

## CONCLUSION ON PESTICIDE PEER REVIEW

### Conclusion on the peer review of the pesticide risk assessment of the active substance azoxystrobin<sup>1</sup>

European Food Safety Authority<sup>2</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

Commission Regulation (EC) No 737/2007<sup>3</sup> (hereinafter referred to as 'the Regulation') lays down the procedure for the renewal of the inclusion of a first group of active substances in Annex I to Council Directive 91/414/EEC and establishes the list of those substances. Azoxystrobin is one of the first group of active substances listed in the Regulation.

In accordance with Article 6 of the Regulation, the notifier Syngenta submitted a dossier on azoxystrobin to the United Kingdom and the Czech Republic, being the designated rapporteur Member State (RMS), and co-rapporteur Member State (co-RMS), respectively. In accordance with Article 10 of the Regulation, the United Kingdom prepared an Assessment Report in consultation with the Czech Republic, which was submitted to the EFSA and the Commission of the European Communities (hereafter referred to as 'the Commission'). The Assessment Report was received by the EFSA on 10 June 2009.

In accordance with Article 11 of the Regulation, the EFSA distributed the Assessment Report to Member States and the notifier for comments on 12 June 2009. The EFSA collated and forwarded all comments received to the Commission on 13 July 2009.

In accordance with Article 12, following consideration of the Assessment Report and the comments received, the Commission requested the EFSA to arrange an expert consultation on the Assessment Report as appropriate and deliver its conclusions on azoxystrobin.

The conclusions presented in this report were reached on the basis of the evaluation of the representative uses of azoxystrobin as a fungicide on cereals and Brassicae vegetables, as proposed by the notifier. Full details of the representative uses can be found in Appendix A to this report.

There were data gaps identified in the section for identity and analytical methods.

In the mammalian toxicology section, an area of concern was raised with regard to the technical specification, since the one agreed during the first Annex I inclusion and the one proposed by the notifier during the Annex I renewal procedure were considered by the experts not to be covered by the batches used in the toxicological assessment. It is noted that if the technical specification as proposed by the rapporteur Member State for the renewal procedure in May 2009 could be agreed on, then this would be considered adequate to cover the toxicological assessment.

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1 On request from the European Commission, Question No EFSA-Q-2009-00809, issued on 12 March 2010.

2 Correspondence: [praper@efsa.europa.eu](mailto:praper@efsa.europa.eu)

3 OJ L169, 29.06.2007, p.10

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No critical area of concern was identified in the residues section. Based on metabolism studies conducted on three distinct plant groups (cereals, fruits and oilseed/pulse crops), the residue in plants was defined as azoxystrobin for monitoring and risk assessment. The same residue definition was set by default for animal products, azoxystrobin being extensively metabolised in animals. However, the definition for risk assessment has to be considered provisional, pending additional information on the toxicological relevance of metabolites L1, L4 and L9. Considering the representative uses on Brassicaceae and cereals, no chronic concerns are expected, the Theoretical Maximum Daily Intake (TMDI) being less than 2% of the Acceptable Daily Intake (ADI). However, an additional chronic exposure of *ca.* 5% ADI has to be considered, as the result of the presence of the metabolite R234886 in groundwater (up to 22 µg/L).

The data available on fate and behaviour in the environment are basically sufficient to carry out the required environmental exposure assessments at EU level for the representative uses. However, the detailed quantification of a group of unidentified, minor transformation products, found in one soil incubation, was not available. Therefore there is no assessment for groundwater contamination of any potentially formed minor soil transformation products that would trigger further evaluation. The potential for groundwater exposure by the metabolite R234886 is predicted to be high over a wide range of geoclimatic conditions represented by the FOCUS groundwater scenarios. Since the concentration of this metabolite was predicted to be above 10 µg/L over a range of FOCUS groundwater scenarios, this was identified as a critical area of concern. However, the metabolite R234886 was considered as non-relevant in groundwater.

The environmental risk assessment indicated no critical areas of concern. The risk assessment to all non-target species was addressed except for the aquatic organisms.

#### **KEY WORDS**

Azoxystrobin, peer review, risk assessment, pesticide, fungicide

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## BACKGROUND

Commission Regulation (EC) No 737/2007<sup>4</sup> (hereinafter referred to as 'the Regulation') lays down the procedure for the renewal of the inclusion of a first group of active substances in Annex I to Council Directive 91/414/EEC and establishes the list of those substances. Azoxystrobin is one of the first group of active substances listed in the Regulation.

In accordance with Article 6 of the Regulation, the notifier Syngenta submitted a dossier on azoxystrobin to the United Kingdom and the Czech Republic, being the designated rapporteur Member State (RMS), and co-rapporteur Member State (co-RMS), respectively. In accordance with Article 10 of the Regulation, the United Kingdom prepared an Assessment Report (The United Kingdom, 2009a) in consultation with the Czech Republic, which was submitted to the EFSA and the Commission of the European Communities (hereafter referred to as 'the Commission'). The Assessment Report was received by the EFSA on 10 June 2009.

In accordance with Article 11 of the Regulation, the EFSA distributed the Assessment Report to Member States and the notifier for comments on 12 June 2009. A 30-day period was provided for commenting. In addition, the EFSA conducted a public consultation on the Assessment Report. The EFSA collated and forwarded all comments received to the Commission on 13 July 2009. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table. The notifier was invited to respond to the comments in column 3 of the Reporting Table. The RMS also provided a response to the comments in column 3.

In accordance with Article 12, following consideration of the Assessment Report and the comments received, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 18 September 2009, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on azoxystrobin. The need for expert consultation was considered in a telephone conference between the EFSA, the RMS, the co-RMS and the Commission on 26 August 2009. On the basis of the comments received, the notifier's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the areas of mammalian toxicology, environmental fate and behaviour and ecotoxicology.

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 consultation with Member State experts, 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 discussions where these 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 December 2009.

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 uses as a fungicide on cereals and Brassicae vegetables, as proposed by the notifier. 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 (EFSA, 2010), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer

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<sup>4</sup> OJ L169, 29.06.2007, p.10

review, from the initial commenting phase to the conclusion. The Peer Review Report comprises the following documents:

- the comments received,
- the Reporting Table (revision 1-1; 27 August 2009),
- the Evaluation Table (5 February 2010),
- the report(s) of the scientific consultation with Member State experts (where relevant).

Given the importance of the Assessment Report including its addendum (compiled version of December 2009 containing all individually submitted addenda) (The United Kingdom, 2009b) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

## THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Azoxystrobin is the ISO common name for methyl (*E*)-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy}phenyl}-3-methoxyacrylate (IUPAC).

The representative formulated product for the evaluation was "Amistar", a suspension concentrate (SC), containing 250 g/L azoxystrobin, registered under different trade names in Europe.

The representative uses are as a fungicide applied to broccoli, cauliflower, Brussels sprouts, kale, barley and wheat. Full details of the GAP can be found in the list of end points in Appendix A to this conclusion.

## CONCLUSIONS OF THE EVALUATION

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

The minimum purity of azoxystrobin as manufactured should not be less than 965 g/kg, which is in compliance with the FAO Specification 571/TC (August 2009).

QC data on the analysis of the technical material are required to support finalisation and agreement of the technical material specification. During the peer review appropriate levels of some impurities could not be agreed on. Toluene was considered as an impurity of toxicological relevance based on its hazards, however the assessment of its maximum level was not finalised.

Besides the specification, 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 azoxystrobin or the respective formulation. The main data regarding the identity of azoxystrobin and its physical and chemical properties are given in Appendix A of this conclusion.

Adequate analytical methods are available for the determination of azoxystrobin in the technical material and in the representative formulation, as well as for the determination of the relevant impurities in the technical material.

The multi-method DFG-S19 is applicable to determine residues of azoxystrobin in dry crops, fruits with high acid content and commodities with high water content. Adequate LC-MS/MS methods are also available to monitor azoxystrobin residues in food of plant origin. Residues of azoxystrobin in animal matrices can be monitored by GC-NPD. Monitoring of residues of azoxystrobin in groundwater, drinking water and surface water can be done by GC-MSD. Pending on the data gap identified in section 4, the residue definition for water might change and therefore further methods could be required in the future. Adequate methods are available for the determination of residues of azoxystrobin in soil and air.

According to the currently agreed classification under Annex I of Directive 67/548/EEC<sup>5</sup>, azoxystrobin is classified as T, and as a consequence, a data gap was identified for adequate analytical methods for body fluids and tissues.

### 2. Mammalian toxicity

Azoxystrobin was discussed at the PRAPeR 71 meeting of experts on Mammalian Toxicology (October 2009). The experts concluded that the specification is covered by the toxicological assessment if it complies with the rapporteur Member State's proposal from May 2009 (Volume 4, Table C.1.2-3; The United Kingdom, 2009a); in the notifier's proposal for the Annex I renewal, which reduces the levels of a number of impurities compared to the specification agreed for Annex I inclusion, two impurities are not covered by the toxicological assessment. The technical specification

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<sup>5</sup> Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. OJ 196 , 16/08/1967 p. 0001 – 0098.

as agreed in the Annex I inclusion is not covered by the toxicological assessment, either. As the proposed technical specification could not be agreed on by the section on physical and chemical properties (refer to section 1), a critical area of concern was raised on this issue.

Low toxicity is observed when azoxystrobin is administered by the oral or dermal routes. An inhalation study using particles with a mass median aerodynamic diameter (MMAD) higher than 14 µm presented a LC<sub>50</sub> of 4.7 mg/L air, while a study using smaller MMAD resulted in a LC<sub>50</sub> of 0.7 mg/L air. Accordingly, azoxystrobin is classified as T, R23, '**Toxic by inhalation**' under Annex I of Directive 67/548/EEC.

The target organs of azoxystrobin are the liver and common bile duct with increased liver weight, altered clinical chemistry profile and, at high dose levels, histopathological changes; reduced bodyweight gain is the most common finding. The relevant short-term and long-term NOAEL is around 20 mg/kg bw/day from the 90-day and 2-year rat studies, supported by the 1-year dog study. No genotoxicity is attributed to azoxystrobin administration *in vivo*; no oncogenic potential was found in rats or mice. Fertility and overall reproductive performance were not impaired; no teratogenicity was observed in either rats or rabbits, while reduced ossification was observed in rats at maternally toxic doses. No specific neurotoxic effects were found in acute and repeated-dose neurotoxicity studies.

Acute oral toxicity and bacterial gene mutation studies were submitted on metabolite R234886, found in plant residues and in groundwater up to 22 µg/L according to environmental models, and on metabolite R230310 (Z-isomer of azoxystrobin). During the PRAPeR 71 meeting the experts confirmed that metabolite R234886 is not relevant in groundwater, and that the hazard assessment on azoxystrobin applies also to the plant metabolites, i.e. R234886, N1, N2, O2, O3, R401553, R405287 and R230310. No conclusion could be drawn on other metabolites found in animal matrices. After the experts' meeting, the rapporteur Member State provided further evaluation on the metabolites found in animal matrices in Addendum 2 to the Assessment Report (The United Kingdom, 2009b). Although this information has not been peer reviewed, EFSA notes there are indications that the reference values of the parent substance would apply also to metabolites M13, M20 and K1 according to the information provided. In relation to the other metabolites found in goats (L1, L4 and L9), no conclusion could be drawn on their toxicological profile, although the rapporteur Member State considers them unlikely to be of toxicological significance at the levels found.

The acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) of azoxystrobin are set at 0.2 mg/kg bw/day, applying an assessment factor of 100. No acute reference dose (ARfD) is allocated. The estimated operator exposure is below the AOEL without using personal protective equipment (PPE) according to both the German and the UK POEM models. Low risk is anticipated for workers and bystanders.

### 3. Residues

Plant metabolism has been investigated in three plant groups; cereals (wheat), fruit crops (grapes) and oilseed/pulse crops (peanut), using <sup>14</sup>C-azoxystrobin either labelled on the pyrimidyl, cyanophenyl or phenylacrylate moieties and considering foliar applications. The metabolism pattern was similar in all plant groups, the parent azoxystrobin being the major compound, accounting for 17-43% TRR in cereal grain and straw, 35-65% TRR in grapes, and 14-48% TRR in peanut hulls and hay. Azoxystrobin was however not detected in peanut nuts, where radioactivity was found to be mainly incorporated in fatty acids (up to 49% TRR). The other major identified metabolites were M28 (R401553), resulting from the cleavage of the ester link between the phenylacrylate and pyrimidyl ring, and metabolite R230310 (Z-isomer of azoxystrobin), both mostly below 10% TRR. Azoxystrobin follows a comparable pattern in rotational crops but with a more extensive metabolism, with more metabolites being formed, most of them as glucose or amino acid conjugates. Based on these studies the residue for monitoring and risk assessment was defined as azoxystrobin only. Sufficient supervised residue trials were provided to derive the MRLs for Brassicaceae, wheat and barley. Azoxystrobin and its Z-isomer (R230310) were shown to be stable up to 10 months and 2 years, in animal and plant

matrices, respectively, when stored frozen at *ca.* -18°C. No significant hydrolysis of azoxystrobin was observed following standard incubations at different pH and temperatures, and transfer factors were proposed for beans, barley and wheat processed commodities. No residues are expected in rotational crops when azoxystrobin is applied according to the representative GAPs.

Azoxystrobin was rapidly excreted in the metabolism studies performed on goats (2N dose) and poultry (8N dose). The transfer in tissues was limited, the TRRs in muscle, fat, milk and egg white being  $\leq 0.02$  mg/kg. Thus, characterisation of residues was only performed in goat liver and kidney, and in poultry liver and egg yolk, where the TRRs were in the range of 0.05 to 1.19 mg/kg. In these matrices, the metabolism was shown to be very extensive, more than 20 compounds being identified/characterised, each accounting mostly for less than 5% of the TRR. Some metabolites (M28, M20, L4...) were however observed in higher proportions in some matrices, depending on the <sup>14</sup>C-label. The parent compound was less than 2% of the TRR, except in egg yolk (12% TRR for the cyanophenyl label). None of these compounds were considered as a sufficient marker for the residue in animal matrices, and the residue for monitoring and risk assessment was then defined by default as azoxystrobin only. However, the definition for risk assessment has to be considered provisional, pending additional information on the toxicological relevance of metabolites L1, L4 and L9. Considering the calculated animal burdens and the results of the feeding studies, no MRLs were proposed for poultry products and a global MRL of 0.01\* mg/kg was set for the other products of animal origin.

The TMDI estimated using the EFSA PRIMo model rev.2 and the MRLs proposed for Brassicae and cereals is less than 2% of the ADI for all diets included in the model. However, an additional chronic exposure of *ca.* 5% of the ADI has to be considered as the result of the presence of the metabolite R234886 in groundwater up to 22 µg/L. The acute exposure was not estimated, since the setting of an ARfD was considered not necessary for azoxystrobin.

#### 4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark, azoxystrobin exhibits moderate to high persistence, forming only one major (>10% applied radioactivity (AR)) soil metabolite, referred to as R234886. However, a data gap was set for detailed quantification of a group of unidentified, minor transformation products found in one soil incubation, to clarify whether this group contains any metabolite that would trigger further evaluations regarding groundwater contamination<sup>6</sup>. The rate of mineralisation to carbon dioxide varied between 1.8-27 % AR after 120 days, depending on the soil and the radiolabel position used. Formations of unextractable residues were a sink, accounting for 6.2-24.5 % AR after 120 days. Under anaerobic conditions, azoxystrobin exhibited similar degradation scheme as under aerobic conditions, forming no novel metabolites. However, in the study on photolysis in soil, two metabolites, R401553 and R402173, reached 5% AR or were formed even above this level at two consecutive time points. Both photolytic metabolites, as well as the metabolite R234886 were found in some field trials at significant levels (>10%). Moreover, metabolite R401553 was found to be minor, but was increasing at the study end of one soil incubation in the laboratory. Metabolite R401553 exhibited very low to low persistence, and metabolite R402173 exhibited low persistence in soil. Metabolite R234886 may be considered to exhibit moderate to high persistence in soil on the basis of the complete data set, considering single first-order (SFO) or biphasic degradation. Concerning the kinetics and the degradation end points to be used in the further evaluation for this metabolite, an extensive expert discussion was conducted (see Report of PRAReR 72 Experts' Meeting, Open point 4.2; EFSA, 2010).

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<sup>6</sup> Assessment for groundwater contamination is necessary for minor metabolites, which account for less than 10%, but more than 5% of the amount of the parent compound in at least two consecutive measurements during a soil incubation, or of which amount is still increasing at the end of the study, therefore it cannot be proved that the maximum formation is already reached (European Commission, 2003).

\* MRL is proposed at the limit of quantification (LOQ)

Dissipation of azoxystrobin was investigated in a number of field trials. After the evaluation of the designs of these studies against the relevant criteria outlined in FOCUS Kinetics (FOCUS, 2006), and after the normalization of the residue data from the accepted trials to FOCUS reference conditions (20°C and pF2 soil moisture content), altogether 13 degradation end points were obtained. In 10 trials, where the surface applications were not followed by soil incorporation, biphasic declines were observed. This was attributed to photolysis on the surface followed by microbiological degradation in the soil. Azoxystrobin exhibits low to medium mobility, while the metabolite R401553 exhibits high to medium mobility in soil. Metabolites R402173 and R234886 exhibited very high to medium mobility in soil, and there was an indication that the adsorption of these metabolites is pH dependent. Soil plateau concentration for long-term use in consecutive years and PEC<sub>soil</sub> for azoxystrobin were calculated based on the worst-case non-normalized field DT<sub>50</sub>. For the metabolites, initial PEC<sub>soil</sub> values were calculated based on the initial PEC<sub>soil</sub> of azoxystrobin.

In laboratory incubations in aerobic natural sediment water systems, azoxystrobin exhibited high persistence (SFO DT<sub>50</sub> 180-234 days), forming the major metabolite R234886. The majority of azoxystrobin partitioned to sediment during the study, only a small percentage ( $\leq 7.6\%$ ) was found in the water phase at the study end, on day 152. However, in the sediment, a significant amount (42-61%) of radioactivity was identified as azoxystrobin at the study end. Mineralisation to carbon dioxide accounted for 2.5-5.1 % AR, while residues not extracted from the sediment represented 5.9 - 6.7 % AR at the end of the study. In an outdoor pond study, azoxystrobin dissipated from the water column with a calculated DT<sub>50</sub> of about 13 days. The residue of azoxystrobin in the sediment was continuously increasing in the first three weeks of the study. The necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC)) were appropriately carried out using the FOCUS (2001) step 1 and step 2 approach (version 1.1 of the steps 1-2 in FOCUS calculator) for azoxystrobin and its metabolites. Moreover, PEC values for surface water and sediment were calculated for azoxystrobin using FOCUS step 3 approach.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (2000) scenarios and models (PELMO 3.3.2 and PEARL 3.3.3<sup>7</sup>). The potential for groundwater exposure from the representative uses by azoxystrobin or the metabolites R401553 and R402173 above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by the relevant FOCUS groundwater scenarios. The potential for groundwater exposure by the metabolite R234886 was concluded to be high over a wide range of geoclimatic conditions represented by the FOCUS groundwater scenarios.

Azoxystrobin has a low potential for volatilization with an estimated atmospheric half-life shorter than 2 days. Therefore, long-range transport through the atmosphere is not expected.

The PEC in soil, surface water, sediment and groundwater, as agreed by the peer review for the representative uses assessed, can be found in Appendix A of this conclusion.

## 5. Ecotoxicology

Azoxystrobin was discussed at the PRAPeR Expert Teleconference 25 on Ecotoxicology (4 November 2009). The environmental risk assessment of azoxystrobin was conducted according to the current guidance documents (see References). The analysis of the batches used in the ecotoxicological tests was not provided, therefore comparison of these batches with the proposed specification could not be assessed.

The toxicity studies indicated a low toxicity of azoxystrobin to birds and mammals, and the risk from the representative uses was assessed as low.

Based on the available data, azoxystrobin and its formulation were considered as very toxic to aquatic organisms. The relevant metabolites R234886, R401553 and R402173 were found to be less toxic than

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<sup>7</sup> Simulations correctly utilised the agreed Q10 of 2.58 and Walker equation coefficient of 0.7

the parent substance. As regards azoxystrobin toxicity, *Skeletonema costatum* ( $E_bC_{50} = 0.098$  mg a.s./L) was found to be the most sensitive species. The experts agreed to use the acute end point of  $LC_{50} = 470$  µg a.s./L (*Oncorhynchus mykiss*) in the acute risk assessment for fish (see Evaluation Table open point 5.5; EFSA, 2010). Low acute risk was identified from azoxystrobin to fish using the PEC<sub>sw</sub> from FOCUS step 3 for all representative uses, except for the Brassicaceae, where the R3 and R4 scenarios breach the Annex VI trigger values. The long-term risk for fish was assessed as low. A data gap was identified by EFSA after the peer-review to refine the acute risk for fish resulting from the use on Brassicaceae.

The experts discussed the three different approaches proposed by the rapporteur Member State to refine the risk to aquatic invertebrates. First approach: using the acute/chronic end points to derive acute/chronic regulatory concentration according to the PPR panel opinion (EFSA, 2005). It was agreed that the range of species used are acceptable. By using the geometric mean, a regulatory concentration of 8.9 µg a.s./L was derived. Second approach: using the acute toxicity end point to derive species sensitive distributions (SSD) and a corresponding  $HC_5$  and, in particular, the lower limit  $HC_5$  (LL $HC_5$ ). The concentration derived from using this approach, 7.15 µg a.s./L, is very close to the concentration using the geometric mean. The experts expressed concern over this approach due to the limited dataset on which it was based and the fact that it is not a standard refinement step. Concerns were raised also over the introduction of a novel approach that had not so far been considered by Member States. Despite this, the experts concluded that it was a useful end point to consider along with the other lines of evidence. Third approach: using the mesocosm study conducted with azoxystrobin. It was agreed that the quality of this study was poor; in particular, because only one application was made, and there was a lack of chemical analysis over time. The experts agreed that each line of evidence was insufficient on its own to be used in the regulatory risk assessment. However, the experts considered that it was possible to use information from all lines to determine a regulatory acceptable concentration (RAC). Based on all of the above information, the experts concluded that after taking all lines of evidence into account, the RAC should be set at **3.3 µg a.s./L**. It should be noted that in selecting this end point the RAC is lower than the NOEAEC of 10 µg a.s./L, the lower limit of the  $HC_5$  of 7.15 µg a.s./L and the geometric mean of 8.9 µg a.s./L, but still higher than the value based on the tier 1 assessment. The risk for aquatic invertebrates based on the use of the RAC was assessed as high when the PEC<sub>sw</sub> FOCUS step 3 was used for some of the relevant scenarios for all the representative uses. The TERs estimated were not so far from the trigger values, indicating that with appropriate mitigation measures the risk for aquatic invertebrates can be addressed. A data gap was identified by EFSA after the peer-review to further refine the risk for aquatic invertebrates.

The risk from azoxystrobin to algae and aquatic plants was considered as low. The risk from the relevant metabolites to aquatic organisms was considered as low.

Hazard quotients (HQ) calculations based on the acute oral and contact toxicity of azoxystrobin indicated a low risk to bees. Laboratory studies on non-target arthropods were provided on the two standard species *Typhlodromus pyri* and *Aphidius rhopalosiphii*. Additional studies were provided with *Chrysoperla carnea*, *Orius laevigatus*, *Coccinella septempunctata*, *Pardosa spp.* and *Poecilus cupreus*, although not required. Based on the assessment of all the studies, the in-field and off-field risk for non-target arthropods was assessed as low.

The risk for earthworms was assessed as low from azoxystrobin and from the relevant metabolites R234886, R401553, R402173. The risk to other soil macro-organism (*Folsomia candida*) was assessed as low. No adverse effects were observed in the field litter bag study provided. Only one of the relevant metabolites in soil is persistent, R234886, however, the  $DT_{50\text{field}}$  of the active substance is 180.7 days, and as the higher tier study last 181 days, it is likely that this metabolite was present, albeit not at the maximum concentration for part of the litter bag study.

The risk for soil micro-organisms from azoxystrobin and its relevant soil metabolites was assessed as low. The risk for non-target plants was assessed as low, and the risk for sewage treatment plants was considered as low.

