CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment of the active substance oxasulfuron

European Food Safety Authority (EFSA)

Abstract

The conclusions of the European Food Safety Authority (EFSA) following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State Italy and co-rapporteur Member State Austria for the pesticide active substance oxasulfuron are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012. The conclusions were reached on the basis of the evaluation of the representative use of oxasulfuron as a herbicide on soya beans. The reliable endpoints, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed. Concerns are identified.

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Keywords: oxasulfuron, peer review, risk assessment, pesticide, herbicide

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Summary

Commission Implementing Regulation (EU) No 844/2012 (hereinafter referred to as 'the Regulation') lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012. Oxasulfuron is one of the active substances listed in Regulation (EU) No 686/2012.

In accordance with Article 1 of the Regulation, the rapporteur Member State (RMS), Italy, and co-rapporteur Member State (co-RMS), Austria, received an application from AgroChem MAKS D.O.O. for the renewal of approval of the active substance oxasulfuron. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Austria), the European Commission and the European Food Safety Authority (EFSA) about the admissibility.

The RMS provided its initial evaluation of the dossier on oxasulfuron in the renewal assessment report (RAR), which was received by EFSA on 29 January 2016. In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, AgroChem MAKS D.O.O., for comments on 29 March 2016. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 30 May 2016.

Following consideration of the comments received on the RAR, it was concluded that additional information should be requested from the applicant and that EFSA should conduct an expert consultation in the area of mammalian toxicology.

In accordance with Article 13(1) of the Regulation, EFSA should adopt a conclusion on whether oxasulfuron can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative use of oxasulfuron as a herbicide on soya beans as proposed by the applicant. Full details of the representative use can be found in Appendix A of this report.

The use of oxasulfuron according to the representative use proposed at EU level results in a sufficient herbicidal efficacy against the target weeds.

Data gaps were identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites.

Data gaps were identified for the physical–chemical properties of the pure active substance, technical properties of the representative formulation and for analytical methods for all compartments, excluding food of animal origin.

Data gaps were also identified in the section mammalian toxicology: the first one was related to missing *in vitro* comparative metabolism data, and the second one to the need of additional investigations of endocrine-disrupting properties.

The overall consumer exposure assessment is regarded as not finalised in view of the outstanding data regarding the metabolism and magnitude of the relevant compounds in rotational crops and the consumer exposure assessment through drinking water. The data requirement for the determination of the residues in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom is also requested.

MRL applications were not included in the RAR.

For environmental fate and behaviour, a data gap was identified for the lack of information to sufficiently identify the individual component MT6. Data gaps were also identified for aerobic degradation (DegT50 and DegT90 values) for metabolites MT6, CGA 171895 (M5), M3, CGA 179710, and oxetan-3-ol (CGA 297691) and for studies on adsorption and desorption for metabolites MT6, oxetan-3-ol (CGA 297691), M3, and CGA 171895 (M5). Furthermore, data gaps were identified for groundwater exposure assessment for metabolites MT6, M3 and CGA 171895 (M5), and for surface water exposure assessment for metabolites MT6 and CGA 171895 (M5). For ground water exposure assessment an issue that cannot be finalised was identified for metabolites MT6, M3, CGA 171895 (M5). It should be noted that with the available toxicological information, these three metabolites would be concluded as relevant groundwater metabolites should they be predicted to occur in groundwater above the parametric drinking water limit of 0.1 μg/L due to the proposed classification of oxasulfuron as reproductive toxicant category 2. The assessment is also not finalised regarding the relevance of groundwater metabolite oxetan-3-ol (CGA 297691) whilst herbicidal screening data are not available.

A data gap was identified for information on the effect of water treatment processes on the nature of residues of both the active substance and its identified metabolites potentially present in surface and groundwater, when surface water or groundwater are abstracted for drinking water. This gap leads to the consumer risk assessment from the consumption of drinking water being not finalised for all the representative uses.

In the area of ecotoxicology, several data gaps were identified. Moreover, issues that cannot be finalised due to the lack of exposure estimates in surface water for the metabolite MT6 and CGA 171895 and in soil for the metabolite MT6. In addition, the assessment could not be finalised for soil macro-organisms and soil microorganisms due to the lack of toxicity data and for non-target terrestrial plants. Critical areas of concern were identified for aquatic plants and earthworms.

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Background

Commission Implementing Regulation (EU) No 844/2012[1] (hereinafter referred to as 'the Regulation') lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009.[2] This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of up to 8 months where additional information is required to be submitted by the applicant in accordance with Article 13(3).

In accordance with Article 1 of the Regulation, the RMS Italy and co-RMS Austria received an application from AgroChem MAKS D.O.O. for the renewal of approval of the active substance oxasulfuron. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Austria), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on oxasulfuron in the RAR, which was received by EFSA on 29 January 2016 (Italy, 2016a).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, AgroChem MAKS D.O.O., for consultation and comments on 29 March 2016. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 30 May 2016. At the same time, the collated comments were 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 13(3) of the Regulation were considered in a telephone conference between EFSA, the RMS and EC on 12 July 2016. 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 EFSA should conduct an expert consultation in the area of mammalian toxicology.

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, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, are 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 December 2016/January 2017.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative use of oxasulfuron as a herbicide on soya beans, as proposed by the applicant. A list of the relevant endpoints for the active substance and the formulation is provided in Appendix A.

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2016), which is a compilation of the documentation developed to evaluate and address all issues raised in the

[1] Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 252, 19.9.2012, p. 26–32.

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

peer review, from the initial commenting phase to the conclusion. The peer review report comprises the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting table (12 July 2016);
- the evaluation table (27 January 2017);
- the report(s) of the scientific consultation with Member States' 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 RAR, including its revisions (Italy, 2016b), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

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 that it has regulatory access to the information on which this conclusion report is based.

The active substance and the formulated product

Oxasulfuron is the ISO common name for oxetan-3-yl 2-[(4,6-dimethylpyrimidin-2-yl) carbamoylsulfamoyl]benzoate (IUPAC).

The representative formulated product for the evaluation was 'Laguna 75 WG', a water-dispersible granule (WG) containing 750 g/kg oxasulfuron.

The representative use evaluated was application by spraying for the control of broad leaved weeds and grasses in soya bean. Full details of the GAP can be found in the list of endpoints in Appendix A.

