trials available for this review.

4) Additional storage stability study on lamb’s lettuce covering a longer storage period to confirm the results from the trials of which the samples were stored for 16 months.

It is highlighted that some of the MRLs derived result from a GAP in one climatic zone only, whereas other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- additional trials on sunflower seeds and soyabean.

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Furthermore, Member States granting authorisations for metobromuron are recommended to implement proper risk mitigation measures (120-day PBI should be respected for cereals and leafy crops, and tops of root crops planted before a PBI of 120 days should not be fed to livestock) in order to avoid the presence of significant residues in rotational crops.

It is noted that the MRL proposals are based on an LOQ of 0.005 mg/kg for each analyte which is lower than the default LOQ. In case during the legal implementation risk managers wish to consider the default LOQ of 0.01 mg/kg for each analyte (resulting in a combined LOQ of 0.02 mg/kg), this will not result in an exceedance of the toxicological reference values.
## Table 1: Summary table

| Code number | Commodity                        | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review MRL (mg/kg) | Outcome of the review Comment |
|-------------|----------------------------------|-------------------------|----------------------|----------------------------------|-------------------------------|
| 152000      | Strawberries                     | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 211000      | Potatoes                         | 0.01*                   | –                    | 0.03                             | Further consideration needed<sup>(a)</sup> Data gaps #1, 2 |
| 213020      | Carrots                          | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 213060      | Parsnips                         | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 251010      | Lamb’s lettuce                   | 0.01*                   | –                    | 0.4                              | Further consideration needed<sup>(a)</sup> Data gaps #1, 3, 4 |
| 252010      | Spinach                          | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 254000      | Water cress                      | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 256030      | Celery leaves                    | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 256040      | Parsley                          | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 256050      | Sage                             | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 256070      | Thyme                            | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 256080      | Basil                            | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 260010      | Beans (fresh, with pods)         | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 260020      | Beans (fresh, without pods)      | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 270010      | Asparagus                        | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 270040      | Fennel                           | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 300010      | Beans (dry)                      | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 300030      | Peas (dry)                       | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 401050      | Sunflower seed                   | 0.01*                   | –                    | 0.015                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
| 401070      | Soya bean                        | 0.01*                   | –                    | 0.015                            | Further consideration needed<sup>(a)</sup> Data gap #1 |
|             | Commodities of animal origin     | 0.01*                   | –                    | 0.01*                            | Further consideration needed<sup>(b)</sup> Data gap #2 |
|             | Other commodities of plant origin| Default MRL (0.01 mg/kg) according to Art 18(1)<sup>(b)</sup> Reg. 396/2005 | –                    | –                                | Further consideration needed<sup>(c)</sup> |

**MRL**: maximum residue level; **CXL**: codex maximum residue limit.

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

Enforcement residue definition (existing): 4-bromophenylurea

Enforcement residue definition (proposed): sum of metobromuron and 4-bromophenylurea, expressed as metobromuron.
Review of the existing MRLs for metobromuron

(a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination F-I in Appendix E).

(b): GAP evaluated at EU level is not supported by data, but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination D-I in Appendix E).

(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

References

EFSA (European Food Safety Authority), 2014. Conclusion on the peer review of the pesticide risk assessment of the active substance metobromuron. EFSA Journal 2014;12(2):3541, 78 pp. https://doi.org/10.2903/j.efsa.2014.3541

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMO revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrnis JO, Miron I, Pedersen R, Racyzk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019a. Pesticide Residue Intake Model- EFSA PRIMO revision 3.1 (update of EFSA PRIMO revision 3). EFSA supporting publication 2019;EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.en-1605

EFSA (European Food Safety Authority), 2019b. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for metobromuron in light of confirmatory data. EFSA supporting publication 2019;EN-1692, 68 pp. https://doi.org/10.2903/sp.efsa.2019.EN-1692

EFSA (European Food Safety Authority), 2021a. Completeness check report on the review of the existing MRLs of metobromuron prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 11 June 2021. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2021b. Member States consultation report on the review of the existing MRLs of metobromuron prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 16 August 2021. Available online: www.efsa.europa.eu

EURLs (European Union Reference Laboratories for Pesticide Residues), 2020. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Analytical methods validated by the EURLs and overall capability of official laboratories to be considered for the review of the existing MRLs for metobromuron. September 2020. Available online: www.efsa.europa.eu

European Commission, 1996. Appendix G. Livestock feeding studies. 7031/VI/95-rev 4, 22 July 1996.

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/VI/95-rev.3, 22 July 1997.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7035/VI/95-rev. 5, 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2000. Residue analytical methods. For pre-registration data requirements for setting MRLs. 7525/VI/95-rev.10.3, June 2000.

European Commission, 2006. Appendix A. Metabolism and distribution in plants. 7028/VI/95-rev.3, 22 July 1997.

European Commission, 2010a. Classes to be used for the setting of EU Pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2014. Review report for the active substance metobromuron. Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 11 July 2014 in view of the approval of metobromuron as active substance in accordance with Regulation (EC) No 1107/2009. SANCO/11070/2014 rev.2, 11 July 2014.

European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.10.3, June 2017.
FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Edition. FAO Plant Production and Protection Paper 197, 264 pp.

France, 2013a. Draft Assessment Report (DAR) on the active substance metobromuron prepared by the rapporteur Member State France in the framework of Commission Regulation (EU) No 188/2011, January 2013. Available online: www.efsa.europa.eu

France, 2013b. Final addendum to the draft assessment report on the active substance metobromuron, compiled by EFSA, October 2013. Available online: www.efsa.europa.eu

France, 2020. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for metobromuron, 18 December 2020 revised on April 2021. Available online: www.efsa.europa.eu

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 4 September 2013.

Abbreviations

a.i. active ingredient
a.s. active substance
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAS Chemical Abstract Service
CF conversion factor for enforcement residue definition to risk assessment residue definition
CIRCA (EU) Communication & Information Resource Centre Administrator
CS capsule suspension
CV coefficient of variation (relative standard deviation)
CXL codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DB dietary burden
DM dry matter
DS powder for dry seed treatment
DT90 period required for 90% dissipation (define method of estimation)
EDI estimated daily intake
EMS evaluating Member State
eq residue expressed as a.s. equivalent
FAO Food and Agriculture Organization of the United Nations
FID flame ionisation detector
GAP Good Agricultural Practice
GC gas chromatography
GC-FID gas chromatography with flame ionisation detector
GC-MS gas chromatography with mass spectrometry
GC-MS/MS gas chromatography with tandem mass spectrometry
GS growth stage
HPLC high-performance liquid chromatography
HPLC-MS high-performance liquid chromatography with mass spectrometry
HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardization
IUPAC International Union of Pure and Applied Chemistry
LC liquid chromatography
LC-MS/MS liquid chromatography with tandem mass spectrometry
| Abbreviation | Definition |
|--------------|------------|
| LOQ          | limit of quantification |
| Mo           | monitoring |
| MRL          | maximum residue level |
| MS           | Member States |
| MS           | mass spectrometry detector |
| MS/MS        | tandem mass spectrometry detector |
| MW           | molecular weight |
| NEDI         | national estimated daily intake |
| NESTI        | national estimated short-term intake |
| NTMDI        | national theoretical maximum daily intake |
| OECD         | Organisation for Economic Co-operation and Development |
| PBI          | plant back interval |
| PF           | processing factor |
| PHI          | preharvest interval |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| PROFile      | (EFSA) Pesticide Residues Overview File |
| QuEChERS     | Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RA           | risk assessment |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| SANCO        | Directorate-General for Health and Consumers |
| SC           | suspension concentrate |
| SEU          | southern European Union |
| SMILES       | simplified molecular-input line-entry system |
| SL           | soluble concentrate |
| SP           | water soluble powder |
| STMR         | supervised trials median residue |
| TAR          | total applied radioactivity |
| TMDI         | theoretical maximum daily intake |
| TRR          | total radioactive residue |
| UV           | ultraviolet (detector) |
| WHO          | World Health Organization |
## Appendix A – Summary of authorised uses considered for the review of MRLs