## 6. Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

### 6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Azoxystrobin	<p>Moderate to high persistence Single first order DT<sub>50</sub> 35.2-248 days (20°C, pF2 soil moisture)</p> <p>Field studies (EU): Single first order DT<sub>50</sub> 121-262 days (n=3, normalized to 20°C and pF2 soil moisture, residues incorporated into the soils after the surface application); Slow phase of double first order in parallel DT<sub>50</sub> 34.5-122 days (n=10, normalized to 20°C and pF2 soil moisture, surface application without incorporation)</p>	The risk from azoxystrobin to earthworms was assessed as low.
R234886	<p>Moderate to high persistence<sup>a</sup> Single first order/double first order in parallel DT<sub>50</sub> 17.8-43.4 days, DT<sub>90</sub> 59 days – too long to reliably estimate (20°C, pF2 soil moisture)</p>	The risk from R234886 to earthworms was assessed as low.
R401553	<p>Very low to low persistence Single first order DT<sub>50</sub> 0.9-1.5 days (20°C, pF2 soil moisture)</p>	The risk from R401553 to earthworms was assessed as low.
R402173	<p>Low persistence Single first order DT<sub>50</sub> 2.4-7.5 days (20°C, pF2 soil moisture)</p>	The risk from R402173 to earthworms was assessed as low.

n: number of data

a: the class of high persistence is based on the assumption that the DT<sub>50</sub> for the soil incubations, where the degradation followed double first order in parallel kinetics, were about 300 days.

## 6.2. Ground water

Ground water assessment could not be finalized for unidentified, minor, soil transformation products (see data gap in section 4).

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
Azoxystrobin	Medium to low mobility K <sub>Foc</sub> 207-594 mL/g	No	Yes	Yes	Azoxystrobin is very toxic to aquatic organisms. The risk for aquatic organisms was assessed as high.
R234886	Very high to medium mobility K <sub>Foc</sub> 21-490 mL/g	Yes (FOCUS); pending on the model (PELMO or PEARL) used: - trigger 0.1µg/L exceeded for 4 or 6 of 7 scenarios for Brassicae, 5 or 7 of 9 scenarios for winter cereals and 3 of 6 scenarios for spring cereals - trigger 0.75 µg/L exceeded for 4 or 5 of 7 scenarios for Brassicae, 4 or 6 of 9 scenarios for winter cereals and 2 or 3 of 6 scenarios for spring cereals - concentration of 10 µg/L exceeded for 2 or 3 of 7 scenarios for Brassicae and 1 of 9 or 6 scenarios for winter and spring cereals (PEARL)	No	No  Rat, oral LD <sub>50</sub> > 5000 mg/kg bw;  Negative in an <i>in vitro</i> bacterial mutation test  Covered by the toxicological assessment of azoxystrobin  Reference values of azoxystrobin apply to this metabolite	R234886 is harmful to aquatic organisms. The risk for aquatic organisms was assessed as low.

R402173	Very high to medium mobility $K_{Foc}$ 25-200 mL/g	No	No	No data, data not needed	R402173 is harmful to aquatic organisms. The risk for aquatic organisms was assessed as low
R401553	High to medium mobility $K_{Foc}$ 66-500 mL/g	No	No	No Covered by the toxicological assessment of azoxystrobin Reference values of azoxystrobin apply to this metabolite	R401553 is harmful to aquatic organisms. The risk for aquatic organisms was assessed as low.

### 6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Azoxystrobin	Azoxystrobin is very toxic to aquatic organisms. The risk for aquatic organisms was assessed as high.
R234886	R234886 is harmful to aquatic organisms. The risk for aquatic organisms was assessed as low.
R402173	R402173 is harmful to aquatic organisms. The risk for aquatic organisms was assessed as low
R401553	R401553 is harmful to aquatic organisms. The risk for aquatic organisms was assessed as low.

**6.4. Air**

Compound (name and/or code)	Toxicology
Azoxystrobin	<p>Rat, LC<sub>50</sub> inhalation 0.7 mg/L air (MMAD &lt;2 µm) ) – T; R23 “toxic by inhalation” (as in Annex I to Directive 67/548/EEC)</p> <p>Rat, LC<sub>50</sub> inhalation &gt; 4.7 mg/L air (MMAD &gt;14 µm)</p>

#### **LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED**

- QC data on the analysis of the technical material are required to support the technical material specification (relevant for all representative uses evaluated; submission date proposed by the notifier: during the written procedure the RMS has advised that data are available but could not be included in the assessment according to Commission Regulation (EC) No 737/2007; see section 1).
- Adequately validated method for monitoring of azoxystrobin residues in body fluids and tissues (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see sections 1 and 2).
- Toxicological relevance of the metabolites L1, L4 and L9 observed in the goat metabolism study but not in rats has to be addressed (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see sections 2 and 3).
- Quantification and, if needed, identification of the unidentified, minor, soil transformation products formed in unspecified quantity (but less than 10 % AR) (relevant for all representative uses evaluated; submission date proposed by the notifier: during the written procedure the RMS has indicated that information is available but could not be included in the assessment according to Commission Regulation (EC) No 737/2007; see section 4).
- Analysis of the batches used in the ecotoxicological tests should be provided (relevant for all representative uses evaluated; data gap identified by EFSA after the peer review; submission data proposed by the notifier: unknown; see section 5).
- The acute risk from azoxystrobin to fish, and the risk assessment for aquatic invertebrates should be further refined (relevant for Brassicae (fish) and for all representative uses (aquatic invertebrates); submission data proposed by the notifier: unknown; see section 5).

#### **PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED**

- Risk mitigation measures should be required to refine the risk to fish arising from the use of azoxystrobin on Brassicae and for the aquatic invertebrates for all representative uses (see section 5).

#### **ISSUES THAT COULD NOT BE FINALISED**

- The technical material specification could not be finalised, as appropriate levels of some impurities could not be agreed on during the peer review (see section 1).
- The residue definition for risk assessment for animal matrices is provisional, pending additional information on the toxicological relevance of metabolites L1, L4 and L9 (see section 3).
- There is a data gap for identification/quantification of the unidentified, minor soil transformation products. Therefore there is no assessment for groundwater contamination of any potentially formed minor soil transformation products that would trigger further evaluation (see section 4).
- The risk assessment for fish and aquatic invertebrates could not be finalised for Brassicae and for all representative uses, respectively, since no PEC<sub>sw</sub> FOCUS step 4 were provided (see section 5).

## CRITICAL AREAS OF CONCERN

- The technical specification as agreed in the Annex I inclusion is not covered by the toxicological assessment. From a toxicological point of view, it should comply with the rapporteur Member State's proposal from May 2009; the proposal made by the notifier for the Annex I renewal procedure, which reduces the levels of a number of impurities compared to the specification agreed for Annex I inclusion, is also not covered by the toxicological assessment with respect to two impurities. None of these new proposals could be agreed on by the section on the identity, physical, chemical and technical properties (see sections 1 and 2).
- The potential for groundwater exposure by the metabolite of azoxystrobin R234886 above the concentration of 10 µg/L is predicted to be high over a wide range of geoclimatic conditions represented by the FOCUS groundwater scenarios. In case of Brassicae, 2 (FOCUS PELMO) or 3 (FOCUS PEARL) out of 7 scenarios; in case of spring cereals, 1 out of 6 scenarios; in case of winter cereals, 1 out of 9 scenarios were identified, where the concentration of 10 µg/L was exceeded by this non-relevant metabolite (in case of cereals all with FOCUS PEARL).

**REFERENCES**

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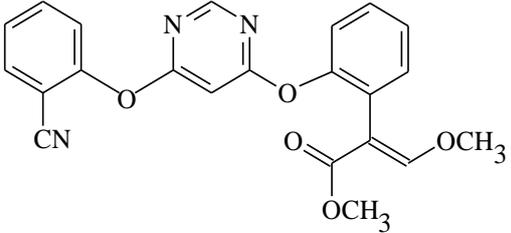
## APPENDICES

### 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)	Azoxystrobin
Function (eg. fungicide)	Fungicide
Rapporteur Member State	UK
Co-rapporteur Member State	Czech Republic

#### Identity (OECD data point IIA 1)

Chemical name (IUPAC)	methyl ( <i>E</i> )-2-{2[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate
Chemical name (CA)	methyl ( <i>E</i> )-2-{2[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy}- $\alpha$ -(methoxymethylene)benzeneacetate
CIPAC No	571
CAS No	131860-33-8
EC No (EINECS or ELINCS)	Not allocated
FAO Specification (including year of publication)	571/TC (August 2009) min. 965 g/kg
Minimum purity of the active substance as manufactured (g/kg)	965 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	Toluene (assessment of maximum level not finalised)
Molecular formula	C <sub>22</sub> H <sub>17</sub> N <sub>3</sub> O <sub>5</sub>
Molecular mass	403.4
Structural formula	

## Physical and chemical properties (Annex II A, point 2)

Melting point (state purity) ‡	116°C (purity: 990 g/kg)
Boiling point (state purity) ‡	Above 360°C
Temperature of decomposition (state purity)	Approximately 345°C at atmospheric pressure
Appearance (state purity) ‡	White crystalline powder, tech. as (962 g/kg) pale brown crystalline powder.
Vapour pressure (state temperature, state purity) ‡	$1.1 \times 10^{-10}$ Pa at 20°C (purity: 990 g/kg)
Henry's law constant ‡	$7.4 \times 10^{-9}$ Pa m <sup>3</sup> mol <sup>-1</sup>
Solubility in water (state temperature, state purity and pH) ‡	pH 5.2: 6.7 mg/L at 20°C (purity: 962 g/kg)
	pH 7.0: 6.7 mg/L at 20°C (purity: 962 g/kg)
	pH 9.2: 5.9 mg/L at 20°C (purity: 962 g/kg)
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20°C in g/L (purity: 962 g/kg)
	Hexane: 0.057
	Octan-1-ol: 1.4
	Methanol: 20
	Toluene: 55
	Acetone: 86
	Ethyl acetate: 130
Acetonitrile: 340	
Dichloromethane: 400	
Surface tension ‡ (state concentration and temperature, state purity)	71.8 mN/m (purity: 962 g/kg) at 20 °C. 90% saturated aqueous solution of technical grade active substance.
Partition co-efficient ‡ (state temperature, pH and purity)	log P <sub>O/W</sub> = 2.5 at 20°C (without pH dependence)
Dissociation constant (state purity) ‡	pK <sub>a1</sub> = <0 (neither acidic nor basic properties)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Pure active substance: 990 g/kg, pH: not considered or necessary as active does not dissociate.
	202.6 nm: 60700 M <sup>-1</sup> ·cm <sup>-1</sup>
	242.7 nm: 17800 M <sup>-1</sup> ·cm <sup>-1</sup>
	295 nm: 302 M <sup>-1</sup> ·cm <sup>-1</sup>
Flammability ‡ (state purity)	Not classified as highly flammable in terms of its burning characteristics and does not self-ignite.
Explosive properties ‡ (state purity)	Not expected to be explosive given an analysis of the bonding groups present.
Oxidising properties ‡ (state purity)	Not an oxidising substance

Summary of representative uses evaluated (*azoxystrobin*)\*

Crop and/or situation (a)	Member State or Country	Product name	F G or 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 as g/L (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min) (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Broccoli	EU	'Amistar' / 'Ortiva'	F	<i>Albugo candida</i> , <i>Alternaria brassicae</i> , <i>Mycosphaerella brassicicola</i> , <i>Peronospora parasitica</i>	SC	250	Foliar spray	BBCH35 - BBCH39	1-2	12	0.042 – 0.125	200-600	0.250	14	[1]
Cauliflower	EU	'Amistar' / 'Ortiva'	F	<i>Albugo candida</i> , <i>Alternaria brassicae</i> , <i>Mycosphaerella brassicicola</i> , <i>Peronospora parasitica</i>	SC	250	Foliar spray	BBCH35 - BBCH39	1-2	12	0.042 – 0.125	200-600	0.250	14	[1]
Brussels sprouts	N EU	'Amistar' / 'Ortiva'	F	<i>Albugo candida</i> , <i>Alternaria brassicae</i> , <i>Mycosphaerella brassicicola</i> , <i>Peronospora parasitica</i>	SC	250	Foliar spray	BBCH35 - BBCH39	1-2	12	0.042 – 0.125	200-600	0.250	14	[1]
Kale	EU	'Amistar' / 'Ortiva'	F	<i>Albugo candida</i> , <i>Alternaria brassicae</i> , <i>Mycosphaerella brassicicola</i> , <i>Peronospora parasitica</i>	SC	250	Foliar spray	BBCH35 - BBCH39	1-2	12	0.042 – 0.125	200-600	0.250	14	[1]

Crop and/ or situation (a)	Member State or Country	Product name	F G or 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 as g/L (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL  min max	water L/ha min max	kg as/ha  min max		

Barley	EU	'Amistar' / 'Ortiva'	F	<i>Pyrenophora teres</i> <i>Puccinia hordei</i> <i>Rhynchosporium secalis</i> <i>Gaeumannomyces graminis</i> var. <i>Tritici</i> Barley spotting	SC	250	Foliar spray	BBCH31 - BBCH59	1-2	14	0.083 – 0.250	100- 300	0.250	35*	*Timing of applications determined primarily by growth stage; 1 <sup>st</sup> no later than BBCH39, 2 <sup>nd</sup> no later than BBCH59. [1]
Wheat	EU	'Amistar' / 'Ortiva'	F	<i>Septoria tritici</i> <i>Septoria nodorum</i> <i>Puccinia striiformis</i> <i>Puccinia recondita</i> <i>Gaeumannomyces graminis</i> var. <i>tritici</i>	SC	250	Foliar spray	BBCH31 - BBCH69	1-2	14	0.083 – 0.250	100- 300	0.250	35**	**Timing of applications determined primarily by growth stage; 1 <sup>st</sup> application no later than BBCH39, 2 <sup>nd</sup> application no later than BBCH69 [1]

[1] There is no agreed technical specification covered by the toxicological risk assessment

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (eg. fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) eg. biting and suckling insects, soil born insects, foliar fungi, weeds

(d) eg. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989

(f) All abbreviations used must be explained

(g) Method, eg. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, eg. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated

(i) g/kg or g/l

(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) PHI - minimum pre-harvest interval

(m) Remarks may include: Extent of use/economic importance/restrictions

## Methods of Analysis

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

Technical as (analytical technique)	GC, CP-Sil 13 CB fused silica capillary column, FID, evaluation by internal standard.
Impurities in technical as (analytical technique)	See <b>Document J</b> HPLC, external standard. Hichrom RPB column with UV detection. GC, split injection on a CP-Sil 13CB capillary column, FID Inorganic impurities, titrimetry (method SB-21/1)
Plant protection product (analytical technique)	GC, CP-Sil 13 CB fused silica capillary column, FID, evaluation by internal standard

### Analytical methods for residues (Annex IIA, point 4.2)

#### Residue definitions for monitoring purposes

Food of plant origin	Azoxystrobin
Food of animal origin	Azoxystrobin
Soil	Azoxystrobin
Water surface	Azoxystrobin
drinking/ground	Azoxystrobin
Air	Azoxystrobin
Body fluids and tissues	Azoxystrobin

#### Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Azoxystrobin and R230310 (Z-isomer) LC-MS/MS LOQs 0.01 mg/kg (cabbage, cereals (grain and straw) for each ILV (LOQ 0.01 mg/kg, cabbage, kale, potato, maize, lettuce, sugar beet) DFG S19 multi-method is applicable to cereals and other dry crops' (grain and straw), 'fruits with high acid content' (grapes) and commodities with high water content (wine) LOQs: 0.02 mg/kg (straw); 0.01 mg/kg (grain, grapes); 10 µg/l (wine) DFG S19 for plant matrices of high water content appropriate for brassica vegetable commodities is not available.
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Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Azoxystrobin and R230310 (Z-isomer) GC-NPD LOQs 0.001 mg/kg (milk), 0.01 mg/kg (liver, muscle, fat, eggs) for each compound
Soil (analytical technique and LOQ)	Azoxystrobin HPLC-MS/MS, HPLC-UV and GC-MSD LOQ 0.02 mg/kg (0.01 mg/kg for R401553, R402173)
Water (analytical technique and LOQ)	Azoxystrobin GC-MSD, LOQ 0.1 µg/L
Air (analytical technique and LOQ)	Azoxystrobin GC-MSD, LOQ 3 µg/m <sup>3</sup>
Body fluids and tissues (analytical technique and LOQ)	Azoxystrobin Open (data gap)

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

	RMS/peer review proposal
Active substance	None

## Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Dose dependent ~75 to 80 % based on biliary (> 70 %) and urinary (2-7 %) excretion. No correction of the AOEL is necessary for oral absorption.
Distribution ‡	Highest values measured in the kidneys followed by liver
Potential for accumulation ‡	No evidence of accumulation
Rate and extent of excretion ‡	Rapidly eliminated with the bile being the main route
Metabolism in animals ‡	Well metabolised (at least 18 metabolites)
Toxicologically relevant compounds (animals and plants) ‡	Azoxystrobin
Toxicologically relevant compounds (environment) ‡	Azoxystrobin

### Acute toxicity (Annex IIA, point 5.2)

Rat LD <sub>50</sub> oral ‡	> 5000 mg/kg bw	-
Rat LD <sub>50</sub> dermal ‡	> 2000 mg/kg bw	-
Rat LC <sub>50</sub> inhalation ‡	0.7 mg/L air (MMAD <sup>8</sup> <2 µm) ) > 4.7 mg/L air (MMAD >14 µm)	R23
Skin irritation ‡	Slight-irritant	-
Eye irritation ‡	Slight irritant	-
Skin sensitisation (guinea pig) ‡	Not a sensitiser (Magnusson and Kligman test)	-

### Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Liver, reduced body weight gain (rats & dogs), common bile duct (male rat)	
Relevant oral NOAEL ‡	21 mg/kg bw/day (90-day rat) 50 mg/kg bw/day (90-day dog) 25 mg/kg bw/day (1-year dog)	
Relevant dermal NOAEL ‡	1000 mg/kg bw/day (21-day dermal, rat, systemic)	
Relevant inhalation NOAEL ‡	No data, not applicable	

<sup>8</sup> Mass Median Aerodynamic Diameter

**Genotoxicity ‡ (Annex IIA, point 5.4)**

Weak clastogenic effects seen <i>in vitro</i> ; Not genotoxic <i>in vivo</i>
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**Long term toxicity and carcinogenicity (Annex IIA, point 5.5)**

Target/critical effect ‡	Liver, common bile duct, reduced body weight gain.
Relevant NOAEL ‡	18 mg/kg bw/day (2-year feeding rat) 37 mg/kg bw/day (2-year mouse)
Carcinogenicity ‡	No carcinogenic potential

**Reproductive toxicity (Annex IIA, point 5.6)**

**Reproduction toxicity**

Reproduction target / critical effect ‡	Minor reductions in pup and parental body weight gain. No effects on reproduction.	
Relevant parental NOAEL ‡	32 mg/kg bw/day	
Relevant reproductive NOAEL ‡	170 mg/kg bw/day	
Relevant offspring NOAEL ‡	32 mg/kg bw/day	

**Developmental toxicity**

Developmental target / critical effect ‡	Reduced ossification (rat); at maternally toxic (reduced body weight gain) dosages. No developmental effect in rabbits Not teratogenic (rat and rabbit)	
Relevant maternal NOAEL ‡	25 mg/kg bw/day (rat) 150 mg/kg bw/day (rabbit)	
Relevant developmental NOAEL ‡	25 mg/kg bw/day (rat) 500 mg/kg bw/day (rabbit)	

**Neurotoxicity (Annex IIA, point 5.7)**

Acute neurotoxicity ‡	No specific neurotoxic effects up to 2000 mg/kg bw NOAEL for general toxicity < 200 mg/kg bw	
Repeated neurotoxicity ‡	No specific neurotoxic effects up to 161 mg/kg bw/day (90-day neurotoxicity study) NOAEL for general toxicity: 39 mg/kg bw/day	
Delayed neurotoxicity ‡	No data – not required	

**Other toxicological studies (Annex IIA, point 5.8)**

Mechanism studies ‡

No data – not required

Studies performed on metabolites or impurities ‡

R234886 – negative in an Ames test; acute oral LD<sub>50</sub> in rats > 5000 mg/kg bw  
Not a relevant groundwater metabolite

z-isomer (R230310) – oral LD<sub>50</sub> in mice > 5000 mg/kg bw, negative in Ames test

**Medical data ‡ (Annex IIA, point 5.9)**

No consistent evidence of adverse effects on production plant workers, users of azoxystrobin based products or members of the public

**Summary (Annex IIA, point 5.10)**

	Value	Study	Safety factor
ADI ‡	0.2 mg/kg bw/day	2-year rat	100
AOEL ‡	0.2 mg/kg bw/day	90-day rat supported by overall short term dog	100
ARfD ‡	Not necessary		

**Dermal absorption ‡ (Annex IIIA, point 7.3)**

Formulation (250g/L SC – Code A12705B)

0.3 % for the concentrate (250 g/L SC formulation) based on *in vivo* rat study, and 0.5 % for the 1:600 spray dilution based on an *in vivo* rat study and *in vitro* data in rat and human skin.

**Exposure scenarios (Annex IIIA, point 7.2)**

Operator

Exposure estimates predict that the proposed uses of ‘Amistar’ (application rate of 0.250 kg azoxystrobin/ha) will result in levels of systemic exposure to azoxystrobin equivalent to:  
Tractor mounted or trailed field crop sprayers  
Without PPE: 0.7 % of the AOEL (German model)  
Without PPE: 7 % of the AOEL (UK POEM)

Workers

Estimates using the EUROPOEM re-entry exposure model predict that levels of systemic exposure to azoxystrobin for unprotected workers will be equivalent to 0.63 % of the AOEL when inspecting treated crops, and 1.25 % of the AOEL during hand-harvesting activities.

Bystanders

Using published surrogate data, bystander exposure to azoxystrobin vapour is estimated to be equivalent to 0.3 % of the AOEL.

Based on a simulated exposure study, bystander exposure to spray drift containing azoxystrobin is estimated to be equivalent to 0.14 % of the AOEL.

Using published drift data and US EPA exposure data, children's exposure to spray drift fallout is estimated to be equivalent to 0.05 % of the AOEL.

**Classification and proposed labelling with regard to toxicological data (Annex II A, point 10)**

Substance classified (azoxystrobin)

RMS/peer review proposal based on Annex I of Directive 67/548/EEC merits further discussion at ECHA based on low probability of generating respirable particles under normal conditions of use.

**T** "Toxic"  
**R23** "Toxic by inhalation"

**Residues**

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

Plant groups covered	Cereals (wheat), Fruit crops (grapes), Oilseeds/Pulses (peanuts)
Rotational crops	Wheat, radish, lettuce
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Azoxystrobin (no significant degradation observed under standard hydrolysis conditions)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
Plant residue definition for monitoring	Azoxystrobin
Plant residue definition for risk assessment	Azoxystrobin
Conversion factor (monitoring to risk assessment)	None

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

Animals covered	Goats, hens
Time needed to reach a plateau concentration in milk and eggs	
Animal residue definition for monitoring	Azoxystrobin
Animal residue definition for risk assessment	Azoxystrobin (provisional)
Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	No

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

Field trials on wheat, millet, radish, turnip, beetroot, mustard greens and leaf lettuce: Residues <0.01 mg/kg (LOQ) in edible part of commodities. In non-edible commodities (animal feed) the highest residues were seen in cereals: up to 0.05 mg/kg in forage, 0.03 mg/kg in hay and 0.04 mg/kg in straw.

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

Azoxystrobin and R230310 stable for up to two years when stored at approximately  $-18^{\circ}\text{C}$  in: grapes, wine, apples, orange oil, orange juice, orange pulp, bananas, peaches, tomatoes (juice and paste), cucumbers, lettuce, carrot root, cereal straw, cereal grain, soybean meal, oilseed rape, pecans and peanut (oil and nut meat).

Azoxystrobin stable for up to ten months when stored at approximately  $-18^{\circ}\text{C}$  in animal tissues, eggs and milk.