Data were submitted to conclude that the use of oxasulfuron according to the representative use proposed at EU level results in a sufficient herbicidal efficacy against the target weeds following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014b).

A data gap has been identified for a search of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on the environment and non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011).

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/3029/99-rev. 4 (European Commission, 2000a), SANCO/3030/99-rev. 4 (European Commission, 2000b), SANCO/10597/2003-rev. 10.1 (European Commission, 2012) and SANCO/825/00-rev. 8.1 (European Commission, 2010).

The reference specification from the first approval was updated. The proposed specification is based on batch data from industrial-scale production. The minimum purity of the technical material is 985 g/kg. There is no FAO specification available.

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 oxasulfuron or the representative formulation; however, data gaps were identified for the surface tension and for the molar extinction coefficient at 290 nm at different pH values of the purified active substance. Data gaps were also identified for the representative formulation for the determination of auto-flammability, accelerated storage stability using an alternative storage condition, and persistent foaming, before and after storage, of the suspension containing water-soluble bags, suspensibility at the lowest recommended rate of use and compatibility of the representative formulation with tank mixes. The main data regarding the identity of oxasulfuron and its physical and chemical properties are given in Appendix A.

The methods used for the generation of pre-approval data required for the risk assessment were not always meeting the requirements of the current guidelines, however were considered acceptable.

Methods of analysis are available for the determination of the active substance in the technical material and representative formulation.

Oxasulfuron can be monitored in soya bean by LC-MS/MS with a LOQ of 0.01 mg/kg; however, data gaps were identified for the independent laboratory validation (ILV) of the method and for additional validation data covering all four plant commodity groups. An analytical method for monitoring residues in food and feed of animal origin is not needed as no MRLs were proposed for the animal matrices.

Data gaps were identified for monitoring methods for the determination of oxasulfuron residues in soil, water, air and body fluids and tissues validated according to the requirements of SANCO/825/00 rev. 8.1.

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/10597/2003-rev. 10.1 (European Commission, 2012), Guidance on dermal absorption (EFSA PPR Panel, 2012) and Guidance on the assessment of non-dietary exposure (EFSA, 2014).

Oxasulfuron has been discussed during the Pesticides Peer Review meeting 148 on mammalian toxicology (October 2016).

In the new technical specification, no toxicologically relevant impurity is present. The batches used in the toxicity studies, containing up to 7% impurities (5.2% more than in the new technical specification), could be considered as a worst-case assessment covering the new technical specification.

Based on the available data, the oral absorption value for oxasulfuron is estimated to be > 80%. Of low acute toxicity, oxasulfuron did not show irritating or sensitising properties, and was considered unlikely to be photoreactive. No data were provided for *in vitro* comparative metabolism, with animal species used in pivotal studies and with human material and a data gap has been identified. In short-term studies, the dog was the most sensitive species, with a relevant NOAEL of 1.3 mg/kg bw per day based on adverse effects in the nervous system and in the testes. In genotoxicity studies, the results of the mammalian cytogenetic test *in vitro* were considered equivocal in the presence of limited cytotoxicity. In the *in vivo* micronucleus test, the exposure of the bone marrow was considered sufficient to support the validity of the negative results, and oxasulfuron was concluded as having no genotoxic potential. In long-term studies, no carcinogenic potential was observed, and the lowest NOAEL of 1.5 mg/kg bw per day was identified in the 18-month mouse study, based on decreased body weight gain (in females), increased liver weights and sciatic nerve degeneration. The heart Schwannoma in rats were considered part of the specific toxicity to the nervous system and it was agreed not to take them into account as carcinogenic effect. They were considered covered by the existing harmonised classification[3] **STOT RE 2 H373** (nervous system). In the multigeneration study, a decreased reproductive performance was observed at the high dose, together with effects in testis, with a NOAEL of 340.5 mg/kg bw per day, leading to a proposal for classification[4] **Repr cat 2 H361f**. Considering the absence of classification under Directive 67/548/EEC, and the lack of detailed justification behind (available to EFSA), the experts agreed that the link between systemic parental toxicity and effects on reproductive toxicity was not sufficiently evident to discard specific effects on reproductive parameters, justifying the new proposal for classification. The parental NOAEL was 14.75 mg/kg bw per day based on a slight effect on body weight gain in females; the offspring NOAEL was 340.5 mg/kg bw per day based on pup body weight development. No teratogenic effect was observed in the developmental toxicity studies. In rats, both maternal and developmental NOAEL are 300 mg/kg bw per day whereas in rabbits, both maternal and developmental NOAELs are 1,000 mg/kg bw per day (high dose tested). In the acute neurotoxicity study, the NOAEL is 10 mg/kg bw based on decreased rectal body temperature (F). Based on the available data (short-term and long-term toxicity) and on the harmonised classification (STOT RE 2, nervous system), oxasulfuron was concluded to be neurotoxic; however, no information on the neurotoxic mode of action was available.

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

[4] It should be noted that harmonised classification and labelling 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.

Oxasulfuron is proposed to be classified as toxic for reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008, and toxic effects in the endocrine organs have been observed in the available data; therefore the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of **endocrine-disrupting properties** may be met. On the basis of the available data (endocrine-related findings observed at high doses in association with other toxic effects) and current knowledge (OECD Conceptual Framework, as analysed in the EFSA Scientific Opinion on the hazard assessment of endocrine disruptors, 2013), the potential endocrine-disrupting properties of oxasulfuron could not be excluded. During the Peer Review experts' meeting it was recommended to clarify whether the reproductive performance in females was affected by endocrine mode of action, and if developmental landmarks in offspring were affected by oxasulfuron. Further data/investigations on mode of action of neurotoxicity could also be useful to identify potential neuroendocrine effects (data gap).

For the metabolite **oxetan-3-ol**, the agreed acceptable daily intake (ADI) is 0.05 mg/kg bw per day based on the 16-week dog study and applying an increased uncertainty factor (UF) of 1,000 for extrapolation of duration and to take into account the limited data available.

For the metabolite **saccharin**, considering its common use in human food as a sweetener, the ADI of 3.8 mg/kg bw per day (for saccharin free acid) established by the Scientific Committee for Food (European Commission, 1997) can be applied. The metabolite OH-saccharin, structurally close to saccharin, can be considered of comparable toxicity.

