CONCLUSION ON PESTICIDE PEER REVIEW

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

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SUMMARY

Carbendazim was one of the 90 substances of the first stage of the review programme covered by Commission Regulation (EC) No 3600/92[3], and was included in Annex I to Directive 91/414/EEC[4] on 1 January 2007 by Commission Directive 2006/135/EC[5], as amended by Commission Directive 2009/152/EC[6]. The inclusion expires on 31 December 2010. In accordance with Article 5(5) of Council Directive 91/414/EEC the notifiers DuPont de Nemours (Deutschland) GmbH, BASF AG, and Bayer CropScience AG made a request to the Commission of the European Communities (hereafter referred to as 'the Commission') for renewal of the inclusion in Annex I of carbendazim. Following the notifiers' submission of the dossier, the rapporteur Member State (RMS), Germany, provided an initial evaluation of carbendazim in the format of a Draft Reassessment Report (DRAR), which was submitted to the Commission on 17 July 2009. The Commission distributed the DRAR to Member States and the EFSA for comments on 28 July 2009. Following consideration of the DRAR and the comments received, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 27 October 2009, the Commission requested the EFSA to undertake a full peer review and, where necessary, to arrange further consultation with Member State experts, and to deliver its conclusions on carbendazim.

The conclusions presented in this report were reached on the basis of the evaluation of the representative uses of carbendazim as a fungicide on cereals, sugar beet, fodder beet, oilseed rape and maize, as proposed by the notifiers. Full details of the representative uses can be found in Appendix A to this report.

The specifications could not be accepted and a data gap is identified. Data gaps are also identified for various physical chemical properties and a method of analysis.

Once the technical specification has been defined, whether the toxicological studies cover the technical specification should be addressed (the available data are not sufficient and a data gap is identified). In addition, the toxicological relevance of a third impurity has to be addressed by the notifier.

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1 On request from the European Commission, Question No EFSA-Q-2009-00911, issued on 30 April 2010.
2 Correspondence: praper@efsa.europa.eu
3 OJ No L 366, 15.12.1992, p.10
4 OJ No L 230, 19.8.1991, p.1
5 OJ No L 349, 12.12.2006, p.37
6 OJ No L 314, 1.12.2009, p.66

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Metabolism in plants has been investigated in three different plant groups: Fruit crops (peach), oilseed/pulses (bean) and cereals (rice). Carbendazim was shown to be the major component of the residues, and the residue for monitoring and risk assessment was defined as the parent compound alone. Residue definitions were also proposed for products of animal origin. No risk for the consumer was identified, the maximum TMDI and IESTI being only 5% of the ADI and 7% of the ARfD.

With regard to environmental fate and behaviour, information is lacking regarding the route of aerobic degradation in soil and a detailed identification/quantification of three unidentified transformation products in one soil metabolism study was not available. As a consequence, the environmental exposure assessment for potential soil metabolites is not finalised for the representative uses at EU level. A data gap is also identified for data on soil photolysis of carbendazim. Taking into consideration the weak acidic properties of carbendazim, and the lack of information on soil degradation and soil adsorption properties, it should be considered that the available environmental exposure assessment does not cover environmental conditions where alkaline soils are predominant.

The long-term risk assessment for birds needs further refinement for the use in sugar beet. A high risk was identified for the aquatic environment. Risk mitigation is needed to achieve TER values above the trigger in at least one full FOCUS scenario. However risk mitigation measures, such as a 20m no-spray buffer zone and run-off mitigation, are not sufficient to achieve TERs above the Annex VI trigger in all FOCUS scenarios. An initial impact on sensitive non-target arthropods can be expected in the in-field area but the potential for recovery/recolonisation of the in-field area was demonstrated. The risk to mammals, bees, earthworms, other non-target soil-dwelling macro- and micro-organisms, non-target plants, and biological methods of sewage treatment was assessed as low.

KEY WORDS

carbendazim, peer review, risk assessment, pesticide, fungicide

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BACKGROUND

Carbendazim was one of the 90 substances of the first stage of the review programme covered by Commission Regulation (EC) No 3600/92[7], and was included in Annex I to Directive 91/414/EEC[8] on 1 January 2007 by Commission Directive 2006/135/EC[9], as amended by Commission Directive 2009/152/EC[10]. The inclusion expires on 31 December 2010.

In accordance with Article 5(5) of Council Directive 91/414/EEC the notifiers DuPont de Nemours (Deutschland) GmbH, BASF AG, and Bayer CropScience AG made a request to the Commission of the European Communities (hereafter referred to as 'the Commission') for renewal of the inclusion in Annex I of carbendazim. On 10 January 2008, in support of their request, the notifiers submitted a dossier to Germany, being the designated rapporteur Member State (RMS). The RMS provided an initial evaluation of carbendazim in the format of a Draft Reassessment Report (DRAR) (DE, 2009), which was submitted to the Commission on 17 July 2009.

The Commission distributed the DRAR to Member States and the EFSA for comments on 28 July 2009. The Commission invited comments to be provided by 25 September 2009. Following consideration of the DRAR and the comments received, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 27 October 2009, the Commission requested the EFSA to undertake a full peer review and, where necessary, to arrange further consultation with Member State experts, and to deliver its conclusions on carbendazim.

The Commission collated all comments received and distributed them to the notifiers for comment on 1 December 2009. Following receipt of the notifiers' comments, the Commission collated all comments received and forwarded them to the RMS for compilation in the format of a Reporting Table. The notifiers were invited to respond to the comments in column 3 of the Reporting Table. The RMS also provided a response to the comments in column 3.

The need for expert consultation was considered in a telephone conference between the EFSA, the RMS, and the Commission on 9 February 2010. On the basis of the comments received, the notifiers' response to the comments, and the RMS's subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the area of mammalian toxicology.

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

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

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in April 2010.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a fungicide on cereals, sugar beet, fodder beet, oilseed rape and maize, as proposed by the notifiers. 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

[7] OJ No L 366, 15.12.1992, p.10
[8] OJ No L 230, 19.8.1991, p.1
[9] OJ No L 349, 12.12.2006, p.37
[10] OJ No L 314, 1.12.2009, p.66

(EFSA, 2010), 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 comprises the following documents:

- the comments received,
- the Reporting Table (revision 1-1; 09 February 2010),
- the Evaluation Table (30 April 2010),
- the report(s) of the scientific consultation with Member State experts (where relevant).

Given the importance of the DRAR including its addendum (compiled version of March 2010 (DE, 2010) containing all individually submitted addenda) 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

Carbendazim is the ISO common name for methyl benzimidazol-2-ylcarbamate or 2-(Methoxycarbonylamino)-benzimidazole (IUPAC).

The representative formulated product for the evaluation was 'DPX-N7872-205' a suspo-emulsion (SE) containing 125 g/L carbendazim and 250 g/L flusilazole.

The representative uses comprise of outdoor foliar spraying against fungi in cereals, sugar beet, fodder beet, oilseed rape and maize. 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

3-Amino-2-hydroxyphenazine (AHP) and 2,3-Diamino-phenazine (DAP) are considered as relevant impurities. Mammalian toxicology has agreed that their maximum content is AHP 0.0005 g/kg and DAP 0.0006 g/kg of the carbendazim content in the technical material (TC). A third impurity may be relevant but this is subject to a data gap for further information on toxicological relevance. The FAO specification sets maximum levels of 0.0005 g/kg of the carbendazim content in the TC for AHP and 0.003 g/kg of the carbendazim content in the TC for DAP. Minimum purity for the active substance in the FAO specification is 960 g/kg.

The proposed specifications for the various sources of carbendazim could not be accepted.

The main data regarding the identity of carbendazim and its physical and chemical properties are given in Appendix A. Data gaps are identified for the following properties of carbendazim: UV spectra, solubility in organic solvents, dissociation constant, flammability, auto-flammability, explosive properties, oxidising properties and surface tension. Persistent foam is a data gap for the formulation.

Residues of carbendazim in plants can be analysed by LC-MS/MS methods. For products of animal origin, methods are available to analyse carbendazim in meat, milk, eggs and fat. A primary method with ILV is not available for liver and kidney; a LC-MS/MS method is available, however this can only be accepted as a confirmatory method because it is not fully validated. No methods are available for animal products for the metabolite 5-OH-carbendazim. However, since no MRLs for animal products are proposed, data gaps have not been identified. For soil, LC-UV and LC-MS methods are available. Water and air are analysed by LC-MS/MS. For body fluids and tissues the animal products method can be used for tissues, and an LC-MS/MS method is available for plasma. However, as the plasma method is not fully validated it can only be accepted as a confirmatory method and a data gap has been identified for a primary method.

2. Mammalian toxicity

A clear conclusion on whether the toxicological studies cover the specifications cannot be drawn as enough data are not available. Two genotoxic impurities were considered relevant, 2, 3-Diamino-phenazine (DAP) and 3-Amino-2-hydroxyphenazine (AHP). Their maximum upper levels are 0.0006 and 0.0005 g/kg, respectively, based on toxicological data. In addition, a third impurity (Code AE F037197) may be relevant (i.e. genotoxic properties) and a data gap has been identified.

Carbendazim is not acutely toxic via the oral, dermal and inhalation routes. It is not a skin or eye irritant but is a skin sensitizer. The liver (increased weight together with clinical chemistry and histopathological findings) and the testes (reduced weight and azoospermia) were the target organs after short-term exposure in rats and dogs, with the dog being the most sensitive species. Besides non-specific effects, a decrease in body weight and food consumption was also observed. The relevant short-term NOAEL is 2.7 mg/kg bw/day based on testes findings in dogs.

Carbendazim caused numerical chromosome aberrations both *in vitro* and *in vivo* as a result of the interference with mitotic spindle proteins, a threshold concentration for aneugenic activity *in vitro* was estimated to be between 0.2-0.6 µg/mL, and the NOEL for aneuploidy *in vivo* is 50 mg/kg bw. Carbendazim did not cause gene mutations or structural chromosomal aberrations. Nevertheless, the RMS informed EFSA that, in the framework of the evaluation of carbendazim under the biocides Directive 98/8/EC, two *in vitro* genotoxicity studies (Ames test and Chromosome aberration test in CHO cells) were presented, which were not submitted by the notifiers in the context of the evaluation under Directive 91/414/EEC. The test material (batch 010310, purity >98 %) was mutagenic in bacteria (TA98, TA1537 with S9) and clastogenic and aneugenic in CHO cells. The impurity profile of the batch tested is currently not known. In the absence of further data, it is not possible to address adequately the relevance of these findings, and as a result there are uncertainties with regard to the data package on genotoxicity submitted under the Directive 91/414/EEC.

In long-term toxicity studies in rats, mice and dogs the target organ was the liver (increased weight, together with clinical chemistry and histopathological findings), with the dog being the most sensitive species. Carcinogenic effects were confined to susceptible mouse strains in which increased incidence of liver tumours was observed, and therefore they were not considered of relevance for humans. The relevant long-term NOAEL is 2.6 mg/kg bw/day based on liver findings in dogs. Reproduction toxicity studies in rats showed that carbendazim produces infertility in males, decreased sperm counts, testicular atrophy and absence of spermatogenesis. The relevant parental, reproductive and offspring NOAEL is 100 mg/kg bw/day. Studies on developmental toxicity by oral gavage in rats and rabbits demonstrated that carbendazim is a developmental toxicant and teratogen. The relevant developmental NOAEL is 10 mg/kg bw/day in rats and rabbits, whereas the maternal NOAELs are 30 and 20 mg/kg bw/day in rats and rabbits respectively. There is no indication of any direct neurotoxic potential of carbendazim. The overall acceptable daily intake (ADI), acceptable operator exposure level (AOEL) and acute reference dose (ARfD) of 0.02 mg/kg bw/day were based on the developmental data in rats and rabbits (NOAEL of 10 mg/kg bw/day), and applying a safety factor of 500. There is a margin of safety of 2500 between the references values and the NOEL for the induction of aneuploidy *in vivo*. This margin was considered adequate to cover uncertainties with regard to species differences, influences of the methodology used (i.e. endpoint for aneuploidy measured *in vivo* (micronucleus) less sensitive than assessed *in vitro* (non-disjunction)) and the possible effects of exposure conditions (i.e. single vs. repeated administration).

Based on the effects described above, classification and labelling with **R43 (May cause sensitisation by skin contact)** in addition to the current classification and labelling as **Muta. Cat. 2; R46** and **Repr. Cat. 2; R60-61** (Annex I, Directive 67/548 EEC, adaptation to technical progress 29), is proposed.

Operator exposure estimates are below the AOEL if personal protective equipment (PPE) is used (gloves during mixing and loading, and standard protective garment as well as sturdy footwear during application). Worker exposure estimates are below the AOEL even if PPE are not used. Bystander exposure is also below the AOEL.

3. Residues

Metabolism in plants was investigated using foliar application of ^{14}C-carbendazim on beans and peaches and ^{14}C-benomyl on rice. An additional study where ^{14}C-carbendazim was applied to strawberry plants via hydroponic solution was provided but was considered to be informative only.

The studies performed in the 1970s or 1980s are relatively poor when compared to the current guidelines but they were considered sufficient to depict the overall metabolism of carbendazim in plants. Parent carbendazim remains the main component of the residues at harvest, accounting for *c.a.* 90%TRR in beans and peaches and 48%-63% TRR in mature rice grain and straw, the other metabolites being detected in low proportions (<10%TRR). However in rice, where all samples were analysed using two different extraction procedures, it must be noted that the metabolite 2-AB appears to be the major component when extracted under alkaline conditions, confirming a rapid degradation of carbendazim to 2-AB under basic conditions. A similar metabolic profile was observed in the rotational crop studies performed at exaggerated rates where parent was shown to be major. Based on these studies, the residues for monitoring and risk assessment were defined as the parent compound carbendazim only. However, it must be highlighted that carbendazim residues might also result from the uses of the active substances benomyl (no longer authorised within EU), and thiophanate-methyl.

