CONCLUSION ON PESTICIDE PEER REVIEW

Peer review of the pesticide risk assessment of the active substance benfuracarb[1]

(Question No EFSA-Q-2009-00200)

Re-issued on 18 February 2009

This conclusion replaces the earlier version published on 8 April 2009[2].

SUMMARY

Benfuracarb is one of the 52 substances of the second stage of the review programme covered by Commission Regulation (EC) No 451/2000[3], as amended by Commission Regulation (EC) No 1490/2002[4]. This Regulation requires the European Food Safety Authority (EFSA) to organise a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within one year a conclusion on the risk assessment to the EU-Commission.

Belgium being the designated rapporteur Member State submitted the DAR on benfuracarb in accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, which was received by the EFSA on 2 August 2004. Following a quality check on the DAR, the peer review was initiated on 17 August 2004 by dispatching the DAR for consultation of the Member States and the sole applicant Otsuka Chemical Co., Ltd. Subsequently, the comments received on the DAR were examined by the rapporteur Member State and the need for additional data was agreed in an evaluation meeting on 7 March 2005. Remaining issues as well as further data made available by the notifier upon request were evaluated in a series of scientific meetings with Member State experts in September 2005.

A discussion of the outcome of the consultation of experts following the procedure set out in Commission Regulation (EC) 451/2000 took place with representatives from the Member States on 8

[1] For citation purposes: Conclusion on pesticide peer review regarding the risk assessment of the active substance benfuracarb. *EFSA Scientific Report* (2009) 239, 1-107

[2] The Background section (pages 11-12) has been updated to clarify the status and availability of the documentation developed during both the initial review process and the resubsmission procedure.

[3] OJ No L 53, 29.02.2000, p. 25

[4] OJ No L 224, 21.08.2002, p. 25

June 2006 leading to the conclusions set out in the EFSA Conclusion issued on 28 July 2006 (EFSA Scientific Report (2006) 89).

Following the Commission Decision of 20 September 2007 (2007/615/EC)[5] concerning the non-inclusion of benfuracarb in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the notifier Otsuka Chemical Co. Ltd made a resubmission application for the inclusion of benfuracarb in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the areas of concern identified in the review report as follows:

- the toxicity of the substance and the high toxicity of some of its metabolites,
- the presence of carcinogenic impurities in the technical substance,
- the consumer exposure which is regarded inconclusive and which indicated, mainly due to certain metabolites, a potential acute risk to certain vulnerable groups of consumers,
- the possible contamination of groundwater, especially by a number of relevant metabolites,
- the substantial lack of data for almost all groups in the ecotoxicological field.

Belgium, being the designated rapporteur Member State, submitted the additional report on benfuracarb (in the format of an updated DAR) to the EFSA on 20 August 2008. In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA dispatched the additional report to Member States and the notifier for consultation. The comments received were subsequently submitted to the Commission for evaluation. In accordance with Article 20 of Commission Regulation (EC) No. 33/2008, the Commission subsequently requested the EFSA, by letter received on 6 November 2008, to arrange a peer review of the evaluation, i.e. the additional report provided by the rapporteur Member State, and to deliver its conclusion on the risk assessment within 90 days.

The peer review was initiated on 6 November 2008 by dispatching the comments received on the additional report to the rapporteur Member State for examination. The rapporteur provided a response to the comments in the reporting table, which was subsequently evaluated by EFSA to identify the remaining issues to be further considered in a series of scientific meetings and teleconferences with Member State experts in January 2009.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in February 2009. The EFSA conclusion has therefore been re-issued to update the risk assessment in the areas of methods of analysis, mammalian toxicology, residues, environmental fate and behaviour, and ecotoxicology.

The original conclusion from the review was reached on the basis of the evaluation of the representative uses presented in the DAR, i.e. use as an insecticide which comprises incorporation into soil (pre-plantation) to control soil and foliar insects, where brassica will be grown.