For **oxasulfuron**, the reference values as derived during the first peer review were confirmed. The ADI is 0.013 mg/kg bw per day, based on the 1-year and 90-day dog studies (UF 100); the Acceptable Operator Exposure Level (AOEL) is 0.013 mg/kg bw per day based on the 90-day and 1-year dog studies; the Acute Reference Dose (ARfD) and Acute Acceptable Operator Exposure Level (AAOEL) are not required based on the available data (acute effects observed at very high doses only). For oxasulfuron, in the absence of dermal absorption study with the representative formulation, the default dermal absorption values are applicable (25% for the concentrate and 75% for the dilution). According to the German BBA model and the EFSA guidance, the operator exposure estimates are below the AOEL when personal protective equipment is worn during mixing/loading and application. According to the EFSA guidance, the exposure of residents and bystanders (adults and children) is also expected to be below the AOEL. According to the EFSA guidance, the exposure estimate for workers wearing adequate work-clothing when re-entering treated crops is below the AOEL.

3. Residues

The assessment in the residue section is based on the OECD guidance document on overview of residue chemistry studies (OECD, 2009), the OECD publication on MRL calculations (OECD, 2011), the European Commission guideline document on MRL setting (European Commission, 2016) and the Joint Meeting on Pesticide Residues (JMPR) recommendations on livestock burden calculations (JMPR, 2004, 2007).

Metabolism in plants was investigated in soya bean (pulse/oilseed), using ^{14}C-oxasulfuron labelled respectively on the phenyl, pyrimidinyl and oxetanyl rings. Studies were conducted at exaggerated dose rates and the experimental design consists of a pre-emergence application (87–381 g a.s./ha) followed by an early post-emergence foliar application (89–97 g a.s./ha) (ca. BBCH GS 12). For all labelling forms, oxasulfuron was shown to be extensively metabolised in all crop parts accounting only for 2% TRR in mature beans. In mature foliage and within 7 days after the foliar application oxasulfuron was almost completely degraded into the glycerol ester of oxasulfuron (**CGA 310785**) (up to 18.7% TRR) and into metabolites resulting from the cleavage of the parent molecule at the sulfonylurea bond and further conjugation, i.e. saccharin (**CGA 27913**) (25.6% TRR), **CGA 177288** (26% TRR) and the glutamine conjugates of the OH pyrimidine amine (**CGA 340355**) (21.5%). In mature beans, the predominant compounds of the total residues were identified as saccharin (**CGA 27913**) (12% TRR; 0.002 mg eq/kg) and glucoside and glutamine conjugates of the OH pyrimidine amine (**CGA 340355**) (10.5% TRR; 0.005 mg eq/kg and 25.6% TRR; 0.011 mg eq/kg, respectively). In regard to the very low actual concentration of saccharin in soya bean and its lower toxicity compared to the parent compound (ADI: 3.8 mg/kg bw per day; Section 2) saccharin is not a relevant compound to be included in the risk assessment residue definition. Furthermore although **CGA 340355** under its conjugated forms occurs at up to 36.2% TRR in mature beans, very low levels of this compound (< 0.01 mg eq/kg) are expected considering the exaggerated dose rates in the metabolism data. It is further noted that **CGA 27913** and **CGA 177288** are common to a number of sulfonylurea compounds and therefore oxasulfuron may be an additional contributor to the overall

exposure of consumers in regard to these compounds, of which an assessment has not yet been performed.

Having regard to the very low levels the different compounds that were observed in the metabolism studies, the residue definition for monitoring and risk assessment is proposed by default as oxasulfuron for the pulses and oilseeds crop group. These residue definitions are identical to the definitions proposed in the framework of the review of the existing MRLs under Article 12 of Regulation (EU) No 396/2005 (EFSA, 2012) and implemented in the EU legislation.

Although confined rotational crops metabolism studies are not triggered for the parent oxasulfuron having regard to the low persistence of oxasulfuron in soil (highest 20°C lab DT_{90} 10.6–97.3 days), metabolism in rotational crops was investigated for the phenyl labelling form of the parent compound only in wheat foliage, wheat grain, mustard leaves and turnip root and was shown to be similar to the metabolic pattern depicted in primary crop. However pending upon the outcome of the requested DT_{50}/DT_{90} values on the metabolites **CGA 171895 (M5)**, **M3**, **CGA 179710**, oxetan-3-ol (**CGA 297691)** and **MT6** (data gaps in Section 4), further rotational crop studies addressing the nature and magnitude of residues in regard to these compounds might be needed.

The investigation of effects of processing on the nature and magnitude of residues was not triggered by the representative use.

Sufficient residue trials were submitted to derive an MRL of 0.01* mg/kg (LOQ) on soya bean. Residue data are supported by storage stability studies where oxasulfuron residues were concluded to be stable for up to 24 months in high oil content matrices.

Metabolism studies on goats and poultry were submitted, although the animal intakes were calculated to be far below the trigger value of 0.004 mg/kg bw per day. Oxasulfuron was extensively excreted in urine and faeces and less than ca. 1% of the administered radioactivity was recovered in eggs, milk and in poultry and ruminants' edible tissues. In goats, oxasulfuron was identified as the major compound of the total residues in all edible tissues (35–84% TRR) for both the phenyl and pyrimidinyl labels whilst for milk and besides the parent compound predominant metabolites were identified as **hydroxy oxasulfuron** (28% TRR), **CGA 27913** (33% TRR) (^{14}C Phenyl) and sulphate conjugate of **C 1801** (67% TRR) (^{14}C Pyrimidinyl). A similar metabolic pattern was observed in poultry matrices where oxasulfuron constituted the major compound of the total residues in all tissues (up to 42% TRR in eggs, 91% TRR in muscle, 88% TRR in fat and 56% TRR in liver) alongside with **CGA 27913** (15% and 32% TRR in fat and egg yolk, respectively) and **C-1801** (10–42% TRR in liver, muscle, fat and eggs). Considering the extremely low total residues recovered in all livestock matrices at the calculated dietary burden, residue definitions and MRLs are not proposed for products of animal origin. Fish metabolism studies were not provided and are not requested as residues were below the LOQ of the method in soya beans and oxasulfuron is concluded to be not fat soluble.

The data requirement for the determination of the residues in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom is not addressed with regard to oxasulfuron and relevant metabolites and considering also the outstanding data on the metabolism of the relevant metabolites in rotational crops.

