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CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance metobromuron[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authority of the rapporteur Member State France, for the pesticide active substance metobromuron are reported. The context of the peer review was that required by Commission Regulation (EU) No 188/2011. The conclusions were reached on the basis of the evaluation of the representative use of metobromuron as a herbicide on potatoes. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. The consumer risk assessment should be considered provisional pending the outcome of the requested toxicological information on the metabolites included in the plant residue definitions. A high long-term risk to birds could not be excluded with the available data.

KEY WORDS

metobromuron, peer review, risk assessment, pesticide, herbicide

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[2] Correspondence: pesticides.peerreview@efsa.europa.eu

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SUMMARY

Metobromuron is a new active substance for which in accordance with Article 6(2) of Council Directive 91/414/EEC France (hereinafter referred to as the 'RMS') received an application from Belchim Crop Protection NV/SA for approval. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2011/253/EU.

The RMS provided its initial evaluation of the dossier on metobromuron in the Draft Assessment Report (DAR), which was received by the EFSA on 10 January 2013. The peer review was initiated on 21 January 2013 by dispatching the DAR for consultation of the Member States and the applicant Belchim Crop Protection NV/SA.

Following consideration of the comments received on the DAR, it was concluded that EFSA should conduct an expert consultation in the areas of mammalian toxicology and ecotoxicology and EFSA should adopt a conclusion on whether metobromuron can be expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC, in accordance with Article 8 of Commission Regulation (EU) No 188/2011.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative use of metobromuron as a herbicide on potatoes, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

In the section on identity, physical/chemical/technical properties and methods of analysis data gaps have been identified for validated methods for analysis of residues in dry, high acid content and high oil content matrices of plant origin and for verification of the extraction efficiency of the proposed enforcement method for high water content plant matrices.

In the mammalian toxicology area, a data gap is identified to address the relative toxicity of three plant metabolites included in the plant residue definitions and one soil metabolite in relation to the parent metobromuron.

In the residues section, the consumer risk assessment should be considered provisional pending the outcome of the requested toxicological information on the metabolites included in the plant residue definitions.

No areas of concern were identified in relation to the fate and behaviour of metobromuron into the environment for the representative use assessed. Pending on the confirmation of the toxicological relevance of four minor soil metabolites, they may need to be further considered in the residue definition for ground water exposure assessment.

An issue that could not be finalised was identified for birds, because a high long-term risk could not be excluded with the available data. Data gaps were identified to further consider the long-term risk to mammals and birds and the risk to aquatic organisms for the situation covered by the FOCUS R3 scenario.

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BACKGROUND

In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009,[3] Council Directive 91/414/EEC[4] continues to apply with respect to the procedure and conditions for approval for active substances for which a decision recognising in principle the completeness of the dossier was adopted in accordance with Article 6(3) of that Directive before 14 June 2011.

Commission Regulation (EU) No 188/2011[5] (hereinafter referred to as 'the Regulation') lays down the 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 on 26 July 1993. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States and the applicant for comments on the initial evaluation in the Draft Assessment Report (DAR) provided by the rapporteur Member State (RMS), and the organisation of an expert consultation, where appropriate.

In accordance with Article 8 of the Regulation, EFSA is required to adopt a conclusion on whether the active substance is expected to meet the conditions provided for in Article 5 of Directive 91/414/EEC within 4 months from the end of the period provided for the submission of written comments, subject to an extension of 2 months where an expert consultation is necessary, and a further extension of up to 8 months where additional information is required to be submitted by the applicant in accordance with Article 8(3).

In accordance with Article 6(2) of Council Directive 91/414/EEC France (hereinafter referred to as the 'RMS') received an application from Belchim Crop Protection NV/SA for approval of the active substance metobromuron. Complying with Article 6(3) of Directive 91/414/EEC, the completeness of the dossier was checked by the RMS. The European Commission recognised in principle the completeness of the dossier by Commission Decision 2011/253/EU.[6]

The RMS provided its initial evaluation of the dossier on metobromuron in the DAR, which was received by the EFSA on 10 January 2013 (France, 2013a). The peer review was initiated on 21 January 2013 by dispatching the DAR to Member States and the applicant Belchim Crop Protection NV/SA for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 8(3) of the Regulation were considered in a telephone conference between the EFSA, the RMS, and the European Commission on 13 May 2013. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof it was concluded that additional information should be requested from the applicant, and that the EFSA should organise an expert consultation in the areas of mammalian toxicology and ecotoxicology.

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ No L 309, 24.11.2009, p. 1-50.
[4] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32, as last amended.
[5] 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 No L 53, 26.2.2011, p. 51-55.
[6] Commission Decision 2011/253/EU of 26 April 2011 recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of metobromuron, S-Abscisic acid, *Bacillus amyloliquefaciens* subsp. *plantarum* D747, *Bacillus pumilus* QST 2808 and *Streptomyces lydicus* WYEC 108 in Annex I to Council Directive 91/414/EEC. OJ No L 106, 27.4.2011, p. 13-14.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, and the additional information to be submitted by the applicant, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert consultation where this took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in November – December 2013.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative use as a herbicide on potatoes, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2013) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR,
- the Reporting Table (13 May 2013),
- the Evaluation Table (9 January 2014),
- the reports of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the additional information (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR including its addendum (compiled version of October 2013 containing all individually submitted addenda (France, 2013b)) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated to have regulatory access to the information on which this conclusion report is based.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Metobromuron is the ISO common name for 3-(4-bromophenyl)-1-methoxy-1-methylurea (IUPAC).

The representative formulated product for the evaluation was 'Metobromuron 500 SC', a suspension concentrate (SC) containing 500 g/L pure metobromuron.

The representative use evaluated comprises application by spraying against weeds on potatoes. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev. 4 (European Commission, 2000) and SANCO/825/00 rev. 8.1 (European Commission, 2010).

The minimum purity of the active substance is 978 g/kg. The specification is based on pilot plant production. No FAO specification exists.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of metobromuron or the representative formulation. The main data regarding the identity of metobromuron and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of metobromuron in technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material.

QuEChERS based HPLC-MS/MS method is available for monitoring of the residues of metobromuron in high water content matrix type of plant origin (LOQ 0.005 mg/kg, potato). However data/justification to address the verification of the extraction efficiency for this method have not been provided and a data gap was identified. In addition data gaps have been also identified for validated methods for analysis of residues in dry, high acid and high oil content matrices of plant origin. A method to monitor residues in food of animal origin is not required considering the representative use evaluated. Appropriate HPLC-MS/MS methods exist for monitoring of metobromuron in soil, water and air with LOQs of 0.01 mg/kg, 0.05 µg/L and 2 µg/m^3 respectively. A method for residues in body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000 rev. 10 - final (European Commission, 2003), SANCO/222/2000 rev. 7 (European Commission, 2004) and SANCO/10597/2003 – rev. 8.1 (European Commission, 2009).

Metobromuron was discussed at the Pesticides Peer Review Meeting 106 in September 2013.

The batches used in the toxicological studies that were used to derive the toxicological reference values support the technical specification; no relevant impurities were identified in the technical specification.

Metobromuron is rapidly and almost completely absorbed after oral administration. The a.s. is widely distributed, the highest concentrations being found in the blood, mainly associated with its cellular components. Metobromuron is completely metabolised, and rapidly excreted mainly via urine.

Low to moderate acute toxicity has been observed when metobromuron is administered by the oral, dermal or inhalation routes. The substance is not irritating to eyes and skin, but may cause sensitisation by skin contact according to a Maximisation test of Magnusson and Kligman.

The primary target organ of metobromuron is the blood system, inducing (regenerative) haemolytic anaemia when administered by the oral and dermal routes to rats and dogs. The haemolytic anaemia is characterised by the formation of methaemoglobin, increased incidence of Heinz bodies, nucleated erythrocytes and reticulocytes, further to decreased erythrocytes count, haematocrit values and haemoglobin concentration. Secondary target organs to the haemolytic anaemia are the spleen (haemosiderin deposit and congestion), liver (increased weight), kidneys (siderosis) and a compensation reaction in the bone marrow. The relevant short-term NOAEL is 1.6 mg/kg bw per day from the 1-year dog study and the long-term NOAEL is 0.8 mg/kg bw per day from the 2-year mouse study. No oncogenic effect was observed in mice, but in rats an increased incidence of mammary gland fibrosarcomas were observed in females and increased incidence of pheochromocytomas in males were considered to be potentially relevant for humans and may indicate that classification as carcinogenic category 2, H351 'suspected of causing cancer' may apply[7]. The NOAEL for carcinogenic effects is 2.6 mg/kg bw per day. No genotoxic potential is attributed to metobromuron. No indication of neurotoxic potential was observed in the toxicity studies presented in the dossier.

No reproductive or fertility effects were observed in a multigeneration toxicity study in rats up to the highest dose tested of 16 mg/kg bw per day; developmental effects consisted of delayed ossification in rats and post-implantation losses in rabbits at maternally toxic doses (decreased body weight gain and food consumption in rats treated with 30 mg/kg bw per day and in rabbits treated with 100 mg/kg bw per day, and mortality in both species treated with 90 to 100 mg/kg bw per day). Considering only acute effects (maternal mortality in rats and rabbits, and post-implantation loss in rabbits), the acute NOAEL in developmental studies is 30 mg/kg bw per day; however the overall maternal and developmental NOAEL is 10 mg/kg bw per day from the rat developmental study. Although metobromuron could inhibit dihydroxytestosterone *in vitro*, no androgenic or anti-androgenic activity was observed in studies performed *in vivo* (Hershberger assay) and no adverse effects were seen that could be indicative of an adverse endocrine modulation.

A data gap was identified to assess the relative toxicity of the three metabolites included in the plant residue definition (see section 3), **CGA 18236** (desmethoxy-metobromuron), **CGA 18237** (4-bromophenylurea) and **CGA 18238** (desmethyl-metobromuron) in comparison with the parent metobromuron. Acute oral toxicity studies, Ames tests and QSAR analysis were provided for the three metabolites that were found at low concentrations in the rat metabolism studies (< 1% of the administered dose for CGA 18238 and CGA 18237) or postulated to be intermediate in the rat metabolism (CGA 18236). These data are insufficient to conclude whether the reference values of the parent are applicable to the metabolites or if new reference values should apply and therefore a data gap was identified to address the consumer exposure to these metabolites. A further data gap was identified to address the toxicity of the metabolite **4-bromoaniline** that was found at low levels in the environment (see section 4) as publicly available information indicate that the metabolite should be regarded as toxic in contact with skin.

The acceptable daily intake (**ADI**) of metobromuron is 0.008 mg/kg bw per day, based on the NOAEL of 0.8 mg/kg bw per day from the 2-year study in mouse, applying a standard uncertainty factor (UF) of 100. The acceptable operator exposure level (**AOEL**) is 0.016 mg/kg bw per day, based on the NOAEL of 1.6 mg/kg bw per day from the 1-year dog study, supported by the multigeneration study in rats, 100 UF applied; no correction regarding oral absorption being necessary. The acute reference

[7] It should be noted that proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals. Classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

dose (**ARfD**) is 0.3 mg/kg bw, based on the NOAEL of 30 mg/kg bw per day for the acute effects observed in the rat and rabbit developmental studies, 100 UF applied.

Dermal absorption is 0.5 % when handling the concentrate formulation and 6.3 % when handling the in-use spray dilution. Estimated operator exposure is below the AOEL when personal protective equipment (PPE) is used, as gloves during mixing and loading operations, and gloves and coveralls during applications according to the German model. Estimated worker exposure is below the AOEL when PPE is considered as gloves, long sleeved shirt and long trousers and bystander exposure is calculated to represent at most 8% of the AOEL.

3. Residues

The assessment in the residue section below is based on the guidance documents listed in the document 1607/VI/97 rev. 2 (European Commission, 1999), and the JMPR recommendations on livestock burden calculations stated in the 2004 and 2007 JMPR reports (JMPR, 2004, 2007).

Metabolism in plants was investigated in potatoes representative of the "root and tuber" vegetable group using metobromuron radiolabelled with ^{14}C in the phenyl ring. The study was conducted with a total of one soil treatment (pre-emergence, five days after seeding) and using experimental design representative of the supported use (2.5 kg radio-labelled a.s./ha). At harvest metobromuron was neither detected in tubers nor in the foliage. TRR of metabolites in the tubers amounted to 18.2 % 4-bromophenylurea (0.017 mg/kg eq.), 1.3 % desmethoxy-metobromuron (0.0012 mg/kg eq.) and 0.6 % desmethyl-metobromuron (0.0006 mg/kg eq.) and in foliage 10.3 % 4-bromophenylurea (0.018 mg/kg eq.), 7.1 % desmethoxy-metobromuron (0.012 mg/kg eq.) and 13.8 % desmethyl-metobromuron (0.024 mg/kg eq.) were detected. Non-extractable residues represented the major part of the radioactivity in tubers (67.9 % TRR, 0.065 mg/kg eq.) and consisted mainly of radioactivity incorporated into the starch fraction (33.5 % TRR, 0.032 mg/kg eq.). A smaller amount of radioactivity was found in the protein fraction (5.5 % TRR, 0.0053 mg/kg eq.). It has been demonstrated that in strong acidic or basic conditions metobromuron and the identified metabolites with 4-bromoaniline moiety (desmethoxy-metobromuron, desmethyl-metobromuron and 4-bromophenylurea) hydrolyse to 4-bromoaniline.