[5] OJ No L246, 21.9.2007, p47

Benfuracarb can be used as insecticide and nematicide. It should be noted that during the peer review process only the use as insecticide was evaluated.

The representative formulated product for the evaluation was "Oncol 8.6G", a granule (GR), registered in France and Spain.

Adequate methods are available to monitor all compounds given in the respective residue definition for food of plant origin, soil and water.

Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues.

Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

Benfuracarb is rapidly and nearly completed absorbed in the rat. The main metabolite of benfuracarb is carbofuran[6] (approximately 30%). The acute inhalatory toxicity is high, whereas the oral toxicity moderate. The toxicity via dermal route was low. It is neither a skin nor an eye irritant nor a skin sensitizer, proposed risk phrases are: T, R23 “Toxic by inhalation” and R22 “Harmful if swallowed”. The critical effects are cholinesterase inhibition. Effects on reproduction parameters were observed such as, decreased male fertility, number of live pups and pup weight was decreased, even the entire second generation was lost. The appropriate classification for reproduction toxicity could not be agreed and the question was forwarded to ECB, R62 is highlighted. ECB has concluded R62 “possible risk of impaired fertility” and this decision was included in the Commission Directive 2009/2/EC of 15 January 2009[7].

The main metabolite of benfuracarb is the active ingredient carbofuran which is more toxic than benfuracarb and presents a lower ADI and ARfD of 0.00015 mg/kg bw/day. The relevant impurity 1,2 dichloroethane, is classified as toxic, Carcinogenic Category 2 (T; R45).

The Acceptable Daily Intake (ADI) of benfuracarb and the Acceptable Operator Exposure Level (AOEL) is 0.01 mg/kg bw/day, safety factor 100. The Acute Reference Dose (ARfD) is 0.02 mg/kg bw, safety factor 100**.**

The default value of 100 % was agreed for the granular formulation ‘Oncol 8.6G’ as no studies were provided. The estimated operator exposure according to the US PHED model is below (86 %) the AOEL only if personal protective equipment as well as respiratory equipment is used.

[6] Carbofuran: 2,3-dihydro-2,2-dimethylbenzofuran-7-yl methylcarbamate
[7] OJ No L11, 16.1.2009, p.6

The metabolism, distribution and residue behaviour of benfuracarb was investigated in various crops with different methods of application and at different timings. As for the evaluation of the notified use in brassicas the studies on cabbage and sugar beet with soil application were the most relevant metabolism data. Based on these studies and on an evaluation by the JMPR 1997 of studies on potato, soya and maize with soil application, a metabolic pathway of benfuracarb in soil treated crops could be established. Benfuracarb, carbofuran and 3-hydroxy-carbofuran as well as conjugates of carbofuran and 3-hydroxy-carbofuran were considered the relevant residues to assess consumer exposure and consumer risk in terms of the notified use in soil treated brassica crops.

In residue field trials the levels of benfuracarb, carbofuran and 3-hydroxy-carbofuran were determined in flowering, head and leafy brassica crops. However, given occasional findings of residues above the LOQ in flowering and leafy brassicas, and the fact that the applied method of analysis did not analyse for the full residue definition for risk assessment, the experts in the PRAPeR experts' meeting TC05 agreed that further residue trials data are required for a robust data base and a conclusive exposure assessment. If with their notification on brassicas the applicant intended a use in the category of brassica vegetables, residue trials on kohlrabi will also be required.

Furthermore, the experts concluded that it is necessary to also address residues in succeeding crops due to the behaviour of carbofuran in soil and due to an indication from the JMPR evaluation 1997 that residues above LOQ could occur in rotated crops.

Sound occurrence data are considered particularly relevant since the toxicological reference values for carbofuran and 3-hydroxy-carbofuran have been lowered and thus even very low residues of these compounds in crops may result in an intake concern for the consumer.