Chronic consumer exposure resulting from the representative use was calculated using the EFSA PRIMo rev.2. The highest chronic exposure calculated as the TMDI with the proposed MRL of 0.01* mg/kg on soya bean represented less than 1% of the ADI (WHO cluster diet F). An acute risk assessment was not conducted as the setting of an ARfD was not necessary for oxasulfuron. This consumer risk assessment can be considered as an update of the assessment conducted in the framework of the review of the existing MRLs (EFSA, 2012), as the representative use supported for the renewal of the active substance and the authorized European use evaluated during the MRL review are identical.

Moreover, the level of metabolite oxetan-3-ol **(CGA 297691)** in groundwater exceeds 0.75 μg/L for a number of scenarios (Section 4) and the consumer risk assessment through drinking water had to be conducted. The additional intake through drinking water of **CGA 297691** is less than 1% of the ADI of oxetan-3-ol for all considered consumer groups. The consumer exposure through drinking water will have to be reconsidered as the groundwater assessment with regard to **MT6**, **CGA 171895 (M5)** and **M3** is not finalised (see Section 4).

The overall consumer exposure assessment is regarded as not finalised in view of the outstanding data regarding the metabolism and magnitude of the relevant compounds in rotational crops and the consumer exposure assessment through drinking water.

4. Environmental fate and behaviour

The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. In soil laboratory incubations under aerobic conditions in the dark, oxasulfuron exhibited low to moderate persistence, forming the major (> 10% applied radioactivity (AR)) metabolites saccharin (CGA 27913) (max. 98.5% AR) and C-1801 (max. 54.7% AR) which exhibited low to high persistence, M3 (max. 25% AR), CGA 171895 (M5) (max. 10.2% AR), CGA 179710 (max. 27.5% AR). A data gap was identified (see Section 7) because data and information provided were not sufficient to identify the unknown metabolite MT6 which in at least two sequential measurements accounts for more than 5% of the amount of active substance added. Furthermore, data gaps were identified (see Section 7) for metabolites CGA 171895 (M5), M3 and CGA 179710 due to the lack of aerobic degradation (DegT50 and DegT90 values) from a minimum of three different soils as required by Commission Regulation No 283/2012. Mineralisation of the phenyl, pyrimidinyl and oxetan ring ^{14}C radiolabel to carbon dioxide accounted for 0.1–57.4% AR after 90–105 days, 1.3–21.3% AR after 90–83 days and 80.4% AR after 120 days, respectively. The formation of unextractable residues (not extracted by acetonitrile/water) for these radiolabels accounted for 1.7–53.9% AR after 90–83 days.

In reliable field soil dissipation studies carried out at two sites in the United States, oxasulfuron exhibited low persistence forming the major (> 10% AR) metabolite oxetan-3-ol (CGA 297691) (max. 21% AR). A data gap was identified (see Section 7) for metabolite oxetan-3-ol (CGA 297691) due to the lack of aerobic degradation (DegT50 and DegT90 values) from a minimum of three different soils. The field data endpoints were not combined with lab values to derive modelling endpoints.

In anaerobic soil incubations, oxasulfuron transformation was similar to that under aerobic conditions, with the degradation pathway being comparable to the one under aerobic conditions. Anaerobic DT_{50} will not be used for the risk assessment. Oxasulfuron is photodegraded quickly on the soil surface. The pattern of metabolites formed is the same for irradiated samples as for dark controls.

The mobility in soil of oxasulfuron and its metabolites relevant for assessment was studied by batch equilibrium tests on a variety of different soils. Oxasulfuron exhibited very high mobility in soil. It was concluded that the adsorption of oxasulfuron was pH dependent. Metabolite saccharin (CGA 27913) exhibited very high soil mobility, metabolite C-1801 exhibited high to slight mobility and CGA 179710 exhibited high to low mobility. It was concluded that the adsorption of these metabolites was not pH dependent. Data gaps were identified for metabolites M3, CGA 171895 (M5), oxetan-3-ol (CGA 297691) and MT6 due to the lack of studies on adsorption and desorption from a minimum of three different soils (see Section 7).

One lysimeter study was carried out in North Carolina for oxasulfuron and soil metabolites after application at 117 g/ha in summer to a loamy sand to sandy clay loam soil. The annual maximum concentration of total radioactivity of oxasulfuron in leachates was 0.7 μg/L. Radioactivity in the leachates was low (8.4% AR). The main compounds found were oxasulfuron (0.62%) and C-1810 (7.78% AR).

Two field leaching studies were carried out with oxasulfuron in vulnerable soils in the United States. One lasted 365 days and was carried out in North Carolina after application of the formulated oxasulfuron at 224 g/ha in summer. Individual annual maximum concentrations of oxasulfuron and metabolites saccharin (CGA 27913), CGA 177288 and C-1801 were below the limit of detection (0.1 ppb) in soil-pore water and in ground water samples. Another field leaching study lasted 763 days and was carried out in Wisconsin after application of the formulated oxasulfuron at 224 g/ha in summer. Oxasulfuron was not detected in soil-pore water or groundwater samples. Metabolite saccharin (CGA 27913) was sporadically detected (up to 0.4 μg/L) in soil-pore water and in ground water samples (up to 3 μg/L), and it was also detected prior to the application. Metabolite CGA 177288 was detected once in ground water (0.17 μg/L), and metabolite C-1801 was detected only once in soil-pore water (0.12 μg/L).

In laboratory incubations in dark aerobic natural sediment water systems, oxasulfuron exhibited moderate persistence, forming the metabolite C1808 (max. 66.7% AR in the total system after 120 days). The unextractable sediment fraction (not extracted by acetonitrile/water) accounted for 19.65–24.6% AR at study end (180 days) for pyrimidyl ring ^{14}C radiolabel, and it accounted for 24.6% AR after 56 days for phenyl ring ^{14}C radiolabel. Mineralisation accounted for 33.25–53.86% AR for pyrimidyl ring ^{14}C radiolabel at study end (180 days), and it accounted for 72.8% AR for phenyl ring ^{14}C radiolabel at study end (182 days).

The rate of decline of oxasulfuron in a laboratory sterile aqueous photolysis experiment was fast relative to that occurred in the aerobic sediment water incubations. Chromatographically resolved components accounted for > 5% AR were C-1801 (51% AR after 7 days), saccharin (CGA 27913) (37% AR after 30 days), oxetan-3-ol (CGA 29769, 91% AR after 30 days), guanidine (33% AR after 30 days), 3-guanidino-1-butene (24% AR after 30 days) and CGA 179710 (5% AR after 30 days).