### A.1. Authorised outdoor uses in northern EU

| Crop and/or situation | MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|-------------|-------------|---------------------------------|---------------|---------|
|                       |               | FG or I     | Crop and/or situation              |             |             |                                 |               |         |
| Strawberries          | SE            | F           | Weeds SC 500 g/L Soil treatment – spraying | 0–9 1       | – –        | 1,000 g a.s./ha                 | n.a.          |         |
|                       |               |             |                                    |             |            |                                 |               |         |
| Potatoes              | AT, BE, FR, PL, NL, UK, IE, HU, CZ | F           | Weeds SC 500 g/L Soil treatment – spraying | 0–9 1       | – –        | 2,000 g a.s./ha                 | n.a.          | Pre-emergence application. |
|                       |               |             |                                    |             |            |                                 |               |         |
| Carrots               | DE            | F           | Weeds SC 400 g/L Soil treatment – spraying | 0–9 1       | – –        | 800 g a.s./ha                   | n.a.          | Authorisation for seed production only. Application before emergence (March to May). |
|                       |               |             |                                    |             |            |                                 |               |         |
| Parsnips              | DE            | F           | Weeds SC 400 g/L Soil treatment – spraying | 0–9 1       | – –        | 800 g a.s./ha                   | n.a.          | Authorisation for seed production only. Application before emergence (March–May). |
| Crop and/or situation | MS or country | F G or I (a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|--------------|-------------|-----------------------------------|-------------|-------------|------------------------------|----------------|---------|
| **Lamb’s lettuces**   | FR F         | F           | Weeds SC 400 g/L                  | Soil treatment spraying | 0-9 1 | -- -- | 500 g a.s./ha | 35 Pre-emergence application: 1 application per crop cycle; up to 3 crop cycles per year. |
| **Spinaches**         | SE F         | F           | Weeds SC 500 g/L                  | Soil treatment spraying | 0-9 1 | -- -- | 1,000 g a.s./ha | n.a. Authorised according to Art. 51, only for use on seed production. |
| **Beans (with pods)** | NL, BE, CZ, DE F | Weeds SC 400 g/L | Soil treatment spraying | 0-9 1 | -- -- | 1,000 g a.s./ha | n.a. |
| **Beans (without pods)** | NL, CZ, DE F | Weeds SC 400 g/L | Soil treatment spraying | 0-9 1 | -- -- | 1,000 g a.s./ha | n.a. |
| **Asparagus**         | BE, FR, DE F | F           | Weeds SC 400 g/L                  | Soil treatment spraying | 99-0 1 | -- -- | 1,500 g a.s./ha | n.a. Treatment after harvesting. |
| **Peas (dry)**        | SE F         | F           | Weeds SC 500 g/L                  | Soil treatment spraying | 0-9 1 | -- -- | 1,000 g a.s./ha | n.a. Authorised according to Art. 51, only for use on seed production. |
| **Sunflower seeds**   | FR, PL F     | F           | Weeds SC 500 g/L                  | Soil treatment spraying | 0-9 1 | -- -- | 1,500 g a.s./ha | n.a. Pre-emergence application. |
| **Soyabean**          | BE, AT, PL F | F           | Weeds SC 500 g/L                  | Soil treatment spraying | 0-9 1 | -- -- | 1,500 g a.s./ha | n.a. |

MS: Member State; a.s.: active substance.

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

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system. 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.

(c): PHI – minimum preharvest interval.
### A.2. Authorised outdoor uses in southern EU

| Crop and/or situation | MS or country | FG or I<sup>a</sup> | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI<sup>d</sup> (days) | Remarks |
|-----------------------|---------------|---------------------|-----------------------------------|-------------|-------------|-------------------------------|----------------|---------|
| **Potatoes**          | PT, BG, FR, EL, HR, IT | F | Weeds | SC 500 g/L Soil treatment – spraying | 0-9 | 1 | – | 2,000 g a.s./ha | n.a. Pre-emergence application. |
| **Carrots**           | PT            | F | Weeds | SC 400 g/L Soil treatment – spraying | 0-9 | 1 | – | 800 g a.s./ha | n.a. Pre-emergence application for seed production only. |
| **Parsnips**          | ES, PT        | F | Weeds | SC 400 g/L Soil treatment – spraying | 0-9 | 1 | – | 200-400 800 g a.s./ha | n.a. Pre-emergence application for seed production only. |
| **Watercresses**      | ES            | F | Weeds | SC 400 g/L Soil treatment – spraying | 0-9 | 1 | – | 200-400 500 g a.s./ha | n.a. Pre-emergence application for seed production only. |
| **Celery leaves**     | ES            | F | Weeds | SC 400 g/L Soil treatment – spraying | 0-9 | 1 | – | 200-400 500 g a.s./ha | n.a. Anethum graveolens only. Pre-emergence application for seed production only. |
| **Parsley**           | ES            | F | Weeds | SC 400 g/L Soil treatment – spraying | 0-9 | 1 | – | 200-400 500 g a.s./ha | n.a. Pre-emergence application for seed production only. |
| **Sage**              | ES            | F | Weeds | SC 400 g/L Soil treatment – spraying | 0-9 | 1 | – | 200-400 500 g a.s./ha | n.a. Pre-emergence application for seed production only. |

