CONCLUSION ON PESTICIDE PEER REVIEW

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

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Prochloraz is one of the 84 substances of the third stage part B of the review programme covered by Commission Regulation (EC) No 1490/2002[3], as amended by Commission Regulation (EC) No 1095/2007[4]. In accordance with the Regulation, at the request of the European Commission, the EFSA organised a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by Ireland, being the designated rapporteur Member State (RMS). The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of prochloraz in Annex I to Council Directive 91/414/EEC.

Following the Commission Decision of 5 December 2008 (2008/934/EC)[5] concerning the non-inclusion of prochloraz in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicants BASF Agro B.V and Makhteshim Agan made a resubmission application for the inclusion of prochloraz in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[6]. The resubmission dossier included further data in response to the issues identified in the DAR.

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Ireland, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 3 August 2010.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicants for comments on 13 August 2010. The EFSA collated and forwarded all comments received to the European Commission on 30 September 2010.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission requested the EFSA to conduct a focused peer review in the areas of mammalian toxicology, residues and ecotoxicology, and to deliver its conclusions on prochloraz.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of prochloraz as a fungicide on cereals (foliar spray and seed treatment) and

[1] On request from the European Commission, Question No EFSA-Q-2010-01466, issued on 13 July 2011.
[2] Correspondence: pesticides.peerreview@efsa.europa.eu
[3] OJ L224, 21.08.2002, p.25
[4] OJ L 246, 21.9.2007, p. 19
[5] OJ L 333, 11.12.2008, p.11
[6] OJ L 15, 18.01.2008, p.5

Suggested citation: European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance prochloraz. EFSA Journal 2011; 9(7):2323. [120 pp.]. doi:10.2903/j.efsa.2011.2323. Available online: www.efsa.europa.eu/efsajournal.htm

mushrooms, as proposed by the applicants. Full details of the representative uses can be found in Appendix A to this report.

For the section identity, physical/chemical/technical properties and methods of analysis it was not possible to finalise the specification and data gaps were identified for prochloraz and the prochloraz copper complex. Data gaps were also identified for a fully validated method of analysis for products of animal origin, a method of analysis for the metabolite BTS 40348 in surface water, and clarification concerning co-formulants in two of the representative formulations.

It was not possible to conclude whether the material used in the toxicology testing is comparable to the technical specification (both missing, see section 1) leading to a data gap and a critical area of concern. A data gap was also identified for the evaluation of the studies addressing the acute toxicity of 'Mirage 45 EC' and non-dietary exposure to prochloraz in 'Mirage 45 EC'.

Based on the metabolism studies conducted on cereals, rapeseed, apple and mushroom, and considering the availability of two different analytical methods, the plant residue definition for enforcement was proposed as "sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz", and for risk assessment as "sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz". On cereals, MRLs and conversion factors were proposed for the BASF dataset only. No MRLs were proposed for cereals from the trials conducted according to the GAPs defined by Makhteshim (540 g a.s./ha), as the samples were only analysed using the common moiety method, and therefore a data gap was identified to provide a full dataset where samples are analysed according to the proposed residue definitions. For animal products, residues were defined as for plants, and MRLs and conversion factors were proposed for ruminant products only. Data gaps were identified for additional information to confirm the stability of prochloraz residues in plant and animal matrices when stored frozen. No acute or chronic risks were identified for consumers.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at the EU level for the representative uses, with the notable exception that: information is missing to confirm that the available fate and behaviour data for prochloraz are appropriate to be used to assess the copper complex and zinc complex variants of prochloraz, and exposure assessments for the representative uses on mushrooms and cereals as foliar spray at an application rate higher than 450g prochloraz/ha were not presented in the RMS assessments.

The potential for endocrine disruption effects in birds needs to be further addressed. Data gaps were also identified to further address the long-term risk to mammals and the risk to earthworm-eating mammals for the representative use as a spray on cereals at rates up to 450 g a.s./ha, and for a risk assessment for the variant zinc complex. Risk assessments for non-target species for the representative uses on cereals with dose rates above 450g a.s./ha and for the representative use on mushrooms were not presented in the RMS assessments.

KEY WORDS

Prochloraz, peer review, risk assessment, pesticide, fungicide

TABLE OF CONTENTS

BACKGROUND

Legislative framework

Commission Regulation (EC) No 1490/2002[7], as amended by Commission Regulation (EC) No 1095/2007[8] lays down the detailed rules for the implementation of the third stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC. This regulates for the European Food Safety Authority (EFSA) the procedure for organising, upon request of the Commission of the European Communities (hereafter referred to as 'the Commission'), a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State.

Commission Regulation (EC) No 33/2008[9] lays down the detailed rules for the application of Council Directive 91/414/EEC for a regular and accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC but which were not included in Annex I. This regulates for the EFSA the procedure for organising the consultation of Member States and the applicant(s) for comments on the Additional Report provided by the designated RMS, and upon request of the Commission the organisation of a peer review and/or delivery of its conclusions on the active substance.

Peer review conducted in accordance with Commission Regulation (EC) No 1490/2002

Prochloraz is one of the 84 substances of the third stage part B of the review programme covered by Commission Regulation (EC) No 1490/2002, as amended by Commission Regulation (EC) No 1095/2007. In accordance with the Regulation, at the request of the Commission, the EFSA organised a peer review of the DAR provided by the designated rapporteur Member State, Ireland, which was received by the EFSA on 26 February 2007 (Ireland, 2007).

The peer review was initiated on 18 June 2007 by dispatching the DAR to Member States and the applicant BASF Agro B.V. for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of prochloraz in Annex I to Council Directive 91/414/EEC.

Peer review conducted in accordance with Commission Regulation (EC) No 33/2008

Following the Commission Decision of 5 December 2008 (2008/934/EC)[10] concerning the non-inclusion of prochloraz in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicants BASF Agro B.V. and Makhteshim Agan made a resubmission application for the inclusion of prochloraz in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the issues identified in the DAR.

In accordance with Article 18, Ireland, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report (Ireland, 2010). The Additional Report was received by the EFSA on 3 August 2010.

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicants for comments on 13 August 2010. In addition, the EFSA conducted a public consultation on the Additional Report. The EFSA collated and forwarded all comments received to the European Commission on 30 September 2010. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table. The applicants were invited to respond to

[7] OJ L224, 21.08.2002, p.25
[8] OJ L246, 21.9.2007, p.19
[9] OJ L 15, 18.01.2008, p.5
[10] OJ L 333, 11.12.2008, p.11

the comments in column 3 of the Reporting Table. The comments and the applicants' response were evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the European Commission decided to further consult the EFSA. By written request, received by the EFSA on 4 November 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on prochloraz within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information was required to be submitted by the applicants in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicants in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission in December 2010; the applicants were also invited to give their view on the need for additional information. On the basis of the comments received, the applicants' 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, residues, and ecotoxicology and that further information should be requested from the applicants in the areas of physical and chemical properties, 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, and the additional information to be submitted by the applicants, 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 June 2011.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulations evaluated on the basis of the representative uses as a fungicide on cereals (foliar spray and seed treatment) and mushrooms, as proposed by the applicants. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report (EFSA, 2011) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

- the comments received on the DAR and the Additional Report,
- the Reporting Table (3 January 2011),
- the Evaluation Table (8 July 2011),
- the report(s) of the scientific consultation with Member State experts (where relevant),
- the comments received on the assessment of the points of clarification (where relevant),
- the comments received on the draft EFSA conclusion.

Given the importance of the DAR and the Additional Report including its addendum (compiled version of June 2011 containing all individually submitted addenda) (Ireland, 2011) 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

Prochloraz is the ISO common name for *N*-propyl-*N*-[2-(2,4,6-trichlorophenoxy)ethyl]imidazole-1-carboxamide (IUPAC).

The representative formulated products for the evaluation are the BASF products 'Sportak 45EW' an emulsion, oil in water (EW) containing 450 g/l prochloraz and 'Prelude 20 FS' a flowable concentrate for seed treatment (FS) containing 218 g/l prochloraz as a complex with copper, and the Makhteshim Agan products 'Mirage 45 EC' an emulsifiable concentrate (EC) containing 450 g/l prochloraz, and 'Mirage 450 SC' a suspension concentrate containing 450 g/l prochloraz as a complex with zinc.

The representative uses evaluated are as a fungicide on cereals either as a seed treatment (copper complex of prochloraz) or as a foliar spray (prochloraz) for the BASF formulations. The Makhteshim uses are as a foliar fungicide on cereals (prochloraz) and a casing treatment on mushrooms (zinc complex of prochloraz). The Makhteshim uses were not fully evaluated by the RMS, however it is clear that the Makhteshim dossier is not complete and this should be considered at re-registration. Full details of the GAP can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The following guidance documents were followed in the production of this conclusion: SANCO/3030/99 rev.4 (European Commission, 2000), Sanco/10597/2003 –rev. 8.1 (European Commission, 2009), and SANCO/825/00 rev. 7 (European Commission, 2004a).

The minimum purity of the active substance as manufactured cannot be concluded as the final specification for BASF prochloraz was rejected by the RMS because the minimum purity was not accepted and some of the impurity levels were not justified by the supplied batch analysis and QC data. The copper variant was not supported with a 5 batch analysis and the methods of analysis were not complete. It should be noted that prochloraz may contain dioxins and furans and the maximum specification level is 0.1 mg/kg.

An FAO specification exists for prochloraz with a minimum purity of 970 g/kg but this is only applicable to Makhteshim Agan.

The main data regarding the identity of prochloraz and its physical and chemical properties are given in Appendix A. A data gap was identified for clarification concerning co-formulants in two of the representative formulations.

It should be noted that the EW formulation is not a stable emulsion in the pesticide container. Therefore labelling the product with a phrase such as 'shake well before use' should be considered.

Prochloraz and the metabolites BTS 44595 and BTS 44596 can be analysed in products of plant origin by LC-MS/MS with an LOQ of 0.01 mg/kg for each compound. A partially validated LC-MS/MS method of analysis for products of animal origin was provided, however further validation and ILV are required. LC-MS/MS and GC-MS methods are available for soil. LC-MS/MS methods are available for water and air for prochloraz. A data gap is identified for a method of analysis for BTS 40348 in surface water. A method of analysis for body fluids and tissues is not required as the active substance is not classified as toxic or very toxic.

2. Mammalian toxicity

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

Prochloraz was discussed at the PRAPeR 86 Experts' Meeting on mammalian toxicology.

Some of the toxicological studies submitted by Makhteshim Agan were not evaluated by the RMS. During the experts' meeting half of the experts expressed the need to have access to the summary of all studies available to conclude on the risk assessment. The RMS considered the data package submitted by Makhteshim Agan as equivalent to that provided by BASF. The following conclusion has been based on the studies evaluated by the RMS and all data have been considered as a whole.

Prochloraz is used alone or as a metal complex. It was agreed at the expert meeting that prochloraz and its copper and zinc complexes are equivalent from a toxicological point of view.

Regarding the technical specification it was not possible to conclude whether the material used in the toxicology testing is comparable to the technical specification (both missing, see section 1) leading to a data gap and a critical area of concern.

Rapid absorption, wide distribution and rapid excretion of prochloraz were observed after oral administration to rats. Oral absorption was estimated at higher than 70%. There was no evidence for accumulation. The main metabolic pathway identified was initial cleavage of the imidazole followed by hydroxylation of the phenyl ring and/or side chain hydrolysis.

Low acute toxicity is observed when prochloraz is administered to rats by the dermal and inhalation routes. It is harmful if swallowed. No skin or eye irritation was observed and there was no potential for skin sensitisation.

In short-term oral studies with mice, rats and dogs, the critical effects were observed in the liver (increased liver size and weight; all species) and prostate (decreased weight; dog). The dog was the most sensitive species. The relevant short-term oral NOAEL is 2.5 mg/kg bw/d (90-d dog study).

No potential for genotoxicity is attributed to the active substance.

In long-term studies with dogs, rats and mice, the critical effects were observed in the liver (increased liver weight and histopathology). The dog was the most sensitive species. The relevant long-term NOAEL is 0.9 mg/kg bw/d (2-year dog study). Hepatocellular tumours were observed in male and female mice from a dose level of 7.5 mg/kg bw/d. Supplementary studies indicated that prochloraz could be considered as a phenobarbitone-type inducer of the hepatic mixed function system of male rats and mice. However, the non-relevance to humans could not be conclusively determined.

In two multigeneration studies with rats (Reader, 1993 and Cozens, 1982 in the Additional Report (Ireland, 2010)) overall reproductive performance was impaired following prochloraz administration to rats. Effects on reduction in body weight and body weight gain, increased liver weight and deaths were associated with dystocia and extended gestation length. Developmental toxicity was observed as reduced mean litter size, increased total litter loss, reduced live birth index, impaired growth and adverse effects on organ weights. In the study by Reader the agreed parental and reproductive NOAEL is 50 ppm (2.26 mg/kg bw/d), and the offspring NOAEL is 150 ppm (6.58 mg/kg bw/d). In the study by Cozens the agreed parental NOAEL is 150 ppm (13 mg/kg bw/d), the reproductive NOAEL is 37.5 ppm (3.1 mg/kg bw/d), and the offspring NOAEL is 150 ppm (13 mg/kg bw/d). In the developmental toxicity studies, there was no evidence of teratogenicity, and the relevant maternal and developmental NOAELs are 25 mg/kg bw/d for the rat and 40 mg/kg bw/d for the rabbit. Public literature reports effects of prochloraz on reduced anogenital distance (Vinggaard et al, 2005 in the Additional Report (Ireland, 2010)) and increased nipple retention (Christiansen et al, 2009) in rats, with the NOAEL for these effects being 30 mg/kg bw/d and 5 mg/kg bw/d, respectively.

No potential for neurotoxicity was observed in the standard toxicity studies. Non-specific neurobehavioural effects were observed in an acute neurotoxicity rat study with a clear NOAEL of 20 mg/kg bw/d.

Based on the effects described above, classification and labelling with R40 (Limited evidence of a carcinogenic effect) and R63 (Possible risk of harm to the unborn child) in addition to the current classification and labelling with R22 (Harmful if swallowed) (CLP00, Annex VI to Regulation (EC) No 1272/2008) were agreed to be proposed by the majority of experts.

The agreed acceptable daily intake (ADI) of prochloraz technical is 0.01 mg/kg bw/d, based on the NOAEL of 0.9 mg/kg bw/d found in the 2-year dog study and applying a safety factor of 100. The agreed acceptable operator exposure level (AOEL) of prochloraz technical is 0.02 mg/kg bw/d, based on the NOAEL of 2.5 mg/kg bw/d found in the 90-d dog study and applying a safety factor of 100, with 70% correction for oral absorption. The agreed acute reference dose (ARfD) of prochloraz technical is 0.025 mg/kg bw based on a NOAEL of 2.5 mg/kg bw/d considering the effects observed in the 90-day dog, multigeneration rat and 14-day dog studies, and applying a safety factor of 100.

The relevant dermal absorption values for 'Sportak 45 EW' are 4.5% for the concentrate, and 13.4% for the dilution; for 'Prelude 20 FS' 0.56% for the concentrate, and 3.9% for the dilution; for 'Mirage 45 EC' 1.23% for the concentrate, and 3.22% for the dilution; for 'Mirage 450 SC' 1.23% for the concentrate, and 3.22% for the dilution.

Considering the representative use in cereal crops (foliar spray application up to 450 g/ha) the estimated operator exposure is below the AOEL (14%) if personal protective equipment (PPE) is used during mixing, loading and application (i.e gloves during mixing and loading and coveralls and sturdy footwear during application) according to the German Model. Operator exposure is above the AOEL even with the use of PPE according to the UK POEM model. Worker exposure is below the AOEL (60%) assuming that workers wear trousers and a long sleeved shirt. Bystander exposure is below the AOEL (3.64%).

Regarding seed treatment in cereal crops the estimated operator exposure is below the AOEL (66 and 99% considering a typical and worst case scenario respectively for bagging inhalation exposure) with the use of PPE (coveralls and gloves) according to the Seed Tropex Model (UK Version). Worker exposure is below the AOEL (40%). Bystander exposure is below the AOEL (5.9%).

Operator exposure estimates in mushroom cultivation are below the AOEL (90%) if PPE (coveralls and gloves) is used during mixing, loading and application according to the Dutch Model. Worker exposure is below the AOEL (0.01%) without PPE. Bystander exposure is not expected. No exposure assessment in cereal crops (foliar application up to 540 g a.s./ha) was provided by the RMS, leading to a data gap and an issue that could not be finalised.

3. Residues

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

Plant metabolism was investigated in three plant groups; in cereals (wheat and barley), oilseeds/pulses (rapeseed) and fruit crops (apple). Most of the studies were conducted with the active substance labelled on the phenyl ring and using foliar treatments or local applications by means of micro-syringes. On cereals, a study using ^{14}C labelling on the imidazole moiety was also provided, as well as a study using seed treatment. In addition, the fate of prochloraz was also investigated in mushroom after application to the surface of the compost bed.

Following foliar applications, prochloraz is rapidly and extensively metabolised. The parent molecule is only detected in significant levels in the samples collected just after the treatment, but with a fast decrease and proportions typically below 10% TRR in the days following the application. In all plant groups, the metabolism proceeds first by the cleavage of the imidazole ring, leading to the metabolite BTS 44596 which is further degraded to the amide metabolite BTS 44595. Both compounds are the most common metabolites detected in all plant parts, representing together 15% to 45% of the TRR in

immature plant samples and up to 13% TRR in wheat grains, 43% TRR in barley grains, 25% TRR in rape seeds and 40% TRR in apples at harvest. These two metabolites undergo further degradation of the lateral side chain, giving several additional metabolites, all accounting for low proportions, with the exception of the metabolites BTS 45186 (2,4,6-TCP) and BTS 9608 which represented 25% and 10% TRR in mature rape seeds. A similar metabolic profile was seen in rotational crops where BTS 44595, BTS 44596, BTS 45186 and BTS 9608 were identified as the major components of the residue.

A comparable profile was observed in wheat following seed treatment applications where only the parent and its metabolites BTS 44595 and BTS 49596 could be identified. In contrast, little metabolism was observed in mushroom when application was done over the growing substrate, with prochloraz remaining by far the most abundant compound, representing 70% TRR 30 days after application.

The plant residue definition was intensively discussed during the PRAPeR TC 53, taking into account the two different analytical methods proposed by the applicants; the common 2,4,6-TCP moiety method and the HPLC-MS/MS L0090 method[11], developed by BASF and analysing separately prochloraz and its two main metabolites BTS 44595 and BTS 44596. For risk assessment, it was agreed to base the residue definition on the common moiety method and to define the residue as "sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz". For monitoring, considering that the common moiety method is not specific to prochloraz and not fully validated for enforcement purposes, the experts decided to base the residue definition on the L0090 method, and therefore to define the residue as: "sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz".

Numerous residue trials conducted on wheat and barley were submitted by both applicants. However, no MRLs were derived for cereals from the trials conducted according to the GAPs defined by Makhteshim Agan (540 g a.s./ha), as the samples were only analysed using the common moiety method, and a data gap was identified to provide a full dataset where samples are analysed according to the proposed residue definitions. Nevertheless, part of the Makhteshim Agan trials performed according to the GAP defined by BASF (450 g a.s./ha $\pm$25%) were considered for the calculation of the STMR and HR values used in the consumer risk assessment. The proposed MRLs for cereals were therefore derived from the BASF dataset only, where samples were analysed for both the total residues as 2,4,6-TCP and according to the L0090 method. In addition, this dataset was used to propose an overall conversion factor for risk assessment of 2.5 for cereals. On mushroom, the MRL was derived from the dataset submitted by Makhteshim Agan, where samples were analysed according to the 2,4,6-TCP moiety method, as it was agreed that the levels measured using this common moiety method represent only a slight overestimation of the levels measured with the L0090 method, as the residues in mushroom were shown to be almost exclusively composed of the parent compound (*c.a.* 70% TRR).

Storage stability studies were submitted where it was demonstrated that residues of prochloraz are stable up to 24 months in cereal grains, when stored at *ca.* -20°C and analysed for total residues as 2,4,6-TCP. In addition, prochloraz and its metabolite BTS 44595 were shown to be stable up to 8 months in wheat grain when analysed for each individual compound using the L0090 method. In contrast, the stability of the metabolite BTS 44596 was not clearly demonstrated, and a data gap was identified to provide a new study, confirming the stability of this metabolite in cereal matrices under frozen conditions. Data gaps were also identified for additional information to confirm the stability of prochloraz, BTS 44595 and BTS 44596 in animal matrices.

Prochloraz was shown to be stable under standard hydrolysis conditions simulating pasteurisation, baking and sterilisation and processing factors were proposed for barley and wheat. The TRRs measured in the rotational crops studies conducted at a 1N dose rate level, indicate that residues of

[11] HPLC-MS/MS L0090 method or modified HPLC-MS/MS L0090 method, referenced L0090/01.

prochloraz, BTS 44595 and BTS 44596 are not expected to be present above 0.01 mg/kg, except in cereals but at levels already covered by the proposed MRLs. However, for the shorter plant-back interval of 30 days, it cannot be excluded that residues above 0.05 mg/kg might be detected in some plant commodities when analysed for the total residues, using the 2,4,6-TCP common moiety method.

Intakes by animals were calculated to be above the trigger value of 0.1 mg/kg DM for beef and dairy cattle only and metabolism studies conducted on cow, goat and poultry were provided. All studies were conducted with prochloraz, although the metabolism studies have shown the parent to be extensively metabolised and not present in plants. These studies were however considered acceptable to address the fate of prochloraz in animals, as the main metabolites identified in plants are also the major metabolites in ruminant matrices.

As for plants, prochloraz was extensively metabolised and only detected in goat liver and fat, but at less than 6% TRR. Radioactive residues were mainly composed of the metabolites BTS 44596, BTS 44595 and BTS 9608, almost present in all matrices and in significant proportions, above 15% TRR. Metabolite 2,4,6-TCP was also identified as a major metabolite in cow liver (19% TRR). In addition, metabolite BTS 54906 was observed as the most abundant component in milk (58% TRR), but in the cow study only. As its presence was not confirmed in the goat metabolism, or in the cow feeding study, even at the highest dose rate (*c.a.* 45 N), it was finally concluded that BTS 54906 should not be considered as a significant metabolite in milk. Considering that BTS 44595 and BTS 44596 are relevant markers for the residues in all animal matrices and since the HPLC-MS/MS L0090 method is also applicable to animal substrates, the PRAPeR TC 53 decided to define the residue for enforcement as "sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz", as for plants. For risk assessment the residue definition was proposed as "sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz". An overall conversion factor for risk assessment of 2 was derived from the cow and goat metabolism studies, considering the respective ratios of the relevant metabolites in the different matrices.

MRLs were proposed for ruminant products from the cow feeding study where animals were dosed with prochloraz. This study is not totally appropriate to derive MRLs as the samples were analysed for total residues as 2,4,6-TCP and not according to the proposed residue definition for monitoring. However, after discussion, the experts in the PRAPeR TC 53 agreed to use these data since the metabolites BTS 44595 and BTS 44596 represent a significant part of the radioactive residues in all ruminant matrices, and therefore the levels measured in this study are acceptable overestimates of the residue levels measured using the L0090 method. Furthermore, such an approach was considered appropriate, having regard to the limited contribution of the ruminant products to the overall consumer dietary intake (<10% ADI). No MRLs were proposed for poultry matrices as it was clear from the metabolism study that significant residues are not expected to be present when the total radioactive residues in the different matrices are expressed on a 1N dose rate basis.

No chronic and acute risk for the consumers was identified. The highest IEDI and IESTI calculated using the EFSA PRIMo model and the STMRs and HRs derived for plant and animal commodities from the samples analysed for the total residues as 2,4,6-TCP, were 12% of the ADI (NL Child) and 42% of the ARfD (bovine liver), respectively.

4. Environmental fate and behaviour

The representative uses assessed (as set out in Appendix A) involve the use of 3 variants of prochloraz (prochloraz, prochloraz copper complex and prochloraz zinc complex). In the RMS assessment of the dossiers it was concluded that the copper and zinc complexes would be readily dissociated and that the studies carried out with prochloraz could be used to assess the fate and behaviour of these two metal complexes. Upon further investigation EFSA questions whether this approach can be defended when considering the available information. Stability constants (log K) for copper and zinc chelate complexes of prochloraz have been measured (experiments in the dossier) giving values of 12.31 and 12.21 respectively. This indicates that these complexes have slightly lower, but essentially comparable complex stability, to the complexes that these metals form with EDTA, a substance known

to exhibit high chelation capacity with metal ligands. T. E. Furia (1972), reports that stability constants between negative values and 1 indicate that ligands will readily dissociate and that with stability constants > 6, metal release from complexes is limited even at very acidic pH. Therefore relevant data gaps have been included in section 7 of this conclusion.

In soil laboratory incubations under aerobic conditions in the dark, prochloraz exhibited moderate to very high persistence, forming the major (>10% applied radioactivity (AR)) metabolites BTS 44596 (max. 12.8 % AR) and BTS 40348, (max. 13.9 % AR), which exhibited low to moderate and low to high persistence respectively. The metabolites M590F040 and imidazole accounted for up to 7.7% AR and 2.6% AR respectively. As M590F040 accounted for > 5% AR and is a carbamate, a groundwater exposure assessment was completed for this metabolite. In the soil where it was formed M590F040 was estimated to exhibit very low persistence. Mineralisation of the imidazole ring radiolabel to carbon dioxide accounted for 11 - 26 % AR, that of the phenyl ring was 1.9 - 31.4 % AR both after 119 to 120 days. The formation of unextractable radioactivity (not extracted by just acetonitrile or acetonitrile followed by acetone:water and acetone) accounted for 15 – 27 and 21 - 42 % AR for these radiolabels respectively, both after 119 to 120 days. In anaerobic soil incubations prochloraz was essentially stable. In a laboratory soil photolysis study BTS 44596 and BTS 44595 were formed as major metabolites accounting for up to 32 and 10.4% AR respectively. Prochloraz was essentially immobile or exhibited low mobility in soil. Its adsorption potential appeared to be reduced as soil pH increased above neutral. M590F040 was also essentially immobile or exhibited low mobility. BTS 44595 exhibited medium to slight soil mobility, BTS 44596 exhibited medium to low soil mobility. It was concluded that the adsorption of all these metabolites was not pH dependent. In satisfactory field dissipation studies carried out at 12 European sites (spray application to the soil surface on bare soil plots in late spring or early summer), prochloraz exhibited moderate to very high persistence. In addition to prochloraz, sample analyses were also carried out for BTS 44596 and BTS 44595 at 9 of the 12 sites. At these trial sites, these metabolites exhibited low to moderate persistence and high to very high persistence respectively. Degradation DT_{50} for use in simulation modelling from these trial sites were appropriately estimated, normalised to FOCUS reference conditions (20ºC and -10kPa), following FOCUS kinetics (FOCUS, 2006) guidance[12]. The results from this exercise are included in Appendix A.

In laboratory incubations in dark aerobic natural sediment-water systems, prochloraz partitioned rapidly from the water phase to the sediment and exhibited very high persistence in the whole system, forming no major metabolites. The unextractable sediment fraction (not extracted by acetonitrile followed by Soxhlet acetonitrile:water) was a relatively limited sink for the phenyl ring 14C radiolabel, accounting for 7.5 – 8.6 % AR at study end (100 days). Mineralisation of this radiolabel accounted for only around 1 % AR at the end of the study. The rate of transformation of prochloraz to BTS 44596 (accounting for 62% AR at 7 test system days) was relatively rapid in a laboratory sterile aqueous photolysis experiment (DT50 estimated at 6.4 days for central European conditions in April).

Predicted environmental concentrations (PEC) in surface water and sediment were calculated for the metabolites BTS 44595, BTS 44596 and BTS 40348 using the FOCUS surface water (FOCUS, 2001) step 1 and step 2 approach (version 1.1 of the Steps 1-2 in FOCUS calculator). Appropriate FOCUS surface water PEC for prochloraz and surface water and sediment PEC for BTS 40348 were available at step 3 (FOCUS, 2001) calculations[13]. For prochloraz sediment PEC, step 2 values were used in the risk assessment. Calculations were presented in the Addendum to the Additional Report (Ireland, 2011), which confirmed that these prochloraz step 2 sediment PEC had higher numerical values than when step 3 sediment values were used as a basis to then account for the accumulation of prochloraz that would be expected to occur in sediment. PEC surface water for prochloraz were also calculated at step 4. For the spray method of application calculations appropriately followed the FOCUS landscape and mitigation (FOCUS, 2007) and FOCUS air (FOCUS, 2008) guidance, with no-spray drift buffer

[12] The normalisation procedure utilised the Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7
[13] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

zones of up to 20 m being implemented for the drainage scenarios (representing a 58 – 92 % spray drift reduction), and combined no-spray buffer zones with vegetative buffer strips of up to 20 m (reducing solute flux and water volume in run-off by 80 % and erosion flux and sediment mass by 95%) being implemented for the run-off scenarios. For the cereal seed treatment use, the guidance contained in EFSA 2004a was followed, so dust drift was included for these prochloraz step 4 surface water exposure assessments. The SWAN tool (version 1.1.4) was appropriately used to implement these mitigation measures and add dry deposition from the air (calculated with the EVA 2.0 tool as recommended by FOCUS air) or dust drift, in these step 4 simulations.

Groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2000) scenarios and the models PEARL 3.3.3, PELMO 3.3.2 and MACRO 4.4.2[14] for the active substance prochloraz and transformation products BTS 44595, BTS 44596, BTS 40348 and M590F040. The potential for groundwater exposure from the representative uses by prochloraz and these metabolites above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios.

The relevant PEC in soil, surface water, sediment, and groundwater covering the representative uses as a cereal seed treatment and cereal foliar spray at doses up to 450g a.s./ha can be found in Appendix A. Exposure assessments (PEC calculations) for the representative uses on mushrooms and cereals as a foliar spray at 540g a.s./ha were not presented by the RMS. The fact that these assessments were absent has been identified in section 7 of this conclusion.

5. Ecotoxicology

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

The proposed technical specifications of prochloraz technical (BASF and Makhteshim Agan) were considered equivalent by the RMS, however, no technical specification was agreed during the peer review and a data gap was identified (see Section 1). Therefore, it was not possible to conclude whether the material used in the ecotoxicology testing is comparable to the technical specification, leading to a critical area of concern and a data gap. The impurities in the proposed specification were not considered to be ecotoxicologically relevant however, as noted above, the proposed specification was not accepted.

Risk assessments for non-target species using the annex II endpoints agreed by the peer review are not available in the RMS assessments for the representative uses on cereals with dose rates above 450g a.s./ha and for the representative use on mushrooms. The fact that these assessments were absent has been identified in section 7 of this conclusion..

Prochloraz is used alone or as a metal complex (prochloraz copper complex and prochloraz zinc complex). The formulation 'Prelude 20 FS' for seed treatment contains copper chloride, for which the risk assessment was finalised. However, there were no toxicity data available with the zinc complex in the ecotoxicology section. Therefore the risk assessment for non-target species was not finalised for the prochloraz zinc complex variant (which is present in the formulation 'Mirage 450 SC') and a data gap was identified for the relevant use on mushrooms.

The acute risk to insectivorous and herbivorous birds via dietary exposure was assessed as low at tier 1 for the representative use on cereals as a spray at rates up to 450g a.s./ha. For the representative use as a seed treatment on cereals, the acute risk to herbivorous birds was assessed as low at tier 1, while the acute risk to granivorous birds was assessed as high. The actual residue on treated seeds subsequent to sowing was determined by means of specific field studies, where an average percentage of 63.65% of

[14] Simulations complied with the EFSA opinion (EFSA, 2004b) and correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

the nominal loading was measured. On the basis of this finding the acute risk to granivorous birds was assessed as low.

The short-term risk to birds was assessed as low at tier 1 for the representative uses on cereals as a spray at dose rates up to 450g a.s./ha and as a seed treatment. The long-term risk to birds was assessed as low for the representative use on cereals as a spray at rates up to 450g a.s./ha based on the measured residue in cereals and arthropods, focal species, and PD refinements. The long-term risk for the representative use as a cereal seed treatment was assessed as low for herbivorous birds at tier 1, whilst the long-term risk to granivorous birds was assessed as low based on the decline of residue on cereal seeds, focal species, PD refinements, and dehusking behaviour.

Prochloraz belongs to the group of imidazole fungicides that are suspected to have potential endocrine disrupting properties. The PRAPeR 87 Experts' Meeting on ecotoxicology discussed the potential endocrine disrupting effects on birds. Indications of potential endocrine disruption effects on reproduction were found in the mammalian toxicity studies. There is no harmonised protocol for studying endocrine disrupting effects in birds. There were two reproduction studies available but neither of these targeted the investigation of endocrine disrupting effects on birds. The TER_{lt} were above but close to the Annex VI trigger, therefore, due to the lack of a margin of safety, and considering that the endpoint does not completely cover endocrine disrupting effects, a data gap was identified for the applicants to further address the endocrine disrupting effects to birds.

The acute risk to mammals via dietary exposure was assessed as low at tier 1 for the representative use as a cereal seed treatment. For the representative use on cereals as a spray at rates up to 450g a.s./ha the acute risk to insectivorous mammals was assessed as low at tier 1, while the acute risk to herbivorous mammals was assessed as low based on the use of the field residue data, focal species, and PD and PT refinements. The PRAPeR 87 Expert's Meeting on ecotoxicology discussed the potential endocrine disrupting effects on mammals. Indications of potential endocrine disruption effects on reproduction were found in the mammalian toxicity studies, and it was agreed to use the lowest available parental and reproductive endpoint of NOAEL 2.26 mg a.s./kg bw/day (based on extended gestation length) to cover the potential endocrine disrupting effects observed in mammals (see Expert Consultation 5.1 of the Evaluation Table).

The long-term risk to mammals was assessed as high based on the use of the NOAEL of 2.26 mg a.s./kg bw/day, and therefore, a data gap was identified during the PRAPeR 87 Experts' Meeting for the applicant to further refine the long-term risk assessment for mammals for the representative uses on cereals as a spray at rates up to 450g a.s./ha, and as a seed treatment. Further data to refine the risk assessment for the representative use as a spray were submitted after the PRAPeR 87 Experts' Meeting (evaluated in the addendum of April 2011 (Ireland, 2011)), however, the long-term risk was still assessed as high, based on focal species, RUD, PT and deposition factors refinements, and therefore the data gap was maintained.

Since the $logP_{ow}$ of prochloraz is 3.53, the risk of secondary poisoning to birds and mammals was assessed in the addendum of April 2011 (Ireland, 2011). The risk of secondary poisoning from prochloraz was considered to be low for birds for the representative uses on cereals as a spray at rates up to 450g a.s./ha and as a seed treatment. The risk for earthworm-eating mammals was assessed as low for the representative use as a cereal seed treatment, however the risk was assessed as high for the representative use on cereals as a spray, and therefore a data gap was identified. The risk for fish-eating mammals was assessed as low for the representative uses on cereals as a spray at rates up to 450g a.s./ha and as a seed treatment.

Based on the toxicity data available for fish, daphnia and algae, prochloraz should be considered as very toxic to aquatic organisms. A similar toxicity was observed for the active substance and the representative formulations 'Sportak 45 EW' and 'Prelude 20 FS' (contains copper chloride complex). Effects on algae (E_bC_{50} = 0.0055 mg a.s. /L) were driving the aquatic risk assessment.

The endocrine disruptive properties of prochloraz to fish were discussed at the PRAPeR 87 Experts' Meeting. Indications of potential endocrine disruption effects on reproduction were found in the fish studies submitted. The proposed NOEC (25 µg a.s./L) based on the Fish Full Life Cycle test was used, and it was questioned whether this endpoint was sufficiently protective for potential endocrine disruption effects on fish. The statistical power of the study was questioned, and it was concluded that performing statistical checks on the data from the study would be useful to determine whether the endpoint is protective. A statistical power analysis with the data was presented in the addendum of April 2011 (Ireland, 2011), and the NOEC of 25 µg a.s./L was considered reliable as a conservative endpoint, and sufficiently protective for potential endocrine disruption effects in fish.

A new aquatic risk assessment based on the use of the new PECsw was included in the addendum (Ireland, 2011). No full FOCUS step 3 scenario resulted in TERs above the Annex VI trigger values for algae for the representative use as a spray on cereals at rates up to 450g a.s./ha. At FOCUSsw step 4 the risk to algae was assessed as low for 5 out of 9 FOCUS scenarios (D2, D3, D4, D5,and D6) based on risk mitigation measures (e.g. no-spray buffer zones of 10m and vegetative run-off buffer strips reducing erosion flux and sediment mass by 85%). When risk mitigation is increased to the ceilings recommended by FOCUS (2007) (afforded by 20m no-spray buffer zones and run-off mitigated by 80% in solution and 95% as eroded soil), all 9 scenarios indicate a low risk. The risk to aquatic organisms was assessed as low at FOCUSsw step 2 for the representative use as a cereal seed treatment. A BCF-value of 371 obtained for whole fish may indicate some potential for bioaccumulation, but the risk of bioaccumulation in fish and other aquatic organisms was considered to be low for prochloraz. The risk from metabolites BTS 44595, BTS 44596, BTS 40348 and M590F040 was assessed as low for aquatic organisms for the representative uses on cereals as a spray at rates up to 450g a.s./ha and as a seed treatment.

The oral and contact HQs for bees were below the Annex VI trigger, indicating a low risk to bees for the use on cereals as a spray at rates up to 450g a.s./ha. The exposure of bees to residue of prochloraz via contaminated pollen resulting from the application of prochloraz to cereals as a seed treatment is considered to be much lower than the exposure during and after application as a spray. Therefore, the risk assessment performed for the spray application also covers the risk assessment for seed treatment.

Whereas the off-field risk was assessed as low for the two standard test species *Aphidius rhopalosiphi* and *Typhlodromus pyri*, the in-field risk was assessed as high for the representative use on cereals as a spray at rates up to 450g a.s./ha. The in-field risk assessment for *T. pyri* and *A. rhopalosiphi* was addressed based on higher tier extended laboratory tests and aged-residue studies. The risk to non-target arthropods from the representative use as a cereal seed treatment was assessed as low based on the extended laboratory studies submitted.

A new risk assessment for soil-organisms was performed based on the use of the PEC soil values reported in the Additional Report (Ireland, 2010). The risk of technical prochloraz and the soil metabolites BTS 44595, BTS 44596, and BTS 40348 to earthworms was assessed as low for the representative uses on cereals as a spray at rates up to 450g a.s./ha and as a seed treatment. The risk of prochloraz and its persistent metabolites in soil BTS 44595 and BTS 40348 to soil non-target macro-organisms was also assessed as low for these uses.

The risk of prochloraz to soil micro-organisms, non-target plants and biological methods for sewage treatment plants was assessed as low for the representative uses on cereals as a spray at rates up to 450g a.s./ha and as a seed treatment.

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

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
prochloraz	moderate to very high persistence biphasic DT_{50} 15-556 days (15-25ºC 40% MWHC soil moisture, DT90 91-2060 days) Field dissipation studies biphasic DT_{50} 0.6-73 days (DT90 55-7545 days)	The risk of prochloraz to soil organisms was assessed as low.
BTS 44595	high to very high persistence Single first-order DT_{50} 199 days (25ºC 40% MWHC soil moisture) Field dissipation studies single first-order DT_{50} 261-443 days	The risk of BTS 44595 to soil organisms was assessed as low.
BTS 44596	low to moderate persistence Single first-order DT_{50} 2.6-48.6 days (20ºC pF 2 soil moisture) Field dissipation studies single first-order DT_{50} 3.3-37 days	The risk of BTS 44596 to soil organisms was assessed as low.
BTS 40348	low to high persistence Single first-order DT_{50} 11-47 days, biphasic 5-103 days (20ºC 40% MWHC soil moisture, DT_{90} 27-402 days)	The risk of BTS 40348 to soil organisms was assessed as low.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
prochloraz	low mobility to immobile K_{Foc} 1222-8654 mL/g pH dependent	No	Yes	Yes	Very toxic to aquatic organisms, endpoint driving the aquatic risk assessment: Effects on algae (EbC50 = 0.0055 mg a.s. /L) (regulatory concentration including a safety factor of 10 = 0.00055 mg a.s./L). A low risk to the aquatic environment was identified.
BTS 44595	medium to slight mobility K_{Foc} 497-2283 mL/g	No	No	Not enough information available. Not needed.	BTS 44595 is toxic to aquatic organisms. A low risk to the aquatic environment was identified.
BTS 44596	medium to low mobility K_{Foc} 392-1749 mL/g	No	No	Not enough information available. Not needed.	BTS 44596 is toxic to aquatic organisms. A low risk to the aquatic environment was identified.
BTS 40348	low to slight mobility K_{Foc} 630-2720 mL/g	No	No	Not enough information available. Not needed.	BTS 40348 is very toxic to aquatic organisms. A low risk to the aquatic environment was identified.

M590F040	low mobility to immobile K_{Foc} 1055-7119 mL/g	No	No	No information available. Not needed.	M590F040 is very toxic to aquatic organisms. A low risk to the aquatic environment was identified.

6.3. Surface water and sediment

Compound (name and/or code)	**Ecotoxicology**
prochloraz	Very toxic to aquatic organisms, endpoint driving the aquatic risk assessment: Effects on algae (EbC50 = 0.0055 mg a.s. /L) (regulatory concentration including a safety factor of 10 = 0.00055 mg a.s./L). A low risk to the aquatic environment was identified.
BTS 44596	BTS 44596 is toxic to aquatic organisms. A low risk to the aquatic environment was identified.
BTS 40348	BTS 40348 is very toxic to aquatic organisms. A low risk to the aquatic environment was identified.

6.4. Air

Compound (name and/or code)	**Toxicology**
prochloraz	Rat LC_{50} > 2.16 mg/l (whole body, 4h)

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

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

- A revised specification for prochloraz that is supported by the available data (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see section 1).
- 5 batch analysis for the prochloraz copper complex with supporting validated methods of analysis (relevant for the representative formulation 'Prelude 20 FS'; submission date proposed by the applicant: unknown; see section 1).
- The level of ethoxylation of the co-formulants should be clarified (relevant for the representative formulations 'Sportak 45 EW' and 'Prelude 20 FS'; submission date proposed by the applicant: unknown; see section 1).
- Fully validated method of analysis for products of animal origin including ILV (relevant for the representative uses on cereals; submission date proposed by the applicants: unknown; see section 1).
- Method of analysis for BTS 40348 in surface water (relevant for all representative uses evaluated; submission date proposed by the applicants: unknown; see section 1).
- Once the specification is finalised, sufficient information is required to demonstrate compliance of the batches tested in the mammalian toxicology and ecotoxicology studies with the final specification (relevant for all representative uses evaluated; submission date proposed by the applicants: unknown; see sections 2 and 5).
- An evaluation of the studies addressing the acute toxicity of 'Mirage 45 EC', and an assessment of the non-dietary exposure to prochloraz in 'Mirage 45 EC' is not available, see section 2.
- A full residue dataset for cereals, conducted according to the GAPs proposed by Mahkteshim Agan (540g a.s./ha) and where samples are analysed according to the proposed residue definitions (relevant for the Makhteshim Agan representative uses on cereals, submission date proposed by the applicant: unknown; see section 3).
- A storage stability study for the metabolite BTS 44596 in cereal matrices covering the length of time the samples from the residue trials were stored frozen, and where samples are not analysed according to a common moiety method (relevant for the representative uses evaluated in cereals, submission date proposed by the applicants: unknown; see section 3).
- A storage stability study for prochloraz and its metabolites BTS 44595 and BTS 44596 in animal matrices where samples are not analysed according to a common moiety method (relevant for the representative uses evaluated in cereals, submission date proposed by the applicants: unknown; see section 3).
- Further information is considered necessary to conclude on whether results from studies on the route and rate of degradation in soil and natural surface water systems dosed with prochloraz might be used alone to assess the fate and behaviour of the variant prochloraz copper complex. Some studies on the variant might be necessary (relevant for used as a cereal seed treatment; submission date proposed by the applicant: unknown; see section 4).

- Further information is considered necessary to conclude on whether results from assessed studies on the route and rate of degradation in soil and natural surface water systems dosed with prochloraz might be used alone to assess the fate and behaviour of the variant prochloraz zinc complex. Some studies on the variant might be necessary (relevant for the use in mushrooms; see section 4).

- Annex III environmental exposure assessments (PEC calculations in soil, surface water, sediment and groundwater) for the representative uses on cereals with dose rates above 450g/ha and for the representative use on mushrooms, using the annex II endpoints agreed by the peer review (contained in Appendix A of the EFSA conclusion) are not available, see section 4.

- Risk assessments for wild non-target species using the annex II endpoints agreed by the peer review for the representative uses on cereals with dose rates above 450g a.s./ha and for the representative use on mushrooms are not available, see section 5.

- The risk assessment of the variant zinc complex to non-target species should be addressed (relevant for the representative use on mushrooms; submission date proposed by the applicant: unknown; see section 5).

- Further information to address the long-term risk to mammals (relevant for the representative uses on cereals as a spray at rates up to 450g a.s./ha and as a seed treatment; submission date proposed by the applicant: unknown; see section 5).

- Further information to address the endocrine disrupting effects on birds (relevant for all representative uses evaluated; submission date proposed by the applicants: unknown; see section 5).

- Further information to address the risk to earthworm-eating mammals (relevant for the representative use in cereals as a spray at rates up to 450g a.s./ha; submission date proposed by the applicant: unknown; see section 5).

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

- The EW formulation is not a stable emulsion in the pesticide container. Therefore labelling the product with a phrase such as ‘shake well before use’ should be considered.

- Considering the representative use in cereal crops (foliar spray application up to 450 g a.s./ha) the estimated operator exposure is below the AOEL if personal protective equipment (PPE) is used during mixing, loading and application (i.e. gloves during mixing and loading and coveralls and sturdy footwear during application) according to the German Model. Worker exposure is below the AOEL assuming that workers wear trousers and a long sleeved shirt (see section 2).

- Regarding seed treatment in cereal crops, the estimated operator exposure is below the AOEL with the use of PPE (coveralls and gloves) according to the Seed Tropex Model (see section 2).

- Operator exposure estimates in mushroom cultivation are below the AOEL if PPE (coveralls and gloves) is used during mixing, loading and application according to the Dutch Model (see section 2).

- Risk mitigation measures comparable to no-spray buffer zones and vegetated run-off buffer strips up to 10m are required to identify a low risk for aquatic organisms for 5 out of 9 FOCUS scenarios (D2, D3, D4, D5,and D6) for the use on cereals as a spray at rates up to 450g a.s./ha. When risk mitigation is increased to the ceilings recommended by FOCUS (2007) (afforded by 20m no-spray buffer zones and run-off mitigated by 80% in solution and 95% as eroded soil), all 9 FOCUS scenarios indicate a low risk (see section 5).

9. Concerns

9.1. Issues that could not be finalised

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

1. The human non-dietary risk assessment for the representative uses on cereals as a foliar spray at application rates above 450g a.s./ha, could not be finalised (see section 2).

2. Conclusions on the groundwater exposure potential and other environmental exposure and consequent environmental risk assessments for the representative uses on mushrooms and cereals as a foliar spray at application rates above 450g a.s./ha, could not be finalised, since these assessments were not presented by the RMS.

3. The environmental exposure assessments for prochloraz copper complex and prochloraz zinc complex could not be finalised. Consequently the groundwater exposure assessment for these two variants was not finalised. The risk assessment to wild non-target species was not finalised for the prochloraz zinc complex variant.

4. The assessment of endocrine disrupting effects on birds could not be finalised.

9.2. Critical areas of concern

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

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

5. There was no agreed specification (see section 1), and it was not possible to establish whether the batches tested in the mammalian toxicology and ecotoxicology studies were in compliance with the proposed specification by BASF and Makhteshim Agan (see sections 2 and 5).

10. Overview of the assessments for each representative use considered

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

In addition to the issues identified in the table below, all columns are grey as it was not possible to conclude whether the material used in the mammalian toxicology and ecotoxicology testing that was used to derive the reference values is comparable to any technical specification (both finalised specifications and comparison of toxicology and ecotoxicology batches to proposed specifications are missing).

Representative use		**cereal seed treatment**	**foliar spray cereals dose up to 450g a.s./ha**	**foliar spray cereals dose 540g a.s./ha**	**spray to compost in mushrooms**
Operator risk	Risk identified				
	Assessment not finalised			X[1]	
Worker risk	Risk identified				
	Assessment not finalised			X[1]	
Bystander risk	Risk identified				
	Assessment not finalised			X[1]	
Consumer risk	Risk identified				
	Assessment not finalised				
Risk to wild non target terrestrial vertebrates	Risk identified	X	X	X	
	Assessment not finalised				X[2,3]
Risk to wild non target terrestrial organisms other than vertebrates	Risk identified				
	Assessment not finalised			X[2]	X[2,3]
Risk to aquatic organisms	Risk identified				
	Assessment not finalised			X[2]	X[2,3]
Groundwater exposure active substance	Legal parametric value breached				
	Assessment not finalised	X[3]		X[2]	X[2,3]
Groundwater exposure metabolites	Legal parametric value breached				
	Parametric value of 10µg/L[(a)] breached				
	Assessment not finalised	X[3]		X[2]	X[2,3]

The superscript numbers in this table relate to the numbered points indicated as concerns

(a): Value for non relevant metabolites prescribed in SANCO/221/2000-rev 10-final, European Commission, 2003

REFERENCES

Christiansen S, Scholze M, Dalgaard M, Vinggaard AM, Axelstad M, et al. 2009 Synergistic Disruption of External Male Sex Organ Development by a Mixture of Four Antiandrogens. Environ Health Perspect 117(12): doi:10.1289/ehp.0900689.

EFSA (European Food Safety Authority), 2011. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance prochloraz.

Furia T. E., 1972. Chapter 6, Sequestrants in Foods, In CRC handbook of food additives, 2nd Ed. 1972. ISBN 9780878195428.

Ireland, 2007. Draft Assessment Report (DAR) on the active substance prochloraz prepared by the rapporteur Member State Ireland in the framework of Directive 91/414/EEC, January 2007.

Ireland, 2010. Additional Report to the Draft Assessment Report on the active substance prochloraz prepared by the rapporteur Member State Ireland in the framework of Commission Regulation (EC) No 33/2008, July 2010.

Ireland, 2011. Final Addendum to the Additional Report on prochloraz, compiled by EFSA, June 2011.

Guidance documents[15]:

EFSA, 2004a. Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA on the appropriateness of using the current FOCUS surface water scenarios for estimating exposure for risk assessment in aquatic ecotoxicology in the context of Council Directive 91/414/EEC1. The EFSA Journal (2004) 145.

EFSA, 2004b. Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS groundwater models comparability and the consistency of this risk assessment of groundwater contamination. The EFSA Journal (2004) 93.

EFSA, 2007. Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA related to the default *Q*10 value used to describe the temperature effect on transformation rates of pesticides in soil. The EFSA Journal (2007) 622.

EFSA, 2009. Guidance Document on Risk Assessment for Birds and Mammals on request of EFSA. EFSA Journal 2009; 7(12):1438.

European Commission, 1999. Guidelines for the generation of data concerning residues as provided in Annex II part A, section 6 and Annex III, part A, section 8 of Directive 91/414/EEC concerning the placing of plant protection products on the market, 1607/VI/97 rev.2, 10/6/1999.

European Commission, 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre- and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414. SANCO/3030/99 rev.4, 11 July 2000.

European Commission, 2002a. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev.2 final, 17 October 2002.

European Commission, 2002b. Guidance Document on Aquatic Ecotoxicology Under Council Directive 91/414/EEC. SANCO/3268/2001 rev 4 (final), 17 October 2002.

European Commission, 2002c. Guidance Document on Risk Assessment for Birds and Mammals Under Council Directive 91/414/EEC. SANCO/4145/2000.

[15] For further guidance documents see http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#council (EC) or http://www.oecd.org/document/59/0,3343,en_2649_34383_1916347_1_1_1_1,00.html (OECD)

European Commission, 2004a. Guidance document on residue analytical methods. SANCO/825/00 rev. 7, 17 March 2004.

European Commission, 2004b. Guidance Document on Dermal Absorption. SANCO/222/2000 rev. 7, 19 March 2004.

European Commission, 2009. Guidance Document on the Assessment of the Equivalence of Technical Materials of Substances Regulated under Council Directive 91/414/EEC. SANCO/10597/2003 – rev. 8.1, May 2009.

FOCUS, 2000. "FOCUS Groundwater Scenarios in the EU review of active substances". Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference SANCO/321/2000-rev.2. 202 pp, as updated by the Generic Guidance for FOCUS groundwater scenarios, version 1.1 dated April 2002.

FOCUS, 2001. "FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC". Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp.

FOCUS (2006). "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration" Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp.

FOCUS (2008). "Pesticides in Air: Considerations for Exposure Assessment". Report of the FOCUS Working Group on Pesticides in Air, EC Document Reference SANCO/10553/2006 Rev 2 June 2008.

FOCUS, 2007. "Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.

JMPR, 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Rome, Italy, 20–29 September 2004, Report 2004, 383 pp.

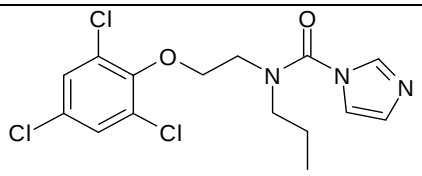
JMPR, 2007. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, Geneva, Switzerland, 18–27 September 2007, Report 2007, 164 pp.

SETAC (Society of Environmental Toxicology and Chemistry), 2001. Guidance Document on Regulatory Testing and Risk Assessment procedures for Plant Protection Products with Non-Target Arthropods. ESCORT 2.

APPENDICES

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

Chapter 2.1 Identity, Physical and Chemical Properties, Details of Uses, Further.

Active substance (ISO Common Name) ‡	Prochloraz
Function (e.g. fungicide)	Fungicide
Rapporteur Member State	Ireland
Co-rapporteur Member State	-
Identity (Annex IIA, point 1)	
Chemical name (IUPAC) ‡	*N*-propyl-*N*-[2-(2,4,6-trichlorophenoxy)ethyl]imidazole-1-carboxamide
Chemical name (CA) ‡	*N*-propyl-*N*-[2-(2,4,6-trichlorophenoxy)ethyl]-1*H*-imidazole-1-carboxamide
CIPAC No ‡	407
CAS No ‡	67747-09-5
EC No (EINECS or ELINCS) ‡	266-994-5
FAO Specification (including year of publication) ‡	970 g/kg min (2009)[1]
Minimum purity of the active substance as manufactured ‡	Open
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Dioxins and furans max. content 0.1 mg/kg. Open for others
Molecular formula ‡	$C_{15}H_{16}Cl_3N_3O_2$
Molecular mass ‡	376.7 g/mol
Structural formula ‡	

[1] FAO/WHO evaluation report based on submission of information from Makhteshim Chemical Works Ltd., Israel (TC, TK, EC, SC)

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	46.3 – 50.3°C (99.0%)
Boiling point (state purity) ‡	Due to the thermal decomposition of the test substance it was not possible to determine the boiling point under normal pressure (99.0%)
Temperature of decomposition (state purity)	Two measurements showed an endothermic effect (melting) in the temperature range 30 - 65°C and a broad exothermal effect in the temperature range 220-450 °C with an energy of 641 and 899 J/g respectively (99.0%)
Appearance (state purity) ‡	White solid (>99 %)
	Technical material: Light brown buff coloured, waxy solid (97.3%)
Vapour pressure (state temperature, state purity) ‡	1.5×10^{-4} Pa at 25 °C (>99.0 %)
Henry's law constant ‡	1.64×10^{-3} Pa m^3 mol^{-1}
Solubility in water (state temperature, state purity and pH) ‡	34.4 mg/l at 25 °C (neutral pH) (99.5 %) 26.5 mg/l at 20°C (purified water) (99.3%) 27.6 mg/l, 24.9 mg/l & 23.6 mg/l at 20°C (pH 5, pH 7 & pH 9 respectively) (99.3%)
	There is almost no effect of pH on the solubility of Prochloraz.
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility (g/100 ml) at 25 °C (>99.0 %): Acetone: > 250 g/L Dichloromethane: > 250 g/L Ethanol: > 250 g/L Ethyl acetate: > 250 g/L Hexane: 7.5 g/L Methanol: > 250 g/L Propan-2-ol: > 250 g/L Toluene: > 250 g/L p-xylene: > 250 g/L
Surface tension ‡ (state concentration and temperature, state purity)	53.07 mN/m at 20 °C (90 % saturated solution) (97.3 %)
Partition co-efficient ‡ (state temperature, pH and purity)	log $P_{O/W}$ = 3.52 at 25 °C (pH 7.8 (99.0 %)) log $P_{O/W}$ = 3.53 at 25 °C (pH 6.7 (99.0 %)) log $P_{O/W}$ = 3.50 at 25 °C (pH 4.3 (99.0 %)) log $P_{O/W}$ = 4.4 at 20-25 °C (pH 9 (98.7 %)) log $P_{O/W}$ = 4.3 at 20-25 °C (pH 7 (98.7 %)) log $P_{O/W}$ = 4.3 at 20-25 °C (pH 4 (98.7 %))
	No dependence of the log $P_{o/w}$ on the pH was observed.
Dissociation constant (state purity) ‡	pKa = 3.8 at 20.3 ± 0.1 °C (>99.0%)

UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	pH 1.4 solution (99.0 %): λ_{max} 300 (nm); ε = 23 (l/ mol*cm) pH 7.1 solution (99.0 %): λ_{max} 300 (nm); ε = 103 (l/ mol*cm) pH 12.8 solution (99.0 %): λ_{max} 300 (nm); ε = 58 (l/ mol*cm)
Flammability ‡ (state purity)	Not flammable (97%).
Explosive properties ‡ (state purity)	Not explosive (96.8%)
Oxidising properties ‡ (state purity)	Not oxidising (96.8%)

The following data have been removed because they are mentioned in the fate and behaviour section:
– Hydrolytical stability
– Photolytical stability
– Quantum yield of direct phototransformation

The relative density was deleted from the list of end points as it is not used to any great extent.