The necessary surface water and sediment exposure assessments (predicted environmental concentration (PEC) calculations) were carried out for oxasulfuron and its metabolites saccharin (CGA 27913), C-1801, M3, CGA 171895 (M5), CGA 179710, oxetan-3-ol (CGA 297691), MT6 and guanidine and 3-guanidine-1-1butene, using the FOCUS (FOCUS, 2001) step 1 and step 2 approach (version 3.2 of the Steps 1–2 in FOCUS calculator). However, a data gap is identified for metabolite MT6, consequent to the lack of data, and for metabolite CGA 171895 (M5), consequent to the use of a not agreed adsorption endpoint.

For oxasulfuron and metabolites C-1801, M3 and CGA 179710 appropriate step 3 (FOCUS, 2001) and for oxasulfuron and metabolite M3 step 4 calculations were available. The step 4 calculations appropriately followed the FOCUS (FOCUS, 2007) guidance, with no-spray drift buffer zones of up to 20 m being implemented for the drainage scenarios (representing a 91–93% spray drift reduction), and combined no-spray buffer zones with vegetative buffer strips of up to 20 m (reducing solute flux in run-off by 80% and erosion run-off of mass adsorbed to soil by 95%) being implemented for the run-off scenarios. The SWAN tool (version 1.1.4) was appropriately used to implement these mitigation measures in the simulations. However, risk managers and others may wish to note that whilst run-off mitigation is included in the step 4 calculations available, the FOCUS (FOCUS, 2007) report acknowledges that for substances with K_{Foc} < 2,000 mL/g (i.e. oxasulfuron), the general applicability and effectiveness of run-off mitigation measures had been less clearly demonstrated in the available scientific literature, than for more strongly adsorbed compounds.

Groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2009) scenarios and the models PEARL 4.4.4 and PELMO 5.5.4 for the active substance oxasulfuron and its metabolites saccharin (CGA 27913), C-1801, M3, CGA 171895 (M5), CGA 179710, oxetan-3-ol (CGA 297691) and MT6. Two sets of calculations were performed using annual application and a second considering application every third year. The potential for groundwater exposure from the representative uses by oxasulfuron and metabolites C-1801 and CGA 179710 above the parametric drinking water limit of 0.1 μg/L was concluded to be low in geoclimatic situations that are represented by all FOCUS groundwater scenarios for the representative use on soya bean. For this representative use on soya bean, the 80th percentile annual average recharge concentrations leaving the top 1 m soil layer were estimated to be > 0.1 μg/L at one out of one scenario for metabolite saccharin (CGA 27913) and > 0.75 μg/L for metabolite oxetan-3-ol (CGA 297691) considering both annual application and application every third year. It was concluded that these can be considered non-relevant groundwater metabolites (see Sections 2 and 3). The groundwater exposure assessment cannot be finalised for metabolite MT6, because of the lack of data, and for metabolites CGA 171895 (M5) and M3, consequent to the use of a not agreed adsorption endpoint. Therefore, a data gap is identified to address the groundwater leaching potential of these metabolites. This leads to the ground water exposure assessment for metabolites MT6, CGA 171895 (M5) and M3 being not finalised (see Section 9). It should be noted that with the available toxicological information (see Section 6) due to the proposed classification of oxasulfuron as reprotoxic, these metabolites would be considered relevant should they be predicted to occur in groundwater above 0.1 μg/L.

The PEC in soil, surface water, sediment, and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion.

The applicant did not provide appropriate information to address the effect of water treatments processes on the nature of the residues that might be present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water. This has led to the identification of a data gap (see Section 7) and results in the consumer risk assessment not being finalised (see Section 9).

5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a,b), SETAC (2001), EFSA (2009), EFSA PPR Panel (2013) and EFSA (2013). According to Regulation (EU) No 283/2013, data should be provided regarding the acute and chronic toxicity to honeybees and data to address the development of honeybee brood and larvae. As the European Commission (2002a) does

not provide a risk assessment scheme which is able to use the chronic toxicity data for adult honeybees and the honeybee brood, when performing the risk assessment according to European Commission (2002a), the risk to adult honeybees from chronic toxicity and the risk to bee brood could not be finalised due to the lack of a risk assessment scheme. Therefore, EFSA (2013) was used for risk assessment in order to reach a conclusion for the representative uses.

According to Regulation 283/2013, EC10/EC20 values together with NOECs should be reported for studies appropriately designed. For oxasulfuron, only NOECs where reported and therefore a data gap was identified.

According to the available toxicity data and the risk assessment a low risk to birds and wild mammals was concluded for all the relevant routes of exposure to oxasulfuron. It has to be noted that no toxicity studies were available for the representative formulation and therefore it should be evaluated at the MS level whether the active substance exhibits a higher toxicity to birds and mammals when formulated.

Toxicity data on fish, aquatic invertebrates, algae and aquatic plants (only on *Lemna* sp.) were available for the active substance. The formulation was only tested on algae and *Lemna* sp. The available data were sufficient to conclude a low risk to fish, aquatic invertebrates and algae by using FOCUS Step 1 PEC_{sw} for the representative use of oxasulfuron. For aquatic plants a high risk was still concluded for one out of two FOCUS scenarios even when using step 4 PEC_{sw} with mitigation measures up to 20 m vegetative buffer strip (data gap).

Toxicity data were available for all the aquatic organisms only for the metabolite oxetan-3-ol (CGA 297691). For the rest of the pertinent metabolites in surface water a screening assessment was conducted. A low risk was identified for the metabolites oxetan-3-ol (CGA 297691), C-1801 and CGA 179710 by using FOCUS Steps 1–3 PEC_{sw}. A high risk cannot be excluded for the metabolite M3 for one out of two FOCUS scenarios by using Step 4 PEC_{sw} with mitigation measures comparable to 20 m vegetative buffer strip and for the metabolite CGA 27913 by using Step 2 PEC_{sw}. For the metabolite MT6 and CGA 171895, the risk assessment could not be carried out due to the lack of reliable PEC estimates (data gap).

For adult honey bees, only an acute oral toxicity study with the active substance (data gap) and a 10-day chronic study with the representative formulation were available. For larvae only a single exposure study was available which is not considered an appropriate study to be used in the risk assessment according to EFSA (2013).