The nature of residues in rotated crops was determined in lettuce, wheat, sugar beet and corn. In this study [Phenyl-(U)-14C]metobromuron was applied to bare soil at a rate of 2.5 kg a.s./ha. The study is 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). However the available data showed that the total residues in harvest samples exceeded 0.01 mg/kg only in the lettuce replanted 29 days after treatment. The analyses of the immature lettuce extracts showed the presence of metobromuron (0.021 mg/kg) and trace amounts of 4-bromophenylurea and desmethoxy-metobromuron. No parent metobromuron was found in any other sample. Based on the available data it can be considered that in case of crop failure, only root crops and leafy crops can be grown in the treated plot, while as rotational crops, cereals can be grown 6 months after application and one year after application all types of crops can be grown. However, considering the normal agricultural practice no quantifiable residues are expected to be found in rotated crops.

A total of 20 supervised residue trials have been conducted on potato, 11 in Northern Europe and 9 in Southern Europe (9 sites, 10 experiments). Among them, 7 Northern trials have not been considered because the analytical method was not fully validated or the maturity of tubers at harvest was not sufficient (below 50 % of the final size of tuber, stage BBCH 41-44). Samples collected were analysed for metobromuron, its metabolites 4-bromophenylurea, desmethoxy-metobromuron and desmethyl-metobromuron as well as for the common moiety 4-bromoaniline (after basic hydrolysis). In NEU, 4 residue trials have been considered among which residue level of 4-bromoaniline was in the range 0.009 and 0.032 mg/kg. The levels of 4-bromophenylurea were below or at the LOQ level of 0.005 mg/kg with exception for one of the trials where the amount determined was 0.007 mg/kg. The

remaining compounds were either not detected or detected but at levels at or below the LOQ of 0.005 mg/kg. In SEU, 9 residue trials have been considered. Residue levels of 4-bromoaniline were in the range <0.005-0.024 mg/kg. For 4-bromophenylurea the range was <0.005-0.008 mg/kg, while metobromuron, desmethoxy-metobromuron and desmethyl-metobromuron were not found at levels above the LOQ.

As the total residues in field trials were significantly below the trigger value of 0.1 mg/kg, no processing study is required.

Residues of metobromuron, desmethyl-metobromuron, desmethoxy-metobromuron and 4-bromophenylurea have been shown to be stable in potato and lamb's lettuce when stored deep frozen at <-18°C for at least 12 months.

As seen in the residue trials, it is not expected that residues of metobromuron and metabolites are present at harvest in potato samples at levels exceeding the common monitoring LOQ of 0.01 mg/kg. Most consistently residues of 4-bromophenylurea were found in potatoes treated with metobromuron (HR of 0.008 mg/kg from the residue trial and almost 20 % of TRR from the metabolism study). Therefore 4-bromophenylurea was set as residue definition for monitoring. Based on the results of the residue trials it has been concluded that total hydrolysable residues analysed as 4-bromoaniline (that include the parent and the metabolites with 4-bromoaniline moiety: desmethoxy-metobromuron, desmethyl-metobromuron and 4-bromophenylurea) and calculated as parent metobromuron is an appropriate plant residue definition for risk assessment. A conversion factor of 3.4 is proposed in potatoes between monitoring and risk assessment residue definitions.

TMDIs for domestic animals have been calculated using the HR found for 4-bromoaniline (0.032 mg/kg). The intakes calculated for pigs and beef cattle were slightly above the trigger value (0.13 *vs.* 0.10 mg/kg dry matter), however it was considered that the requirement for livestock metabolism study can be waived on the basis that the calculations account the worst case situation (60 % intake of potatoes for pigs and beef cattle and all compounds that can be hydrolysed to 4-bromoaniline).

Based on the individual results for 4-bromophenylurea an MRL of 0.01 mg/kg is proposed for potatoes. The content of 4-bromophenylurea in the rejected trials (tubers collected at stage BBCH 41-44), that could be considered as worst case, is similar to that found in the rest of the NEU and SEU trials (H-test, 5%). Moreover, if the values from the rejected studies are considered in the calculations, the MRL would not be affected. Therefore it is considered that additional trials in NEU are not needed.

No acute or chronic risks were identified for the consumers using the EFSA PRIMO model rev 2.0. The highest TMDI, 10.5 % of ADI for metobromuron (FR Toddler), is calculated considering a default MRL of 0.01 mg/kg in all commodities and, for potato, the proposed MRL of 0.01 mg/kg multiplied by the conversion factor of 3.4 derived from the residue trials. The IESTI calculated using the HR of 4-bromoaniline amounts to 1.6 % of the ARfD for metobromuron (0.3 mg/kg bw). However the consumer risk assessment should be considered provisional pending the outcome of the requested toxicological information on the metabolites included in the residue definitions (see section 2).

4. Environmental fate and behaviour

Route and rate of degradation was investigated in five soils under laboratory dark aerobic conditions at 20 °C (four soils) and 25 °C (one soil) with radiolabelled metobromuron. Metobromuron exhibited moderate persistence in these soils. No major metabolites were identified in these experiments. Major part of radioactivity was converted to non-extractable residues in soil (55.8 – 74.1 % AR after 118 d). Mineralisation accounted for 10.8 to 19.7 % AR at the end of the studies (118 d) performed at 20 °C. Four minor metabolites were identified: desmethoxy-metobromuron (3 %), desmethyl-metobromuron (1.2 %), 4-bromophenylurea (1.8 %) and 4-bromoaniline (1.7 %). None of them reached levels of 5 % or higher over the time of the study. However, data gaps for toxicological information have been identified due to its presence in food residues and/or existing indications of adverse toxicological

properties (see section 2). In case these metabolites were to be assessed as toxicological relevant metabolites they may need to be further considered in the residue definition for ground water exposure assessment. Aerobic degradation of major anaerobic metabolite desmethoxy-metobromuron was investigated in three soils at 20 °C. This anaerobic metabolite exhibits moderate to medium persistence under aerobic conditions.

An additional degradation study was performed under anaerobic conditions in one soil. Under these conditions, metobromuron exhibits medium persistence. Desmethoxy-metobromuron was identified as a major metabolite under anaerobic conditions (>10 % AR after 90 d). Photodegradation was investigated in one soil. Degradation was slightly enhanced by photolysis but no new metabolites were identified.

Field soil dissipation of metobromuron was investigated in a field trial in Switzerland (Nicollier, G. 1995 in France 2013a). Re-homogenisation of upper soil layer was performed after application. This study gives qualitative indications of potential higher formation of metabolites and / or unextractable residues than observed in the laboratory studies. However, in EFSA's view reliability of this study for environmental risk assessment is questionable. Field dissipation was investigated in four additional sites in Germany, France (2 sites, one North and one South) and Spain. Metobromuron exhibits moderate to medium persistence in these field trials. PEC soil was calculated for the representative use based on the worst case field DT_{50}.

Reliable batch soil adsorption/desorption studies are available for metobromuron (5 soils) and major anaerobic metabolite desmethoxy-metobromuron (3 soils). Metobromuron may be classified as medium to high mobile and desmethoxy-metobromuron may be classified as medium mobile according to these studies.

Metobromuron is stable to hydrolysis at 20 °C in buffered pHs 4, 7 and 9 aqueous solutions. According the available aqueous photolysis study, photolysis may contribute to the degradation of metobromuron in the aquatic environment. A number of photolysis metabolites were formed but only desbromo-metobromuron significantly exceeded 10 % AR and needs further consideration in the environmental risk assessment (max. 35.0 % AR). No readily biodegradation test is available for metobromuron. Metobromuron is not considered to be readily biodegradable. Fate and behaviour of metobromuron in the aquatic environment was investigated in two laboratory dark aerobic water/sediment systems. Metobromuron partitioned with sediment and degraded in the whole system with half-lives of 33.2 to 34.5 d. Two major metabolites were formed: desmethoxy-metobromuron and 4-bromophenylurea (both > 10 % AR in water and sediment phases). Maximum unextractable residues in the sediment amounted 43.1 – 52.7 % AR and mineralisation (as CO_2) to 3.1-10.9 % AR. PEC SW were calculated for metobromuron up to FOCUS SW Step 4 with 20 m spray drift buffer and 20 m vegetative run-off mitigation strip taking into account volatilisation and re-deposition of metobromuron following recommendations of FOCUS Air and EVA 2.0.1 model (FOCUS, 2001; FOCUS, 2007; FOCUS, 2008). PEC SW were also calculated for metabolites desmethoxy-metobromuron, 4-bromophenylurea, desbromo-metobromuron up to FOCUS SW Step 2 (FOCUS, 2001).

Potential groundwater contamination was assessed by 20 year average calculation of 80th percentile 1 m depth leachate concentration for metobromuron and major anaerobic metabolite desmethoxy-metobromuron with FOCUS GW PEARL 3.3.3, PELMO 3.3.2 (FOCUS, 2000; EFSA PPR Panel, 2004) and FOCUS GW PEARL 4.4.4 and PELMO 4.4.3 (FOCUS, 2009) assuming one annual application of 2000 g/ha of metobromuron on potatoes. The limit of 0.1 µg/L was not exceeded for any of the scenarios by any of the compounds simulated. [8]

[8] A Q10 of 2.58 (EFSA PPR Panel, 2007) and Walker equation coefficient of 0.7 was used in these simulations and for the normalisation of the degradation input parameters used in the modelling.

A two years lysimeter study in two different lysimeter systems in Germany with application rate comparable to the representative use is available. No metobromuron or metobromuron metabolites were identified at levels above 0.1 µg /L in the leachates collected in these lysimeters.

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a, 2002b, 2002c), SETAC (2001), and EFSA PPR Panel (2009).

A low acute risk from dietary exposure was indicated for birds and mammals at the first tier risk assessment while the long-term risk was concluded as high. Refined long-term risk assessments based on generic focal species and ecological data were discussed at the Pesticides Peer Review Meeting 105 in September 2013. As regards to birds, it was agreed to use the NOEL of 21.6 mg/kg bw per day. The experts at the meeting questioned the use of generic focal species such as linnet (*Carduelis cannabina*), skylark (*Alauda arvensis*) and yellow wagtail (*Motacilla flava*) (instead of real focal species) in combination with the ecological data (*i.e.* PT values). In general, it was acknowledged that real focal species should be used in higher tier risk assessment. However, for the representative use under evaluation, the experts concluded that the proposed generic species might be considered as suitable for Northern and Southern Europe, except skylark which was considered suitable only for Northern and Central Europe. Regarding the PT parameters, it was concluded that the data provided were not sufficient to support the proposed values. Overall, high long-term risk to birds could not be excluded and therefore a data gap and an issue that could not be finalised were identified. As regards to mammals, it was agreed to apply the 90th percentile PT value and the worst-case PD values. On this basis the refined TER was slightly below the trigger (*i.e.* TER of 4.93). Given the potential uncertainties from the data set used for the refined risk assessment, EFSA considered it necessary to identify a data gap to further address the long-term risk to mammals e.g. by a weight of evidence approach accounting for uncertainty in the available refined risk assessment.

Several toxicity studies were available on fish, aquatic invertebrates, algae and aquatic plants with metobromuron technical, the metabolites (only on algae and aquatic plants) and the formulated product 'Metobromuron 500 SC'. The risk assessments of the active substance indicated a low acute risk to fish and a low acute and chronic risk to daphnids with PECsw FOCUS Step 2. Higher tier risk assessments were needed for fish (chronic), algae and aquatic plants. The risk was low based on FOCUS Step 4 PECsw calculations which included mitigation measures comparable to up to 20 m of no-spray buffer zone in combination with 20 m vegetated buffer strips to mitigate run-off for all the scenarios, except for the R3 scenario (data gap). The risk for algae and aquatic plants was assessed as low for the metabolites with FOCUS Step 2.

The risk to terrestrial non-target plants was assessed as low providing that mitigation measures such as no-spray in-field buffer zone up to 10 m are applied.

The risk was assessed as low for bees, non-target arthropods, earthworms, soil macro and micro-organisms and biological methods for sewage treatment plants.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Metobromuron	moderate $DT_{50\ lab\ 20\ C}$ = 24.6 – 49.7 d	Low risk for soil organisms
Desmethoxy-metobromuron (only to be assessed for anaerobic conditions)	moderate to medium $DT_{50\ lab\ 20\ C}$= 49.9 – 72.5 d	Low risk for soil organisms

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
Metobromuron	Medium to high Koc = 122 – 199 mL/g	FOCUS GW: No Lysimeter: No	yes	Yes	Low risk to aquatic organisms in surface water for FOCUS step 4 scenarios, including mitigation measures, except for R3 scenario where a high risk could not be excluded

Desmethoxy-metobromuron (only to be assessed for anaerobic conditions)	Medium Koc = 184 -198 mL/g	FOCUS GW: No Lysimeter: No	No data, not required	Rat acute oral LD_{50} > 2000 mg/kg bw Negative Ames test Relevant based on the carcinogenic properties of the parent compound metobromuron[(a)]	Low risk to aquatic organisms in surface water

(a) It should be noted that proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals. Classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
Metobromuron	Low risk to aquatic organisms for FOCUS step 4 scenarios, including mitigation measures, except for R3 scenario where a high risk could not be excluded
Desmethoxy-metobromuron	Low risk to aquatic organisms
4-bromophenylurea	Low risk to aquatic organisms
desbromo-metobromuron (aqueous photolysis metabolite max. 35.0 % AR),	Low risk to aquatic organisms

6.4. Air

Compound (name and/or code)	**Toxicology**
Metobromuron	Rat LC_{50} inhalation > 1.6 mg/L air/4h, nose only exposure (highest attainable concentration); no classification proposed

7. List of studies to be generated, still ongoing or available but not peer reviewed

This is a complete list of the data gaps identified during the peer review process, including those areas where a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 7 of Directive 91/414/EEC concerning information on potentially harmful effects).