<sup>a</sup> FG or I: Front (F) or Intermediate (I)
<sup>b</sup> Type: a.s. = active substance
<sup>c</sup> Range of growth stages and season: PH1
<sup>d</sup> PHI = Pre-Harvest Interval
| Crop and/or situation | MS or country | F G or I (a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|--------------|-------------|-----------------------------------|-------------|------------|-------------------------------|---------------|---------|
|                       |              |             |                                   | Type(b)     | Conc. a.s. | Method kind                   |               |         |
| Thyme                 | ES           | F           | Weeds                             | SC          | 400 g/L   | Soil treatment – spraying     |               | n.a.    |
|                       |              |             |                                   |             |           |                               |               |         |
|                       |              |             |                                   | Soil treatment – spraying |          |                               |               |         |
|                       |              |             |                                   | 0-9         | 1         |                               |               |         |
|                       |              |             |                                   | Number min- max |          |                               |               |         |
|                       |              |             |                                   | Interval between application (min) |          |                               |               |         |
|                       |              |             |                                   | a.s./hL min- max |          |                               |               |         |
|                       |              |             |                                   | Water L/ha min- max |          |                               |               |         |
|                       |              |             |                                   | Rate and unit |          |                               |               |         |
|                       |              |             |                                   |             |           |                               | 500 g a.s./ha |         |
|                       |              |             |                                   |               |           |                               | n.a.          |         |
|                       |              |             |                                   |               |           |                               |               |         |
| Basil                 | ES           | F           | Weeds                             | SC          | 400 g/L   | Soil treatment – spraying     |               | n.a.    |
|                       |              |             |                                   |             |           |                               |               |         |
|                       |              |             |                                   | Soil treatment – spraying |          |                               |               |         |
|                       |              |             |                                   | 0-9         | 1         |                               |               |         |
|                       |              |             |                                   | Number min- max |          |                               |               |         |
|                       |              |             |                                   | Interval between application (min) |          |                               |               |         |
|                       |              |             |                                   | a.s./hL min- max |          |                               |               |         |
|                       |              |             |                                   | Water L/ha min- max |          |                               |               |         |
|                       |              |             |                                   | Rate and unit |          |                               | 500 g a.s./ha |         |
|                       |              |             |                                   |               |           |                               | n.a.          |         |
| Asparagus             | PT, FR, EL, ES | F         | Weeds                             | SC          | 400 g/L   | Soil treatment – spraying     |               | n.a.    |
|                       |              |             |                                   |             |           |                               |               |         |
|                       |              |             |                                   | Soil treatment – spraying |          |                               |               |         |
|                       |              |             |                                   | 99 to 0     | 1         |                               |               |         |
|                       |              |             |                                   | Number min- max |          |                               |               |         |
|                       |              |             |                                   | Interval between application (min) |          |                               |               |         |
|                       |              |             |                                   | a.s./hL min- max |          |                               |               |         |
|                       |              |             |                                   | Water L/ha min- max |          |                               |               |         |
|                       |              |             |                                   | Rate and unit |          |                               | 1,500 g a.s./ha|         |
|                       |              |             |                                   |               |           |                               | n.a.          |         |
| Florence fennels      | ES           | F           | Weeds                             | SC          | 400 g/L   | Soil treatment – spraying     |               | n.a.    |
|                       |              |             |                                   |             |           |                               |               |         |
|                       |              |             |                                   | Soil treatment – spraying |          |                               |               |         |
|                       |              |             |                                   | 0-9         | 1         |                               |               |         |
|                       |              |             |                                   | Number min- max |          |                               |               |         |
|                       |              |             |                                   | Interval between application (min) |          |                               |               |         |
|                       |              |             |                                   | a.s./hL min- max |          |                               |               |         |
|                       |              |             |                                   | Water L/ha min- max |          |                               |               |         |
|                       |              |             |                                   | Rate and unit |          |                               | 200-400 g a.s./ha |         |
|                       |              |             |                                   |               |           |                               | n.a.          |         |
| Beans (dry)           | ES, PT       | F           | Weeds                             | SC          | 400 g/L   | Soil treatment – spraying     |               | n.a.    |
|                       |              |             |                                   |             |           |                               |               |         |
|                       |              |             |                                   | Soil treatment – spraying |          |                               |               |         |
|                       |              |             |                                   | 0-9         | 1         |                               |               |         |
|                       |              |             |                                   | Number min- max |          |                               |               |         |
|                       |              |             |                                   | Interval between application (min) |          |                               |               |         |
|                       |              |             |                                   | a.s./hL min- max |          |                               |               |         |
|                       |              |             |                                   | Water L/ha min- max |          |                               |               |         |
|                       |              |             |                                   | Rate and unit |          |                               | 200-400 g a.s./ha |         |
|                       |              |             |                                   |               |           |                               | n.a.          |         |
| Sunflower seeds       | PT, BG, FR, EL, HR, IT, ES | F         | Weeds                             | SC          | 500 g/L   | Soil treatment – spraying     |               | n.a.    |
|                       |              |             |                                   |             |           |                               |               |         |
|                       |              |             |                                   | Soil treatment – spraying |          |                               |               |         |
|                       |              |             |                                   | 0-9         | 1         |                               |               |         |
|                       |              |             |                                   | Number min- max |          |                               |               |         |
|                       |              |             |                                   | Interval between application (min) |          |                               |               |         |
|                       |              |             |                                   | a.s./hL min- max |          |                               |               |         |
|                       |              |             |                                   | Water L/ha min- max |          |                               |               |         |
|                       |              |             |                                   | Rate and unit |          |                               | 1,500 g a.s./ha |         |
|                       |              |             |                                   |               |           |                               | n.a.          |         |
| Soyabeans             | PT           | F           | Weeds                             | SC          | 500 g/L   | Soil treatment – spraying     |               | n.a.    |
|                       |              |             |                                   |             |           |                               |               |         |
|                       |              |             |                                   | Soil treatment – spraying |          |                               |               |         |
|                       |              |             |                                   | 0-9         | 1         |                               |               |         |
|                       |              |             |                                   | Number min- max |          |                               |               |         |
|                       |              |             |                                   | Interval between application (min) |          |                               |               |         |
|                       |              |             |                                   | a.s./hL min- max |          |                               |               |         |
|                       |              |             |                                   | Water L/ha min- max |          |                               |               |         |
|                       |              |             |                                   | Rate and unit |          |                               | 2,000 g a.s./ha |         |
|                       |              |             |                                   |               |           |                               | n.a.          |         |

MS: Member State; a.s.: active substance.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system. 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.
(c): PHI – minimum pre-harvest interval.

www.efsa.europa.eu/efsajournal 22 EFSA Journal 2021;19(9):6841

Review of the existing MRLs for metobromuron
### A.3. Authorised indoor uses in EU

| Crop and/or situation | MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|-------------|------------|-------------------------------|---------------|---------|
|                       |               |             |                                   | Type(b) Conc. a.s. | Method kind | Range of growth stages and season(c) | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit |                       | |
| Lamb's lettuces       | FR            | I           | Weeds                             | SC 400 g/L | Soil treatment – spraying | 0-9           | 1                             | –             | –                   | 500 g a.s./ha | 35                  | Pre-emergence application: 1 application per crop cycle; up to 3 crop cycles per year. |
| Asparagus             | IT            | I           | Weeds                             | SC 400 g/L | Soil treatment – spraying | 99-0          | 1                             | –             | –                   | 1,500 g a.s./ha | n.a.                | Treatment after harvesting. |

**MS:** Member State; **a.s.:** active substance.

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

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system. Growth stage ranges 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.