Based on the available information, a low acute oral and chronic risk to adult bees was concluded. A low risk was also concluded for the exposure via consumption of contaminated water (i.e. guttation, surface water and puddle water). No data were submitted estimating the oxasulfuron concentration in puddle water. However, a low risk was also concluded for exposure via residues in puddle water, as the concentration needed to trigger a high risk would have to be many orders of magnitude higher than PEC_{sw} values calculated with FOCUS Step 1. The risk assessment for larvae could not be performed due to the lack of a suitable endpoint. Other assessments included sublethal effects (i.e. HPG, data gap), accumulative effects, and metabolites occurring in pollen and nectar (data gap). Data to perform a risk assessment for bumble bees and solitary bees were not available.

For non-target arthropods, high in-field risk was identified at Tier 1 for one of the two standard species (*Typhlodromus pyri*). Extended laboratory studies were available showing no concern. However, the studies were not conducted according to the representative use as reported in the GAP (lower application rate). However, considering the small effects reported in the extended laboratory studies (max 12%) and the low off-field risk, a low in-field risk was also concluded.

A low risk to earthworms was concluded for oxasulfuron and the metabolites CGA 1801, CGA 171895, CGA 297691, M3 and CGA 179710. For the metabolite saccharin (CGA 27913), a high risk was identified using the lowest available endpoint (EFSA, 2015) (data gap). For the soil metabolite MT6, no reliable PEC estimates are available and therefore the risk assessment to soil organisms could not be performed (data gap). No data were available on soil macro-organisms other than earthworms both for active substance and metabolites (data gap). Low risk to soil microorganisms was identified for the active substances and the pertinent metabolites.

For non-target terrestrial plants only a seedling emergence study was available. Since the vegetative vigour study was not available, the risk assessment could not be finalised (data gap).

A low risk is concluded for biological methods of sewage treatment.

With regard to the endocrine-disrupting potential, pending on the data gap identified in Section 2, further data might be needed to draw a firm conclusion on the potential for endocrine disruption of oxasulfuron.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Tables 1–4)

Table 1: Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Oxasulfuron	Low to moderate persistence Single first order DT_{50} 3.2–29.3 days (DT_{90} 10.6–97.3 days; laboratory conditions at 25–20°C, 40% MWHC soil moisture) USA field dissipation studies single first order DT_{50} 3.2–5.9 days	Low risk to earthworms. Data gap for other soil macro-organisms and soil microorganims
Saccharin (CGA 27913)	Low to high persistence Biphasic kinetics and single first order DT_{50} 4.6–237.4 days (DT_{90} 28.8–788.6 days; laboratory conditions at 20°C, 40% MWHC soil moisture)	High risk to earthworms. Data gap for other soil macro-organisms and soil microorganism
M3	Data gap	Low risk to earthworms. Data gap for other soil macro-organisms and soil microorganism
M5 (CGA 171895)	Data gap	Low risk to earthworms. Data gap for other soil macro-organisms and soil microorganism
C1801	Low to high persistence Single first order DT_{50} 3.2–468 days (DT_{90} 10.8–1,560 days; laboratory conditions at 25–20°C, 75% of FC at 0.33 bar)	Low risk to earthworms. Data gap for other soil macro-organisms and soil microorganism
CGA 179710	Data gap	Low risk to earthworms. Data gap for other soil macro-organisms and soil microorganism
Oxetan-3-ol (CGA 297691)	Data gap	Low risk to earthworms. Data gap for other soil macro-organisms and soil microorganism
MT6	Data gap	Assessment not finalised for all soil organisms

Table 2: Groundwater

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses[a]	Pesticidal activity	Toxicological relevance
Oxasulfuron	Very high mobility K_{Foc} 17–30 mL/g	No	Yes	Yes
Saccharin (CGA 27913)	Very high mobility K_{Foc} 3–20 mL/g	Yes Soya beans: 1/1 FOCUS scenario (0.208–0.472 µg/L, annual application; 0.075–0.184 µg/L, application every third year)	No	No ADI 3.8 mg/kg bw per day (EC, 1997)

Compound (name and/or code)	Mobility in soil	> 0.1 µg/L at 1 m depth for the representative uses[a]	Pesticidal activity	Toxicological relevance
M3	Data gap	Data gap	Information not available	Toxicologically relevant based on proposed classification Repr cat 2 for oxasulfuron
M5 (CGA 171895)	Data gap	Data gap	Information not available	Toxicologically relevant based on proposed classification Repr cat 2 for oxasulfuron
C1801	High to slight mobility K_{Foc} 54–2,124 mL/g	No	Assessment not triggered, not required	Assessment not triggered, not required
CGA 179710	High to low mobility K_{Foc} 143–601 mL/g	No	Assessment not triggered, not required	Assessment not triggered, not required
Oxetan-3-ol (CGA 297691)	Data gap	Yes Soya beans: 1/1 FOCUS scenario (2.436–3.004 µg/L, annual application; 1.029–1.270 µg/L, application every third year)	Data gap	No ADI 0.05 mg/kg bw per day
MT6	Data gap	Data gap	Information not available	Toxicologically relevant based on proposed classification Repr cat 2 for oxasulfuron

(a): At least one FOCUS scenario or relevant lysimeter.

Table 3: Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Oxasulfuron	High risk for one out of two FOCUS scenarios
Saccharin (CGA 27913)	High risk by using Step 2 PEsw[a]
M3	High risk for one out of two FOCUS scenarios[a]
M5 (CGA 171895)	Assessment not finalised
C1801	Low risk
CGA 179710	Low risk
Oxetan-3-ol (CGA 297691)	Low risk
MT6	Assessment not finalised

(a): High risk cannot be excluded based on a screening assessment.

Table 4: Air

Compound (name and/or code)	Toxicology
Oxasulfuron	LC_{50} > 5,082 mg/m^3 (4 h, nose-only exposure)

7. Data gaps

This is a list of data gaps identified during the peer review process, including those areas in which 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 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful effects).