- Validated methods for analysis of residues in dry, high acid content and high oil content matrices of plant origin and verification of the extraction efficiency of the proposed enforcement method for high water content plant matrices (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1)

- Toxicological information allowing to conclude on the relative toxicity and respective reference values of metabolites CGA 18236 (desmethoxy-metobromuron), CGA 18237 (4-bromophenylurea) and CGA 18238 (desmethyl-metobromuron) included in the plant residue definitions (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see sections 2, 3 and 4)

- Toxicological information on the environmental metabolite 4-bromoaniline (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see sections 2 and 4)

- Pending on the provision of information on the toxicological properties of the metabolites CGA 18236 (desmethoxy-metobromuron), CGA 18237 (4-bromophenylurea) and CGA 18238 (desmethyl-metobromuron) and 4-bromoaniline further consideration on the residue definition for assessment of groundwater exposure may be necessary (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see sections 2, 3 and 4)

- The long-term risk to birds and mammals should be further considered (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5)

- The risk to aquatic organisms for the situation covered by the R3 FOCUS scenario should be further addressed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 5)

8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- Estimated operator exposure is below the AOEL when PPE is used: gloves during mixing and loading operations, and gloves and coveralls during applications according to the German model (see section 2).

- Estimated worker exposure is below the AOEL when PPE is considered as gloves, long sleeved shirt and long trousers (see section 2).

- Mitigation measures (e.g. up to 20 m no-spray buffer zone and up to 20 m vegetated buffer strip) were needed to manage the risk for aquatic organisms for the situation covered by the FOCUS scenarios D3, D4, D6, R1, R2 (see section 5).

- Mitigation measures (e.g. up to 10 m in-field no-spray buffer zone) were needed to manage the risk to terrestrial non-target plants (see section 5).

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as an issue that could not be finalised where there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC and where the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

1. The consumer risk assessment should be considered provisional pending the outcome of the toxicological information requested on the metabolites included in the residue definitions.

2. A high long-term risk to birds could not be excluded with the available data.

9.2. Critical areas of concern

An issue is listed as a critical area of concern where there is enough information available to perform an assessment for the representative uses in line with the Uniform Principles of Annex VI to Directive 91/414/EEC, and where this assessment does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern where the assessment at a higher tier level could not be finalised due to a lack of information, and where the assessment performed at the lower tier level does not permit to conclude that for at least one of the representative uses it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater or any unacceptable influence on the environment.

No critical areas of concern have been identified for the assessed representative use.

9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in section 8, has been evaluated as being effective, then 'risk identified' is not indicated in this table.)

Representative use		**Potatoes**
Operator risk	Risk identified	
	Assessment not finalised	
Worker risk	Risk identified	
	Assessment not finalised	
Bystander risk	Risk identified	
	Assessment not finalised	
Consumer risk	Risk identified	
	Assessment not finalised	X[1]
Risk to wild non target terrestrial vertebrates	Risk identified	
	Assessment not finalised	X[2]
Risk to wild non	Risk identified	

target terrestrial organisms other than vertebrates	Assessment not finalised	
Risk to aquatic organisms	Risk identified	X (R3 scenario)
	Assessment not finalised	
Groundwater exposure active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure metabolites	Legal parametric value breached	
	Parametric value of 10µg/L breached	
	Assessment not finalised	
Comments/Remarks		

The superscript numbers in this table relate to the numbered points indicated in sections 9.1 and 9.2. Where there is no superscript number see sections 2 to 6 for further information.

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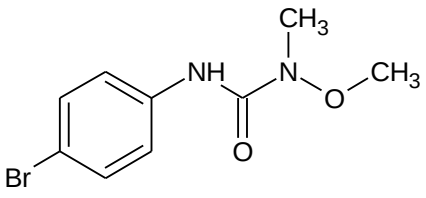
APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name)	Metobromuron
Function (*e.g.* fungicide)	Herbicide
Rapporteur Member State	France

Identity (OECD data point IIA 1)

Chemical name (IUPAC)	3-(4-bromophenyl)-1-methoxy-1-methylurea
Chemical name (CA)	N'-(4-bromophenyl)-N-methoxy-N-methylurea
CIPAC No	168
CAS No	3060-89-7
EEC No (EINECS or ELINCS)	221-301-5
FAO Specification (including year of publication)	not available
Minimum purity of the active substance as manufactured (g/kg)	978 g/kg (purity was based on commercial scale production of 5 batches)
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	no relevant impurities
Molecular formula	$C_9H_{11}BrN_2O_2$
Molecular mass	259.1
Structural formula	

Physical-chemical properties (OECD data point IIA 2)

Melting point (state purity)	95.6°C – 97.5°C (98.48%)
Boiling point (state purity)	Decomposition at 173.2°C (98.48%)
Temperature of decomposition	173.2°C (98.48%)
Appearance (state purity)	Very light yellow crystalline solid with a musty, naphthalenic odour (98.48%)
Relative density (state purity)	D_4^{20}=1.52 (98.48%)
Surface tension	72.2 mN/m (90% solution of water solubility) (98.48%)
Vapour pressure (in Pa, state temperature)	2.19 x 10^{-4} Pa at 25°; 1.44x10^{-4} Pa at 20°C (98.48%)
Henry's law constant (Pa m^3 mol^{-1})	1.14 x 10^{-4}Pa · m^3 · mol^{-1} at 20°C
Solubility in water (g/l or mg/l, state temperature)	0.328 g/L at 20°C (98.48%) (Due to high pKa of 12.0 and the solubility < 1 g/L effect of pH was not investigated)
Solubility in organic solvents (in g/L or mg/L, state temperature)	(98.48%) solubility at 20°C Heptane: <10g/L 1,2-Dichloro~~m~~ethane: >250g/L Methanol: >250g/L Acetone: >250g/L Xylene: 50 - 57g/L Ethyl Acetate: >250g/L
Partition co-efficient (log P_{OW}) (state pH and temperature)	Log Po/w = 2.48 at 20°C and pH 7.3 (98.48%) (effect of pH was not investigated, not required)
Dissociation constant	pKa=12.0 at 20°C
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	λ Max: 245 nm (all pH ranges)
Flammability	Not highly flammable
Explosive properties	Not explosive
Oxidising properties ‡ (state purity)	Not oxidising

Summary of representative uses evaluated (metobromuron)

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc of a.s. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	Kg a.s./hl min max (g/hl)	Water l/ha min max	kg a.i./ha min max (kg/ha)		
Potatoes	EU	Metobromuron 500 SC	F	Weeds	SC	500 g/L	Overall broadcast spraying	00	1	n.a.	1.0	200	2.0	Not applicable	

(a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage at 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
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	High Performance Liquid Chromatography (HPLC), equipped with UV-DAD detector
Impurities in technical as (principle of method)	High Performance Liquid Chromatography (HPLC) equipped with UV detector, Gas Chromatography equipped with Mass Detector (MS), GC ECD and Thermal Energy Analyser (TEA)
Plant protection product (principle of method)	High Performance Liquid Chromatography (HPLC), equipped with UV-DAD detector

Residue definitions for monitoring purposes

Food of plant origin	4-Bromophenylurea
Food of animal origin	No residue definition was set for animal products
Soil	Metobromuron
Water surface	Metobromuron
drinking/ground	Metobromuron
Air	Metobromuron

Monitoring/Enforcement methods

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	High Performance Liquid Chromatography (HPLC), equipped with tandem Mass Detector (MS/MS) [QuECheRS multiresidue method] The LOQ is 0.005 mg/kg for potato The LOQ is 0.01 mg/kg for lamb's lettuce Data/justification to address the verification of the extraction efficiency of the enforcement method provided for high water content matrix are required. Validated method(s) for analysis of residues in dry, high acid content and high oil content matrices is required.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	None, not triggered
Soil (principle of method and LOQ)	High Performance Liquid Chromatography (HPLC), equipped with tandem Mass Detector (MS/MS) The LOQ is 0.01 mg/kg for soil
Water (principle of method and LOQ)	High Performance Liquid Chromatography (HPLC), equipped with tandem Mass Detector

	(MS/MS) The LOQ is 0.05 µg/L for drinking, ground and surface water
Air (principle of method and LOQ)	High Performance Liquid Chromatography (HPLC), equipped with tandem Mass Detector (MS/MS) The LOQ is 2.0 µg/m^3 for air
Body fluids and tissues (principle of method and LOQ)	None, not triggered

Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)

	RMS/peer review proposal
Active substance	

Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	> 80%, based on urinary excretion, cage wash, carcass and tissues residues within 24h
Distribution ‡	Widely distributed, highest value in blood. Metobromuron seems to associate with blood cellular component
Potential for accumulation ‡	No evidence for accumulation
Rate and extent of excretion ‡	Rapid and extensive > 90% within 72h, mainly via urine (75%) within 24 h, 10% via faeces
Metabolism in animals ‡	Complete degradation, N-demethylation/N-demethoxylation, phenyl ring hydroxylation and conjugation
Toxicologically relevant compounds ‡ (animals and plants)	Metobromuron
Toxicologically relevant compounds ‡ (environment)	Metobromuron

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	1000-2000 mg/kg bw (female rat) 1290-2150 mg/kg bw (male mice)	**Acute tox 4, H302**
Rat LD_{50} dermal ‡	> 3000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 1.6 mg/L air/4h, nose only exposure (highest attainable concentration)	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Sensitiser (Magnusson & Kligman)	**Skin sens, H317**

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Blood system: regenerative haemolytic anemia, body weight effects (all species) Rat: spleen, bone marrow Mouse: spleen Dog: liver, kidney, spleen, bone marrow	
Relevant oral NOAEL ‡	28-day, rat: < 2.7 mg/kg bw per day 28-day, mouse: < 13.8 mg/kg bw per day 1-year, dog: 1.59 mg/kg bw per day	**STOT RE 2, H373**
Relevant dermal NOAEL ‡	28-day, rat: 40 mg/kg bw per day	
Relevant inhalation NOAEL ‡	No data – not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

	Metobromuron is unlikely to be genotoxic	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	Rat: Blood system, mammary gland, adrenals Mouse: Blood system	
Relevant NOAEL ‡	2.6 mg/kg bw per day;2-year, rat 0.8 mg/kg bw per day; 2-year, mouse	
Carcinogenicity ‡	Increased incidence of mammary gland fibrosarcoma in female and pheochromocytomas in male rat. NOAEL carcinogenicity: 2.6 and 3.4 mg/kg bw per day in males and females No carcinogenicity potential in mouse	**Carc. cat 2, H351**

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental toxicity: haemolytic regenerative anemia Offspring's and reproductive toxicity: no effects	
Relevant parental NOAEL ‡	1.38 mg/kg bw per day	
Relevant reproductive NOAEL ‡	16.03 mg/kg bw per day (highest dose tested)	
Relevant offspring NOAEL ‡	16.03 mg/kg bw per day (highest dose tested)	

Developmental toxicity

Developmental target / critical effect ‡	Parental toxicity: reduced bw gain and feed consumption (rats and rabbits) and mortality (rabbits) Developmental toxicity: Delayed ossification (rats) and post-implantation losses (rabbits)	
Relevant maternal NOAEL ‡	Rats: 10 mg/kg bw per day (30 mg/kg bw per day for acute effects) Rabbits: 30 mg/kg bw per day	
Relevant developmental NOAEL ‡	Rats: 10 mg/kg bw per day Rabbits: 30 mg/kg bw per day	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	No data – not required	
Repeated neurotoxicity ‡	No data – not required	
Delayed neurotoxicity ‡	No data – not required	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	4-weeks oral feeding study in rat + 9 weeks recovery - reversibility of haemolytic effects - no sperm effects LOAEL 3.3 mg/kg bw per day (heamatological changes) Hershberger assay No androgenic or anti-androgenic potential seen up to 100 mg/kg bw per day *In vitro* assays (T47D-Luc Reporter gene assay (stable transfection) and prostate specific antigen (PSA) expresssion assay) indicate that metabromuron may inhibit dihydroxytestosterone (DHT) expression, either as decreased luciferase activity or decreased PSA formation; quantitative comparison among several analogues of phenyl ureas was not conclusive and no correlated effects were found *in vivo*.
Studies performed on metabolites or impurities ‡	CGA 18236 (desmethoxy-metobromuron): Rat oral LD_{50} > 2000 mg/kg bw Negative Ames test Toxicological profile similar to metobromuron in QSAR models – further data required to address consumer exposure
	CGA 18237 (4-bromophenylurea): Rat oral LD_{50} between 300 and 2000 mg/kg bw (Acute tox 4, H302) Negative Ames test Toxicological profile similar to metobromuron in QSAR models – further data required to address consumer exposure
	CGA 18238 (desmethyl-metobromuron): Rat oral LD_{50} oral > 2000 mg/kg bw Negative Ames test Toxicological profile similar to metobromuron in QSAR models – further data required to address consumer exposure
	4-bromoaniline: publicly available information indicate that this environmental metabolite should be regarded as toxic in contact with skin – data required

Medical data ‡ (Annex IIA, point 5.9)

Limited data on medical surveillance of manufacturing plant personnel (commercial scale production of 5 batches) did not indicate abnormal behaviour, health complaints or change in the health status of the workers linked to metobromuron production.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.008 mg/kg bw per day	mouse, 2-year study	100
AOEL ‡	0.016 mg/kg bw per day	dog, 1-year, supported by the rat multigeneration study	100*
ARfD ‡	0.3 mg/kg bw	rat and rabbit, developmental studies	100

*no correction needed regarding oral absorption

Dermal absorption ‡ (Annex IIIA, point 7.3)

Formulation Metobromuron 500 SC (suspension concentrate containing 500 g metobromuron/L, e.g. BCP 222 H)	Concentrate: 0.5% In-use spray dilution (1:50): 6.3% *In vitro* study through human skin

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Estimated exposure using tractor mounted equipment (application rate: 2 kg metobromuron/ha, 200L min. spray volume) % of AOEL German model: Without PPE 508% With PPE (gloves during M/L, coverall during application) 123% With PPE (gloves during M/L and gloves and coverall during application) 39% UK-POEM: Without PPE 3321% With PPE (gloves during M/L and application) 512%
Workers	EUROPOEM II worker re-entry model for crop inspection % of AOEL Without PPE: 394% With PPE (gloves, long sleeved shirt, long trousers):

	39%
Bystanders	Estimated exposure: 8% of the AOEL

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

Substance classified	Metobromuron
Harmonised classification	Currently not listed in Annex VI of Regulation (EC) No 1272/2008[9] (as amended)
RMS/peer review proposal [10]	<u>Considering the criteria of Regulation (EC) 1272/2008 (as amended):</u> Acute tox. 4 –H302 'Harmful if swallowed' Skin sens. H317 'May cause an allergic skin reaction' Carc. cat 2 –H351 'Suspected of causing cancer' STOT RE cat 2 –H373 'May causes damage to blood system through prolonged or repeated exposure'

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

[10] It should be noted that proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals. Classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008.

Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	Potato
Rotational crops	Lettuce (30 and 365 days), wheat (180 days), sugar beet (365 days), corn (365 days)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Not necessary
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not relevant
Plant residue definition for monitoring	4-bromophenylurea
Plant residue definition for risk assessment	total hydrolysable residue analyzed as 4-bromoaniline and expressed as parent metobromuron
Conversion factor (monitoring to risk assessment)	3.4

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Not required
Time needed to reach a plateau concentration in milk and eggs	Not relevant
Animal residue definition for monitoring	Not required
Animal residue definition for risk assessment	Not required
Conversion factor (monitoring to risk assessment)	Not relevant
Metabolism in rat and ruminant similar (yes/no)	Not required
Fat soluble residue: (yes/no)	No

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

	Lettuce (30 and 365 days), wheat (180 days), sugar beet (365 days), corn (380) – Metobromuron of metabolite never detected except traces in mature lettuce at the 29 replanting interval. In case of crop failure, only potatoes (or another root crop) and lettuce (or another leafy crop) can be grown in the treated plot. For rotational crops, it is possible to estimate that cereals can be grown 6 months after application and one year after application no quantifiable residues are expected whatever the crop grown.

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)

Residues of metobromuron, desmethyl-metobromuron, desmethoxy-metobromuron and 4-bromophenylurea have been shown to be stable in potato and lamb's lettuce when stored deep frozen at <-18°C for at least 12 months.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant	Poultry	Pig
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	no	no	no
Potential for accumulation (yes/no)	no	no	no
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	NA	NA	NA
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) Residue levels in matrices : Mean (max) mg/kg		
Muscle	Not required	Not required	Not required
Liver	Not required	Not required	Not required
Kidney	Not required	Not required	Not required
Fat	Not required	Not required	Not required
Milk	Not required		
Eggs		Not required	

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses (mg/kg) (a)	Recommendation/comments	MRL estimated from trials according to the representative use (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (b)
Potato	NEU, field	2 x <0.005; 0.005; 0.007	Not enough trials to derive an MRL	NA	0.007	0.005
	SEU, field	6 x <0.005; 2 x 0.005; 0.008	Sufficient data are available to support the intended use and derive a MRL.	0.01	0.008	0.005
	EU, field	8 x <0.005; 3 x 0.005; 0.007; 0.008	-	0.01	0.008	0.005

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
(c) Highest residue

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.008 mg/kg bw per day
TMDI (% ADI) according to WHO European diet	Highest TMDI: 10.5% ADI (FR Toddler)
TMDI (% ADI) according to French diets	-
IEDI (WHO European Diet) % ADI)	Highest IEDI: 1.6 % ADI (NL Child)
NEDI (specify diet) (% ADI)	-
Factors included in IEDI and NEDI	$STMR_{RA}$ (potatoes only)
ARfD	0.3 mg/kg bw
IESTI (%ARfD)	1.6 % ARfD (potatoes)
NESTI (% ARfD) according to national (to be specified) large portion consumption data	-
Factors included in IESTI and NESTI	Highest residue (HR)

The consumer risk assessment should be considered provisional pending the outcome of the toxicological information requested on the metabolites included in the residue definitions.

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Not applicable, no residues

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

4-bromophenylurea:	
Potato	0.01 mg/kg

Environmental fate and behaviour

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralization after 100 days ‡	10.8-19.7% (day 118, study end); 27.3% (day 168, study end)
Non-extractable residues after 100 days ‡	55.8-74.1% (day 118, study end); 57.2% (day 168, study end)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	None

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡

Mineralization after 100 days	4.0% (day 90 of anaerobic incubation, study end)
Non-extractable residues after 100 days	53.7% (day 90 of anaerobic incubation, study end)
Metabolites that may require further consideration for risk assessment – name and/or code, % of applied (range and maximum)	Desmethoxy-metobromuron (5.1% after 60 days, 14.9% after 90 days)

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment – name and/or code, % of applied (range and maximum)	None

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies

Parent	Aerobic conditions						
Soil type	OC %	pH	t. °C / % MWHC	DT_{50}/DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	χ^2	Method of calculation
Silt, Les Barges	1.7	7.7	25 / 75 % FC	25.7 / 85.3	33.8	5.88	SFO
Silt loam, Fislis	2.00	6.72	20 / pF2.0-2.5	24.6 / 81.3	24.6	3.91	SFO
Clay, Speyer 6S	1.44	7.30	20 / pF2.0-2.5	28.4 / 94.3	28.4	5.17	SFO
Loamy sand, Speyer 2.2	1.83	6.12	20 / pF2.0-2.5	49.7 / 165.1	49.7	3.25	SFO
Sandy loam, Longwoods	1-1.5	7.5	20 / pF2.0-2.5	40.3 / 133.8	40.3	2.2	SFO

Geometric mean	- / -	34.3	-	-

Desmethoxy-metobromuron	Aerobic conditions							
Soil type	OC %	pH	t. °C / % MWHC	DT_{50}/DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	χ^2	Method of calculation
Sandy loam, Longwoods	1.53	7.33	20 / pF2.0-2.5	49.9 / 165.6	- *	49.9	6.6	SFO
Clay, Speyer 6S	1.79	7.13	20 / pF2.0-2.5	72.5 / 240.9	-*	72.5	6.4	SFO
Silt loam, Fislis	1.28	7.07	20 / pF2.0-2.5	61.5 / 204.4	-*	61.5	6.1	SFO
Geometric mean (n=3)				- / -	-	60.6	-	-

* desmethoxy-metobromuron as test item

Field studies

Parent	Aerobic conditions								
Soil type	Location	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	χ^2	DT_{50} (d) Norm.	Method of calculation
Clay	St. Aubin, Switzerland		6.6	0-10	18.3	60.8	-*	8.8	SFO
Silt loam	Harthau, Germany		6.3	0-60	4.1	55.1	10.7	5.4	DFOP for actual DT values, SFO for normalised values
Loam	La Chapelle de Guinchay, N France		4.9	0-60	73.3	243.6	19.7	47.0	SFO
Sandy clay loam	Sevilla, Spain		6.6	0-60	71.1	236.1	13.7	64.5	SFO
Clay	Nimes, S France		7.8	0-60	32.9	109.3	6.4	38.9	SFO
Geometric mean (n=5)					-	-	-	22.4	-

* not reported, $r^2 = 0.9922$

Met 1	Aerobic conditions – not studied								
Soil type	Location		pH	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (r^2)	DT_{50} (d) Norm.	Method of circulation
-	-	-	-	-	-	-	-	-	-
Geometric mean/median					-	-	-	-	-

pH dependence ‡ (yes / no) (if yes type of dependence)	No
Soil accumulation and plateau concentration ‡	Not studied, not required

Laboratory studies ‡

Parent	Anaerobic conditions					
Soil type	pH ($CaCl_2$)	t. °C / % MWHC	DT_{50}/DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of circulation
Silt loam	6.43	20 / pF2.5	73.7 / 245.0	-	0.93348	SFO
Geometric mean/median		-	-	-	-	-

Met 1	Anaerobic conditions – not studied						
Soil type	pH	t. °C / % MWHC	DT_{50}/DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of circulation
-	-	-	-	-	-	-	-
Geometric mean/median		-	-	-	-	-	-

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil type	OC %	Soil pH ($CaCl_2$)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silt loam	2.51	7.25	-	-	3.81	152	0.92
Clay	1.89	7.0	-	-	2.30	122	0.93
Loamy sand	2.16	5.4	-	-	2.85	132	0.90
Silt loam	4.05	5.38	-	-	7.82	193	0.84
Sandy loam	1.28	7.4	-	-	2.55	199	0.87
Arithmetic mean (n=5)						160	0.89
pH dependence, Yes or No			No				

Metabolite 1 ‡ desmethoxy-metobromuron							
Soil type	OC %	Soil pH ($CaCl_2$)	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Silt loam	1.28	7.1	-	-	3.82	298	0.723
Clay	1.69	7.1	-	-	3.66	217	0.763
Sandy loam	1.44	7.2	-	-	2.65	184	0.738
Arithmetic mean (n=3)					3.38	233	0.741
pH dependence, Yes or No			No correlation could be investigated (small pH range)				

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	No data available – not required
Aged residues leaching ‡	No data available – not required
Lysimeter/ field leaching studies ‡	Location: Germany Soil properties: sandy loam, pH 5.7, OC% 1.5 Date of application: 7 May 1991 Duration: 2 years Rate of application: 2000 g/ha Cropping: potato during summer 1991, winter wheat autumn 1991 to summer 1992, winter barley autumn 1992 to spring 1993 Annual rainfall: 1st year 887.2 mm, 2nd year 890.2 mm Leachate: annual average concentration 0.24 to 0.56 µg/L Metobromuron in leachate: not detected

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50}: 73.3 days (longest field $DT_{50,}$ non-normalised) Kinetics: SFO
Application data	Number of applications: 1 Rate of application: 2000 g as/ha Crop interception: 0% Depth of soil layer: 5 cm Bulk density 1.5 g/cm^3

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average

Initial		2.667		-	
Short term	24h	2.642	2.654	-	-
	2d	2.617	2.642	-	-
	4d	2.568	2.617	-	-
Long term	7d	2.496	2.580	-	-
	21d	2.186	2.419	-	-
	28d	2.046	2.343	-	-
	50d	1.662	2.125	-	-
	100d	1.036	1.725	-	-
Plateau concentration		Not calculated, not required			

Metabolite I	Desmethoxy-metobromuron
Method of calculation	Conversion from the parent PECsoil with formation of 100% and 5.1%.
Application data	A molar ratio of 0.884 (metobromuron 259.1 g/mol, desmethoxy-metobromuron 229.1 g/mol)

$PEC_{(s)}$ (mg/kg)		**Formation rate: 100%** Actual	Time weighted average	**Formation rate: 5.1%** Actual	Time weighted average
Initial		2.358		0.120	
Short term	24h	-	-	-	-
	2d	-	-	-	-
	4d	-	-	-	-
Long term	7d	-	-	-	-
	28d	-	-	-	-
	50d	-	-	-	-
	100d	-	-	-	-
Plateau concentration		Not calculated, not required			

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4: stable at 20°C, DT_{50} 31.5 d at 50°C, DT_{50} 1.6 d at 70°C pH 7: stable at 20°C, DT_{50} 27.2 d at 50°C, DT_{50} 1.6 d at 70°C pH 9: stable at 20°C, DT_{50} 32.6 d at 50°C, DT_{50} 1.6 d at 70°C
Photolytic degradation of active substance and	DT_{50} 5.6 days at pH 7, corresponding to 12.1 days

metabolites above 10 % ‡	natural summer sunlight at 30-40 °N Photolytic metabolites: desbromo-metobromuron (max. 35.0 % AR), 1-(4-hydroxyphenyl)-3-methylurea (max. 9.8 % AR), 3-(4-hydroxyphenyl)-1-methoxy-1-methylurea (max. 7.1 % AR)
Quantum yield of direct phototransformation in water at Σ > 290 nm	0.006702 molecules degraded photon^{-1}
Readily biodegradable ‡ (yes/no)	No

Degradation in water / sediment

Parent	Distribution (max. in water 100 % after 0 d; max. in sed 28.7 % after 14 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}/DT_{90} whole sys.	St. (χ^2)	DT_{50}/DT_{90} water	St. (r^2)	DT_{50}/DT_{90} sed	St. (r^2)	Method of calculation
River	8.11	7.20	20	33.2 / 110.3	4.24	18.3 / 60.9	11.2	-	-	SFO
				-	-	14.5 / 70.5	2.66	-	-	DFOP
Pond	8.30	7.13	20	34.5 / 114.6	2.77	14.3 / 47.7	11.6	-	-	SFO
				-	-	11.3 / 58.6	1.94	-	-	DFOP
Geometric mean				33.84 / -		16.18 / - (SFO)		-		-

Metabolite	Two metabolites >10 % AR were formed. No DT_{50} values were calculated for metabolites. <u>Desmethoxy-metobromuron</u> Distribution (max. in water 12.8 % after 99 d; max. in sed 23.5 % after 99 d; max. in whole system 36.3 %) <u>4-bromophenylurea</u> Distribution (max. in water 10.0 % after 134 d; max. in sed 13.6 % after 134 d; max. in whole system 23.7 %)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
-	-	-	-	-	-	-	-	-	-	-
Geometric mean/median				-		-		-		-

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study)	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)
River	8.11	7.20	10.9 % after 170 d	43.1 % after 170 d	43.1 % after 170 d