(c): 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 (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Root crops                        | Potatoes    | Soil treatment, 1 × 2.5 kg a.s./ha (BBCH 05) | 17 and 34 DAT (leaves), 63 DAT (immature potatoes), 111 DAT (harvest, foliage and tubers) | Radiolabelled active substance: [phenyl-14C]-metobromuron (France, 2013a,b; EFSA, 2014) |
| Leafy crops                       | Lamb’s lettuce | Soil treatment, 0.75 kg/ha | 34 (immature leaves) and 52 (mature leaves) DAT | Radiolabelled active substance: [phenyl-14C]-metobromuron (France, 2020) |
| Pulses/oilseeds                   | Sunflower seeds | Soil treatment, 1.5 kg/ha | 61 (immature whole plant) and 126 (seeds, heads, stalks) DAT | Radiolabelled active substance: [phenyl-14C]-metobromuron (France, 2020) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                     | Carrot      | Bare soil, 2 kg a.s./ha | 30, 118 | Radiolabelled active substance: [phenyl-14C]-metobromuron (France, 2020) |
| Leafy crops                          | Spinach     | Bare soil, 2 kg a.s./ha | 30, 118 | Radiolabelled active substance: [phenyl-14C]-metobromuron (France, 2020) |
| Cereal (small grain)                 | Wheat       | Bare soil, 2 kg a.s./ha | 30, 118 | Radiolabelled active substance: [phenyl-14C]-metobromuron (France, 2020) |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Not triggered | In all raw commodities, residues were below 0.1 mg/kg except in lamb’s lettuce which is expected to be consumed raw (see Appendix B.1.2.1) and the total theoretical maximum daily intake is not exceeding 10% of the acceptable daily intake (ADI) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Not triggered | See comment above |
| Sterilisation (20 min, 120°C, pH 6)      | Not triggered | See comment above |
| Other processing conditions             | Not triggered | See comment above |
Can a general residue definition be proposed for primary crops? Yes

Rotational crop and primary crop metabolism similar? Yes

Residue pattern in processed commodities similar to residue pattern in raw commodities? Yes

Plant residue definition for monitoring (RD-Mo) Sum of metobromuron and 4-bromophenylurea, expressed as metobromuron (limited to soil application only).

Plant residue definition for risk assessment (RD-RA) Total hydrolysable residues analysed as 4-bromoaniline and expressed as metobromuron (limited to soil application only).

Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)

| Matrices with high water content, high oil content, high acid content and dry matrices (France, 2013a, b; EFSA, 2014; France, 2020): |
|---|
| • HPLC–MS/MS (QuEChERS multiresidue method, highly specific) |
| • Individual LOQs 0.005 mg/kg for each analyte (metobromuron, desmethyl-metobromuron, desmethoxy-metobromuron and metabolite 4-bromophenylurea), combined enforcement LOQ 0.01 mg/kg. |
| • ILV available in high water and high oil content commodities with the same LOQs. |
| Data to address the extraction efficiency of the enforcement method provided are required (data gap). |
| • QuEChERS for enforcement in routine analysis, default LOQs 0.01 mg/kg for each analyte (metobromuron and 4-bromophenylurea), combined LOQ 0.02 mg/kg (EURLs, 2020). |

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category          | Commodity     | T (°C) | Stability period | Compounds covered                                                                 | Comment/ Source                  |
|-----------------------------------|-------------------|---------------|--------|-----------------|------------------------------------------------------------------------------------|----------------------------------|
|                                   | High water content| Lamb's lettuce| –18    | 12 Months       | Metobromuron, desmethyl-metobromuron, desmethoxy-metobromuron and 4-bromophenylurea | France (2013a,b), EFSA (2014)    |
|                                   |                   | Potatoes      | –18    | 12 Months       | Metobromuron, desmethyl-metobromuron, desmethoxy-metobromuron and 4-bromophenylurea | France (2013a,b), EFSA (2014)    |
|                                   |                   | Carrots       | –18    | 36 Months       | Metobromuron, desmethyl-metobromuron, desmethoxy-metobromuron and 4-bromophenylurea | France (2020)                    |
|                                   |                   | Green beans   | –18    | ≤ 12 Months     | 4-bromophenylurea, desmethyl-metobromuron                                         | France (2020)                    |
|                                   |                   | Green beans   | –18    | 36 Months       | Metobromuron, desmethoxy-metobromuron                                              | France (2020)                    |
|                                   | High oil content  | Sunflower seeds| –18    | ≤ 12 Months     | 4-bromophenylurea                                                                | France (2020)                    |
|                                   |                   | Sunflower seeds| –18    | 24 Months       | Metobromuron, desmethyl-metobromuron, desmethoxy-metobromuron                      | France (2020)                    |
|                                   | High acid content | Grapes        | –18    | 36 Months       | Metobromuron, desmethyl-metobromuron, desmethoxy-metobromuron and 4-bromophenylurea | France (2020)                    |
|                                   | Dry commodities  | Dry beans     | –18    | 36 Months       | Metobromuron, desmethyl-metobromuron, desmethoxy-metobromuron and 4-bromophenylurea | France (2020)                    |
# B.1.2. Magnitude of residues in plants

## B.1.2.1. Summary of residues data from the supervised residue trials – Primary crops

| Commodity                      | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|--------------------------------|------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|---------------|-----------------|-------|
| Strawberries                   | NEU              | Mo: –                                                           | No residues are expected since metobromuron is applied the first year of planting, and strawberries are not intended for human consumption the first year. Residue trials are not required. | 0.01* (tentative)(e)   | 0.01          | 0.01            | 1     |
| Potato                         | NEU              | Mo: < 0.011; < 0.011; 0.013; RA: 0.009; 0.017; 0.026; 0.032     | Trials on potato compliant with the GAP (France, 2013a,b, 2020; EFSA, 2014). Common moiety analysis used for RA results (resulting in LOQ 0.005 mg/kg). MRL\_OECD = 0.023 | 0.03 (tentative)(e)   | 0.013         | 0.011           | 1.9(f) |
|                                 | SEU              | Mo: < 0.011; < 0.011; < 0.011; RA: 0.005; 0.005; 0.006; 0.011; 0.012; 0.024; 0.008; 0.009; 0.023 | Trials on potato compliant with the GAP (France, 2013a,b, 2020; EFSA, 2014). Common moiety analysis used for RA results (resulting in LOQ 0.005 mg/kg). MRL\_OECD = 0.02 | 0.02 (tentative)(e) | 0.015          | 0.011           | 1.9(f) |
| Carrots/Parsnips               | NEU/SEU          | Mo: –                                                           | No residues are expected since pre-emergence application of metobromuron is only authorised for seed production. Residue trials are not required. | 0.01* (tentative)(e)   | 0.01          | 0.01            | 1     |
| Lamb’s lettuce/corn salads     | NEU              | Mo: 0.110; 0.157; RA: 0.844; 0.434                             | Trials on lamb’s lettuce compliant with GAP (France, 2020). Number of trials is not sufficient to derive MRL proposal and risk assessment values. | –                      | –             | –              | –     |
| Indoor                         | Mo: 0.053 (i); 0.096 (i); 0.158; RA: 0.22; 0.50; 0.578       | Trials on lamb’s lettuce performed with dose rate within the 25% deviation (2) or with result scaled down according to the proportionality principle (1) (France, 2020). | 0.4 (tentative)(g)     | 0.16          | 0.10            | 4.2   |
| Spinaches                      | NEU              | Mo: –                                                           | No residues are expected since pre-emergence application of metobromuron is only authorised for seed production. Residue trials are not required. | 0.01* (tentative)(e)   | 0.01          | 0.01            | 1     |
| Commodity                        | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|---------------------------------|-----------------------------|----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------------------|----------------------------|----------------|
| Watercress, Celery leaves, Parsley, Sage, Thyme, Basil and edible flowers | SEU                         | Mo: – RA: –                                                      | No residues are expected since pre-emergence application of metobromuron is only authorised for seed production. Residue trials are not required. | 0.01* (tentative)<sup>(e)</sup> | 0.01                     | 0.01                       | 1              |
| Beans (with pods), Beans (without pods) | NEU                         | Mo: < 0.011; < 0.011; < 0.011; < 0.011; < 0.011; < 0.011; RA: < 0.005; 0.009; 0.010; 0.013; 0.015; 0.028; 0.037; 0.081 | Trials on beans with pods compliant with GAP (France, 2020). Extrapolation to beans without pods is applicable. Common moiety analysis used for RA results (resulting in LOQ 0.005 mg/kg). MRL<sub>OECD</sub> = 0.01 | 0.01* (tentative)<sup>(e)</sup> | 0.01                     | 0.01                       | 2.6(f)         |
| Asparagus                        | NEU, SEU Indoor             | Mo: – RA: –                                                      | No residues are expected since metobromuron is applied in the field after the edible part of the crop is harvested, and long before the next harvest. Residue trials are not required. | 0.01* (tentative)<sup>(e)</sup> | 0.01                     | 0.01                       | 1              |
| Florence fennels                 | SEU                         | Mo: – RA: –                                                      | No residues are expected since pre-emergence application of metobromuron is only authorised for seed production. Residue trials are not required. | 0.01* (tentative)<sup>(e)</sup> | 0.01                     | 0.01                       | 1              |
| Beans (dry), Peas (dry)          | NEU                         | Mo: < 0.011; < 0.011; < 0.011; < 0.011; < 0.011; < 0.011; RA: < 0.005; < 0.005; < 0.005; < 0.005; < 0.005; 0.006; 0.010 | Trials on sunflower seeds compliant with GAP (France, 2020). Common moiety analysis used for RA results (resulting in LOQ 0.005 mg/kg). MRL<sub>OECD</sub> = 0.01 | 0.015 (tentative)<sup>(e)</sup> | 0.012                    | 0.011                      | 1              |