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

	<b>Ruminant:</b>	<b>Poultry:</b>	<b>Pig:</b>
	Conditions of requirement of feeding studies		
Expected intakes by livestock $\geq 0.1$ mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	10.24/12.37 mg/kg DM (dairy/beef cattle)	1.36 mg/kg DM	3.84 mg/kg DM
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues $\geq 0.01$ mg/kg in edible tissues	No	No	No
	<b>Feeding studies:</b> (Feeding rate up to 45N in poultry study and up to 24N in the cattle study) Residue levels in matrices : max (mg/kg)		
Muscle	<0.01 (20N dose)	<0.01 mg/kg (45N dose)	Not addressed
Liver	0.01 (2N dose)	<0.01 mg/kg (45N dose)	Not addressed
Kidney	0.01 (6N dose)	<0.01 mg/kg (45N dose)	Not addressed
Fat	0.02 mg/kg (6N dose)	<0.01 mg/kg (45N dose)	Not addressed
Milk	0.004 mg/kg (2N dose)		
Eggs		<0.01 mg/kg (45N dose)	

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/ Southern field or glasshouse,	Trials results relevant to the representative uses  (a)	Recommendation/comments		MRL	HR	STMR
					estimated from trials according to representative uses	(c)	(b)
Cauliflower	N EU	2x <0.01, 0.01, 0.02, 0.03, 0.05, 0.13, 0.14	R <sub>max</sub> = 0.22	R <sub>ber</sub> = 0.22	1.0	0.23	<b>0.03</b>
	S EU	2x <0.01, 0.03, 0.23	R <sub>max</sub> = 0.62	R <sub>ber</sub> = 0.36			
Broccoli	N EU	<0.01, 0.01, 0.04, 0.09	R <sub>max</sub> = 0.23	R <sub>ber</sub> = 0.16	2.0	0.58	<b>0.08</b>
	S EU	2x 0.04, 0.11, 0.58,	R <sub>max</sub> = 1.53	R <sub>ber</sub> = 0.93			
Kale	N EU	0.08, 0.30, 0.31, 0.67, 1.4, 1.6, 1.7, 3.5	R <sub>max</sub> = 4.79	R <sub>ber</sub> = 3.35	5.0	3.5	<b>1.04</b>
	S EU	0.12, 0.15, 0.32, 1.3	R <sub>max</sub> = 3.35	R <sub>ber</sub> = 2.11			
Brussels sprout	N EU	3x 0.02, 0.03, 3 x 0.04, 0.05	R <sub>max</sub> = 0.07	R <sub>ber</sub> = 0.08	0.5	0.16	<b>0.06</b>
	S EU	0.03, 0.05, 0.06, 0.16	R <sub>max</sub> = 0.37	R <sub>ber</sub> = 0.27			
Barley	N EU	<u>Grain</u> : <0.01, 0.01, 0.02, 2x 0.04, 0.08, 0.20, 0.43 <u>Straw</u> : 0.11, 0.39, 0.48, 0.91, 1.3, 1.5, 2.7, 5.1,	R <sub>max</sub> = 0.57	R <sub>ber</sub> = 0.37 (grain)	1.0	0.43 (5.5 straw)	<b>0.10</b>
	S EU	<u>Grain</u> : 0.01, 0.03, 0.04, 0.08, 2 x 0.10, 0.11, 0.13, 0.28 <u>Straw</u> : 0.65, 1.2, 1.3, 2x 2.3, 2.5, 2.9, 4.8, 5.5	R <sub>max</sub> = 0.34	R <sub>ber</sub> = 0.24 (grain)			
Wheat	N EU	<u>Grain</u> : 3 x <0.01, 0.01, 2 x 0.04, 0.07, 0.09, 0.23 <u>Straw</u> : 0.34, 0.58, 0.65, 0.75, 0.82, 1.5, 2x 1.6, 2.0	R <sub>max</sub> = 0.27	R <sub>ber</sub> = 0.16 (grain)	0.3	0.23 (6.2 straw)	<b>0.04</b>
	S EU	<u>Grain</u> : 3 x <0.01, 0.01, 0.02, 0.03, 2 x 0.04, 0.14 <u>Straw</u> : 1.2, 1.6, 1.9, 2.0, 3.2, 2x 3.5, 3.8, 6.2	R <sub>max</sub> = 0.16	R <sub>ber</sub> = 0.08 (grain)			

(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	0.2 mg/kg/day
TMDI (% ADI) according to EFSA PRIMo model rev.2	<2% ADI for all diets included in the PRIMo model. Additional chronic exposure of <i>ca.</i> 5% ADI has to be considered, as the result of the presence of the metabolite R234886 in groundwater (up to 22 µg/L).
NEDI (UK diet) (% ADI)	
NEDI (EU diets) (% ADI)	
Factors included in IEDI and NEDI	None
ARfD	Not required
IESTI (% ARfD)	Not relevant
NESTI (% ARfD) according to national large portion consumption data	Not relevant
Factors included in IESTI and NESTI	Not required

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

Bean processing studies were evaluated to support uses on cauliflower, broccoli, kale (leafy brassicas) and Brussels sprouts.

Crop / processed crop	Number of studies	Transfer factor	% Transference*
Beans with pods → tips	3	1.6	
Beans with pods → trimmed beans	3	0.41	
Beans with pods → blanched beans	3	<0.3	
Beans with pods → canned beans	3	0.42	
Beans with pods → cooked beans	3	<0.29	
Barley grain → cleaned grain	1	0.8	
Barley grain → malt	4	<0.19	
Barley grain → malt sprouts	1	0.4	
Barley grain → spent grain	3	0.61	
Barley grain → flocs	1	0.6	
Barley grain → wort	2	<0.35	
Barley grain → spent yeast	3	0.31	
Barley grain → young beer	2	<0.35	
Barley grain → beer	4	<0.23	
Barley grain → abrasion dust	4	3.25	
Barley grain → pot barley	4	<0.25	
Wheat → cleaned grain	2	0.42	
Wheat → offal/screenings	2	12.4	
Wheat → bran	4	1.67	
Wheat → flour type 550	4	0.45	
Wheat → wholemeal flour	4	0.68	

Crop / processed crop	Number of studies	Transfer factor	% Transference*
Wheat → bread type 550	2	0.57	
Wholemeal bread	4	0.51	
Wheat germ	2	0.30	

\*Calculated on the basis of distribution in the different portions, parts, or products as determined through balance studies

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

**- Plant products**

**Flowering brassica**

Cauliflower

1 mg/kg

Broccoli

2 mg/kg

**Leafy brassica**

Kale

5 mg/kg

**Head brassica**

Brussels sprouts

0.5 mg/kg

**Cereals**

Barley (grain)

1 mg/kg

Wheat (grain)

0.3 mg/kg

**- Animal products**

All animal products (Except poultry products)

0.01\* mg/kg

\*MRL is set at the level of LOQ.

## Environmental fate and behaviour

### Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1)

Mineralization after 100 days ‡	21.4-27.0 % after 120 d, ( <sup>14</sup> C-Cyanophenyl-label) 1.8-19.0 % after 120 d, ( <sup>14</sup> C-Pyrimidinyl-label) 1.9-26.0 % after 120 d, ( <sup>14</sup> C-Phenylacrylate-label)
Non-extractable residues after 100 days ‡	23.5-24.5 % after 120 d, ( <sup>14</sup> C-Cyanophenyl-label) 16.5-22.0 % after 120 d, ( <sup>14</sup> C-Pyrimidinyl-label) 6.2-19.3 % after 120 d, ( <sup>14</sup> C-Phenylacrylate-label)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	(E)-2-(2-[6-cyanophenoxy]-pyrimidin-4-yloxy]-phenyl)-3-methoxyacrylic acid (metabolite I, R234886), 28.8% after 360 days

### Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.2)

Anaerobic degradation ‡	
Mineralization after 100 days	0.3-4.7 % after 120 d, ( <sup>14</sup> C-Cyanophenyl-label) 2.3-2.7 % after 120 d, ( <sup>14</sup> C-Pyrimidinyl-label) 0.0-3.8 % after 120 d, ( <sup>14</sup> C-Phenylacrylate-label)
Non-extractable residues after 100 days	3.4-15.3 % after 120 d, ( <sup>14</sup> C-Cyanophenyl-label) 5.2-9.6 % after 120 d, ( <sup>14</sup> C-Pyrimidinyl-label) 6.2-9.0 % after 120 d, ( <sup>14</sup> C-Phenylacrylate-label)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	(E)-2-(2-[6-cyanophenoxy]-pyrimidin-4-yloxy]-phenyl)-3-methoxyacrylic acid (metabolite I, R234886), 67.7% after 181 days.
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Greater than 5% at 2 consecutive time points;  R401553 (Compound 28) - 5.0 % (day 9.8) – 5.7 % (day 31.3) - <sup>14</sup> C-pyrimidinyl-label.  R402173 (Compound 30) – 5.4% (day 9.8) – 7.6% (day 31.3) - C-pyrimidinyl label.

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

Laboratory studies ‡

Parent	Aerobic conditions						
	X <sup>9</sup>	pH (H <sub>2</sub> O)	t. °C / % MWHC	DT <sub>50</sub> /DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20°C pF2/10kPa	St. (chi <sup>2</sup> )	Method of calculation
18 Acres (sandy clay loam) (Tummon, 1995)		6.4	20 °C / 40 % MWHC	56.4/187	35.2	3.70	SFO
East Anglia (sand)		7.9	20 °C / 40 % MWHC	66.9/222	57.2	5.34	SFO
Wisborough Green (silty clay loam)		5.9	20 °C / 40 % MWHC	94.1/313	54.1	5.60	SFO
18 Acres (sandy clay loam) (Warinton, 1996)		7	75% 1/3 bar moisture 20 °C	87.0/289	65.2	2.06	SFO
Hyde Farm (sandy clay loam)		7	75% 1/3 bar moisture 20 °C	72.8/242	48.5	7.10	SFO
Visalia (sandy loam)		8.4	75% 1/3 bar moisture 20 °C	141.6/470	79.9	2.97	SFO
Derbyshire (clay loam)		7.5	Field capacity 20 °C	118.4/393	118.4	4.84	SFO
Holland (sandy loam)		8.2	Field capacity 20 °C	153.4/510	153.4	1.92	SFO
Lincolnshire (sandy loam)		7.4	Field capacity 20°C	248/824	248	7.5	SFO
Geometric mean				109.4/363.3 <sup>a</sup>	84.5 <sup>a</sup>		

<sup>a</sup> = True geometric mean (geometric mean of 18 Acres soils taken first).

R234886	Aerobic conditions							
Soil type	X <sup>2</sup>	pH	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d)	f. f. k <sub>dp</sub> /k <sub>f</sub>	DT <sub>50</sub> (d) 20°C pF2/10kPa	St. (chi <sup>2</sup> )	Method of calculation
Frensham (sandy loam)		6.6	20°C/40% MWHC	45.2/2136 <sup>(d)</sup>	- <sup>(c)</sup>	30.4	3.9	DFOP
Wisborough Green (silty clay loam)		6.4	20°C/40% MWHC	36.7/2124 <sup>(e)</sup>	- <sup>(c)</sup>	21.2	4.3	DFOP
East Anglia (loamy sand)		7.9	20°C/40% MWHC	56.5/188	- <sup>(c)</sup>	43.4	3.3	SFO
Hyde Farm (sandy clay loam)		7.0	20°C/ 75% 1/3 bar	31.8/105.6	0.9716	21.2	12.3	SFO
18 Acres (sandy clay loam)		7.0	20°C/ 75% 1/3 bar	23.7/78.8	0.7764	17.8	5.9	SFO

X<sup>2</sup> This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Geometric mean		37.1/371.7	0.874	25.4 <sup>(b)</sup>		
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<sup>(b)</sup> = A default slow phase DFOP DT<sub>50</sub> of 1000 days for the Frensham and Wisborough Green soils was used to calculate a geometric mean normalised DT<sub>50</sub> of 110.4 days for use in the groundwater modelling.

<sup>(c)</sup> = R234886 applied as parent therefore no formation fractions

<sup>(d)</sup> = Additional DFOP parameters for the Frensham soil are as follows:  $k_1 = 0.0464462 \text{ d}^{-1}$ ,  $k_2 = 0.0007 \text{ d}^{-1}$ ,  $g = 0.554106$

<sup>(e)</sup> = Additional DFOP parameters for the Wisborough Green soil are as follows:  $k_1 = 0.0570421 \text{ d}^{-1}$ ,  $k_2 = 0.0007 \text{ d}^{-1}$ ,  $g = 0.557696$

R401553		Aerobic conditions						
Soil type	X <sup>2</sup>	pH	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d)	f. f. k <sub>dp</sub> /k <sub>f</sub>	DT <sub>50</sub> (d) 20°C pF2/10kPa	St. (chi <sup>2</sup> )	Method of calculation
Frensham (sandy loam)		6.6	20°C/40% MWHC	1.36 /4.52	<sup>(d)</sup>	0.9	9.1	SFO
Wisborough Green (silty clay loam)		6.4	20°C/40% MWHC	1.59/ 5.29	<sup>(d)</sup>	0.9	10.9	SFO
East Anglia (loamy sand)		7.9	20°C/40% MWHC	2.01/ 6.68	<sup>(d)</sup>	1.5	12.3	SFO
Geometric mean				1.63/ 5.43		1.07		

<sup>(d)</sup> = R401553 applied as parent therefore no formation fractions

R402173		Aerobic conditions						
Soil type	X <sup>2</sup>	pH	t. °C / % MWHC	DT <sub>50</sub> / DT <sub>90</sub> (d)	f. f. k <sub>dp</sub> /k <sub>f</sub>	DT <sub>50</sub> (d) 20°C pF2/10kPa	St. (chi <sup>2</sup> )	Method of calculation
Frensham (sandy loam)		6.6	20°C/40% MWHC	8.44/28.0	<sup>(e)</sup>	5.7	8.6	SFO
Wisborough Green (silty clay loam)		6.4	20°C/40% MWHC	4.24/ 14.1	<sup>(e)</sup>	2.4	12.3	SFO
East Anglia (loamy sand)		7.9	20°C/40% MWHC	9.80/ 32.6	<sup>(e)</sup>	7.5	12.7	SFO
Geometric mean/median				7.05/ 23.43		4.68		

<sup>(e)</sup> = R402173 applied as parent therefore no formation fractions

Field studies ‡

Parent		Aerobic conditions									
Soil type. (USDA)	Location (country or USA state).	X <sup>2</sup>	pH	Depth (cm)	DT <sub>50</sub> (d) actual	DT <sub>90</sub> (d) actual	DT <sub>50</sub> (d) 20°C pF2/10 kPa	St (chi <sup>2</sup> )	DT50 quick phase <sup>b</sup>	DT50 slow phase <sup>b</sup>	Method of calculation
Azoxystrobin applied to bare soil and incorporated.											

Sandy clay loam	Spalding, Lincolnshire	-	7.5 (0-15 cm)	30	261.9	869.9	106.7	10.6	-	-	SFO
Silty clay loam	Nagele, Netherlands	-	7.9 (0-15 cm)	30	186.4	619.3	86.3	10.2	-	-	SFO
Sandy clay loam (0-20cm depth)	Shirebrook, Derbyshire	-	6.7 (0-20 cm)	30	120.9	401.7	56.1	17.2	-	-	SFO
Azoxystrobin applied to soil surface and not incorporated											
Clay loam	Volpedo, Italy		8.2(0-20cm)	30					2.62	80.6	DFOP
Sandy loam	Bienenbutter-Varendorf, Germany		6.4(0-30cm)	30					2.95	61.3	DFOP
Sandy clay loam	Saxa-Anhalt, Germany		6.6(0-30cm)	30					1.64	93.7	DFOP
Clay loam	Isle/ Sorgue, France		8.5(0-20cm)	30					4.65	121.6	DFOP
Sandy loam	Monteux Vaucluse, France		8.5 (0-20cm)	30					4.03	68	DFOP
Silt loam	St Vigor, France		6.1(0-20cm)	30					3.02	34.5	DFOP
Silty clay loam	Massalombarda, France		8.3(0-20cm)	30					1.39	105	DFOP
Clay loam	Grisolles, France		7.7(0-20cm)	30					13.3	66	DFOP
Clay	Cambridgeshire, UK		8.0 (0-20cm)	30					2.09	93.7	DFOP
Clay	Somerset, UK		8.1(0-20cm)	30					0.42	73.7	DFOP
Geometric mean <sup>a</sup>					180.7	600.4	80.2		2.55	75.9	

a = the DT<sub>50</sub> used by the RMS in the slow phase (microbial degradation) groundwater modelling and surface water modelling was the geometric mean of the soil incorporated field studies (80.2 days) and the slow phase of the soil non-incorporated studies (75.9 days) = 78 days.

b = Q10 of 2.58 for the correction of the temperature effect was used in the normalization procedure for the whole, biphasic decline

pH dependence ‡  
(yes / no) (if yes type of dependence)

Soil accumulation and plateau concentration ‡

No

A plateau concentration of 0.646 mg/kg occurred after the seventh year of application. The steady-state concentration (immediately before application) plateaued at 0.246 mg/kg.

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type (USDA)	X <sup>10</sup>	pH	t. °C / % MWHC	DT <sub>50</sub> /DT <sub>90</sub> (d)	DT <sub>50</sub> (d) 20°C pF2/10kPa	St. (chi <sup>2</sup> )	Method of calculation
Sandy clay loam	-	7.0	20 °C / flooded	59.8/198	59.8/162.68	3.41	SFO
Sandy loam	-	7.0	20 °C / flooded	49.0/163	49.0/198.23	6.76	SFO
Geometric mean/median				54.1/180	54.1/180		

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X<sup>3</sup> This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

**Soil adsorption/desorption (Annex IIA, point 7.1.2)**

<b>Parent ‡</b>							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy clay loam	1.7	7.5	12	690	7.9	465	0.84
Loamy sand A	1.7	7.8	6.0	357	4	235	0.82
Loamy sand B	3.0	7.9	9.0	304	6.2	207	0.85
Sand	0.3	5.5	2.1	724	1.5	500	0.84
Silty clay loam	1.6	4.9	12	739	9.5	594	0.90
Clay loam	2.8	5.5	20	718	15	536	0.90
Arithmetic mean/median					7.35/7.05	423/482	0.86/0.86
pH dependence (yes or no)			no				

<b>Metabolite R401553</b>							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy clay loam	1.74	7.5	3.0	172	1.9	110	0.81
Loamy sand	0.29	6.8	1.1	376	0.76	260	0.81
Sandy loam	2.96	8.5	3.6	121	2.4	81	0.84
Silty clay loam	2.15	6.2	17.6	808	11	500	0.89
Silty clay loam	2.38	5.6	2.2	90	1.6	66	0.85
Clay loam	2.61	5.4	3.6	138	2.9	110	0.92
Arithmetic mean/median					3.43/2.15	188/110	0.85/0.85
pH dependence (yes or no)			no				

<b>Metabolite R402173</b>							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy clay loam	1.74	7.5	0.7	40	0.65	37	0.96
Loamy sand	0.29	6.8	0.29	101	0.27	93	0.95
Sandy loam	2.96	8.5	0.80	27	0.74	25	0.96
Silty clay loam	2.15	6.2	5.5	254	4.2	200	0.92
Silty clay loam	2.38	5.6	2.4	100	2.0	86	0.93
Clay loam	2.61	5.4	3.2	124	2.9	110	0.96
Arithmetic mean/median					1.79/1.37	91.8/90	0.95/0.96
pH dependence (yes or no)			yes				

<b>Metabolite R234886</b>							
Soil Type	OC %	Soil pH	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy sand	2.96	7.5	1.0	34	0.82	28	0.90
Clay loam	2.78	4.8	14.2	514	10	360	0.89
Loamy sand	1.68	7.3	0.55	32.4	0.35	21	0.76
Sand	0.29	4.6	2.3	772	1.4	490	0.79
Silty clay loam	1.62	4.2	9.1	564	6.8	420	0.90
Sandy clay loam	1.74	6.8	1.1	65	0.85	49	0.85
Arithmetic mean/median					3.37/1.125	228/205	0.85/0.87
pH dependence (yes or no)			yes				

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

Column leaching ‡	No leaching observed
Aged residues leaching ‡	Ageing for 30 d
Lysimeter/ field leaching studies ‡	Not submitted - not required

**PEC (soil) (Annex IIIA, point 9.1.3)**

Parent	DT <sub>50</sub> (d): 262 days
Method of calculation	Kinetics: SFO Field or Lab: representative worst case from field (incorporated) studies.
Application data	Crop: brassicae Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm <sup>3</sup> % plant interception: 40 % Number of applications: 2 Interval (d): 12 Application rate(s): 250 g as/ha

PEC <sub>(s)</sub> (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.200		0.394	
Short term 24h	0.199	0.200	0.393	0.393

	2d	0.199	0.199	0.392	0.393
	4d	0.198	0.199	0.390	0.392
Long term	7d	0.189	0.195	0.372	0.383
	28d	0.186	0.193	0.366	0.380
	50d	0.175	0.187	0.345	0.369
	100d	0.154	0.176	0.302	0.346
<b>Parent</b>					DT <sub>50</sub> (d): 262 days
Method of calculation					Kinetics: SFO Field or Lab: representative worst case from field (incorporated) studies.
Application data					Crop: cereals Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm <sup>3</sup> % plant interception: 70 % Number of applications: 2 Interval (d): 14 Application rate(s): 250 g as/ha
<b>PEC<sub>(s)</sub></b> (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average	
Initial	0.100		0.196		
Short term	24h	0.100	0.196	0.196	
	2d	0.099	0.100	0.195	0.196
	4d	0.099	0.099	0.194	0.195
Long term	7d	0.095	0.097	0.186	0.191
	28d	0.093	0.096	0.182	0.189
	50d	0.088	0.094	0.172	0.184
	100d	0.077	0.088	0.151	0.173

**Metabolite R401553**

Method of calculation

Molecular weight relative to the parent: 0.529  
 DT<sub>50</sub> (d): not required  
 Kinetics: -  
 Field or Lab: -

Application data

Crop: brassicae  
 Application rate assumed: 250 g as/ha (assumed Met R401553 is formed at a maximum of 17 % (max found in field studies) of the applied dose)

PEC<sub>(s)</sub>  
 (mg/kg)

Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
0.018		0.036	

Initial

Application data

Crop: cereals  
 Application rate assumed: 250 g as/ha (assumed Met R401553 is formed at a maximum of 17 % (max found in field studies) of the applied dose)

PEC<sub>(s)</sub>  
 (mg/kg)

Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
0.009		0.018	

Initial

**Metabolite R402173**

Method of calculation

Molecular weight relative to the parent: 0.826  
 DT<sub>50</sub> (d): not required  
 Kinetics: -  
 Field or Lab: -

Application data

Crop: brassicae  
 Application rate assumed: 250 g as/ha (assumed Met R402173 is formed at a maximum of 17 % (max found in field studies) of the applied dose)

PEC<sub>(s)</sub>  
 (mg/kg)

Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
0.028		0.055	

Initial

Application data

Crop: cereals  
 Application rate assumed: 250 g as/ha (assumed Met R402173 is formed at a maximum of 17 % (max found in field studies) of the applied dose)

<b>PEC<sub>(s)</sub></b> (mg/kg)	Single application	Single application	Multiple application	Multiple application
	Actual	Time weighted average	Actual	Time weighted average
Initial	0.014		0.028	

**Metabolite R234886**

Method of calculation

Molecular weight relative to the parent: 0.965  
 DT<sub>50</sub> (d): not required  
 Kinetics: -  
 Field or Lab: -

Application data

Crop: brassicae  
 Application rate assumed: 250 g as/ha (assumed Met R234886 is formed at a maximum of 28.8 % of the applied dose)

<b>PEC<sub>(s)</sub></b> (mg/kg)	Single application	Single application	Multiple application	Multiple application
	Actual	Time weighted average	Actual	Time weighted average
Initial	0.056		0.110	

Application data

Crop: cereals  
 Application rate assumed: 250 g as/ha (assumed Met R234886 is formed at a maximum of 28.8 % of the applied dose)

<b>PEC<sub>(s)</sub></b> (mg/kg)	Single application	Single application	Multiple application	Multiple application
	Actual	Time weighted average	Actual	Time weighted average
Initial	0.028		0.054	

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

Hydrolytic degradation of the active substance and metabolites &gt; 10 % ‡

Photolytic degradation of active substance and metabolites above 10 % ‡

 Quantum yield of direct phototransformation in water at  $\lambda > 290$  nm

Readily biodegradable ‡ (yes/no)

Hydrolytically stable (pH 5 – 9 at 25°C)
DT <sub>50</sub> = 8.7 d ( <sup>14</sup> C-pyrimidinyl) 11.9 d ( <sup>14</sup> C-phenylacrylate) 13.9 d ( <sup>14</sup> C-cyanophenyl)
R230310 only degradate greater than 10% (Z-isomer of azoxystrobin)
R401553 (8.9%)
R402173 (2.4%)
No data submitted
No data submitted

**Degradation in water / sediment**

Parent	Distribution (max in water 91.2 % AR after 0 d, (Virginia), Max. sed 90.5 % after 0 d (Old Basing))									
Water / sediment system	pH water phase	pH sed	t. °C	DT <sub>50</sub> -DT <sub>90</sub> whole sys.	St. (Chi <sup>2</sup> )	DT <sub>50</sub> -DT <sub>90</sub> water	St. (r <sup>2</sup> )	DT <sub>50</sub> -DT <sub>90</sub> sed	St. (r <sup>2</sup> )	Method of calculation
Old Basing	7.5	7.8	20° C	234/777	2.440	-	-	-	-	SFO
Virginia water	6.4	6.9	20° C	180/598	4.095	-	-	-	-	SFO
Geometric mean/median				205/682		-		-		

Metabolite R234886	Distribution (max in water 10.8 % after 152 d, Max. sed 15.6% after 152 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT <sub>50</sub> -DT <sub>90</sub> whole sys.	St. (r <sup>2</sup> )	DT <sub>50</sub> -DT <sub>90</sub> water	r <sup>2</sup>	DT <sub>50</sub> -DT <sub>90</sub> sed	St. (r <sup>2</sup> )	Method of calculation
Old Basing	7.5	7.8	20° C	- *		-*		-*		
Virginia Water	6.4	6.9	20° C	- *		-*		-*		
Geometric mean/median				-						

\* In the exposure assessment a default worst case DT<sub>50</sub> of 1000 days was used for water, sediment and whole system and therefore no DT<sub>50</sub>s were calculated from the above study.