Summary of representative uses evaluated (*Prochloraz - BASF*)*

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 (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		
Cereals/TS	N & S Europe	PRELUDE 20 FS	F	*Pyrenophora spp* *Fusarium spp* *Septoria spp* *Tilletia spp* *Ustilago spp*	FS	218 g/lPZ	Seed treatment	BBCH00	1	n.a.	100 mL /100 kg seeds	1 L water / 100 kg seeds (range 0.8 – 1.2)	20 g a.s./100 kg seeds (estimated to equate to 0.033kg a.s./ha)	n.a.	Drilling rate of 180 kg seeds/ha used to estimate the dose rate per ha
Cereals/Foliar	N & S Europe	Sportak 45EW	F	*Pseudocercosporella herpotrichoïdes* *Helmonthosporium* *Rhynchosporium spp,* *Septoria spp,* *Erysiphe spp* *Powdery mildew* *Pyrenophora teres* *Fusarium spp*	EW	450 g/l	Spray	BBCH30-31 BBCH39-59	1-2	14	0.1125-0.225	200 - 400	0.450	35 - 42	

Remarks :
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. bittin and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. vegetable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph N°2, 1989
(f) All abreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench…
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment must be indicated
(i) g/kg or g/l
(j) Growth stage at least 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) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI - minimum Pre-Harvest Interval
(m) Remarks may include : extent of use/economic importance/restrictions

Summary of representative uses evaluated (*Prochloraz - Makhteshim*)*

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 (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	g as/ha min-max		
Wheat	North EU	Mirage 45 EC	F	Pseudocercosporella herpetrichoides	EC	450 g/l	Spraying	BBCH 30-32	1	Not relevant	0.113-0.180	300-400	450-540	F[1]	
Wheat	North EU	Mirage 45 EC	F	Pseudocercosporella herpetrichoides Septoria spp	EC	450 g/l	Spraying	BBCH 30-59 A1: BBCH 30-39 A2: BBCH 39-59	1-2	10-21 days	0.113-0.180	300-400	450-540	35-42	
Wheat	South EU	Mirage 45 EC	F	Pseudocercosporella herpetrichoides	EC	450 g/l	Spraying	BBCH 30-32	1	Not relevant	0.113-0.180	300-400	450-540	F[1]	
Wheat	South EU	Mirage 45 EC	F	Pseudocercosporella herpetrichoides Septoria spp	EC	450 g/l	Spraying	BBCH 30-59	1-2	10-21 days	0.113-0.180	300-400	450-540	35-42	
Barley	North EU	Mirage 45 EC	F	*Pyrenophora teres* *Erysiphe graminis* *Rhynchosporium Secalis*	EC	450 g/l	Spraying	BBCH 30-49	1	Not relevant	0.113-0.180	300-400	450-540	F[1]	
Barley	South EU	Mirage 45 EC	F	*Pyrenophora teres* *Erysiphe graminis* *Rhynchosporium Secalis*	EC	450 g/l	Spraying	BBCH 30-49	1	Not relevant	0.113-0.180	300-400	450-540	F[1]	
Mushrooms	EU	Mirage 450 SC	I	*Verticillium fungicola*	SC	450 g/l (expressed as Prochloraz)	Soil spraying	Start of fructification	1	Not relevant	0.150-0.300	1500-3000	4500 (0.45 g/m^2)	10	

Remarks: F[1]: The pre-harvest interval for the envisaged area of application is covered by the application conditions and/or growing period remaining between the envisaged application and harvest; it is not necessary to lay down/indicate PHI.

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. bittin and sucking insects, soil born insects, foliar fungi, weeds
(d) e.g. vegetable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph N°2, 1989
(f) All abreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench…
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment must be indicated
(i) g/kg or g/l
(j) Growth stage at least 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) The minimum and maximum number of applications possible under practical conditions of use must be provided
(l) PHI - minimum Pre-Harvest Interval
(m) Remarks may include : extent of use/economic importance/restrictions

Chapter 2.2 Methods of Analysis

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

Technical as (analytical technique)	CIPAC MT 4565[1]. HPLC - UV
Impurities in technical as (analytical technique)	HPLC - UV and GC with FID. Confirmed by LC-MS/MS or GC/MS
Plant protection product (analytical technique)	HPLC - UV

[1] Also applicable to analysis of Prochloraz Zn complex

Analytical methods for residues (Annex IIA, point 4.2)

Residue Definitions For Monitoring Purposes

Food of plant origin	The residue definition for food of plant origin is "Sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz".
Food of animal origin	The residue definition for food of animal origin is "Sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz".
Soil	Prochloraz
Water surface	Prochloraz and BTS 40348
drinking/ground	Prochloraz
Air	Prochloraz

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	LC/MS/MS (LOQ = 0.01 mg/kg)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	LC/MS/MS (LOQ = 0.01 mg/kg) partially validated. Open for full validation and ILV.
Soil (analytical technique and LOQ)	LC-MS/MS (LOQ = 0.01 mg/kg) GC-MS (LOQ = 0.01 mg/kg)
Water (analytical technique and LOQ)	LC-MS/MS (LOQ = 0.05 µg/L) – Surface and drinking water. Open for a method for BTS 40348 in surface water
Air (analytical technique and LOQ)	LC-MS/MS (LOQ = 0.30 µg/m^3)
Body fluids and tissues (analytical technique and LOQ)	No methods of analysis for Prochloraz for body fluids and tissue were submitted by either applicant on the basis that prochloraz is not classified as toxic or very toxic.

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

	RMS/peer review proposal
Active substance	Prochloraz is not explosive, oxidising or flammable and is not classified from a phys.chem. point of view.

Chapter 2.3 Impact on Human and Animal Health

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

Rate and extent of absorption:	Rapidly absorbed, > 70% within 48 hours.
Distribution:	Widely distributed, highest residues associated with the organs of elimination (kidney and liver).
Potential for accumulation:	No evidence for bioaccumulation.
Rate and extent of excretion:	In male rats the main route of excretion is via the urine with levels ranging from 45% to 72% (low single dose-high multiple dose). In females the main route of elimination varies depending on exposure type. Single doses are primarily excreted via the faeces, however, the route of excretion can vary according to dose level in multi-dose studies. High multi-doses favour excretion via the urine.
Metabolism in animals	Extensively metabolised with an initial cleavage of the imidazole followed by hydroxylation of the phenyl ring and/or side chain hydrolysis.
Toxicologically significant compounds (animals, plants and environment)	Parent compound

Acute toxicity (Annex IIA, point 5.2)

	Prochloraz		Prochloraz-Copper	
Rat LD_{50} oral	1,023 mg/kg bw	**Xn:R22**	>2000 mg/kg bw	
Rat LD_{50} dermal	2,100 mg/kg bw		>5000 mg/kg bw	
Rat LC_{50} inhalation	> 2.16 mg/l (whole body, 4h)		No data.	
Skin irritation	Not irritant		Not irritant	
Eye irritation	Not irritant		Not irritant	
Skin sensitisation (test method used and result)	Non-sensitising (M&K)		Non-sensitising (M&K)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Dogs, mice, rats: ↑ liver size/weight Dogs: ↓ prostate weight	
Lowest relevant oral NOAEL	Dogs: 2.5 mg/kg bw/day Mice: 6 mg/kg bw/day (males) Rats:6 mg/kg bw/day	
Lowest relevant dermal NOAEL	1000 mg/kg bw/day (21 day rat study) based on intracytoplasmic inclusions of the renal cortical epithelium (males)	
Lowest relevant inhalation NOAEL / NOEL	Not relevant	

Genotoxicity (Annex IIA, point 5.4)

Prochloraz	No genotoxic potential	
Prochloraz-Copper	Ames test: Negative	

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

Target/critical effect	Dogs, rat and mice: ↑ liver weight and histopathology	
Lowest relevant NOAEL	Dogs: 0.9 mg/kg bw/d Rat:-5.1 mg/kg bw/d Mice:7.5 mg/kg bw/d	
Carcinogenicity	No evidence in the rat. Hepatocellular tumours in the mouse	**Cat 3; Xn: R40**

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Parental:↓ body weight and body weight gain, mortality, ↑ liver weight, ↑ adverse clinical signs. Reproductive: Extended gestation and dystocia Offspring: ↓ mean litter size & weight from birth to weaning, ↑ total litter loss, ↓ live birth index, impaired growth & adverse effects on organ weights	**Cat 3 R63**
Relevant parental NOAEL ‡	2.26 mg/kg bw/day (Reader, 1993) 13 mg/kg bw/day (Cozens et al, 1982)	
Relevant reproductive NOAEL ‡	2.26 mg/kg bw/day (Reader, 1993) 3.1 mg/kg bw/day (Cozens et al, 1982)	
Relevant offspring NOAEL ‡	6.58 mg/kg bw/day (Reader, 1993) 13 mg/kg bw/d (Cozens et al, 1982)	

Developmental toxicity

Developmental target / critical effect ‡	Maternal: Rat and rabbits: ↓ body weight gain and food consumption, ↑ liver weight Developmental: Rat:↓ litter size, implantation & viability index & ↑ number of dead foetuses. ↓ Mean foetus weight Rabbit: ↑ foetal resorptions	
Relevant maternal NOAEL ‡	Rat: 25 mg/kg bw/d Rabbit: 40 mg/kg bw/d	
Relevant developmental NOAEL ‡	Rat: 25 mg/kg bw/d Rabbit: 40 mg/kg bw/d	

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	Rat: Non-specific neurobehavioural effects NOAEL= 20 mg/kg bw/day	
Repeated neurotoxicity ‡	No data-not required	
Delayed neurotoxicity ‡	No data-not required	

Other toxicological studies (Annex IIA, point 5.8)

Studies performed on metabolites or impurities ‡	
Metabolism of BTS 44 596	Rapid excretion (48h) via urine (>50% m/f). Low tissue residues
Acute oral (rat) $LD_{50,}$ BTS 44 595/596	LD_{50} > 3,200 mg/kg bw
Acute oral (rat) $LD_{50,}$ BTS 19036	LD_{50} > 800 < 1,600 mg/kg bw
Ames test BTS 44 595/596	Not genotoxic
Mechanism studies ‡	
Cholinesterase activity of Prochloraz	No evidence in rat or dog
Liver induction of Prochloraz	Potent phenobarbitone-type inducer of hepatic MFOs
Chloracnegenic potential	Prochloraz showed no evidence of such

Medical data (Annex IIA, point 5.9)

No adverse health effects have been observed in Prochloraz plant operators since BASF has owned the product. Specific signs of poisoning or clinical tests are not known. No specific antidote is known. Consult safety data sheet/precautions and treatment should be symptomatic and supportive.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI	**0.01mg/kg bw/day**	Two-year dog study	100
AOEL systemic	**0.02 mg/kg bw/day**	90-day dog study	125*
ARfD (Acute Reference Dose)	**0.025 mg/kg bw**	90-day dog, multigeneration rat and 14-day dog studies	100

*Correction for low oral absorption (70 %).

Dermal absorption (Annex IIIA, point 7.3) BASF

Estimated human *in vivo* dermal absorption	Sportak 45 EW: 4.5% for the concentrate, 13.4% for the dilution. Prelude 20FS: 0.56% for the concentrate, 3.9% for the dilution

Dermal absorption (Annex IIIA, point 7.3) MAK

In vitro dermal absorption, human	Mirage 45 EC: 1.23% for the concentrate, 3.22% for the dilution. Mirage 450 SC: 1.23% for the concentrate, 3.22% for the dilution.

Exposure scenarios (including method of calculation): **Cereal crops (foliar spray application up to 450 g/ha)** (Sportak 45 EW)

Operator	Below the AOEL (14%) if PPE is worn during M&L&A (German BBA model)
Workers	Below the AOEL (60%) assuming the use of trousers and long sleeved shirt (German BBA model (Biologische Bundesanstalt) [Hoernicke E. et al.; 1998])
Bystanders	Below the AOEL (3.64%) (Lloyd & Bell 1983, EPPO

	(2000) and UK & German Bystander model of exposure)

Exposure scenarios (including method of calculation): **Seed treatment in cereal crops** (Prelude 20 FS)

Operator	Below the AOEL (66-99%) with PPE (Seed Tropex Model)
Workers	Below the AOEL (40%) (Seed Tropex Model)
Bystanders	Below the AOEL (5.9%) (Seed Tropex Model)

Exposure scenarios (including method of calculation): **Mushroom cultivation** (Mirage 450SC)

Operator	Below the AOEL (90%) when PPE is worn (Dutch Greenhouse model)
Workers	Worker exposure is below the AOEL (0.01%) without PPE
Bystanders	Bystander exposure is not expected

Exposure scenarios (including method of calculation):): **Cereal crops (foliar spray application up to 450 g/ha) (**Mirage 45 EC)

Operator	No assessment provided.
Workers	No assessment provided.
Bystanders	No assessment provided.

Classification and proposed labelling

	peer review proposal
Substance classified - Prochloraz	**Xn; R22;** Harmful if swallowed **Cat 3: Xn; R40;** Limited evidence of a carcinogenic effect **Cat 3: Xn R63;** Possible risk of harm to the unborn child

Chapter 2.4: 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, barley) foliar treatment - Cereals (wheat) seed treatment - Oilseeds (rapeseed) foliar treatment - Fruit crops(apple) application to individual fruits - Mushrooms application to the compost bed
Rotational crops	Wheat, spring barley, cabbage, lettuce, radishes and potato.
Metabolism in rotational crops similar to metabolism in primary crops?	The main metabolites observed in rotational crops (BTS 44595, BTS 44596, BTS 45186 and BTS 9608) are also the major metabolites in the primary crop studies.
Processed commodities	Standard hydrolysis studies corresponding to pasteurisation, baking /brewing/boiling and sterilisation.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Prochloraz stable under standard hydrolytic conditions.
Plant residue definition for monitoring	Sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz
Plant residue definition for risk assessment	Sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz
Conversion factor (monitoring to risk assessment)	Cereals: 2.5 Mushrooms: 1

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

Animals covered	Cow, Goat and poultry
Animal residue definition for monitoring	Sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz
Animal residue definition for risk assessment	Sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz
Conversion factor (monitoring to risk assessment)	Ruminant products: 2 Derived from the ratios (prochloraz + BTS 44595 + BTS 44596) / (Compounds containing 2,4,6-TCP moiety) observed in the cow and goat metabolism studies.
Metabolism in rat and ruminant similar (yes/no)	Yes.
Fat soluble residue: (yes/no)	Yes. Prochloraz and its main animal metabolites BTS 44595 and BTS 44596 are fat soluble (log $P_{O/W}$ = 3.5 to 4.4). Moreover, residue levels significantly higher in fat than in muscle.

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

- For plant back intervals of 120 and 365 days and application at a1N dose rate on bare soil, TRRs ≤0.02 mg/kg in lettuce and radish roots except in cereal forage (0.05 mg/kg) and straw (0.43 mg/kg).

- For plant back interval of 30 days and application at a 1N dose rate on bare soil, TRRs in the range of 0.02 to 0.16 mg/kg in cabbage, lettuce, radish root and leaves. Individual values for prochloraz, BTS 44595 and BTS 44596 <0.01 mg/kg, except for BTS 44595 in radish roots (0.018 mg/kg).

- For plant back intervals >200 days and application at a 1N dose rate on a cereal grown as a primary crop, TRRs <0.01 mg/kg in potato tubers and winter wheat sown as rotational crop.

No residues expected above the LOQ (<0.03 mg/kg) in rotational crops when samples analysed according to the residue definition for enforcement, except in cereal straw. Potential values close to the LOQ of 0.05 mg/kg in some crops for the plant back interval of 30 days, when analysed for total residues as 2,4,6-TCP.

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

Studies conducted with incurred residues (-20°C):
When analysed for total residues as 2,4,6-TCP, residues stable up to:
- 24 months in cereal grains, maize leaves,
- 12 months in sugar beets

Samples spiked with prochloraz, BTS 44595 and/or BTS 44596 (-18°C or -20°C):
When analysed for total residues as 2,4,6-TPC, residues stable up to:
- 36 months in rape seeds,
- 18 months in cereal grains
- 12 months in animal matrices (muscle, milk & egg)

Studies where samples are spiked and analysed for the individual compounds using the L0090 method (-18°C):
- Prochloraz and BTS 44595 stable up to 8 months in wheat grain, orange, rape seed and lettuce. Stability of BTS 44596 questionable. New study required (data gap).
- Prochloraz and BTS 44596 stable up to 5 months in milk (data gap: further information in other animal matrices required and for metabolite BTS 44595).

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	**Yes** 2.2 / 5.4 mg/kg DM dairy/beef cattle	No. 0.06 mg/kg DM	No 0.07 mg/kg DM
Potential for accumulation (yes/no):	Yes	No	Not required.
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	Yes	No	Not required.
	Cattle feeding studies: Lowest dose level of 200 mg/animal/day corresponding to a 4.6 N and 2.5 N dose level for dairy and beef cattle, respectively. **Residue levels in matrices:** Mean (max) mg/kg analysed for total residues as 2,4,6-TCP expressed as prochloraz		
Muscle	<0.05 (<0.05)	Not required.	Not required.
Liver	2.8 (3.3)	Not required.	Not required.
Kidney	0.52 (0.59)	Not required.	Not required.
Fat	0.16 (0.24)	Not required.	Not required.
Milk	0.05*		
Eggs		Not required.	

* Set at the LOQ of the method.

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 Region. field	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according representative use	HR (mg/kg) (c)	STMR (mg/kg) (b)
Residue levels expressed according to the residue definition for monitoring (sum prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz) (Samples analysed using the BASF HPLC-MS/MS L0090 or L0090/01 method)						
Wheat grain	N-EU	10x <0.03, 004	Only BASF trials were considered to derive MRLs for wheat and barley as the samples from the Makhteshim Agan (MAK) trials were not analysed according to the proposed residue definition for monitoring.	0.05	0.04	0.03
	S-EU	9x <0.03 (0.37, Sp trial, considered as an outlier)				
Wheat straw	N-EU	0.39, 0.52, 0.57, 0.69, 0.97, 0.99, 0.99, 1.11, 1.13, 1.20, 1.67		-	1.67	0.99
	S-EU	0.59, 0.74, 1.02, 1.18, 1.39, 1.60, 2.28,2.42, 3.28		-	3.28	1.39
Barley grain	N-EU	2x <0.03, 2x 0.03, 004, 3x 0.05, 2x 0.06, 0.09	R_{ber}: 0.12, R_{max}: 0.10	0.10	0.09	0.05
	S-EU	5x <0.03, 2x 0.03, 2x 0.04 (0.60, Sp trial, considered as an outlier)	R_{ber}: 0.07, R_{max}: 0.05		0.04	0.03
Barley straw	N-EU	0.50, 0.52, 0.60, 0.63, 0.89, 0.93, 1.12, 1.32, 1.76, 1.88, 2.06		-	2.06	0.93
	S-EU	0.28, 0.46, 0.68, 1.08, 1.09, 1.11, 1.17, 1.24, 1.33		-	1.33	1.09
Wheat grain	N+S-EU	6x <0.03 (seed treatment)	Foliar applications more critical.	-	0.03	0.03
Residue levels expressed according to the residue definition for risk assessment (prochloraz plus metabolites containing the 2,4,6-TCP expressed as prochloraz) (Samples analysed using the 2,4,6,-TCP common moiety method)						
Wheat grain	N-EU	11x <0.05 (BASF) 4x <0.04, 7x <0.05, 0.05 (MK)	The results from the Makhteshim Agan (MAK) residue trials performed according to the BASF GAPs (2x 450 g a.s./ha ±25%) were taken into account in order to calculate the STMR and HR values for consumer risk assessment (total residues as 2,4,6-TCP). BASF values are not sorted in increasing order but respecting the order of the trials as above for monitoring.	-	0.14	0.05
	S-EU	8x <0.05, 0.05 (BASF) <0.04, 3x <0.05, 0.06, 0.07, 0.137 (MAK)				
Wheat straw	N-EU	0.76, 0.66, 1.50, 1.70, 1.70, 3.50, 1.70, 2.40, 1.30, 4.0, 2.3 (BASF) <0.04, 0.13, 0.14, 0.20, 0.30, 1.8, 3.6, 4.4, 5.3, 5.9, 9.2 (MAK)		-	9.2	1.70
	S-EU	1.0, 1.9, 2.0, 2.4, 1.8, 1.9, 4.0, 2.3, 4.8 (BASF) 0.3, 4.1, 4.6, 5.9, 6.1, 6.6, 8.5 (MAK)		-	8.5	3.2
Barley grain	N-EU	4x <0.05, 2x 0.07, 2x 0.08, 0.11, 0.12, 0.16 (BASF) 0.023, <0.04, 0.04, 0.06, 0.07 (MAK)		-	0.16	0.07
	S-EU	6x <0.05, 2x 0.06, 0.11 (BASF) 3x <0.04 (MAK)		-	0.11	0.05
Barley straw	N-EU	0.78, 1.6, 1.97, 1.9, 2.4, 2.7, 2.10, 2.7, 3.6, 5.4, 3.3 (BASF) 0.10, 0.22, 0.23, 0.47, 1.72 (MAK)		-	5.4	1.94
	S-EU	0.73, 1.2, 1.73, 2.2, 2.5, 2.7, 2.9, 3.8, 1.5 (BASF) 0.17, 0.46, 0.97 (MAK)		-	3.8	1.62
Wheat grain	N+S-EU	6x <0.05 (BASF), 3x <0.05 (MAK) (seed treatment)			0.05	0.05

Crop	Northern/ Southern Region. field	Trials results relevant to the representative uses (a)	Recommendation/comments	MRL estimated from trials according representative use	HR (mg/kg) (c)	STMR (mg/kg) (b)
Mushroom	Indoor	3x <0.05, 0.08, 0.44, 0.94, 0.99, 1.05	Samples analysed for total residues as 2,4,6-TCP, but considered acceptable to derive MRL according to the proposed residue definition for enforcement, since the metabolism study has shown the residues in mushroom to be almost exclusively composed of the parent compound (*c.a.* 70% TRR). R_{ber}: 2.0, R_{max}: 1.9	2	1.05	0.26

(a): Numbers of trials in which particular residue levels were reported *e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 2x 0.1, 2x 0.15, 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)[7]

ADI	0.01 mg/kg bw/day
TMDI according to EFSA PRIMo Model rev.2 (% ADI)	Highest TMDI: 35% ADI (IE Child)
IEDI according to EFSA PRIMo Model rev.2	Highest IEDI: 12% ADI (NL Child)
NEDI (specify diet) (% ADI)	Not required.
Factors included in IEDI and NEDI	TMDI: MRLs and conversion factor of 2.5 for cereals and 2 for ruminant products IEDI: STMRs and HRs derived from studies where samples were analysed for total residue as 2,4,6-TCP.
ARfD	0.025 mg/kg bw.
IESTI according to EFSA PRIMo rev.2 Model (% ARfD)	Highest IESTI: 42% ARfD (Bovine liver)
NESTI (% ARfD) according to national (to be specified) large portion consumption data	Not required.
Factors included in IESTI and NESTI	HRs derived from studies where samples were analysed for total residue as 2,4,6-TCP.

[7] To be done on the basis of WHO guidelines and recommendations with the deviations within the EU so far accepted (especially diets).

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor [8]	
Barley grain to beer	4	mean 0.08 (0.03 to 0.10)		
Wheat grain to bran	1[a]	4.3		
Wheat grain to flour (type 550)	1[a]	0.6		

[a]: A total of 4 studies was provided, but initial levels in the grains (RAC) were <LOQ in 3 studies. Thus, the transfer factor is derived from one study only , where significant residues were detected in grain (0.09 mg/kg).

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

Plant products

Wheat, rye and triticale grains	0.05 mg/kg
Barley and oats	0.1 mg/kg
Mushrooms	2.0 mg/kg

Ruminant products

Milk	0.03* mg/kg
Fat	0.1 mg/kg
Meat	0.03* mg/kg
Liver	2.0 mg/kg
Kidney	0.3 mg/kg

When the MRL is proposed at the LOQ, this should be annotated by an asterisk (*) after the figure.

Chapter 2.5: Fate and Behaviour in the Environment

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

Mineralization after 100 days ‡	*$^{14}CO_2$* *11-26* % after *119* d, [^{14}C-imidazole]-label (n[16]= *2, 20°C*) *1-2* % after *364*d, [^{3}H-phenyl]-label (n= *2, 20°C*) The amount of $^{3}H_2O$ in this study was 3-19 % after *119* d, [^{3}H-phenyl]-label (n= *2, 20°C*) *28* % after *120* d, [^{14}C-phenyl]-label (n= *1, 20°C*) 20.7-28 % after *120* d, [^{14}C-phenyl]-label (n= *2, 25°C)* *1.9 – 31.4 %* after 120 d, [^{14}C-trichlorophenyl]-label (n= 4 soils at 20^{0}C); Sterile conditions: *<0.01*% after *28/30* d [^{14}C-phenyl]-label (n= *2)*
Non-extractable residues after 100 days ‡	*15-27*% after *119* d, [^{14}C-imidazole]-label (n= *2, 20°C*) *15-24* % after *119*d, [^{3}H-phenyl]-label (n= *2, 20°C*) *23* % after *120* d, [^{14}C-phenyl]-label (n= *1, 20°C*) 28.9-35.6% after *182*d, [^{14}C-phenyl]-label (n= *2, 25°C)* *21.3 – 42.5* % after *120* d, [^{14}C-trichlorophenyl]-label (n= *4, 20°C*) Sterile conditions: *3.1-5**% after *28*/30* d [^{14}C-phenyl]-label (n= *2)*
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	<u>*BTS 44595 :*</u> 2.7 – 6.3% (n = 4, 20^{0}C) <u>*BTS 44596 :*</u> 7.0 – 12.8 % (n = 4, 20^{0}C) <u>*M590F040 :*</u> 7.7% (n = 1, 20^{0}C) <u>*BTS 40348 :*</u> 3.4 - 13.9% (n = 4, 20^{0}C) <u>*Imidazole*</u> 0.8 – 2.6% (n=2, 20°C)

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

Anaerobic degradation ‡

Mineralization after 100 days	*9.3-12.5*% after *60* d, [^{14}C-imidazole prochloraz]-label (n= *2*) *0.01-0.04* % after *60* d, [^{3}H-phenyl prochloraz]-label (n= *2*) *2.0-2.2* % after *59/63*d [respectively], [^{14}C-phenyl prochloraz]-label (n= *2*) *The Anaerobic studies were only carried out for 59 - 60 days after establishing anaerobic conditions:*

16 n corresponds to the number of soils.
* also observed on day 14 and 29 in some trials.

Non-extractable residues after 100 days	*8-23.88* % after *60* d, [^{14}C-imidazole prochloraz]-label (n= *2*) *9.37-22.68* % after *60* d, [^{3}H-phenyl prochloraz]-label (n= *2*) *24.2-26.2%* after *60* d, [^{14}C-phenyl prochloraz]-label (n= *2*)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	*Metabolites mainly formed during aerobic pre-incubation* All metabolites observed occurred at levels < 8 % AR Metabolites mainly formed during aerobic pre-incubation BTS 44 596: Max. 1.2% ([^{14}C]imidazole, 20°C) Max. 7.2% ([^{3}H]phenoxy, 20°C) Max. 2.4% ([^{14}C]phenoxy, 25°C) BTS 44 595: Max. 2.0% ([^{14}C]phenoxy, 25°C) BTS 45 186: Max. 4.0% ([^{3}H]phenoxy, 20°C) Max. 0.7% ([^{14}C]phenoxy, 25°C) Imidazole: Max. 2.6% ([^{14}C]imidazole, 20°C)

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Values are quoted in terms of % AR.

System	Volatiles: org	Volatiles: CO_2	Parent	BTS 44 596	BTS 44 595	NER
Irradiat. day 15*	0.33	5.28	37.0	31.8	10.4	8.1
Dark control day 15	0.68	0.05	86.7	3.3		3.8

* Days after application, 16 hr irradiation per day.

15 days ≈ 31 days of natural sunlight (assuming 75% average daily radiation and 16 hours of sunlight per day at 30-40 °N).