<sup>(a)</sup> Region/Indoor: SEU = South Europe, NEU = North Europe.
<sup>(b)</sup> HR: Harmonised Result.
<sup>(c)</sup> STMR: Scientifically derived MRL.
<sup>(d)</sup> CF: Conversion factor.
<sup>(e)</sup> Tentative MRL.
<sup>(f)</sup> Common moiety analysis used for RA results (resulting in LOQ 0.005 mg/kg).
<sup>(h)</sup> Common moiety analysis used for RA results (resulting in LOQ 0.005 mg/kg).
| Commodity       | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL<sup>(c)</sup> (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|-----------------|-----------------------------|----------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|------------------------|------------------------|------------------------|
| Sunflower seeds | SEU                         | Mo: < 0.011; 0.012 RA: < 0.005; < 0.005                         | Residue trials compliant with GAP (France, 2020). Number of trials is not sufficient to derive MRL proposal and risk assessment values. Common moiety analysis used for RA results (resulting in LOQ 0.005 mg/kg). MRL<sub>OECD</sub> = 0.01 | —                                     | —                      | —                      | —                      |
| Soyabean        | NEU                         | Mo: < 0.011; < 0.011; < 0.011; < 0.011; < 0.011; 0.012 RA: < 0.005; < 0.005; < 0.005; < 0.005; < 0.005; 0.005; 0.006; 0.010 | Trials on sunflower seeds compliant with GAP (France, 2020). Extrapolation to soyabean is applicable. Common moiety analysis used for RA results (resulting in LOQ 0.005 mg/kg). MRL<sub>OECD</sub> = 0.01 | 0.015 (tentative)<sup>(e)</sup> | 0.012                  | 0.011                   | 1<sup>(h)</sup> |
|                 | SEU                         | —                                                              | No residue trials available.                                                                                                                                                                                                                                             | —                                     | —                      | —                      | —                      |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.

*: Indicates that the MRL is proposed at the limit of quantification.

<sup>(a)</sup>: 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.

<sup>(b)</sup>: Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

<sup>(c)</sup>: Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

<sup>(d)</sup>: Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

<sup>(e)</sup>: MRL is tentative since data on the extraction efficiency of the enforcement method provided for high water, high oil and high acid content matrices and dry commodities is not available.

<sup>(f)</sup>: The median CF was recalculated considering only the risk assessment residue levels (and corresponding enforcement values) above LOQ (> 0.011 mg/kg), merging northern and southern data sets.

<sup>(g)</sup>: MRL is tentative since one additional trial on lamb's lettuce, additional information on the suitability of the analytical method used in the trials available and an additional storage stability study on lamb's lettuce are required.

<sup>(h)</sup>: A median CF of 1 can be applied since residues according to the enforcement residue definition are higher than residues according to the residue according to the residue definition for risk assessment.

<sup>(i)</sup>: These results are from samples stored for 16 months. Considering that these are the lowest values and that a degradation was observed in another high-water content commodity after 12 months, an additional storage stability study on lamb's lettuce covering a longer storage period is still required to confirm the results from these trials.
B.1.2.2. Residues in rotational crops

a) Overall summary

Residues in rotational and succeeding crops expected based on confined rotational crop study?

Yes

Based on the results of the confined rotational crop study, residues of parent metobromuron, 4-bromophenlyurea and desmethoxy-metobromuron above 0.01 mg/kg cannot be excluded. However, mitigation measures could be proposed: 120-day PBI should be respected for cereals and leafy crops, and tops of root crops planted before a PBI of 120 days should not be fed to livestock.

Residues in rotational and succeeding crops expected based on field rotational crop study?

Not available

See comment above

PBI: plant-back interval.

B.1.2.3. Processing factors

No processing studies are available and are not required under this review since in all raw commodities residues were below 0.1 mg/kg except in lamb’s lettuce which is expected to be consumed raw (see Appendix B.1.2.1) and the total theoretical maximum daily intake is not exceeding 10% of the acceptable daily intake (ADI).

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Yes/No) | Comments |
|----------------------------|-----------------------------|---------------------------|---------------------------|--------------------------|----------|
|                            | mg/kg bw per day       | mg/kg DM | Median | Maximum | Median | Maximum | Dairy cattle | Potato, process waste | Yes | – |
| Cattle (all)               | 0.042                   | 0.042  | 1.43   | 1.44    |        |         | Dairy cattle | Potato, process waste | Yes | – |
| Cattle (dairy only)        | 0.042                   | 0.042  | 1.08   | 1.09    |        |         | Dairy cattle | Potato, process waste | Yes | – |
| Sheep (all)                | 0.048                   | 0.048  | 1.43   | 1.44    |        |         | Ram/Ewe     | Potato, process waste | Yes | – |
| Sheep (ewe only)           | 0.048                   | 0.048  | 1.43   | 1.44    |        |         | Ram/Ewe     | Potato, process waste | Yes | – |
| Swine (all)                | 0.017                   | 0.018  | 0.75   | 0.77    |        |         | Swine (breeding) | Potato, process waste | Yes | – |
| Poultry (all)              | 0.014                   | 0.014  | 0.20   | 0.20    |        |         | Poultry broiler | Potato, dried pulp | Yes | – |
| Poultry (layer only)       | 0.010                   | 0.011  | 0.15   | 0.15    |        |         | Poultry layer | Potato, dried pulp | Yes | – |
| Fish                       | –                        | –      | –      | –       | –      | –         | –             | –             | –   | – |

bw: body weight; DM: dry matter.
(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.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Livestock (available studies) | Animal          | Dose (mg/kg bw/d) | Duration (days) | Comment/Source                                                                 |
|------------------------------|-----------------|-------------------|-----------------|--------------------------------------------------------------------------------|
| Laying hen                   | –               | –                 | –               | No study available (data gap).                                                  |
| Lactating ruminants          | –               | –                 | –               | No study available (data gap).                                                  |
| Pig                          | –               | –                 | –               | No study available. Study might be required based on the results of the metabolism study on ruminants.|
| Fish                         | –               | –                 | –               | No study available.                                                             |