**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)

Old Basing	7.5	7.8	2.5% after 152 days	5.9% after 152 days	5.9% after 152 days
Virginia Water	6.4	6.9	5.1% after 152 days	6.7% after 152 days	6.7% after 152 days

Parent (applied at 25 g a.s/ha)	Distribution (max in water 10.3 µg/l after 3 hrs. Max. sed 0.039 mg/kg after 21 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT <sub>50</sub> -DT <sub>90</sub> whole sys.	St. (r <sup>2</sup> )	DT <sub>50</sub> -DT <sub>90</sub> water (days)	St. (r <sup>2</sup> )	DT <sub>50</sub> -DT <sub>90</sub> sed	St. (r <sup>2</sup> )	Method of calculation
Outdoor pond	9.06	7.5		Not calculated		13.1/43.6		Not calculated		SFO
Geometric mean/median						13.1/43.6 <sup>#</sup>				

<sup>#</sup> Not used in exposure modelling but provided here for information

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

#### Parent

Parameters used in FOCUS<sub>sw</sub> step 1 and 2

Version control no.1.1 of FOCUS STEP 1 + 2:  
Molecular weight 403.4 (g/mol):  
Water solubility 6.0 (mg/L):  
K<sub>fOC</sub> (L/kg): 427<sup>#</sup>  
DT<sub>50</sub> soil (d): 78 days (the geometric mean of the soil incorporated field studies (80.2 days) and the slow phase of the soil non-incorporated studies (75.9 days)).  
DT<sub>50</sub> water/sediment system (d): 205 (geomean of sediment water studies)  
DT<sub>50</sub> water (d): 1000  
DT<sub>50</sub> sediment (d): 205 (whole system)  
Crop interception (%): 40 (brassica)  
70 (cereals)

Parameters used in FOCUS<sub>sw</sub> step 3 (if performed)

Vapour pressure: 1.1 x 10<sup>-10</sup>  
K<sub>om</sub>/K<sub>oc</sub>: 427  
1/n: 0.86 (Freundlich exponent)

Application rate

Crop: wheat  
Crop interception: 70%  
Number of applications: 2  
Interval (d): 14  
Application rate(s): 250 g as/ha  
Application window: March-May

Crop: brassica  
Crop interception: 40%  
Number of applications: 2  
Interval (d): 12

Application rate(s): 250 g as/ha  
 Application window: March-May

# = Whilst a Kfoc of 427 was accepted for use in the modelling the correct mean Kfoc was 423 L/kg.

FOCUS STEP 1	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	110.8	-	453.5	-
	24 h	108.8	109.8	464.4	459.0
	2 d	108.4	109.2	462.9	461.3
	4 d	107.7	108.6	459.7	461.3
	7 d	106.6	108.0	455.1	459.6
	14 d	104.1	106.6	444.5	454.7
	21 d	101.7	105.4	434.1	449.5
	28 d	99.3	104.2	423.9	444.4
	42 d	94.7	101.8	404.3	434.3

Brassica (2 x 250 g a.s/ha)					
FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	14.6	-	60.6	-
	24 h	14.2	14.4	60.5	60.5
	2 d	14.2	14.3	60.4	60.5
	4 d	14.1	14.2	60.2	60.4
	7 d	14.1	14.2	59.9	60.2
	14 d	13.9	14.1	59.2	59.9
	21 d	13.8	14.0	58.5	59.5
	28 d	13.6	13.9	57.8	59.2
	42 d	13.3	13.8	56.5	58.5
Southern EU	0 h	26.3	-	110.3	-
	24 h	25.9	26.1	110.1	110.2
	2 d	25.8	26.0	109.9	110.1
	4 d	25.8	25.9	109.5	109.9
	7 d	25.6	25.8	109.0	109.6

Brassica (2 x 250 g a.s/ha)					
FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	14 d	25.3	25.6	107.7	109.0
	21 d	25.0	25.5	106.5	108.3
	28 d	24.7	25.3	105.2	107.7
	42 d	24.2	25.0	102.8	106.5

Winter cereals (2 x 250 g a.s/ha)					
FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>sed</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	8.69	-	35.49	-
	24 h	8.33	8.51	35.43	35.46
	2 d	8.32	8.42	35.37	35.43
	4 d	8.29	8.36	35.25	35.37
	7 d	8.25	8.32	35.08	35.28
	14 d	8.15	8.26	34.67	35.08
	21 d	8.06	8.21	34.27	34.87
	28 d	7.97	8.16	33.87	34.67
	42 d	7.78	8.07	33.09	34.27
Southern EU	0 h	14.48	-	60.13	-
	24 h	14.12	14.30	60.03	60.08
	2 d	14.10	14.20	59.93	60.03
	4 d	14.05	14.14	59.73	59.93
	7 d	13.98	14.08	59.43	59.78
	14 d	13.82	13.99	58.74	59.43
	21 d	13.66	13.91	58.06	59.09
	28 d	13.50	13.82	57.38	58.74
	42 d	13.19	13.66	56.06	58.07

The following table summarises the highest FOCUS STEP 3 PEC<sub>sw</sub> and PEC<sub>sed</sub> for each scenario/crop. For all PECs see the further tables below.  
 Keys for water body types: d – ditch, s – stream, p – pond

		Maximum PEC		
Scena	Water	Brassicas	Spring cereals	Winter cereals

rio	body						
		Water (µg/l)	Sediment (µg/kg)	Water (µg/l)	Sediment (µg/kg)	Water (µg/l)	Sediment (µg/kg)
D1	d	-	-	3.432 (2 apps)	25.22 (2 apps)	3.684 (2 apps)	19.27 (2 apps)
D1	s	-	-	2.143 (2 apps)	13.71 (2 apps)	2.3 (2 apps)	11.24 (2 apps)
D2	d	-	-	-	-	4.208 (2 apps)	18.29 (2 apps)
D2	s	-	-	-	-	2.629 (2 apps)	10.16 (2 apps)
D3	d	1.584 (1 app)	0.796 (2 apps)	1.589 (1 app)	1.171 (2 apps)	1.584 (1 app)	0.927 (2 apps)
D4	p	0.447 (1 app)	3.131 (1 app)	0.851 (2 apps)	5.577 (2 apps)	0.764 (2 apps)	5.063 (2 apps)
D4	s	1.185 (2 apps)	1.15 (1 app)	1.367 (1 app)	2.031 (2 apps)	1.37 (1 app)	1.944 (2 apps)
D5	p	-	-	0.108 (2 apps)	1.096 (2 apps)	0.208 (2 apps)	2.07 (2 apps)
D5	s	-	-	1.478 (1 app)	0.401 (2 apps)	1.461 (1 app)	0.569 (2 apps)
D6	d	-	-	-	-	1.593 (1 app)	1.466 (2 apps)
R1	p	0.746 (2 apps)	4.517 (2 apps)	-	-	0.549 (2 app)	3.103 (2 apps)
R1	s	3.512 (2 apps)	2.808 (2 apps)	-	-	3.042 (2 app)	3.32 (2 apps)
R2	s	1.505 (2 apps)	2.006 (2 apps)	-	-	-	-
R3	s	5.806 (2 apps)	3.652 (2 apps)	-	-	2.605 (1 and 2 apps)	1.241 (1 app)
R4	s	7.584 (2 apps)	4.24 (2 apps)	3.437 (1 and 2 apps)	2.884 (1 app)	4.585 (2 apps)	4.215 (2 apps)

Brassica (1 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
D3	d	0 h	1.584		0.757	
		24 h	0.742	1.224	0.624	0.734
		2 d	0.106	0.791	0.496	0.684
		4 d	0.009	0.412	0.367	0.584
		7 d	0.003	0.237	0.284	0.484
		14 d	0.001	0.119	0.206	0.368

<b>Brassica (1 x 250 g a.s/ha)</b>						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
					21d	-
		28 d	-	0.060	0.146	0.272
		42 d	-	0.040	0.118	0.226
D4	p	0 h	0.447		3.131	
		24 h	0.446	0.447	3.131	3.131
		2 d	0.445	0.446	-	3.131
		4 d	0.441	0.446	-	3.131
		7 d	0.434	0.445	-	3.131
		14 d	0.415	0.440	-	3.129
		21 d	0.397	0.435	-	3.126
		28 d	0.384	0.429	-	3.123
		42 d	0.351	0.415	-	3.111
D4	s	0 h	1.183		1.15	
		24 h	0.009	0.491	1.147	1.149
		2 d	0.008	0.441	1.139	1.148
		4 d	0.007	0.414	1.117	1.146
		7 d	0.005	0.374	1.073	1.141
		14 d	0.008	0.312	0.968	1.125
		21 d	0.008	0.294	0.909	1.097
		28 d	0.006	0.267	0.934	1.065
		42 d	0.008	0.204	0.843	1.017
R1	p	0 h	0.483		2.945	
		24 h	0.473	0.478	2.945	2.945
		2 d	0.465	0.474	2.942	2.945
		4 d	0.452	0.466	2.938	2.945
		7 d	0.436	0.457	2.934	2.944
		14 d	0.405	0.439	2.926	2.943
		21 d	0.378	0.423	2.916	2.941
		28 d	0.418	0.421	2.902	2.938
		42 d	0.426	0.419	2.865	2.933
R1	s	0 h	1.824		1.842	

<b>Brassica (1 x 250 g a.s/ha)</b>						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
					24 h	0.039
		2 d	0.004	0.740	1.523	1.690
		4 d	0.001	0.371	1.395	1.585
		7 d	0.001	0.212	1.29	1.493
		14 d	0	0.122	1.168	1.372
		21 d	0	0.083	1.064	1.291
		28 d	0	0.073	1.093	1.253
		42 d	0.002	0.077	1.073	1.195
R2	s	0 h	1.383		0.836	
		24 h	0	0.488	0.73	0.793
		2 d	0	0.259	0.671	0.754
		4 d	0	0.130	0.609	0.701
		7 d	0	0.074	0.562	0.654
		14 d	0.001	0.055	0.500	0.594
		21 d	0.656	0.037	0.460	0.557
		28 d	0	0.033	0.612	0.538
		42 d	0	0.031	0.470	0.534
R3	s	0 h	2.551		1.533	
		24 h	0.700	2.201	1.166	1.449
		2 d	0.017	1.197	0.951	1.305
		4 d	0.005	0.603	0.756	1.105
		7 d	0.002	0.346	0.630	0.939
		14 d	0.001	0.173	0.500	0.755
		21 d	0.000	0.116	0.434	0.661
		28 d	0.003	0.127	0.670	0.655
		42 d	0.001	0.101	0.568	0.654
R4	s	0 h	4.379		2.183	
		24 h	0.044	3.325	1.512	1.950
		2 d	0.007	1.672	1.195	1.709
		4 d	0.002	0.838	0.923	1.481
		7 d	0.001	0.479	0.751	1.298

<b>Brassica (1 x 250 g a.s/ha)</b>						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
		14 d	0.001	0.398	1.039	1.256
		21 d	0.001	0.326	1.089	1.200
		28 d	0.835	0.252	1.236	1.145
42 d	0.094	0.193	0.897	1.099		

<sup>†</sup> simulated period too short for calculation

<b>Brassica (2 x 250 g a.s/ha)</b>						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
D3	d	0 h	1.383		0.796	
		24 h	0.646	1.068	0.679	0.776
		2 d	0.092	0.689	0.562	0.730
		4 d	0.008	0.359	0.443	0.640
		7 d	0.002	0.207	0.364	0.549
		14 d	0.001	0.104	0.282	0.439
		21 d	0.000	0.070	0.239	0.382
		28 d	0.005	0.103	0.211	0.343
		42 d	0.001	0.069	0.175	0.322
D4	p	0 h	0.085		0.788	
		24 h	0.085	0.085	-	0.787
		2 d	0.084	0.085	-	0.785
		4 d	0.084	0.085	-	0.782
		7 d	0.083	0.084	-	0.777
		14 d	0.080	0.084	-	0.763
		21 d	0.076	0.082	-	0.745
		28 d	-	0.081	-	0.722
		42 d	-	0.071	-	0.660

<b>Brassica (2 x 250 g a.s/ha)</b>						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
D4	s	0 h	1.185		0.382	
		24 h	0.002	0.346	0.380	0.382
		2 d	0.001	0.194	0.377	0.381
		4 d	0	0.175	0.368	0.380
		7 d	0	0.151	0.349	0.376
		14 d	0	0.124	0.308	0.364
		21 d	0	0.098	0.275	0.349
		28 d	0	0.079	0.250	0.335
		42 d	0	0.056	-	0.290
R1	p	0 h	0.746		4.517	
		24 h	0.734	0.740	4.517	4.517
		2 d	0.724	0.734	4.516	4.517
		4 d	0.707	0.725	4.515	4.517
		7 d	0.684	0.713	4.512	4.517
		14 d	0.639	0.688	4.515	4.515
		21 d	0.6	0.666	4.509	4.515
		28 d	0.621	0.655	4.497	4.515
		42 d	0.59	0.638	4.427	4.511
R1	s	0 h	3.512		2.808	
		24 h	0.075	2.824	2.234	2.613
		2 d	0.007	1.424	1.948	2.404
		4 d	0.002	0.714	1.685	2.137
		7 d	0.001	0.412	1.502	1.917
		14 d	0.000	0.298	1.285	1.660
		21 d	0.000	0.237	1.155	1.516
		28 d	0.001	0.207	1.188	1.455
		42 d	0.002	0.187	1.622	1.384
R2	s	0 h	1.505		2.006	
		24 h	0.003	1.276	1.715	1.887
		2 d	0.002	0.678	1.566	1.782
		4 d	0.001	0.34	1.415	1.647

<b>Brassica (2 x 250 g a.s/ha)</b>						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
		7 d	0.000	0.194	1.299	1.529
		14 d	0.000	0.103	1.150	1.379
		21 d	0.000	0.069	1.052	1.289
		28 d	0.370	0.081	1.414	1.244
		42 d	0.000	0.067	1.072	1.231
		R3	s	0 h	5.806	
		24 h	1.598	5.009	2.800	3.448
		2 d	0.038	2.725	2.306	3.107
		4 d	0.010	1.373	1.872	2.650
		7 d	0.004	0.787	1.586	2.277
		14 d	0.001	0.427	1.284	1.862
		21 d	0.001	0.286	1.124	1.647
		28 d	0.008	0.289	1.614	1.626
		42 d	0.002	0.229	1.362	1.603
R4	s	0 h	7.584		4.240	
		24 h	0.078	5.759	3.023	3.823
		2 d	0.013	2.896	2.467	3.394
		4 d	0.004	1.452	1.982	2.862
		7 d	0.002	0.853	1.659	2.51
		14 d	0.001	0.678	1.966	2.455
		21 d	0.003	0.621	2.088	2.307
		28 d	0.432	0.472	2.217	2.245
		42 d	0.000	0.391	1.508	2.093

- simulated period too short for calculation

<b>Spring cereals (1 x 250 g a.s/ha)</b>						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
D1	d	0 h	1.819		14.9	
		24 h	1.692	1.747	-	14.89

Spring cereals (1 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
		2 d	1.621	1.700	-	14.88
		4 d	1.530	1.636	-	14.88
		7 d	1.437	1.616	-	14.86
		14 d	1.261	1.567	-	14.77
		21d	1.080	1.520	-	14.70
		28 d	0.903	1.479	-	14.66
		42 d	0.619	1.441	-	14.54
D1	s	0 h	1.403		8.209	
		24 h	0.453	1.089	-	8.193
		2 d	0.033	1.028	-	8.186
		4 d	0.006	1.014	-	8.176
		7 d	0.003	1.005	-	8.159
		14 d	0.002	0.97	-	8.083
		21d	0.001	0.935	-	8.024
		28 d	0.001	0.907	-	7.977
		42 d	0.001	0.890	-	7.854
D3	d	0 h	1.589		0.969	
		24 h	1.114	1.358	0.861	0.954
		2 d	0.420	1.059	0.714	0.914
		4 d	0.040	0.61	0.536	0.813
		7 d	0.008	0.356	0.416	0.690
		14 d	0.002	0.18	0.301	0.532
		21d	0.001	0.12	0.246	0.449
		28 d	0.001	0.091	0.212	0.396
		42 d	0.000	0.061	0.171	0.329
D4	p	0 h	0.271		2.039	
		24 h	0.271	0.271	2.039	2.039
		2 d	0.270	0.271	2.039	2.039
		4 d	0.268	0.271	2.039	2.039
		7 d	0.263	0.270	-	2.039
		14 d	0.252	0.267	-	2.038

Spring cereals (1 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
					21 d	0.241
		28 d	0.236	0.260	-	2.035
		42 d	0.216	0.252	-	2.029
D4	s	0 h	1.367		0.701	
		24 h	0.002	0.375	0.699	0.701
		2 d	0.001	0.277	0.694	0.700
		4 d	0.000	0.257	0.680	0.698
		7 d	0.000	0.227	0.653	0.694
		14 d	0.000	0.182	0.587	0.684
		21 d	0.000	0.173	0.556	0.667
		28 d	0.000	0.157	0.585	0.646
		42 d	0.000	0.120	0.528	0.621
D5	p	0 h	0.065		0.474	
		24 h	0.063	0.064	0.474	0.474
		2 d	0.062	0.063	0.473	0.474
		4 d	0.061	0.062	0.473	0.474
		7 d	0.059	0.061	0.472	0.473
		14 d	0.056	0.059	0.470	0.473
		21 d	0.053	0.057	0.467	0.473
		28 d	0.051	0.056	0.465	0.473
		42 d	0.047	0.054	0.46	0.472
D5	s	0 h	1.478		0.374	
		24 h	0.01	0.568	0.275	0.343
		2 d	0.002	0.286	0.216	0.303
		4 d	0.001	0.144	0.162	0.250
		7 d	0.000	0.082	0.128	0.206
		14 d	0.000	0.041	0.097	0.159
		21 d	0.000	0.028	0.082	0.136
		28 d	0.000	0.021	0.073	0.121
		42 d	0.000	0.014	0.061	0.103
R4	s	0 h	3.437		2.884	

Spring cereals (1 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
		24 h	2.195	2.333	2.262	2.711
		2 d	0.679	2.220	1.908	2.517
		4 d	0.005	1.146	1.564	2.248
		7 d	0.973	0.962	1.707	2.045
		14 d	0.001	0.573	1.218	1.793
		21 d	0.000	0.392	1.024	1.584
		28 d	0.000	0.295	0.902	1.440
		42 d	0.000	0.196	0.745	1.251

Spring cereals (2 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
D1	d	0 h	3.432		25.22	
		24 h	3.355	3.417	-	25.20
		2 d	3.398	3.388	-	25.20
		4 d	3.348	3.384	-	25.19
		7 d	3.246	3.361	-	25.18
		14 d	2.975	3.260	-	25.07
		21 d	2.767	3.151	-	25.00
		28 d	2.960	3.085	-	24.95
		42 d	2.541	2.996	-	24.82
D1	s	0 h	2.143		13.71	
		24 h	2.090	2.135	-	13.69
		2 d	2.114	2.114	-	13.68
		4 d	2.081	2.111	-	13.67
		7 d	2.007	2.095	-	13.65
		14 d	1.819	2.022	-	13.55
		21 d	1.679	1.946	-	13.47
		28 d	1.824	1.9	-	13.41
		42 d	1.465	1.842	-	13.25

Spring cereals (2 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
D3	d	0 h	1.391		1.171	
		24 h	1.088	1.231	1.088	1.161
		2 d	0.652	1.056	0.958	1.134
		4 d	0.110	0.689	0.769	0.934
		7 d	0.016	0.413	0.625	0.759
		14 d	0.004	0.210	0.478	0.759
		21 d	0.002	0.141	0.405	0.659
		28 d	0.001	0.103	0.357	0.593
		42 d	0.000	0.122	0.296	0.506
D4	p	0 h	0.851		5.577	
		24 h	0.850	0.851	5.577	5.577
		2 d	0.847	0.850	-	5.577
		4 d	0.841	0.849	-	5.577
		7 d	0.827	0.847	-	5.576
		14 d	0.790	0.839	-	5.573
		21 d	0.755	0.829	-	5.568
		28 d	0.725	0.816	-	5.562
		42 d	0.660	0.789	-	5.539
D4	s	0 h	1.184		5.577	
		24 h	0.002	0.851	5.577	5.577
		2 d	0.001	0.850	-	5.577
		4 d	0.000	0.849	-	5.577
		7 d	0.000	0.847	-	5.576
		14 d	0.000	0.839	-	5.573
		21 d	0.000	0.829	-	5.568
		28 d	0.000	0.816	-	5.562
		42 d	0.000	0.789	-	5.539
D5	p	0 h	0.108		0.401	
		24 h	0.106	0.107	0.315	1.096
		2 d	0.105	0.106	0.263	1.096
		4 d	0.103	0.105	0.213	1.096

<b>Spring cereals (2 x 250 g a.s/ha)</b>						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
		7 d	0.101	0.104	0.181	1.096
		14 d	0.097	0.102	0.148	1.096
		21 d	0.093	0.099	0.131	1.096
		28 d	0.090	0.097	0.120	1.095
		42 d	0.084	0.094	0.104	1.093
		D5	s	0 h	1.278	
24 h	0.009			0.491	0.315	0.374
2 d	0.002			0.247	0.263	0.339
4 d	0.001			0.124	0.213	0.292
7 d	0.000			0.071	0.181	0.252
14 d	0.000			0.037	0.148	0.208
21 d	0.000			0.031	0.131	0.186
28 d	0.000			0.027	0.120	0.171
42 d	0.000			0.024	0.104	0.164
R4	s	0 h	3.437		2.881	
		24 h	2.195	2.333	2.259	2.707
		2 d	0.679	2.220	1.905	2.513
		4 d	0.005	1.146	1.561	2.245
		7 d	0.973	0.962	1.705	2.041
		14 d	0.001	0.586	1.248	1.813
		21 d	0.000	0.400	1.043	1.606
		28 d	0.000	0.300	0.917	1.459
		42 d	0.000	0.200	0.756	1.268

simulated period too short for calculation

<b>Winter cereals (1 x 250 g a.s/ha)</b>						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
D1	d	0 h	2.037		10.81	

Winter cereals (1 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
		24 h	1.906	1.963	10.80	10.81
		2 d	1.830	1.914	10.80	10.81
		4 d	1.730	1.845	10.77	10.80
		7 d	1.623	1.772	10.70	10.80
		14 d	1.417	1.649	10.44	10.76
		21d	1.209	1.598	10.10	10.71
		28 d	1.009	1.567	9.72	10.67
		42 d	1.689	1.524	8.961	10.63
		D1	s	0 h	1.404	
24 h	0.454			1.09	5.686	5.691
2 d	0.034			1.067	5.671	5.690
4 d	0.007			1.063	5.584	5.685
7 d	0.003			1.057	5.097	5.674
14 d	0.002			1.023	4.822	5.626
21d	0.002			0.987	4.634	5.539
28 d	0.001			0.964	4.011	5.418
42 d	0.001			0.934	3.413	5.328
D2	d	0 h	2.099		9.144	
		24 h	1.265	1.943	9.129	9.138
		2 d	2.009	1.895	9.091	9.131
		4 d	0.882	1.830	9.056	9.105
		7 d	0.872	1.756	8.963	9.075
		14 d	0.698	1.176	8.784	9.016
		21d	1.234	1.020	8.628	8.945
		28 d	0.860	0.962	-	8.906
		42 d	0.863	0.939	-	8.817
D2	s	0 h	1.673		5.363	
		24 h	1.564	1.611	5.341	5.359
		2 d	1.503	1.571	5.337	5.357
		4 d	1.429	1.517	5.308	5.346
		7 d	0.583	1.443	5.261	5.329