A sufficient number of supervised residue trials were submitted to derive MRLs for barley, wheat (including rye and triticale), maize, sugar beet and rape seed. The trial results are supported by the storage stability studies showing carbendazim residues to be stable for more than 30 months when stored frozen at -20°C in water-containing matrices (sugar beet, tomato) and cereal straw. However, the stability in wheat grains was questionable, with low recoveries after 6 and 12 months, and a new storage stability study in cereal grains is identified as a data gap. A standard hydrolysis study shows no significant degradation of carbendazim under conditions simulating pasteurisation, baking or sterilisation. A processing study was submitted for barley only.

Livestock metabolism studies were submitted for dairy cow and laying hens. Carbendazim was extensively metabolised by hydroxylation to 5-OH-carbendazim (up to 48% TRR in kidney and milk), and to a lesser extent to 4-OH-carbendazim (up to 28% TRR in milk). Based on these studies, the residue for monitoring and risk assessment in animal matrices was defined as “sum of carbendazim, and 5-OH-carbendazim expressed as carbendazim”, except for milk where the residue definition for risk assessment was proposed as “sum of carbendazim, 5-OH-carbendazim and 4-OH-carbendazim expressed as carbendazim”. Feeding studies performed on dairy cow and laying hen were submitted. Samples were analysed according to the proposed residue definition for risk assessment and a conversion factor for risk assessment was derived for milk. However, no MRLs were proposed for products of animal origin since, considering the estimated intakes by animals resulting from the representative uses, no residues are expected to be present in significant levels in animal matrices.

No risk for the consumer was identified, the maximum TMDI and IESTI being only 5% of the ADI (DK Child) and 7% of the ARfD.

4. Environmental fate and behaviour

Four non-GLP studies were provided to investigate the aerobic route of degradation of carbendazim in soil (7 soils investigated, with non-radiolabelled carbendazim or carbendazim radiolabelled in the imidazole position). Because of the poorly documented studies and relevant deficiencies in the experimental designs, it was concluded that the available information was not sufficient to address the route of degradation of carbendazim in soil under aerobic conditions. A data gap was also identified for detailed identification/quantification of three unidentified transformation products found in one soil incubation, to clarify whether any of these metabolites would trigger a further exposure assessment in the environmental compartments. The only identified metabolite was 2-aminobenzimidazole (2-AB) up to 4-8% AR after 240 d.

In soil laboratory incubations under anaerobic conditions, where the active substance benomyl (a precursor of carbendazim) was applied, carbendazim accounted for 41-54% AR, whereas 2-AB was a minor component (< 2% AR). A data gap was identified for photolysis degradation in soil for carbendazim.

Reliable aerobic degradation rates of carbendazim were available for only 3 soils, and indicated that carbendazim exhibits moderate persistence in soil. Dissipation of carbendazim was investigated also in four German field trials. Field degradation rates normalized to FOCUS reference conditions at 20°C and 10 kPa, were in the range 10-50 days, confirming that accumulation of carbendazim in soil is not expected. Because the range of the pH values for soils tested in both laboratory and field trials was limited to acidic conditions (soil pH 4.7-6.8, n= 7) it was concluded that the rate of degradation/dissipation of carbendazim in soil does not cover neutral and alkaline conditions.

Carbendazim is medium mobile in soil. There was no indication that adsorption of carbendazim was pH dependent (pH values of the soils tested: 5.2-7.0).

A major (> 10%AR) degradation product of carbendazim was observed in the hydrolytic degradation study at higher pH values (pH 9). This corresponded to metabolite 2-AB up to 30% AR after 30 d.

In laboratory incubations in dark aerobic natural sediment water systems (2 systems investigated), carbendazim exhibited moderate to medium persistence, forming no major metabolites. The metabolite 2-aminobenzimidazole was detected at a maximum peak value of 6.3% AR in the sediment after 76 days of incubation. The majority of carbendazim partitioned to sediment during the study, and only a small percentage (≤ 0.2% AR) was found in the water phase at the study end (120d). Mineralisation was low or low to moderate in the two systems (4.7% AR and 20.4% AR). Relatively high amounts of non-extractable residues (55.2-59.4% AR after 120d) were formed in the sediment of both systems.

A revised surface water and sediment exposure assessment (Predicted environmental concentrations (PEC)) was appropriately carried out by the RMS using the FOCUS (2001) up to step 4 (Addendum 3 (DE, 2010)). The EFSA agreed the revised calculations based on soil DT50lab of 40 days normalised to FOCUS reference conditions (worst case value as reliable DT50 values are available for 3 soils only); arithmetic mean of the Freundlich isotherm (1/n) of 0.97; a DT50water = 75 days (worst case from the water/sediment studies) and DT50sed = 1000 days. Appropriate mitigation measures for spray drift and run-off in line with the recommendations of the FOCUS landscape and mitigation report (FOCUS, 2007) were adopted at step 4 simulations. FOCUS PECsw and PECsed were calculated at step 1 for the soil metabolite 2-AB for the spray drift route of entry. The drainage and run-off for soil of as yet unknown soil metabolites may need to be addressed.

The necessary groundwater exposure assessment for carbendazim was revised by the RMS in Addendum 3 following the recommendations of the peer review (worst case normalised soil DT50lab = 40 d; arithmetic mean of the Freundlich isotherm (1/n) = 0.97; arithmetic mean Koc = 225 mL/g). The PECgw calculations were simulated with the FOCUS PEARL 2.2.2 model based on three usage regimes that differed from those reported in the GAP table. However, as the application rates considered were higher than the ones indicated for the representative uses, the EFSA considers the assessment acceptable. The potential for groundwater exposure from the representative uses by carbendazim 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 PEC in soil, surface water, sediment and groundwater covering the representative uses can be found in Appendix A.

5. Ecotoxicology

No assessment was provided concerning whether the ecotoxicological studies provided cover the specifications. In addition, the ecotoxicological relevance of impurity Code AE F037197 should be further addressed and a data gap is identified.

The acute, short-term and long-term risk to birds and mammals was assessed as low for exposure to carbendazim alone. However the first-tier long-term TERs were below the trigger for exposure to the second active substance (flusilazole). The RMS presented a refined risk assessment including a risk assessment for combined exposure in an addendum (DE, 2010). The acute and short-term risk was assessed as low but the long-term TERs were below the trigger. Refinement of the risk assessment was based on yellowhammer (*Emberiza citronella*) and generic focal species (woodlark *Lullula arborea*, yellow wagtail *Motacilla flava* and wood pigeon *Columba palumbus*), as suggested in the new EFSA Guidance Document on the risk assessment for birds and mammals (EFSA, 2009). EFSA agrees with the risk assessment presented by the RMS. However the refined TERs for the generic focal species yellow wagtail were below the trigger for the use in sugar beet based on a mixed diet of ground-dwelling and leaf-dwelling arthropods. While the arguments presented by the RMS may be sufficient to conclude on a safe use in sugar beet in Northern Europe, EFSA is of the opinion that further refinement of the risk assessment is necessary for the use in sugar beet in Southern Europe since the TER of 3.5 is clearly below the trigger of 5.

The first-tier TERs for the acute and long-term risk to mammals were above the trigger for both carbendazim and flusilazole. No risk assessment for combined exposure was conducted. However, since the TERs clearly exceeded the Annex VI trigger it is not expected that combined exposure to the formulated product would result in TERs below the trigger. Overall it is concluded that the risk to mammals is low for the representative uses.

Carbendazim is very toxic to aquatic organisms. Acute LC50/EC50 of 0.019 mg a.s./L and 0.15 mg a.s./L were observed for fish and daphnids. The chronic toxicity endpoint for daphnids (NOEC = 0.0015 mg a.s./L) was driving the aquatic risk assessment. The endpoints for the representative formulation (including the second active substance flusilazole) are similar to technical carbendazim. Therefore it can be assumed that the risk assessment for the active substance covers the risk from exposure to the second active substance.

No full FOCUS step 3 scenario resulted in TERs above the trigger for the use on spring and winter cereals, and winter and spring oilseed rape. No aquatic risk assessment was presented for the use on sugar beet (lower application rates of 3 x 62.5 g a.s./ha) and maize (same application rates as for cereals and oilseed rape of 2 x 100 g a.s./ha). However, it is assumed that the risk assessment for cereals also covers the risk from these two uses.

Overall it can be concluded that risk mitigation (comparable to 10m or 20m no-spray buffer zones) is necessary for all representative uses in order to achieve TERs above the trigger in at least one full FOCUS scenario. However, it should be noted that it was not demonstrated that a 20m no-spray buffer zone, including run-off mitigation, would be sufficient as a risk mitigation measure to achieve TERs above the Annex VI trigger in all FOCUS scenarios.

The in-field HQ value was <2 for the indicator species *Aphidius rhopalosiphi* but was >2 for *Typhlodromus pyri*. The off-field HQ values indicated a low off-field risk. In an aged residue study it was demonstrated that adverse effects are <50% after 28 days of ageing of residues. It can be concluded that an initial impact on sensitive arthropod species can be expected in the in-field area but recovery/recolonisation is possible within one season.

The risk to bees, earthworms, other soil-dwelling macro- and micro-organisms, non-target plants and biological methods of sewage treatment was assessed as low.

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

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
carbendazim	moderate persistence Single first order DT_{50} 26-40 days (20°C, 10kPa soil moisture)	The risk to earthworms and soil micro-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
carbendazim	medium mobility K_{Foc} 200-246 mL/g	no	Yes	Yes	Very toxic to aquatic organisms. A high risk was identified for aquatic organisms from exposure in surface water.

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
carbendazim	Very toxic to aquatic organisms (acute LC50 fish = 0.019 mg a.s./L, the chronic NOEC for daphnids of 0.0015 mg a.s./L) is driving the aquatic risk assessment. A high risk for the aquatic environment was identified (no full FOCUS step3 scenario resulted in TERs above the Annex VI trigger).

6.4. Air

Compound (name and/or code)	Toxicology
carbendazim	Not acutely toxic (LC50>5.8 mg/L air (4-h exposure, head/nose-only)

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

- A reliable specification should be proposed based on the supporting batch data (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown see section 1).
- The following physchem properties of the active substance have been identified as data gaps: UV spectra, solubility in organic solvents, the dissociated species, flammability, auto-flammability, explosive properties, oxidising properties and surface tension (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown, see section 1).
- Persistent foam of the formulation (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Primary fully validated method for body fluids (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 1).
- Once the technical specification has been defined (see section 1) whether the toxicological and ecotoxicological studies cover the technical specification has to be addressed (relevant for all representative uses evaluated, data gap identified in the reporting table, data of submission unknown, see sections 2 and 5).
- The toxicological and ecotoxicological relevance assessment of the impurity Code AE F037197 as the setting of an upper limit, if needed, has to be addressed (relevant of all representative uses evaluated, data gap identified in the reporting table, data of submission unknown, see sections 2 and 5).
- The relevance of the positive results of *in vitro* genotoxicity studies (Ames test and Chromosome aberration test in CHO cells) performed with carbendazim technical (batch 010310, purity >98 %) available under the biocide regulation should be evaluated (relevant of all representative uses evaluated, see section 2).
- A storage stability study of carbendazim residues in cereal grains is required in order to support the results of the supervised residue trials (relevant for the representative uses on cereals; data gap identified in the reporting table, submission date proposed by the notifier: unknown; see section 3).
- Adequate route of aerobic degradation of carbendazim in soil (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).
- Estimates of aerobic degradation rates of carbendazim in neutral-alkaline soils (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).
- Quantification and, if needed, identification of the unidentified soil transformation products formed in one aerobic soil degradation study (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).
- Pending adequate data on route of aerobic degradation in soil, further consideration of run-off or drainage to surface water of soil metabolites may be required (see section 4).
- Adequate soil photolysis study for carbendazim (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).

- The long-term risk to birds needs to be refined further (relevant for the use in sugar beet in Southern Europe, data gap proposed by EFSA after receipt of the addenda, see section 5).

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

- The use of personal protective equipment (PPE) of gloves during mixing and loading, and standard protective garment as well as sturdy footwear during application, is needed to reduce the operator exposure to below the AOEL. See section 2.

- Risk mitigation measures comparable to 10m or 20m no-spray buffer zones are needed to achieve TER values above the trigger in at lease one or more full FOCUS scenarios.

ISSUES THAT COULD NOT BE FINALISED

- According to the dossier submitted under Directive 91/414/EEC carbendazim caused numerical chromosome aberrations both *in vitro* and *in vivo* as a result of the interference with mitotic spindle proteins, a threshold concentration for aneugenic activity *in vitro* was estimated to be between 0.2-0.6 µg/mL, and the NOEL for aneuploidy *in vivo* is 50 mg/kg bw. Carbendazim did not cause gene mutations or structural chromosomal aberrations. However, in the context of the evaluation of carbendazim under the Directive 98/8/EC, two *in vitro* genotoxicity studies (Ames test and Chromosome aberration test in CHO cells) were presented, which were not submitted by the notifiers in the context of the evaluation under Directive 91/414/EEC. The test material (batch 010310, purity >98 %) was mutagenic in bacteria (TA98, TA1537 with S9) and clastogenic and aneugenic in CHO cells. The impurity profile of the batch tested is currently not known. Therefore the relevance of these new studies (in the absence of the raw data and the impurity profile) to the current assessment of carbendazim could not be finalised.