			(study end)	(study end)	(study end)
Pond	8.30	7.13	3.1 % after 170 d (study end)	52.7 % after 134 d	44.7 % after 170 d (study end)

PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)

Metobromuron Parameters used in FOCUSsw step 1 and 2	Models used: Steps1-2 v.1.1; SWASH 2.1; MACRO v4.3b; PRZM v3.21b; TOXSWA v2.1.2.F2; SWAN v1.1.4 Molar mass = 259.1 g/mol Water solubility = 329 mg/L Kfoc = 159.6 mL/g DT_{50} in soil = 22.4 days (normalised field geometric mean, SFO, n=5) DT_{50} in water/sediment system: 33.85 days (average of 2 systems, SFO) DT_{50} in water: 33.85 days DT_{50} in sediment: 33.85 days
Parameters used in FOCUSsw step 3 (if performed)	Additional parameters to Steps1-2: Vapour pressure = 1.44 x 10^{-4} Pa 1/n = 0.89 DT_{50} in sediment: 1000 days Plant uptake factor = 0.5 (systemic compound)
Application rate	Number of applications: 1 Rate of application: 2000 g as/ha Crop interception: 0% Steps1-2: N+S Europe, March-May Step3 and 4: application window 30 days starting 14 days pre-emergence

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	568.09		877.31	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	111.98		173.74	
	24 h	108.86	110.42	170.22	171.98
	2 d	106.65	109.09	166.77	170.24
	4 d	102.37	106.80	160.08	166.82
	7 d	96.27	103.58	150.54	161.87

	14 d	83.42	96.64	130.44	151.06
	21 d	72.28	90.33	113.02	141.22
	28 d	62.63	84.58	97.93	132.24
	42 d	47.02	74.54	73.52	116.54
Southern EU	0 h	209.12		325.86	
	24 h	204.03	206.58	325.63	325.75
	2 d	199.90	204.27	319.03	324.04
	4 d	191.87	200.07	306.23	318.32
	7 d	180.44	194.08	287.98	309.19
	14 d	156.35	181.10	249.53	288.75
	21 d	135.47	169.29	216.21	269.99
	28 d	117.38	158.52	187.33	252.85
	42 d	88.12	139.70	140.64	222.86

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3 ditch (application 4th May)		0 h	10.468		2.804	
		24 h	4.928	8.115	2.100	2.678
		2 d	0.641	5.183	1.556	2.413
		4 d	0.026	2.676	1.126	1.957
		7 d	0.007	1.535	0.872	1.574
		14 d	0.002	0.769	0.639	1.171
		21 d	0.001	0.513	0.531	0.979
		28 d	0.001	0.385	0.464	0.860
		42 d	<0.001	0.257	0.382	0.715
D4 pond (application 17th May)		0 h	0.682		3.472	
		24 h	0.680	0.682	3.471	3.472
		2 d	0.676	0.681	3.471	3.471
		4 d	0.665	0.679	3.470	3.471
		7 d	0.640	0.675	3.468	3.471
		14 d	0.605	0.657	3.459	3.470
		21 d	0.596	0.639	3.446	3.469
		28 d	0.538	0.630	3.428	3.467
		42 d	0.445	0.605	3.385	3.461
D4 stream		0 h	8.870		2.167	

(application 17th May)		24 h	0.097	1.436	2.162	2.166
		2 d	0.094	1.344	2.144	2.164
		4 d	0.090	1.137	2.102	2.154
		7 d	0.083	0.966	2.030	2.136
		14 d	0.115	0.812	1.902	2.092
		21 d	0.606	0.681	1.990	2.051
		28 d	0.433	0.599	1.862	2.021
		42 d	0.167	0.512	1.607	1.980

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6 ditch (application 2nd April)		0 h	10.517		8.043	
		24 h	0.431	9.444	7.727	8.014
		2 d	0.201	8.951	7.216	7.940
		4 d	0.197	7.514	6.287	7.683
		7 d	0.198	5.332	5.438	7.188
		14 d	0.186	4.317	4.616	6.258
		21 d	6.499	3.304	4.319	5.707
		28 d	0.472	2.607	4.101	5.358
		42 d	0.515	1.917	3.744	4.970
D6 ditch, 2nd (application 25th July)		0 h	13.870		14.525	
		24 h	11.750	13.716	14.317	14.503
		2 d	8.652	13.063	13.853	14.442
		4 d	7.995	11.025	13.964	14.235
		7 d	5.490	9.456	13.405	14.077
		14 d	2.130	7.218	11.689	13.770
		21 d	1.431	5.537	10.715	13.235
		28 d	1.184	5.678	10.153	12.691
		42 d	1.044	4.559	9.437	11.840
R1 pond (application 26th April)		0 h	0.826		1.844	
		24 h	0.808	0.817	1.844	1.844
		2 d	0.792	0.809	1.844	1.844
		4 d	0.765	0.793	1.842	1.844
		7 d	0.750	0.777	1.835	1.844
		14 d	0.685	0.750	1.806	1.841

		21 d	0.593	0.714	1.767	1.837
		28 d	0.515	0.674	1.721	1.830
		42 d	0.388	0.609	1.620	1.812

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R1 stream (application 26th April)		0 h	32.178		6.506	
		24 h	0.016	13.926	2.780	4.635
		2 d	0.006	6.972	2.070	3.626
		4 d	0.002	3.488	1.533	2.741
		7 d	2.194	1.994	2.187	2.161
		14 d	0.007	1.488	2.023	1.876
		21 d	0.001	1.035	1.344	1.784
		28 d	0.001	0.804	1.121	1.651
		42 d	<0.001	0.560	0.867	1.428
R2 stream (application 1st March)		0 h	28.029		23.719	
		24 h	22.030	16.495	19.063	21.586
		2 d	0.036	12.942	18.949	20.576
		4 d	0.017	7.316	15.991	19.386
		7 d	0.021	5.075	15.145	18.135
		14 d	0.004	2.572	12.230	15.940
		21 d	0.002	1.755	10.323	14.423
		28 d	0.003	1.439	9.591	13.396
		42 d	0.001	0.980	7.989	11.876
R3 stream (application 28th March)		0 h	119.305		19.453	
		24 h	0.843	48.910	10.246	16.025
		2 d	0.090	24.614	7.745	12.879
		4 d	0.028	12.333	5.856	9.947
		7 d	0.255	8.564	6.813	8.416
		14 d	0.006	4.521	4.265	6.838
		21 d	0.027	3.754	5.740	6.392
		28 d	0.005	2.932	4.276	6.024
		42 d	0.008	1.956	3.346	5.266

FOCUS STEP 4a (5m drift buffer) Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3 ditch (application 4th May)		0 h	3.432		1.055	
		24 h	1.877	2.857	0.809	1.010
		2 d	0.275	1.874	0.601	0.916
		4 d	0.011	0.973	0.434	0.748
		7 d	0.003	0.558	0.336	0.603
		14 d	0.001	0.280	0.246	0.449
		21 d	<0.001	0.187	0.204	0.376
		28 d	<0.001	0.140	0.179	0.331
		42 d	<0.001	0.094	0.147	0.275
D4 pond (application 17th May)		0 h	0.684		3.481	
		24 h	0.683	0.684	3.481	3.481
		2 d	0.679	0.684	3.481	3.481
		4 d	0.667	0.682	3.480	3.481
		7 d	0.642	0.677	3.477	3.480
		14 d	0.607	0.659	3.468	3.480
		21 d	0.598	0.642	3.455	3.478
		28 d	0.539	0.632	3.437	3.476
		42 d	0.446	0.608	3.394	3.470
D4 stream (application 17th May)		0 h	3.844		2.159	
		24 h	0.099	1.436	2.154	2.158
		2 d	0.094	1.344	2.136	2.156
		4 d	0.090	1.137	2.094	2.146
		7 d	0.083	0.966	2.022	2.128
		14 d	0.115	0.812	1.895	2.084
		21 d	0.606	0.681	1.984	2.043
		28 d	0.433	0.599	1.855	2.014
		42 d	0.167	0.512	1.601	1.973

FOCUS STEP 4a (5m drift buffer) Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6 ditch (application		0 h	9.621		7.942	
		24 h	8.113	9.444	7.628	7.913

2nd April)		2 d	6.053	8.951	7.119	7.839
		4 d	2.301	7.514	6.193	7.583
		7 d	0.763	5.332	5.348	7.089
		14 d	0.482	4.317	4.534	6.163
		21 d	0.532	3.304	4.243	5.617
		28 d	0.495	2.607	4.030	5.271
		42 d	0.374	1.917	3.680	4.879
D6 ditch, 2nd (application 25th July)		0 h	13.868		12.819	
		24 h	11.748	13.715	12.632	12.797
		2 d	8.650	13.061	12.188	12.739
		4 d	7.995	11.023	12.434	12.539
		7 d	5.489	9.455	11.927	12.457
		14 d	2.129	7.217	10.398	12.105
		21 d	1.430	5.536	9.553	11.663
		28 d	1.183	4.494	9.086	11.203
		42 d	1.043	3.601	8.508	10.489
R1 pond (application 26th April)		0 h	0.835		1.866	
		24 h	0.816	0.825	1.865	1.866
		2 d	0.800	0.817	1.865	1.865
		4 d	0.773	0.802	1.863	1.865
		7 d	0.757	0.785	1.857	1.865
		14 d	0.692	0.758	1.827	1.862
		21 d	0.599	0.721	1.787	1.858
		28 d	0.520	0.681	1.741	1.851
		42 d	0.392	0.617	1.638	1.833

FOCUS STEP 4a (5m drift buffer) Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R1 stream (application 26th April)		0 h	32.178		6.454	
		24 h	0.016	13.926	2.731	4.584
		2 d	0.006	6.972	2.024	3.576
		4 d	0.002	3.488	1.490	2.693
		7 d	2.194	1.994	2.148	2.116
		14 d	0.007	1.488	1.990	1.836
		21 d	0.001	1.035	1.315	1.747

		28 d	0.001	0.790	1.096	1.617
		42 d	<0.001	0.542	0.845	1.397
R2 stream (application 1st March)		0 h	28.029		23.689	
		24 h	22.030	16.495	19.035	21.555
		2 d	0.036	12.942	18.922	20.546
		4 d	0.016	7.316	15.967	19.357
		7 d	0.021	5.075	15.124	18.108
		14 d	0.004	2.572	12.212	15.916
		21 d	0.002	1.746	10.308	14.402
		28 d	0.003	1.439	9.577	13.376
		42 d	0.001	0.969	7.977	11.859
R3 stream (application 28th March)		0 h	119.305		19.288	
		24 h	0.842	48.910	10.100	15.865
		2 d	0.090	24.614	7.612	12.727
		4 d	0.027	12.332	5.741	9.807
		7 d	0.255	8.564	6.714	8.289
		14 d	0.006	4.399	4.187	6.731
		21 d	0.027	3.754	5.674	6.296
		28 d	0.005	2.871	4.217	5.936
		42 d	0.008	1.915	3.297	5.190

FOCUS STEP 4b (10m drift and run-off buffer) Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3 ditch (application 4th May)		0 h	1.820		0.597	
		24 h	1.054	1.560	0.458	0.573
		2 d	0.160	1.033	0.342	0.520
		4 d	0.006	0.538	0.248	0.426
		7 d	0.002	0.309	0.192	0.344
		14 d	0.001	0.155	0.140	0.256
		21 d	<0.001	0.103	0.117	0.215
		28 d	<0.001	0.078	0.102	0.189
		42 d	<0.001	0.052	0.084	0.157
D4 pond (application		0 h	0.662		3.395	
		24 h	0.661	0.662	3.395	3.395

17th May)		2 d	0.657	0.662	3.395	3.395
		4 d	0.646	0.660	3.394	3.395
		7 d	0.622	0.656	3.392	3.395
		14 d	0.591	0.638	3.383	3.394
		21 d	0.583	0.622	3.370	3.393
		28 d	0.526	0.613	3.354	3.391
		42 d	0.436	0.589	3.312	3.385
D4 stream (application 17th May)		0 h	2.098		2.156	
		24 h	0.098	1.436	2.151	2.155
		2 d	0.094	1.344	2.133	2.153
		4 d	0.090	1.137	2.092	2.143
		7 d	0.083	0.966	2.019	2.125
		14 d	0.115	0.812	1.893	2.081
		21 d	0.606	0.681	1.981	2.040
		28 d	0.433	0.599	1.853	2.011
		42 d	0.167	0.512	1.599	1.970

FOCUS STEP 4b (10m drift and run-off buffer) Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6 ditch (application 2nd April)		0 h	9.621		7.916	
		24 h	8.113	9.444	7.603	7.887
		2 d	6.053	8.951	7.093	7.813
		4 d	2.301	7.514	6.169	7.557
		7 d	0.763	5.332	5.325	7.063
		14 d	0.482	4.317	4.513	6.139
		21 d	0.532	3.304	4.224	5.593
		28 d	0.495	2.607	4.011	5.248
		42 d	0.374	1.917	3.664	4.855
D6 ditch, 2nd (application 25th July)		0 h	13.868		12.374	
		24 h	11.748	13.714	12.188	12.352
		2 d	8.650	13.061	11.743	12.295
		4 d	7.994	11.022	12.038	12.097
		7 d	5.489	9.454	11.535	12.036
		14 d	2.129	7.217	10.060	11.673

		21 d	1.430	5.535	9.251	11.254
		28 d	1.183	4.494	8.810	10.817
		42 d	1.043	3.375	8.267	10.139
R1 pond (application 26th April)		0 h	0.425		1.030	
		24 h	0.416	0.420	1.030	1.030
		2 d	0.408	0.416	1.030	1.030
		4 d	0.394	0.408	1.029	1.030
		7 d	0.384	0.400	1.026	1.030
		14 d	0.350	0.385	1.010	1.029
		21 d	0.303	0.366	0.988	1.026
		28 d	0.263	0.345	0.963	1.023
		42 d	0.200	0.328	0.907	1.013