Winter cereals (1 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
		14 d	0.280	0.884	5.175	5.295
		21d	0.242	0.674	5.063	5.255
		28 d	0.248	0.595	-	5.225
		42 d	0.224	0.541	-	5.170
D3	d	0 h	1.584		0.789	
		24 h	0.818	1.252	0.661	0.768
		2 d	0.135	0.834	0.527	0.718
		4 d	0.011	0.438	0.39	0.616
		7 d	0.003	0.253	0.302	0.512
		14 d	0.001	0.127	0.219	0.390
		21d	0.001	0.085	0.18	0.328
		28 d	0.000	0.064	0.156	0.289
		42 d	0.000	0.043	0.126	0.240
D4	p	0 h	0.239		1.819	
		24 h	0.239	0.239	-	1.819
		2 d	0.239	0.239	-	1.819
		4 d	0.237	0.239	-	1.819
		7 d	0.233	0.238	-	1.818
		14 d	0.223	0.236	-	1.817
		21 d	0.214	0.233	-	1.815
		28 d	0.210	0.229	-	1.813
		42 d	0.193	0.223	-	1.805
D4	s	0 h	1.370		0.659	
		24 h	0.002	0.4	0.657	0.659
		2 d	0.001	0.244	0.653	0.658
		4 d	0.000	0.222	0.641	0.656
		7 d	0.000	0.187	0.615	0.652
		14 d	0.000	0.169	0.554	0.642
		21 d	0.000	0.163	0.523	0.625
		28 d	0.000	0.147	0.545	0.606
		42 d	0	0.113	0.49	0.582

Winter cereals (1 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
D5	p	0 h	0.104		0.944	
		24 h	0.102	0.103	0.944	0.944
		2 d	0.101	0.102	0.944	0.944
		4 d	0.099	0.101	0.944	0.944
		7 d	0.097	0.100	0.943	0.944
		14 d	0.093	0.097	0.942	0.944
		21 d	0.090	0.095	0.940	0.943
		28 d	0.086	0.094	-	0.943
		42 d	0.081	0.090	-	0.942
D5	s	0 h	1.461		0.343	
		24 h	0.003	0.369	0.271	0.316
		2 d	0.002	0.186	0.23	0.287
		4 d	0.001	0.094	0.191	0.250
		7 d	0.001	0.062	0.165	0.220
		14 d	0.000	0.049	0.138	0.185
		21 d	0.000	0.041	0.124	0.177
		28 d	0.000	0.035	0.114	0.175
		42 d	0.000	0.028	0.1	0.169
D6	d	0 h	1.593		0.702	
		24 h	0.054	0.649	0.591	0.670
		2 d	0.023	0.343	0.515	0.624
		4 d	0.014	0.232	0.436	0.557
		7 d	0.008	0.191	0.377	0.515
		14 d	0.006	0.149	0.310	0.474
		21 d	0.005	0.119	0.274	0.435
		28 d	0.004	0.096	0.249	0.416
		42 d	0.004	0.074	0.217	0.406
R1	p	0 h	0.304		1.743	
		24 h	0.300	0.302	1.743	1.743
		2 d	0.297	0.301	1.743	1.743
		4 d	0.290	0.297	1.742	1.743

Winter cereals (1 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
		7 d	0.282	0.293	1.741	1.743
		14 d	0.263	0.283	1.736	1.742
		21 d	0.247	0.274	1.731	1.741
		28 d	0.235	0.266	1.723	1.740
		42 d	0.215	0.265	1.700	1.736
		R1	s	0 h	2.716	
24 h	0.006			1.445	1.157	1.302
2 d	0.003			0.725	1.036	1.22
4 d	0.008			0.363	1.027	1.109
7 d	0.003			0.325	0.859	1.042
14 d	0.053			0.227	0.714	0.973
21 d	0.000			0.18	0.635	0.939
28 d	0.000			0.141	0.723	0.883
42 d	0.000			0.106	0.578	0.838
R3	s	0 h	2.605		1.241	
		24 h	0.011	1.404	0.983	1.154
		2 d	0.005	0.708	0.834	1.053
		4 d	2.249	0.356	0.689	0.919
		7 d	0.003	0.365	0.583	0.866
		14 d	0.001	0.214	0.465	0.743
		21 d	0.000	0.143	0.402	0.655
		28 d	0.000	0.107	0.359	0.594
		42 d	0.000	0.072	0.300	0.512
R4	s	0 h	3.548		1.654	
		24 h	0.028	2.557	1.151	1.481
		2 d	0.006	1.285	0.903	1.296
		4 d	0.006	0.877	1.043	1.208
		7 d	0.001	0.502	0.75	1.081
		14 d	0.000	0.251	0.547	0.864
		21 d	0.000	0.178	0.460	0.745
		28 d	0.690	0.164	1.094	0.688

Winter cereals (1 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
			42 d	0.000	0.118	0.527

\* simulated period too short for calculation

Winter cereals (2 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
			D1	d	0 h	3.684
24 h	3.606	3.666			19.26	19.27
2 d	3.627	3.636			19.25	19.26
4 d	3.572	3.622			19.2	19.26
7 d	3.459	3.595			19.08	19.25
14 d	3.172	3.480			18.63	19.19
21d	2.945	3.366			18.05	19.16
28 d	3.074	3.282			17.41	19.14
42 d	2.574	3.172			16.08	19.1
D1	s	0 h	2.300		11.24	
		24 h	2.264	2.290	11.23	11.24
		2 d	2.265	2.269	11.2	11.23
		4 d	2.226	2.258	11.05	11.23
		7 d	2.148	2.240	10.18	11.21
		14 d	1.946	2.160	9.375	11.12
		21d	1.753	2.080	9.207	10.96
		28 d	1.901	2.017	7.945	10.75
		42 d	1.145	1.945	6.76	10.35
D2	d	0 h	4.208		18.29	
		24 h	2.527	2.948	18.26	18.28
		2 d	4.036	2.605	18.18	18.26
		4 d	1.776	2.501	18.12	18.21
		7 d	1.759	2.331	17.93	18.15
		14 d	1.413	2.19	17.58	18.04
		21d	2.471	2.035	17.26	17.9

Winter cereals (2 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
					28 d	1.730
		42 d	1.740	1.879	-	17.66
D2	s	0 h	2.629		10.16	
		24 h	1.434	1.725	10.12	10.15
		2 d	2.462	1.655	10.11	10.15
		4 d	1.035	1.609	10.06	10.13
		7 d	1.020	1.55	9.971	10.1
		14 d	0.811	1.236	9.775	10.03
		21 d	1.281	1.133	9.597	9.956
		28 d	1.039	1.112	-	9.895
		42 d	1.003	1.085	-	9.788
D3	d	0 h	1.386		0.927	
		24 h	0.808	1.128	0.813	0.909
		2 d	0.183	0.792	0.685	0.868
		4 d	0.015	0.426	0.543	0.773
		7 d	0.005	0.247	0.444	0.668
		14 d	0.002	0.125	0.341	0.537
		21 d	0.001	0.156	0.288	0.466
		28 d	0.001	0.118	0.254	0.442
		42 d	0.000	0.079	0.209	0.394
D4	p	0 h	0.764		5.063	
		24 h	0.764	0.764	-	5.063
		2 d	0.762	0.764	-	5.062
		4 d	0.756	0.763	-	5.061
		7 d	0.744	0.761	-	5.06
		14 d	0.712	0.754	-	5.055
		21 d	0.681	0.744	-	5.048
		28 d	0.656	0.733	-	5.039
		42 d	0.598	0.710	-	5.014

Winter cereals (2 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
D4	s	0 h	1.185		1.944	
		24 h	0.002	0.829	1.939	1.944
		2 d	0.001	0.768	1.926	1.942
		4 d	0.000	0.714	1.888	1.938
		7 d	0.000	0.627	1.811	1.928
		14 d	0.000	0.576	1.628	1.899
		21 d	0.000	0.541	1.515	1.850
		28 d	0.000	0.484	1.528	1.793
		42 d	0.000	0.369	1.363	1.704
D5	p	0 h	0.208		2.070	
		24 h	0.208	0.208	2.070	2.070
		2 d	0.207	0.208	2.070	2.070
		4 d	0.205	0.208	2.069	2.070
		7 d	0.202	0.207	2.069	2.070
		14 d	0.200	0.204	2.066	2.069
		21 d	0.192	0.203	-	2.069
		28 d	0.183	0.201	-	2.068
		42 d	0.169	0.196	-	2.063
D5	s	0 h	1.278		0.569	
		24 h	0.009	0.492	0.48	0.541
		2 d	0.002	0.248	0.425	0.505
		4 d	0.001	0.167	0.372	0.457
		7 d	0	0.159	0.335	0.453
		14 d	0	0.127	0.293	0.444
		21 d	0	0.106	0.268	0.435
		28 d	0	0.091	0.25	0.43
		42 d	0	0.074	0.222	0.416
D6	d	0 h	1.416		1.466	
		24 h	0.066	1.269	1.376	1.455
		2 d	0.035	1.106	1.238	1.426
		4 d	0.022	0.729	1.038	1.340

Winter cereals (2 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
					7 d	0.013
		14 d	0.010	0.316	0.72	1.026
		21 d	0.042	0.232	0.629	0.917
		28 d	0.016	0.182	0.569	0.842
		42 d	0.008	0.168	0.482	0.814
R1	p	0 h	0.549		3.103	
		24 h	0.539	0.544	3.103	3.103
		2 d	0.531	0.539	3.103	3.103
		4 d	0.518	0.532	3.102	3.103
		7 d	0.500	0.522	3.099	3.103
		14 d	0.466	0.503	3.09	3.102
		21 d	0.436	0.486	3.087	3.100
		28 d	0.422	0.473	3.077	3.098
		42 d	0.408	0.45	3.048	3.094
R1	s	0 h	3.042		3.320	
		24 h	0.052	2.416	2.786	3.137
		2 d	0.006	1.218	2.516	2.935
		4 d	0.002	0.611	2.255	2.681
		7 d	0.001	0.35	2.056	2.466
		14 d	0.000	0.227	1.799	2.201
		21 d	0.000	0.18	1.633	2.042
		28 d	0.001	0.16	1.693	1.986
		42 d	0.002	0.153	1.662	1.857
R3	s	0 h	2.605		1.233	
		24 h	0.011	1.404	0.975	1.146
		2 d	0.005	0.708	0.827	1.045
		4 d	2.249	0.356	0.682	0.911
		7 d	0.003	0.365	0.741	0.857
		14 d	0.001	0.218	0.531	0.794
		21 d	0.000	0.163	0.449	0.713
		28 d	0.000	0.123	0.397	0.649

Winter cereals (2 x 250 g a.s/ha)						
FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
			Actual	TWA	Actual	TWA
				42 d	0.000	0.082
R4	s	0 h	4.585		4.215	
		24 h	3.192	4.498	3.279	4.032
		2 d	0.021	3.069	2.805	3.726
		4 d	0.005	1.54	2.365	3.257
		7 d	0.002	0.881	2.056	2.852
		14 d	0.001	0.454	1.711	2.386
		21 d	0.000	0.303	1.516	2.138
		28 d	1.471	0.294	1.814	1.972
		42 d	0.000	0.236	1.298	1.817

simulated period too short for calculation

### Metabolite R401553

Parameters used in FOCUS<sub>sw</sub> step 1 and 2

Molecular weight: 213.2  
 Water solubility (mg/L): 560  
 Soil or water metabolite: soil + water metabolite  
 K<sub>foc</sub>/ (L/kg): 188  
 DT<sub>50</sub> soil (d): 1.1 days  
 DT<sub>50</sub> water/sediment system (d): 1000  
 DT<sub>50</sub> water (d): 1000  
 DT<sub>50</sub> sediment (d): 1000  
 Crop interception (%):  
 Brassicae: average crop cover (40 %)  
 Cereals: full canopy (70 %)  
 Maximum occurrence observed (% molar basis with respect to the parent)  
 Water/Sediment: 8.9%

Parameters used in FOCUS<sub>sw</sub> step 3 (if performed)

Not performed

Application rate

Crop: Brassica  
 Number of applications: 2  
 Interval (d): 12  
 Application rate(s): 250 g as/ha  
 Depth of water body: 30 cm (STEP 1 and 2)  
 Application window: March to May

Crop: Wheat  
 Number of applications: 2  
 Interval (d): 14  
 Application rate(s): 250 g as/ha  
 Depth of water body: 30 cm (STEP 1 and 2)  
 Application window: March to May

FOCUS STEP 1 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	12.19		22.51	
	24h	12.14	12.16	22.82	22.66
	2d	12.13	12.15	22.80	22.74
	4d	12.11	12.14	22.77	22.76
	7d	12.09	12.12	22.72	22.76
	14d	12.03	12.09	22.61	22.71
	21d	11.97	12.06	22.50	22.66
	28d	11.91	12.03	22.40	22.61
	42d	11.80	11.97	22.18	22.50

Brassica (2 x 250 g a.s/ha)					
FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.220		0.394	
	24 h	0.209	0.215	0.393	0.394
	2 d	0.209	0.212	0.393	0.393
	4 d	0.209	0.211	0.393	0.393
	7 d	0.209	0.210	0.392	0.392
	14 d	0.208	0.209	0.390	0.392

<b>Brassica (2 x 250 g a.s/ha)</b>					
FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	21 d	0.207	0.208	0.388	0.391
	28 d	0.206	0.208	0.386	0.390
	42 d	0.204	0.207	0.382	0.388
Southern EU	0 h	0.278		0.502	
	24 h	0.267	0.273	0.502	0.502
	2 d	0.267	0.270	0.502	0.502
	4 d	0.267	0.268	0.501	0.502
	7 d	0.266	0.268	0.500	0.501
	14 d	0.265	0.267	0.498	0.500
	21 d	0.264	0.266	0.495	0.499
	28 d	0.262	0.265	0.493	0.498
	42 d	0.260	0.264	0.488	0.495

<b>Cereals (2 x 250 g a.s/ha)</b>					
FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.191		0.339	
	24 h	0.180	0.186	0.339	0.339
	2 d	0.180	0.183	0.339	0.339
	4 d	0.180	0.182	0.338	0.339
	7 d	0.180	0.181	0.338	0.338
	14 d	0.179	0.180	0.336	0.338
	21 d	0.178	0.180	0.334	0.337
	28 d	0.177	0.179	0.333	0.336
	42 d	0.175	0.178	0.330	0.334
Southern EU	0 h	0.220		0.394	
	24 h	0.209	0.215	0.393	0.393
	2 d	0.209	0.212	0.393	0.393
	4 d	0.209	0.211	0.392	0.393

Cereals (2 x 250 g a.s/ha)					
FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	7 d	0.208	0.210	0.392	0.393
	14 d	0.207	0.209	0.390	0.392
	21 d	0.206	0.208	0.388	0.391
	28 d	0.205	0.208	0.386	0.390
	42 d	0.203	0.207	0.382	0.388

### Metabolite R402173

Parameters used in FOCUSsw step 1 and 2

<p>Molecular weight: 333.3</p> <p>Water solubility (mg/L): 61</p> <p>Soil or water metabolite: soil + water metabolite</p> <p>K<sub>foc</sub>/ (L/kg): 25 (for water) 200 (for sediment)</p> <p>(As adsorption of R402173 is pH dependent, a worst-case approach was taken using the lowest K<sub>foc</sub> for the surface water PEC calculation and the highest K<sub>foc</sub> for sediment PEC calculation).</p> <p>DT<sub>50</sub> soil (d): 4.7 days</p> <p>DT<sub>50</sub> water/sediment system (d): 1000</p> <p>DT<sub>50</sub> water (d): 1000</p> <p>DT<sub>50</sub> sediment (d): 1000</p> <p>Crop interception (%):</p> <p>Brassicae: average crop cover (40 %)</p> <p>Cereals: full canopy (70 %)</p> <p>Maximum occurrence observed (% molar basis with respect to the parent)</p> <p>Water/Sediment: 2.4%</p>
<p>Parameters used in FOCUSsw step 3 (if performed)</p> <p>Not performed</p>

Application rate

Crop: Brassica  
 Number of applications: 2  
 Interval (d): 12  
 Application rate(s): 250 g as/ha  
 Depth of water body: 30 cm (STEP 1 and 2)  
 Application window: March to May

Crop: Wheat  
 Number of applications: 2  
 Interval (d): 14  
 Application rate(s): 250 g as/ha  
 Depth of water body: 30 cm (STEP 1 and 2)  
 Application window: March to May

FOCUS STEP 1 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	22.75		36.96	
	24h	22.73	22.74	37.08	37.02
	2d	22.71	22.73	37.06	37.00
	4d	22.68	22.71	37.00	37.00
	7d	22.63	22.69	36.93	37.00
	14d	22.52	22.63	36.75	36.92
	21d	22.41	22.58	36.57	36.83
	28d	22.31	22.52	36.39	36.75
	42d	22.09	22.42	36.04	36.57

Brassica (2 x 250 g a.s/ha)					
FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.960		1.564	
	24 h	0.959	0.960	1.563	1.564
	2 d	0.958	0.959	1.562	1.563
	4 d	0.957	0.958	1.560	1.562
	7 d	0.955	0.957	1.557	1.560
	14 d	0.950	0.955	1.549	1.557
	21 d	0.946	0.952	1.542	1.553

<b>Brassica (2 x 250 g a.s/ha)</b>					
FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	28 d	0.941	0.950	1.534	1.549
	42 d	0.932	0.946	1.519	1.542
Southern EU	0 h	1.842		3.002	
	24 h	1.840	1.841	3.000	3.001
	2 d	1.839	1.840	2.998	3.000
	4 d	1.836	1.839	2.994	2.998
	7 d	1.832	1.837	2.988	2.995
	14 d	1.824	1.832	2.973	2.988
	21 d	1.815	1.828	2.959	2.980
	28 d	1.806	1.824	2.945	2.973
	42 d	1.789	1.815	2.916	2.959

<b>Cereals (2 x 250 g a.s/ha)</b>					
FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>sw</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.503		0.818	
	24 h	0.502	0.502	0.818	0.818
	2 d	0.501	0.502	0.817	0.818
	4 d	0.501	0.501	0.816	0.817
	7 d	0.500	0.501	0.815	0.816
	14 d	0.497	0.500	0.811	0.815
	21 d	0.495	0.498	0.807	0.813
	28 d	0.492	0.497	0.803	0.811
	42 d	0.488	0.495	0.795	0.807
Southern EU	0 h	0.927		1.511	
	24 h	0.926	0.927	1.510	1.510
	2 d	0.925	0.926	1.509	1.510
	4 d	0.924	0.925	1.507	1.509
	7 d	0.922	0.924	1.503	1.507
	14 d	0.918	0.922	1.496	1.503

Cereals (2 x 250 g a.s/ha)					
FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	21 d	0.913	0.920	1.489	1.500
	28 d	0.909	0.918	1.482	1.496
	42 d	0.900	0.913	1.467	1.489

**Metabolite R234886**

Parameters used in FOCUSsw step 1 and 2

<p>Molecular weight: 389.4  Water solubility (mg/L): 57  Soil or water metabolite: soil + water metabolite  Kfoc/ (L/kg): 21 (for water)  490 (for sediment)  (As adsorption of R234886 is pH dependent, a worst-case approach was taken using the lowest Kfoc for the surface water PEC calculation and the highest Kfoc for sediment PEC calculation).   DT<sub>50</sub> soil (d): 112.1 days (note the correct DT<sub>50</sub> soil to be used for conservative 1<sup>st</sup> tier modelling is 110.4 d)  DT50 water/sediment system (d): 1000  DT<sub>50</sub> water (d): 1000  DT<sub>50</sub> sediment (d): 1000  Crop interception (%):  Brassicae: average crop cover (40 %)  Cereals: full canopy (70 %)  Maximum occurrence observed (% molar basis with respect to the parent)  Water/Sediment: 17.7%<sup>a</sup> (whole system)</p>
<p>Not performed</p>

Parameters used in FOCUSsw step 3 (if performed)

Application rate

Crop: Brassica  
 Number of applications: 2  
 Interval (d): 12  
 Application rate(s): 250 g as/ha  
 Depth of water body: 30 cm (STEP 1 and 2)  
 Application window: March to May

Crop: Wheat  
 Number of applications: 2  
 Interval (d): 14  
 Application rate(s): 250 g as/ha  
 Depth of water body: 30 cm (STEP 1 and 2)  
 Application window: March to May

<sup>a</sup>: note that the correct maximum occurrence level of this metabolite was agreed to be 18.1% AR (derived by calculating the individual mean for each of 3 label positions from data from 3 TLC solvent systems prior to calculating an overall mean)

FOCUS STEP 1 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	45.86		137.3	
	24h	45.80	45.83	139.6	138.4
	2d	45.77	45.81	139.5	139.0
	4d	45.71	45.78	139.3	139.2
	7d	45.61	45.73	139.0	139.1
	14d	45.39	45.62	138.3	138.9
	21d	45.17	45.50	137.6	138.6
	28d	44.96	45.39	137.0	138.3
	42d	44.52	45.18	135.6	137.6

Brassicas (2 x 250 g a.s)					
FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	5.765		17.53	
	24 h	5.755	5.760	17.52	17.53
	2 d	5.751	5.756	17.51	17.52
	4 d	5.743	5.751	17.49	17.51
	7 d	5.731	5.745	17.45	17.49
	14 d	5.703	5.731	17.36	17.45

Brassicas (2 x 250 g a.s)					
FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	21 d	5.675	5.717	17.28	17.41
	28 d	5.648	5.703	17.20	17.36
	42 d	5.593	5.676	17.03	17.28
	0 h	10.85		33.02	
Southern EU	24 h	10.84	10.8	33.00	33.01
	2 d	10.83	10.84	32.98	33.00
	4 d	10.82	10.83	32.93	32.98
	7 d	10.79	10.82	32.86	32.94
	14 d	10.74	10.79	32.70	32.86
	21 d	10.69	10.77	32.55	32.78
	28 d	10.64	10.74	32.39	32.70
	42 d	10.54	10.69	32.08	32.55

Cereals (2 x 250 g a.s/ha)					
FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	3.205		9.740	
	24 h	3.197	3.201	9.733	9.737
	2 d	3.195	3.198	9.726	9.733
	4 d	3.190	3.195	9.713	9.726
	7 d	3.184	3.192	9.693	9.716
	14 d	3.168	3.184	9.646	9.693
	21 d	3.153	3.176	9.599	9.669
	28 d	3.138	3.168	9.553	9.646
	42 d	3.107	3.153	9.460	9.600
Southern EU	0 h	5.734		17.44	
	24 h	5.724	5.729	17.43	17.43
	2 d	5.720	5.726	17.42	17.43
	4 d	5.712	5.721	17.39	17.42
	7 d	5.700	5.715	17.35	17.40
	14 d	5.673	5.701	17.27	17.36

Cereals (2 x 250 g a.s/ha)					
FOCUS STEP 2 Scenario	Day after overall maximum	PEC <sub>SW</sub> (µg/L)		PEC <sub>SED</sub> (µg/kg)	
		Actual	TWA	Actual	TWA
	21 d	5.645	5.687	17.19	17.31
	28 d	5.618	5.673	17.10	17.27
	42 d	5.564	5.646	16.94	17.19

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

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter )

For FOCUS gw modelling, values used –  
 Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance.  
 Model(s) used: FOCUS-PELMO 3.3.2, FOCUS-PEARL 3.3.3  
 Scenarios (list of names): Châteaudun, Hamburg, Jokionen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla, Thiva  
 Crop: brassicae, winter cereals, spring cereals  
 Geometric mean parent DT<sub>50field</sub> 78 d (the geometric mean of the soil incorporated field studies (80.2 days) and the slow phase of the soil non-incorporated studies (75.9 days)).  
 (microbial), DT<sub>50field</sub> 3 d (photolysis) (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58).  
 K<sub>foc</sub>: parent, arithmetic mean 427<sup>#</sup>, 1/n= 0.86.

Metabolites:

**R401553**  
 Geometric mean DT<sub>50lab</sub> 1.1 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58).  
 Formation fraction from parent = 0.392  
 Formation fraction from R402173 = 0.468  
 K<sub>foc</sub>: arithmetic mean 188, 1/n= 0.85.

**R402173**  
 Geometric mean DT<sub>50lab</sub> 4.7 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58).  
 Formation fraction from parent = 0.385  
 K<sub>foc</sub>: worst case 25, 1/n= 0.96.