- Route of aerobic degradation in soil.

- The environmental exposure assessment for potential soil metabolites is not finalised for the representative uses at EU level.

- The available environmental exposure assessment (soil, ground water and surface water) does not cover environmental conditions where alkaline soils are predominant.

- The long-term risk to birds is not finalised for the use on sugar beet in Southern Europe.

CRITICAL AREAS OF CONCERN

- The proposed reference specification is not acceptable because it is not supported by the available data, and a clear conclusion on whether the toxicological studies cover the specifications cannot be drawn as the available data are not sufficient. In addition, no assessment was provided as to whether the ecotoxicological studies cover the specifications.

REFERENCES

DE, 2009. Draft Reassessment Report on the active substance carbendazim, prepared by the rapporteur Member State Germany in accordance with Article 5(5) of Council Directive 91/414/EEC, July 2009.

DE, 2010. Final Addendum to Assessment Report on carbendazim, compiled by EFSA, March 2010.

EFSA (European Food Safety Authority), 2010. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance carbendazim.

Guidance documents[11]:

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

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.

[11] 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)

APPENDICES

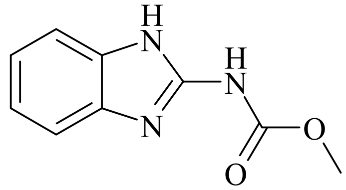
APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, physical and chemical properties, details of uses, further information

Active substance (ISO Common Name) ‡	carbendazim
Function (*e.g.* fungicide)	fungicide

Rapporteur Member State	Federal Republic of Germany
Co-rapporteur Member State	none

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	methyl benzimidazol-2-ylcarbamate or 2-(Methoxycarbonylamino)-benzimidazole
Chemical name (CA) ‡	methyl 1H-benzimidazol-2-ylcarbamate
CIPAC No ‡	263
CAS No ‡	10605-21-7
EC No (EINECS or ELINCS) ‡	EEC: 613-048-00-8; EINECS:234-232-0
FAO Specification (including year of publication) ‡	AGP: CP/220 (1992); 960 g/kg AHP 0.0005 g/kg of the carbendazim content in the TC DAP 0.003 g/kg of the carbendazim content in the TC
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	AHP 0.0005 g/kg of the carbendazim content in the TC DAP 0.0006 g/kg of the carbendazim content in the TC
Molecular formula ‡	$C_9H_9N_3O_2$
Molecular mass ‡	191.21 g/mol
Structural formula ‡	

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	302 – 307 °C (under decomposition) (> 99 %)
Boiling point (state purity) ‡	Not applicable
Temperature of decomposition (state purity)	302 – 307 °C (under decomposition) (> 99 %)
Appearance (state purity) ‡	Pure: almost colourless crystalline solid, odourless;
	Tech.: sand-coloured to light grey crystalline powder, odourless
Vapour pressure (state temperature, state purity) ‡	9×10^{-5} Pa (20 °C); 1.5×10^{-4} Pa (25 °C)
Henry's law constant ‡	3.6×10^{-3} Pa m^3 mol^{-1} (24 °C)
Solubility in water (state temperature, state purity and pH) ‡	pH 4: 29 mg/L pH 7: 8 mg/L pH 8: 7 mg/L 24 °C, (> 99 %)
Solubility in organic solvents ‡ (state temperature, state purity)	Open
Surface tension ‡ (state concentration and temperature, state purity)	Open
Partition co-efficient ‡ (state temperature, pH and purity)	pH 5: log $P_{O/W}$ 1.4 pH 7 + 9: log $P_{O/W}$ 1.5 all at 25 °C, (98 % radiochemical)
Dissociation constant (state purity) ‡	pKa = 4.2 (99.6 %) Open for identification of the dissociated species
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Open
Flammability ‡ (state purity)	Open
Explosive properties ‡ (state purity)	Open
Oxidising properties ‡ (state purity)	Open

Summary of representative uses evaluated (*Carbendazim*)

Crop and/ or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controll ed	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days)	Remarks
(a)			(b)	(c)	Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL min - max (l)	water L/ha min - max	g as/ha min - max (l)	(m)	
Cereals: Wheat, Rye, Triticale (winter, spring)	BE, LU CZ, DE, IRL, UK PL,	Punch SE Harvesan Punch C Escudo Forte	F	Stem, foliar and ear diseases	SE	Flusiliazole 250 g/L Carbendazim 125 g/L	Hydraulic sprayer overall	BBCH 69-71	2	14		100-400	Flusiliazole 200 g as/ha Carbendazim 100 g as/ha	N/A*	[1] [2]
	FR	Punch CS						BBCH 59-61				100-150		42	Minimum PHI
	SP PT	Punch CS Contrast CS						BBCH 69-71				100-600		N/A*	
Cereals: Barley (winter, spring)	BE, LU DE, IRL, UK PL,	Punch SE Harvesan Punch C Escudo Forte	F	Foliar and ear diseases	SE	Flusiliazole 250 g/L Carbendazim 125 g/L	Hydraulic sprayer overall	BBCH 49-51	2	14		100-400	Flusiliazole 200 g as/ha Carbendazim 100 g as/ha	42	[1] [2]
	FR	Punch CS						BBCH 59-61				100-150		42	Minimum PHI
	SP PT	Punch CS Contrast CS						BBCH 69-71				100-600		N/A*	
Sugar and fodder beet North	BE, LU DE, IRL, UK	Punch SE Harvesan Punch C	F	Foliar diseases	SE	Flusiliazole 250 g/L Carbendazim 125 g/L	Hydraulic sprayer overall	Full crop cover BBCH 49	2	28		100-150	Flusiliazole 150 g as/ha Carbendazim 75 g as/ha	42	[1] [2]

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL min - max (l)	water L/ha min - max	g as/ha min - max (l)		
Sugar and fodder beet	FR	Punch CS	F	Foliar diseases	SE	Flusiliazole 250 g/L Carbendazim 125 g/L	Hydraulic sprayer overall	Full crop cover BBCH 49	2	28		100-150	Flusiliazole 125 g as/ha Carbendazim 62.5 g as/ha	35 - 42	[1] [2]
Sugar and fodder beet South	SP PT	Punch CS Contrast CS	F	Foliar diseases	SE	Flusiliazole 250 g/L Carbendazim 125 g/L	Hydraulic sprayer overall	Full crop cover BBCH 49	3	14		100-400	Flusiliazole 125 g as/ha Carbendazim 62.5 g as/ha	15	[1] [2]
Oil seed rape	FR	Punch CS	F	Foliar and pod diseases	SE	Flusiliazole 250 g/L Carbendazim 125 g/L	Hydraulic sprayer overall	Flowering declining; majority of petals fallen BBCH 67	2	21		100-150	Flusiliazole 200 g as/ha Carbendazim 100 g as/ha	63	[1] [2]
Oil seed rape	UK, DE	Punch SE Harvesan	F	Foliar and pod diseases	SE	Flusiliazole 250 g/L Carbendazim 125 g/L	Hydraulic sprayer overall	Flowering declining; majority of petals fallen BBCH 67	2	21		100-400	Flusiliazole 200 g as/ha Carbendazim 100 g as/ha	N/A*	[1] [2]
Maize	FR	Punch CS	F	Foliar diseases	SE	Flusiliazole 250 g/L Carbendazim 125 g/L	Hydraulic sprayer overall	BBCH 75	2	21		100-150	Flusiliazole 200 g as/ha Carbendazim 100 g as/ha	28	[1] [2]

[1] No specifications are accepted because they are not supported by the available data and a clear conclusion on whether toxicological studies cover the specifications cannot be drawn as the available data are not sufficient.
[2] The environmental risk assessment is not finalised (see section 4)
* For cereals and oil seed rape, the pre-harvest interval is governed by the growing period remaining between the final application and harvest at crop maturity which may vary depending on local conditions. The residues at harvest are determined more by growth stage at final application than PHI in days.

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)	(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g.

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I) (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989 (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl). (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application (k) Indicate the minimum and maximum number of application possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval

Methods of analysis)

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

Technical as (analytical technique)	HPLC-UV
Impurities in technical as (analytical technique)	by HPLC-DAD, ion chromatography, Karl-Fischer-titration or by argentometric titration AHP/DAP: HPLC-UV or HPLC-fluorescence detection
Plant protection product (analytical technique)	HPLC-UV

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		carbendazim
Food of animal origin		sum of carbendazim and 5-OH-carbendazim expressed as carbendazim
Soil		carbendazim
Water	surface	carbendazim
	drinking/ground	carbendazim
Air		carbendazim
Body fluids and tissues		carbendazim

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	LC-MS/MS, 0.01 mg/kg carbendazim (raisin, wheat flour, lemon, cucumber) confirmation by second MS/MS transition, ILV included LC-MS/MS, 0.05 mg/kg carbendazim (wheat grain, wheat straw, rape seed), ILV provided
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	LC-MS/MS, 0.05 mg/kg carbendazim (meat, milk, eggs, fat), ILV provided LC-MS/MS, 0.01 mg/kg carbendazim (liver/kidney, only for confirmation) acceptable methods (primary method and ILV) for carbendazim in liver/kidney are missing acceptable methods (primary method, confirmatory method, ILV) for 5-OH-carbendazim in meat, egg, milk, fat, liver/kidney are missing
Soil (analytical technique and LOQ)	LC-UV, 0.02 mg/kg carbendazim LC-MS, 0.02 mg/kg carbendazim
Water (analytical technique and LOQ)	LC-MS/MS, 0.1 µg/L carbendazim (drinking water, ground water surface water)
Air (analytical technique and LOQ)	LC-MS/MS, 0.3 µg/m³ carbendazim (ambient air, warm humid air)

Body fluids and tissues (analytical technique and LOQ)	LC-MS/MS, 0.05 mg/kg carbendazim (meat) LC-MS/MS, 0.0006 mg/L carbendazim (plasma), only for confirmation Acceptable primary method for body fluids is open.

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

	RMS/peer review proposal
Active substance	-

Impact on human and animal health

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

Rate and extent of oral absorption ‡	Rapid, about 80-85 %, based on oral and iv studies
Distribution ‡	Wide, highest residues in liver and kidney
Potential for accumulation ‡	No evidence for accumulation
Rate and extent of excretion ‡	About 85 % complete within 72 h (urine: ~60 %, faeces: ~25 %), more than 45 % within 6 h
Metabolism in animals ‡	Extensively metabolised (oxidation, sulphate and glucuronide conjugates)
Toxicologically relevant compounds ‡ (animals and plants)	Carbendazim and metabolites
Toxicologically relevant compounds ‡ (environment)	Carbendazim and metabolites

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	> 10000 mg/kg bw	
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	> 5.8 mg/L air (4-h exposure, head/nose-only)	
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Non-sensitiser (Buehler) Sensitiser (M&K)	R43

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Liver (wt ↑, clinical chemistry, histological findings), testes (wt ↓, azoospermia at high doses), bw gain and feed intake ↓	
Relevant oral NOAEL ‡	90-d, rat: 163 mg/kg bw/d 90-d, dog: 2.7 mg/kg bw/d	
Relevant dermal NOAEL ‡	10-d (7 d/wk) & 21-d (5 d/wk), rabbit (overall): local effects: 10 mg/kg bw/d systemic effects: 2000 mg/kg bw/d	
Relevant inhalation NOAEL ‡	No data – not required	

Genotoxicity ‡ (Annex IIA, point 5.4)

	Numerical chromosome aberrations both *in vitro* and *in vivo* as a result of the interference with mitotic spindle proteins. Threshold concentration for aneugenic activity *in vitro* between 0.2-0.6 µg/mL; NOEL for aneuploidy induction *in vivo*: 50 mg/kg bw.	R46 (Muta. Cat. 2)

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

Target/critical effect ‡	Liver (wt ↑, histological findings, clinical chemistry), bw ↓, at higher doses in rats: RBC (slight anaemia, equivocal evidence); additionally in mice and dogs: mortality ↑	
Relevant NOAEL ‡	2-yr, rat: 22 mg/kg bw/d 18-mo, mouse: approx. 22.5 mg/kg bw/d 2-yr, dog: 2.6 mg/kg bw/d	
Carcinogenicity ‡	Liver tumours in CD-1 mice at 81 mg/kg bw/d and above and in Swiss mice at 45 mg/kg bw/d and above but not in NMRKf mice; no relevance for humans No evidence for carcinogenicity in rats (and dogs)	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Adult: bw gain ↓ Reproduction and fertility: infertility in male rats, sperm numbers ↓, testicular atrophy and absence of spermatogenesis Offspring: bw ↓	R60 (Repr. Cat. 2)
Relevant parental NOAEL ‡	100 mg/kg bw/d	
Relevant reproductive NOAEL ‡	100 mg/kg bw/d	
Relevant offspring NOAEL ‡	100 mg/kg bw/d	

Developmental toxicity

Developmental target / critical effect ‡	Maternal: Rat: bw gain ↓, clinical signs of toxicity, abortions Rabbit: bw gain ↓, abortions Developmental: Rat: high resorption rate, foetal wt ↓, skeletal variations, malformations (e.g. hydrocephalus, anophthalmia) Rabbit: implantation ↓, resorptions ↑, live litter size ↓, skeletal malformations	R61 (Repr. Cat. 2)
Relevant maternal NOAEL ‡	Rat: 30 mg/kg bw/d Rabbit: 20 mg/kg bw/d	
Relevant developmental NOAEL ‡	Rat: 10 mg/kg bw/d Rabbit: 10 mg/kg bw/d	