FOCUS STEP 4b (10m drift and run-off buffer) Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R1 stream (application 26th April)		0 h	13.722		2.829	
		24 h	0.007	5.895	1.220	2.027
		2 d	0.003	2.951	0.902	1.584
		4 d	0.001	1.477	0.664	1.195
		7 d	0.904	0.844	0.935	0.940
		14 d	0.003	0.638	0.912	0.816
		21 d	<0.001	0.444	0.595	0.781
		28 d	<0.001	0.339	0.495	0.725
		42 d	<0.001	0.235	0.381	0.627
R2 stream (application 1st March)		0 h	12.772		6.057	
		24 h	10.030	7.537	4.240	5.249
		2 d	0.014	5.914	4.401	4.948
		4 d	0.006	3.329	3.399	4.514
		7 d	0.008	2.305	3.415	4.163
		14 d	0.001	1.166	2.683	3.592
		21 d	0.001	0.790	2.195	3.211
		28 d	0.001	0.651	2.127	2.981
		42 d	<0.001	0.440	1.725	2.631

R3 stream (application 28th March)		0 h	54.514		8.918	
		24 h	0.220	22.614	4.496	7.276
		2 d	0.038	11.383	3.351	5.799
		4 d	0.012	5.703	2.487	4.417
		7 d	0.061	3.870	2.845	3.678
		14 d	0.003	1.999	1.764	2.937
		21 d	0.012	1.706	2.510	2.751
		28 d	0.002	1.309	1.837	2.597
		42 d	0.002	0.874	1.423	2.266

FOCUS STEP 4c (20m drift and run-off buffer) Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3 ditch (application 4th May)		0 h	0.946		0.325	
		24 h	0.560	0.819	0.248	0.312
		2 d	0.087	0.545	0.186	0.283
		4 d	0.003	0.284	0.135	0.232
		7 d	0.001	0.163	0.105	0.188
		14 d	<0.001	0.082	0.077	0.140
		21 d	<0.001	0.055	0.064	0.117
		28 d	<0.001	0.041	0.056	0.103
		42 d	<0.001	0.027	0.046	0.086
D4 pond (application 17th May)		0 h	0.643		3.318	
		24 h	0.641	0.643	3.318	3.318
		2 d	0.638	0.642	3.318	3.318
		4 d	0.626	0.641	3.317	3.318
		7 d	0.603	0.636	3.315	3.318
		14 d	0.577	0.620	3.306	3.317
		21 d	0.569	0.604	3.294	3.315
		28 d	0.514	0.597	3.278	3.313
		42 d	0.425	0.573	3.237	3.308
D4 stream (application 17th May)		0 h	1.513		2.154	
		24 h	1.287	1.436	2.149	2.154
		2 d	0.996	1.344	2.132	2.151
		4 d	0.724	1.137	2.090	2.142

		7 d	0.754	0.966	2.018	2.123
		14 d	0.444	0.812	1.891	2.079
		21 d	0.236	0.681	1.979	2.038
		28 d	0.380	0.599	1.851	2.009
		42 d	0.122	0.512	1.598	1.968

FOCUS STEP 4c (20m drift and run-off buffer) Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D6 ditch (application 2nd April)		0 h	9.621		7.900	
		24 h	8.113	9.444	7.587	7.871
		2 d	6.053	8.951	7.078	7.797
		4 d	2.301	7.514	6.154	7.541
		7 d	0.763	5.332	5.311	7.048
		14 d	0.482	4.317	4.500	6.124
		21 d	0.532	3.304	4.212	5.579
		28 d	0.495	2.607	4.000	5.235
		42 d	0.374	1.917	3.654	4.841
D6 ditch, 2nd (application 25th July)		0 h	13.868		12.111	
		24 h	11.747	13.714	11.933	12.089
		2 d	8.650	13.061	11.494	12.033
		4 d	7.994	11.022	11.802	11.836
		7 d	5.488	9.454	11.314	11.788
		14 d	2.129	7.217	9.866	11.419
		21 d	1.430	5.535	9.075	11.014
		28 d	1.183	4.494	8.649	10.590
		42 d	1.043	3.375	8.127	9.933
R1 pond (application 26th April)		0 h	0.244		0.622	
		24 h	0.239	0.241	0.622	0.622
		2 d	0.234	0.239	0.621	0.622
		4 d	0.226	0.234	0.621	0.621
		7 d	0.220	0.229	0.619	0.621
		14 d	0.200	0.220	0.609	0.621
		21 d	0.173	0.209	0.596	0.619
		28 d	0.150	0.202	0.581	0.617

		42 d	0.114	0.197	0.547	0.611

FOCUS STEP 4c (20m drift and run-off buffer) Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R1 stream (application 26th April)		0 h	7.017		1.479	
		24 h	0.004	3.007	0.648	1.068
		2 d	0.001	1.505	0.478	0.836
		4 d	<0.001	0.753	0.352	0.632
		7 d	0.456	0.431	0.490	0.497
		14 d	0.002	0.327	0.489	0.432
		21 d	<0.001	0.228	0.317	0.414
		28 d	<0.001	0.174	0.264	0.385
		42 d	<0.001	0.121	0.203	0.333
R2 stream (application 1st March)		0 h	6.696		2.774	
		24 h	5.257	3.955	1.837	2.364
		2 d	0.007	3.104	1.939	2.221
		4 d	0.003	1.745	1.435	1.995
		7 d	0.004	1.207	1.480	1.826
		14 d	<0.001	0.611	1.144	1.560
		21 d	<0.001	0.413	0.922	1.385
		28 d	0.001	0.341	0.913	1.284
		42 d	<0.001	0.230	0.730	1.131
R3 stream (application 28th March)		0 h	28.612		4.800	
		24 h	0.119	11.907	2.429	3.916
		2 d	0.021	5.995	1.801	3.123
		4 d	0.007	3.004	1.331	2.376
		7 d	0.032	2.023	1.507	1.971
		14 d	0.001	1.045	0.934	1.567
		21 d	0.007	0.893	1.346	1.467
		28 d	0.001	0.686	0.981	1.386
		42 d	0.001	0.458	0.758	1.209

Desmethoxy-metobromuron (=R2)

Parameters used in FOCUSsw step 1 and 2

Molar mass = 229.1 g/mol
Water solubility = 1000 mg/L (default)
Kfoc = 233 mL/g

	DT_{50} in soil : 1000 days (default) DT_{50} in water/sediment system: 1000 days (default) DT_{50} in water: 1000 days (default) DT_{50} in sediment: 1000 days (default) Max. occurrence in water/sediment system: 36.3% Max. occurrence in soil: 3.0% (in aerobic conditions)
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Number of applications: 1 Rate of application: 2000 g as/ha Crop interception: 0% Steps1-2: N+S Europe, March-May
Main routes of entry	Drift (metabolite formed only at low levels in soil)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	19.396		31.438	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	7.568		16.725	
	24 h	7.178	7.373	16.713	16.719
	2 d	7.173	7.274	16.702	16.713
	4 d	7.163	7.221	16.678	16.702
	7 d	7.148	7.193	16.644	16.684
	14 d	7.114	7.162	16.563	16.644
	21 d	7.079	7.140	16.483	16.604
	28 d	7.045	7.121	16.403	16.563
	42 d	6.977	7.084	16.245	16.484
Southern EU	0 h	10.259		22.990	
	24 h	9.867	10.063	22.975	22.983
	2 d	9.860	9.964	22.959	22.975
	4 d	9.847	9.909	22.927	22.959
	7 d	9.826	9.878	22.879	22.935
	14 d	9.779	9.840	22.768	22.879
	21 d	9.731	9.812	22.658	22.824
	28 d	9.684	9.786	22.549	22.769

	42 d	9.591	9.736	22.331	22.659

4-Bromophenylurea (=R3)	
Parameters used in FOCUSsw step 1 and 2	Molar mass = 215.1 g/mol Water solubility = 1000 mg/L (default) Kfoc = 59.52 mL/g (KOCWIN) DT_{50} in soil = 1000 days (default) DT_{50} in water/sediment system: 1000 days (default) DT_{50} in water: 1000 days (default) DT_{50} in sediment: 1000 days (default) Max. occurrence in water/sediment system: 23.7% Max. occurrence in soil: 1.8%
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Number of applications: 1 Rate of application: 2000 g as/ha Crop interception: 0% Steps1-2: N+S Europe, March-May
Main routes of entry	Drift (metabolite formed only at low levels in soil)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	12.85		5.49	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	5.27		3.08	
	24 h	5.18	5.22	3.08	3.08
	2 d	5.18	5.20	3.08	3.08
	4 d	5.17	5.19	3.08	3.08
	7 d	5.16	5.18	3.07	3.08
	14 d	5.13	5.16	3.05	3.07
	21 d	5.11	5.15	3.04	3.06
	28 d	5.08	5.14	3.02	3.05
	42 d	5.04	5.11	3.00	3.04
Southern EU	0 h	7.11		4.18	
	24 h	7.02	7.06	4.18	4.18
	2 d	7.02	7.04	4.17	4.18
	4 d	7.01	7.03	4.17	4.17

	7 d	6.99	7.01	4.16	4.17
	14 d	6.96	6.99	4.14	4.16
	21 d	6.92	6.98	4.12	4.15
	28 d	6.89	6.96	4.10	4.14
	42 d	6.82	6.93	4.06	4.12

Desbromo-metobromuron (=R6) Parameters used in FOCUSsw step 1 and 2	Molar mass = 180.2 g/mol Water solubility = 1000 mg/L (default) Kfoc = 129.4 mL/g (KOCWIN) DT_{50} in soil = 1000 days (default) DT_{50} in water/sediment system: 1000 days (default) DT_{50} in water: 1000 days (default) DT_{50} in sediment: 1000 days (default) Max. occurrence in water/sediment system: 35.0% (from aqueous photolysis study) Max. occurrence in soil: 0.1%
Parameters used in FOCUSsw step 3 (if performed)	Not performed
Application rate	Number of applications: 1 Rate of application: 2000 g as/ha Crop interception: 0% Steps1-2: N+S Europe, March-May
Main routes of entry	Drift (metabolite not formed in soil)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	4.87		0.51	

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	4.48		5.03	
	24 h	4.04	4.26	5.02	5.02
	2 d	4.01	4.14	5.02	5.02
	4 d	4.08	4.08	5.01	5.02
	7 d	3.88	4.01	5.00	5.01
	14 d	3.86	3.94	4.98	5.00
	21 d	3.84	3.91	4.95	4.99
	28 d	3.82	3.89	4.93	4.98

	42 d	3.79	3.86	4.88	4.95
Southern EU	0 h	4.48		5.13	
	24 h	4.04	4.26	5.12	5.13
	2 d	4.01	4.14	5.12	5.12
	4 d	4.16	4.09	5.11	5.12
	7 d	3.96	4.05	5.10	5.12
	14 d	3.94	4.00	5.08	5.10
	21 d	3.92	3.98	5.05	5.09
	28 d	3.90	3.96	5.03	5.08
	42 d	9.86	3.93	4.98	5.05

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Models used: FOCUS-PEARL 3.3.3 and 4.4.4, FOCUS-PELMO 3.3.2 and 4.4.3 Simulations were performed separately for metabolite R2 (desmethoxy-metobromuron). <u>Input parameters for metobromuron</u>: Molar mass = 259.1 g/mol Water solubility = 329 mg/L Vapour pressure = 1.44 x 10^{-4} Pa Kfoc = 159.6 mL/g; Kfom = 92.6 mL/g 1/n = 0.89 DT_{50} = 22.4 days (normalised field geometric mean, SFO, n=5) Plant uptake factor = 0.5 (systemic compound) <u>Input parameters for desmethoxy-metobromuron:</u> Molar mass = 229.1 g/mol Water solubility = 329 mg/L (parent value as surrogate) Vapour pressure = 1.44 x 10^{-4} Pa (parent value as surrogate) Kfoc = 233 mL/g; Kfom = 135.2 mL/g 1/n = 0.741 DT_{50} = 60.6 days (normalised laboratory geometric mean, SFO, n=3) Plant uptake factor = 0
Application rate	Number of applications: 1 Rate of application: 2000 g/ha for metobromuron; 231.7 g/ha for metabolite (taking into account molar ration of 0.884 and maximum occurrence in soil of 13.1%; note that correct value would have been

14.9%) Application date: 7 days before emergence Crop interception: 0%

PEC (gw) – FOCUS modelling result (80th percentile annual average concentration at 1m)

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			1	2	3
FOCUS-PEARL 3.3.3/Potato	Chateaudun	0.001	-	-	-
	Hamburg	0.005	-	-	-
	Jokioinen	<0.001	-	-	-
	Kremsmunster	0.001	-	-	-
	Okehampton	0.003	-	-	-
	Piacenza	0.089	-	-	-
	Porto	<0.001	-	-	-
	Sevilla	<0.001	-	-	-
	Thiva	<0.001	-	-	-

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			1	2	3
FOCUS-PELMO 3.3.2/Potato	Chateaudun	<0.001	-	-	-
	Hamburg	<0.001	-	-	-
	Jokioinen	<0.001	-	-	-
	Kremsmunster	<0.001	-	-	-
	Okehampton	<0.001	-	-	-
	Piacenza	0.002	-	-	-
	Porto	<0.001	-	-	-
	Sevilla	<0.001	-	-	-
	Thiva	<0.001	-	-	-

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Desmethoxy-metobromuron	2	3
FOCUS-PEARL 4.4.4/Potato	Chateaudun	<0.001	<0.001	-	-
	Hamburg	0.003	<0.001	-	-
	Jokioinen	<0.001	<0.001	-	-
	Kremsmunster	0.001	<0.001	-	-
	Okehampton	0.002	<0.001	-	-

	Piacenza	0.001	<0.001	-	-
	Porto	<0.001	<0.001	-	-
	Sevilla	<0.001	<0.001	-	-
	Thiva	<0.001	<0.001	-	-

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			Desmethoxy-metobromuron	2	3
FOCUS-PELMO 4.4.3/Potato	Chateaudun	<0.001	<0.001	-	-
	Hamburg	0.003	<0.001	-	-
	Jokioinen	<0.001	<0.001	-	-
	Kremsmunster	0.001	<0.001	-	-
	Okehampton	0.003	<0.001	-	-
	Piacenza	0.003	<0.001	-	-
	Porto	0.001	<0.001	-	-
	Sevilla	<0.001	<0.001	-	-
	Thiva	<0.001	<0.001	-	-

PEC (gw) From lysimeter / field studies

Parent	1st year	2nd year	3rd year
Annual average (µg/L)	No metobromuron was detected in leachates	-	-

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡	No studied, not required.
Quantum yield of direct phototransformation	No studied, not required.
Photochemical oxidative degradation in air ‡	DT_{50} of 0.76 days derived by the Atkinson model (AOPWIN 1.92a) using OH concentration of 1.5 x 10^{-6} cm^{-3} (12-hour day)
Volatilisation ‡	Volatilisation from soil or plant surface not studied. Volatilisation has been taken into account for PECsw (dry deposition calculated with EVA 2.0.1).
Metabolites	None

PEC (air)

Method of calculation	Not calculated, not required.