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

Laboratory studies ‡

Prochloraz (parent compound)	Aerobic conditions						
Soil type	OC	pH	t. °C / actual soil moisture %	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa*	χ^2	Method of calculation
Sandy loam	2.56	7.3	20/40	14.4/90.8	22.1	5.8	DFOP/pseudo-SFO (DFOP

							slow phase)
Sandy loam	1.43	7.2	20/40	277.4/1472.4	141.8	6.2	DFOP/pseudo-SFO (DFOP slow phase)
Loamy sand	1.57	6.1	20/40	37.0/403.3	936.1	6.9	DFOP/pseudo-SFO (DFOP slow phase)
Loamy sand	0.76	6.2	20/40	81.2/935	706.0	7.5	DFOP/pseudo-SFO (DFOP slow phase)
Sandy loam	1.11	7.5	15/40	198.1/719.0	105.9	1.0	DFOP/pseudo-SFO (DFOP slow phase)
Loamy sand	1.45	7.0	15/40	556.0/2060.0	353.6	0.4	DFOP/pseudo-SFO (DFOP slow phase)
Sandy loam	1.11	7.5	25/40	84.5/568.6	259.2	2.5	DFOP/pseudo-SFO (DFOP slow phase)
Loamy sand	1.45	7.0	25/40	158.2/671.1	311.1	3.6	DFOP/pseudo-SFO (DFOP slow phase)
Geometric mean/median			----	----	223.62/285.15	----	----

*normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

BTS 44596 (metabolite of prochloraz)	Aerobic conditions; all values determined for the compound applied as a parent							
Soil type	pH	OC [%]	t. °C / soil moisture content [%]	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa*	χ^2	Method of calculation
Sandy loam	7.7	2.6	20/pF 2.5	6.8/58.6	----	16.6	1.7	FOMC/ pseudo-SFO
Silt loam	5.2	4.6	20/pF 2.5	9.1/52.2	----	15.7	2.5	DFOP/ pseudo-SFO
Loamy sand	6.0	2.4	20/pF 2.5	16.6/55.1	----	16.6	4.5	SFO
Sandy loam	7.3	2.56	20/40	3.9/12.9	----	2.6	24.7	SFO
Sandy loam	7.2	1.43	20/40	48.1/159.7	----	33.8	15.3	SFO
Loamy sand	6.1	1.57	20/40	51.9/172.6	----	48.6	9.5	SFO
Loamy sand	6.2	0.76	20/40	54.4/180.9	----	54.5	7.4	SFO
Geometric mean/median			----	----	----	19.33/16.6	-----	----

*normalised using a Walker equation coefficient of 0.7

BTS 44595 (metabolite of prochloraz)	Aerobic conditions; The precursor in this fit was prochloraz, the fit to the prochloraz precursor was DFOP							
Soil type	pH	OC [%]	t. °C / soil moisture content [%]	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa*	χ^2	Method of calculation
Loamy sand	7.0	1.45	25/40	199.3/ 662.0	1	273.7	19.0	SFO

*normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

M590F040 (metabolite of prochloraz)	Aerobic conditions; all values determined for the compound applied as a parent							
Soil type	pH	OC [%]	t. °C / soil moisture content [%]	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa*	χ^2	Method of calculation
Sandy loam	7.3	2.56	20/40	0.8/2.8	----	0.5	26.8	SFO

*normalised using a Walker equation coefficient of 0.7

BTS 40348 (metabolite of prochloraz)	Aerobic conditions; all values determined for the compound applied as a parent, except [a] where the precursor in assessment was M590F040 and [b] where the precursor was prochloraz							
Soil type	OC [%]	pH	t. °C / soil moisture content [%]	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa*	χ^2	Method of calculation
Sandy loam	1.35	7.2	20/40	4.81/27.23	----	3.58	6.38	FOMC/SFO
Loamy sand	1.78	5.8	20/40	103.5/ 402.37	----	90.4	0.93	DFOP/SFO
Loamy sand	0.94	5.8	20/40	38.15/ 252.65	----	90.9	1.94	DFOP/ pseudo-SFO
Sandy loam	2.56	7.3	20/40	10.9/36.2	0.625[a]	7.3	8.6	SFO
Sandy loam	1.43	7.2	20/40	46.7/155.1	0.9002[b]	32.8	6.8	SFO
SFO Geometric mean/median			----	----	----	23.4/32.8	-----	----

*normalised using a Walker equation coefficient of 0.7

Imidazole (metabolite of prochloraz)	Aerobic conditions; all values determined for the compound applied as a parent							
Soil type	OC [%]	pH	t. °C / soil moisture content [%]	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa*	χ^2	Method of calculation
Sandy loam	1.31	7.1	20/40	2.5/8.4	----	1.6	11.5	SFO
Loamy sand	0.83	5.6	20/40	2.4/8.1	----	1.6	14.4	SFO
Loamy sand	0.97	6.1	20/40	1.8/6.0	----	2.4	21.1	SFO
Geometric mean			----	----	----	1.83	-----	----

*normalised using a Walker equation coefficient of 0.7

Field studies ‡

The following field studies were used in the risk assessment.

The kinetic endpoints derived for the individual trials and their evaluation when not normalised to FOCUS reference conditions

The best-fit results were evaluated. The complete set of data is presented in the table below.
The soils used in the study were classified for the soil type as follows (USDA classification):

- Niederkirchen (study A 88789): Sandy loam
- Meissner Vockerode (study A 88789): Loam
- Goch-Nierswalde (study A 88789): Silt loam
- Elsenfeld-Ruck (study A 88789): Silt loam
- Goch-Nierswalde (study A 88676): Sandy loam
- Willingham-3 (study A 88732): Sandy clay loam
- Isleham-1 (study A 88732): Loamy sand
- Isleham-2 (study A 88732): Sandy clay loam
- Weeze-Wemb (study A 88733): Loamy sand
- Keeken (study A 88733): Silty clay loam
- Cottenham (study A 88740): Sandy loam
- Chishill (study A 88740): Clay loam
- Duglilo (study C022251): Silt loam
- Cullera (study C02251): Sandy loam
- Anna (study C02251): Clay loam

Study	Trial site	Soil characteristics		Compound	Best-fit selection		Parameters estimation			Kinetic endpoints	
		pH	OC/ OM (%)		Selected model	χ^2 error	Param.	Estimated value	Standard error (S)	DT_{50} [days]	DT_{90} [days]
A88789	Nieder-kirchen	7.3	1.5[1)]	BAS 590F[5)]	DFOP	13.6	M_0[7)]	0.2286	0.0119	3.17	76.01
							k_1	0.2849	0.0496		
							k_2	0.0065	0.0045		
							g	0.8359	0.0518		
	Meissner Vockerode	6.4	2.1[1)]	BAS 590F[5)]	FOMC	15.7	M_0[7)]	0.3936	0.02017	0.60	55
							α	0.3683	0.07097		
							β	0.1068	0.07944		
	Goch-Nierswalde	5.9	3.5[1)]	BAS 590F[5)]	DFOP	37.1[6)]	M_0[7)]	0.187	0.0340	27.8	187.2
							k_1	0.0516	0.1297		
							k_2	0.0083	0.0191		
							g	0.5285	1.0568		
	Elsenfeld-Rück	7.0	2.1[1)]	BAS 590F[5)]	DFOP	15.8	M_0[7)]	0.2338	0.02414	36.6	280
							k_1	0.3332	0.3163		
							k_2	0.006671	0.00240		
							g	0.3608	0.1120		
A88676	Goch-Nierswalde	5.95	2.0[2)]	BAS 590F[5)]	FOMC	8.3	M_0[7)]	0.6017	0.02583	1.9	456.4[8)]
							α	0.3004	0.03868		
							β	0.2141	0.1038		
				BTS 44596	SFO	9.9	ff_{596}	0.6587	0.07165	ff	0.65[9)]
							k	0.01873	0.004325	37.0[9)]	122.9[9)]
A88732	Willingham -3	7.5	2.0[3)]	BAS 590F[5)]	DFOP	8.35	M_0[7)]	0.3608	0.0147	5.59	496.63
							k_1	0.2042	0.0399		
							k_2	0.0020	0.00081		
							g	0.7301	0.0343		
	Isleham-1	7.5	11.5[3)]	BAS 590F[5)]	FOMC	16.5	M_0[7)]	0.4297	0.03909	4.6	2439.9[8)]
							α	0.2598	0.1088		
							β	0.3454	0.6508		
	Isleham-2	7.2	23.5[3)]	BAS 590F[5)]	FOMC	15.7	M_0[7)]	0.2005	0.01668	17.5	168.4
							α	0.9449	0.5616		
							β	16.14	16.99		

The kinetic endpoints derived for the individual trials and their evaluation when not normalised to FOCUS reference conditions (continued).

Study	Trial site	Soil characteristics		Compound	Best-fit selection		Parameters estimation			Kinetic endpoints	
		pH	OC/ OM (%)		Selected model	χ^2 error	Param.	Estimated value	Standard error (S)	DT_{50} [days]	DT_{90} [days]
A88733	Weeze-Wemb	5.8	3.8[1)]	BAS 590F[5)]	FOMC	11.5	M_0[7)]	0.1564	0.00991	18.1	349
							α	0.6215	0.2012		
							β	8.805	6.271		
	Keeken	6.1	4.4[1)]	BAS 590F[5)]	FOMC	15.2	M_0[7)]	0.3998	0.04287	73.2	7544.7[8)]
							α	0.3593	0.2191		
							β	12.45	19.37		
A88740	Cottenham	----	1.5[3)]	BAS 590F[5)]	DFOP	31.1[6)]	M_0[7)]	0.6443	0.0891	1.39	208.77
							k_1	1.1665	0.8221		
							k_2	0.0064	0.0038		
							g	0.6196	0.0998		
A88744	Chishill	7.0	3.6[4)]	BAS 590F[5)]	DFOP	30.0[6)]	M_0[7)]	0.6074	0.0752	33.0	918.6
							k_1	0.0316	0.0275		
							k_2	0.00095	0.0036		
							g	0.7595	0.2811		
C022251	Dugliolo (Italy)	8.6	0.9[2)]	BAS 590F[5)]	FOMC	7.5	M_0[7)]	0.5327	0.01648	5.2	125
							α	0.5654	0.08056		
							β	2.157	0.6010		
				BTS 44595	SFO	27.0	ff_{595}	0.2712	0.04756	ff	0.27[9)]
							k	0.001816	0.001215	381.7[9)]	1267.9[9)]
				BTS 44596	SFO	21.1	ff_{596}	1.0[10)]	---	ff	1.00
							k	0.1102	0.01585	6.3[9)]	20.9[9)]
	Cullera (Spain)	7.8	0.9[2)]	BAS 590F[5)]	DFOP	15.1	M_0[7)]	0.2795	0.01153	3.5	127
							k_1	0.3160	0.0588		
							k_2	0.007539	0.003231		
							g	0.7402	0.04726		
				BTS 44595	SFO	16.2	ff_{595}	0.3517	0.09601	ff	0.35[9)]
							k	0.001563	0.001137	443.5[9)]	1473.2[9)]
				BTS 44596	SFO	19.4	ff_{596}	0.7672	0.1405	ff	0.77[9)]
							k	0.09667	0.003231	7.2[9)]	23.8[9)]
	Anna (Spain)	7.9	1.2[2)]	BAS 590F[5)]	DFOP	21.9	M_0[7)]	0.4122	0.01576	5.0	161
							k_1	0.2479	0.04441		
							k_2	0.006062	0.002597		
							g	0.7047	0.05485		
				BTS 44595	SFO	16.1	ff_{595}	0.3960	0.0603	ff	0.40[9)]
							k	0.002654	0.001082	261.2[9)]	867.6[9)]
				BTS 44596	SFO	19.9	ff_{596}	1.0[10)]	----	ff	1.00
							k	0.2131	0.04181	3.3[9)]	10.8[9)]

Footnotes to the table:

1) reported as humus or humus content;
2) reported as organic carbon;
3) reported as organically bound carbon;
4) reported as organic matter;
5) codename for prochloraz;
6) the fit bears high level of uncertainty, should be considered with caution;
7) value expressed in mg/kg;
8) value recalculated by the RMS/Co-RMS using the optimised parameters;
9) the kinetic endpoint for the metabolite derived with parent compound used as a precursor;
10) value fixed to 1.0 after violating the constraint.

The kinetic endpoints derived for the individual trials and their evaluation when normalised to FOCUS reference conditions. Normalised using a Q10 of 2.58 and a Walker equation coefficient of 0.7

Prochloraz	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	OC/ OM [%]	pH	Depth (cm)	DT_{50} (d) fast	DT_{50}(d) slow	χ^2	DT_{50} (d) for modelling	Method of calculation
Sandy loam, bare soil	Goch-Nierswalde (Germany)	2.0[2]	5.95	0-30	0.9	51.4	11.8	51.4	DFOP
Loamy sand/bare soil	Weeze-Wemb (Germany)	3.8[1]	5.8	0-30	3.3	28.6	14.1	28.6	DFOP
Silty clay loam/bare soil	Keeken (Germany)	4.4[1]	6.1	0-30	16.7	136.6	16.1	136.6	DFOP
Loam/bare soil	Meissner-Vockerode (Germany)	2.1[1]	6.4	0-30	0.4	39.2	10.9	39.2	DFOP
Sandy loam/bare soil	Niederkirchen (Germany)	1.5[1]	7.3	0-30	2.5	76.1	12.6	76.1	DFOP
Silt loam/bare soil	Elsenfeld-Ruck (Germany)	2.1[1]	7.0	0-30	3.0	54.9	16.2	54.9	DFOP
Sandy clay loam/bare soil	Isleham-2 (UK)	23.5[3]	7.2	0-30	9.2	67.1	20.7	67.1	DFOP
Sandy loam/bare soil	Cottenham (UK)	1.5[3]	----	0-30	0.7	47.5	31.3	47.5	DFOP
Clay loam/bare soil	Chishill (UK)	3.6[4]	7.0	0-30	26.9	244.7	16.2	244.7	DFOP
Silt loam/bare soil	Dugliolo (Italy)	0.9[2]	8.6	0-30	2.7	62.3	10.1	62.3	DFOP
Sandy loam/bare soil	Cullera (Spain)	0.9[2]	7.8	0-30	2.5	63.7	15.8	63.7	DFOP
Clay loam/bare soil	Anna (Spain)	1.2[2]	7.9	0-30	2.8	111.1	24.0	111.1	DFOP
Geometric mean/ ***median***					----	----	----	**68.8/** ***63.0***	DFOP slow phase

Footnotes to the table:

1) reported as humus or humus content;
2) reported as organic carbon;
3) reported as organically bound carbon;
4) reported as organic matter;

BTS 44596	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	OC [%]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	χ^2	DT_{50} (d) Norm*.	Method of calculation
Sandy loam, bare soil	Goch-Nierswalde (Germany)	2.0	5.95	0-30	----	----	9.0	35.8	SFO
Silt loam/bare soil	Dugliolo (Italy)	0.9	8.6	0-30	----	----	20.2	4.8	SFO
Sandy loam/bare soil	Cullera (Spain)	0.9	7.8	0-30	----	----	15.4	4.1	SFO
Clay loam/bare soil	Anna (Spain)	1.2	7.9	0-30	----	----	16.5	2.5	SFO
Geometric mean					**----**	**----**	----	**6.5**	----

*Normalised using a Q10 of 2.58 and a Walker equation coefficient of 0.7

BTS 44595	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	OC [%]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	χ^2	DT_{50} (d) Norm*.	Method of calculation
Silt loam/bare soil	Dugliolo (Italy)	2.0	8.6	0-30	----	----	22.8	145.0	SFO
Sandy loam/bare soil	Cullera (Spain)	0.9	7.8	0-30	----	----	13.9	266.8	SFO
Clay loam/bare soil	Anna (Spain)	0.9	7.9	0-30	----	----	14.5	200.4	SFO
Geometric mean					**----**	1.2	----	**197.9**	----

*Normalised using a Q10 of 2.58 and a Walker equation coefficient of 0.7

DT_{50} values recommended for modelling calculations

Type of calculations	Substance	DT_{50} [days]	Remarks
PEC_{SOIL}	**Prochloraz**	α = 0.3593 β = 12.45	Value recommended for calculation of PEC_{SOIL} for substance applied as liquid spray in cereals – worst case field FOMC values (best fit), obtained in Keeken trial.
		2272.5	Value recommended for calculation of PEC_{SOIL} for substance applied as seed treatment in cereals – worst case pseudo SFO value obtained by conversion from FOMC DT_{90} = 7544.7 days obtained in Keeken trial.
	BTS 44596	37.0	Longest unnormalised field DT_{50} value (Goch-Nierswalde trial); SFO kinetics
	BTS 44595	443.5	Longest unnormalised field DT_{50} value (Cullera trial); SFO kinetics
	M590F040	1	Value reported by Erzgräber (2009b) for the compound fitted as “ghost compartment” in evaluation of the laboratory studies; SFO kinetics
	BTS 40348	103.3	The longest unnormalised laboratory DT_{50} value reported by Hassink (2009); SFO kinetics

PEC_{GW}	**Prochloraz**	68.8	Geometric mean, normalised value from field studies; pseudo-SFO kinetics (slow phase-DFOP DT_{50} value)
	BTS 44596	6.5	Geometric mean, normalised value from field studies reported by Spickermann (2009); SFO kinetics
	BTS 44595	197.9	Geometric mean, normalised value from field studies reported by Spickermann (2009); SFO kinetics
	M590F040	1	Value reported by Erzgräber (2009b) for the compound fitted as "ghost compartment" in evaluation of the laboratory studies; SFO kinetics
	BTS 40348	90.9	Longest normalised laboratory DT_{50} reported by Hassink (2009); SFO kinetics
PEC_{SW}	**Prochloraz**	68.8	Geometric mean, normalised value from field studies; pseudo-SFO kinetics (slow phase-DFOP DT_{50} value)
	BTS 44596	6.5	Geometric mean, normalised value from field studies reported by Spickermann (2009); SFO kinetics
	BTS 44595	197.9	Geometric mean, normalised value from field studies reported by Spickermann (2009); SFO kinetics
	M590F040	1	Value reported by Erzgräber (2009b) for the compound fitted as "ghost compartment" in evaluation of the laboratory studies; SFO kinetics
	BTS 40348	90.9	Longest normalised laboratory DT_{50} reported by Hassink (2009); SFO kinetics

pH dependence ‡ (yes / no) (if yes type of dependence)	No.
Soil accumulation and plateau concentration ‡	**Study A88783**, Bare plot & maize treated with nominal rate of 1.0 kg prochloraz/ha for a total of three years. In both the bare soil and maize plots, the accumulated residues appeared to have reached limiting values of 0.33 and 0.29 mg/kg, respectively, after two years.

Laboratory studies ‡

Parent: prochloraz	Anaerobic conditions						
Soil type	X	pH	t. °C	DT_{50} /DT_{90} (d)	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam	1.11 % OC	7.5	25	264		-	SFO
Sandy loam	1.06 % OC	7.2	25	230		-	SFO

All metabolites were < 10% AR.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent: Prochloraz								
Soil name	**Soil type (USDA)**	**Soil properties**		**Adsorption distribution coefficients**		**Freundlich adsorption coefficients**		
		pH	OC [%]	K_d [mL/g]	K_{dOC} [mL/g]	K_f [mL/g]	K_{fOC} [1)] [mL/g]	1/n
La Gironda	Silty clay loam	7.5	3.84	97	2524	59	1544	0.810
Bruch West	Sandy loam	7.4	2.38	44	1831	30	1268	0.784
Nierswalde Wildacker	Silt loam	6.5	1.63	200	12295	130	7975.5	0.862
Li 10	Loamy sand	5.9	0.88	74	8375	44	5000	0.783
LUFA 2.1	Sand	5.2	0.52	72	13775	45	8653.8	0.834
Albington	Sandy loam	7.3	2.15	53.77	2500	30.83	1433	0.85
Icklingham	Sand	7.5	1.28	28.55	2226	15.63	1222	0.81
Chapel Farm	Clay loam	7.7	3.14	113.89	3627	54.5	1734	0.83
Sutton Bonington	Sandy loam	4.7	3.2	----	----	86.8	2712.5	0.77
Magadales Farm	Silty clay loam	6.5	2.6	----	----	101.7	3911.5	0.76
pH dependence:				Yes, there are two sets of K_f and K_{fOC} values – lower for pH ≥ 7.0 and higher for pH < 7.0				
Arithmetic mean for pH ≥ 7.0						**37.99**	**1440.2**	**0.815**
Arithmetic mean for pH < 7.0						**81.5**	**5650.7**	**0.801**

1) All the values were verified by the RMS for the present submission and, where necessary, the corrected K_{fOC} values are reported.

Metabolite: BTS 44596						
Soil name	**Soil type (USDA)**	**Soil properties**		**Freundlich adsorption coefficients**		
		pH	OC [%]	K_f [mL/g]	K_{foc} [mL/g]	1/n
La Gironda	Silty clay loam	7.5	3.84	17.53	456.6	0.733
Bruch West	Sandy loam	7.4	2.38	9.33	392.0	0.768
Nierswalde Wildacker	Silt loam	6.5	1.63	25.50	1748.7	0.811
Li 10	Loamy sand	5.9	0.88	8.02	911.9	0.763
LUFA 2.1	Sand	5.2	0.52	4.94	949.9	0.798
Albington	Sandy loam	7.3	2.15	15.6	725	0.86
Icklingham	Sand	7.5	1.28	8.6	672	0.83
Chapel Farm	Clay loam	7.7	3.14	25.8	821	0.82
Arithmetic mean				**14.79**	**834.64**	**0.798**
Median value (n = 8)				**12.47**	**773**	**0.805**
pH dependence				Not observed		

Metabolite: BTS 44595						
Soil name	**Soil type (USDA)**	**Soil properties**		**Freundlich adsorption coefficients**		
		pH	OC [%]	K_f [mL/g]	K_{foc} [mL/g]	1/n
La Gironda	Silty clay loam	7.5	3.84	22	577	0.807
Bruch West	Sandy loam	7.4	2.38	12	497	0.842
Nierswalde Wildacker	Silt loam	6.5	1.63	37	2283	0.864
Li 10	Loamy sand	5.9	0.88	12	1398	0.854
LUFA 2.1	Sand	5.2	0.52	9.0	1724	0.882
Polk County, NE	Loamy sand	7.2	1.74	19.94	1146	0.78
York County, NE	Clay loam	7.0	3.69	65.68	1688	0.82
Carlyle, IL	Silt loam	5.7	1.57	14.68	935	0.82
Pikeville, NC	Loamy sand	6.4	0.93	11.25	1209	0.79
Arithmetic mean				**22.62**	**1273**	**0.829**
Median value (n = 9)				**14.68**	**1209**	**0.820**
pH dependence				Not observed		

Metabolite: M590F040						
Soil name	**Soil type (USDA)**	**Soil properties**		**Freundlich adsorption coefficients**		
		pH	OC [%]	K_f [mL/g]	K_{foc} [mL/g]	1/n
La Gironda	Silty clay loam	7.5	3.84	40.51	1055.0	0.914
Bruch West	Sandy loam	7.4	2.38	29.31	1231.4	0.935
Nierswalde Wildacker	Silt loam	6.5	1.63	116.04	7118.8	0.988
Li 10	Loamy sand	5.9	0.88	16.78	1906.4	0.820
LUFA 2.1	Sand	5.2	0.52	14.45	2778.4	0.926
Arithmetic mean				**43.42**	**2818**	**0.917**
pH dependence				Not observed		

Metabolite: BTS 40348						
Soil name	**Soil type (USDA)**	**Soil properties**		**Freundlich adsorption coefficients**		
		pH	OC [%]	K_f [mL/g]	K_{foc} [mL/g]	1/n
La Gironda	Silty clay loam	7.5	3.84	45.42	1182.7	0.852
Bruch West	Sandy loam	7.4	2.38	14.99	630.1	0.803
Nierswalde Wildacker	Silt loam	6.5	1.63	44.34	2720.3	0.843
Li 10	Loamy sand	5.9	0.88	12.88	1464.2	0.818
LUFA 2.1	Sand	5.2	0.52	8.11	1558.8	0.852
Arithmetic mean				**25.15**	**1511.22**	**0.834**
pH dependence				Not observed		

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

Column leaching ‡	Eluation (mm): *200* mm Time period (d): *48* hr
	Leachate: *0* % total residues/radioactivity in leachate Soil layers were not analysed. [Study A91244]
Aged residues leaching ‡	Study supplied, however results are not reliable. No further data required
Lysimeter/ field leaching studies ‡	Not submitted/not considered relevant.

PEC(soil) (Annex IIIA, point 9.1.3)

1) Calculations for prochloraz applied as spray liquid in cereals (formulation Sportak 45 EW).

Prochloraz – parent compound Method of calculation	DT_{50} (d) – not used; Other kinetic parameters: $\alpha = 0.3593$, $\beta = 12.45$ Kinetics: FOMC Field or Lab: representative worst case from field studies; Calculations performed using "Escape ver. 1.0" modelling tool; method of calculation: parent and two metabolites in sequence
Application data	Crop: cereals, spring and winter Depth of soil layer: 5 cm for 1-year PEC_{SOIL} calculations and the accum. PEC_{SOIL} after reaching max., 20 cm for background concentration in calculation of the accumulation potential. Soil bulk density: 1.5 g/cm^3 % plant interception: -single application – 70% - multiple application: 70% for first application, 70% for second application Number of applications: 1-2 Interval (d):14 days (multiple application) Application rate(s): Single application: 450 g a.s./ha; Multiple application: 450 g a.s./ha/treatment; Mode of calculation selected for reporting: Mode 1 – residues from different applications considered separately

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.1800		0.3173	
Short term	24h	0.1751	0.1775	0.3106	0.3139
	2d	0.1706	0.1752	0.3044	0.3107
	4d	0.1629	0.1709	0.2934	0.3047
Long term	7d	0.1533	0.1654	0.2795	0.2967
	28d	0.1179	0.1409	0.2238	0.2601
	50d	0.1008	0.1266	0.1946	0.2377
	100d	0.0816	0.1083	0.1599	0.2068
Plateau concentration		Single application: Final background conc: 0.1416 mg/kg after 33 years; max accum. PEC_S = 0.3216 mg/kg Multiple application: Final background conc: 0.2829 mg/kg after 33 years; max accum. PEC_S = 0.6002 mg/kg			

BTS 44596 (metabolite) Method of calculation	Molecular weight relative to the parent: 353.6/376.7 DT_{50} (d): 37.0 days Kinetics: SFO Field or Lab: representative worst case from field studies. Calculations performed using "Escape ver. 1.0" modelling tool; method of calculation: parent and two metabolites in sequence
Application data	Application rate assumed: Single application: 450 g as/ha; multiple application: 2 x 450 g as/ha; Assumed formation fraction: 0.468; Mode of calculation selected for reporting: Mode 1 – residues from different applications considered separately

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.0203		0.0400	
Short term	24h	0.0203	0.0203	0.0400	0.0400
	2d	0.0203	0.0203	0.0400	0.0400
	4d	0.0202	0.0203	0.0399	0.0400
Long term	7d	0.0201	0.0203	0.0396	0.0400
	28d	0.0179	0.0199	0.0352	0.0393
	50d	0.0149	0.0192	0.0292	0.0379
	100d	0.0091	0.0169	0.0180	0.0333
Plateau concentration		Single application: Final background conc: 0.0007 mg/kg after 15 years; max accum. PEC_S = 0.0210 mg/kg Multiple application: Final background conc: 0.0015 mg/kg after 15 years; max accum. PEC_S = 0.0415 mg/kg			

BTS 44595 (metabolite) Method of calculation	Molecular weight relative to the parent: 325.62/376.7 DT_{50} (d): 443.5 days Kinetics: SFO Field or Lab: representative worst case from field studies. Calculations performed using "Escape ver. 1.0" modelling tool; method of calculation: parent and two metabolites in sequence
Application data	Application rate assumed: Single application: 450 g as/ha; multiple application: 2 x 450 g as/ha; Assumed formation fraction: 0.302; Mode of calculation selected for reporting: Mode 1 –

			residues from different applications considered separately		
PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.0108		0.0216	
Short term	24h	0.0108	0.0108	0.0216	0.0216
	2d	0.0108	0.0108	0.0216	0.0216
	4d	0.0108	0.0108	0.0216	0.0216
Long term	7d	0.0108	0.0108	0.0216	0.0216
	28d	0.0107	0.0108	0.0215	0.0215
	50d	0.0107	0.0108	0.0213	0.0215
	100d	0.0104	0.0107	0.0207	0.0215
Plateau concentration		Single application: Final background conc: 0.0062 mg/kg after 12 years; max accum. PEC_S = 0.0169 mg/kg Multiple application: Final background conc: 0.0123 mg/kg after 12 years; max accum. PEC_S = 0.0339 mg/kg			

M590F040 (metabolite) Method of calculation			Molecular weight relative to the parent: 340.6/376.7 DT_{50} (d): 1 days Kinetics: SFO Field or Lab: representative worst case from laboratory studies. Calculations performed using "Escape ver. 1.0" modelling tool; method of calculation: parent and two metabolites in sequence		
Application data			Application rate assumed: Single application: 450 g as/ha; multiple application: 2 x 450 g as/ha; Assumed formation fraction: 0.082; Mode of calculation selected for reporting: Mode 1 – residues from different applications considered separately		
PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.0006		0.0008	
Short term	24h	0.0006	0.0006	0.0008	0.0008
	2d	0.0005	0.0005	0.0008	0.0008
	4d	0.0005	0.0005	0.0007	0.0008
Long term	7d	0.0004	0.0005	0.0006	0.0007
	28d	0.0001	0.0003	0.0002	0.0005

	50d	0.0001	0.0002	0.0001	0.0004
	100d	< 0.0001	0.0001	0.0001	0.0003
Plateau concentration		Single application: Final background conc: < 0.0001 mg/kg after 15 years; max accum. PEC_S = 0.0006 mg/kg Multiple application: Final background conc: < 0.0001 mg/kg after 15 years; max accum. PEC_S = 0.0008 mg/kg			

BTS40348 (metabolite) Method of calculation	Molecular weight relative to the parent: 282.6/376.7 DT_{50} (d): 103.3 days Kinetics: SFO Field or Lab: representative worst case from laboratory studies. Calculations performed using "Escape ver. 1.0" modelling tool; method of calculation: parent and two metabolites in sequence
Application data	Application rate assumed: Single application: 450 g as/ha; multiple application: 2 x 450 g as/ha; Assumed formation fraction: 0.140; Mode of calculation selected for reporting: Mode 1 – residues from different applications considered separately

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.0006		0.0011	
Short term	24h	0.0006	0.0010	0.0011	0.0011
	2d	0.0006	0.0010	0.0011	0.0011
	4d	0.0006	0.0010	0.0011	0.0011
Long term	7d	0.0006	0.0010	0.0011	0.0011
	28d	0.0005	0.0010	0.0011	0.0011
	50d	0.0005	0.0010	0.0010	0.0011
	100d	0.0004	0.0009	0.0009	0.0011
Plateau concentration		Single application: Final background conc: 0.0001 mg/kg after 15 years; max accum. PEC_S = 0.0006 mg/kg Multiple application: Final background conc: 0.0001 mg/kg after 15 years; max accum. PEC_S = 0.0012 mg/kg			

2) Calculations for prochloraz applied as a seed treatment (formulation Prelude 20 FS).