Neurotoxicity (Annex IIA, point 5.7)

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

Delayed neurotoxicity ‡	Hen: no evidence for delayed neurotoxicity up to 5000 mg/kg bw. Clinical signs for neurotoxicity (ataxia, leg weakness) and systemic toxicity (salivation). $NOAEL_{delayed\ neurotoxicity}$: 5000 mg/kg bw $NOAEL_{neurotoxicity}$: 2500 mg/kg bw $NOAEL_{systemic\ toxicity}$: < 500 mg/kg bw	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies ‡	Rats and mice: hepatic enzyme induction (phase I and II) but in different extends in these species No or minor effects on cellular respiratory function in isolated rat liver mitochondria Interaction with microtubules, inhibition of polymerisation; NOAEL: 50 mg/kg bw
Studies performed on metabolites or impurities ‡	2-aminobenzimidazole (metabolite): Ames: negative Rat ALD oral: 3400 mg/kg bw 90-d, dog: 2.3 mg/kg bw/d (liver toxicity) 90-d, rat: 8.2 mg/kg bw/d (bw gain ↓) 5-hydroxy carbendazim (metabolite): Ames: negative 2,3-diaminophenazine (impurity): Ames: positive 2-amino-3-hydroxyphenazine (impurity): Ames: positive

Medical data ‡ (Annex IIA, point 5.9)

	No adverse effects in manufacturing personnel reported. One poisoning incident reported in open literature.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI ‡	0.02 mg/kg bw	Developmental, rat & rabbit	500
AOEL ‡	0.02 mg/kg bw/d	Developmental, rat & rabbit	500
ARfD ‡	0.02 mg/kg bw	Developmental, rat & rabbit	500

Dermal absorption ‡ (Annex IIIA, point 7.3)

Active substance	Carbendazim (as): 10 % (default, considering the available supplementary study results)
Formulation (DPX-N7872-205)	DPX-N7872-205: 100 % (default, no data available)

Exposure scenarios (Annex IIIA, point 7.2)

Operator	**German model** Estimated exposure is below the AOEL (78% if gloves are worn when handling the product during mixing/loading and standard protective garment as well as sturdy footwear is worn during application). **UK POEM** Estimated exposure is above the AOEL (751% if gloves are worn during mixing/loading and during application).
Workers	**German re-entry exposure estimate** 50 % of AOEL without PPE.
Bystanders	**BBA data:** Exposure estimate: 2.4 % of AOEL.

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

	RMS/peer review proposal
Substance classified (Carbendazim)	Directive 67/548/EEC: T R46 (Muta. Cat. 2) R60 (Repr. Cat. 2) R61 (Repr. Cat. 2) Additional proposal: R43

Residues

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

Plant groups covered	Fruit crops (peach), Pulses/oilseed (beans) Cereals (rice, with benomyl) Strawberry informative only
Rotational crops	Alfalfa, lettuce, radish, ryegrass, soybean plants
Metabolism in rotational crops similar to metabolism in primary crops?	yes
Processed commodities	Hydrolysis study
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes
Plant residue definition for monitoring	Carbendazim
Plant residue definition for risk assessment	Carbendazim
Conversion factor (monitoring to risk assessment)	none

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

Animals covered	Ruminants (cows) and poultry (laying hens)
Time needed to reach a plateau concentration in milk and eggs	Milk: 1 day Eggs: 14 days
Animal residue definition for monitoring	sum of carbendazim and 5-OH-carbendazim, expressed as carbendazim
Animal residue definition for risk assessment	Milk: Sum of carbendazim, 4- and 5-OH-carbendazim, calculated as carbendazim Other animal matrices: sum of carbendazim and 5-OH-carbendazim, expressed as carbendazim
Conversion factor (monitoring to risk assessment)	Milk: 2 Other animal matrices: not applicable
Metabolism in rat and ruminant similar (yes/no)	No (in rats 4-OH-carbendazim was not found, but Tox suggests that reference values set for carbendazim are also applicable to 4-OH-carbendazim)
Fat soluble residue: (yes/no)	no

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

	Not relevant

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

Green beans	3 months
Soybean, beans and refined oil	18 months
Soybean, meal	9 months
Sugar beet, roots and tops	60 months
Tomatoes, fruits	30 months
Tomato, wet pomace, juice and puree	6 months
Wheat straw	36 months
Wheat grain	New study requested (data gap)

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 0.45/0.9 mg/kg DM (Dairy/beef cattle)	<0.1 0.037 mg/kg DM	Not calculated
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	No	No	No
	Feeding studies: Ruminant: 2 mg/kg diet; Poultry: 5 mg/kg diet Residue levels in matrices : Maximum (mg/kg)		
	carbendazim / 4-OH / 5-OH-carbendazim	carbendazim / 4-OH / 5-OH-carbendazim	
Muscle	<0.01/<0.05/<0.01	<0.05/<0.05/<0.05	
Liver	<001/<0.05/<0.01	<0.05/<0.05/<0.05	
Kidney	<001/<0.05/<0.01	<0.05/<0.05/<0.05	
Fat	<001/0.09/0.02	<0.05/<0.05/<0.05	
Milk	<0.01/<0.01/0.01		
Eggs		<0.05/<0.05/<0.05	

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 or glasshouse	**Trials results relevant to the representative uses** (a)	**Recommendation/comments**	**MRL** estimated from trials according to representative use	**HR** (mg/kg) (c)	**STMR** (mg/kg) (b)
Wheat, rye and triticale	North	11x <0.01, 2x <0.03, 10x <0.05, 0.05, 0.07	Trials from Northern Europe were used for MRL and risk assessment	0.1	0.07	0.03
	South	4x <0.01, 2x 0.01, 2x 0.02, 0.06			0.06	0.01
Barley	North	4x <0.01,2x 0.01, 6x 0.02, 2x <0.05	R_{mac}: 0.06 mg/kg R_{ber}: 0.04 mg/kg	0.1	0.05	0.02
	South	no data				
Maize	North	no data		0.01*	0.01	0.01
	South	5x <0.01				
Sugar beets	North	Roots: 8x <0.01 Leaves and tops: 4x <0.01, 0.01, 0.02, 0.03, 0.04		0.01*	0.01 (roots) 0.04 (tops)	0.01 (roots) 0.01 (tops)
	South	no data				
Oilseed rape	North	7x <0.01,13x <0.02, <0.03,2x <0.05		0.05*	0.05	0.02
	South	no data				

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

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

ADI	0.02 mg/kg bw/d
TMDI (% ADI) according to EFSA PRIMo Model rev2	Maximum TMDI: 5% ADI (DK Child)
TMDI (% ADI) according to national (to be specified) diets	
IEDI (WHO European Diet) (% ADI)	
NEDI (specify diet) (% ADI)	
Factors included in IEDI and NEDI	None
ARfD	0.02 mg/kg bw
IESTI (% ARfD) according to EFSA PRIMo Model rev2	Maximum IESTI: 7% ARfD (Wheat)
NESTI (% ARfD) according to national (to be specified) large portion consumption data	
Factors included in IESTI and NESTI	none

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

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%)
		Transfer factor	Yield factor	
Barley:				
pearl barley, malt, green malt, spent grain, trub and yeast	2	<0.3		
pearling dust	2	1.2		
beer	2	<0.06		

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

Barley, rye, triticale and wheat	0.1 mg/kg
Maize	0.01* mg/kg
Sugar beets	0.01* mg/kg
Rape seeds	0.05* mg/kg
Products of animal origin	Not necessary when considering the supported uses

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

Fate and behaviour in the environment

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

Mineralisation after 100 days ‡	Data gap identified for adequate route of aerobic degradation in soil
Non-extractable residues after 100 days ‡	Data gap identified for adequate route of aerobic degradation in soil
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Data gap identified for quantification/identification of three unidentified soil transformation products formed in one aerobic soil metabolism study. (2-AB one times >5% AR)

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

Anaerobic degradation ‡	
Mineralisation after 100 days	anaerobic degradation study dosed with benomyl, a precursor of carbendazim ca max. 20 % after 180 d (estimated expecting a recovery of 100 %)
Non-extractable residues after 100 days	anaerobic degradation study dosed with benomyl, a precursor of carbendazim max. 20 – 28 % after 180 d
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No relevant metabolites (2-AB max 1,5 % after 180)
Soil photolysis ‡	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	No data, data gap identified

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

Laboratory studies ‡

Parent	Aerobic conditions								
Soil type	X[1]	pH	t. °C	% MWHC	DT_{50} (d)	DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	χ2 error	Method of calculation
Sand 1		6.8	22	40	37	123	37	7	SFO
Loamy Sand		5.2	22	40	37	226		3	DFOP
		5.2	22	40	44	146	40	9	SFO
Sand 2		4.7	15	40	34	112	20 / 26*	4	SFO
Sand 2		4.7	20	40	31	102	27 / 26*	5	SFO
Sand 2		4.7	25	40	26	86	33 / 26*	5	SFO
Maximum (n=3) as modelling endpoint							40		
Worst case as trigger endpoint					37				

DT_{50} re-calculated based on residue values using ModelMaker software
*geomean of DT_{50} values (n=3) for one soil tested at three temperatures

Field studies ‡

Parent	Aerobic conditions								
Soil type (bare soil)	Location	X[1]	pH	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	χ^2 error	DT_{50} (d) 20 °C, 10pKa	Method of calculation
Silty Sand	D-Frankfurt-Schwanheim		5.8	0-20	78	257	13	50	SFO
Loam	D-Gersthofen		5.6	0-20	11	36	20	14*	SFO
Loam	D- Bornheim		6.9	0-20	18	59	30	13	SFO
Loamy sand	D-Stelle		4.8	0-20	16	54	22	10	SFO
Geometric mean (d)					22	54		17	
worst case(d)					78	257		50	

*Modelling DT_{50}= FOMC DT_{90}/3.32

pH dependence ‡ (yes / no) (if yes type of dependence)	no
Soil accumulation and plateau concentration ‡	not triggered

[1] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	X[2]	pH	t. °C	DT_{50} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Sandy loam		6.5	25	both >180 d			estimation
Silt loam		6.4	25				
Geometric mean/median							

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	OC %	Soil pH	K_d (mL/g)	K_{oc} (mL/g)	K_f (mL/g)	K_{foc} (mL/g)	1/n
Sand	0.8	7.0			1.6	200	0.87
Sand	2.58	6.8			6.3	246	1.12
Sandy loam	1.0	5.2			2.3	230	0.91
Arithmetic mean						225	0.97
pH dependence, Yes or No			no				

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

Column leaching ‡	Spitzer 1990 Eluation (mm): 393 mm Time period (d): 2 d,
	Leachate: < 0.14 % of HOE 017411 in leachate
Aged residues leaching ‡	no additional data required
Lysimeter/ field leaching studies ‡	no additional data required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 78 days Kinetics: SFO, maximum field (n = 4), not normalised

[2] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Application data	Crop: cereals (late) Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 70 % and 90 % Number of applications: 2 Interval (d): 14 Application rate(s): 100 g as/ha

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		-/-		0.049	
Short term	24 h	-/-	-/-	0.048	0.048
	2 d	-/-	-/-	0.047	0.048
	4 d	-/-	-/-	0.046	0.048
Long term	7 d	-/-	-/-	0.043	0.047
	28 d	-/-	-/-	0.033	0.043
	50 d	-/-	-/-	0.021	0.039
	100 d	-/-	-/-	0.009	0.032
Plateau concentration		-/-			

Parent Method of calculation	DT$_{50}$ (d): 78 days Kinetics: SFO, maximum field (n = 4), not normalised

Application data	Crop: maize Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 75 % and 75 % Number of applications: 2 Interval (d): 21 Application rate(s): 100 g as/ha

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		-/-		0.061	
Short term	24 h	-/-	-/-	0,060	0,061
	2 d	-/-	-/-	0,059	0,060
	4 d	-/-	-/-	0,057	0,060
Long term	7 d	-/-	-/-	0,054	0,059
	28 d	-/-	-/-	0,042	0,054
	50 d	-/-	-/-	0,027	0,049
	100 d	-/-	-/-	0,011	0,040
Plateau concentration		-/-			

Application data	Crop: sugar beet (NE) Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm3 % plant interception: 70 % and 75 % Number of applications: 2 Interval (d): 28 Application rate: 75 g as/ha

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		-/-		0.033	
Short term	24 h	-/-	-/-	0.033	0.033
	2 d	-/-	-/-	0.033	0.033
	4 d	-/-	-/-	0.031	0.033
Long term	7 d	-/-	-/-	0.029	0.032
	28 d	-/-	-/-	0.023	0.030
	50 d	-/-	-/-	0.015	0.027
	100 d	-/-	-/-	0.006	0.022
Plateau concentration		-/-			

Application data	Crop: sugar beet (SE) Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm3 % plant interception: 70 %, 90 % and 90 % Number of applications: 3 Interval (d): 14 Application rate: 62.5 g as/ha

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		-/-		0.035	
Short term	24 h	-/-	-/-	0.035	0.035
	2 d	-/-	-/-	0.034	0.035
	4 d	-/-	-/-	0.033	0.035
Long term	7 d	-/-	-/-	0.031	0.034
	28 d	-/-	-/-	0.024	0.031
	50 d	-/-	-/-	0.016	0.028
	100 d	-/-	-/-	0.006	0.023
Plateau concentration		-/-			

Application data	Crop: oilseed rape Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm3 % plant interception: 40 % and 80 % Number of applications: 2 Interval (d): 21 Application rate: 100 g as/ha