7.1. Data gaps identified for the representative uses evaluated

- A search of the scientific peer-reviewed open literature on the active substance (including the ISO common name) and its relevant metabolites, dealing with side effects on the environment and non-target species and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011; relevant for all representative uses evaluated; submission date proposed by the applicant: unknown).
- Surface tension of the purified active substance (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 1).
- The molar extinction coefficient at 290 nm at different pH values of the purified active substance (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 1).
- Auto-flammability of the representative formulation (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 1).
- Accelerated storage stability using an alternative storage condition, and persistent foaming, before and after storage, of the suspension containing water-soluble bags (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 1).
- Suspensibility of the representative formulation at the lowest recommended rate of use (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 1).
- Compatibility of the representative formulation with tank mixes (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 1).
- Screening studies to evaluate the biological (herbicidal) activity of the soil degradation products of oxasulfuron that may leach to groundwater (M3, M5(CGA 171895), MT6 and oxetan-3-ol (CGA 297691)) (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 6).
- Monitoring methods for the determination of oxasulfuron residues in all four plant commodity groups with ILV (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 1).
- Monitoring methods for the determination of oxasulfuron residues in soil, water, air and body fluids and tissues validated according to the requirements of SANCO/825/00 rev. 8.1 (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 1).
- Comparative *in vitro* metabolism study, on animal species used in pivotal studies and on human material. Further considerations might need to be given if unique metabolites are observed with human material (relevant for all representative uses; submission date proposed by the applicant: unknown; see Section 2).
- Additional investigations of endocrine-disrupting potential of oxasulfuron should be provided to clarify whether the reproductive performance in females was affected by endocrine mode of action, and if developmental landmarks in offspring were affected by oxasulfuron. Further data/investigations on mode of action of neurotoxicity could also be useful to identify potential neuroendocrine effects (relevant for all representative uses; submission date proposed by the applicant: unknown; see Section 2).
- Determination of the residues in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).

- The potential for residues of CGA 27913 and C 1801 to be present in the rotational crops is requested (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3.1).
- Data and information to sufficiently identify the individual component MT6 which occurred at least in two sequential measurements at more than 5% of the amount of active substance added were not available. Consequently, aerobic degradation (DegT50 and DegT90 values) from a minimum of three different soils is not available for MT6 (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 4).
- Aerobic degradation (DegT50 and DegT90 values) from a minimum of three different soils are not available for metabolites CGA 171895 (M5), M3, CGA 179710 and oxetan-3-ol (CGA 297691) (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 4).
- Studies on adsorption and desorption from a minimum of three different soils are not available for metabolites oxetan-3-ol (CGA 297691), M3, CGA 171895 (M5) and MT6 (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 4).
- No acceptable PEC_{soil} calculations were provided for metabolite MT6 (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Sections 4 and 5).
- No PEC_{gw} calculations were provided for metabolite MT6 (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 4).
- No acceptable PEC_{gw} calculations were provided for metabolites M3 and CGA 171895 (M5) (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 4).
- No acceptable $PEC_{sw/sed}$ calculations were provided for metabolites MT6 and CGA 171895 (M5) (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Sections 4 and 5).
- Information on the effect of water treatment processes on the nature of residues of both the active substance and its identified metabolites potentially present in surface and groundwater, when surface water or groundwater are abstracted for drinking water, were not sufficient in order to assess the consumer risk from the consumption of drinking water (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 4).
- To calculate EC10/EC20 values, according to Regulation 283/2013, for studies appropriately designed (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Further data to address the chronic risk to aquatic macrophytes due to exposure to oxasulfuron (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Further data to address the risk to aquatic organisms when exposed to the metabolite M3 and CGA 27913 (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Suitable data to address the acute contact risk to adult honeybee (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Suitable data to address the risk to honeybee larvae (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Based on EFSA (2013), suitable data to address the risk of sublethal effects (e.g. HPG development effects) to honeybees due to exposure to oxasulfuron (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Information to assess the risk to honeybees due to plant metabolites occurring in pollen and nectar (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Further information to address the risk to earthworms when exposed to the metabolite saccharin (CGA 27913) (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).
- Further information to address the risk to soil macro-organisms other than earthworms when exposed to oxasulfuron and pertinent metabolites (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).

- Further information to address the effects of oxasulfuron on the vegetative vigour of non-target terrestrial plants relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 5).

7.2. Data gaps identified for the maximum residue level applications

MRL applications were not included in the RAR.

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

Use of personal equipment is required for operators in order to have exposure estimates below the AOEL (see Section 2).

9. Concerns

9.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if 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 in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011[5] and if 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).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

1) The overall consumer exposure assessment cannot be finalised in view of the outstanding data regarding the metabolism and magnitude of the relevant compounds in rotational crops and the consumer exposure assessment through drinking water (see Section 3.1).
2) The ground water exposure assessment cannot be finalised considering the lack of data for metabolites MT6, M3 and CGA 171895 (M5) (see Section 4). The groundwater relevance assessment regarding biological screening for herbicidal activity of oxetan-3-ol (CGA 297691) could not be finalised (see Section 6).
3) The risk assessment to aquatic organisms cannot be finalised considering the lack of exposure estimates for metabolites MT6 and CGA 171895 (M5) (see Sections 4 and 5).
4) The risk assessment to earthworms cannot be finalised considering the lack of exposure estimates for metabolites MT6 (see Sections 4 and 5).
5) The risk to soil macro-organisms other than earthworms could not be finalised due to the lack data for oxasulfuron and the pertinent soil metabolites (see Section 5).
6) The risk to soil microorganisms could not be finalised for the pertinent soil metabolites due to the lack of data (see Section 5).
7) The risk to non-target terrestrial plants could not be finalised to the lack of toxicity data on the vegetative vigour (see Section 5).

9.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion 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.

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

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at the lower tier level does not permit the conclusion 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 if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

8) The risk to aquatic organisms was assessed as high for one out of the two relevant FOCUS surface water scenarios for the representative use of oxasulfuron (see Section 5).
9) High risk to earthworms was identified for the metabolite saccharin (CGA 27913) (see Section 5).

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 Table 5).

Table 5: Overview of concerns

Representative use		Soya bean
Operator risk	Risk identified	
	Assessment not finalised	
Worker risk	Risk identified	
	Assessment not finalised	
Resident/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	
Risk to wild non-target terrestrial organisms other than vertebrates	Risk identified	X[9]
	Assessment not finalised	X[4,5,6,7]
Risk to aquatic organisms	Risk identified	X[8]
	Assessment not finalised	X[3]
Groundwater exposure to active substance	Legal parametric value breached	
	Assessment not finalised	
Groundwater exposure to metabolites	Legal parametric value breached[(a)]	
	Parametric value of 10 µg/L[(b)] breached	
	Assessment not finalised	X[2]

Columns are grey if no safe use can be identified. The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–6 for further information.
(a): When the consideration for classification made in the context of this evaluation under Regulation (EC) No 1107/2009 is confirmed under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008.
(b): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission, 2003.