Time needed to reach a plateau concentration in milk and eggs (days)

|                       | Milk: –         | No study available |
|                       | Eggs: –         | No study available |

Metabolism in rat and ruminant similar

|                       | Inconclusive    | No study available |

Can a general residue definition be proposed for animals?

|                       | Inconclusive    | No study available |

Animal residue definition for monitoring (RD-Mo)

|                       | No residue definition could be proposed. |

Animal residue definition for risk assessment (RD-RA)

|                       | No residue definition could be proposed. |

Fat soluble residues

|                       | Inconclusive    | No study available |

Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)

|                       | No analytical methods available (data gap) |

B.2.1.2. Stability of residues in livestock

No storage stability studies are available. Depending on the results of the livestock metabolism study, storage stability studies might be required.
B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies

No feeding studies are available, and it was not possible to derive MRLs for livestock. Depending on the results of the livestock metabolism study, livestock feeding studies might be required.

B.3. Consumer risk assessment

| ARfD | 0.3 mg/kg bw (European Commission, 2014) |
|------|-----------------------------------------|
|      | Potato: 1% of ARfD                      |
|      | Lamb's lettuce: 0.6% of ARfD           |
|      | Milk (cattle): 0.4% of ARfD            |
|      | Carrots: 0.2% of ARfD                  |

Highest IESTI, according to EFSA PRIMo (rev.3.1)

| NESTI (% ARfD) | Not assessed in this review. |

Assumptions made for the calculations

The calculation is based on the highest residue levels expected in raw agricultural commodities (or median residue levels for dry beans and peas, sunflower seeds and soyabeans), except for the livestock commodities for which the existing EU MRL was used for an indicative calculation. The following CF for risk assessment were also applied: 1.9 for potato, 2.6 for beans (with and without pods), 4.2 for lamb’s lettuce; 1 for strawberries, carrots, parsnips, spinach, watercress, celery leaves, parsley, sage, thyme, basil, edible flowers, asparagus, Florence fennels, beans (dry), peas (dry), sunflower seeds and soyabeans.

| ADI | 0.008 mg/kg bw per day (European Commission, 2014) |
|-----|-------------------------------------------------|
|     | Potato: 1% of ADI                                |
|     | Lamb’s lettuce: 0.6% of ADI                      |
|     | Milk (cattle): 0.4% of ADI                        |
|     | Carrots: 0.2% of ADI                              |

TMDI according to EFSA PRIMo

Not assessed in this review.

NTMDI, according to (to be specified) Not assessed in this review.

Highest IEDI, according to EFSA PRIMo (rev.3.1)

| NEDI (% ADI) | Not assessed in this review. |

Assumptions made for the calculations

The calculation is based on the median residue levels derived for raw agricultural commodities, multiplied by the conversion factor for risk assessment, except for the livestock commodities for which the existing EU MRL was used. The following CF for risk assessment were also applied: 1.9 for potato, 2.6 for beans (with and without pods), 4.2 for lamb’s lettuce, 1 for strawberries, carrots, parsnips, spinach, watercress, celery leaves, parsley, sage, thyme, basil, edible flowers, asparagus, Florence fennels, beans (dry), peas (dry), sunflower seeds and soyabeans.

The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.

ADI: acceptable daily intake; bw: body weight; NEDI: national estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; IEDI: international estimated daily intake; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake.
Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/2/2003).

Metabolite(s)
ADI (mg/kg bw per day)
Intake of groundwater metabolites (% ADI)

### B.4. Proposed MRLs

| Code number | Commodity                  | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment               |
|-------------|----------------------------|-------------------------|----------------------|-----------------------|-----------------------|
| 152000      | Strawberries               | 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 211000      | Potatoes                   | 0.01*                   | –                    | 0.03                  | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gaps #1, 2       |
| 213020      | Carrots                    | 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 213060      | Parsnips                   | 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 251010      | Lamb's lettuce             | 0.01*                   | –                    | 0.4                   | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gaps #1, 3       |
| 252010      | Spinach                    | 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 254000      | Water cress                | 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 256030      | Celery leaves              | 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 256040      | Parsley                    | 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 256050      | Sage                       | 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 256070      | Thyme                      | 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 256080      | Basil                      | 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 260010      | Beans (fresh, with pods)   | 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 260020      | Beans (fresh, without pods)| 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 270010      | Asparagus                  | 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 270040      | Fennel                     | 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 300010      | Beans (dry)                | 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 300030      | Peas (dry)                 | 0.01*                   | –                    | 0.01*                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |
| 401050      | Sunflower seed             | 0.01*                   | –                    | 0.015                 | Further consideration needed<sup>(a)</sup> |
|             |                            |                         |                      |                       | Data gap #1           |

**Enforcement residue definition (existing):** 4-bromophenylurea

**Enforcement residue definition (proposed):** sum of metobromuron and 4-bromophenylurea, expressed as metobromuron
### Review of the existing MRLs for metobromuron

| Code number | Commodity                        | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review                          | MRL (mg/kg) | Comment                              |
|-------------|----------------------------------|-------------------------|----------------------|-----------------------------------------------|-------------|--------------------------------------|
| 401070      | Soya bean                        | 0.01*                   | –                    | Further consideration needed<sup>(a)</sup>   | 0.015       | Data gap #1                          |
| –           | Commodities of animal origin     | 0.01*                   | –                    | Further consideration needed<sup>(b)</sup>   | 0.01*       | Data gap #2                          |
| –           | Other commodities of plant origin| Default MRL (0.01 mg/kg)| –                    | Further consideration needed<sup>(c)</sup>   | –           |                                      |

**MRL**: Maximum residue level; **CXL**: Codex maximum residue limit.

*Indicates that the MRL is set at the limit of quantification.