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		-/-		0.093	
Short term	24 h	-/-	-/-	0.092	0.093
	2 d	-/-	-/-	0.091	0.092
	4 d	-/-	-/-	0.087	0.091
Long term	7 d	-/-	-/-	0.082	0.090
	28 d	-/-	-/-	0.064	0.082

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
50 d	-/-	-/-	0.041	0.075
100 d	-/-	-/-	0.017	0.062
Plateau concentration	-/-			

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 5: > 350 d at 22 - 25 °C Met 2-AB: 3 % AR (30 d)
	pH 7: > 350 d at 22 - 25 °C Met 2-AB: 3 % AR (30 d)
	pH 9: 54 - 124 d at 20- 25 °C Met 2-AB: 30 % AR (30 d)
Photolytic degradation of active substance and metabolites above 10 % ‡	no photolytic degradation during 7 days at 25 °C
Quantum yield of direct phototransformation in water at Σ > 290 nm	not calculated
Readily biodegradable ‡ (yes/no)	not readily biodegradable

Degradation in water / sediment

Parent	Distribution (e.g. max in water 103.2 % AR after 0 d. Max. in sediment. 68 % AR after 28 d, system)									
Water / sediment system	pH water phase	pH sed.	t. °C	DT_{50} / DT_{90} whole sys.	χ^2 error	DT_{50} / DT_{90} water	St. (r^2)	DT_{50} / DT_{90} sed.	St.	Method of calculation
Bickenbach	8.5	8.0	20	15.1/ 50	11					SFO
						10.8/ 36	0.995	n.d.		1st order
Unter Widdersheim	8.1	7.5	20	75.2/ 249.7	12					SFO
						5.8/ 19.2	0.965	n.d.		1st order
Geometric mean/median				33.7		7.9				

Mineralisation and non extractable residues					
Water / sediment system	pH water phase	pH sed.	Mineralisation x % after 120 d (end of the study)	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after 120 d (end of the study)
Bickenbach	8.5	8.0	20.4	63.4 (62 d)	55.2
Unter Widdersheim	8.1	7.5	4.7	59.4 (120 d)	59.4

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

Carbendazim Parameters used in $FOCUS_{sw}$ step 1 and 2	Version control no. of FOCUS calculator: ver. 1.1, FOCUS 2002 Molecular weight (g/mol): 191.1 Water solubility (mg/L): 6 K_{OC}/K_{OM} (L/kg): 225 (arithmetic mean) DT_{50} soil (d): 30 days (DegT50 lab used in STEP 1&2 calculations in accordance with FOCUS SFO) DT_{50} water/sediment system (d): 75 (representative worst case from sediment water studies) DT_{50} water (d): 1000 DT_{50} sediment (d): 75 Crop interception (%): none

Parameters used in FOCUS$_{sw}$ step 3	Version control no.'s of FOCUS software: ver. 1.1, FOCUS 2002 Vapour pressure: 9×10^{-5} Water solubility (mg/L): 8 DT_{50} soil (d): 40 days (worst case DegT50 lab, as reliable soilDT50 values are available for only 3 soils) K_{om}/K_{oc}: 225 1/n: 0.97(Freundlich exponent general or for soil, susp. solids or sediment respectively) DT_{50} water/sediment system (d): 75 (representative worst case from sediment water studies) DT_{50} water (d): 75 DT_{50} sediment (d): 1000		
Parameters used in FOCUS$_{sw}$ step 4	Input parameters see FOCUS$_{sw}$ step 3 combined with following mitigation measures if required: -10 m drift buffer -10 m drift buffer and runoff reduction according to the -FOCUS landscape and mitigation report -20 m drift buffer and runoff reduction according to the FOCUS landscape and mitigation report		
	*90th percentile worst case values for reduction efficiencies for different widths of vegetated buffers and different phases of surface runoff [FOCUS (2007)]		
	Buffer width (m)	10 - 12	18 - 20
	Reduction in volume of runoff water (%) Reduction in mass of pesticide transported in aqueous phase (%)	60 60	80 80
	Reduction in mass of eroded sediment (%) Reduction in mass of pesticide transported in sediment phase (%)	85 85	95 95
Application rate	Crop: winter oilseed rape Crop interception: 40 and 80 % Number of applications: 2 Interval (d): according to PAT (> 184 d) Application rate(s): 2 × 100 g as/ha Application window: applications in autumn followed by spring application		
	Location	Application Window	
	D2	26-Mar -6-Nov	
	D3	31 Mar – 24 Nov	
	D4	20-Apr – 25 Oct	
	D5	16-Mar – 11-Nov	
	R1	21-Mar – 26-Oct	

Application rate	Crop: spring oilseed rape Crop interception: 40 and 80 % Number of applications: 2 Interval (d): according to PAT (21 days) Application rate(s): 100 g as/ha Application window: applications in spring	
	Location	Application Window
	D1	07-Jun -28-Jul
	D3	29-Apr – 19-Jun
	D4	20-May – 10-Jul
	D5	03-Apr – 24-May
	R1	29-Apr – 19-Jun
Application rate	Crop: winter oilseed rape Crop interception: 80 and 80 % Number of applications: 2 Interval (d): according to PAT (21 days) Application rate(s): 100 g as/ha Application window: applications in spring	
	Location	Application Window
	D2	26-Mar -16-May
	D3	31 Mar – 21-May
	D4	20-Apr – 10-Jun
	D5	16-Mar – 06-May
	R1	21-Mar – 11-May
Application rate	Crop: spring cereals Crop interception: 70 and 90 % Number of applications: 2 Interval (d): according to PAT (14 days) Application rate(s): 100 g as/ha Application window: applications in spring	
	Location	Application Window
	D1	27-May -10-Jul
	D3	12-May – 25-Jun
	D4	18-May – 1-Jul
	D5	11-Apr – 25-May
	R4	11-Apr – 25-May

Application rate	Crop: winter cereals Crop interception: 70 and 90 % Number of applications: 2

Interval (d): according to PAT (14 days) Application rate(s): 100 g as/ha Application window: applications in spring	
Location	Application Window
D1	18-May -1-Jul
D2	29-Apr – 12-Jun
D3	7-May – 26-Jun
D4	13-May – 26-Jun
D5	6-Apr – 20-May
D6	22-Mar – 5-May
R1	22-Apr -5-Jun
R3	23-Mar – 6-May
R4	6-Apr – 20-May

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	53.121		115.385	
	24 h	52.660	52.891	118.486	116.935
	2 d	52.624	52.767	118.404	117.690
	4 d	52.551	52.677	118.240	118.006
	7 d	52.442	52.600	117.994	118.054

Spring and winter cereals

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	10.500		23.185	
	24 h	10.393	10.447	23.123	23.154
Southern EU	0 h	9.385		20.689	
	24 h	9.274	9.329	20.634	20.662

autumn application followed by spring application to winter oilseed rape; 2 × 100 g as/ha

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D2	ditch	0 h	4.981		9.335	
D2	stream	0 h	3.135		5.413	
D3	ditch	0 h	0.556		0.204	

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC$_{SW}$ (µg/L)		PEC$_{SED}$ (µg/kg)	
			Actual	TWA	Actual	TWA
D4	pond	0 h	0.831		2.343	
D4	stream	0 h	1.343		1.059	
D5	pond	0 h	0.588		1.807	
D5	stream	0 h	0.631		0.531	
R1	pond	0 h	0.068		0.227	
R1	stream	0 h	1.949		0.417	

autumn application followed by spring application to winter oilseed rape; 2 × 100 g as/ha 10 m drift buffer						
FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC$_{SW}$ (µg/L)		PEC$_{SED}$ (µg/kg)	
			Actual	TWA	Actual	TWA
D2	ditch	0 h	4.981		9.265	
D2	stream	0 h	3.135		5.369	
D3	ditch	0 h	0.075		0.031	
D4	pond	0 h	0.828		2.324	
D4	stream	0 h	1.343		1.057	
D5	pond	0 h	0.585		1.789	
D5	stream	0 h	0.631		0.527	
R1	pond	0 h	0.062		0.207	
R1	stream	0 h	1.949		0.414	

Single application to winter oilseed rape; 100 g as/ha, 10 m drift buffer						
FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC$_{SW}$ (µg/L)		PEC$_{SED}$ (µg/kg)	
			Actual*	TWA	Actual	TWA
D3	ditch	0 h	0.092			

*only global maximum PECsw caused by drift reported since this is the relevant endpoint for aquatic risk assessment

autumn application followed by spring application to winter oilseed rape; 2 × 100 g as/ha 10 m drift buffer and runoff reduction						
FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC$_{SW}$ (µg/L)		PEC$_{SED}$ (µg/kg)	
			Actual	TWA	Actual	TWA

R1	pond	0 h	0.030		0.104	
R1	stream	0 h	0.836		0.186	

autumn application followed by spring application to winter oilseed rape; 2 × 100 g as/ha 20 m drift buffer and runoff reduction						
FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC$_{SW}$ (µg/L)		PEC$_{SED}$ (µg/kg)	
			Actual	TWA	Actual	TWA
R1	stream	0 h	0.436		0.098	

2 × spring application to spring oilseed rape; 2 × 100 g as/ha

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC$_{SW}$ (µg/L)		PEC$_{SED}$ (µg/kg)	
			Actual	TWA	Actual	TWA
D1	ditch	0 h	1.622		4.923	
D1	stream	0 h	1.107		2.470	
D3	ditch	0 h	0.555		0.198	
D4	pond	0 h	0.239		0.754	
D4	stream	0 h	0.474		0.292	
D5	pond	0 h	0.109		0.446	
D5	stream	0 h	0.508		0.192	
R1	pond	0 h	0.199		0.402	
R1	stream	0 h	1.662		0.678	

2 × spring application to spring oilseed rape; 2 × 100 g as/ha
10 m drift buffer

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC$_{SW}$ (µg/L)		PEC$_{SED}$ (µg/kg)	
			Actual	TWA	Actual	TWA
D1	ditch	0 h	1.622		4.457	
D1	stream	0 h	1.107		2.464	
D3	ditch	0 h	0,075		0.029	
D4	pond	0 h	0.237		0.737	
D4	stream	0 h	0.294		0.290	
D5	pond	0 h	0.102		0.431	
D5	stream	0 h	0.117		0.171	
R1	pond	0 h	0.190		0.379	
R1	stream	0 h	1.662		0.672	

Single spring application to spring oilseed rape; 100 g as/ha
10 m drift buffer

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual*	TWA	Actual	TWA
D3	ditch	0 h	0.092			
D5	pond	0 h	0.105			
D5	stream	0 h	0.137			

*only global maximum PECsw caused by drift reported since this is the relevant endpoint for aquatic risk assessment

2 × spring application to spring oilseed rape; 2 × 100 g as/ha
10 m drift buffer and runoff reduction

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R1	pond	0 h	0.086		0.176	
R1	stream	0 h	0.757		0.262	

2 × spring application to spring oilseed rape; 2 × 100 g as/ha
20 m drift buffer and runoff reduction

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R1	pond	0 h	0.045		0.095	
R1	stream	0 h	0.397		0.134	

2 × spring application to winter oilseed rape; 2 × 100 g as/ha

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D2	ditch	0 h	3.250		4.962	
D2	stream	0 h	2.042		2.549	
D3	ditch	0 h	0.555		0.203	
D4	pond	0 h	0.129		0.429	
D4	stream	0 h	0.472		0.167	
D5	pond	0 h	0.101		0.391	
D5	stream	0 h	0.520		0.204	
R1	pond	0 h	0.102		0.282	
R1	stream	0 h	1.839		0.417	
R3	stream	0 h	1.478		0.305	

2 × spring application to winter oilseed rape; 2 × 100 g as/ha
10 m drift buffer

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D2	ditch	0 h	3.250		4.886	
D2	stream	0 h	2.042		2.502	
D3	ditch	0 h	0.075		0.029	
D4	pond	0 h	0.128		0.413	
D4	stream	0 h	0.182		0.166	
D5	pond	0 h	0.089		0.376	
D5	stream	0 h	0.119		0.158	
R1	pond	0 h	0.095		0.257	
R1	stream	0 h	1.839		0.414	
R3	stream	0 h	1.478		0.296	

Single spring application to winter oilseed rape; 100 g as/ha
10 m drift buffer

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual*	TWA	Actual	TWA
D3	ditch	0 h	0.091			
D5	pond	0 h	0.094			
D5	stream	0 h	0.138			

*only global maximum PECsw caused by drift reported since this is the relevant endpoint for aquatic risk assessment

2 × spring application to winter oilseed rape; 2 × 100 g as/ha
10 m drift buffer

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R1	pond	0 h	0.045		0.129	
R1	stream	0 h	0.834		0.186	
R3	stream	0 h	0.655		0.133	

2 × spring application to winter oilseed rape; 2 × 100 g as/ha
10 m drift buffer

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R1	stream	0 h	0.436		0.098	
R3	stream	0 h	0.340		0.069	

2 × spring application to spring cereals; 2 × 100 g as/ha

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D1	ditch	0 h	1.450		5.300	
D1	stream	0 h	0.981		2.461	
D3	ditch	0 h	0.555		0.208	
D4	pond	0 h	0.196		0.645	
D4	stream	0 h	0.470		0.253	
D5	pond	0 h	0.100		0.402	
D5	stream	0 h	0.505		0.176	
R4	stream	0 h	2.952		1.057	