PEC (a)

Maximum concentration	Not calculated, not required.

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: metobromuron, desmethoxy-metobromuron Surface water: metobromuron, desmethoxy-metobromuron (from soil and water/sediment system), 4-bromophenylurea (from water/sediment system), desbromo-metobromuron. Sediment: metobromuron, desmethoxy-metobromuron (from soil and water/sediment system), 4-bromophenylurea (from water/sediment system) Groundwater: metobromuron, desmethoxy-metobromuron Air: metobromuron

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	Not available
Surface water (indicate location and type of study)	Not available
Ground water (indicate location and type of study)	Not available
Air (indicate location and type of study)	Not available

Effects on non-target organisms

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw per day)	End point (mg/kg feed)
Bird ‡				
Japanese quail	a.s.	Acute	1429	-
	Preparation	Acute	-	-
Japanese quail	a.s.	Short-term	>274.1	>10000
Bobwhite quail	a.s.	Long-term	NOEL = 21.6*	NOEC = 240*
Mammals ‡				
Mouse	a.s.	Acute	2098**	-
Rat	Preparation	Acute	> 2000	-
rat	a.s.	Long-term	19***	150
Additional higher tier studies ‡				
-				

* at this endpoint the number of 14 day survivors per female was 5.4% less than the control.
** acute oral LD50 in mice for both sexes calculated in the study report by probit analysis method (2098 mg/kg bw) and considered to be relevant for mammals risk assessment as it is more conservative than the acute oral LD50 in rat for both sexes (2603 mg/kg bw). (See vol. 3 B.9.3.1)
*** Overall mean test substance intake (See vol. 3 B.9.3.1)

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Potatoes : 1 × 2000 g a.s/ha

Indicator species	Time scale	ETE	TER[1]	Annex VI Trigger
BIRDS				
Screening step				
Small granivorous bird	Acute	49.40	28.9	10
	Long-term	12.08	**1.8**	5
Tier 1 (Birds)				
Small granivorous bird	Long-term	12.1	**1.8**	5
Small omnivorous bird		8.7	**2.5**	
Small insectivorous bird		6.2	**3.5**	
MAMMALS				
Screening step				
Small granivorous mammal	Acute	28.8	72.8	10
	Long-term	7.00	**2.7**	5
Tier 1 (Mammals)				

Small omnivorous mammal	Long-term	6.04	**3.1**	5
Higher tier refinement (Mammals)_based on refined PT value of 0.71				
Small omnivorous mammal (woodmice)	Long-term	4.31	4.41	5
Higher tier refinement (Mammals)_based on refined PD values (Approach 2)				
Small omnivorous mammal (woodmice)	Long-term (Approach 2)	5.42	**3.50**	5
Higher tier refinement (Mammals)_based on refined PD values (Approach 2) combined with refined PT value of 0.71				
Small omnivorous mammal (woodmice)	Long-term (Approach 2)	3.85	4.93	5

[1] in higher tier refinement, a brief detail of any refinements used is provided (e.g., PT, PD or refined endpoint)

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Test organism	Test	Test item	Toxicity endpoint	Toxicity value
Fish				
Rainbow trout (*Salmo gairdneri*)	Acute	Metobromuron technical	96 h LC_{50}	**43 mg a.s./L**
Rainbow trout (*Oncorrhynchus mykiss*)		Metobromuron 500 SC		> 100 mg/L (i.e. >42.6 mg a.s./L)
Carp (*Cyprinus carpio*)		Metobromuron technical		43.1 mg a.s./L
Rainbow trout (*Oncorrhynchus mykiss*)	Chronic / juvenile growth	Metobromuron technical	28 d NOEC	0.50 mg a.s./L (based on mean measured conc.)*
Fathead minnow (*Pimephales promelas*)	Chronic / short-term repro-duction assay	Metobromuron technical	21 d NOEC	0.25 mg a.s./L (based on nominal conc.) No endocrine effects up to and including 0.8 mg a.s./L*
Aquatic invertebrates				
Water flea (*Daphnia magna*)	Acute	Metobromuron technical	48 h EC_{50}	**44.1 mg/L**
		Metobromuron 500 SC	48 h EC_{50}	> 100 mg/L (i.e.>42.6 mg a.s./L)
	Chronic	Metobromuron technical	21 d NOEC	≥ 10 mg/L
Algae				
Green algae (*Pseudokirchneriella*	Chronic	Metobromuron technical	E_rC_{50} (72 h) E_bC_{50} (72 h)	0.63 mg/L 0.17 mg/L

Test organism	Test	Test item	Toxicity endpoint	Toxicity value
subcapitata)			E_yC_{50} (72 h)	0.13 mg/L
		Metobromuron 500 SC	E_rC_{50} (72 h) E_bC_{50} (72 h) E_yC_{50} (72 h)	1.39 mg/L (i.e. 0.59 mg a.s./L) 0.34 mg/L (i.e. 0.14 mg a.s./L) 0.29 mg/L (i.e. 0.12 mg a.s./L)
		Desmethoxy-metobromuron	E_rC_{50} (72 h) E_bC_{50} (72 h) E_yC_{50} (72 h)	0.43 mg/L 0.15 mg/L 0.14 mg/L
		4-bromophenylurea	E_rC_{50} (72 h) E_bC_{50} (72 h) E_yC_{50} (72 h)	>100 mg/L 29.0 mg/L 28.7 mg/L
		Desbromo-metobromuron	E_rC_{50} (72 h) E_bC_{50} (72 h) E_yC_{50} (72 h)	2.0 mg/L 1.25 mg/L 0.76 mg/L
Blue-green algae (*Anabaena flos-aquae)*	chronic	Metobromuron technical	E_rC_{50} (72 h) E_bC_{50} (72 h) E_yC_{50} (72 h)	1.09 mg/L 0.23 mg/L 0.25 mg/L
		Metobromuron 500 SC	E_rC_{50} (72 h) E_bC_{50} (72 h) E_yC_{50} (72 h)	10.6 mg/L (i.e. 4.51 mg a.s./L) 0.93 mg/L (i.e. 0.40 mg a.s./L) 0.73 mg/L (i.e. 0.31 mg a.s./L)
Aquatic plants				
Duckweed (*Lemna gibba*)	Chronic	Metobromuron technical	E_rC_{50} (7 d) E_yC_{50} (7 d)	0.31 mg/L 0.15 mg/L
		Metobromuron 500 SC	E_rC_{50} (7 d) E_yC_{50} (7 d) NOAEC based on recovery:	0.73 mg/L (i.e. 0.311 mg a.s./L) 0.24 mg/L (i.e. 0.102 mg a.s./L) 5 mg/L (i.e. 2.1 mg a.s./L)
		Desmethoxy-metobromuron	E_rC_{50} (7 d) E_yC_{50} (7 d)	0.63 mg/L 0.19 mg/L
		4-bromophenylurea	E_rC_{50} (7 d) E_yC_{50} (7 d)	>100 mg/L 36.6 mg/L
		Desbromo-metobromuron	E_rC_{50} (7 d) E_yC_{50} (7 d)	1.28 mg/L 0.46 mg/L
Parrot feather *Myriophyllum aquaticum*	chronic	Metobromuron 500 SC	E_rC_{50} (7 d) (shoot length) E_yC_{50} (7 d) (shoot length)	>23.1 mg/L (i.e. >9.80 mg a.s./L) 11.0 mg/L (i.e. 4.67 mg a.s./L)

* The results of the 21-day fish short-term reproduction assay are in line with the results of the 28-day prolonged fish test on rainbow trout, where, likewise, no adverse effect other than growth inhibition was observed. The NOEC of 0.5 mg a.s./L

from the 28d prolonged fish study is above the NOEC of 0.25 mg a.s./L and below the LOEC of 0.8 mg a.s./kg from the 21d short-term reproduction assay. Thus, disregarding the fact that different test guidelines were followed and other fish species were tested, the result is supportive of the original NOEC of 0.5 mg a.s./L. Therefore, the overall NOEC for fish was 0.5 mg/L (see full justification in section B.9.2-1-1; Fish short-term reproduction assay – Test for endocrine disruption).

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

FOCUS Step 1

Risk assessment has been conducted directly from FOCUS Step 2

FOCUS Step 2_ FOCUS Step 4

Application rate (kg as/ha)	Crop	Test item	Organism	Time-scale	Scenario		Distance (m)	TER	Annex VI Trigger
FOCUS Step 2 PECs (initial)									
1 x 2.0	Potatoes	Metobromuron technical	Fish	acute			default	205.6	100
1 x 2.0	Potatoes	Metobromuron technical	Fish	Chronic (NOEC 28d)			default	**2.4**	10
1 x 2.0	Potatoes	Metobromuron technical	Aquatic invertebrates	acute			default	210.9	100
1 x 2.0	Potatoes	Metobromuron technical	Aquatic invertebrates	chronic			default	≥47.82	10
1 x 2.0	Potatoes	Metobromuron technical	Algae	chronic			default	**0.57**	10
		Desmethoxy-metobromuron						13.6	10
		4-bromophenyl-urea						4037	10
		Desbromo-metobromuron						169.6	10
1 x 2.0	Potatoes	Metobromuron technical	Aquatic plants	chronic			default	**0.49**	10
		Desmethoxy-metobromuron						18.5	10
		4-bromophenyl-urea						5148	10
		Desbromo-metobromuron						102.7	10
FOCUS Step 3 PECs (initial)									
1 x 2.0	Potatoes	Metobromuron technical	Fish	Overall NOEC (Chronic and Short term reproduction)	D3	Ditch	default	47.8	10

Application rate (kg as/ha)	Crop	Test item	Organism	Time-scale	Scenario		Distance (m)	TER	Annex VI Trigger
					D4	Pond		733.1	10
						Stream		56.4	10
					D6	Ditch		47.5	10
					R1	Pond		605.3	10
						Stream		15.5	10
					R2	Stream		17.8	10
					R3	Stream		**4.2**	10
1 x 2.0	Potatoes	Metobromuron technical	Algae	chronic	D3	Ditch	default	11.5	10
					D4	Pond		176	10
						Stream		13.5	10
					D6	Ditch		11.4	10
					R1	Pond		145.3	10
						Stream		**3.7**	10
					R2	Stream		**4.3**	10
					R3	St		**1.0**	10

Application rate (kg as/ha)	Crop	Test item	Organism	Time-scale	Scenario		Distance (m)	TER	Annex VI Trigger
						ream			
1 x 2.0	Potatoes	Metobromuron technical	Aquatic plants	chronic	D3	Ditch	default	**9.7**	10
					D4	Pond		149.6	10
						Stream		11.5	10
					D6	Ditch		**9.7**	10
					R1	Pond		123.5	10
						Stream		**3.2**	10
					R2	Stream		**3.6**	10
					R3	Stream		**0.85**	10
FOCUS Step 4 PECs (initial) considering NOEC of 250 µg a.s/L (21d NOEC from short term reproduction assay)									
1 x 2.0	Potatoes	Metobromuron technical	Fish	NOEC of 250 µg a.s/L	D3	Ditch	5m drift	72.84	10
					D4	Pond		365.5	
						Stream		65.04	
					D6	Ditch		25.98	
					R1	Pond		299.4	

Application rate (kg as/ha)	Crop	Test item	Organism	Time-scale	Scenario		Distance (m)	TER	Annex VI Trigger
						Stream		**7.77**	
					R2	Stream		**8.92**	
					R3	Stream		**2.10**	
1 x 2.0	Potatoes	Metobromuron technical	Fish	NOEC of 250 µg a.s/L	R1	Stream	10 m drift and run-off	18.22	10
					R2	Stream		19.57	
					R3	Stream		**4.59**	
1 x 2.0	Potatoes	Metobromuron technical	Fish	NOEC of 250 µg a.s/L	R3	Stream	20 m drift + run-off	**8.74**	10
1 x 2.0	Potatoes	Metobromuron technical	Algae	chronic	D3	Ditch	5m drift	35.0	10
					D4	Pond		175.4	10
						Stream		31.2	10
					D6	Ditch		12.5	10
					R1	Pond		143.7	10
						Stream		**3.7**	10
					R2	Stre		**4.3**	10