**R234886**  
 Geometric mean DT<sub>50lab</sub> 112.1 d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58) (note the correct DT<sub>50</sub> soil to be used for conservative 1<sup>st</sup> tier

Application rate

<p>modelling is 110.4 d)</p> <p>Formation fraction from parent = 0.874.</p> <p><math>K_{foc}</math>: worst case 21, <math>1/n = 0.76</math></p> <p><math>K_{foc}</math>: scenario specific <math>K_{foc}</math>, <math>1/n = 0.85</math>.</p> <p><u>Scenario specific <math>K_{foc}</math> for R234886.</u></p> <p>Châteaudun = 24</p> <p>Hamburg = 133</p> <p>Jokioinen = 159</p> <p>Kremsmünster = 38</p> <p>Okehampton = 242</p> <p>Piacenza = 68</p> <p>Porto = 624</p> <p>Sevilla = 50</p> <p>Thiva = 38</p>
<p>Application rate: 250 g/ha.</p> <p>No. of applications: 2</p> <p>Time of application (month or season): March – September</p>

# = Whilst a  $K_{foc}$  of 427 was accepted for use in the modelling the correct mean  $K_{foc}$  was 423 L/kg.

**PEC(gw) - FOCUS modelling results (80<sup>th</sup> percentile annual average concentration at 1m)**

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			R401553	R402173	R234886
PELMO /brassicae	Châteaudun	<0.001	<0.001	<0.001	16.9400
	Hamburg	<0.001	<0.001	<0.001	1.4070
	Jokioinen	<0.001	<0.001	<0.001	0.0010
	Kremsmünster	<0.001	<0.001	<0.001	12.3380
	Porto	<0.001	<0.001	<0.001	0.0000
	Sevilla	<0.001	<0.001	<0.001	0.0000
	Thiva	<0.001	<0.001	<0.001	5.0320
	PELMO /winter cereals	Châteaudun	<0.001	<0.001	<0.001
Hamburg		<0.001	<0.001	<0.001	0.6570
Jokioinen		<0.001	<0.001	<0.001	0.0050
Kremsmünster		<0.001	<0.001	<0.001	6.3880
Okehampton		<0.001	<0.001	<0.001	0.0290
Piacenza		<0.001	<0.001	<0.001	4.3320
Porto		<0.001	<0.001	<0.001	0.0000
Sevilla		<0.001	<0.001	<0.001	0.0420
PELMO /spring cereals	Châteaudun	<0.001	<0.001	<0.001	7.5350
	Hamburg	<0.001	<0.001	<0.001	0.4900
	Jokioinen	<0.001	<0.001	<0.001	0.0000
	Kremsmünster	<0.001	<0.001	<0.001	5.8520

	Okehampton	<0.001	<0.001	<0.001	0.0050
	Porto	<0.001	<0.001	<0.001	0.0000

	Scenario	Parent (µg/L)	Metabolite (µg/L)		
			R401553	R402173	R234886
PEARL/brassicae	Châteaudun	<0.001	<0.001	0.0002	21.9240
	Hamburg	<0.001	<0.001	0.0005	2.8653
	Jokioinen	<0.001	<0.001	0.0011	0.3354
	Kremsmünster	<0.001	<0.001	0.0002	14.9838
	Porto	<0.001	<0.001	<0.001	0.0000
	Sevilla	<0.001	<0.001	0.0001	6.1281
	Thiva	<0.001	<0.001	0.0036	12.5173
	PEARL/winter cereals	Châteaudun	<0.001	<0.001	<0.001
Hamburg		<0.001	<0.001	0.0004	1.1657
Jokioinen		<0.001	<0.001	0.0001	0.0851
Kremsmünster		<0.001	<0.001	0.0003	6.8948
Okehampton		<0.001	<0.001	0.0008	0.1173
Piacenza		<0.001	<0.001	0.0001	4.2226
Porto		<0.001	<0.001	<0.001	0.0000
Sevilla		<0.001	<0.001	<0.001	1.6584
Thiva		<0.001	<0.001	<0.001	6.9287
PEARL/spring cereals	Châteaudun	<0.001	<0.001	<0.001	10.6130
	Hamburg	<0.001	<0.001	0.0004	1.2242
	Jokioinen	<0.001	<0.001	0.0002	0.0811
	Kremsmünster	<0.001	<0.001	0.0002	6.9973
	Okehampton	<0.001	<0.001	0.0004	0.0997
	Porto	<0.001	<0.001	<0.001	0.0000

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

Direct photolysis in air ‡	Not studied - no data requested
Quantum yield of direct phototransformation	Not studied - no data requested
Photochemical oxidative degradation in air ‡	DT <sub>50</sub> of 2.7 hours derived by the Atkinson model (AOPWIN version 1.8). OH (12h) concentration assumed = 1.5 x 10 <sup>6</sup> cm <sup>-3</sup>
Volatilisation ‡	No significant tendency for volatilisation was observed from soil and bean leaf surfaces up to 24 hours after the application of radiolabelled azoxystrobin (dose rates: 264 or 291 g as/ha).
Metabolites	None

### PEC (air)

Method of calculation	Expert judgement, based on vapour pressure, dimensionless Henry's Law Constant and information on volatilisation from plants and soil.
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**PEC<sub>(a)</sub>**

Maximum concentration

Assumed to be negligible

**Residues requiring further assessment**

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).

Soil: Azoxystrobin, R234886, R402173, R401553

Surface water: Azoxystrobin, R234886, R402173, R401553

Sediment: Azoxystrobin, R234886, R402173, R401553

Ground water: Azoxystrobin, R234886, R402173, R401553

Air: Azoxystrobin

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

Soil (indicate location and type of study)

No data submitted

Surface water (indicate location and type of study)

No data submitted

Ground water (indicate location and type of study)

No data submitted

Air (indicate location and type of study)

No data submitted

**Points pertinent to the classification and proposed labelling with regard to fate and behaviour data**

Candidate for R53

## Ecotoxicology

### 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/day)	End point (mg/kg feed)
<b>Birds ‡</b>				
<i>Bobwhite quail</i>	a.s.	Acute	>2000	
<i>Bobwhite quail</i>	a.s.	Short-term	>5200	>1179
<i>Bobwhite quail</i>	a.s.	Long-term	1200	117
<b>Mammals ‡</b>				
Rat	a.s.	Acute	>5000	n.r.
Rat	a.s.	Long-term	32	300

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

Brassicacae at 2 x 250 g a.s./ha

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
<b>Tier 1 (Birds)</b>				
Medium herbivorous bird	Acute	21.5	>93	10
Small insectivorous bird	Acute	13.5	>148	10
Medium herbivorous bird	Short-term	11.4	>103	10
Small insectivorous bird	Short-term	7.5	>157	10
Medium herbivorous bird	Long-term	6.0	20	5
Small insectivorous bird	Long-term	7.5	16	5
<b>Tier 1 (Mammals)</b>				
Medium herbivorous mammal	Acute	7.92	>631	10
Medium herbivorous mammal	Long-term	2.23	14	5

Late cereals at 2 x 250 g a.s./ha

Indicator species/Category1	Time scale	ETE	TER	Annex VI Trigger
<b>Tier 1 (Birds)</b>				
Small insectivorous bird	Acute	13.5	>148	10
Small insectivorous bird	Short-term	7.5	>157	10
Small insectivorous bird	Long-term	7.5	16	5
<b>Tier 1 (Mammals)</b>				
Insectivorous mammal	Acute	2.21	>2262	10

Indicator species/Category1	Time scale	ETE	TER	Annex VI Trigger
Insectivorous mammal	Long-term	0.80	40	5

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
<b>Laboratory tests</b>				
Fish				
<i>Oncorhynchus mykiss</i>	250 SC	96 hr (flow-through)	Mortality, EC <sub>50</sub>	0.28 (n)
<i>Oncorhynchus mykiss</i>	a.s.	96 hr (flow-through)	Mortality, EC <sub>50</sub>	0.47 <sup>a</sup> (m)
<i>Lepomis macrochirus</i>	a.s.	96 hr (flow-through)	Mortality, EC <sub>50</sub>	1.1 <sup>b</sup> (m)
<i>Pimephales promelas</i>	a.s.	33 day (flow-through)	Growth NOEC	0.147 <sup>b</sup> (m)
<i>Oncorhynchus mykiss</i>	R234886	96 hr (flow-through)	Mortality, EC <sub>50</sub>	>150 <sup>b</sup> (m)
<i>Oncorhynchus mykiss</i>	R401553	96 hr (static)	Mortality, EC <sub>50</sub>	>120 <sup>c</sup> (n)
<i>Oncorhynchus mykiss</i>	R402173	96 hr (static)	Mortality, EC <sub>50</sub>	62 <sup>c</sup> (n)
Aquatic invertebrate				
<i>Daphnia magna</i>	250 SC	48 h (static)	Mortality, EC <sub>50</sub>	0.11 <sup>a</sup> (n)
<i>Daphnia magna</i>	a.s.	48 h (static)	Mortality, EC <sub>50</sub>	0.23 <sup>b</sup> (m)
<i>Macrocyclops fuscus</i>	a.s.	48 h (static)	Mortality, EC <sub>50</sub>	0.13 <sup>a</sup> (n)
<i>Daphnia magna</i>	a.s.	21 d (static)	Reproduction, NOEC	0.044 <sup>b</sup> (m)
<i>Mysidopsis bahia</i>	a.s.	96 h (static)	Mortality	0.055 <sup>c</sup> (n)

<i>Mysidopsis bahia</i>	a.s.	48 h (static)	Mortality	0.068 <sup>c</sup> (n)
<i>Mysidopsis bahia</i>	a.s.	28-day	Reproduction (endpoint is based on adult mortality)	0.00954 <sup>c</sup> (mm)
<i>Crassostrea gigas</i>	a.s.	48 hr (static)	Mortality, EC <sub>50</sub>	1.3 <sup>c</sup> (n)
<i>Daphnia magna</i>	R234886	48 h (static)	Mortality, EC <sub>50</sub>	>180 <sup>b</sup> (n)
<i>Daphnia magna</i>	R401553	48 h (static)	Mortality, EC <sub>50</sub>	>120 <sup>c</sup> (n)
<i>Daphnia magna</i>	R402173	48 h (static)	Mortality, EC <sub>50</sub>	>100 <sup>c</sup> (n)
Sediment dwelling organisms				
<i>Chironomus riparius</i>	a.s.	28 d (static)	NOEC	0.8 <sup>a</sup>
Algae				
<i>Selenastrum capricornutum</i>	250 SC	72 h (static)	EC <sub>50</sub>	0.16 <sup>a</sup> (n)
<i>Selenastrum capricornutum</i>	a.s.	72 h (static)	EC <sub>50</sub>	0.36 <sup>a</sup> (m)
<i>Skeletonema costatum</i>	a.s.	72 h (static)	Biomass: E <sub>b</sub> C <sub>50</sub> Growth rate: E <sub>r</sub> C <sub>50</sub>	0.098 <sup>c</sup> 0.3 <sup>c</sup> (n)
<i>Navicula pelliculosa</i>	a.s.	120 h (static)	Biomass: E <sub>b</sub> C <sub>50</sub> Growth rate: E <sub>r</sub> C <sub>50</sub>	0.014 <sup>c</sup> 0.146 <sup>c</sup> (n)
<i>Anabaena flos-aquae</i>	a.s.	120 h (static)	Biomass: E <sub>b</sub> C <sub>50</sub> Growth rate: E <sub>r</sub> C <sub>50</sub>	9.5 <sup>c</sup> 13.9 <sup>c</sup> (m)
<i>Selenastrum capricornutum</i>	R234886	72 h (static)	EC <sub>50</sub>	47.0 <sup>b</sup> (m)
<i>Selenastrum capricornutum</i>	R402173	72 h (static)	Biomass: E <sub>b</sub> C <sub>50</sub> Growth rate: E <sub>r</sub> C <sub>50</sub>	67 <sup>c</sup> 67 <sup>c</sup> (n)
<i>Selenastrum capricornutum</i>	R401553	72 h (static)	Biomass: E <sub>b</sub> C <sub>50</sub> Growth rate: E <sub>r</sub> C <sub>50</sub>	>120 <sup>c</sup> >120 <sup>c</sup> (n)

Higher plant				
<i>Lemna gibba</i>	a.s.	14 d (static)	Dry weight, EC <sub>50</sub> Fronds, EC <sub>50</sub>	>6.4 <sup>c</sup> 3.2 <sup>c</sup> (n)
Mesocosm				

The mesocosm study is considered to be a well-conducted mesocosm with an appropriate diversity and abundance of species. It should be noted that azoxystrobin was only applied once, and concentrations were only measured 21 hours after application and not throughout the course of the study. Species/groups were present in sufficient numbers to allow appropriate statistical analysis.

The Notifier proposed that the no observed ecologically adverse effects concentration (NOEAEC) is 10 µg/L. No uncertainty or assessment factor was proposed.

From the summary above it can be concluded that there were effects at all concentrations, hence it is not possible to establish a NOEC. The treatment related effects at 10 µg/L were considered to be relatively short-lived and restricted to decreases in the following parameters:

*Daphnia* spp – effects at 10 µg/L were noted at 3, 7 and 14 days  
 Total cladocera – effects at 10 µg/L were noted at 3, 7 and 14 days  
*Copepoda nauplii* – effects at day 35  
*Copepoda Cyclopoid copepodites* – effects at 10 µg/L were noted at days 7 and 10,  
*Copepoda Cyclopoid* adults – effects were noted on day 3 only  
*Sphaeriidae* – significantly fewer on days 72 and 93 for samples collected via nets, there were significantly fewer on days 22, 30 44 and 72.  
 Total mollusc – in samples collected via nets were lower on days 22 and 72  
 Total macroinvertebrates – in sample collected via nets were lower on day 30.

The following groups increased and were probably the result of indirect effects:

*Chydorus* – significantly greater numbers on study day 10 and 28  
*Pompholyx* sp – significantly greater numbers than the control on day 14 only  
*Testudinella* sp – there were significantly greater numbers than the control on days 42 and 35.  
 Total rotifer – there were significantly greater numbers than the control on days 3, 35, 42 and 56.

It should however be noted that there was only one application and there was only chemical analysis 21 hours after application; due to this it is proposed that the effect concentrations should be based on the initial nominal concentrations.

<sup>a</sup> Agreed endpoint

<sup>b</sup> Taken from original DAR

<sup>c</sup> Submitted with this application

n = nominal

m = measured

mm = mean measured

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

**FOCUS Step1**

Cereals and brassica at 2 x 250 g a.s./ha

Test substance	Organism	Toxicity endpoint (mg a.s./L)	Time scale	PEC <sub>i</sub> (mg a.s./L)	PEC <sub>tw</sub>	TER	Annex VI Trigger
a.s.	Fish ( <i>Oncorhynchus mykiss</i> )	0.47	Acute	0.1108	n.r.	<u>4.2</u>	100
'250 SC'	Fish ( <i>Oncorhynchus mykiss</i> )	0.28	Acute	0.1108	n.r.	<u>2.5</u>	100
a.s.	Fish ( <i>Pimephales promelas</i> )	0.147	Chronic	0.1108	n.r.	<u>1.3</u>	10
a.s.	Aquatic invertebrates ( <i>Daphnia magna</i> )	0.23	Acute	0.1108	n.r.	<u>2.1</u>	100
'250 SC'	Aquatic invertebrates ( <i>Daphnia magna</i> )	0.11	Acute	0.1108	n.r.	<u>1.0</u>	100
a.s.	Sediment-dwelling organisms ( <i>Chironomus riparius</i> )	0.8	Chronic	0.1108	n.r.	<u>7.2</u>	10
a.s.	Aquatic invertebrates ( <i>Macrocylops fuscus</i> )	0.13	Acute	0.1108	n.r.	<u>1.2</u>	100
a.s.	Aquatic invertebrates ( <i>Mysidopsis bahia</i> )	0.055	Acute	0.1108	n.r.	<u>0.5</u>	100
a.s.	Aquatic invertebrates ( <i>Daphnia magna</i> )	0.044	Chronic	0.1108	n.r.	<u>0.4</u>	10
a.s.	Aquatic invertebrates ( <i>Mysidopsis bahia</i> )	0.00954	Chronic	0.1108	n.r.	<u>0.09</u>	10
a.s.	Algae ( <i>Selenastrum capricornutum</i> )	0.014	Chronic	0.1108	n.r.	<u>0.1</u>	10

Test substance	Organism	Toxicity endpoint (mg a.s./L)	Time scale	PEC <sub>i</sub> (mg a.s./L)	PEC <sub>twa</sub>	TER	Annex VI Trigger
'250 SC'	Algae ( <i>Selenastrum capricornutum</i> )	0.16	Chronic	0.1108	n.r.	<u>1.4</u>	10
a.s.	Higher plants ( <i>Lemna gibba</i> )	3.2	Chronic	0.1108	n.r.	28	10
Metabolite R234886	Fish ( <i>Oncorhynchus mykiss</i> )	>150	Acute	0.046	n.r.	>3261	100
Metabolite R234886	Aquatic invertebrates ( <i>Daphnia magna</i> )	>180	Acute	0.046	n.r.	>3913	100
Metabolite R234886	Algae ( <i>Selenastrum capricornutum</i> )	47.0	Chronic	0.046	n.r.	1022	10
Metabolite R401553	Fish ( <i>Oncorhynchus mykiss</i> )	>120	Acute	0.012	n.r.	>10000	100
Metabolite R401553	Aquatic invertebrates ( <i>Daphnia magna</i> )	>120	Acute	0.012	n.r.	>10000	100
Metabolite R401553	Algae ( <i>Selenastrum capricornutum</i> )	>120	Chronic	0.012	n.r.	>10000	10
Metabolite R402173	Fish ( <i>Oncorhynchus mykiss</i> )	62	Acute	0.023	n.r.	2696	100
Metabolite R402173	Aquatic invertebrates ( <i>Daphnia magna</i> )	>100	Acute	0.023	n.r.	>4348	100
Metabolite R402173	Algae ( <i>Selenastrum capricornutum</i> )	67	Chronic	0.023	n.r.	2913	10

## FOCUS Step 2

TER for aquatic organisms at FOCUS Step 2 assuming application to brassicae in NMS (for details see Table B.8.6.4)

Test substance	N/S	Organism	Toxicity endpoint (mg a.s./L)	Time scale	PEC <sub>i</sub> (mg a.s./L)	TER	Annex VI Trigger
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Test substance	N/S	Organism	Toxicity endpoint (mg a.s./L)	Time scale	PEC <sub>i</sub> (mg a.s./L)	TER	Annex VI Trigger
a.s.	N	Fish ( <i>Oncorhynchus mykiss</i> )	0.47	Acute	0.0146	<b><u>32</u></b>	100
'250 SC'	N	Fish ( <i>Oncorhynchus mykiss</i> )	0.28	Acute	0.0146	<b><u>19</u></b>	100
a.s.	N	Fish ( <i>Pimephales promelas</i> )	0.147	Chronic	0.0146	10	10
a.s.	N	Aquatic invertebrates ( <i>Daphnia magna</i> )	0.23	Acute	0.0146	<b><u>16</u></b>	100
'250 SC'	N	Aquatic invertebrates ( <i>Daphnia magna</i> )	0.11	Acute	0.0146	<b><u>7.5</u></b>	100
a.s.	N	Sediment-dwelling organisms ( <i>Chironomus riparius</i> )	0.8	Chronic	0.0146	55	10
a.s.	N	Aquatic invertebrates ( <i>Macrocyclus fuscus</i> )	0.13	Acute	0.0146	<b><u>8.9</u></b>	100
a.s.	N	Aquatic invertebrates ( <i>Mysidopsis bahia</i> )	0.055	Acute	0.0146	<b><u>3.8</u></b>	100
a.s.	N	Aquatic invertebrates ( <i>Daphnia magna</i> )	0.044	Chronic	0.0146	<b><u>3.0</u></b>	10
a.s.	N	Aquatic invertebrates ( <i>Mysidopsis bahia</i> )	0.00954	Chronic	0.0146	<b><u>0.6</u></b>	10
a.s.	N	Algae ( <i>Navicula pelliculosa</i> )	0.014	Chronic	0.0146	<b><u>1.0</u></b>	10
'250 SC'	N	Algae ( <i>Selenastrum capricornutum</i> )	0.16	Chronic	0.0146	11	10

TER for aquatic organisms at FOCUS Step 2 assuming application to winter cereals in NMS (for details see Table B.8.6.5)

Test substance	N/S	Organism	Toxicity endpoint (mg a.s./L)	Time scale	PEC <sub>i</sub> (mg a.s./L)	TER	Annex VI Trigger
a.s.	N	Fish ( <i>Oncorhynchus mykiss</i> )	0.47	Acute	0.0087	<b><u>54</u></b>	100
'250 SC'	N	Fish ( <i>Oncorhynchus mykiss</i> )	0.28	Acute	0.0087	<b><u>32</u></b>	100
a.s.	N	Fish ( <i>Pimephales promelas</i> )	0.147	Chronic	0.0087	17	10

Test substance	N/S	Organism	Toxicity endpoint (mg a.s./L)	Time scale	PEC <sub>i</sub> (mg a.s./L)	TER	Annex VI Trigger
a.s.	N	Aquatic invertebrates ( <i>Daphnia magna</i> )	0.23	Acute	0.0087	<u>26</u>	100
'250 SC'	N	Aquatic invertebrates ( <i>Daphnia magna</i> )	0.11	Acute	0.0087	<u>13</u>	100
a.s.	N	Sediment-dwelling organisms ( <i>Chironomus riparius</i> )	0.8	Chronic	0.0087	92	10
a.s.	N	Aquatic invertebrates ( <i>Macrocyclops fuscus</i> )	0.13	Acute	0.0087	<u>15</u>	100
a.s.	N	Aquatic invertebrates ( <i>Mysidopsis bahia</i> )	0.055	Acute	0.0087	<u>6.3</u>	100
a.s.	N	Aquatic invertebrates ( <i>Daphnia magna</i> )	0.044	Chronic	0.0087	<u>5.1</u>	10
a.s.	N	Aquatic invertebrates ( <i>Mysidopsis bahia</i> )	0.00954	Chronic	0.0087	<u>1.1</u>	10
a.s.	N	Algae ( <i>Navicula pelliculosa</i> )	0.014	Chronic	0.0087	<u>1.6</u>	10
'250 SC'	N	Algae ( <i>Selenastrum capricornutum</i> )	0.16	Chronic	0.0087	18	10

TERs for aquatic organisms at FOCUS Step 2 assuming application to Brassicae in SMS (for details see Table B.8.6.6)

Test substance	N/S	Organism	Toxicity endpoint (mg a.s./L)	Time scale	PEC <sub>i</sub> (mg a.s./L)	TER	Annex VI Trigger
a.s.	N	Fish ( <i>Oncorhynchus mykiss</i> )	0.47	Acute	0.0263	<u>18</u>	100
'250 SC'	N	Fish ( <i>Oncorhynchus mykiss</i> )	0.28	Acute	0.0263	<u>11</u>	100
a.s.	N	Fish ( <i>Pimephales promelas</i> )	0.147	Chronic	0.0263	<u>5.6</u>	10
a.s.	N	Aquatic invertebrates ( <i>Daphnia magna</i> )	0.23	Acute	0.0263	<u>8.7</u>	100
'250 SC'	N	Aquatic invertebrates ( <i>Daphnia magna</i> )	0.11	Acute	0.0263	<u>4.2</u>	100

Test substance	N/S	Organism	Toxicity endpoint (mg a.s./L)	Time scale	PEC <sub>i</sub> (mg a.s./L)	TER	Annex VI Trigger
a.s.	N	Sediment-dwelling organisms ( <i>Chironomus riparius</i> )	0.8	Chronic	0.0263	30	10
a.s.	N	Aquatic invertebrates ( <i>Macrocyclops fuscus</i> )	0.13	Acute	0.0263	<b>4.9</b>	100
a.s.	N	Aquatic invertebrates ( <i>Mysidopsis bahia</i> )	0.055	Acute	0.0263	<b>2.1</b>	100
a.s.	N	Aquatic invertebrates ( <i>Daphnia magna</i> )	0.044	Chronic	0.0263	<b>1.7</b>	10
a.s.	N	Aquatic invertebrates ( <i>Mysidopsis bahia</i> )	0.00954	Chronic	0.0263	<b>0.4</b>	10
a.s.	N	Algae ( <i>Navicula pelliculosa</i> )	0.014	Chronic	0.0263	<b>0.5</b>	10
'250 SC'	N	Algae ( <i>Selenastrum capricornutum</i> )	0.16	Chronic	0.0263	<b>6.1</b>	10

TER for aquatic organisms at FOCUS Step 2 assuming application to winter cereals in SMS (for details see Table B.8.6.7)

Test substance	N/S	Organism	Toxicity endpoint (mg a.s./L)	Time scale	PEC <sub>i</sub> (mg a.s./L)	TER	Annex VI Trigger
a.s.	N	Fish ( <i>Oncorhynchus mykiss</i> )	0.47	Acute	0.0145	<b>32</b>	100
'250 SC'	N	Fish ( <i>Oncorhynchus mykiss</i> )	0.28	Acute	0.0145	<b>19</b>	100
a.s.	N	Fish ( <i>Pimephales promelas</i> )	0.147	Chronic	0.0145	10	10
a.s.	N	Aquatic invertebrates ( <i>Daphnia magna</i> )	0.23	Acute	0.0145	<b>16</b>	100
'250 SC'	N	Aquatic invertebrates ( <i>Daphnia magna</i> )	0.11	Acute	0.0145	<b>7.6</b>	100
a.s.	N	Sediment-dwelling organisms ( <i>Chironomus riparius</i> )	0.8	Chronic	0.0145	55	10
a.s.	N	Aquatic invertebrates ( <i>Macrocyclops fuscus</i> )	0.13	Acute	0.0145	<b>9.0</b>	100
a.s.	N	Aquatic invertebrates ( <i>Mysidopsis bahia</i> )	0.055	Acute	0.0145	<b>3.8</b>	100

Test substance	N/S	Organism	Toxicity endpoint (mg a.s./L)	Time scale	PEC <sub>i</sub> (mg a.s./L)	TER	Annex VI Trigger
a.s.	N	Aquatic invertebrates ( <i>Daphnia magna</i> )	0.044	Chronic	0.0145	<u>3.0</u>	10
a.s.	N	Aquatic invertebrates ( <i>Mysidopsis bahia</i> )	0.00954	Chronic	0.0145	<u>0.7</u>	10
a.s.	N	Algae ( <i>Navicula pelliculosa</i> )	0.014	Chronic	0.0145	<u>1.0</u>	10
'250 SC'	N	Algae ( <i>Selenastrum capricornutum</i> )	0.16	Chronic	0.0145	11	10

### Refined aquatic risk assessment using higher tier FOCUS modelling.

#### FOCUS Step 3

#### Brassicaceae

Acute and chronic fish toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on brassicae (for further details see Section B.8.6 and Tables B.8.6.24 and B.8.6.28 ).