2 × spring application to spring cereals; 2 × 100 g as/ha
10 m drift buffer

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D1	ditch	0 h	1.450		4.803	
D1	stream	0 h	0.981		2.452	
D3	ditch	0 h	0.075		0.030	
D4	pond	0 h	0.195		0.629	
D4	stream	0 h	0.231		0.252	
D5	pond	0 h	0.091		0.387	
D5	stream	0 h	0.116		0.155	
R4	stream	0 h	2.952		1.049	

Single spring application to spring cereals; 100 g as/ha
10 m drift buffer

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual*	TWA	Actual	TWA
D3	ditch	0 h	0.092			
D5	pond	0 h	0.094			
D5	stream	0 h	0.135			

*only global maximum PECsw caused by drift reported since this is the relevant endpoint for aquatic risk assessment

2 × spring application to spring cereals; 2 × 100 g as/ha
10 m drift buffer and runoff reduction

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R4	stream	0 h	1.337		0.468	

2 × spring application to spring cereals; 2 × 100 ag s/ha
20 m drift buffer and runoff reduction

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R4	stream	0 h	0.699	0.245	0.245	

2 × spring application to winter cereals; 2 × 100 g as/ha

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D1	ditch	0 h	1.321		3.720	
D1	stream	0 h	0.832		1.945	
D2	ditch	0 h	2.669		4.950	
D2	stream	0 h	1.670		2.322	
D3	ditch	0 h	0.555		0.200	
D4	pond	0 h	0.154		0.504	
D4	stream	0 h	0.474		0.192	
D5	pond	0 h	0.130		0.473	
D5	stream	0 h	0.522		0.232	
D6	ditch	0 h	0.594		0.632	
R1	pond	0 h	0.190		0.407	
R1	stream	0 h	2.474		0.661	
R3	stream	0 h	2.992		1.091	
R4	stream	0 h	2.957		1.049	

2 × spring application to winter cereals; 2 × 100 g as/ha
10 m drift buffer

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D1	ditch	0 h	1.321		3.356	
D1	stream	0 h	0.832		1.945	
D2	ditch	0 h	2.669		4.576	
D2	stream	0 h	1.670		2.287	

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC$_{SW}$ (µg/L)		PEC$_{SED}$ (µg/kg)	
			Actual	TWA	Actual	TWA
D3	ditch	0 h	0.075		0.029	
D4	pond	0 h	0.152		0.486	
D4	stream	0 h	0.204		0.190	
D5	pond	0 h	0.117		0.448	
D5	stream	0 h	0.129		0.209	
D6	ditch	0 h	0.080		0.092	
R1	pond	0 h	0.181		0.383	
R1	stream	0 h	2.474		0.656	
R3	stream	0 h	2.992		1.076	
R4	stream	0 h	2.957		1.041	

Single spring application to winter cereals; 100 g as/ha
10 m drift buffer

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC$_{SW}$ (µg/L)		PEC$_{SED}$ (µg/kg)	
			Actual*	TWA	Actual	TWA
D3	ditch	0 h	0.092			
D5	pond	0 h	0.122			
D5	stream	0 h	0.149			
D6	ditch	0h	0.098			

*only global maximum PECsw caused by drift reported since this is the relevant endpoint for aquatic risk assessment

2 × spring application to winter cereals; 2 × 100 g as/ha
10 m drift buffer and runoff reduction

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC$_{SW}$ (µg/L)		PEC$_{SED}$ (µg/kg)	
			Actual	TWA	Actual	TWA
R1	stream	0h	1.125		0.288	
R3	stream	0h	1.366		0.454	
R4	stream	0 h	1.340		0.464	

2 × spring application to winter cereals; 2 × 100 ag s/ha
20 m drift buffer and runoff reduction

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC$_{SW}$ (µg/L)		PEC$_{SED}$ (µg/kg)	
			Actual	TWA	Actual	TWA
R1	stream	0h	0.590		0.150	
R3	stream	0h	0.717		0.236	

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
R4	stream	0 h	0.701		0.243	

Metabolite 2-AB Parameters used in FOCUS step 1 and 2	Molecular weight: 133.15 Water solubility (mg/L): 6 Soil or water metabolite: < 10 % K_{oc}/K_{om} (L/kg): 175 (estimated with PCKOCWIN Program) DT_{50} soil (d): no entry via soil (If necessary, Lab or field. In accordance with FOCUS SFO) DT_{50} water/sediment system (d): 300 (representative worst case from sediment water studies) DT_{50} water (d): 1000 DT_{50} sediment (d): 300 Crop interception (%): none Maximum occurrence observed (% molar basis with respect to the parent): 6.3 Water:< LOD Sediment: 6.3
Application rate	Crop: spring and winter cereals and oilseed rape Number of applications: 2 Interval (d): 21 Application rate(s): 100 g as/ha Depth of water body: 30 cm Application window: spring application
Main routes of entry	drift

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	0.081		0	
	24 h	0.065	0.073	0.114	0.057
	2 d	0.065	0.069	0.114	0.086
	4 d	0.065	0.067	0.114	0.100
	7 d	0.065	0.066	0.114	0.106
	14 d	0.065	0.066	0.113	0.110
	21 d	0.064	0.065	0.113	0.111
	28 d	0.064	0.065	0.112	0.111
	42 d	0.064	0.065	0.111	0.111

PEC ground water (Annex IIIA, point 9.2.1)

Method of calculation and type of study (PEC $_{GW}$ modelling)	For FOCUSgw modelling, values used - Modelling using FOCUS model(s), with appropriate $FOCUS_{gw}$ scenarios, according to FOCUS guidance. Model(s) used: FOCUS PEARL 2.2.2 Scenarios (list of names): 9 EU-scenarios Crop: Winter cereals, spring and winter oilseed rape (see below) worst case parent soil DT_{50lab} : 40 d (normalisation to 10kPa, 20 °C with Q10 of 2.2). K_{OC}: parent, average 225 mL/g, $^{1}/_{n}$ = 0.97 Metabolites: no
Application rate	Crop: winter oilseed rape Application rate: 200 g/ha.(autumn) + 250 g/ha (spring) No. of applications: 2, interval > 28 d[3] Time of application (month or season): 1st appl. BBCH 14 (40 % interception), 2nd appl.: BBCH 20 (80 % interception)
Application rate	Crop: spring oilseed rape Application rate: 100 g/ha No. of applications: 2, interval 21 d Time of application (month or season): 1st appl. BBCH 14 (40 % interception), 2nd appl.: BBCH 20 (80 % interception)
Application rate	Crop: cereals Application rate: 250 g/ha No. of applications: 2, interval 14 d Time of application (month or season): 1st appl. BBCH 30-39 (70 % interception), 2nd appl. BBCH 40 (90 % interception)

[3] for winter oil seed rape the minimum interval indicated in the GAP table is 21d

PEC$_{gw}$ - FOCUS modelling results (80th percentile annual average concentration at 1 m)

winter oilseed rape	Scenario	Parent (µg/L)	
		FOCUS PEARL	
	Chateaudun	0.003	
	Hamburg	0.029	
	Jokioinen	-	
	Kremsmunster	0.018	
	Okehampton	0.032	
	Piacenza	0.081	
	Porto	< 0.001	
	Sevilla	-	
	Thiva	-	

spring oilseed rape	Scenario	Parent (µg/L)	
		FOCUS PEARL	
	Chateaudun	-	
	Hamburg	-	
	Jokioinen	0.001	
	Kremsmunster	-	
	Okehampton	0.011	
	Piacenza	-	
	Porto	< 0.001	
	Sevilla	-	
	Thiva	-	

winter cereals	Scenario	Parent (µg/L)	
		FOCUS PEARL	
	Chateaudun	0.001	
	Hamburg	0.013	
	Jokioinen	0.001	
	Kremsmunster	0.008	
	Okehampton	0.013	
	Piacenza	0.022	
	Porto	< 0.001	
	Sevilla	< 0.001	
	Thiva	< 0.001	

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

Direct photolysis in air ‡	Not studied
Quantum yield of direct phototransformation	Not studied
Photochemical oxidative degradation in air ‡	according to Atkinson (AOP, version 1.91) DT50 = 0.640 h (0.053 days) with an OH-radical concentration of 1.5×10^6/cm^3 (12 h-average) DT50 = 1.919 h (0.080 days) with an OH-radical concentration of 0.5×10^6 /cm^3 (24 h-average) k_{OH}-value = 200.6528×10^{-12} cm^3 × molecule^{-1} × s^{-1}
Volatilisation ‡	from plant surfaces (BBA guideline): 4 % overall loss after 6 hours (not relevant for further assessment)
	from soil surfaces (BBA guideline): 21 % overall loss after 6 hours (not relevant for further assessment)
Metabolites	None

PEC_{air}

Method of calculation	vapour pressure: 9 x 10^{-5} Pa at 20 °C Henry's Law Constant: 3,6 x 10^{-3} Pa x m^3 x mol^{-1}. volatilisation from plants and soil: no relevant path

$PEC_{(a)}$

Maximum concentration	0.175 mg as/kg

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater	Soil: provisionally carbendazim only; however, a data gap was identified for an adequate route of aerobic

exposure assessment is triggered.	degradation in soil Surface Water: provisionally carbendazim only; however, a data gap was identified for the identification/quantification of potential soil major metabolites that would trigger further assessment regarding surface water contamination via runoff and drainage Sediment: provisionally carbendazim only; however, a data gap was identified for the identification/quantification of potential soil major metabolites that would trigger further assessment regarding surface water contamination via runoff and drainage Ground water: -provisionally carbendazim only; however, a data gap was identified for the identification/quantification of potential soil metabolites that would trigger further assessment regarding groundwater contamination Air: carbendazim

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

Soil (indicate location and type of study)	No data
Surface water (indicate location and type of study)	No data
Ground water (indicate location and type of study)	No data
Air (indicate location and type of study)	No data

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

R53

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	Endpoint (mg/kg bw/day)	Endpoint (mg/kg feed)
Birds ‡				
Colinus virginianus	as	Acute	LD_{50} > 2250	-/-
Anas platyrhynchos	as	Short-term	LDD_{50} = 615	LC_{50} ~ 5000
Anas platyrhynchos	as	Long-term	NOEL = 26.4	NOEC = 212
Mammals ‡				
Dog	as	Acute	LD_{50} > 5000	-/-
Rat	as	Long-term	NOEL = 22.5	-/-
Additional higher tier studies ‡				
-/-				

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

Cereals, 2 × 100 g as/ha

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Small insectivore	Acute	5.406	> 416	10
Small insectivore	Short-term	3.015	204	10
Small insectivore	Long-term	3.015	8.8	5
Tier 1 (Mammals)				
Insectivore	Acute	0.882	> 5672	10
Insectivore	Long-term	0.321	70	5

Sugar beet (NE), 2 × 75 g as/ha

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Small insectivore	Acute	4.055	> 555	10
Medium herbivore	Acute	5.455	> 413	10
Small insectivore	Short-term	2.261	272	10
Medium herbivore	Short-term	2.508	245	10
Small insectivore	Long-term	2.261	11.7	5
Medium herbivore	Long-term	1.329	19.9	5
Tier 1 (Mammals)				

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Medium herbivore	Acute	1.991	> 2512	10
Medium herbivore	Long-term	0.483	47	5

Sugar beet (SE), 3 × 62.5 g as/ha

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Small insectivore	Acute	3.379	> 666	10
Medium herbivore	Acute	5.372	> 419	10
Small insectivore	Short-term	1.884	326	10
Medium herbivore	Short-term	2.850	216	10
Small insectivore	Long-term	1.884	14.0	5
Medium herbivore	Long-term	1.510	17.5	5
Tier 1 (Mammals)				
Medium herbivore	Acute	1.960	> 2551	10
Medium herbivore	Long-term	0.555	41	5

Oilseed rape, 2 × 100 g as/ha (covering also maize)

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
Small insectivore	Acute	5.406	> 416	10
Medium herbivore	Acute	7.934	> 284	10
Small insectivore	Short-term	3.015	204	10
Medium herbivore	Short-term	3.952	156	10
Small insectivore	Long-term	3.015	8.8	5
Medium herbivore	Long-term	2.095	12.6	5
Tier 1 (Mammals)				
Medium herbivore	Acute	2.895	> 1727	10
Medium herbivore	Long-term	0.765	29	5

1 in higher tier refinement provide brief details of any refinements used (e.g. residues, PT, PD or AV)
2 for cereals indicate if it is early or late crop stage
3 If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

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)	Endpoint	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss	as	96 hr (static)	Mortality, LC_{50}	0.19_{nom}
Ictalurus punctatus	as	96 hr (static)	Mortality, LC_{50}	$0.019\ _{nom}$
Oncorhynchus mykiss	as	21 d (flow through)	Growth NOEC	0.0032_{nom}
Oncorhynchus mykiss	Preparation	96 hr (static)	Mortality, EC_{50}	1.1_{nom} (prep.)
Aquatic invertebrate				
Daphnia magna	as	48 h (static)	Mortality, EC_{50}	0.15_{nom}
Daphnia magna	as	21 d (semi-static)	Reproduction, NOEC	0.0015_{mm}
Daphnia magna	Preparation	48 h (static)	Mortality, EC_{50}	1.28_{nom} (prep.)
Sediment dwelling organisms				
Chironomus riparius	as	28 d (static)	NOEC	0.0133_{nom}
Algae				
Pseudokirchneriella subcapitata	as	72 h (static) 120 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	7.7_{mm} $> 11_{mm}$
Pseudokirchneriella subcapitata	Preparation	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	2.4_{nom} (prep.) 8.7_{nom} (prep.)
Higher plant – not submitted, not required				
Microcosm or mesocosm tests				
not required				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether endpoints are presented as units of preparation or as