- **(a)**: Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination F-I in Appendix E).
- **(b)**: GAP evaluated at EU level is not supported by data, but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination D-I in Appendix E).
- **(c)**: There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
## Appendix C – Pesticide Residue Intake Model (PRIMo)

### PRIMo(EU)

- **Metobromuron**
  - Mode of action: Contact
  - EIR (mg/kg): 0.01
  - Toxicological reference values:
    - LOQs (mg/kg) range from: 0.01 to: 0.01
    - ADI (mg/kg bw per day): 0.2
    - ARfD (mg/kg bw): 0.2

**Details – chronic risk**

- Source of ADI: EFSA PRIMo revision 3.1; 2021/01/06
- Year of evaluation: 2014
- Comments: Normal mode

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

- No of diets exceeding the ADI: ---
- Exposure resulting from commodities not under assessment: ---
- Highest contributor to exposure (in % of ADI): Beans (with pods) 10%
- 2nd contributor to exposure (in % of ADI): Milk: Cattle 6%
- 3rd contributor to exposure (in % of ADI): Swine: Muscle/meat 5%

| Commodity/group of commodities | Exposure (µg/kg per day) | Percentage of ADI | Risk Assessment |
|-------------------------------|--------------------------|-------------------|----------------|
| Milk: Cattle                  | 0.77                     | 7%                | Prolonged       |
| Swine: Muscle/meat            | 0.77                     | 7%                | Prolonged       |
| Beans (with pods)             | 0.3%                     | 0.3%              | Prolonged       |
| Bovine: Muscle/meat           | 0.3%                     | 0.3%              | Prolonged       |
| Eggs: Chicken                 | 0.3%                     | 0.3%              | Prolonged       |
| Sheep's wool                  | 0.3%                     | 0.3%              | Prolonged       |
| Lamb's lettuce/corn salads    | 0.3%                     | 0.3%              | Prolonged       |
| Lamb's visceral organs        | 0.3%                     | 0.3%              | Prolonged       |
| Sheep's milk                  | 0.3%                     | 0.3%              | Prolonged       |

**Conclusion:**

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of metobromuron is unlikely to present a public health concern.

**DISCLAIMER:** Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

---

www.efsa.europa.eu/efsajournal 35 EFSA Journal 2021;19(9):6841
The acute risk assessment is based on the ARID. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union. The calculation is based on the large portion of the most critical consumer group.

### Unprocessed commodities

| Highest % of ARfD/ADI | Commodities          | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities          | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|----------------------|--------------------------|---------------------|-----------------------|----------------------|--------------------------|---------------------|
| 1%                    | Potatoes             | 0.03/0.03                | 4.4                 | 0.4%                  | Lamb's lettuce/corn salads | 0.40/0.67                | 1.3                 |
| 0.6%                  | Lamb's lettuce/corn salads | 0.40/0.67                | 1.9                 | 0.3%                  | Potatoes             | 0.03/0.03                | 0.85                |
| 0.4%                  | Milk: Cattle         | 0.01/0.01                | 1.2                 | 0.1%                  | Milk: Cattle         | 0.01/0.01                | 0.39                |
| 0.2%                  | Carrots              | 0.01/0.01                | 0.63                | 0.07%                 | Beans (with pods)    | 0.01/0.03                | 0.20                |
| 0.1%                  | Parsnips             | 0.01/0.01                | 0.36                | 0.07%                 | Carrots              | 0.01/0.01                | 0.20                |
| 0.10%                 | Beans (with pods)    | 0.01/0.03                | 0.30                | 0.06%                 | Florence fennels    | 0.01/0.01                | 0.19                |
| 0.08%                 | Milk: Goat           | 0.01/0.01                | 0.24                | 0.06%                 | Milk: Goat          | 0.01/0.01                | 0.18                |
| 0.08%                 | Spinachos            | 0.01/0.01                | 0.23                | 0.05%                 | Milk: Sheep         | 0.01/0.01                | 0.15                |
| 0.07%                 | Beans (without pods) | 0.01/0.03                | 0.21                | 0.05%                 | Parsnips            | 0.01/0.01                | 0.14                |
| 0.06%                 | Asparagus            | 0.01/0.01                | 0.19                | 0.04%                 | Poultry: Muscle     | 0.01/0.01                | 0.12                |
| 0.06%                 | Beans                | 0.01/0.01                | 0.18                | 0.03%                 | Beans (without pods)| 0.01/0.03                | 0.10                |
| 0.06%                 | Poultry: Muscle/meat | 0.01/0.01                | 0.17                | 0.03%                 | Strawberries        | 0.01/0.01                | 0.09                |
| 0.05%                 | Strawberries         | 0.01/0.01                | 0.16                | 0.03%                 | Asparagus           | 0.01/0.01                | 0.08                |
| 0.05%                 | Florence fennels     | 0.01/0.01                | 0.16                | 0.02%                 | Beans               | 0.01/0.01                | 0.07                |
| 0.04%                 | Eggs: Chicken        | 0.01/0.01                | 0.12                | 0.02%                 | Soyabeans           | 0.02/0.01                | 0.06                |

### Processed commodities

| Highest % of ARfD/ADI | Commodities | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|-------------|--------------------------|---------------------|-----------------------|-------------|--------------------------|---------------------|
| 0.9%                  | Potatoes/fried | 0.03/0.03                | 2.7                 | 0.1%                  | Parsnips/boiled | 0.01/0.01                | 0.21                |
| 0.4%                  | Potatoes/dried (flakes) | 0.03/0.1                | 1.2                 | 0.06%                 | Florence fennels/boiled | 0.01/0.01                | 0.19                |
| 0.2%                  | Parsnips/boiled | 0.01/0.01                | 0.51                | 0.06%                 | Poppies/chips    | 0.03/0.02                | 0.18                |
| 0.2%                  | Florence fennels/boiled | 0.01/0.01                | 0.45                | 0.04%                 | Beans (without pods)/boiled | 0.01/0.03                | 0.13                |
| 0.1%                  | Carrots/juice     | 0.01/0.01                | 0.36                | 0.04%                 | Potatoes/dried (flakes) | 0.01/0.01                | 0.12                |
| 0.1%                  | Beans (with pods)/boiled | 0.01/0.03                | 0.33                | 0.03%                 | Spinachos/frozen; boiled | 0.01/0.01                | 0.08                |
| 0.0%                  | Spinachos/frozen; boiled | 0.01/0.01                | 0.14                | 0.03%                 | Carrots/canned    | 0.01/0.01                | 0.08                |
| 0.0%                  | Pears/canned      | 0.01/0.01                | 0.07                | 0.02%                 | Beans/canned      | 0.01/0.01                | 0.07                |
| 0.0%                  | Soyabeans/soya drink | 0.02/0.01                | 0.05                | 0.01%                 | Pears/canned      | 0.01/0.01                | 0.03                |
| 0.0%                  | Sunflower seeds/oils | 0.02/0.02                | 0.03                |                       |              |                          |                     |
| 0.0%                  | Soyabeans/boiled  | 0.02/0.02                | 0.02                |                       |              |                          |                     |

### Results for children

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

### Results for adults

- No exceedance of the ARfD/ADI was identified.