	Toxicity endpoint (µg a.s./L)		FOCUS Step 3 worse case global max PEC <sub>sw</sub> (µg a.s./L)			TER	Annex VI
Fish ( <i>O. mykiss</i> )	280	Acute	D3(Vredepel)	d	1.584	177	100
			D4(Skousbo)	p	0.447	626	
			D4(Skousbo)	s	1.185	236	
			R1(Weiherbach)	p	0.746	375	
			R1(Weiherbach)	s	3.512	<u>80</u>	
			R2 (Porto)	s	1.505	186	
			R3(Bologna)	s	5.806	<u>48</u>	
			R4(Roujan)	s	7.584	<u>37</u>	
Fish ( <i>Pimephales promelas</i> )	147	Chronic	D3(Vredepel)	d	1.584	93	10
			D4(Skousbo)	p	0.447	329	
			D4(Skousbo)	s	1.185	124	
			R1(Weiherbach)	p	0.746	197	
			R1(Weiherbach)	s	3.512	<u>42</u>	
			R2 (Porto)	s	1.505	98	
			R3(Bologna)	s	5.806	<u>25</u>	
			R4(Roujan)	s	7.584	<u>19</u>	

Acute aquatic invertebrate toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on brassicae (for further details see Section B.8.6 and Tables B.8.6.24 and B.8.6.28 )

	Toxicity endpoint (µg a.s./L)		FOCUS Step 3 worse case global max PEC <sub>sw</sub> (µg a.s./L)			TER	Annex VI
			D3(Vredepel)	d	1.584	<u>69</u>	
			D4(Skousbo)	p	0.447	246	
			D4(Skousbo)	s	1.185	<u>93</u>	

	Toxicity endpoint ( $\mu\text{g a.s./L}$ )		FOCUS Step 3 worse case global max PECsw ( $\mu\text{g a.s./L}$ )			TER	Annex VI
<i>Daphnia magna</i>	110	Acute	R1(Weiherbach)	p	0.746	147	100
			R1(Weiherbach)	s	3.512	<b>31</b>	
			R2 (Porto)	s	1.505	<b>73</b>	
			R3(Bologna)	s	5.806	<b>19</b>	
			R4(Roujan)	s	7.584	<b>14</b>	
<i>Macrocyclus fuscus</i>	130	Acute	D3(Vredepel)	d	1.584	<b>82</b>	100
			D4(Skousbo)	p	0.447	291	
			D4(Skousbo)	s	1.185	110	
			R1(Weiherbach)	p	0.746	174	
			R1(Weiherbach)	s	3.512	<b>37</b>	
			R2 (Porto)	s	1.505	<b>86</b>	
			R3(Bologna)	s	5.806	<b>22</b>	
R4(Roujan)	s	7.584	<b>17</b>				
<i>Mysidopsis bahia</i>	55	Acute	D3(Vredepel)	d	1.584	<b>34</b>	100
			D4(Skousbo)	p	0.447	123	
			D4(Skousbo)	s	1.185	<b>46</b>	
			R1(Weiherbach)	p	0.746	<b>6.7</b>	
			R1(Weiherbach)	s	3.512	<b>16</b>	
			R2 (Porto)	s	1.505	<b>36</b>	
			R3(Bologna)	s	5.806	<b>9.5</b>	
R4(Roujan)	s	7.584	<b>7.5</b>				

Chronic aquatic invertebrate toxicity/exposure ratios (TERs) for azoxystrobin FOCUS Step3 PEC for the use on brassicae (for further details see Section B.8.6 and Tables B.8.6.24 and B.8.6.28)

	Toxicity endpoint ( $\mu\text{g a.s./L}$ )		FOCUS Step 3 worse case global max PECsw ( $\mu\text{g a.s./L}$ )			TER	Annex VI
<i>Daphnia magna</i>	44	Chronic	D3(Vredepel)	d	1.584	28	10
			D4(Skousbo)	p	0.447	98	
			D4(Skousbo)	s	1.185	37	
			R1(Weiherbach)	p	0.746	59	
			R1(Weiherbach)	s	3.512	12	
			R2 (Porto)	s	1.505	29	
			R3(Bologna)	s	5.806	<b>7.6</b>	
			R4(Roujan)	s	7.584	<b>5.8</b>	
<i>Mysidopsis bahia</i>	9.54	Chronic	D3(Vredepel)	d	1.584	<b>6.0</b>	10
			D4(Skousbo)	p	0.447	21	
			D4(Skousbo)	s	1.185	<b>8.1</b>	
			R1(Weiherbach)	p	0.746	13	
			R1(Weiherbach)	s	3.512	<b>2.7</b>	
			R2 (Porto)	s	1.505	<b>6.3</b>	
			R3(Bologna)	s	5.806	<b>1.6</b>	
R4(Roujan)	s	7.584	<b>1.3</b>				

Algae toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on brassicae (for further details see Section B.8.6 and Tables B.8.6.24 and B.8.6.28)

	Toxicity endpoint (µg a.s./L)		FOCUS Step 3 worse case global max PECsw (µg a.s./L)			TER	Annex VI
<i>Navicula pelliculosa</i>	14	Chronic	D3(Vredepel)	d	1.584	<b>8.8</b>	10
			D4(Skousbo)	p	0.447	31	
			D4(Skousbo)	s	1.185	12	
			R1(Weiherbach)	p	0.746	19	
			R1(Weiherbach)	s	3.512	<b>4.0</b>	
			R2 (Porto)	s	1.505	<b>9.3</b>	
			R3(Bologna)	s	5.806	<b>2.4</b>	
			R4(Roujan)	s	7.584	<b>1.8</b>	

### Spring cereals

Acute fish toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on spring cereals (for further details see Section B.8.6 and Table B.8.6.32)

	Toxicity endpoint (µg a.s./L)		FOCUS Step 3 worse case global max PECsw (µg a.s./L)			TER	Annex VI
Fish ( <i>O. mykiss</i> )	280	Acute	D1(Lanna)	d	3.432	<b>82</b>	100
			D1(Lanna)	s	2.143	131	
			D3(Vredepel)	d	1.589	176	
			D4(Skousbo)	p	0.851	329	
			D4(Skousbo)	s	1.367	205	
			D5 (La Jailliere)	p	0.108	2592	
			D5 (La Jailliere)	s	1.478	189	
			R4(Roujan)	s	3.437	<b>81</b>	
Fish ( <i>Pimephales promelas</i> )	147	Chronic	D1(Lanna)	d	3.432	43	10
			D1(Lanna)	s	2.143	69	
			D3(Vredepel)	d	1.589	92	
			D4(Skousbo)	p	0.851	173	
			D4(Skousbo)	s	1.367	107	
			D5 (La Jailliere)	p	0.108	1361	
			D5 (La Jailliere)	s	1.478	99	
			R4(Roujan)	s	3.437	43	

Acute aquatic invertebrate toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on spring cereals (for further details see Section B.8.6 and Tables B.8.6.32 and B.8.6.36)

	Toxicity endpoint (µg a.s./L)		FOCUS Step 3 worse case global max PECsw (µg a.s./L)			TER	Annex VI
<i>Daphnia magna</i>	110	Acute	D1(Lanna)	d	3.432	<b>32</b>	100
			D1(Lanna)	s	2.143	<b>51</b>	
			D3(Vredepel)	d	1.589	69	
			D4(Skousbo)	p	0.851	129	
			D4(Skousbo)	s	1.367	<b>80</b>	
			D5 (La Jailliere)	p	0.108	407	
			D5 (La Jailliere)	s	1.478	<b>74</b>	
			R4(Roujan)	s	3.437	<b>32</b>	
			D1(Lanna)	d	3.432	<b>38</b>	

	Toxicity endpoint (µg a.s./L)		FOCUS Step 3 worse case global max PECsw (µg a.s./L)			TER	Annex VI
<i>Macrocyclus fuscus</i>	130	Acute	D1(Lanna)	s	2.143	<b>61</b>	100
			D3(Vredepel)	d	1.589	<b>82</b>	
			D4(Skousbo)	p	0.851	<b>153</b>	
			D4(Skousbo)	s	1.367	<b>95</b>	
			D5 (La Jailliere)	p	0.108	1204	
			D5 (La Jailliere)	s	1.478	88	
			R4(Roujan)	s	3.437	38	
<i>Mysidopsis bahia</i>	55	Acute	D1(Lanna)	d	3.432	<b>16</b>	100
			D1(Lanna)	s	2.143	<b>26</b>	
			D3(Vredepel)	d	1.589	<b>35</b>	
			D4(Skousbo)	p	0.851	<b>65</b>	
			D4(Skousbo)	s	1.367	<b>40</b>	
			D5 (La Jailliere)	p	0.108	509	
			D5 (La Jailliere)	s	1.478	<b>37</b>	
R4(Roujan)	s	3.437	16				

Chronic aquatic invertebrate toxicity/exposure ratios (TERs) for azoxystrobin FOCUS Step3 PEC for the use on spring cereals (for further details see Section B.8.6 and Tables B.8.6.32 and B.8.6.36 )

	Toxicity endpoint (µg a.s./L)		FOCUS Step 3 worse case global max PECsw (µg a.s./L)			TER	Annex VI
<i>Daphnia magna</i>	44	Chronic	D1(Lanna)	d	3.432	13	10
			D1(Lanna)	s	2.143	20	
			D3(Vredepel)	d	1.589	28	
			D4(Skousbo)	p	0.851	52	
			D4(Skousbo)	s	1.367	32	
			D5 (La Jailliere)	p	0.108	407	
			D5 (La Jailliere)	s	1.478	30	
R4(Roujan)	s	3.437	13				
<i>Mysidopsis bahia</i>	9.54	Chronic	D1(Lanna)	d	3.432	<b>2.8</b>	10
			D1(Lanna)	s	2.143	<b>4.4</b>	
			D3(Vredepel)	d	1.589	<b>6.0</b>	
			D4(Skousbo)	p	0.851	11	
			D4(Skousbo)	s	1.367	<b>7.0</b>	
			D5 (La Jailliere)	p	0.108	88	
			D5 (La Jailliere)	s	1.478	<b>6.5</b>	
R4(Roujan)	s	3.437	2.8				

Algae toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on spring cereals (for further details see Section B.8.6 and Tables B.8.6.32 and B.8.6.36)

	Toxicity endpoint (µg a.s./L)		FOCUS Step 3 worse case global max PECsw (µg a.s./L)			TER	Annex VI
			D1(Lanna)	d	3.432	<b>4.1</b>	
			D1(Lanna)	s	2.143	<b>6.5</b>	
			D3(Vredepel)	d	1.589	<b>8.8</b>	

<i>Navicula pelliculosa</i>	14	Acute	D4(Skousbo)	p	0.851	16	10
			D4(Skousbo)	s	1.367	10	
			D5 (La Jailliere)	p	0.108	129	
			D5 (La Jailliere)	s	1.478	<b>9.5</b>	
			R4(Roujan)	s	3.437	<b>4.1</b>	

### Winter cereals

Acute and chronic fish toxicity/exposure ratios (TERs) for azoxystrobin FOCUS Step3 PEC for the use on winter cereals (for further details see Section B.8.6 and Tables B.8.6.40 and B.8.6.44)

	Toxicity endpoint ( $\mu\text{g a.s./L}$ )		FOCUS Step 3 worse case global max PECsw ( $\mu\text{g a.s./L}$ )			TER	Annex VI
Fish ( <i>O. mykiss</i> )	280	Acute	D1(Lanna)	d	3.684	<b>76</b>	100
			D1(Lanna)	s	2.300	122	
			D2(Brimstone)	d	4.208	<b>66</b>	
			D2(Brimstone)	s	2.629	106	
			D3(Vredepel)	d	1.584	177	
			D4(Skousbo)	p	0.764	366	
			D4(Skousbo)	s	1.370	204	
			D5(La Jailliere)	p	0.208	1346	
			D5(La Jailliere)	s	1.461	192	
			D6(Thiva)	d	1.593	176	
			R1(Weiherbach)	p	0.549	510	
			R1(Weiherbach)	s	3.042	<b>92</b>	
R3 (Bologna)	s	2.605	107				
Fish ( <i>Pimephales promelas</i> )	147	Acute	D1(Lanna)	d	3.684	40	10
			D1(Lanna)	s	2.300	64	
			D2(Brimstone)	d	4.208	<b>35</b>	
			D2(Brimstone)	s	2.629	56	
			D3(Vredepel)	d	1.584	93	
			D4(Skousbo)	p	0.764	192	
			D4(Skousbo)	s	1.370	107	
			D5(La Jailliere)	p	0.208	707	
			D5(La Jailliere)	s	1.461	101	
			D6(Thiva)	d	1.593	92	
			R1(Weiherbach)	p	0.549	268	
			R1(Weiherbach)	s	3.042	48	
			R3 (Bologna)	s	2.605	56	
R4 (Roujan)	s	4.585	<b>32</b>				

Acute aquatic invertebrate toxicity/exposure ratios (TERs) for azoxystrobin FOCUS Step3 PEC for the use on winter cereals (for further details see Section B.8.6 and Tables B.8.6.40 and B.8.6.44)

	Toxicity endpoint ( $\mu\text{g a.s./L}$ )		FOCUS Step 3 worse case global max PECsw ( $\mu\text{g a.s./L}$ )			TER	Annex VI
			D1(Lanna)	d	3.684	<b>30</b>	
			D1(Lanna)	s	2.300	<b>48</b>	
			D2(Brimstone)	d	4.208	<b>26</b>	

	Toxicity endpoint (µg a.s./L)		FOCUS Step 3 worse case global max PECsw (µg a.s./L)			TER	Annex VI
<i>Daphnia magna</i>	110	Acute	D2(Brimstone)	s	2.629	<b>42</b>	100
			D3(Vredepel)	d	1.584	<b>69</b>	
			D4(Skousbo)	p	0.764	144	
			D4(Skousbo)	s	1.370	<b>80</b>	
			D5(La Jailliere)	p	0.208	529	
			D5(La Jailliere)	s	1.461	<b>75</b>	
			D6(Thiva)	d	1.593	<b>69</b>	
			R1(Weiherbach)	p	0.549	200	
			R1(Weiherbach)	s	3.042	<b>36</b>	
			R3 (Bologna)	s	2.605	<b>42</b>	
			R4 (Roujan)	s	4.585	<b>24</b>	
<i>Macrocyclops fuscus</i>	130	Acute	D1(Lanna)	d	3.684	<b>35</b>	100
			D1(Lanna)	s	2.300	<b>56</b>	
			D2(Brimstone)	d	4.208	<b>31</b>	
			D2(Brimstone)	s	2.629	<b>49</b>	
			D3(Vredepel)	d	1.584	<b>82</b>	
			D4(Skousbo)	p	0.764	170	
			D4(Skousbo)	s	1.370	<b>95</b>	
			D5(La Jailliere)	p	0.208	625	
			D5(La Jailliere)	s	1.461	89	
			D6(Thiva)	d	1.593	<b>82</b>	
			R1(Weiherbach)	p	0.549	237	
			R1(Weiherbach)	s	3.042	<b>43</b>	
			R3 (Bologna)	s	2.605	<b>50</b>	
R4 (Roujan)	s	4.585	<b>28</b>				
<i>Mysidopsis bahia</i>	55	Acute	D1(Lanna)	d	3.684	<b>15</b>	100
			D1(Lanna)	s	2.3	<b>24</b>	
			D2(Brimstone)	d	4.208	<b>13</b>	
			D2(Brimstone)	s	2.629	<b>21</b>	
			D3(Vredepel)	d	1.584	<b>35</b>	
			D4(Skousbo)	p	0.764	<b>72</b>	
			D4(Skousbo)	s	1.37	<b>40</b>	
			D5(La Jailliere)	p	0.208	264	
			D5(La Jailliere)	s	1.461	<b>38</b>	
			D6(Thiva)	d	1.593	<b>35</b>	
			R1(Weiherbach)	p	0.549	100	
			R1(Weiherbach)	s	3.042	<b>18</b>	
			R3 (Bologna)	s	2.605	<b>21</b>	
R4 (Roujan)	s	4.585	<b>12</b>				

Chronic aquatic invertebrate toxicity/exposure ratios (TERs) for azoxystrobin FOCUS Step3 PEC for the use on winter cereals (for further details see Section B.8.6 and Tables B.8.6.40 and B.8.6.44)

	Toxicity endpoint (µg a.s./L)		FOCUS Step 3 worse case global max PECsw (µg a.s./L)			TER	Annex VI
			D1(Lanna)	d	3.684	12	
			D1(Lanna)	s	2.3	19	

	Toxicity endpoint ( $\mu\text{g a.s./L}$ )		FOCUS Step 3 worse case global max PECsw ( $\mu\text{g a.s./L}$ )			TER	Annex VI
<i>Daphnia magna</i>	44	Chronic	D2(Brimstone)	d	4.208	10	10
			D2(Brimstone)	s	2.629	17	
			D3(Vredepel)	d	1.584	28	
			D4(Skousbo)	p	0.764	58	
			D4(Skousbo)	s	1.37	32	
			D5(La Jailliere)	p	0.208	211	
			D5(La Jailliere)	s	1.461	30	
			D6(Thiva)	d	1.593	28	
			R1(Weiherbach)	p	0.549	80	
			R1(Weiherbach)	s	3.042	14	
			R3 (Bologna)	s	2.605	17	
			R4 (Roujan)	s	4.585	<b>9.6</b>	
<i>Mysidopsis bahia</i>	9.54	Chronic	D1(Lanna)	d	3.684	<b>2.6</b>	10
			D1(Lanna)	s	2.3	<b>4.1</b>	
			D2(Brimstone)	d	4.208	<b>2.3</b>	
			D2(Brimstone)	s	2.629	<b>3.6</b>	
			D3(Vredepel)	d	1.584	<b>6.0</b>	
			D4(Skousbo)	p	0.764	12	
			D4(Skousbo)	s	1.37	<b>7.0</b>	
			D5(La Jailliere)	p	0.208	46	
			D5(La Jailliere)	s	1.461	<b>6.5</b>	
			D6(Thiva)	d	1.593	<b>6.0</b>	
			R1(Weiherbach)	p	0.549	17	
			R1(Weiherbach)	s	3.042	<b>3.1</b>	
			R3 (Bologna)	s	2.605	<b>3.7</b>	
			R4 (Roujan)	s	4.585	<b>2.1</b>	

Algae toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on winter cereals (for further details see Section B.8.6 and Tables B.8.6.40 and B.8.6.44)

	Toxicity endpoint ( $\mu\text{g a.s./L}$ )		FOCUS Step 3 worse case global max PECsw ( $\mu\text{g a.s./L}$ )			TER	Annex VI
<i>Navicula pelliculosa</i>	14	Chronic	D1(Lanna)	d	3.684	<b>3.8</b>	10
			D1(Lanna)	s	2.300	<b>6.1</b>	
			D2(Brimstone)	d	4.208	<b>3.3</b>	
			D2(Brimstone)	s	2.629	<b>5.3</b>	
			D3(Vredepel)	d	1.584	<b>8.8</b>	
			D4(Skousbo)	p	0.764	18	
			D4(Skousbo)	s	1.370	<b>10</b>	
			D5(La Jailliere)	p	0.208	67	
			D5(La Jailliere)	s	1.461	<b>9.6</b>	
			D6(Thiva)	d	1.593	<b>8.8</b>	
			R1(Weiherbach)	p	0.549	25	
			R1(Weiherbach)	s	3.042	<b>4.6</b>	
			R3 (Bologna)	s	2.605	<b>5.4</b>	
			R4 (Roujan)	s	4.585	<b>3.1</b>	

Refined risk assessment for fish – the refined risk assessment used the endpoint from the study using the active substance rather than the formulation, i.e. the endpoint was 470 µg a.s./L compared to 270 µg a.s./L used in the above risk assessment.

### Brassicacae

Acute fish toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on brassicacae (for further details see Section B.8.6 and B.8.6.24)

	Toxicity endpoint (µg a.s./L) <sup>1</sup>		FOCUS Step 3 worse case global max PECsw (µg a.s./L)			TER	Annex VI
Fish ( <i>O mykiss</i> )	470	Acute	D3(Vredepel)	d	1.584	297	100
			D4(Skousbo)	p	0.447	1051	
			D4(Skousbo)	s	1.185	397	
			R1(Weiherbach)	p	0.746	630	
			R1(Weiherbach)	s	3.512	134	
			R2 (Porto)	s	1.505	312	
			R3(Bologna)	s	5.806	<b>81</b>	
			R4(Roujan)	s	7.584	<b>62</b>	

<sup>1</sup> Endpoint based on study that used the active substance rather than the formulation

### Spring cereals

Acute fish toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on spring cereals (for further details see Section B.8.6 and B.8.6.32)

	Toxicity endpoint (µg a.s./L) <sup>1</sup>		FOCUS Step 3 worse case global max PECsw (µg a.s./L)			TER	Annex VI
Fish ( <i>O mykiss</i> )	470	Acute	D1(Lanna)	d	3.432	137	100
			D1(Lanna)	s	2.143	219	
			D3(Vredepel)	d	1.589	296	
			D4(Skousbo)	p	0.851	552	
			D4(Skousbo)	s	1.367	344	
			D5 (La Jailliere)	p	0.108	4352	
			D5 (La Jailliere)	s	1.478	318	
			R4(Roujan)	s	3.437	137	

<sup>1</sup> Endpoint based on study that used the active substance rather than the formulation

### Winter cereals

Acute fish toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on winter cereals (for further details see Section B.8.6 and Tables B.8.6.32 and B.8.6.36)

	Toxicity endpoint (µg a.s./L) <sup>1</sup>		FOCUS Step 3 worse case global max PECsw (µg a.s./L)			TER	Annex VI
			D1(Lanna)	d	3.684	127	
			D1(Lanna)	s	2.300	204	
			D2(Brimstone)	d	4.208	112	
			D2(Brimstone)	s	2.629	179	

Fish ( <i>O. mykiss</i> )	470	Acute	D3(Vredepel)	d	1.584	297	100
			D4(Skousbo)	p	0.764	615	
			D4(Skousbo)	s	1.370	343	
			D5(La Jailliere)	p	0.208	2250	
			D5(La Jailliere)	s	1.461	322	
			D6(Thiva)	d	1.593	295	
			R1(Weiherbach)	p	0.549	856	
			R1(Weiherbach)	s	3.042	155	
			R3 (Bologna)	s	2.605	180	
			R4 (Roujan)	s	4.585	103	

<sup>1</sup> Endpoint based on study that used the active substance rather than the formulation

Refined risk assessment using the ‘regulatory concentration’ of 5 µg a.s./L; the regulatory concentration was obtained by using information from the mesocosm as well as the lower limit of the HC5 and regulatory concentration based on the ‘Method 1’ of the PPR opinion<sup>11</sup>. These latter approaches were based on the following additional aquatic invertebrate data.