Prochloraz – parent compound Method of calculation	DT_{50} (d) – 2272.5; Kinetics: Pseudo-SFO (backcalculated from FOMC DT_{90} = 7544.7 days) Field or Lab: representative worst case from field studies; Calculations performed using "Escape ver. 1.0" modelling tool; method of calculation: parent and two metabolites in sequence
Application data	Crop: cereals, seed treatment Depth of soil layer: 20 cm for 1-year PEC_{SOIL} calculations and the accum. PEC_{SOIL} after reaching max., 20 cm for background concentration in calculation of the accumulation potential. Soil bulk density: 1.5 g/cm^3 % plant interception: 0% Number of applications: 1 Interval (d):not applicable Application rate(s): 33.1 g a. s./ha Mode of calculation selected for reporting: Mode 1 – residues from different applications considered separately

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		0.0110		----	
Short term	24h	0.0110	0.0110	----	----
	2d	0.0110	0.0110	----	----
	4d	0.0110	0.0110	----	----
Long term	7d	0.0110	0.0110	----	----
	28d	0.0109	0.0110	----	----
	50d	0.0109	0.0109	----	----
	100d	0.0107	0.0109	----	----
Plateau concentration		Final background conc: 0.0937 mg/kg after 18 years; max accum. PEC_S = 0.1047 mg/kg			

BTS 44596 (metabolite) Method of calculation	Molecular weight relative to the parent: 353.6/376.7 DT_{50} (d): 37.0 days Kinetics: SFO Field or Lab: representative worst case from field studies. Calculations performed using "Escape ver. 1.0" modelling tool; method of calculation: parent and two

			metabolites in sequence		
Application data			Application rate assumed: 33.1 g as/ha; Assumed formation fraction: 0.128; Mode of calculation selected for reporting: Mode 1 – residues from different applications considered separately		
$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		<0.0001		----	
Short term	24h	<0.0001	<0.0001	----	----
	2d	<0.0001	<0.0001	----	----
	4d	<0.0001	<0.0001	----	----
Long term	7d	<0.0001	<0.0001	----	----
	28d	<0.0001	<0.0001	----	----
	50d	<0.0001	<0.0001	----	----
	100d	<0.0001	<0.0001	----	----
Plateau concentration		Final background conc: 0.0001 mg/kg after 18 years; max accum. PEC_S = 0.0002 mg/kg			

BTS 44595 (metabolite) Method of calculation			Molecular weight relative to the parent: 325.62/376.7 DT_{50} (d): 443.5 days Kinetics: SFO Field or Lab: representative worst case from field studies. Calculations performed using “Escape ver. 1.0” modelling tool; method of calculation: parent and two metabolites in sequence		
Application data			Application rate assumed: 33.1 g as/ha; Assumed formation fraction: 0.063; Mode of calculation selected for reporting: Mode 1 – residues from different applications considered separately		
$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		<0.0001		----	
Short term	24h	<0.0001	<0.0001	----	----
	2d	<0.0001	<0.0001	----	----
	4d	<0.0001	<0.0001	----	----
Long term	7d	<0.0001	<0.0001	----	----
	28d	<0.0001	<0.0001	----	----

	50d	<0.0001	<0.0001	----	----
	100d	<0.0001	<0.0001	----	----
Plateau concentration		Final background conc: 0.0001 mg/kg after 19 years; max accum. PEC_S = 0.0001 mg/kg			

M590F040 (metabolite)

Method of calculation	Molecular weight relative to the parent: 340.6/376.7 DT_{50} (d): 1 days Kinetics: SFO Field or Lab: representative worst case from laboratory studies. Calculations performed using "Escape ver. 1.0" modelling tool; method of calculation: parent and two metabolites in sequence
Application data	Application rate assumed: 33.1 g as/ha; Assumed formation fraction: 0.082; Mode of calculation selected for reporting: Mode 1 – residues from different applications considered separately

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		<0.0001		----	
Short term	24h	<0.0001	<0.0001	----	----
	2d	<0.0001	<0.0001	----	----
	4d	<0.0001	<0.0001	----	----
Long term	7d	<0.0001	<0.0001	----	----
	28d	<0.0001	<0.0001	----	----
	50d	<0.0001	<0.0001	----	----
	100d	< 0.0001	<0.0001	----	----
Plateau concentration		Final background conc: < 0.0001 mg/kg after 18 years; max accum. PEC_S = <0.0001 mg/kg			

BTS40348 (metabolite)

Method of calculation	Molecular weight relative to the parent: 282.6/376.7 DT_{50} (d): 103.3 days Kinetics: SFO Field or Lab: representative worst case from laboratory studies. Calculations performed using "Escape ver. 1.0" modelling tool; method of calculation: parent and two metabolites in sequence
Application data	Application rate assumed: 33.1 g as/ha; Assumed formation fraction: 0.140;

			Mode of calculation selected for reporting: Mode 1 – residues from different applications considered separately		
PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		<0.0001		----	
Short term	24h	<0.0001	<0.0001	----	----
	2d	<0.0001	<0.0001	----	----
	4d	<0.0001	<0.0001	----	----
Long term	7d	<0.0001	<0.0001	----	----
	28d	<0.0001	<0.0001	----	----
	50d	<0.0001	<0.0001	----	----
	100d	<0.0001	<0.0001	----	----
Plateau concentration		Final background conc: 0.0001 mg/kg after 18 years; max accum. PEC$_S$ = 0.0001 mg/kg			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: Prochloraz stable at 22 °C; stable at 25^{0}C
	pH 7: Prochloraz stable at 22 °C; stable at 25^{0}C
	pH 9: DT_{50} 78.9 d at 22 °C (1st order, linear regression r^2=0.9786); 39.2 days at 25^{0}C (1st order, non-linear regression, r^2 = 0.9942); Metabolite: BTS 40348 - 39.6% AR (DAT 30)
Photolytic degradation of active substance and metabolites above 10 % ‡	Prochloraz: DT_{50} : 1.3-1.6 d (r^2=0.987-1.0) Natural light, central Europe; DT_{50} 4.46 d (June), 6.38 d (April) Met: BTS44596 61.7 %AR (7 d) DT_{50} for BTS44596 47.9 d (r^2=1.0)
Quantum yield of direct phototransformation in water at Σ > 290 nm	0.14
Readily biodegradable ‡ (yes/no)	Prochloraz: No Prochloraz $CuCl_2$ complex: No

Degradation in water / sediment

Parent	Distribution (max in water 96.3 after 0 d. Max. sed 87 % after 28 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
Rampton Ditch	7.8	7.9	20	333/1107	χ^2 = 2.4	3.5/11.7	χ^2 = 7.8	594/1974	χ^2 = 1.2	SFO
River Granta	9.0	7.4	20	272/1171 (DFOP slow phase 387/1285)	χ^2 = 2.5	0.5/6.6	χ^2 = 3.7	978/3250	χ^2 = 3.0	DFOP – whole system + water phase; SFO – sediment phase
Geometric mean			----	359/1139		----		----		----

Metabolites	Distribution (BTS44595: max in water 1.6% after 0.25 d. Max. sed 2.3% after 63 d; BTS44596: max in water 1.9% after 0 d. Max. sed 5.4% after 100 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-
-	-	-	-	-	-	-	-	-	-	-
Geometric mean/median										

Mineralization and non extractable residues (Prochloraz)					
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)
Rampton Ditch	7.8	7.9	1.0 % after 100d	11.7% after 63 d	8.6% after 100d
River Granta	9.0	7.4	0.6 % after 100 d	11.4% after 30 d	7.5 % after 100d

Repeat the corresponding rows for as many metabolites as necessary

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

1) Calculations for prochloraz applied as spray liquid in cereals (formulation Sportak 45 EW).

Parent – **Prochloraz** Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: ver. 1.1 Molecular weight (g/mol): 376.7 Water solubility (mg/L):34.4 K_{fOC} (L/kg): 1440.5 (Prochloraz); 5650.7 (Prochloraz-1) DT_{50} soil (d): 68.8 days (Field geomean normalised value. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 359 days DT_{50} water (d): 359 DT_{50} sediment (d): 1000 Crop interception (%): 50%
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: SWASH v. 2.1 Vapour pressure: 1.5 E-4 Pa @ 25^0C K_{fOC}: 1440.5 (Prochloraz); 5650.7 (Prochloraz-1) 1/n: 0.815 (Prochloraz); 0.801 (Prochloraz-1)
Application rate	Crop: spring cereals Crop interception: 50 % (step 1 and 2) Number of applications: 1 or 2 Interval (d): 14 Application rate(s): 450 g as/ha Application window: Step 1& Step 2 – March - May; Step 3: a) for a single application: D1: 15 June – 15 July D3: 15 May – 14 June; D4: 15 May – 14 June; D5: 15 May – 14 June; R4: 15 April – 15 May; b) for a multiple application: D1: 15 June – 29 July; D3: 15 May – 28 June; D4: 15 May – 18 June; D5: 15 May – 28 June; R4: 15 April – 29 May; Step 4: as at Step 3 Crop: winter cereals Crop interception: 50 % (step 1 and 2) Number of applications: 1 or 2 Interval (d): 14 Application rate(s): 450 g as/ha Application window: Step 1& Step 2 – March - May; Step 3:

a)		for	a	single	application:
D1:	15	April	–	14	May;
D2:	01	April	–	01	May;
D3:	01	April	–	01	May;
D4:	15	April	–	15	May;
D5:	01	April	–	01	May;
D6:	01	March	–	01	April;
R1:	01	April	–	01	May;
R3:	01	March	–	01	April;
R4: 01 March – 01 April;					
b)		for	a	multiple	application:
D1:	15	April	–	29	May;
D2:	15	April	–	29	May;
D3:	01	April	–	15	May;
D4:	15	April	–	29	May;
D5:	01	April	–	15	May;
D6:	01	March	–	14	April;
R1:	01	April	–	15	May;
R3:	01	March	–	14	April;
R4: 01 March – 14 April;					

Step 4: as at Step 3

Mitigation measures at Step 4:

- 5 –meters wide buffer zone mitigating only the spray drift
- 10-meters wide buffer zone/VFS to mitigate spray drift and runoff; the reduction in runoff flux and volume was set to 60 %, while the reduction in erosion flux and sediment mass was set to 85 % as recommended by FOCUS L&M Guidelines;
- 15 meters buffer zone in combination with 20-meters VFS to mitigate the spray drift and runoff; the reduction in runoff flux and volume was set to 80 %, while the reduction in erosion flux and sediment mass was set to 95 % as recommended by FOCUS L&M Guidelines;
- 20-meters wide buffer zone/VFS to mitigate spray drift and runoff; the reduction in runoff flux and volume was set to 80 %, while the reduction in erosion flux and sediment mass was set to 95 % as recommended by FOCUS L&M Guidelines;
- Aerial deposition from volatilised prochloraz as calculated by the EVA 2.0 for the vapour pressure range 10^{-4} to 10^{-5} Pa at these distances were added in the simulations.

BTS 44596 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 353.6 Water solubility (mg/L): 7 (20ºC) Soil or water metabolite: soil and water metabolite K_{fOC} (L/kg): 834.8 DT_{50} soil (d): 6.5 days (Field normalised geomean value. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 1000 days DT_{50} water (d): 1000 days DT_{50} sediment (d): 1000days Crop interception (%):cereals - 50% Maximum occurrence observed (% molar basis with respect to the parent) Soil: 46.8 % Water/sediment system: 61.7 % (max. observed in aqueous photolysis study; worst case value)
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed
Application rate	Crop: winter cereals Crop interception: 50% Number of applications: 1 or 2 Interval (d): 14 Application rate(s): 450 g a.s./ha Application window: Step 1& Step 2 – March - May; Crop: spring cereals Crop interception: 50% Number of applications: 1 or 2 Interval (d): 14 Application rate(s): 450 g a.s./ha Application window: Step 1& Step 2 – March - May;
Main routes of entry	Standard FOCUS Step1 & Step 2 assumptions

BTS 44595 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 325.62 Water solubility (mg/L): 100 (20ºC) Soil or water metabolite: soil and water metabolite K_{fOC} (L/kg): 1272.8 DT_{50} soil (d): 197.9 days (Field normalised geomean value. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 1000 days DT_{50} water (d): 1000 days DT_{50} sediment (d): 1000days Crop interception (%):cereals - 50% Maximum occurrence observed (% molar basis with respect to the parent) Soil: 30.2 % Water/sediment system: 5.9 % (max. observed in aqueous photolysis study; worst case value)
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed
Application rate	Crop: winter cereals Crop interception: 50% Number of applications: 1 or 2 Interval (d): 14 Application rate(s): 450 g a.s./ha Application window: Step 1& Step 2 – March - May; Crop: spring cereals Crop interception: 50% Number of applications: 1 or 2 Interval (d): 14 Application rate(s): 450 g a.s./ha Application window: Step 1& Step 2 – March - May;
Main routes of entry	Standard FOCUS Step1 & Step 2 assumptions

M590F040 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 340.6 Water solubility (mg/L): 1 (20ºC) Soil or water metabolite: soil metabolite K_{fOC} (L/kg): 2818.1 DT_{50} soil (d): 1 days (Lab. value reported for compound defined as "ghost compartment". In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 1000 days DT_{50} water (d): 1000 days DT_{50} sediment (d): 1000days Crop interception (%):cereals - 50% Maximum occurrence observed (% molar basis with respect to the parent) Soil: 8.2 % Water/sediment system: 0.01 %
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed
Application rate	Crop: winter cereals Crop interception: 50% Number of applications: 1 or 2 Interval (d): 14 Application rate(s): 450 g a.s./ha Application window: Step 1& Step 2 – March - May; Crop: spring cereals Crop interception: 50% Number of applications: 1 or 2 Interval (d): 14 Application rate(s): 450 g a.s./ha Application window: Step 1& Step 2 – March - May;
Main routes of entry	Standard FOCUS Step1 & Step 2 assumptions

BTS 40348 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 282.6 Water solubility (mg/L): 1000 (20ºC) Soil or water metabolite: soil metabolite K_{fOC} (L/kg): 1511.2 DT_{50} soil (d): 91 days (Lab normalised worst case value. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 1000 days DT_{50} water (d): 1000 days DT_{50} sediment (d): 1000days Crop interception (%):cereals - 50% Maximum occurrence observed (% molar basis with respect to the parent) Soil: 14.0 % Water/sediment system: 0.01%
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: SWASH v. 2.1 Vapour pressure: 1.0 E-10 Pa @ 20^0C K_{fOC}: 1511.2 1/n: 0.834
Application rate	Crop: winter cereals Crop interception: 50 % (step 1 and 2) Number of applications: 1 or 2 Interval (d): 14 Application rate(s): 450 g a.s./ha Application window: Step 1& Step 2 – March - May; Crop: spring cereals Crop interception: 50 % (step 1 and 2) Number of applications: 1 or 2 Interval (d): 14 Application rate(s): 450 g a.s./ha Application window: Step 1& Step 2 – March - May;
Main routes of entry	Standard FOCUS Step1 & Step 2 assumptions; At Step 3 Drainage - for D scenarios, or Runoff – for R scenarios;

a) results for a single application – 1 x 450 g a. s./ha;

Results of Step 1 & Step 2 Calculations for Prochloraz and its metabolites (only max. values used in aquatic risk assessment reported):

Compound	STEP 1		STEP 2			
			North Europe		South Europe	
	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]
Prochloraz[1)]	55.497	758.759	6.742	91.303	11.675	162.313
Prochloraz 1[2)]	21.715	1020	4.139	122.602	4.139	217.931
BTS 44596	33.582	269.612	3.409	26.418	5.444	43.399
BTS 44595	14.730	185.659	1.531	19.202	2.962	37.412
M590F040	2.338	65.877	0.015	0.414	0.029	0.826
BTS 40348	5.226	78.966	0.507	7.661	1.014	15.321

1) The results are reported for the compound assuming its lower K_{oc} – 1440.5 mL/g;
2) The results are reported for the compound assuming its higher K_{oc} – 5650.5 mL/g;

The results of the STEP 3 calculations of PEC_{SW} for Prochloraz applied in Winter cereals (only max. values used in aquatic risk assessment reported). Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Prochloraz		BTS 40348	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [1)]	Dissolved	Total [1)]	Dissolved
D1- ditch	2.965	2.956	0.0389	0.0387
D1 – stream	2.494	2.486	0.0245	0.0243
D2- ditch	2.886	2.877	0.0497	0.0494
D2 – stream	2.280	2.272	0.0312	0.0309
D3 - ditch	2.851	2.842	<1.0 E-6	<1.0 E-6
D4 - pond	0.0985	0.0979	2.98 E-3	2.95 E-3
D4 – stream	2.263	2.255	0.0166	0.0165
D5 – pond	0.0987	0.0981	3.56 E-4	3.51 E-4
D5 – stream	2.296	2.289	2.68 E-3	2.66 E-3
D6 – ditch	2.850	2.841	0.0169	0.0168
R1 – pond	0.123	0.123	3.61 E-3	3.57 E-3
R1 – stream	1.879	1.873	0.0145	0.0144
R3 – stream	2.640	2.631	0.0181	0.0179
R4 – stream	1.879	1.873	0.0208	0.0207

1) including the substance adsorbed to suspended particles

The results of the STEP 3 calculations of PEC_{SW} for Prochloraz-1 applied in Winter cereals (only max. values used in aquatic risk assessment reported). Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Prochloraz		BTS 40348	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [1)]	Dissolved	Total [1)]	Dissolved
D1- ditch	2.880	2.840	8.29 E-3	8.22 E-3
D1 – stream	2.448	2.412	5.25 E-3	5.20 E-3
D2- ditch	2.865	2.825	0.0210	0.0208
D2 – stream	2.269	2.235	0.0132	0.0131
D3 - ditch	2.851	2.811	<1.0 E-6	<1.0 E-6
D4 - pond	0.0984	0.0957	1.53 E-3	1.51 E-3
D4 – stream	2.263	2.229	0.0108	0.0107
D5 – pond	0.0984	0.0957	1.72 E-4	1.69 E-4
D5 – stream	2.296	2.263	1.56 E-3	1.54 E-3
D6 – ditch	2.850	2.810	0.0112	0.0111
R1 – pond	0.0985	0.0959	5.62 E-3	5.56 E-3
R1 – stream	1.879	1.850	0.0226	0.0224
R3 – stream	2.640	2.602	0.0271	0.0269
R4 – stream	1.879	1.851	0.0377	0.0375

1) including the substance adsorbed to suspended particles

The results of the STEP 3 calculations of PEC_{SW} for Prochloraz applied in Spring cereals (only max. values used in aquatic risk assessment reported). Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Prochloraz		BTS 40348	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [1)]	Dissolved	Total [1)]	Dissolved
D1- ditch	2.907	2.898	0.0113	0.0112
D1 – stream	2.526	2.517	7.15 E-3	7.08 E-3
D3 - ditch	2.852	2.843	<1.0 E-6	<1.0 E-6
D4 - pond	0.0986	0.0981	3.55 E-3	3.51 E-3
D4 – stream	2.364	2.356	0.0120	0.0119
D5 – pond	0.0986	0.0980	8.4 E-5	8.3 E-5
D5 – stream	2.646	2.616	7.11 E-4	7.01 E-4
R4 – stream	1.887	1.881	0.0240	0.0238

1) including the substance adsorbed to suspended particles

The results of the STEP 3 calculations of PEC_{SW} for Prochloraz-1 applied in Spring cereals (only max. values used in aquatic risk assessment reported). Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Prochloraz		BTS 40348	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [1)]	Dissolved	Total [1)]	Dissolved
D1- ditch	2.887	2.846	1.52 E-3	1.51 E-3
D1 – stream	2.525	2.489	9.66 E-4	9.55 E-4
D3 - ditch	2.852	2.812	<1.0 E-6	<1.0 E-6
D4 - pond	0.0984	0.0957	1.94 E-3	1.92 E-3
D4 – stream	2.364	2.329	7.65 E-3	7.58 E-3
D5 – pond	0.0985	0.0958	3.8 E-5	3.7 E-5
D5 – stream	2.624	2.587	3.72 E-4	3.66 E-4
R4 – stream	1.887	1.858	0.0390	0.0388

1) including the substance adsorbed to suspended particles

The results of the STEP 4 calculations of PEC_{SW} for Prochloraz applied in Winter cereals (only max. values used in aquatic risk assessment reported)
Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Buffer zone: 5 meters		Buffer zone: 10 meters		Buffer zone: 15[1)] meters		Buffer zone: 20 meters	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [2)]	Dissolved	Total [2)]	Dissolved	Total [2)]	Dissolved	Total [2)]	Dissolved
D1- ditch	0.959	0.955	0.590	0.587	0.440	0.438	0.355	0.353
D1 – stream	0.971	0.967	0.547	0.545	0.391	0.390	0.309	0.307
D2- ditch	0.834	0.831	0.483	0.481	0.346	0.344	0.268	0.267
D2 – stream	0.868	0.865	0.472	0.470	0.328	0.327	0.252	0.251
D3 - ditch	0.779	0.776	0.430	0.428	0.299	0.298	0.228	0.227
D4 - pond	0.113	0.112	0.0823	0.0818	0.0648	0.0644	0.0528	0.0525
D4 – stream	0.854	0.851	0.460	0.457	0.316	0.314	0.240	0.239
D5 – pond	0.113	0.113	0.0825	0.0820	0.0650	0.0646	0.0531	0.0527
D5 – stream	0.858	0.854	0.459	0.457	0.315	0.314	0.240	0.238
D6 – ditch	0.788	0.785	0.436	0.434	0.305	0.303	0.232	0.231
R1 – pond; RO not mitig.	0.131	0.130	0.118	0.117	0.111	0.110	0.106	0.105
R1 – pond; RO mitig.	n. a.[3)]	n. a.[3)]	0.0823	0.0818	0.0648	0.0644	0.0528	0.0525
R1 – stream; RO not mitig.	0.730	0.727	0.601	0.598	0.601	0.598	0.601	0.598
R1 – stream; RO mitig.	n. a.[3)]	n. a.[3)]	0.400	0.398	0.277	0.276	0.211	0.210
R3 – stream; RO not mitig.	1.105	1.100	1.105	1.100	1.105	1.100	1.105	1.100
R3 – stream; RO mitig.	n. a.[3)]	n. a.[3)]	0.551	0.549	0.382	0.381	0.291	0.289
R4 – stream; RO not mitig.	0.963	0.959	0.963	0.959	0.963	0.959	0.963	0.959
R4 – stream; RO mitig.	n. a.[3)]	n. a.[3)]	0.435	0.433	0.277	0.276	0.228	0.226

1) The reduction factors for runoff used here were such as for the 18-20 meters VFS;
2) including the substance adsorbed to suspended particles
3) not applicable – runoff was not mitigated for this buffer zone

The results of the STEP 4 calculations of PEC_{SW} for Prochloraz-1 applied in Winter cereals (only max. values used in aquatic risk assessment reported)
Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Buffer zone: 5 meters		Buffer zone: 10 meters		Buffer zone: 15[1)] meters		Buffer zone: 20 meters	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [2)]	Dissolved	Total [2)]	Dissolved	Total [2)]	Dissolved	Total [2)]	Dissolved
D1- ditch	0.873	0.857	0.505	0.495	0.356	0.348	0.271	0.265
D1 – stream	0.925	0.909	0.501	0.491	0.345	0.338	0.263	0.257
D2- ditch	0.814	0.799	0.463	0.454	0.326	0.319	0.248	0.243
D2 – stream	0.857	0.842	0.461	0.452	0.317	0.310	0.241	0.235
D3 - ditch	0.779	0.765	0.430	0.421	0.0647	0.0628	0.228	0.223
D4 - pond	0.113	0.110	0.0822	0.0799	0.299	0.293	0.0528	0.0512
D4 – stream	0.854	0.839	0.460	0.450	0.316	0.309	0.240	0.235
D5 – pond	0.113	0.110	0.0821	0.0798	0.0647	0.0627	0.0527	0.0511
D5 – stream	0.858	0.843	0.459	0.450	0.315	0.308	0.240	0.234
D6 – ditch	0.788	0.774	0.436	0.427	0.305	0.298	0.232	0.227
R1 – pond; RO not mitig.	0.113	0.110	0.0823	0.0800	0.0648	0.0629	0.0529	0.0513
R1 – pond; RO mitig.	n. a.[3)]	n. a.[3)]	0.0823	0.0799	0.0647	0.0628	0.0528	0.0512
R1 – stream; RO not mitig.	0.730	0.717	0.400	0.392	0.277	0.271	0.211	0.206
R1 – stream; RO mitig.	n. a.[3)]	n. a.[3)]	0.400	0.392	0.277	0.271	0.211	0.206
R3 – stream; RO not mitig.	1.013	0.995	0.552	0.541	0.382	0.374	0.291	0.284
R3 – stream; RO mitig.	n. a.[3)]	n. a.[3)]	0.552	0.541	0.382	0.374	0.291	0.284
R4 – stream; RO not mitig.	0.730	0.717	0.400	0.392	0.277	0.271	0.235	0.229
R4 – stream; RO mitig.	n. a.[3)]	n. a.[3)]	0.400	0.392	0.277	0.271	0.211	0.206

1) The reduction factors for runoff used here were such as for the 18-20 meters VFS;
2) including the substance adsorbed to suspended particles
3) not applicable – runoff was not mitigated for this buffer zone

The results of the STEP 4 calculations of PEC_{SW} for Prochloraz applied in Spring cereals (only max. values used in aquatic risk assessment reported):
Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Buffer zone: 5 meters		Buffer zone: 10 meters		Buffer zone: 15[1)] meters		Buffer zone: 20 meters	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [2)]	Dissolved	Total [2)]	Dissolved	Total [2)]	Dissolved	Total [2)]	Dissolved
D1- ditch	0.920	0.917	0.541	0.538	0.387	0.385	0.299	0.298
D1 – stream	0.925	0.922	0.494	0.491	0.341	0.340	0.260	0.259
D3 - ditch	0.783	0.780	0.432	0.430	0.310	0.299	0.229	0.228
D4 - pond	0.113	0.113	0.0825	0.0820	0.0650	0.0645	0.0530	0.0527
D4 – stream	0.896	0.892	0.485	0.483	0.334	0.333	0.254	0.253
D5 – pond	0.113	0.113	0.0825	0.0820	0.0649	0.0645	0.0530	0.0526
D5 – stream	0.991	0.987	0.536	0.534	0.369	0.368	0.281	0.280
R4 – stream; RO not mitig.	1.060	1.056	1.060	1.056	1.060	1.056	1.060	1.056
R4 – stream; RO mitig.	n. a.[3)]	n. a.[3)]	0.484	0.482	0.279	0.278	0.254	0.253

1) The reduction factors for runoff used here were such as for the 18-20 meters VFS;
2) including the substance adsorbed to suspended particles
3) not applicable – runoff was not mitigated for this buffer zone

The results of the STEP 4 calculations of PEC_{SW} for Prochloraz-1 applied in Spring cereals (only max. values used in aquatic risk assessment reported)
Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Buffer zone: 5 meters		Buffer zone: 10 meters		Buffer zone: 15[1)] meters		Buffer zone: 20 meters	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [2)]	Dissolved	Total [2)]	Dissolved	Total [2)]	Dissolved	Total [2)]	Dissolved
D1- ditch	0.898	0.882	0.519	0.509	0.366	0.358	0.278	0.272
D1 – stream	0.925	0.908	0.493	0.483	0.341	0.333	0.259	0.253
D3 - ditch	0.783	0.769	0.432	0.423	0.301	0.294	0.229	0.224
D4 - pond	0.113	0.110	0.0823	0.0799	0.0648	0.0628	0.0528	0.0512
D4 – stream	0.896	0.880	0.485	0.475	0.334	0.327	0.254	0.249
D5 – pond	0.113	0.110	0.0824	0.0801	0.0649	0.0630	0.0529	0.0513
D5 – stream	0.991	0.974	0.536	0.526	0.369	0.362	0.281	0.275
R4 – stream; RO not mitig.	0.737	0.723	0.403	0.395	0.279	0.273	0.247	0.242
R4 – stream; RO mitig.	n. a.[3)]	n. a.[3)]	0.366	0.358	0.279	0.273	0.190	0.185

1) The reduction factors for runoff used here were such as for the 18-20 meters VFS;
2) including the substance adsorbed to suspended particles
3) not applicable – runoff was not mitigated for this buffer zone

b) results for a multiple application – 2 x 450 g a. s./ha;

Results of Step 1 & Step 2 Calculations for Prochloraz and its metabolites (only max. values used in aquatic risk assessment reported):