### Conclusion

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

---

**Review of the existing MRLs for metobromuron**

[www.efsa.europa.eu/efsajournal](www.efsa.europa.eu/efsajournal) 36 EFSA Journal 2021;19(9):6841
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                |
|                                       |                       |                        |
| **Risk assessment residue definition:** | total hydrolysable residues analysed as 4-bromoaniline and expressed as metobromuron |
| Carrot culls                          | 0.01*                 | STMR<sub>Mo</sub> × CF (1) |
| Potato culls                          | 0.02                  | STMR<sub>Mo</sub> × CF (1.9) |
| Bean seed (dry)                       | 0.01*                 | STMR<sub>Mo</sub> × CF (1) |
| Cowpea seed                           | 0.01*                 | STMR<sub>Mo</sub> × CF (1) |
| Pea (Field pea) seed (dry)            | 0.01*                 | STMR<sub>Mo</sub> × CF (1) |
| Soybean seed                          | 0.01                  | STMR<sub>Mo</sub> × CF (1) |
| Potato process waste                  | 0.42                  | STMR<sub>Mo</sub> × CF (1.9) × default PF (20)<sup>(a)</sup> |
| Potato dried pulp                     | 0.79                  | STMR<sub>Mo</sub> × CF (1.9) × default PF (38)<sup>(a)</sup> |
| Soybean meal                          | 0.01                  | STMR<sub>Mo</sub> × CF (1) × default PF (13)<sup>(a)</sup> |
| Soybean hulls                         | 0.14                  | STMR<sub>Mo</sub> × CF (1) × default PF (2)<sup>(a)</sup> |
| Sunflower meal                        | 0.02                  | STMR<sub>Mo</sub> × CF (1) × default PF (2)<sup>(a)</sup> |

*: Indicates that the input value is proposed at the limit of quantification.
STMR: supervised trials median residue; HR: highest residue; CF: conversion factor; PF: processing factor.
(a): In the absence of processing factors supported by data, default processing factor was included in the calculation to consider the potential concentration of residues in these commodities.

### D.2. Consumer risk assessment

| Commodity                          | Chronic risk assessment | Acute risk assessment |
|------------------------------------|-------------------------|-----------------------|
|                                    | Input value (mg/kg)     | Comment               |
|                                    |                         |                       |
| **Risk assessment residue definition:** | total hydrolysable residues analysed as 4-bromoaniline and expressed as metobromuron |
| Strawberries                       | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) |
| Potatoes                           | 0.02                    | STMR<sub>Mo</sub> × CF (1.9) (tentative) |
| Carrots                            | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) |
| Parsnips                           | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) |
| Lamb's lettuce/corn salads         | 0.42                    | MR<sub>Mo</sub> × CF (4.2) (tentative) |
| Spinaches                          | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) |
| Watercress                         | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) |

EFSA Journal 2021;19(9):6841

www.efsa.europa.eu/efsajournal
| Commodity                        | Chronic risk assessment | Acute risk assessment |
|---------------------------------|-------------------------|-----------------------|
|                                 | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| Celery leaves                   | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) | 0.01*                   | HR<sub>Mo</sub> × CF (1) (tentative) |
| Parsley                         | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) | 0.01*                   | HR<sub>Mo</sub> × CF (1) (tentative) |
| Sage                            | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) | 0.01*                   | HR<sub>Mo</sub> × CF (1) (tentative) |
| Thyme                           | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) | 0.01*                   | HR<sub>Mo</sub> × CF (1) (tentative) |
| Basil and edible flowers        | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) | 0.01*                   | HR<sub>Mo</sub> × CF (1) (tentative) |
| Beans (with pods)               | 0.026                   | STMR<sub>Mo</sub> × CF (2.6) (tentative) | 0.026                   | HR<sub>Mo</sub> × CF (2.6) (tentative) |
| Beans (without pods)            | 0.026                   | STMR<sub>Mo</sub> × CF (2.6) (tentative) | 0.026                   | HR<sub>Mo</sub> × CF (2.6) (tentative) |
| Asparagus                       | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) | 0.01*                   | HR<sub>Mo</sub> × CF (1) (tentative) |
| Florence fennels                | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) | 0.01*                   | HR<sub>Mo</sub> × CF (1) (tentative) |
| Beans (dry)                     | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) |
| Peas (dry)                      | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) | 0.01*                   | STMR<sub>Mo</sub> × CF (1) (tentative) |
| Sunflower seeds                 | 0.011                   | STMR<sub>Mo</sub> × CF (1) (tentative) | 0.011                   | STMR<sub>Mo</sub> × CF (1) (tentative) |
| Soyabeans                       | 0.011                   | STMR<sub>Mo</sub> × CF (1) (tentative) | 0.011                   | STMR<sub>Mo</sub> × CF (1) (tentative) |
| Animal commodities              | 0.01*                   | EU MRL                | 0.01*                   | EU MRL                |

STMR: median residue level; HR: highest residue; Mo: monitoring; CF: conversion factor; EU MRL: existing European maximum residue level.

*: Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations
### Appendix F – Used compound codes

| Code/trivial name | IUPAC name/SMILES notation/InChIKey(a) | Structural formula(b) |
|------------------|----------------------------------------|-----------------------|
| Metobromuron     | 3-(4-bromophenyl)-1-methoxy-1-methylurea<br>WLFDQEVORAMCM-UHFFFAOYSA-N<br>Brc1ccc(N(-O)N(C)OC)cc1 | ![Structural formula](image1.png) |
| 4-bromoaniline   | 4-bromoaniline<br>WDFQ8ORIUYODSI-UHFFFAOYSA-N<br>Nc1ccc(Br)cc1 | ![Structural formula](image2.png) |
| Desmethyl-metobromuron | N-(4-bromophenyl)-N′-methoxyurea<br>NPLWLNIXIWUSKD-UHFFFAOYSA-N<br>Brc1ccc(N(-O)NOC)cc1 | ![Structural formula](image3.png) |
| Desmethoxy-metobromuron | N-(4-bromophenyl)-N′-methylurea<br>OKUKWIEAXKUDI-UHFFFAOYSA-N<br>Brc1ccc(N(-O)NC)cc1 | ![Structural formula](image4.png) |
| 4-bromophenylurea | N-(4-bromophenyl)urea<br>PFQUUCXMPUNRLA-UHFFFAOYSA-N<br>Brc1ccc(NC(N)=O)cc1 | ![Structural formula](image5.png) |
| HHAC-0073        | One example of several possible glycoside structures: 1-O-(((4-bromophenyl)carbamoyl)amino)-β-D-glucopyranose<br>LCIPFHLBLNZNAZ-ZIQFBCGOSA-N<br>Brc1ccc(cc1)NC(-O)NO[C@@H]1O[C@H](CO)[C@@H](O)[C@H](O)[C@H]1O | ![Structural formula](image6.png) |
| HHAC-079         | N1-Glycoside of desmethyl-metobromuron<br>One example of several possible glycoside structures: 1-O-(((4-bromophenyl)carbamoyl)(methoxy)amino)-β-D-glucopyranose<br>SXVUWKNGHQEKP-RELIVKGS-N<br>Brc1ccc(cc1)NC(-O)N[OC][C@@H]1O[C@H](CO)[C@@H](O)[C@H](O)[C@H]1O | ![Structural formula](image7.png) |
| Code/trivial name | IUPAC name/SMILES notation/InChiKey\(^{(a)}\) | Structural formula\(^{(b)}\) |
|------------------|---------------------------------------------|------------------|
| HHAC-090         | 1-(4-bromophenyl)-3-methoxy-1-[3,4,5-trihydroxy-6-(hydroxy-methyl)oxan-2-yl]urea (a): ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019). (b): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019). | ![Structural formula](image-url) |
| HHAC-091         | One example of several possible glycoside structures: N’-(4-bromophenyl)-N-[((\beta\-D-glucopyranosyloxy)methyl]-N-methoxyurea ZRLHIRVIVHOUQH-RKQHYHRCSA-N Brc1ccc(cc1)NC(=O)N(CO[C@@H]1O[C@H](O)[C@H](O)[C@H][C@H]1O)OC | ![Structural formula](image-url) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.