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

FOCUS Steps 1, 2 and 3

FOCUS Step 1: spring application of 100 g as/ha to spring and winter cereals and oilseed rape (overall worst case)
FOCUS Step 2: spring application of 100 g as/ha to spring and winter cereals
FOCUS Step 3: 2 × spring applications at 100 g as/ha to spring cereals

Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrates acute	Invertebrates prolonged	Algae	Sed. dweller prolonged
		I. punctatus	*O. mykiss*	*Daphnia magna*	*Daphnia magna*	*P. subcapitata*	*C. riparius*
		LC_{50} 19 µg/L	NOEC 3.2 µg/L	EC_{50} 150 µg/L	NOEC 1.5 µg/L	E_bC_{50} 7700 µg/L	NOEC 13.3 µg/L
FOCUS Step 1							
	53.121	0.4	0.1	2.8	0.0	145.0	0.3
FOCUS Step 2							
North Europe	5.355	3.5	0.6	28.0	0.3	1437.9	2.5
South Europe	9.385	2.0	0.3	16.0	0.2	820.5	1.4
FOCUS Step 3							
D1/ditch	1.45	13.1	2.2	103.4	1.0	5310.3	9.2
D1/ stream	0.981	19.4	3.3	152.9	1.5	7849.1	13.6
D3/ditch	0.555	34.2	5.8	270.3	2.7	13873.9	24.0
D4/pond	0.196	96.9	16.3	765.3	7.7	39285.7	67.9
D4/stream	0.47	40.4	6.8	319.1	3.2	16383.0	28.3
D5/pond	0.1	190.0	32.0	1500.0	15.0	77000.0	133.0
D5/stream	0.505	37.6	6.3	297.0	3.0	15247.5	26.3
R4/stream	2.952	6.4	1.1	50.8	0.5	2608.4	4.5

FOCUS Step 1: spring application of 100 g as/ha to spring and winter cereals and oilseed rape (overall worst case)
FOCUS Step 2: spring application of 100 g as/ha to spring and winter cereals
FOCUS Step 3: 2 × spring applications at 100 g as/ha to winter cereals

Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrates acute	Invertebrates prolonged	Algae	Sed. dweller prolonged
		I. punctatus	*O. mykiss*	*Daphnia magna*	*Daphnia magna*	*P. subcapitata*	*C. riparius*
		LC_{50} 19 µg/L	NOEC 3.2 µg/L	EC_{50} 150 µg/L	NOEC 1.5 µg/L	E_bC_{50} 7700 µg/L	NOEC 13.3 µg/L
FOCUS Step 1							
	53.121	0.4	0.1	2.8	0.0	145.0	0.3
FOCUS Step 2							
North Europe	5.355	3.5	0.6	28.0	0.3	1437.9	2.5
South Europe	9.385	2.0	0.3	16.0	0.2	820.5	1.4
FOCUS Step 3							
D1/ditch	1.321	14.4	2.4	113.6	1.1	5828.9	10.1
D1/ stream	0.832	22.8	3.8	180.3	1.8	9254.8	16.0
D2/ditch	2.669	7.1	1.2	56.2	0.6	2885.0	5.0
D2/stream	1.67	11.4	1.9	89.8	0.9	4610.8	8.0
D3/ditch	0.555	34.2	5.8	270.3	2.7	13873.9	24.0
D4/pond	0.154	123.4	20.8	974.0	9.7	50000.0	86.4
D4/stream	0.474	40.1	6.8	316.5	3.2	16244.7	28.1
D5/pond	0.13	146.2	24.6	1153.8	11.5	59230.8	102.3
D5/stream	0.522	36.4	6.1	287.4	2.9	14751.0	25.5
D6/ditch	0.594	32.0	5.4	252.5	2.5	12963.0	22.4

Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrates acute	Invertebrates prolonged	Algae	Sed. dweller prolonged
R1/pond	0.19	100.0	16.8	789.5	7.9	40526.3	70.0
R1/stream	2.474	7.7	1.3	60.6	0.6	3112.4	5.4
R3/stream	2.992	6.4	1.1	50.1	0.5	2573.5	4.4
R4/stream	2.957	6.4	1.1	50.7	0.5	2604.0	4.5

FOCUS Step 1: spring application of 100 g as/ha to spring and winter cereals and oilseed rape (overall worst case)
FOCUS Step 2: spring application of 100 g as/ha to spring and winter oilseed rape
FOCUS Step 3: 2 × spring applications at 100 g as/ha to spring oil seed rape

Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrates acute	Invertebrates prolonged	Algae	Sed. dweller prolonged
		I. punctatus	*O. mykiss*	*Daphnia magna*	*Daphnia magna*	*P. subcapitata*	*C. riparius*
		LC_{50} 19 µg/L	NOEC 3.2 µg/L	EC_{50} 150 µg/L	NOEC 1.5 µg/L	E_bC_{50} 7700 µg/L	NOEC 13.3 µg/L
FOCUS Step 1							
	53.121	0.4	0.1	2.8	0.0	145.0	0.3
FOCUS Step 2							
North Europe	3.852	4.9	0.8	38.9	0.4	1999.0	3.5
South Europe	5.848	3.2	0.5	25.6	0.3	1316.7	2.3
FOCUS Step 3							
D1/ditch	1.622	11.7	2.0	92.5	0.9	4747.2	8.2
D1/stream	1.107	17.2	2.9	135.5	1.4	6955.7	12.0
D3/ditch	0.555	34.2	5.8	270.3	2.7	13873.9	24.0
D4/pond	0.239	79.5	13.4	627.6	6.3	32217.6	55.6
D4/stream	0.474	40.1	6.8	316.5	3.2	16244.7	28.1
D5/pond	0.109	174.3	29.4	1376.1	13.8	70642.2	122.0
D5/stream	0.508	37.4	6.3	295.3	3.0	15157.5	26.2
R1/pond	0.199	95.5	16.1	753.8	7.5	38693.5	66.8
R1/stream	1.662	11.4	1.9	90.3	0.9	4633.0	8.0

FOCUS Step 1: spring application of 100 g as/ha to spring and winter cereals and oilseed rape (overall worst case)
FOCUS Step 2: spring application of 100 g as/ha to spring and winter oilseed rape
FOCUS Step 3: 2 × spring applications at 100 g as/ha to winter oil seed rape

Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrates acute	Invertebrates prolonged	Algae	Sed. dweller prolonged
		I. punctatus	*O. mykiss*	*Daphnia magna*	*Daphnia magna*	*P. subcapitata*	*C. riparius*
		LC_{50} 19 µg/L	NOEC 3.2 µg/L	EC_{50} 150 µg/L	NOEC 1.5 µg/L	E_bC_{50} 7700 µg/L	NOEC 13.3 µg/L
FOCUS Step 1							
	53.121	0.4	0.1	2.8	0.0	145.0	0.3
FOCUS Step 2							
North Europe	3.852	4.9	0.8	38.9	0.4	1999.0	3.5
South Europe	5.848	3.2	0.5	25.6	0.3	1316.7	2.3
FOCUS Step 3							
D2/ditch	3.25	5.8	1.0	46.2	0.5	2369.2	4.1
D2/stream	2.042	9.3	1.6	73.5	0.7	3770.8	6.5
D3/ditch	0.555	34.2	5.8	270.3	2.7	13873.9	24.0
D4/pond	0.129	147.3	24.8	1162.8	11.6	59689.9	103.1
D4/stream	0.472	40.3	6.8	317.8	3.2	16313.6	28.2
D5/pond	0.101	188.1	31.7	1485.1	14.9	76237.6	131.7
D5/stream	0.52	36.5	6.2	288.5	2.9	14807.7	25.6
R1/pond	0.102	186.3	31.4	1470.6	14.7	75490.2	130.4
R1/stream	1.839	10.3	1.7	81.6	0.8	4187.1	7.2

FOCUS Step 1: spring application of 100 g as/ha to spring and winter cereals and oilseed rape (overall worst case)
FOCUS Step 2: winter oilseed rape autumn application followed by spring application (relative worst case)
FOCUS Step 3: autumn application followed by spring application at 2 × 100 g as/ha to winter oil seed rape

Scenario	PEC global max (µg/L)	Fish acute	Fish prolonged	Invertebrates acute	Invertebrates prolonged	Algae	Sed. dweller prolonged
		I. punctatus	*O. mykiss*	*Daphnia magna*	*Daphnia magna*	*P. subcapitata*	*C. riparius*
		LC_{50} 19 µg/L	NOEC 3.2 µg/L	EC_{50} 150 µg/L	NOEC 1.5 µg/L	E_bC_{50} 7700 µg/L	NOEC 13.3 µg/L
FOCUS Step 1							
	53.121	0.4	0.1	2.8	0.0	145.0	0.3
FOCUS Step 2							
North Europe	10.500	1.8	0.3	14.3	0.1	733.3	1.3
South Europe	8.656	2.2	0.4	17.3	0.2	889.6	1.5
FOCUS Step 3							
D2/ditch	4.981	3.8	0.6	30.1	0.3	1545.9	2.7
D2/stream	3.135	6.1	1.0	47.8	0.5	2456.1	4.2
D3/ditch	0.556	34.2	5.8	269.8	2.7	13848.9	23.9
D4/pond	0.831	22.9	3.9	180.5	1.8	9265.9	16.0
D4/stream	1.343	14.1	2.4	111.7	1.1	5733.4	9.9
D5/pond	0.588	32.3	5.4	255.1	2.6	13095.2	22.6
D5/stream	0.631	30.1	5.1	237.7	2.4	12202.9	21.1
R1/pond	0.068	279.4	47.1	2205.9	22.1	113235.3	195.6
R1/stream	1.949	9.7	1.6	77.0	0.8	3950.7	6.8

FOCUS Step 4

2 × spring applications of carbendazim at 100 g as/ha to spring cereals (related to NOEC of 1.5 µg as/L)

Scenario/ water body	D1/ ditch	D1/ stream	D3/ ditch	D4/ pond	D4/ stream	D5/ pond	D5/ stream	R4/ stream
Refinement	10 m buffer zone (drift reduction only)							
PEC (µg/L)	1.45	0.981	0.092	0.195	0.231	0.094	0.135	2.952
Peak caused by	D	D	S (single appl.)	D	D	S (single appl.)	S (single appl.)	R
TER	1.0	1.5	16.3	7.7	6.5	16.0	11.1	0.5
Refinement	10 m buffer zone (drift reduction + run-off reduction)							
PEC (µg/L)	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	1.337
Peak caused by	-/-	-/-	-/-	-/-	-/-	-/-	-/-	R
TER	-/-	-/-	-/-	-/-	-/-	-/-	-/-	1.1
Refinement	20 m buffer zone (drift reduction + run-off reduction)							
PEC (µg/L)	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	0.699
Peak caused by	-/-	-/-	-/-	-/-	-/-	-/-	-/-	R
TER	-/-	-/-	-/-	-/-	-/-	-/-	-/-	2.1

2 × spring applications at 100 g as/ha to winter cereals (drainage scenarios, related to NOEC of 1.5 µg as/L)

Scenario/ water body	D1/ ditch	D1/ stream	D2/ ditch	D2/ stream	D3/ ditch	D4/ pond	D4/ stream	D5/ pond	D5/ stream	D6/ ditch
Refinement	10 m buffer zone (drift reduction only)									
PEC (µg/L)	1.321	0.832	2.669	1.67	0.092	0.152	0.204	0.122	0.149	0.098
Peak caused by	D	D	D	D	S (single appl.)	D	D	S (single appl.)	S (single appl.)	S (single appl.)
TER	1.1	1.8	0.6	0.9	16.3	9.9	7.4	12.3	10.1	15.3
Refinement	10 m buffer zone (drift reduction + run-off reduction)									
PEC (µg/L)	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.
Peak caused by	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
TER	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

Refinement	20 m buffer zone (drift reduction + run-off reduction)									
PEC (µg/L)	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.
Peak caused by	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-
TER	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-

2 × spring applications at 100 g as/ha to winter cereals (run-off scenarios, related to NOEC of 1.5 µg as/L)

Scenario/ water body	R1/ pond	R1/ stream	R3/ stream	R4/ stream
Refinement	10 m buffer zone (drift reduction only)			
PEC (µg/L)	0.181	2.474	2.992	2.957
Peak caused by	R	R	R	R
TER	8.3	0.6	0.5	0.5
Refinement	10 m buffer zone (drift reduction + run-off reduction)			
PEC (µg/L)	not calc.	1.125	1.366	1.34
Peak caused by	-/-	R	R	R
TER	-/-	1.3	1.1	1.1
Refinement	20 m buffer zone (drift reduction + run-off reduction)			
PEC (µg/L)	not calc.	0.59	0.717	0.701
Peak caused by	-/-	R	R	R
TER	-/-	2.5	2.1	2.1

2 × spring applications of carbendazim at 100 g as/ha to spring oil seed rape (related to NOEC of 1.5 µg as/L)

Scenario/ water body	D1/ ditch	D1/ stream	D3/ ditch	D4/ pond	D4/ stream	D5/ pond	D5/ stream	R1/ pond	R1/ stream
Refinement	10 m buffer zone (drift reduction only)								
PEC (µg/L)	1.622	1.107	0.092	0.237	0.294	0.105	0.137	0.19	1.662
Peak caused by	D	D	S (single appl.)	D	D	S (single appl.)	S (single appl.)	R	R
TER	0.9	1.4	16.3	6.3	5.1	14.3	10.9	7.9	0.9