Compound	STEP 1		STEP 2			
			North Europe		South Europe	
	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]
Prochloraz[1)]	110.993	1520	12.382	168.235	21.599	300.913
Prochloraz-1[2)]	43.429	2040	4.377	226.015	7.531	404.133
BTS 44596	67.163	539.223	4.907	37.394	7.400	58.191
BTS 44595	29.459	371.318	2.969	37.293	5.764	72.841
M590F040	4.676	131.754	0.015	0.415	0.029	0.827
BTS 40348	10.451	157.932	0.963	14.547	1.925	29.091

1) The results are reported for the compound assuming its lower K_{oc} – 1440.5 mL/g;
2) The results are reported for the compound assuming its higher K_{oc} – 5650.5 mL/g;

The results of the STEP 3 calculations of PEC_{SW} for Prochloraz applied in Winter cereals (only max. values used in aquatic risk assessment reported). Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Prochloraz		BTS 40348	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [1)]	Dissolved	Total [1)]	Dissolved
D1- ditch	2.989	2.979	0.105	0.105
D1 – stream	2.252	2.245	0.0662	0.0658
D2- ditch	2.598	2.589	0.127	0.126
D2 – stream	2.252	2.244	0.0795	0.0790
D3 - ditch	2.494	2.486	<1.0 E-6	<1.0 E-6
D4 - pond	0.135	0.134	6.62 E-3	6.56 E-3
D4 – stream	1.979	1.972	0.0333	0.0331
D5 – pond	0.139	0.138	8.35 E-4	8.24 E-4
D5 – stream	2.165	2.158	5.62 E-3	5.57 E-3
D6 – ditch	2.514	2.505	0.0270	0.0268
R1 – pond	0.247	0.245	7.84 E-3	7.77 E-3
R1 – stream	1.625	1.619	0.0310	0.0308
R3 – stream	2.284	2.276	0.0360	0.0358
R4 – stream	2.163	2.155	0.0410	0.0407

1) including the substance adsorbed to suspended particles

The results of the STEP 3 calculations of PEC_{SW} for Prochloraz-1 applied in Winter cereals (only max. values used in aquatic risk assessment reported). Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Prochloraz		BTS 40348	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [1)]	Dissolved	Total [1)]	Dissolved
D1- ditch	2.668	2.630	0.0297	0.0295
D1 – stream	2.184	2.151	0.0188	0.0186
D2- ditch	2.549	2.512	0.0604	0.0600
D2 – stream	2.224	2.191	0.0379	0.0376
D3 - ditch	2.494	2.458	<1.0 E-6	<1.0 E-6
D4 - pond	0.127	0.124	3.40 E-3	3.37 E-3
D4 – stream	1.979	1.949	0.0225	0.0223
D5 – pond	0.126	0.123	2.81 E-4	2.76 E-4
D5 – stream	2.274	2.240	2.45 E-3	2.42 E-3
D6 – ditch	2.515	2.478	0.0188	0.0187
R1 – pond	0.124	0.121	0.0133	0.0132
R1 – stream	1.625	1.599	0.0525	0.0522
R3 – stream	2.283	2.249	0.0531	0.0527
R4 – stream	1.625	1.600	0.0782	0.0778

1) including the substance adsorbed to suspended particles

The results of the STEP 3 calculations of PEC_{SW} for Prochloraz applied in Spring cereals (only max. values used in aquatic risk assessment reported). Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Prochloraz		BTS 40348	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [1)]	Dissolved	Total [1)]	Dissolved
D1- ditch	3.783	3.771	0.0231	0.0230
D1 – stream	2.186	2.179	0.0145	0.0144
D3 - ditch	2.503	2.493	<1.0 E-6	<1.0 E-6
D4 - pond	0.136	0.135	7.83 E-3	7.76 E-3
D4 – stream	2.101	2.094	0.0249	0.0247
D5 – pond	0.139	0.139	2.99 E-4	2.95 E-4
D5 – stream	2.303	2.295	2.14 E-3	2.11 E-3
R4 – stream	1.635	1.629	0.0415	0.0412

1) including the substance adsorbed to suspended particles

The results of the STEP 3 calculations of PEC_{SW} for Prochloraz-1 applied in Spring cereals (only max. values used in aquatic risk assessment reported). Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Prochloraz		BTS 40348	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [1]	Dissolved	Total [1]	Dissolved
D1- ditch	3.261	3.216	4.06 E-3	4.02 E-3
D1 – stream	2.185	2.152	3.57 E-3	2.54 E-3
D3 - ditch	2.500	2.464	<1.0 E-6	<1.0 E-6
D4 - pond	0.127	0.124	4.42 E-3	4.38 E-3
D4 – stream	2.101	2.070	0.0165	0.0163
D5 – pond	0.133	0.129	1.30 E-4	1.28 E-4
D5 – stream	2.302	2.269	1.09 E-3	1.08 E-3
R4 – stream	1.633	1.607	0.0623	0.0619

1) including the substance adsorbed to suspended particles

The results of the STEP 4 calculations of PEC_{SW} for Prochloraz applied in Winter cereals (only max. values used in aquatic risk assessment reported)
Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Buffer zone: 5 meters		Buffer zone: 10 meters		Buffer zone: 15[1] meters		Buffer zone: 20 meters	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [2]	Dissolved	Total [2]	Dissolved	Total [2]	Dissolved	Total [2]	Dissolved
D1- ditch	1.084	1.080	0.713	0.710	0.562	0.560	0.479	0.476
D1 – stream	0.916	0.912	0.551	0.549	0.419	0.417	0.349	0.348
D2- ditch	0.850	0.847	0.542	0.540	0.542	0.540	0.542	0.540
D2 – stream	0.816	0.812	0.438	0.436	0.340	0.338	0.340	0.338
D3 - ditch	0.667	0.665	0.367	0.366	0.257	0.255	0.194	0.193
D4 - pond	0.165	0.165	0.119	0.119	0.0930	0.0924	0.0752	0.0748
D4 – stream	0.729	0.726	0.386	0.384	0.263	0.261	0.198	0.197
D5 – pond	0.170	0.169	0.123	0.122	0.0957	0.0951	0.0775	0.0771
D5 – stream	0.798	0.794	0.422	0.420	0.287	0.286	0.217	0.216
D6 – ditch	0.770	0.767	0.445	0.443	0.312	0.311	0.236	0.235
R1 – pond; RO not mitig.	0.263	0.261	0.241	0.240	0.228	0.227	0.220	0.219
R1 – pond; RO mitig.	n. a.[3]	n. a.[3]	0.130	0.129	0.0908	0.0902	0.0737	0.0732
R1 – stream; RO not mitig.	1.385	1.380	1.385	1.380	1.385	1.380	1.385	1.380
R1 – stream; RO mitig.	n. a.[3]	n. a.[3]	0.630	0.627	0.330	0.329	0.330	0.329
R3 – stream; RO not mitig.	1.678	1.672	1.678	1.672	1.678	1.672	1.678	1.672
R3 – stream; RO mitig.	n. a.[3]	n. a.[3]	0.767	0.764	0.402	0.401	0.402	0.401
R4 – stream; RO not mitig.	2.163	2.155	2.163	2.155	2.163	2.155	2.163	2.155
R4 – stream; RO mitig.	n. a.[3]	n. a.[3]	0.978	0.974	0.511	0.509	0.511	0.509

1) The reduction factors for runoff used here were such as for the 18-20 meters VFS;
2) including the substance adsorbed to suspended particles
3) not applicable – runoff was not mitigated for this buffer zone

The results of the STEP 4 calculations of PEC_{SW} for Prochloraz-1 applied in Winter cereals (only max. values used in aquatic risk assessment reported)
Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Buffer zone: 5 meters		Buffer zone: 10 meters		Buffer zone: 15[1)] meters		Buffer zone: 20 meters	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [2)]	Dissolved	Total [2)]	Dissolved	Total [2)]	Dissolved	Total [2)]	Dissolved
D1- ditch	0.829	0.814	0.476	0.466	0.328	0.321	0.251	0.246
D1 – stream	0.781	0.767	0.416	0.408	0.284	0.278	0.215	0.210
D2- ditch	0.792	0.778	0.457	0.448	0.316	0.309	0.243	0.237
D2 – stream	0.788	0.773	0.410	0.401	0.276	0.270	0.208	0.204
D3 - ditch	0.667	0.655	0.367	0.359	0.253	0.248	0.194	0.189
D4 - pond	0.155	0.151	0.112	0.109	0.0863	0.0839	0.0705	0.0684
D4 – stream	0.729	0.715	0.386	0.377	0.259	0.253	0.198	0.193
D5 – pond	0.154	0.150	0.111	0.108	0.0856	0.0832	0.0699	0.0679
D5 – stream	0.836	0.820	0.444	0.435	0.289	0.283	0.229	0.223
D6 – ditch	0.769	0.755	0.444	0.435	0.307	0.300	0.236	0.230
R1 – pond; RO not mitig.	0.151	0.147	0.109	0.106	0.0841	0.0817	0.0688	0.0668
R1 – pond; RO mitig.	n. a.[3)]	n. a.[3)]	0.109	0.106	0.0846	0.0822	0.0684	0.0664
R1 – stream; RO not mitig.	0.620	0.608	0.335	0.328	0.315	0.308	0.315	0.308
R1 – stream; RO mitig.	n. a.[3)]	n. a.[3)]	0.335	0.328	0.231	0.225	0.174	0.170
R3 – stream; RO not mitig.	0.857	0.841	0.463	0.454	0.355	0.348	0.355	0.348
R3 – stream; RO mitig.	n. a.[3)]	n. a.[3)]	0.463	0.454	0.319	0.312	0.241	0.235
R4 – stream; RO not mitig.	0.620	0.608	0.534	0.524	0.534	0.524	0.534	0.524
R4 – stream; RO mitig.	n. a.[3)]	n. a.[3)]	0.335	0.328	0.231	0.225	0.174	0.170

1) The reduction factors for runoff used here were such as for the 18-20 meters VFS;
2) including the substance adsorbed to suspended particles
3) not applicable – runoff was not mitigated for this buffer zone

The results of the STEP 4 calculations of PEC_{SW} for Prochloraz applied in Spring cereals (only max. values used in aquatic risk assessment reported):
Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Buffer zone: 5 meters		Buffer zone: 10 meters		Buffer zone: 15[1] meters		Buffer zone: 20 meters	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [2]	Dissolved	Total [2]	Dissolved	Total [2]	Dissolved	Total [2]	Dissolved
D1- ditch	1.207	1.202	0.703	0.700	0.506	0.504	0.384	0.383
D1 – stream	0.775	0.772	0.413	0.411	0.285	0.283	0.215	0.214
D3 - ditch	0.680	0.677	0.384	0.382	0.269	0.268	0.204	0.203
D4 - pond	0.167	0.166	0.120	0.120	0.0949	0.0943	0.0761	0.0756
D4 – stream	0.771	0.768	0.413	0.412	0.283	0.282	0.214	0.213
D5 – pond	0.171	0.170	0.123	0.123	0.0971	0.0965	0.0777	0.0773
D5 – stream	0.836	0.833	0.446	0.444	0.305	0.303	0.230	0.0229
R4 – stream; RO not mitig.	1.075	1.071	1.075	1.071	1.075	1.071	1.075	1.071
R4 – stream; RO mitig.	n. a.[3]	n. a.[3]	0.491	0.489	0.257	0.256	0.257	0.256

1) The reduction factors for runoff used here were such as for the 18-20 meters VFS;
2) including the substance adsorbed to suspended particles
3) not applicable – runoff was not mitigated for this buffer zone

The results of the STEP 4 calculations of PEC_{SW} for Prochloraz-1 applied in Spring cereals (only max. values used in aquatic risk assessment reported)
Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Buffer zone: 5 meters		Buffer zone: 10 meters		Buffer zone: 15[1] meters		Buffer zone: 20 meters	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [2]	Dissolved	Total [2]	Dissolved	Total [2]	Dissolved	Total [2]	Dissolved
D1- ditch	1.007	0.989	0.570	0.559	0.403	0.395	0.304	0.297
D1 – stream	0.774	0.760	0.412	0.404	0.284	0.277	0.214	0.209
D3 - ditch	0.680	0.667	0.378	0.370	0.269	0.263	0.204	0.199
D4 - pond	0.155	0.151	0.111	0.108	0.0874	0.0849	0.0707	0.0686
D4 – stream	0.771	0.757	0.403	0.395	0.283	0.277	0.214	0.109
D5 – pond	0.162	0.158	0.116	0.113	0.0911	0.0885	0.0737	0.0716
D5 – stream	0.836	0.821	0.445	0.436	0.305	0.298	0.230	0.225
R4 – stream; RO not mitig.	0.626	0.614	0.338	0.330	0.265	0.259	0.265	0.259
R4 – stream; RO mitig.	n. a.[3]	n. a.[3]	0.299	0.293	0.232	0.227	0.175	0.171

1) The reduction factors for runoff used here were such as for the 18-20 meters VFS;
2) including the substance adsorbed to suspended particles
3) not applicable – runoff was not mitigated for this buffer zone

Additionally the 21-day TWA PEC_{SW} values, also used in the aquatic Risk Assessment, are reported below.

21-day TWA PEC_{SW} for Prochloraz and Prochloraz-1 applied in Winter Cereals

Assessment tier		21-day TWA PEC_{SW} [µg/L] for:			
		Prochloraz[1)]		Prochloraz-1[2)]	
		Single application	Double application	Single application	Double application
STEP 1		51.784	103.569	17.787	35.574
STEP 2	North Europe	6.273	11.558	2.069	3.979
	South Europe	11.145	20.403	3.465	7.069
STEP 3	D1 – ditch	1.228	1.940	0.957	1.350
	D1 – stream	0.0832	0.192	0.0270	0.113
	D2 – ditch	0.387	0.783	0.330	0.634
	D2 – stream	0.0257	0.608	0.00739	0.522
	D3 – ditch	0.132	0.235	0.127	0.227
	D4 – Pond	0.0759	0.111	0.0689	0.0923
	D4 – stream	0.00850	0.0206	0.00718	0.0132
	D5 – pond	0.0763	0.115	0.0690	0.0935
	D5 – stream	0.00472	0.0138	0.00466	0.0364
	D6 – ditch	0.148	0.758	0.140	0.648
	R1 – pond	0.106	0.211	0.0680	0.0890
	R1 – stream	0.0492	0.111	0.0180	0.0289
	R3 – stream	0.0828	0.0938	0.0431	0.0408
	R4 – stream	0.127	0.280	0.0352	0.0802

1) assumed low K_{OC} – 1440.5 mL/g;
2) assumed high K_{OC} – 5650.7 mL/g;

21-day TWA PEC_{SW} for Prochloraz and Prochloraz-1 applied in Spring Cereals

Assessment tier		21-day TWA PEC_{SW} [µg/L] for:			
		Prochloraz[1)]		Prochloraz-1[2)]	
		Single application	Double application	Single application	Double application
STEP 1		51.784	103.569	17.787	35.574
STEP 2	North Europe	6.273	11.558	2.069	3.979
	South Europe	11.145	20.403	3.465	7.069
STEP 3	D1 – ditch	1.730	2.494	1.310	1.678
	D1 – stream	0.113	0.188	0.105	0.181
	D3 – ditch	0.142	0.286	0.136	0.275
	D4 – Pond	0.0763	0.112	0.0691	0.0932
	D4 – stream	0.0127	0.0300	0.0125	0.0295
	D5 – pond	0.0773	0.116	0.0701	0.0977
	D5 – stream	0.0300	0.0681	0.0293	0.0668
	R4 – stream	0.168	0.145	0.0519	0.0544

1) assumed low K_{OC} – 1440.5 mL/g;
2) assumed high K_{OC} – 5650.7 mL/g;

2) Calculations for prochloraz applied as a seed treatment (formulation Prelude 20 FS).

Parent – **Prochloraz** Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: ver. 1.1 Molecular weight (g/mol): 376.7 Water solubility (mg/L):34.4 K_{fOC} (L/kg): 1440.5 (Prochloraz); 5650.7 (Prochloraz-1) DT_{50} soil (d): 68.8 days (Field geomean normalised value. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 359 days DT_{50} water (d): 359 DT_{50} sediment (d): 1000 Crop interception (%): 0%
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: SWASH v. 2.1 Vapour pressure: 1.5 E-4 Pa @ 25^0C K_{fOC}: 1440.5 (Prochloraz); 5650.7 (Prochloraz-1) 1/n: 0.815 (Prochloraz); 0.801 (Prochloraz-1)
Application rate	Crop: spring cereals Crop interception: 0 % Number of applications: 1 Interval (d): not applicable Application rate(s): 33.1 g as/ha Application window: Step 1& Step 2 – March - May; Step 3: D1: 21 April – 22 May D3: 18 March – 17 April; D4: 12 April – 12 May; D5: 01 March – 31 March; R4: 01 March – 31 March; Crop: winter cereals Crop interception: 0 % Number of applications: 1 Interval (d): not applicable Application rate(s): 33.1 g as/ha Application window: Step 1& Step 2 – October-February; Step 3: D1: 11 September – 11 October; D2: 11 October – 10 November; D3: 07 November – 07 December; D4: 08 September – 08 October; D5: 27 October – 26 November; D6: 16 November – 16 December; R1: 29 October – 28 November; R3: 17 November – 17 December; R4: 27 October – 26 November;

	Dust drift values: Ditch: 1.9274% Pond: 0.2191% Stream: 1.4304%
BTS 44596 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 353.6 Water solubility (mg/L): 7 (20ºC) Soil or water metabolite: soil and water metabolite K_{foC} (L/kg): 834.8 DT_{50} soil (d): 6.5 days (Field normalised geomean value. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 1000 days DT_{50} water (d): 1000 days DT_{50} sediment (d): 1000days Crop interception (%):cereals - 0% Maximum occurrence observed (% molar basis with respect to the parent) Soil: 12.8 % Water/sediment system: 61.7 % (max. observed in aqueous photolysis study)
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed
Application rate	Crop: winter cereals Crop interception: 0% Number of applications: 1 Interval (d): not applicable Application rate(s): 33.1 g a.s./ha Application window: Step 1& Step 2 – October - February; Crop: spring cereals Crop interception: 0% Number of applications: 1 Interval (d): Not applicable Application rate(s): 33.1 g a.s./ha Application window: Step 1& Step 2 – March - May;
Main routes of entry	Standard FOCUS Step1 & Step 2 assumptions

BTS 44595 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 325.62 Water solubility (mg/L): 100 (20ºC) Soil or water metabolite: soil and water metabolite K_{fOC} (L/kg): 1272.8 DT_{50} soil (d): 197.9 days (Field normalised geomean value. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 1000 days DT_{50} water (d): 1000 days DT_{50} sediment (d): 1000days Crop interception (%):cereals - 0% Maximum occurrence observed (% molar basis with respect to the parent) Soil: 6.3 % Water/sediment system: 5.9 % (max. observed in aqueous photolysis study)
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed
Application rate	Crop: winter cereals Crop interception: 0% Number of applications: 1 Interval (d): not applicable Application rate(s): 33.1 g a.s./ha Application window: Step 1& Step 2 – October - February; Crop: spring cereals Crop interception: 0% Number of applications: 1 Interval (d): not applicable Application rate(s): 33.1 g a.s./ha Application window: Step 1& Step 2 – March - May;
Main routes of entry	Standard FOCUS Step1 & Step 2 assumptions

M590F040 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 340.6 Water solubility (mg/L): 1 (20ºC) Soil or water metabolite: soil metabolite K_{fOC} (L/kg): 2818.1 DT_{50} soil (d): 1 days (Lab. value reported for compound defined as "ghost compartment". In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 1000 days DT_{50} water (d): 1000 days DT_{50} sediment (d): 1000days Crop interception (%):cereals - 0% Maximum occurrence observed (% molar basis with respect to the parent) Soil: 8.2 % Water/sediment system: 0.01 %
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed
Application rate	Crop: winter cereals Crop interception: 0% Number of applications: 1 Interval (d): not applicable Application rate(s): 33.1 g a.s./ha Application window: Step 1& Step 2 – October - February; Crop: spring cereals Crop interception: 0% Number of applications: 1 Interval (d): Not applicable Application rate(s): 33.1 g a.s./ha Application window: Step 1& Step 2 – March - May;
Main routes of entry	Standard FOCUS Step1 & Step 2 assumptions

BTS 40348 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 282.6 Water solubility (mg/L): 1000 (20ºC) Soil or water metabolite: soil metabolite K_{fOC} (L/kg): 1511.2 DT_{50} soil (d): 91 days (Lab normalised worst case value. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 1000 days DT_{50} water (d): 1000 days DT_{50} sediment (d): 1000days Crop interception (%):cereals - 0% Maximum occurrence observed (% molar basis with respect to the parent) Soil: 14.0 % Water/sediment system: 0.01%
Parameters used in FOCUSsw step 3 (if performed)	Calculations not performed
Application rate	Crop: winter cereals Crop interception: 0% Number of applications: 1 Interval (d): not applicable Application rate(s): 33.1 g a.s./ha Application window: Step 1& Step 2 – October - February; Crop: spring cereals Crop interception: 0% Number of applications: 1 Interval (d): not applicable Application rate(s): 33.1 g a.s./ha Application window: Step 1& Step 2 – March - May;
Main routes of entry	Standard FOCUS Step1 & Step 2 assumptions;

Results of Step 1 & Step 2 Calculations for Prochloraz and its metabolites (only max. values used in aquatic risk assessment reported):

Crop: Winter Cereals						
Compound	**STEP 1**		**STEP 2**			
			North Europe		**South Europe**	
	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]
Prochloraz[1)]	3.766	54.253	1.809	22.055	1.447	20.844
Prochloraz 1[2)]	1.289	72.833	0.619	34.978	0.495	27.983
BTS 44596	0.625	5.220	0.204	1.704	0.163	1.363
BTS 44595	0.222	2.827	0.109	1.394	0.088	1.115
M590F040	0.171	4.831	0.005	0.151	0.004	0.121
BTS 40348	0.382	5.791	0.186	2.809	0.149	2.247
Crop: Spring Cereals						
Compound	**STEP 1**		**STEP 2**			
			North Europe		**South Europe**	
	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]
Prochloraz[1)]	3.766	54.253	0.724	10.422	1.447	20.844
Prochloraz 1[2)]	1.289	72.833	0.248	13.991	0.495	27.983
BTS 44596	0.625	5.220	0.082	0.682	0.163	1.363
BTS 44595	0.222	2.827	0.044	0.558	0.088	1.115
M590F040	0.171	4.831	0.002	0.060	0.004	0.121
BTS 40348	0.382	5.791	0.074	1.123	0.149	2.247

1) The results are reported for the compound assuming its lower K_{oc} – 1440.5 mL/g;
2) The results are reported for the compound assuming its higher K_{oc} – 5650.5 mL/g;

The results of the STEP 3 calculations of $PEC_{SW}$for Prochloraz applied in Winter cereals (only max. values used in aquatic risk assessment reported) Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	**Drift not included**		**Drift included**	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [1)]	Dissolved	Total [1)]	Dissolved
D1- ditch	<1.0 E-6	<1.0 E-6	0.212	0.21
D1 – stream	<1.0 E-6	<1.0 E-6	0.186	0.185
D2- ditch	<1.0 E-6	<1.0 E-6	0.213	0.211
D2 – stream	Solution not found by TOXSWA		0.189	0.188
D3 - ditch	<1.0 E-6	<1.0 E-6	0.209	0.208
D4 - pond	1 E-6	1 E-6	7.29 E-3	7.22 E-3
D4 – stream	1.8 E-5	1.8 E-5	0.181	0.180
D5 – pond	1 E-6	<1.0E-6	7.29 E-3	7.22 E-3
D5 – stream	7E-6	7E-6	0.196	0.195
D6 – ditch	5 E-6	4 E-6	0.211	0.210
R1 – pond	7.01 E-4	6.91 E-4	7.29 E-3	7.22 E-3
R1 – stream	0.0616	0.0612	0.138	0.137
R3 – stream	0.0794	0.0790	0.192	0.191
R4 – stream	0.0264	0.0262	0.139	0.138

1) including the substance adsorbed to suspended particles

The results of the STEP 3 calculations of PEC_{SW} for Prochloraz-1 applied in Winter cereals (only max. values used in aquatic risk assessment reported) Note the sediment dweller risk assessment was finalised using Step 2 PEC_{SED} values. These Step 2 values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Drift not included		Drift included	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [1)]	Dissolved	Total [1)]	Dissolved
D1- ditch	<1.0 E-6	<1.0 E-6	0.212	0.207
D1 – stream	<1.0 E-6	<1.0 E-6	0.186	0.181
D2- ditch	<1.0 E-6	<1.0 E-6	0.213	0.208
D2 – stream	<1.0 E-6	<1.0 E-6	0.189	0.185
D3 - ditch	<1.0 E-6	<1.0 E-6	0.209	0.204
D4 - pond	<1.0 E-6	<1.0 E-6	7.29 E-3	6.96 E-3
D4 – stream	1 E-6	1 E-6	0.181	0.177
D5 – pond	<1.0 E-6	<1.0 E-6	7.29 E-3	6.96 E-3
D5 – stream	<1.0 E-6	<1.0 E-6	0.196	0.191
D6 – ditch	<1.0 E-6	<1.0 E-6	0.211	0.206
R1 – pond	1.46 E-3	1.37 E-3	7.29 E-3	6.96 E-3
R1 – stream	0.0231	0.0222	0.138	0.134
R3 – stream	0.0289	0.0279	0.192	0.187
R4 – stream	0.0245	0.0237	0.139	0.135

1) including the substance adsorbed to suspended particles

The results of the STEP 3 calculations of PEC_{SW} for Prochloraz applied in Spring cereals (only max. values used in aquatic risk assessment reported): Note the aquatic invertebrate risk assessment was finalised using Step 2 PEC values. Step 2 PEC_{SED} values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Drift not included		Drift included	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [1)]	Dissolved	Total [1)]	Dissolved
D1- ditch	<1.0 E-6	<1.0 E-6	0.211	0.210
D1 – stream	<1.0 E-6	<1.0 E-6	0.174	0.173
D3 - ditch	<1.0 E-6	<1.0 E-6	0.210	0.208
D4 - pond	<1.0 E-6	<1.0 E-6	7.29 E-3	7.22 E-3
D4 – stream	<1.0 E-6	<1.0 E-6	0.163	0.162
D5 – pond	<1.0 E-6	<1.0 E-6	7.29 E-3	7.22 E-3
D5 – stream	<1.0 E-6	<1.0 E-6	0.162	0.161
R4 – stream	3.71 E-3	3.67 E-3	0.138	0.137

1) including the substance adsorbed to suspended particles

The results of the STEP 3 calculations of PEC_{SW} for Prochloraz-1 applied in Spring cereals (only max. values used in aquatic risk assessment reported). Note the aquatic invertebrate risk assessment was finalised using Step 2 PEC values. Step 2 PEC_{SED} values were shown to be higher than the Step 3 PECsed values including accumulation in the Addendum/corrigendum 1 to the Additional report-Section B.8. Consequently only the Step 2 PEC_{SED} values are included in this list of endpoints

FOCUS Scenario	Drift not included		Drift included	
	PEC_{SW} [µg/L]		PEC_{SW} [µg/L]	
	Total [1)]	Dissolved	Total [1)]	Dissolved
D1- ditch	<1.0 E-6	<1.0 E-6	0.211	0.206
D1 – stream	<1.0 E-6	<1.0 E-6	0.174	0.170
D3 - ditch	<1.0 E-6	<1.0 E-6	0.210	0.205
D4 - pond	<1.0 E-6	<1.0 E-6	7.29 E-3	6.96 E-3
D4 – stream	<1.0 E-6	<1.0 E-6	0.163	0.159
D5 – pond	<1.0 E-6	<1.0 E-6	7.28 E-3	6.95 E-3
D5 – stream	<1.0 E-6	<1.0 E-6	0.162	0.158
R4 – stream	0.0123	0.0118	0.138	0.135

1) including the substance adsorbed to suspended particles

Additionally the 21-day TWA PEC_{SW} values, also used in the aquatic Risk Assessment, are reported below.