9.4. Issues related to the maximum residue level applications

9.4.1. Issues not finalised under the maximum residue level applications

Not relevant.

9.4.2. Consumer risk identified under the maximum residue level applications

Not relevant.

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Abbreviations

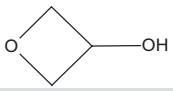
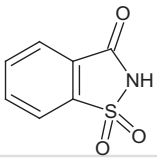
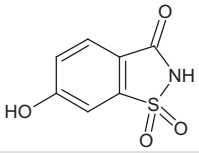
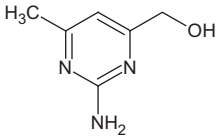
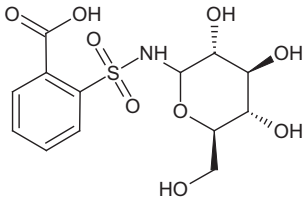
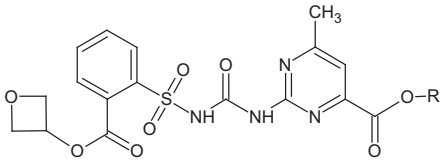
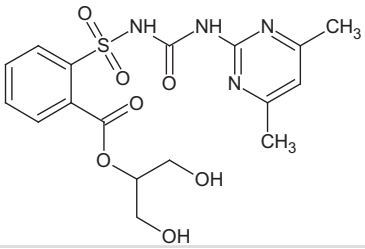
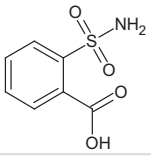
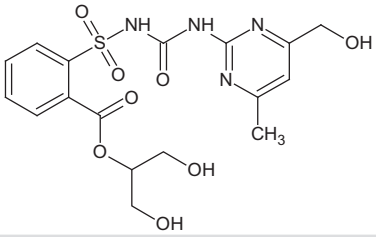
a.s.	active substance
ADI	acceptable daily intake
AAOEL	acute acceptable operator exposure level
AOEL	acceptable operator exposure level
ARfD	acute reference dose
bw	body weight
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
EEC	European Economic Community
FAO	Food and Agriculture Organization of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
GS	growth stage
HPG	hypopharygeal glands
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting of 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_{Foc}	Freundlich organic carbon adsorption coefficient
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography–mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue level
MS	mass spectrometry
MWHC	maximum water-holding capacity
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration

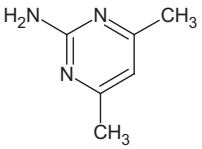
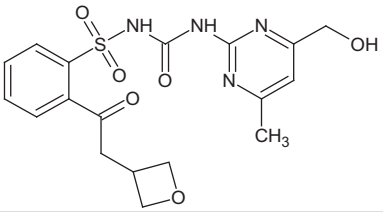
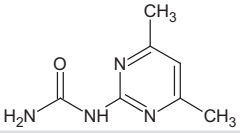
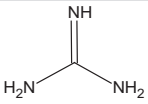
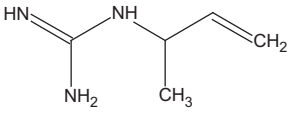
PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
RAR	renewal assessment report
RMS	rapporteur Member State
SMILES	simplified molecular-input line-entry system
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UF	uncertainty factor
WG	water-dispersible granule
WHO	World Health Organization

Appendix A – List of endpoints for the active substance and the representative formulation

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2017.4722.

Appendix B – Used compound codes

Code/trivial name[a]	Chemical name/SMILES notation	Structural formula
Oxetan-3-ol **CGA 297691**	Oxetan-3-ol OC1COC1	
Saccharin CGA 27913	1,2-benzothiazol-3(2*H*)-one 1,1-dioxide O=C2NS(=O)(=O)c1ccccc12	
OH-Saccharin CGA-223501	6-hydroxy-1,2-benzothiazol-3(2*H*)-one 1,1-dioxide Oc1ccc2c(c1)S(=O)(=O)NC2=O	
CGA 340355 **OH-pyrimidine-amine**	(2-amino-6-methylpyrimidin-4-yl) methanol Cc1cc(CO)nc(N)n1	
***N* glucoside conjugate of CGA 120844**	*N*-[(2-carboxyphenyl)sulfonyl]-D-glucopyranosylamine O=S(=O)(NC1O[C@H](CO)[C@@H](O)[C@H](O)[C@H]1O)c2ccccc2C(=O)O	
M3	Unknown conjugate/ester of 6-methyl-2-{[({2-[(oxetan-3-yloxy) carbonyl]phenyl}sulfonyl)carbamoyl] amino}pyrimidine-4-carboxylic acid	
CGA-310785	1,3-dihydroxypropan-2-yl 2-{[(4,6-dimethylpyrimidin-2-yl)carbamoyl] sulfamoyl}benzoate O=C(Nc1nc(C)cc(C)n1)NS(=O)(=O)c2ccccc2C(=O)OC(CO)CO	
CGA-177288	2-sulfamoylbenzoic acid O=S(N)(=O)c1ccccc1C(=O)O	
M5 CGA 171895	1,3-dihydroxypropan-2-yl 2-({[4-(hydroxymethyl)-6-methylpyrimidin-2-yl]carbamoyl}sulfamoyl)benzoate O=C(Nc1nc(C)cc(CO)n1)NS(=O)(=O)c2ccccc2C(=O)OC(CO)CO	

Code/trivial name[a]	Chemical name/SMILES notation	Structural formula
C-1801	4,6-dimethylpyrimidin-2-amine Cc1cc(C)nc(N)n1	
OH-CGA-277476	oxetan-3-yl 2-({[4-(hydroxymethyl)-6-methylpyrimidin-2-yl]carbamoyl}sulfamoyl)benzoate O=C(OC1COC1)c2ccccc2S(=O)(=O)NC(=O)Nc3nc(C)cc(CO)n3	
CGA 179710	1-(4,6-dimethylpyrimidin-2-yl)urea O=C(N)Nc1nc(C)cc(C)n1	
Guanidine	Guanidine N=C(N)N	
3-Guanidino-1-butene	1-but-3-en-2-ylguanidine N=C(N)NC(C)C=C	

(a): The compound name in bold is the name used in the conclusion.