Refinement	10 m buffer zone (drift reduction + run-off reduction)								
PEC (µg/L)	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	0.086	0.757
Peak caused by	-/-	-/-	-/-	-/-	-/-	-/-	-/-	R	R
TER	-/-	-/-	-/-	-/-	-/-	-/-	-/-	17.4	2.0
Refinement	20 m buffer zone (drift reduction + run-off reduction)								
PEC (µg/L)	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	0.045	0.397
Peak caused by	-/-	-/-	-/-	-/-	-/-	-/-	-/-	R	R
TER	-/-	-/-	-/-	-/-	-/-	-/-	-/-	33.3	3.8

2 × spring applications of carbendazim at 100 g as/ha to winter oil seed rape (related to NOEC of 1.5 µg as/L)

Scenario/ water body	D2/ ditch	D2/ stream	D3/ ditch	D4/ pond	D4/ stream	D5/ pond	D5/ stream	R1/ pond	R1/ stream	R3/ stream
Refinement			10 m buffer zone (drift reduction only)							
PEC (µg/L)	3.25	2.042	0.091	0.128	0.182	0.094	0.138	0.095	1.839	1.478
Peak caused by	D	D	S (single appl.)	D	D	S (single appl.)	S (single appl.)	R	R	R
TER	0.5	0.7	16.5	11.7	8.2	16.0	10.9	15.8	0.8	1.0
Refinement	10 m buffer zone (drift reduction + run-off reduction)									
PEC (µg/L)	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	0.045	0.834	0.655
Peak caused by	-/-	-/-	-/-	-/-	-/-	-/-	-/-	R	R	R
TER	-/-	-/-	-/-	-/-	-/-	-/-	-/-	33.3	1.8	2.3
Refinement	20 m buffer zone (drift reduction + run-off reduction)									
PEC (µg/L)	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	0.436	0.34
Peak caused by	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	R	R
TER	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	3.4	4.4

Autumn application followed by spring application of carbendazim at 2 × 100 g as/ha to winter oil seed rape (related to NOEC of 1.5 µg as/L)

Scenario/ water body	D2/ ditch	D2/ stream	D3/ ditch	D4/ pond	D4/ stream	D5/ pond	D5/ stream	R1/ pond	R1/ stream
Refinement	10 m buffer zone (drift reduction only)								
PEC (µg/L)	4.981	3.135	0.092	0.828	1.343	0.585	0.631	0.062	1.949
Peak caused by	D	D	S (single appl.)	D	D	D	D	R	R
TER	0.3	0.5	16.3	1.8	1.1	2.6	2.4	24.2	0.8
Refinement	10 m buffer zone (drift reduction + run-off reduction)								
PEC (µg/L)	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	0.03	0.836
Peak caused by	-/-	-/-	-/-	-/-	-/-	-/-	-/-	R	R
TER	-/-	-/-	-/-	-/-	-/-	-/-	-/-	50.0	1.8
Refinement	20 m buffer zone (drift reduction + run-off reduction)								
PEC (µg/L)	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	not calc.	0.436
Peak caused by	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	R
TER	-/-	-/-	-/-	-/-	-/-	-/-	-/-	-/-	3.4

Bioconcentration

	Active substance	Metabolite1	Metabolite2	Metabolite3
log $K_{O/W}$	1.56	-/-	-/-	-/-
Bioconcentration factor (BCF)[1] ‡	Study not triggered	-/-	-/-	-/-
Annex VI Trigger for the bioconcentration factor	-/-	-/-	-/-	-/-
Clearance time (days) (CT_{50})	-/-	-/-	-/-	-/-
(CT_{90})	-/-	-/-	-/-	-/-
Level and nature of residues (%) in organisms after the 14 day depuration phase	-/-	-/-	-/-	-/-

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

* based on total ^{14}C or on specific compounds

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)
as ‡	-	> 50
Preparation[1]	100	> 271
Metabolite 1	-	-
Field or semi-field tests		
not required		

[1] for preparations indicate whether endpoint is expressed in units of as or preparation

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

Crop and application rate application rate 1 x 100 g as/ha or 1 x 850 g product/ha

Test substance	Route	Hazard quotient	Annex VI Trigger
as	Contact	< 2	50
as	oral	-	50
Preparation	Contact	< 3.2	50
Preparation	oral	8.5	50

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

Laboratory tests with standard sensitive species

Species	Test Substance	Endpoint	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡	Carbendazim 500 SC	Mortality	> 30 (as)
Aphidius rhopalosiphi ‡	Carbendazim 500 SC	Mortality	> 3000 (as)
Typhlodromus pyri ‡	Carbendazim 125 g/L + Flusilazole 250 g/L	Mortality	> 1.6 L/ha (prep.)
Aphidius rhopalosiphi ‡	Carbendazim 125 g/L + Flusilazole 250 g/L	Mortality	0.129 L/ha (prep.)

[1] for preparations indicate whether endpoint is expressed in units of as or preparation

Cereals, oilseed rape 2 × 100 g as/ha (2 × 0.8 L/ha prep.)

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Carbendazim	*Typhlodromus pyri*	> 30	5.7	0.13 (1 m)	2
Carbendazim	*Aphidius rhopalosiphi*	> 3000	0.06	0.001 (1 m)	2
Carbendazim 125 g/L + Flusilazole 250 g/L	*Typhlodromus pyri*	0.129 L/ha	10.5	0.25 (1 m)	2
Carbendazim 125 g/L + Flusilazole 250 g/L	*Aphidius rhopalosiphi*	> 1.6 L/ha	0.85	0.02 (1 m)	2

Sugar beet (NE) 2 × 75 g as/ha (2 × 0.6 L/ha prep.)

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Carbendazim	*Typhlodromus pyri*	> 30	4.3	0.10 (1 m)	2
Carbendazim	*Aphidius rhopalosiphi*	> 3000	0.04	0.001 (1 m)	2
Carbendazim 125 g/L + Flusilazole 250 g/L	*Typhlodromus pyri*	0.129 L/ha	7.9	0.19 (1 m)	2
Carbendazim 125 g/L + Flusilazole 250 g/L	*Aphidius rhopalosiphi*	> 1.6 L/ha	0.64	0.02 (1 m)	2

Sugar beet (SE) 3 × 62.5 g as/ha (3 × 0.5 L/ha prep.)

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Carbendazim	*Typhlodromus pyri*	> 30	4.8	0.10 (1 m)	2
Carbendazim	*Aphidius rhopalosiphi*	> 3000	0.05	0.001 (1 m)	2
Carbendazim 125 g/L + Flusilazole 250 g/L	*Typhlodromus pyri*	0.129 L/ha	8.9	0.18 (1 m)	2
Carbendazim 125 g/L + Flusilazole 250 g/L	*Aphidius rhopalosiphi*	> 1.6 L/ha	0.72	0.01 (1 m)	2

[1] indicate distance assumed to calculate the drift rate

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	Endpoint	% effect[3]	Trigger value
Typhlodromus pyri	Protonymphs	Carbendazim 125 g/L + Flusilazole 250 g/L Bean leaves 14 d	0 - 1.6 L/ha (prep.)	Mortality Reproduction	LR_{50} = 0.177 L/ha (prep.) ER_{50} > 0.16 < 0.80 L/ha (prep.)	50 %
Typhlodromus pyri	Protonymphs	Carbendazim 125 g/L + Flusilazole 250 g/L Grape-vine leaves 14 d	2 × 1 L/ha (prep.) Aged-residue study	Mortality Reproduction	5 DALT: 67.7 % 28 DALT: 3.1 % 5 DALT: -/- 28 DALT: 24 %	50 %
Aphidius rhopalosiphi	Adults	Carbendazim 125 g/L + Flusilazole 250 g/L Barley seedlings 48 h	1.6 L/ha (prep.)	Mortality Reproduction	- 2 % - 20 %	50 %
Chrysoperla carnea	Larvae	Carbendazim 125 g/L + Flusilazole 250 g/L wheat seedlings until pupation	1.6 L/ha (prep.)	Mortality Reproduction	15 % 15 %	50 %
Coccinella septempunctata	Larvae	Carbendazim 125 g/L + Flusilazole 250 g/L wheat seedlings until pupation	1.6 L/ha (prep.)	Mortality Reproduction	24 % -60 %	50 %

1 indicate whether initial or aged residues
2 for preparations indicate whether dose is expressed in units of as or preparation
3 indicate if positive percentages relate to adverse effects or not

Field or semi-field tests
not submitted

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

Test organism	Test substance	Time scale	Endpoint[1]
Earthworms			
Eisenia fetida	as ‡	Acute 14 days	LC_{50} = 5.4 mg as/kg d.w.soil
Eisenia fetida	as ‡	Chronic 8 weeks	NOEC = 1.0 mg as/kg d.w.soil
Eisenia fetida	Preparation	Acute	LC_{50} = 384.9 mg prep./kg d.w.soil
Eisenia fetida	Preparation	Chronic	NOEC = 5.2 mg prep./kg d.w.soil = 0.61 mg as/kg d.w.soil
Other soil macro-organisms – not required			
Soil micro-organisms			
Nitrogen mineralisation	as ‡	42 d	+ 27 % effect at day 28 at 4.8 mg as/kg d.w.soil (mg as/ha) + 5 % effect at day 42 at 4.8 mg as/kg d.w.soil (mg as/ha)
Carbon mineralisation	as ‡	28 d	+ 5 % effect at day 28 at 4.8 mg as/kg d.w.soil
Field studies[2]			
not required			

1 indicate where endpoint has been corrected due to log $P_{o/w}$ > 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

Cereals, 2 × 100 g as/ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia fetida	as ‡	Acute	0.049 mg as/kg	110	10
Eisenia fetida	as ‡	Chronic	0.049 mg as/kg	20	5
Eisenia fetida	Preparation	Acute	0.049 mg as/kg	955	10
Eisenia fetida	Preparation	Chronic	0.049 mg as/kg	12	5

Maize, 2 × 100 g as/ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia fetida	as ‡	Acute	0.061 mg as/kg	89	10
Eisenia fetida	as ‡	Chronic	0.061 mg as/kg	16	5
Eisenia fetida	Preparation	Acute	0.061 mg as/kg	767	10
Eisenia fetida	Preparation	Chronic	0.061 mg as/kg	10	5

Sugar beet (NE), 2 × 75 g as/ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia fetida	as ‡	Acute	0.033 mg as/kg	164	10
Eisenia fetida	as ‡	Chronic	0.033 mg as/kg	30	5
Eisenia fetida	Preparation	Acute	0.033 mg as/kg	1418	10
Eisenia fetida	Preparation	Chronic	0.033 mg as/kg	18	5

Sugar beet (SE), 3 × 62.5 g as/ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia fetida	as ‡	Acute	0.035 mg as/kg	154	10
Eisenia fetida	as ‡	Chronic	0.035 mg as/kg	29	5
Eisenia fetida	Preparation	Acute	0.035 mg as/kg	1337	10
Eisenia fetida	Preparation	Chronic	0.035 mg as/kg	17	5

oilseed rape, 2 × 100 g as/ha

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
Eisenia fetida	as ‡	Acute	0.093 mg as/kg	58	10
Eisenia fetida	as ‡	Chronic	0.093 mg as/kg	11	5
Eisenia fetida	Preparation	Acute	0.093 mg as/kg	503	10
Eisenia fetida	Preparation	Chronic	0.093 mg as/kg	6.6	5

[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (e.g. plateau PEC)

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

Preliminary screening data

Effects on vegetative vigour (visible response, total shoot dry weight) of 6 species tested with an application rate of 0.8 L/ha Visible response: -0.74 to 3.21 % (onion and oat, respectively) Shoot dry weight: -16.61 to 10.72 % of control shoot dry weight (onion and oat, respectively)

Laboratory dose response tests – not required

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

Not required

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

Test type/organism	endpoint
Activated sludge	
BOD5	Not affected by carbendazim concentrations up to 1000 mg/L nutrient solution

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

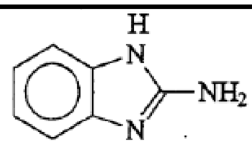
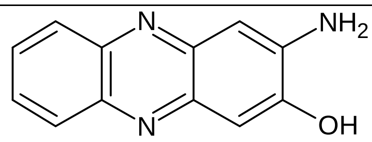
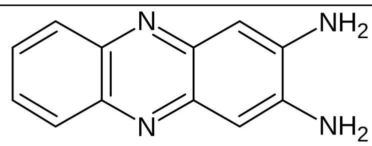
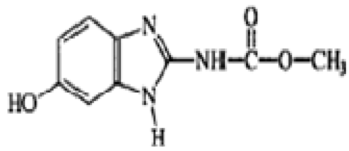
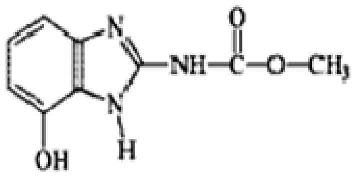
Compartment	
soil	Carbendazim
water	Carbendazim
sediment	Carbendazim
groundwater	Carbendazim

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

	RMS/peer review proposal
Active substance	R 50/53

	RMS/peer review proposal
Preparation	R50/53

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
2-AB	2-aminobenzimidazole	
AHP	3-Amino-2-hydroxyphenazine	
DAP	2,3-Diamino-phenazine	
5-OH-carbendazim	5-hydroxy-benzimidazol-2-yl	
4-OH-carbendazim	4-hydroxy-benzimidazol-2-yl	

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
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
LC-UV	liquid chromatography with ultra violet detection
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
SE	suspo-emulsion
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)
TC	technical material
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