21-day TWA PEC_{SW} for Prochloraz and Prochloraz-1 applied in Winter Cereals

Assessment tier		21-day TWA PEC_{SW} [µg/L] for:			
		Prochloraz[1)]		Prochloraz-1[2)]	
STEP 1		3.691		1.263	
STEP 2	North Europe	1.786		0.613	
	South Europe	1.429		0.490	
STEP 3		No dust drift	Dust drift included	No dust drift	Dust drift included
	D1 – ditch	0.000000	0.115	Not calculated	0.0905
	D1 – stream	0.000000	0.00793	Not calculated	0.00761
	D2 – ditch	0.000000	0.0618	0.000000	0.0555
	D2 – stream	No data	0.0519	0.000000	0.0480
	D3 – ditch	Not calculated	0.00710	0.000000	0.00676
	D4 – Pond	0.000001	0.00550	0.000000	0.00502
	D4 – stream	0.000000	0.00252	0.000000	0.00245
	D5 – pond	0.000000	0.00557	0.000000	0.00509
	D5 – stream	0.000000	0.00359	0.000000	0.00349
	D6 – ditch	0.000000	0.0424	0.000000	0.0384
	R1 – pond	0.000504	0.00565	0.000976	0.00500
	R1 – stream	0.00125	0.00239	0.000518	0.00159
	R3 – stream	0.00482	0.00631	0.00258	0.00397
	R4 – stream	0.000893	0.00140	0.000947	0.00137

1) assumed low K_{OC} – 1440.5 mL/g;
2) assumed high K_{OC} – 5650.7 mL/g;

21-day TWA PEC_{SW} for Prochloraz and Prochloraz-1 applied in Spring Cereals

Assessment tier		21-day TWA PEC_{SW} [µg/L] for:			
		Prochloraz[1)]		Prochloraz-1[2)]	
STEP 1		3.691		1.263	
STEP 2	North Europe	0.715		0.245	
	South Europe	1.429		0.490	
STEP 3		No dust drift	Dust drift included	No dust drift	Dust drift included
	D1 – ditch	0.000000	0.0325	Not calculated	0.0310
	D1 – stream	0.000000	0.000964	Not calculated	0.000942
	D3 – ditch	Not calculated	0.00946	Not calculated	0.00904
	D4 – Pond	0.000001	0.00541	No data	0.00495
	D4 – stream	No data	0.000441	0.000000	0.000431
	D5 – pond	0.000000	0.00536	0.000000	0.00491
	D5 – stream	0.000000	0.000266	0.000000	0.000260
	R4 – stream	0.000193	0.00120	0.00109	0.00117

1) assumed low K_{OC} – 1440.5 mL/g;
2) assumed high K_{OC} – 5650.7 mL/g;

PEC (groundwater) (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 models, with appropriate FOCUSgw scenarios, according to FOCUS guidance.
	Model(s) used: FOCUS PEARL ver. 3.3.3, FOCUS PELMO ver. 3.3.2 and FOCUS MACRO ver. 4.4.2.
	Scenarios: Chateaudun, Hamburg, Jokioinen, Kremsmunster, Okehampton, Piacenza, Porto, Sevilla, Thiva
	Crop: Winter Cereals, Spring Cereals, application as spray liquid or seed treatment (incorporation)
	Q10=2.58, Walker equation coefficient 0.7
	Substance-specific input parameters:
	Prochloraz:
	M = 376.7 g/mol;
	S_{H2O} = 34.4 mg/L (@ 25^{0}C);
	p = 1.5 E-4 Pa(@ 25^{0}C);
	DT_{50} = 68.8 days (geomean, field studies, normalisation to pF2, 20^{0}C with Q_{10} = 2.58)
	K_{fOC} = 1440.5 mL/g; K_{fOM} = 835.6 mL/g; 1/n = 0.815 (all values arithmetic means).
	Prochloraz-1:
	M = 376.7 g/mol;
	S_{H2O} = 34.4 mg/L (@ 25^{0}C);
	p = 1.5 E-4 Pa(@ 25^{0}C);
	DT_{50} = 68.8 days (geomean, field studies, normalisation to pF2, 20^{0}C with Q_{10} = 2.58)
	K_{fOC} = 5650.7 mL/g; K_{fOM} = 3277.7 mL/g; 1/n = 0.801 (all values arithmetic means).
	BTS 44596:
	M = 353.6 g/mol;
	S_{H2O} = 7 mg/L (@ 20^{0}C);
	p = 1.0 E-10 Pa (@ 20^{0}C);
	DT_{50} = 6.5 days (geomean, field studies, normalisation to pF2, 20^{0}C with Q_{10} = 2.58)
	K_{fOC} = 834.8 mL/g; K_{fOM} = 484.2 mL/g; 1/n = 0.798 (all values arithmetic means).
	Transformation parent --> BTS 44596 *ff* = 1;
	BTS 44595:
	M = 325.62 g/mol;
	S_{H2O} = 100 mg/L (@ 20^{0}C);
	p = 1.0 E-10 Pa(@ 20^{0}C);
	DT_{50} = 197.9 days (geomean, field studies, normalisation to pF2, 20^{0}C with Q_{10} = 2.58)
	K_{fOC} = 1272.8 mL/g; K_{fOM} = 738.3 mL/g; 1/n = 0.828

	(all values arithmetic means). Transformation : BTS 44596 --> BTS 44595 *ff* = 1; **M590F040:** M = 340.6 g/mol; S_{H2O} = 1 mg/L (@ 20^0C); p = 1.0 E-10 Pa(@ 20^0C); DT_{50} = 1 days (lab. value reported for compound defined as "ghost compartment"; normalisation to pF2, 20^0C with Q_{10} = 2.58) K_{fOC} = 2818.1 mL/g; K_{fOM} = 1634.6 mL/g; 1/n = 0.917 (all values arithmetic means). Transformation : parent --> M590F040 *ff* = 1; **BTS 40348:** M = 282.6 g/mol; S_{H2O} = 1000 mg/L (@ 20^0C); p = 1.0 E-10 Pa(@ 20^0C); DT_{50} = 91 days (longest laboratory value, normalisation to pF2, 20^0C with Q_{10} = 2.58) K_{fOC} = 1511.2 mL/g; K_{fOM} = 876.6 mL/g; 1/n = 0.834 (all values arithmetic means). Transformation : M590F040 --> BTS 40348 *ff* = 1;
Application rate	Application rate: Seed treatment: 33.1 g a. s./ha; Spray liquid: 2 x 450 g a. s./ha; Crop interception: Seed treatment: 0%; Spray liquid: 70% for both first and second applications; No. of applications: Seed treatment: 1; Spray liquid: 2; Interval between the application: Seed treatment: not applicable; Spray liquid: 14 days; Time of application: Seed treatment: depends on scenario and crop (dates are given in the table below):

FOCUS Scenario	Application date for:	
	Winter cereals	Spring cereals
Chateaudun	20 October (Julian day 293)	20 February (Julian day 51)

Hamburg	12 October	10 March
Jokioinen	10 September	07 May
Kremsmunster	25 October	10 March
Okehampton	07 October	25 March
Piacenza	25 November	----
Porto	15 November	20 February
Sevilla	15November	----
Thiva	15 November	----

Spray liquid: depends on scenario and crop:

winter cereals:

FOCUS Scenario	Application date for:	
	1st application	2nd application
Chateaudun	10 April (Julian day 135)	24 April (Julian day 149)
Hamburg	10 April	24 April
Jokioinen	01 June	15 June
Kremsmunster	10 April	24 April
Okehampton	10 April	24 April
Piacenza	10 March	24 March
Porto	10 March	24 March
Sevilla	10 March	24 March
Thiva	10 March	24 March

spring cereals:

FOCUS Scenario	Application date for:	
	1st application	2nd application
Chateaudun	15 May (Julian day 100)	29 May (Julian day 114)
Hamburg	15 May	29 May
Jokioinen	15 June	29 June
Kremsmunster	15 May	29 May
Okehampton	15 May	29 May
Piacenza	----	----
Porto	15 April	29 April
Sevilla	----	----
Thiva	----	----

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m) after application as a spray liquid (two applications)

a. Spring cereals

1) Modelling tool: FOCUS PEARL 3.3.3.						
FOCUS Scenario	80th percentile PEC_{GW} values [µg/L] for:					
	Prochloraz	Prochloraz-1	BTS 44596	BTS 44595	M590F040	BTS 40348
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
2) Modelling tool: FOCUS PELMO 3.3.2.						
FOCUS Scenario	80th percentile PEC_{GW} values [µg/L] for:					
	Prochloraz	Prochloraz-1	BTS 44596	BTS 44595	M590F040	BTS 40348
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
3) Modelling tool: FOCUS MACRO 4.4.2.						
FOCUS Scenario	80th percentile PEC_{GW} values [µg/L] for:					
	Prochloraz	Prochloraz-1	BTS 44596	BTS 44595	M590F040	BTS 40348
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

b. Winter cereals

1) Modelling tool: FOCUS PEARL 3.3.3.						
FOCUS Scenario	80th percentile PEC_{GW} values [µg/L] for:					
	Prochloraz	Prochloraz-1	BTS 44596	BTS 44595	M590F040	BTS 40348
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
2) Modelling tool: FOCUS PELMO 3.3.2.						
FOCUS Scenario	80th percentile PEC_{GW} values [µg/L] for:					
	Prochloraz	Prochloraz-1	BTS 44596	BTS 44595	M590F040	BTS 40348
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
3) Modelling tool: FOCUS MACRO 4.4.2.						
FOCUS Scenario	80th percentile PEC_{GW} values [µg/L] for:					
	Prochloraz	Prochloraz-1	BTS 44596	BTS 44595	M590F040	BTS 40348
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m) after application as a seed treatment

a. Spring cereals

1) Modelling tool: FOCUS PEARL 3.3.3.						
FOCUS Scenario	**80th percentile PEC_{GW} values [µg/L] for:**					
	Prochloraz	**Prochloraz-1**	**BTS 44596**	**BTS 44595**	**M590F040**	**BTS 40348**
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
2) Modelling tool: FOCUS PELMO 3.3.2.						
FOCUS Scenario	**80th percentile PEC_{GW} values [µg/L] for:**					
	Prochloraz	**Prochloraz-1**	**BTS 44596**	**BTS 44595**	**M590F040**	**BTS 40348**
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
3) Modelling tool: FOCUS MACRO 4.4.2.						
FOCUS Scenario	**80th percentile PEC_{GW} values [µg/L] for:**					
	Prochloraz	**Prochloraz-1**	**BTS 44596**	**BTS 44595**	**M590F040**	**BTS 40348**
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

b. Winter cereals

1) Modelling tool: FOCUS PEARL 3.3.3.						
FOCUS Scenario	**80th percentile PEC_{GW} values [µg/L] for:**					
	Prochloraz	**Prochloraz-1**	**BTS 44596**	**BTS 44595**	**M590F040**	**BTS 40348**
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
2) Modelling tool: FOCUS PELMO 3.3.2.						
FOCUS Scenario	**80th percentile PEC_{GW} values [µg/L] for:**					
	Prochloraz	**Prochloraz-1**	**BTS 44596**	**BTS 44595**	**M590F040**	**BTS 40348**
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Thiva	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
3) Modelling tool: FOCUS MACRO 4.4.2.						
FOCUS Scenario	**80th percentile PEC_{GW} values [µg/L] for:**					
	Prochloraz	**Prochloraz-1**	**BTS 44596**	**BTS 44595**	**M590F040**	**BTS 40348**
Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

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_{50} of *4.93* hours derived by the Atkinson model (version 1.88). OH (24 h) concentration assumed = 5 x 10^5 radicals/cm^3
Volatilisation ‡	from plant surfaces (*Phaseolus vulgaris [bean plants]*, BBA guideline): 14.4% AR after *24* hours (n=2)
	from soil surfaces (Speyer 2.1, BBA guideline): 0.8 % AR (n=2) after *24* hours
Metabolites	No data available on soil metabolites

PEC (air)

Method of calculation	Not calculated.

$PEC_{(a)}$

Maximum concentration	Not calculated.

Residues requiring further assessment

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure.	Soil: Prochloraz, BTS 44 595, BTS 44 596 and BTS 40348 Surface Water: Prochloraz, BTS 44 596 and BTS 40348 Sediment: Prochloraz, BTS 44 596 and BTS 40348 Ground water: Prochloraz, BTS 44 595, BTS 44 596, M590F040 and BTS 40348 Air: Prochloraz,

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

Soil (indicate location and type of study)	No data provided - none requested
Surface water (indicate location and type of study)	Surface water monitoring programs: France: no findings Norway: 2 detections Sweden: very few findings; Only prochloraz was analysed for, metabolites were not sought
Groundwater (indicate location and type of study)	Groundwater monitoring programs: Denmark: no findings France: no findings Only prochloraz was analysed for, metabolites were not sought
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

Not readily biodegradable; Candidate for R53.

Chapter 2.6 Effects on Non-target Species

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)
Birds ‡				
Bobwhite quail	Prochloraz	Acute	LD_{50} = 662	-
Mallard duck	Prochloraz	Acute	LD_{50} >1954	-
Hybrid red-legged partridge	Prochloraz	Acute	LD_{50} = 707	-
Bobwhite quail	BAS 590 05 F	Acute	LD_{50} >2000	-
Bobwhite quail	Prochloraz	Short-term	LC_{50} >1580	LD_{50} >5200
Mallard duck	Prochloraz	Short-term	LC_{50} >1763	LD_{50} >5200
Bobwhite quail	Prochloraz	Long-term	NOEC = 14.16	NOEC = 160
Bobwhite quail	Prochloraz	Long-term	NOEC = 33.1	NOEC = 450
Mammals ‡				
Rat	Prochloraz	Acute	LD_{50}=1023	
Rat	Prochloraz	Short-term	NOEC=25*	
Mice	Prochloraz	Short-term	NOEC=96	
Rat	Prochloraz		NOAEL=2.26	
Additional higher tier studies ‡				
*Ecologically relevant NOAEL=25, (Considering the use pattern of BAS 590 00F, the exposure period used in the rat teratology study was considered to be more realistic for the wild animal risk assessment than the long-term multi-generation study (even the endpoints determined in the teratology study are considered to represent a worst case, as repeated dosing by gavage would not represent a field exposure to wild animals under natural conditions). The NOEC derived from the teratology study (maternal and developmental toxicity) was considered more relevant. The magnitude of effects observed at 25 mg/kg bw/day would remain undetected under natural conditions and thus would be of no ecological relevance.				

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

(1) SPORTAK 45 EW– Cereals 2 x 450 g a.s. /Ha

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds) - late crop growth stage (BBCH growth stages 30-31 and 39-59 with a spraying interval of 14 days).				
Large herbivorous bird Insectivorous bird	Acute	33.7 24.3	19.6 27.2	10
Large herbivorous bird Insectivorous bird	Short-term	20.8 13.6	>76 >116	10
Large herbivorous bird Insectivorous bird	Long-term	11.0 13.6	**3.01** **2.44**	5
Earthworm-eating birds	Long-term	4.8	6.9	5
Fish-eating birds	Long-term	1.65	20	5

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Higher tier refinement (Herbivorous Birds). Refinement of risk to herbivorous birds is based on data on actual residues of prochloraz in cereals.				
Large herbivorous bird	Acute	N/A	N/A	10
Large herbivorous bird	Short-term	N/A	N/A	10
Large herbivorous bird	Long-term	4.44	7.0	5
Higher tier refinement (Insectivorous Birds). Refinement of risk to insectivorous birds is based on data on residues in arthropods, specific focal species of relevance (skylark and yellow wagtail) and PD refinement.				
Insectivorous bird:	Acute	N/A	N/A	10
Insectivorous bird:	Short-term	N/A	N/A	10
Skylark	Long-term	4.62	7.16	5
Yellow wagtail	Long-term	2.93	11.3	5
Tier 1 (Mammals) Prochloraz				
Early herbivorous mammal	Acute	106.59	**9.6**	10
Late insectivorous mammal	Acute	3.97	258	10
Early herbivorous mammal	Long-term	34.77	**0.06**	5
Late insectivorous mammal	Long-term	1.45	1.5	5
Earthworm-eating mammal	Long-term	6.1	**0.51**	5
Fish-eating mammals.		0.13	23	5
Higher tier refinement (Mammals)				
Small herbivorous mammal	Acute	32.5	31.5	10
Hare	Long-term	2.12	1.06	5
Woodmouse	Long-term	1.7	1.4	5
Higher tier refinement (Mammals). Refinement of risk to off-crop herbivorous mammals is based on the initial foliar residues in cereal plants, specific focal species of relevance (hare and woodmouse) and refinement of the PD value. Refinement of risk to in-crop herbivorous mammals is based on the specific focal species of relevance (hare), the Pt value and crop residue data				

[1] in higher tier refinement brief details of any refinements used (e.g., residues, PT, PD or AV) are indicated
[2] early or late crop stage is indicated where relevant
[3] No requirement to adjust Annex VI Trigger value during the risk assessment.
N/A = not applicable

(2) Prelude 20 FS – Cereal seeds 100 mL/ 100 kg seeds (33 g a.s./ha)

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds) – herbivorous birds grazing on emerging cereal shoots from seeds treated with BAS 590 05 F – small granivorous bird; long term exposure estimate not realistic - scenario based on reproduction).				
Large herbivorous bird Small granivorous bird	Acute	0.264 76	2508 **8.7**	10

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Large herbivorous bird Small granivorous bird	Short-term	0.264 76	5985 20.8	10
Large herbivorous bird Small granivorous bird	Long-term	0.264 76	125.4 **0.44**	5
Earthworm-eating birds	Long-term	0.11	283	5
Fish-eating birds	Long-term	0.30	110	5
Higher tier refinement (Birds). Acute Six field trials were conducted in the UK, Germany and the Netherlands to measure initial prochloraz residue levels on seeds exposed on the soil surface and also to measure the residue decline on these seeds. Since the results of the studies were consistent with each other, they were pooled to finally form an average percentage of 63.65%. Therefore, it was justified to use a correction factor of 0.64 on the nominal loading in the refined acute risk. The acute risk to granivorous birds was assessed as low. Long-term Refinement of risk to granivorous birds is based on data on initial residues of prochloraz on cereal seeds, decline of residues on cereal seeds, focal species of relevance, PD refinement and taking into account the dehusking behaviour.				
Small granivorous bird	Acute	48.64	13.61	10
Not applicable	Short-term	-	-	10
Rook	Long-term	4.16	7.96	5
Red-legged partridge	Long-term	2.20	15.07	5
Skylark	Long-term	4.61	7.18	5
Yellowhammer	Long-term	2.02	16.38	5
House sparrow	Long-term	6.06	5.46	5
Tree sparrow	Long-term	3.94	8.40	5
Chaffinch	Long-term	4.45	7.4	5
Greenfinch	Long-term	2.62	12.63	5
Tier 1 (Herbivorous Mammals)				
Early small herbiv. mammal	Acute	0.834	1226	10
Early small herbiv. mammal	Long-term	0.834	2.7	5
Earthworm-eating mammal	Long-term	0.14	22.1	
Fish-eating mammals.	Long-term	0.19	16.32	
Tier 1 (Granivorous mammals)				
Wood mouse	Acute	46	22.24	10
Wood mouse	Long-term	46	**0.05**	5
Higher Tier Refinement (granivorous mammals)				
Wood mouse (spring sowings)	Long-term	2.36	0.935	5
Wood mouse (autumn sowings)	Long-term	2.06	1.09	5

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Higher tier refinement (Granivorous Mammals). Refinement of long-term risk to granivorous mammals is based on data on initial residues of prochloraz on cereal seeds, decline of residues on cereal seeds, the specific focal species of relevance (wood mouse), the PD refinement and information on dehusking behaviour.				

[1] in higher tier refinement brief details of any refinements used (e.g., residues, PT, PD or AV) are indicated
[2] early or late crop stage is indicated where relevant
[3] No requirement to adjust Annex VI Trigger value during the risk assessment.

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[1] (mg/L)
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	Prochloraz	96 hr (static)	Mortality, LC_{50}	1.5 ($_{mm}$)
Cyprinodon variegatus	Prochloraz	96 hr (static)	Mortality, LC_{50}	1.2 ($_{mm}$)
Oncorhynchus mykiss	Prochloraz	28 d (flow-through)	Behavioural abnormalities NOEC	0.18 ($_{mm}$)
Pimephales promelas	Prochloraz	36 d (flow-through) ELS	NOEC	0.0485 ($_{mm}$)
Pimephales promelas	Prochloraz	189 d (flow-through) FFLC	NOEC	0.0249 ($_{mm}$)
Cyprinus carpio	Prochloraz $CuCl_2$ complex	96 hr (static)	Mortality, EC_{50}	1.355 ($_{mm}$)
Oncorhynchus mykiss	BAS 590 00F Sportak 45 EW	96 hr (flow-through)	Mortality, EC_{50}	2.8 mg preparation/L ($_{nom}$)
Oncorhynchus mykiss	SPORTAK 45 EW	28 d (flow-through)	Not provided	-
Oncorhynchus mykiss	BTS 44595	96 hr (flow-through)	Mortality, EC_{50}	5.4 ($_{nom}$)
Oncorhynchus mykiss	BTS 44596	96 hr (flow-through)	Mortality, EC_{50}	4.9 ($_{mm}$)
Oncorhynchus mykiss	BTS 40348	96 hr (static)	Mortality, LC_{50}	12.0 ($_{nom}$)
Aquatic invertebrate				
Daphnia magna	Prochloraz	48 h (static)	Mortality, EC_{50}	4.3 ($_{mm}$)
Mysidopsis bahia	Prochloraz	96 h (flow through)	Mortality, EC_{50}	0.77 ($_{mm}$)
Daphnia magna	Prochloraz	21 d (flow through)	Reproduction, NOEC	0.0222 ($_{mm}$)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Daphnia magna	Prochloraz $CuCl_2$ complex	48 h (static)	Mortality, EC_{50}	0.468 ($_{nom}$)
Daphnia magna	Prochloraz $CuCl_2$ complex	21 d (semi-static)	Reproduction, growth, NOEC	0.02 ($_{nom}$)
Daphnia magna	SPORTAK 45 EW	48 h (static)	Mortality, EC_{50}	9.5 mg preparation/L ($_{nom}$)
Daphnia magna	SPORTAK 45 EW	48 h (static)	Mortality, EC_{50}	7.21 mg preparation/L ($_{nom}$)
Daphnia magna	SPORTAK 45 EW	21 d (static)	Not provided	-
Daphnia magna	BTS 44595	48 h (static)	Mortality, EC_{50}	15.4 ($_{nom}$)
Daphnia magna	BTS 44596	48 h (static)	Mortality, EC_{50}	6.5 ($_{mm}$)
Daphnia magna	BTS 40348	48 h (static)	Immobilization, EC_{50}	3.44 ($_{nom}$)
Sediment dwelling organisms				
Chironomus riparius	Prochloraz	28 d (static)	NOEC	$\geq$ 0.8 ($_{nom}$) or $\geq$ 8.96mg/kg ($_{nom}$)
Algae				
Scenedesmus subspicatus.	Prochloraz	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.0055 ($_{nom}$) >0.032 ($_{nom}$)
Scenedesmus subspicatus.	Prochloraz $CuCl_2$ complex	96 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.0241 ($_{nom}$) >0.0505 ($_{nom}$)
Scenedesmus subspicatus.	SPORTAK 45 EW	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.0915 mg preparation/L ($_{nom}$) >0.200 mg preparation/L ($_{nom}$)
Pseudokirchneriella subcapitata	BAS 590 00 F	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	1.23 mg preparation/L ($_{nom}$) 4.86 mg preparation/L ($_{nom}$)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (mg/L)
Desmodesmus subspicatus (formerly *Scenedesmus subspicatus*)	BAS 590 00 F	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.054 mg preparation/L ($_{nom}$) 0.941 mg preparation/L ($_{nom}$)
Scenedesmus subspicatus.	BTS 44595	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	7.1 ($_{nom}$) 11.8 ($_{nom}$)
Scenedesmus subspicatus.	BTS 44596	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	2.0 ($_{mm}$) 2.7 ($_{mm}$)
Pseudokirchneriella subcapitata	M590F040	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.72 ($_{mm}$) 2.10 ($_{mm}$)
Pseudokirchneriella subcapitata	BTS 40348	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	0.58 ($_{nom}$) 2.99 ($_{nom}$)
Higher plants				
Lemna gibba	Prochloraz	7 d (semi-static)	Fronds, E_bC_{50} Fronds, E_rC_{50}	0.171 ($_{nom}$) 0.109 ($_{nom}$)
Lemna gibba	Sportak 45 EW	14 d (static)	Not provided	-
Lemna gibba	BTS 44595	14 d (static)	Not provided	-
Lemna gibba	BTS 44596	14 d (static)	Not provided	-
Microcosm or mesocosm tests: not required				
Indicate if not required				

[1] Toxicity is based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$), as indicated. In the case of preparations, end points are presented as units of preparation or a.s, as indicated.

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

FOCUS Step1

(1) SPORTAK 45 EW- Cereals 1 x 450 g a.s. /Ha (winter and spring cereals)

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_{max} (mg/L)	TER	Annex VI Trigger[1]
Prochloraz.	Fish	1.2	Acute	0.0555	**21.6**	100
Prochloraz	Fish	0.0249	Chronic	0.0555	**0.45**	10
Prochloraz	Aquatic invertebrates	0.77	Acute	0.0555	**13.9**	100
Prochloraz	Aquatic invertebrates	0.0222	Chronic	0.0555	**0.4**	10

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_{max} (mg/L)	TER	Annex VI Trigger[1]
Prochloraz	Algae	0.0055	Chronic	0.0555	**0.1**	10
Prochloraz	Higher plants	0.109	Chronic	0.0555	**1.96**	10
Prochloraz	Sediment-dwelling organisms[2]	0.8mg/L or 8.96mg/kg	Chronic	0.0555mg/L or 1.02mg/kg	14.4 **8.8**	10
BTS 44595	Fish	5.4	Acute	0.01473	366.6	100
BTS 44595	Aquatic invertebrates	15.4	Acute	0.01473	1045.5	100
BTS 44595	Algae	11.8	Chronic	0.01473	482.0	10
BTS 44596	Fish	4.9	Acute	0.03358	145.9	100
BTS 44596	Aquatic invertebrates	6.5	Acute	0.03358	193.6	100
BTS 44596	Algae	2.7	Chronic	0.03358	59.6	10
BTS 40348	Fish	12.0	Acute	0.00523	2294	100
BTS 40348	Aquatic invertebrates	3.44	Acute	0.00523	657.7	100
BTS 40348	Algae	0.58	Chronic	0.00523	110.9	10
M590F040	Algae	0.72	Chronic	0.00234	307.7	10

[1] No requirement to adjust Annex VI Trigger value during the risk assessment.
[2] PEC_{sed} were used in the risk assessment.

(2) SPORTAK 45 EW- Cereals 2 x 450 g **)** a.s./Ha (winter and spring cereals)

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_{max} (mg/L)	TER	Annex VI Trigger[1]
Prochloraz.	Fish *(Cyprinodon variegatus)*	1.2	Acute	0.11099	**10.8**	100
Prochloraz	Fish (*Pimephales promelas*)	0.0249	Chronic	0.11099	**0.22**	10
Prochloraz	Aquatic invertebrates	0.77	Acute	0.11099	**6.9**	100
Prochloraz	Aquatic invertebrates	0.0222	Chronic	0.11099	**0.2**	10
Prochloraz	Algae	0.0055	Chronic	0.11099	**0.05**	10
Prochloraz	Higher plants	0.109	Chronic	0.11099	**0.98**	10
Prochloraz	Sediment-dwelling organisms	0.8mg/L or 8.96mg/kg	Chronic	0.11099mg/L or 2.04mg/kg	**7.2** **4.4**	10
BTS 44595	Fish	5.4	Acute	0.02946	183.3	100
BTS 44595	Aquatic invertebrates	15.4	Acute	0.02946	522.7	100
BTS 44595	Algae	11.8	Chronic	0.02946	241.0	10
BTS 44596	Fish	4.9	Acute	0.06716	**73.0**	100
BTS 44596	Aquatic invertebrates	6.5	Acute	0.06716	**96.8**	100

Test substance	Organism	Toxicity end point (mg/L)	Time scale	PEC_{max} (mg/L)	TER	Annex VI Trigger[1]
BTS 44596	Algae	2.7	Chronic	0.06716	29.8	10
BTS 40348	Fish	12.0	Acute	0.0105	1143	100
BTS 40348	Aquatic invertebrates	3.44	Acute	0.0105	323.8	100
BTS 40348	Algae	0.58	Chronic	0.0105	55.2	10
M590F040	Algae	0.72	Chronic	0.0047	153.2	10
BAS 590 00F	Fish	2.8	Acute	ditch 0.00726	385.7	100
				pond 0.00025	11200	
				stream 0.00539	519.5	
BAS 590 00F	Aquatic invertebrates	7.21	Acute	ditch 0.00726	993.1	100
				pond 0.00025	28840	
				stream 0.00539	1337.7	
BAS 590 00F	Algae	0.2	Chronic	ditch 0.00726	**7.4**	10
				pond 0.00025	216.0	
				stream 0.00539	10.02	

[1] No requirement to adjust Annex VI Trigger value during the risk assessment.