Application rate (kg as/ha)	Crop	Test item	Organism	Time-scale	Scenario		Distance (m)	TER	Annex VI Trigger
						am			
					R3	Stream		**1.0**	10
1 x 2.0	Potatoes	Metobromuron technical	Algae	chronic	R1	Pond	10 m drift + run-off	282.4	10
						Stream		**8.7**	10
					R2	Stream		9.4	10
					R3	Stream		**2.2**	10
1 x 2.0	Potatoes	Metobromuron technical	Algae	chronic	R1	Pond	20 m drift + run-off	491.8	10
						Stream		17.1	10
					R2	Stream		17.9	10
					R3	Stream		**4.2**	10
1 x 2.0	Potatoes	Metobromuron technical	Aquatic plants	chronic	D3	Ditch	5m drift	29.7	10
					D4	Pond		149.1	10
						Stream		26.5	10
					D6	Ditch		10.6	10
					R1	P		122.2	10

Application rate (kg as/ha)	Crop	Test item	Organism	Time-scale	Scenario		Distance (m)	TER	Annex VI Trigger
						Pond			
						Stream		**3.2**	10
					R2	Stream		**3.6**	10
					R3	Stream		**0.85**	10
1 x 2.0	Potatoes	Metobromuron technical	Aquatic plants	chronic	R1	Pond	10 m drift + run-off	240	10
						Stream		**7.4**	10
					R2	Stream		**8.0**	10
					R3	Stream		**1.9**	10
1 x 2.0	Potatoes	Metobromuron technical	Aquatic plants	chronic	R1	Pond	20 m drift + run-off	418	10
						Stream		14.5	10
					R2	Stream		15.2	10
					R3	Stream		**3.6**	10

	Active substance	Metabolites
Log P_{OW}	2.48	Not available,

		not triggered
Bioconcentration factor (BCF)[1] ‡	Not available, not triggered	Not available, not triggered
Annex VI Trigger for the bioconcentration factor	-	-
Clearance time (days) (CT_{50})	Not available, not triggered	Not available, not triggered
(CT_{90})	Not available, not triggered	Not available, not triggered
Level and nature of residues (%) in organisms after the 14 day depuration phase	Not available, not triggered	Not available, not triggered

[1] only required if log $P_{O/W}$ >3.

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s. ‡	-	-
Preparation[1]	119.1 µg/bee (i.e. 50.68 µg a.s./bee)	>200 µg/bee (i.e. >85.10 µg a.s./bee)
Field or semi-field tests		
Indicate if not required		

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Potatoes: 1 × 2.0 kg as/ha

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	-	50
a.s.	oral	-	50
Preparation	Contact	<23.5	50
Preparation	oral	39.5	50

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡	Metobromuron 500 SC	Mortality	LR_{50} = 99.9 mL product /ha (i.e. 51.2 g a.s./ha)

Species	Test Substance	End point	Effect (LR_{50} g/ha[1])
Aphidius rhopalosiphi ‡	Metobromuron 500 SC	Mortality	LR_{50} > 8000 mL product/ha (i.e. > 4098 g a.s./ha)

[1] for preparations, end point is expressed in units of preparation and a.s.

Potatoes: 1 × 2.0 kg as/ha

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1] (1 m)	Trigger
Metobromuron 500 SC	*Typhlodromus pyri*	LR_{50} = 99.9 mL product /ha (i.e. 51.2 g a.s./ha)	**39.08**	1.08	2
Metobromuron 500 SC	*Aphidius rhopalosiphi*	LR_{50} > 8000 mL product/ha (i.e. > 4098 g a.s./ha)	0.49	-	2

[1] indicate distance assumed to calculate the drift rate

Extended laboratory studies ‡

Species	Test substance, substrate and duration	Dose (g as/ha)[1,2]	End point	% effect [3]	PERoff-field [g a.s./ha]*	% Effect off-field	Trigger value
Typhlodromus pyri	Metobromuron 500 SC	30 to 540 mL product/ha (i.e. 15.4 to 277 g a.s./ha)	LR_{50} = 130 mL product/ha (i.e. 66.6 g a.s./ha) ER_{50} > 127 mL product/ha (i.e. > 65.1 g a.s./ha)	**50 % effect on mortality at 130 mL product/ha (i.e. 66.6 g as/ha)** 20.7 % effect on reproduction at 127 mL product/ha (i.e. 65.1 g as/ha)	55.4	<50 %	<50 %

Species	Test substance, substrate and duration	Dose (g as/ha)[1,2]	End point	% effect [3]	PERoff-field [g a.s./ha]*	% Effect off-field	Trigger value
Aleochara bilineata	Metobromuron 500 SC	Up to 4 L product/ha (i.e. 2049 g a.s./ha)	ER_{50} > 2049 g a.s./ha	No effect on reproduction and parasitizing efficiency up to and including 4L product/ha (i.e. 2049 g a.s./ha)	55.4	<50%	<50 %
Pardosa ssp.	Metobromuron 500 SC	Up to 4 L product/ha (i.e. 2049 g a.s./ha)	LR_{50} > 2049 g a.s./ha	26.5% (21.9% corrected for controls) survival at 4L product/ha (i.e. LR_{50} > 2049 g a.s./ha)	55.4	<50%	<50 %

[1] initial residues
[2] for preparations dose is expressed in units of preparation and a.s.
[3] positive percentages relate to adverse effects
* 2.77% of the maximum single application rate (1 m distance)

Aged residue test ‡

Species	Test substance, substrate and duration	Dose (g/ha)[1,2]	End point	% effect	Trigger value
Typhlodromus pyri	Metobromuron 500 SC	Up to 4 L product/ha (i.e. 2049 g a.s./ha)	Mortality (corr.) at 4L/ha Effect on reprod. at 4 L/ha	40.6% (day 0) 15.1% (day 7) 39.3% (day 0) 16.8% (day 7)	<50 %

[1] initial (day 0) and aged residues (day 7)
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

Field or semi-field tests
Not required

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point[1]
Earthworms			
	a.s. ‡	Acute 14 days	LC_{50} = 467 mg a.s./kg dry soil LC_{50} corr. = 233.5 mg a.s./kg dry soil
	a.s. ‡	Chronic 8 weeks	-
	Preparation	Acute	-
	Preparation	Chronic	NOEC > 281.4 mg product/kg dry soil (>119.74 mg a.s./kg dry soil)
	Desmethoxy-metobromuron	Acute	LC_{50} > 1000 mg/kg dry soil
Other soil macro-organisms			
Soil mite	a.s. ‡	-	-
Hypoaspis aculeifer	Preparation	Chronic 14 days	$NOEC_{reprod}$ = 55.6 mg product/kg dry soil (23.66 mg a.s./kg dry soil)
Collembola	a.s. ‡	-	-
Folsomia candida	Preparation	Chronic 28 days	$NOEC_{reprod}$ = 55.6 mg product/kg dry soil (23.66 mg a.s./kg dry soil)
Soil micro-organisms			
Nitrogen mineralisation	a.s. ‡	-	-
	Preparation	84 days	at 65.87 mg Metobromuron 500 SC: < ±25% at all samplings
	Desmethoxy-metobromuron	28 days	at 3.15 mg Desmethoxy-metobromuron: < ±25% at all samplings
Carbon mineralisation	a.s. ‡	-	-
	Preparation	28 days	at 65.87 mg Metobromuron 500 SC: < ±25% at all samplings
	Desmethoxy-metobromuron	28 days	at 3.15 mg Desmethoxy-metobromuron: < ±25% at all samplings
Field studies[2]			
Not required			

[1] end point (e.g. LC_{50corr}) has been corrected due to log Pow >2.0 when soil with high organic content (10% peat) has been used in the toxicity test

Toxicity/exposure ratios for soil organisms

Potatoes: 1 × 2.0 kg as/ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
	a.s. ‡	Acute	2.667	87.6	10
	a.s. ‡	Chronic	-	-	5
	Preparation	Acute	-	-	10
	Preparation	Chronic	2.667	>44.9	5
	Desmethoxy-metobromuron	Acute	0.120	>8333	10
Other soil macro-organisms					
Soil mite	a.s. ‡	-	-	-	-
	Preparation	Chronic	2.667	8.9	5
Collembola	a.s. ‡	-	-	-	-
	Preparation	Chronic	2.667	8.9	5

[2] PEC soil max

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Not required for herbicides as ER_{50} tests should be provided

Laboratory dose response tests

Species	EC_{50} values [L Metobromuron 500 SC/ha]					
	Vegetative vigour			Seedling emergence and growth		
	Mortality	Injury	Fresh weight	Emergence	Injury	Fresh weight
Allium cepa	2.57	1.28	0.61	>7.5	0.41	0.11
Lolium perenne	4.90	0.48	0.36	>7.5	2.67	0.91
Triticum aestivum	>7.5	1.57	1.27	>7.5	5.88	4.67
Zea mays	>7.5	1.08	1.34	>7.5	>7.5	3.71
Beta vulgaris	1.14	0.33	0.22	>7.5	0.51	0.49
Brassica napus	1.04	0.38	0.27	>7.5	0.67	0.43
Cucumis sativa	2.41	0.14	0.46	>7.5	0.49	0.56
Lycopersicon esculentum	0.77	0.37	0.25	>7.5	0.85	1.03
Sinapis alba	3.46	0.40	0.79	>7.5	0.22	0.26
Spinacia oleraceae	0.92	0.17	0.19	>7.5	0.31	0.25
Overall lowest EC_{50}	0.14			0.11		
Overall lowest median HC_5 (lower limit-upper limit)	0.1169 (0.0439-0.2035)			0.0882 (0.0213-0.1970)		

Application rate (kg as/ha)	Crop	Test	Buffer distance (m)	TER	Annex VI Trigger
Based on overall lowest ER_{50} (Tier 1)					
1 x 2.0	Potatoes	Seedling emergence	1 (default)	**0.99**	5
			5	**4.82**	5
			10	9.48	5
		Vegetative vigour	1 (default)	**1.26**	5
			5	6.14	5
			10	12.07	5
Based on median HC_5 (Tier 2)					
1 x 2.0	Potatoes	Seedling emergence	1 (default)	**0.80**	1
			5	3.87	1
			10	7.60	1
		Vegetative vigour	1 (default)	1.06	1
			5	5.13	1
			10	10.08	1
Based on lower limits HC_5 (Tier 2)					
1 x 2.0	Potatoes	Seedling emergence	1 (default)	**0.20**	1
			5	**0.93**	1
			10	1.83	1
		Vegetative vigour	1 (default)	**0.40**	1
			5	1.92	1
			10	3.78	1

Additional studies (e.g. semi-field or field studies)

none

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	end point
Activated sludge	The 3-hour EC_{50} was clearly higher than the highest test concentration of 100 mg/L (calculated 154.8 mg/L)

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	metobromuron
Water	metobromuron
sediment	metobromuron
groundwater	metobromuron

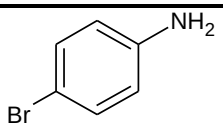
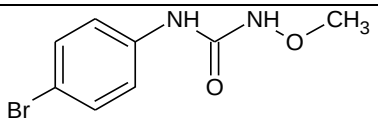
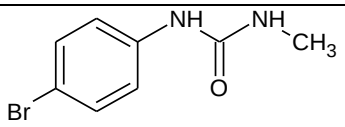
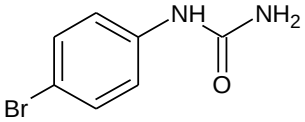
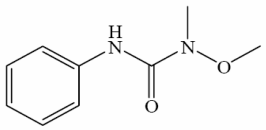
Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)*

RMS/peer review proposal

Active substance	**Classification acc. to Reg. 1272/2008:** Proposed Label: Symbol: Warning, GHS09 Indication of danger: Aquatic Acute Category 1, Chronic Category 1 (M-factor: 1) Risk phrases: H400, H410 Safety phrases: P273, P391, P501

* It should be noted that classification is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name*	Structural formula**
4-bromoaniline CGA 18239 R4	4-bromoaniline	
Desmethyl-metobromuron CGA 18238 II6	1-(4-bromophenyl)-3-methoxyurea	
Desmethoxy-metobromuron CGA 18236 II5	1-(4-bromophenyl)-3-methylurea	
4-bromophenylurea CGA 18237 II4 R3	1-(4-bromophenyl)urea	
desbromo-metobromuron R6 HHAC-022	1-methoxy-1-methyl-3-phenylurea	

* ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

ABBREVIATIONS

1/n	slope of Freundlich isotherm
λ	wavelength
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticides Analytical Council Limited
CL	confidence limits
cm	centimetre
d	day
DAA	days after application
DAD	diode array detector
DAR	draft assessment report
DAT	days after treatment
DHT	dihydroxytestosterone
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EFSA	European Food Safety Authority
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FID	flame ionisation detector
FIR	Food intake rate

FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GC-ECD	gas chromatography with electron capture detector
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
GSH	glutathion
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPLC-MS/MS	high pressure liquid chromatography with tandem mass spectrometry
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
µg	microgram
mg	milligram
mL	millilitre
mm	millimetre
mN	milli-newton
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity

NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NPD	nitrogen phosphorous detector
OECD	Organisation for Economic Co-operation and Development
OM	organic matter content
Pa	pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
POEM	Predictive Operator Exposure Model
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PPR	Panel on Plant Protection Products and their Residues
PRIMO	Pesticide Residue Intake Model
PSA	prostate specific antigen
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QuEChERS	quick, easy, cheap, effective, rugged and safe (method)
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
REACH	Registration, Evaluation, Authorisation of CHemicals
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SETAC	Society of Environmental Toxicology and Chemistry
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
STOT-RE	specific target organ toxicity – repeated exposure
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)

TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year