Summary table of all available data on the acute toxicity of azoxystrobin to aquatic invertebrates.

Species	48-h EC/LC50 (µg a.s./L)	Reference; report number (a)
<i>Mysidopsis bahia</i> (marine shrimp)	68	Grinell et al, 1993; BL4785/B
<i>Mysidopsis bahia</i> (marine shrimp)	55* (96 hour LC50)	Grinell et al, 1993; BL4785/B
<i>Macrocyclops fuscus</i> (Cyclopoid copepod crustacean)	130	Farrelly et al, 1995a; RJ1793B
<i>Daphnia pulex</i> (Water flea; cladoceran crustacean)	200	Rapley et al, 1995b; RJ1798B
<i>Chironomus riparius</i> (Midge larva; dipteran insect)	210	Farrelly et al, 1995d; RJ1792B
<i>Daphnia magna</i> (Water flea; cladoceran crustacean)	280	Rapley et al, 1995a; RJ1797B
<i>Gammarus pulex</i> (Freshwater shrimp; amphipod crustacean)	350	Farrelly et al, 1995b; RJ1782B
<i>Crassostrea gigas</i> (Pacific oyster)	1300	Kent et al, 1994; BL4842/B
<i>Chaoborus crystallinus</i> (Phantom midge larva; dipteran insect)	1600	Farrelly et al, 1995e; RJ1792B
<i>Cloeon dipterum</i> (Mayfly nymph; ephemeropteran insect)	3200	Farrelly et al, 1995g; RJ1795B
<i>Asellus aquaticus</i> (Water-louse; isopod crustacean)	>4000	Farrelly et al, 1995c; RJ1789B
<i>Ischnura elegans</i> (Damselfly nymph; zygopteran insect)	>4000	Farrelly et al. 1995f; RJ1794B
<i>Notonecta glauca</i> (Water-boatman; hemipteran insect)	>4000	Rapley et al 1995c; RJ1799B
<i>Brachyonus calyciflorus</i> (Rotifer)	>4000	Farrelly et al 1995h; RJ1791B
<i>Lymnaea stagnalis</i> (Pond snail; gastropod mollusc)	>4000	Farrelly et al 1995i; RJ1796B

<sup>11</sup> See ref [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620775612.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620775612.htm)

\* The Mysid study was conducted over 96 hours, the Notifier proposed using the 48 hour end point as this was in line with the duration of the other studies. The RMS has carried out an assessment using both end points, i.e. the 48 hour LC<sub>50</sub> of 68 µg a.s./L and the 96 hour LC<sub>50</sub> of 55 µg a.s./L.

Acute aquatic invertebrate toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on brassicae (for further details see Section B.8.6 and B.8.6.24)

	Toxicity endpoint (µg a.s./L) <sup>12</sup>		FOCUS Step 3 worse case global max PECsw (µg a.s./L)			TER	Trigger value <sup>13</sup>
Aquatic invertebrates	3.3	Acute + Chronic	D3(Vredepel)	D	1.584	2.1	1
			D4(Skousbo)	P	0.447	7.4	
			D4(Skousbo)	S	1.185	2.8	
			R1(Weiherbach)	P	0.746	4.4	
			R1(Weiherbach)	S	3.512	<b>0.9</b>	
			R2 (Porto)	S	1.505	2.2	
			R3(Bologna)	S	5.806	<b>0.6</b>	
R4(Roujan)	s	7.584	<b>0.4</b>				

Acute and chronic aquatic invertebrate toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on spring cereals (for further details see Section B.8.6 and B.8.6.32)

	Toxicity endpoint (µg a.s./L) <sup>14</sup>		FOCUS Step 3 worse case global max PECsw (µg a.s./L)			TER	Trigger value <sup>15</sup>
Aquatic invertebrates	3.3	Acute + chronic	D1(Lanna)	d	3.432	<b>0.9</b>	1
			D1(Lanna)	s	2.143	1.5	
			D3(Vredepel)	d	1.589	2.1	
			D4(Skousbo)	p	0.851	3.9	
			D4(Skousbo)	s	1.367	2.4	
			D5 (La Jailliere)	p	0.108	30	
			D5 (La Jailliere)	s	1.478	2.2	
			R4(Roujan)	s	3.437	<b>0.9</b>	

Acute aquatic invertebrate toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on winter cereals (for further details see Section B.8.6 and B.8.6.40)

	Toxicity endpoint (µg a.s./L) <sup>16</sup>		FOCUS Step 3 worse case global max PECsw (µg a.s./L)			TER	Trigger value <sup>17</sup>
Aquatic invertebrates	3.3	Acute + chronic	D1(Lanna)	d	3.684	<b>0.9</b>	1
			D1(Lanna)	s	2.300	1.4	
			D2(Brimstone)	d	4.208	<b>0.8</b>	
			D2(Brimstone)	s	2.629	1.3	
			D3(Vredepel)	d	1.584	2.1	

<sup>12</sup> This endpoint is based on data from the mesocosm study, the first tier toxicity data and the lower limit of the HC5 – see EFSA conclusion for full details.

<sup>13</sup> Amended trigger value as the assessment factor has been built in to the endpoint.

<sup>14</sup> This endpoint is based on data from the mesocosm study, the first tier toxicity data and the lower limit of the HC5.

<sup>15</sup> Amended trigger value as the assessment factor has been built in to the endpoint.

<sup>16</sup> This endpoint is based on data from the mesocosm study, the first tier toxicity data and the lower limit of the HC5.

<sup>17</sup> Amended trigger value as the assessment factor has been built in to the endpoint.

Toxicity endpoint ( $\mu\text{g a.s./L}$ ) <sup>16</sup>		FOCUS Step 3 worse case global max PECsw ( $\mu\text{g a.s./L}$ )			TER	Trigger value <sup>17</sup>
		D4(Skousbo)	p	0.764	4.3	
		D4(Skousbo)	s	1.370	2.4	
		D5(La Jailliere)	p	0.208	15.9	
		D5(La Jailliere)	s	1.461	2.2	
		D6(Thiva)	d	1.593	2.1	
		R1(Weiherbach)	p	0.549	6.0	
		R1(Weiherbach)	s	3.042	1.1	
		R3 (Bologna)	s	2.605	1.3	
		R4 (Roujan)	s	4.585	<b>0.7</b>	

### Refined risk assessment for algae

Algae toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on brassicae (for further details see Section B.8.6 and Tables B.8.6.24 and B.8.6.28)

Toxicity endpoint ( $\mu\text{g a.s./L}$ )		FOCUS Step 3 worse case global max PECsw ( $\mu\text{g a.s./L}$ )			TER	Trigger value	
Algae	262	Chronic	D3(Vredepel)	d	1.584	165	10
			D4(Skousbo)	p	0.447	586	
			D4(Skousbo)	s	1.185	221	
			R1(Weiherbach)	p	0.746	351	
			R1(Weiherbach)	s	3.512	75	
			R2 (Porto)	s	1.505	174	
			R3(Bologna)	s	5.806	45	
			R4(Roujan)	s	7.584	34	

Acute and chronic aquatic invertebrate toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on spring cereals (for further details see Section B.8.6 and Tables B.8.6.32 and B.8.6.36)

Toxicity endpoint ( $\mu\text{g a.s./L}$ )		FOCUS Step 3 worse case global max PECsw ( $\mu\text{g a.s./L}$ )			TER	Trigger value	
Algae	262	Chronic	D1(Lanna)	d	3.432	76	10
			D1(Lanna)	s	2.143	122	
			D3(Vredepel)	d	1.589	165	
			D4(Skousbo)	p	0.851	308	
			D4(Skousbo)	s	1.367	192	
			D5 (La Jailliere)	p	0.108	2426	
			D5 (La Jailliere)	s	1.478	177	
			R4(Roujan)	s	3.437	76	

Acute aquatic invertebrate toxicity/exposure ratios (TER) for azoxystrobin FOCUS Step3 PEC for the use on winter cereals (for further details see Section B.8.6 and B.8.6.40 and B.8.6.44)

	Toxicity endpoint ( $\mu\text{g a.s./L}$ )		FOCUS Step 3 worse case global max PEC <sub>sw</sub> ( $\mu\text{g a.s./L}$ )			TER	Trigger value
			D	S	PEC		
Algae	262	Chronic	D1(Lanna)	d	3.684	71	10
			D1(Lanna)	s	2.300	114	
			D2(Brimstone)	d	4.208	62	
			D2(Brimstone)	s	2.629	100	
			D3(Vredepel)	d	1.584	165	
			D4(Skousbo)	p	0.764	343	
			D4(Skousbo)	s	1.370	191	
			D5(La Jailliere)	p	0.208	1260	
			D5(La Jailliere)	s	1.461	179	
			D6(Thiva)	d	1.593	164	
			R1(Weiherbach)	p	0.549	477	
			R1(Weiherbach)	s	3.042	86	
			R3 (Bologna)	s	2.605	100	
R4 (Roujan)	s	4.585	57				

Bioconcentration	
	Active substance
logP <sub>O/W</sub>	2.5
Bioconcentration factor (BCF) <sup>1</sup>	n.n.
Annex VI Trigger for the bioconcentration factor	n.r.
Clearance time (days) (CT <sub>50</sub> )	n.r.
(CT <sub>90</sub> )	n.r.
Level and nature of residues (%) in organisms after the 14 day depuration phase	n.r.

<sup>1</sup> only required if log P<sub>O/W</sub> >3.

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

Test substance	Acute oral toxicity (LD <sub>50</sub> $\mu\text{g/bee}$ )	Acute contact toxicity (LD <sub>50</sub> $\mu\text{g/bee}$ )
a.s.	>25 $\mu\text{g a.s./bee}$	>200 $\mu\text{g a.s./bee}$
Preparation <sup>1</sup>	>200 $\mu\text{g a.s./bee}$	>200 $\mu\text{g a.s./bee}$

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

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	<1.25	50
a.s.	oral	<10	50

Test substance	Route	Hazard quotient	Annex VI Trigger
Preparation	Contact	<1.25	50
Preparation	oral	<1.25	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 <sub>50</sub> g a.s./ha <sup>1</sup> )
<i>Typhlodromus pyri</i>	Glass plate	Mortality	>1500 g a.s./ha
<i>Aphidius rhopalosiphi</i>	Glass plate	Mortality	>1000 g a.s./ha

'A12705' – Cereals, 2 x 1.0L with 14 day interval (250 g a.s./ha; BBCH 31 on) and Brassicas, 2 x 1.0L with 12 day interval (250 g a.s./ha; BBCH 35 on)<sup>1</sup>

Appl. rate (g a.s./ha)	MAF	Drift <sup>2</sup> % @1m	VDF	SF	max. exposure [g/ha]		LR50 [g a.s./ha]	HQ		AnnexVI
					in	off		in	off	
<i>Aphidius rhopalosiphi</i>										
250	1.7	-	-	-	425	-	>1000	<0.425		2
250	1.7	2.38	10	10		10.2	>1000		<0.01	2
<i>Typhlodromus pyri</i>										
250	1.7	-	-	-	425	-	>1500	<0.238		2
250	1.7	2.38	10	10		10.2	>1500		0.007	2

<sup>1</sup> Whilst the application interval is less for brassicas, i.e. 12 versus 14 days, the MAF according to ESCORT 2 is the same, i.e. the 'risk' from the two uses can be considered to be the same.

<sup>2</sup> SANCO 10329/2002

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	Endpoint
Earthworms			
<i>Eisenia fetida</i>	a.s.	Acute 14 days	LC <sub>50</sub> 283 mg a.s./kg d.w.soil <sup>1</sup>
	YF10537	Chronic 8 weeks	NOEC 20 mg a.s./kg d.w.soil <sup>2</sup>
	250SC	Chronic 8 weeks	NOEC 3.0 kg a.s./kg d.w.soil <sup>1</sup>
	'250 SC'	Acute	LC <sub>50</sub> 881 mg a.s./kg d.w.soil <sup>1</sup>
	R234886	Acute	LC <sub>50</sub> >1000 mg a.s./kg d.w.soil <sup>2</sup>

Test organism	Test substance	Time scale	Endpoint
Earthworms			
	R401553 (SYN501657)	Acute	LC <sub>50</sub> >1000 mg a.s./kg d.w.soil <sup>2</sup>
	R402173 (SYN501114)	Acute	LC <sub>50</sub> >1000 mg a.s./kg d.w.soil <sup>2</sup>

<sup>1</sup> – endpoints taken from original DAR/agreed list of endpoints

<sup>2</sup> – endpoints submitted with the renewal of Annex I listing

### Toxicity/exposure ratios for soil organisms

#### Cereals and Brassicas

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Earthworms					
	a.s.	Acute (corrected endpoint)	0.394 <sup>2</sup>	359	10
	'YF 10537'	Chronic (corrected endpoint)	0.394 <sup>2</sup>	25.4	5
	R234886	Acute (corrected endpoint)	0.110 <sup>2</sup>	4545	10
	R401553	Acute (corrected endpoint)	0.036 <sup>2</sup>	13889	10
	a.s.	Acute	0.196 <sup>3</sup>	719	10
	a.s.	Chronic	0.196 <sup>3</sup>	51	5
	R234886	Acute (corrected endpoint)	0.054 <sup>3</sup>	9259	10
	R401553	Acute (corrected endpoint)	0.018 <sup>3</sup>	27778	10
	R402173	Acute (corrected endpoint)	0.028 <sup>3</sup>	17857	10
	R402173	Acute (corrected endpoint)	0.055 <sup>3</sup>	9091	10
	a.s.	Acute	0.646 <sup>4</sup>	219	10
	YF 10537	Chronic	0.646 <sup>4</sup>	15.5	5

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Other soil macro-organisms					
Collembola	'YF10537'	28d	Cereals 0.196 mg a.s./kg soil Brassicas 0.394 mg a.s./kg soil	127  64	5
Collembola	'YF10537'	28d NOECcorr=25	Peak accumulation PEC Brassicas 0.646 mg a.s./kg soil	39	5
Higher Tier - field litter bag study					
Straw degradation in soil	A12705A	max. 5% deviation from after 181d control straw degradation @ 0.5514 mg a.s./kg d.wt. soil	Cereals 0.196 mg a.s./kg soil Brassicas 0.394 mg a.s./kg soil assuming 5 cm incorporation depth;	Less than 10% effect at the initial PEC	10% <sup>5</sup>
Straw degradation in soil	A12705A	max. 5% deviation from after 181d control straw degradation @ 0.5514 mg a.s./kg d.wt. soil	Peak accumulation PEC Brassicas 0.646 mg a.s./kg soil assuming 5 cm incorporation depth;	Effects at 0.5514 mg a.s./kg soil are less than 10%	10% <sup>5</sup>

<sup>2</sup> PEC based on two applications to brassicas at the rate of 2 times 250 g a.s./ha

<sup>3</sup> PEC based on two applications to cereals at the rate of 2 times 250 g a.s./ha

<sup>4</sup> PEC based on peak plateau concentration

<sup>5</sup> threshold proposed by EPFES guidance

Test organism	Test substance	Time scale	Endpoint
Soil micro-organisms			
Nitrogen mineralisation	R234886	28 days	No effect at 1 and 10 mg/kg soil dry weight
	R401553	28 days	No effect at 0.528 and 2.643 mg test item /kg dry wt soil

Test organism	Test substance	Time scale	Endpoint
	R402173	28 days	No effect at 0.826 and 4.131 mg test item/kg dry soil
Carbon mineralisation	R234886	28 days	No effect at 1 and 10 mg/kg soil dry weight
	R401553	28 days	No effect at 0.528 and 2.643 mg test item /kg dry wt soil
	R402173	28 days	No effect at 0.826 and 4.131 mg test item/kg dry soil

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

#### Preliminary screening data

Laboratory dose response tests

Most sensitive species	Test substance	ER <sub>50</sub> (g/ha) <sup>2</sup> vegetative vigour	ER <sub>50</sub> (g/ha) <sup>2</sup> emergence	Exposure <sup>1</sup> (g/ha) <sup>2</sup>	TER	Trigger
Lettuce, radish, wheat	Azoxystrobin	n.a.	>20 mg a.s./kg soil emergence	0.009 mg a.s./kg soil	>2222	5

<sup>1</sup> based on Ganzelmeier drift data)

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

Test type/organism	end point
Activated sludge	NOEC
<i>Pseudomonas sp</i>	>3.2 mg/L

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

Compartment	
soil	azoxystrobin
water	azoxystrobin
sediment	azoxystrobin
groundwater	azoxystrobin

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

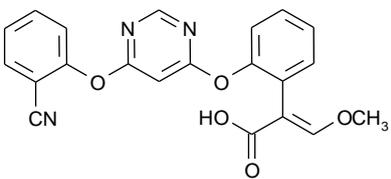
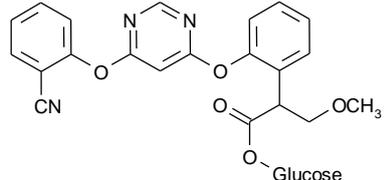
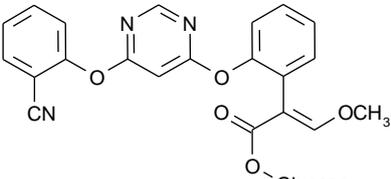
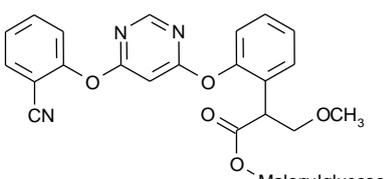
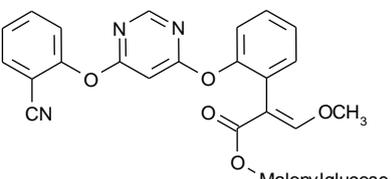
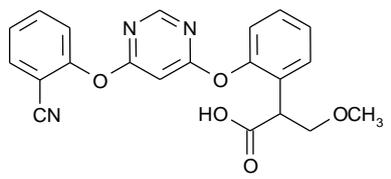
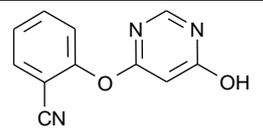
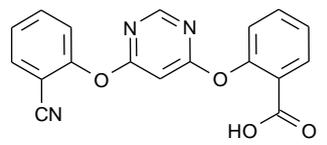
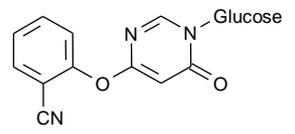
Active substance

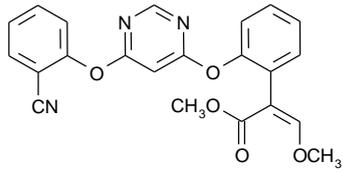
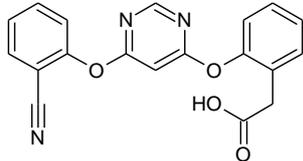
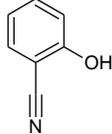
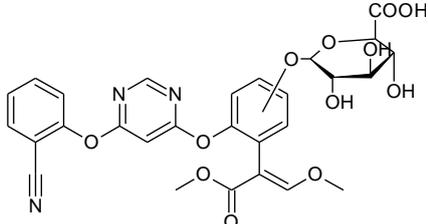
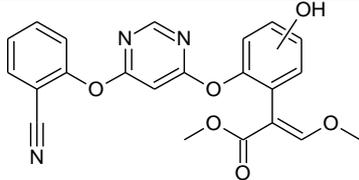
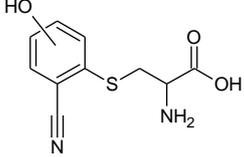
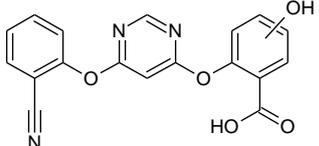
RMS/peer review proposal
Hazard symbol: N
Risk phrases: R50/53
Safety phrases: S60/61

Preparation

RMS/peer review proposal
Hazard symbol: N Risk phrases: R50/53 Safety phrases: S60/61 or S35/37

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
<b>R234886</b> (Compound 2)	(2 <i>E</i> )-2-(2-([6-(2-cyanophenoxy)pyrimidin-4-yl]oxy)phenyl)-3-methoxyprop-2-enoic acid	
<b>N1</b>	glucosyl ( <i>E</i> )-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxypropionate	
<b>N2</b>	glucosyl (2 <i>E</i> )-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate	
<b>O2</b>	glucosylmalonyl 2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxypropionate	
<b>O3</b>	glucosylmalonyl (2 <i>E</i> )-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate	
<b>U5</b>	2-(2-([6-(2-cyanophenoxy)pyrimidin-4-yl]oxy)phenyl)-3-methoxypropanoic acid	
<b>R401553</b> M28	4-(2-cyanophenoxy)-6-hydroxypyrimidine or 2-[(6-hydroxypyrimidin-4-yl)oxy]benzotrile	
<b>R402173</b>	2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]benzoic acid	
<b>R405287</b> M42	6-(2-cyanophenoxy)-3-glucosylpyrimidin-4-one	

<p><b>R230310</b></p> <p>Z-isomer of azoxystrobin</p> <p><b>M09</b></p>	<p>methyl (Z)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate</p>	
<p><b>M20</b></p>	<p>(2-[[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy]phenyl)acetic acid</p>	
<p><b>M13</b></p>	<p>2-hydroxybenzonitrile</p>	
<p><b>K1</b></p>	<p>4-[[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy]-3-[(1E)-1,3-dimethoxy-3-oxoprop-1-en-2-yl]phenyl glucopyranuronic acid</p>	
<p><b>L1</b></p>	<p>methyl (2E)-2-(2-[[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy]-x-hydroxyphenyl)-3-methoxyprop-2-enoate</p>	
<p><b>L4</b></p>	<p>S-(2-cyano-x-hydroxyphenyl)cysteine</p>	
<p><b>L9</b></p>	<p>2-[[6-(2-cyanophenoxy)pyrimidin-4-yl]oxy]-x-hydroxybenzoic acid</p>	

\* The metabolite name in bold is the name used in the conclusion.

## ABBREVIATIONS

1/n	slope of Freundlich isotherm
$\varepsilon$	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
$\mu\text{g}$	microgram
$\mu\text{m}$	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 Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DFOP	double first order in parallel kinetics
DM	dry matter
DT <sub>50</sub>	period required for 50 percent disappearance (define method of estimation)
DT <sub>90</sub>	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC <sub>50</sub>	effective concentration (biomass)
EC <sub>50</sub>	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER <sub>50</sub>	emergence rate/effective rate, median
ErC <sub>50</sub>	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-MSD	gas chromatography-mass selective detector
GC-NPD	gas chromatography-nitrogen phosphorous selective 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-UV	high pressure liquid chromatography – ultra violet detection
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
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
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
$LD_{50}$	lethal dose, median; dosis letalis media
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
mg	milligram
mL	millilitre
mm	millimetre
MMAD	mass median aerodynamic diameter
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
NOEAEC	no observed ecologically adverse effects concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC <sub>air</sub>	predicted environmental concentration in air
PEC <sub>gw</sub>	predicted environmental concentration in ground water
PEC <sub>sed</sub>	predicted environmental concentration in sediment
PEC <sub>soil</sub>	predicted environmental concentration in soil
PEC <sub>sw</sub>	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK <sub>a</sub>	negative logarithm (to the base 10) of the dissociation constant
P <sub>ow</sub>	partition coefficient between <i>n</i> -octanol and water
POEM	Predictive Operator Exposure Model
PPE	personal protective equipment
ppm	parts per million (10 <sup>-6</sup> )
ppp	plant protection product
PT	proportion of diet obtained in the treated area
QC	quality control
QSAR	quantitative structure-activity relationship
r <sup>2</sup>	coefficient of determination
RAC	regulatory acceptable concentration
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
t <sub>1/2</sub>	half-life (define method of estimation)
TER	toxicity exposure ratio
TER <sub>A</sub>	toxicity exposure ratio for acute exposure
TER <sub>LT</sub>	toxicity exposure ratio following chronic exposure
TER <sub>ST</sub>	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WHO	World Health Organisation
wk	week
yr	year