(3) Prelude 20 FS – Cereal seeds 100 mL/ 100 kg seeds (33 g a.s./ha) - Winter cereals, Southern Europe Scenario

Test substance	Organism	Toxicity end point (mg Prochloraz/L)	Time scale	PEC_i (mg Prochloraz/L)	TER	Annex VI Trigger[1]
Prochloraz. $CuCl_2$-complex	Fish	1.33	Acute	0.00377	359.4	100
Prochloraz $CuCl_2$-complex	Aquatic invertebrates	0.468	Acute	0.00377	124.1	100
Prochloraz $CuCl_2$-complex	Aquatic invertebrates	0.02	Chronic	0.00377	**5.3**	10
Prochloraz $CuCl_2$-complex	Algae	0.0241	Chronic	0.00377	**6.39**	10

[1] No requirement to adjust Annex VI Trigger value during the risk assessment.
[3] PEC_{sw} has been used rather than PEC_{sed}

FOCUS Step 2

(1) SPORTAK 45 EW- Cereals 1 x 450 g a.s. /Ha (BBCH growth stages 30-31)

Test substance	N/S[1]	Organism[2]	Toxicity end point (mg/L)	Time scale	PEC[3] (mg/L)	TER	Annex VI Trigger[4]
Prochloraz	S	Fish	1.2	Acute	0.012	100	100
Prochloraz	N	Fish	1.2	Acute	0.0067	179.1	100
Prochloraz	S	Fish	0.0249	Chronic	0.012	**2.08**	10
Prochloraz	N	Fish	0.0249	Chronic	0.0067	**3.72**	10
Prochloraz	S	Aquatic invertebrates	0.77	Acute	0.012	**64.2**	100
Prochloraz	N	Aquatic invertebrates	0.77	Acute	0.0067	114.9	100
Prochloraz	S	Aquatic invertebrates	0.0222	Chronic	0.012	**1.9**	10
Prochloraz	N	Aquatic invertebrates	0.0222	Chronic	0.0067	**3.3**	10
Prochloraz	S	Algae	0.0055	Chronic	0.012	**0.5**	10
Prochloraz	N	Algae	0.0055	Chronic	0.0067	**0.82**	10
Prochloraz	S	Higher plants	0.109	Chronic	0.012	**9.08**	10
Prochloraz	N	Higher plants	0.109	Chronic	0.0067	16.27	10
Prochloraz	S	Sediment-dwelling organisms[5]	0.8mg/L or 8.96mg/kg	Chronic	0.022mg/L or 0.218mg/kg	36.4 41.1	10
Prochloraz	N	Sediment-dwelling organisms[5]	0.8mg/L or 8.96mg/kg	Chronic	0.012mg/L or 0.123mg/kg	66.7 72.8	10

[1] Northern of Southern scenario indicated as appropriate
[2] Only critical groups which fail at Step 1 are included.
[3] maximum or twa values have been used where appropriate, as indicated.
[4] No requirement to adjust Annex VI Trigger value during the risk assessment.
[5] PEC_{sed} were used in the risk assessment.

.

(2) SPORTAK 45 EW- Cereals 2 x 450 g a.s. /Ha (BBCH growth stages 30-31 and 39-59 with a spraying interval of 14 days). Winter and spring cereals, Northern and Southern Europe.

Test substance	N/S[1]	Organism[2]	Toxicity end point (mg/L)	Time scale	PEC[3] (mg/L)	TER	Annex VI Trigger[4]
Prochloraz	S	Fish	1.2	Acute	0.022	**54.5**	100
Prochloraz	N	Fish	1.2	Acute	0.012	100	100
Prochloraz	S	Fish	0.0249	Chronic	0.022	**1.13**	10
Prochloraz	N	Fish	0.0249	Chronic	0.012	2.08	10
Prochloraz	S	Aquatic invertebrates	0.77	Acute	0.022	**35.0**	100
Prochloraz	N	Aquatic invertebrates	0.77	Acute	0.012	**64.2**	100

Test substance	N/S[1]	Organism[2]	Toxicity end point (mg/L)	Time scale	PEC[3] (mg/L)	TER	Annex VI Trigger[4]
Prochloraz	S	Aquatic invertebrates	0.0222	Chronic	0.022	**1.0**	10
Prochloraz	N	Aquatic invertebrates	0.0222	Chronic	0.012	**1.9**	10
Prochloraz	S	Algae	0.0055	Chronic	0.022	**0.3**	10
Prochloraz	N	Algae	0.0055	Chronic	0.012	**0.46**	10
BAS 590 00F		Algae	0.2	Chronic	0.022	10	10
BAS 590 00F		Algae	0.2	Chronic	0.012	16	10
Prochloraz	S	Higher plants	0.109	Chronic	0.022	**5.0**	10
Prochloraz	N	Higher plants	0.109	Chronic	0.012	**9.08**	10
Prochloraz	S	Sediment-dwelling organisms	0.8mg/L or 8.96mg/kg	Chronic	0.022mg/L or 0.404mg/kg	36.4 22.2	10
Prochloraz	N	Sediment-dwelling organisms	0.8mg/L or 8.96mg/kg	Chronic	0.012mg/L or 0.226mg/kg	66.7 39.6	10
BTS 44596	S	Fish	4.9	Acute	0.0074	662.2	100
BTS 44596	N	Fish	4.9	Acute	0.005	980	100
BTS 44596	S	Aquatic invertebrates	6.5	Acute	0.0074	878.4	100
BTS 44596	N	Aquatic invertebrates	6.5	Acute	0.005	1300	100

[1] Northern of Southern scenario indicated as appropriate
[2] Only critical groups which fail at Step 1 are included.
[3] maximum values have been used
[4] No requirement to adjust Annex VI Trigger value during the risk assessment.

(2) Prelude 20 FS – Cereal seeds 100 mL/ 100 kg seeds (33 g a.s./ha).

Test substance	N/S[1]	Organism[2]	Toxicity end point ((mg Prochloraz/L)	Time scale	PEC[3] (mg Prochloraz/L)	TER	Annex VI Trigger[4]
Prochloraz $CuCl_2$-complex	S	Aquatic invertebrates	0.02	Chronic	0.0018	11.1	10
Prochloraz $CuCl_2$-complex	N	Aquatic invertebrates	0.02	Chronic	0.0015	13.3	10
Prochloraz	N	Algae	0.0241	Chronic	0.0015	16.1	10
Prochloraz	S	Algae	0.0241	Chronic	0.0018	13.1	10

[1] Northern or Southern scenario indicated as appropriate
[2] Only critical groups which fail at Step 1 are included.
[3] maximum or twa values have been used where appropriate, as indicated.
[4] No requirement to adjust Annex VI Trigger value during the risk assessment.

Refined aquatic risk assessment using higher tier FOCUS modelling.

FOCUS Step 3

(1) SPORTAK 45 EW- Cereals 1 x 450 g a.s./Ha (BBCH growth stages 30-31) – **no buffer zone**

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg/L)	PEC[4]	TER	Annex VI trigger[5]
Prochloraz	D1 – R4	Ditch, stream, pond	Fish	Chronic	0.0249	0.0001-0.0029	**8.5**-249.0	10
Prochloraz	D1 – R4	Ditch, stream, pond	Aquatic invertebrates	Acute	0.77	0.0001-0.0029	259.3-7700	100
Prochloraz	D1 – R4	Ditch, stream, pond	Aquatic invertebrates	Chronic	0.0222	0.0001-0.0029	**7.4**-222	10
Prochloraz	D1 – R4	Ditch, stream, pond	Algae	Chronic	0.0055	0.0001-0.0029	**1.8**-55	10
Prochloraz	D1 – R4	Ditch, stream, pond	Aquatic plants	Chronic	0.109	0.0001-0.0029	36.7.1-1090	10

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] Only critical groups which fail at Step 2, are included.
[4] PEC_{sw}, or PEC_{sed}; maximum or twa values have been used where appropriate, as indicated.
[5] No requirement to adjust Annex VI Trigger value during the risk assessment

(1) SPORTAK 45 EW- Cereals 2 x 450 g a.s. /Ha (BBCH growth stages 30-31 and 39-59 with a spraying interval of 14 days) – **no buffer zone**

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg/L)	PEC[4]	TER	Annex VI trigger[5]
Prochloraz	D1 – R4	Ditch, stream, pond	Fish	Acute	1.2	0.0001-0.0038	317.5-8571.4	100
Prochloraz	D1 – R4	Ditch, stream, pond	Fish	Chronic	0.0249	0.0001-0.0038	**8.5**-249	10
Prochloraz	D1 – R4	Ditch, stream, pond	Aquatic invertebrates	Acute	0.77	0.0001-0.0038	204.2-5500	100
Prochloraz	D1 – R4	Ditch, stream, pond	Aquatic invertebrates	Chronic	0.0222	0.0001-0.0038	**7.4**-158.6	10
Prochloraz	D1 – R4	Ditch, stream, pond	Algae	Chronic	0.0055	0.0001-0.0038	1.5-39.3	10
Prochloraz	D1 – R4	Ditch, stream,	Aquatic plants	Chronic	0.109	0.0001-0.0038	28.9-778.6	10

Test substance	Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg/L)	PEC[4]	TER	Annex VI trigger[5]
		pond						

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] Only critical groups which fail at Step 2, are included.
[4] PEC_{sw}, or PEC_{sed}; maximum or twa values have been used where appropriate, as indicated.
[5] No requirement to adjust Annex VI Trigger value during the risk assessment

FOCUS Step 4

(1) SPORTAK 45 EW- Cereals 1 x 450 g a.s. /Ha (BBCH growth stages 30-31) **5 and 10 m Buffer zone**

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg/L)	Buffer zone distance	PEC[4]	TER	Annex VI trigger[5]
D1 – R4	Ditch, stream, pond	Fish	Chronic	0.0249	5 m	0.0008-0.0012	20.55 29.5	10
D1 – R4	Ditch, stream, pond	Aquatic invertebrates	Chronic	0.0222	10m	0.0005 0.0011	20.0 -28.4	10
D1 – R4	Ditch, stream, pond	Algae	Chronic	0.0055	5m	0.0008-0.0012	**5.1-7.05**	10
D1 – R4	Ditch, stream, pond	Algae	Chronic	0.0055	10 m	0.0005 0.0011	**4**.95-12.5	10
formulation BAS 590 00 F	ditch	Algae	Chronic	0.054	10 m	0.001	54	10

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] Only critical groups which fail at Step 3, are included.
[4] PEC_{sw}, or PEC_{sed}; maximum values have been used where.
[5] No requirement to adjust Annex VI Trigger value during the risk assessment

(2) SPORTAK 45 EW- Cereals 2 x 450 g a.s. /Ha (BBCH growth stages 30-31 and 39-59 with a spraying interval of 14 days) – **10 and 20 m Buffer zone**

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg/L)	Buffer zone distance	PEC[4]	TER	Annex VI trigger[5]
D1 – R4	Ditch, stream, pond	Fish	Chronic	0.0249	5 m	0.001-.0007	23.0-37.1	10
D1 – R4	Ditch, stream, pond	Aquatic invertebrates	Chronic	0.0222	5 m	0.001-.0007	13.2-33.1	10
D1 – R4	Ditch, stream,	Algae	Chronic	0.0055	5 m	0.001-.0007	**2.55-8.9**	10

Scenario[1]	Water body type[2]	Test organism[3]	Time scale	Toxicity end point (mg/L)	Buffer zone distance	PEC[4]	TER	Annex VI trigger [5]
	pond							
D1 – R4	Ditch, stream, pond	Algae	Chronic	0.0055	10 m	0.000119-0.00098	**5.6** – 47	10
D1 – R4	Ditch, stream, pond	Algae	Chronic	0.0055	20 m	0.0001-0.0005	11.7-75	10

[1] drainage (D1-D6) and run-off (R1-R4)
[2] ditch/stream/pond
[3] Only critical groups which fail at Step 3, are included.
[4] PEC_{sw}, or PEC_{sed}; maximum or twa values have been used where appropriate, as indicated.
[5] No requirement to adjust Annex VI Trigger value during the risk assessment

Bioconcentration – Bluegill Sunfish				
	Prochloraz	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	3.53	-	-	-
Bioconcentration factor (BCF)[1] ‡	371*	-	-	-
Annex VI Trigger for the bioconcentration factor	100	-	-	-
Clearance time (days) (CT_{50})	3.4	-	-	-
(CT_{90})	11.4	-	-	-
Level and nature of residues (%) in organisms after the 14 day depuration phase	c 9% in viscera, 27 % in edible tissue, 23% in non-edible tissue and 15% in whole fish tissues.	-	-	-

[1] required as log $P_{O/W}$ >3.
* based on total ^{14}C

Bioconcentration – Rainbow Trout				
	Prochloraz	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	3.53	-	-	-
Bioconcentration factor (BCF)[1] ‡	196.5*	-	-	-
Annex VI Trigger for the bioconcentration factor	100	-	-	-
Clearance time (days) (CT_{50})	8	-	-	-
(CT_{90})	2.4	-	-	-

Bioconcentration – Rainbow Trout				
Level and nature of residues (%) in organisms after the 14 day depuration phase	c 22 % in edible tissue, 26% in non-edible tissue and 26% in whole fish tissues.	-	-	-

[1] required as log $P_{O/W}$ >3.
* based on total ^{14}C

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

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
Prochloraz ‡	>101.06	141.28
BAS 590 00 F[1]	27.4 µg a.s. /bee	46.7µg a.s. /bee
BAS 590 05 F[1]	99.24 µg a.s. /bee	>100 µg a.s. /bee
Field or semi-field tests: IIIA 10.4.3/1 Schmitzer S. (2005): Toxicity testing of BAS 590 00 F on honey bees (*Apis mellifera* L.) in the cage under field conditions. **Conclusion:** BAS 590 00 F applied at a rate of 1.14 kg/ha (corresponding to 450 g a.s./ha) under semi-field conditions (cage) to *Phacelia tanacetifolia* during active foraging conditions caused no adverse effects on mortality, flight density, behaviour or brood. III A 10.4.4/1 Davies L.G. and Arnold D.J. (1983)- A field study of the effect on honeybees of Prochloraz applied to oilseed rape. **Conclusion:** BAS 590 00 F applied up to 500 g a.s./ha to oilseed rape during active foraging conditions caused no adverse effects on adult bee population, brood development as well as honey and wax production		
Indicate if not required		

[1] End point is expressed in units of a.s.

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

SPORTAK 45 EW- Cereals 2 x 450 g a.s. /Ha (BBCH growth stages 30-31 and 39-59 with a spraying interval of 14 days)

Test substance	Route	Hazard quotient	Annex VI Trigger
Prochloraz	Contact	<3.2	50
Prochloraz	oral	<4.5	50
BAS 590 00 F (laboratory test)	Contact	16.4	50
BAS 590 00 F (laboratory test)	oral	9.6	50

BAS 590 05F –
The foliar spray application may be considered as a worse case than seed treatment application. Since the risk assessment performed for foliar spray use demonstrated a low risk confirmed in field studies, when prochloraz was applied during the bee flight, low risk to bees resulting from seed treatment application is anticipated.

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

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Effect (LR_{50} L product/ha[1])
Typhlodromus pyri ‡	BAS 590 00 F	Mortality	0.0985
Aphidius rhopalosiphi ‡	BAS 590 00 F	Mortality	0.18906

[1] end point is expressed in units of product.

SPORTAK 45 EW- Cereals 2 x 450 g a.s. /Ha (BBCH growth stages 30-31 and 39-59 with a spraying interval of 14 days). HQ based on 1 m distance.

Test substance	Species	Effect (LR_{50} g a.s. /ha)	HQ in-field	HQ off-field[1]	Trigger
BAS 590 00 F	*Typhlodromus pyri*	44.3	**20.3**	0.48	2
BAS 590 00 F	*Aphidius rhopalosiphi*	85.1	**10.57**	0.25	2

[1] 1 m distance assumed to calculate the drift rate

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose [1,2]	End point	% effect[3]	Trigger value
T. pyri	proto-nymph	BAS 590 00 F Inert substrate 7 days	0.05, 0.125, 0.3, 0.8, 2.0 Lproduct/ha Initial residues	No LR_{50} could be derived due to high mortality at all dose levels	-	50 %
T. pyri	proto-nymph	BAS 590 00 F *Phaseolus vulgaris* 14 days	0.05, 1.0, 2.0 Lproduct/ha Initial residues	LR_{50}>2 L product/ha	No significant adverse effects. 24 % increase in fecundity at highest dose level, compared to control	50 %

Species	Life stage	Test substance, substrate and duration	Dose [1,2]	End point	% effect[3]	Trigger value
A. rhopalosiphi	adult	BAS 590 00 F *Phaseolus vulgaris* 15 days	2.0 Lproduct/ha Initial residues	LR_{50} >2 L product/ha	60% redution in no. mummies/female was observed However, this apparent effect on fecundity was believed to be an indirect effect of repellency, during the initial 48hr exposure period (repellency causing less foraging, thereby reducing the parasitisation capacity during the fecundity stage).	50 %
A. rhopalosiphi	adult	BAS 590 00 F on barley seedlings 25 days	2 x 1.0 Lproduct/ha (days 0 & 7) fresh & aged residues	43 % corrected mortality (DAT 0); 7% corrected mortality (DAT 7) and 0% corrected mortality (DAT 14)	No significant effects on fecundity. Repellency was not observed.	50 %
A. rhopalosiphi	adult	BAS 590 00 F Inert substrate 48 hour	1.0 Lproduct/ha Initial residues	No LR_{50} could be derived due to high mortality (93.3%) at tested rate	-	50 %
A. rhopalosiphi	adult	BAS 590 00 F on barley seedlings 13 days	1.0 Lproduct/ha Initial residues	LR_{50} >1 L product/ha	27 % corrected mortality (DAT2) No significant effects on fecundity. Repellency was not observed.	50 %

Species	Life stage	Test substance, substrate and duration	Dose [1,2]	End point	% effect[3]	Trigger value
C. septempunctata	adult	BAS 590 00 F *Phaseolus vulgaris* 15 days	0.05, 1.0, 2.0 Lproduct/ha Initial residues	LR_{50} >2 L product/ha	>50% effects on reproduction (no. eggs/female/day) were seen at 2 L/ha and also at 0.5L/ha, but no significant effects were seen at 1L/ha. The effects observed at 0.5 L/ha were due to low egg production in one box only and was not considered treatment related	50 %
E. balteatus	larvae	BAS 590 00 F *Vitus vinifera* 3 weeks	0.05, 1.0, 2.0 Lproduct/ha Initial residues	LR_{50} >2 L product/ha	No significant effects on fecundity at any rate	50 %
P. cupreus	adult	BAS 590 00 F Inert substrate 14 days	2.0 Lproduct/ha Initial residues	LR_{50} >2 L product/ha	No adverse effects on organism at rate tested	50 %
P. cupreus	adult	BAS 590 00 F Inert substrate 14 days	1.0 Lproduct/ha Direct overspray	LR_{50} >1 L product/ha	No adverse effects on organism at rate tested	50 %
Pardosa sp.	adult	BAS 590 00 F Inert substrate 14 days	0.05, 1.0, 2.0 Lproduct/ha Initial residues	LR_{50} >2 L product/ha	No adverse effects on organism at any rate	50 %
*A. bilineat*a	adult	BAS 590 05 F-treated wheat seeds in natural soil 75 days	1.0 mL/kg seeds (66 g/ha Prochloraz-$CuCl_2$)	Reproductive effects	No significant effects on fecundity at rate tested	50 %
P. cupreus	larvae pupae adults	BAS 590 05 F treated wheat seeds in natural soil 58 days	69.3 g/ha Prochloraz-$CuCl_2$-complex	Effects on mortality and development	No adverse effects on tested organisms at any stage	50 %
Pardosa spp.	adult	BAS 590 05 F-treated wheat seeds in natural soil 75 days	69.3 g/ha Prochloraz-$CuCl_2$-complex	Effects on mortality & food consumption	No adverse effects on organism at any rate	50 %

[1] indicate whether initial or aged residues

[2] dose is expressed in units of L preparation/ha or mL/kg seeds as indicated
[3] if positive percentages relate to adverse effects, details are provided

Field or semi-field tests
Indicate if not required: **Not required**

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

Test organism	Test substance	Time scale	End point[1]
Earthworms			
Eisenia fetida	Prochloraz ‡	Acute 14 days	LC_{50corr} > 500 mg a.s./kg d.w.soil
Eisenia fetida	Prochloraz ‡	Chronic (56-day repro)	$NOAEC_{corr}$ = 4.2 mg a.s./kg d.w.soil
Eisenia fetida	BAS 590 00 F	Acute 14 days	LC_{50corr} = 227.4 mg formulation/kg d.w.soil
Eisenia fetida	BAS 590 00 F	Chronic	Not provided
Eisenia fetida	BTS 44595	Acute 14 days	LC_{50corr} > 500 mg/kg d.w.soil
Eisenia fetida	BTS 44595	Chronic (56-day repro)	$NOAEC_{corr}$ = 1.25 mg/kg d.w.soil
Eisenia fetida	BTS 44596	Acute 14 days	LC_{50corr} > 500 mg/kg d.w.soil
Eisenia fetida	BTS 40348	Acute 14 days	LC_{50corr} > 398.4 mg/kg d.w.soil
Eisenia fetida	BTS 40348	Chronic (56-day repro)	$NOEC_{corr}$ = 24 mg/kg d.w.soil
Eisenia fetida	M590F040	Acute 14 days	LC_{50corr} > 192.8 mg/kg d.w.soil
Other soil macro-organisms			
Soil mite	a.s. ‡		Not provided
Soil mite	Preparation		Not provided
Soil mite	Metabolite 1		Not provided
Collembola			
Folsomia candida	a.s. ‡	Chronic	Not provided
Folsomia candida	BAS 590 05 F	Chronic	$NOEC_{corr}$ = 500 mg formulation/kg soil (equivalent to 100 mg Prochloraz/kg soil)
Folsomia candida	Metabolite 1		Not provided
Folsomia candida	BTS 44595	Chronic	$NOEC_{corr}$ = 250 mg /kg soil
Folsomia candida	BTS 40348	Chronic	$NOEC_{corr}$ = 500 mg /kg soil
Soil micro-organisms			
Nitrogen transformation	a.s. ‡		Not provided
	BTS 44595		+22.45 % effect at day 32 at 10.0 mg a.s./kg d.w.soil

Test organism	Test substance	Time scale	End point[1]
	BTS 44596		-6.75 % effect at day 28 at 10.0 mg a.s./kg d.w.soil
	BTS 40348		+0.2% effect at day 28 at 0.77 mg AE C449589 BTS 40348/kg d.w. soil
	M590F040		+0.6% effect at day 28 at 0.50 mg M590F040/kg d.w. soil
	BAS 590 00 F		+8.3 % effect at day 28 at 12 L/ha
Carbon transformation	a.s. ‡		Not provided
	BTS 44595		+9.66 % effect at day 28 at 10.0 mg a.s./kg d.w.soil
	BTS 44596		+0.23 % effect at at day 28 at 10.0 mg a.s./kg d.w.soil
	BTS 40348		+1.2% effect at day 28 at 0.77 mg BTS 40348/kg d.w. soil
	M590F040		-0.3% effect at day 28 at 0.50 mg M590F040/kg d.w. soil
	BAS 590 00 F		+1.0 % effect at day 28 at 12 L/ha
Field studies[2]: In a field decomposition study, no significant effect on organic matter decomposition was observed following treatment with 1.2 kg a.s./ha over 9 months.			
Indicate if not required			

[1] End point has been corrected by a conversion factor of two to address the organic content of the soil due to log Pow >2.0 (e.g. LC_{50corr})
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

Toxicity/exposure ratios for soil organisms

(1) SPORTAK 45 EW– spray application to cereals (2 x 450 g a.s. /Ha)

Test organism	Test substance	Time scale	Soil PEC_{ini}	Soil $PEC_{accu\ max}$	TER [1)]	Trigger
Earthworms						
Eisenia fetida	Prochloraz	Acute	0.3173	- 0.6002	> 833	10
Eisenia fetida	Prochloraz	Chronic	0.3173	- 0.6002	7.0	5
Eisenia fetida	BAS 590 00 F	Acute	0.452	-	503.1	10
Eisenia fetida	BAS 590 00 F	Chronic	-	-	-	5
Eisenia fetida	BTS 44595	Acute	0.0169	0.0339	> 14749	10
Eisenia fetida	BTS 44595	Chronic	-	0.0339	36.9	5
Eisenia fetida	BTS 44596	Acute	0.0210	0.0415	> 12048	10
Eisenia fetida	BTS 44596	Chronic	-	-	-	5
Eisenia fetida	M590F040	Acute	0.0006	0.0008	>498000	10
Eisenia fetida	BTS 40348	Acute	0.0006	0.0012	160667	10
Eisenia fetida	BTS 40348	Chronic	0.0006	0.0012	20000	5
Other soil macro-organisms						

Test organism	Test substance	Time scale	Soil PEC_{ini}	Soil $PEC_{accu\ max}$	TER [1)]	Trigger
Soil mite	a.s.	-	-	-	-	-
	Preparation	-	-	-	-	-
	Metabolite 1	-	-	-	-	-
Collembola	Prochloraz	Chronic	0.3173	0.6002	166.6	5
	BTS 44595	Chronic	0.0169	0.0339	7375	5
	BTS 40348	Chronic	0.0006	0.0012	416667	5
	BAS 590 05 F	Chronic	0.452	-	1106	5
Refined risk assessment Not Relevant						

[1)] all TER values were calculated using maximum available PEC_{soil} value, i.e. accu max

(2) Prelude 20 FS – Treatment of cereal seeds 100 mL/ 100 kg seeds (33 g a.s./ha).

Test organism	Test substance	Time scale	Soil PEC_{ini}	Soil $PEC_{accu\ max}$	TER [1)]	Trigger
Earthworms						
Eisenia fetida	Prochloraz	Acute	0.0110	0.1047	>4775	10
Eisenia fetida	Prochloraz	Chronic	0.0110	0.1047	40.1	5
Eisenia fetida	BTS 44595	Acute	<0.0001	0.0001	>5000000	10
Eisenia fetida	BTS 44595	Chronic	<0.0001	0.0001	12500	5
Eisenia fetida	BTS 44596	Acute	<0.0001	0.0002	>2500000	10
Eisenia fetida	BTS 40348	Acute	<0.0001	<0.0001	>3984000	10
Eisenia fetida	BTS 40348	Chronic	<0.0001	<0.0001	>240000	5
Other soil macro-organisms						
Soil mite	a.s.	-	-	-	-	-
	Preparation	-	-	-	-	-
	Metabolite 1	-	-	-	-	-
Collembola	Prochloraz	Chronic	0.0800	-	1250	5
	BAS 590 05 F	Chronic	-	0.1338	747	5
Refined risk assessment Not Relevant						

[1)] all TER values were calculated using maximum available PEC_{soil} value, i.e. accu max

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

Preliminary screening data

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

Laboratory dose response tests

Most sensitive species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
Oats-in crop	BAS 590 00 F	>1.0 L BAS 590 00 F/ha	-	0.450 g a.s./ha	-	50 %
Oats-off crop	BAS 590 00 F	23.8 mL BAS 590 00 F/ha	-	0.011 g a.s./ha	-	50 %

[1] The maximum off-crop exposure of plants has to be assumed as approx. 23.8 mL/ha (0.011 g/ha) (2.38% drift rate representing the 82th percentile for two times applying 1.0 L BAS 590 00 F/ha). Thus the exposure is more than 40 times less than the ER_{50} for all plant species tested. See "Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC"
[2] dose is expressed in units of a.s. as indicated

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

Not applicable

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

Test type/organism	end point
Activated sludge	EC_{50} = 120 mg a.s./L
Pseudomonas sp	Not applicable

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

Compartment	
soil	Prochloraz
water	Prochloraz, BTS 40348
sediment	Prochloraz
groundwater	Prochloraz

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

	RMS proposal *	
Prochloraz	N	Dangerous for the environment
	R50/53	Very toxic to aquatic organisms, may cause long term adverse effects in the environment
	S1	Keep locked up
	S56	Dispose of this material and its container to hazardous or special waste collection point
	S61	Avoid release to the environment. Refer to special instructions/safety data sheet

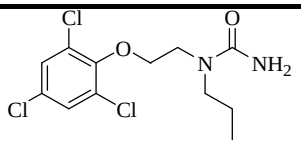
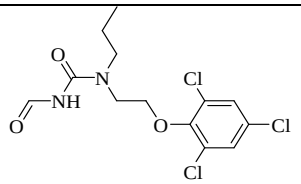
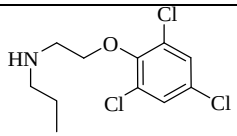
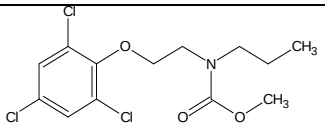
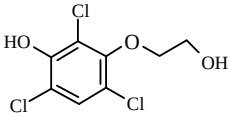
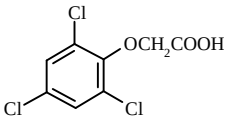
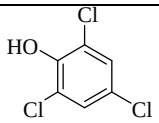
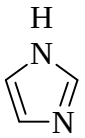
*References: Sowig & Gosch (2002c); Hill *et al.* (1986)

	RMS proposal*	
BAS 590 00 F	N:	Dangerous for the environment
	R50/53:	Very toxic to aquatic organisms, may cause long term adverse effects in the environment

S1	Keep locked up
S56	Dispose of this material and its container to hazardous or special waste collection point
S61	Avoid release to the environment. Refer to special instructions/safety data sheet

*References: Young & Abedi (2002);

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
BTS 44595	1-propyl-1-[2-(2,4,6 trichlorophenoxy)ethyl]urea	
BTS 44596	3-formyl-1-propyl-1-[2-(2,4,6-trichlorophenoxy)ethyl]urea	
BTS 40348	N-propyl-N-2-(2,4,6-trichlorophenoxy)-ethylamine	
M590F040	Methyl N-propyl-N-[2-(2,4,6-trichloro-phenoxy) -ethyl] carbamate	
BTS 54906		
BTS 9608	2,4,6-trichlorophenoxyacetic acid	
2,4,6-TCP **BTS 45186**	2,4,6-trichlorophenol	
Imidazole	1H-imidazole	

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

ABBREVIATIONS

1/n	slope of Freundlich isotherm
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical 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
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FID	Flame ionisation detector
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography

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
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content

Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
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
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TSH	thyroid stimulating hormone (thyrotropin)
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WBC	white blood cell
WG	water dispersible granule
WHO	World Health Organisation
wk	week
yr	year