From a study with lactating goats it was concluded that benfuracarb and its metabolites are unlikely to accumulate in edible animal tissues and no significant total residues are expected to occur when brassicas are fed to livestock.

Due to their different toxicological endpoints the consumer risk has been separately assessed for benfuracarb residues and for carbofuran and 3-hydroxy-carbofuran residues. The estimated chronic and acute dietary intake of benfuracarb was found to be below the toxicological reference values for benfuracarb. Since residue data on the full residue definition for risk assessment and on rotated crops are still required with regard to carbofuran and 3-hydroxy-carbofuran residues, the consumer risk assessment cannot be finalised.

In a provisional assessment, the estimated chronic dietary intake of the benfuracarb metabolites carbofuran and 3-hydroxy-carbofuran was found to be below the ADI of carbofuran. However, an acute exposure concern was identified for adults and children (up to 396% of carbofuran ARfD) consuming leafy and flowering brassica. These estimates are based on residue values obtained in residue trials. Also for head brassica it is difficult to demonstrate conclusively that there is no risk for the consumer even though residues in the available trials were below the LOQ; however further data are necessary for a robust consumer exposure and risk assessment.

It should also be noted that with the predicted concentrations of carbofuran in groundwater a significant acute and chronic exposure of the consumer is expected through the consumption of drinking water derived from groundwater, if any restriction to mitigate groundwater exposure were not effective. The predicted concentrations in the most vulnerable scenarios may even lead to the exceedance of the toxicological reference values.

Benfuracarb is rapidly degraded in soil under laboratory dark aerobic conditions yielding carbofuran (maximum 84.6 % AR after 2 d) as a major metabolite. Carbofuran exhibits low to very high persistence in aerobic soils. Carbofuran degraded further to minor metabolites (< 10% AR), among them 3-keto carbofuran and 3-hydroxy-carbofuran, which contain the carbamate moiety. These metabolites exhibited very low to low persistence in soil.

Other minor metabolites were detected (maximum sum of them: 34.9 % AR after 0.24 d) that individually did not reach the 10 % AR. Mineralization was high at the end of the study (CO_2 = 27.7 % AR – 66.6 % AR, after 120 days, n = 4). The amount of unextractable residues reached a maximum = 74.1 % at the end of the study in one of the soils (after 120 days).

No soil photolysis study has been provided for benfuracarb. Carbofuran is photolytically stable on the soil surface, according the data available in carbofuran dossier.

It was estimated, by the HPLC method, that benfuracarb may be classified as immobile in soil (K_{doc} = 9100 mL / g). Carbofuran may be classified as a very high mobile compound (K_{Foc} = 17 – 28 mL / g). 3-hydroxy-carbofuran has very high to high mobility in soil, while 3-keto-carbofuran exhibits very high to low mobility in soil.

In a lysimeter study where two different lysimeters were investigated, benfuracarb was found in individual samples at maximum amounts of 0.25 µg / L and carbofuran at maximum amounts of 0.16 µg / L. Annual average concentrations for individual components could not been calculated. Two other lysimeter studies are available in the carbofuran additional report (November 2008), but these studies were not summarised for the benfuracarb peer review.

Hydrolysis of benfuracarb is pH dependent with half lives between less than half hour (pH 4) and 26.9 d (pH 9). In the natural water experiment (pH ≈ 7-8) photolysis seems not to contribute significantly to the aqueous degradation of benfuracarb. However, irradiation seems to enhance the degradation of the metabolite carbofuran to carbofuran phenol.

Benfuracarb is not readily biodegradable.

A study with two water sediment systems is available for benfuracarb. Both systems are in the alkaline range (pH $_{water}$ 7.8-8.0). Main compounds found in the water phase are benfuracarb and carbofuran (maximum = 58.26 % AR after 2d). Main compounds found in the sediment phase are carbofuran (maximum = 25.31 % after 14 d) and carbofuran-phenol (maximum = 13.6 % after 14 d).

The cumulative amounts of CO_2 at the end of the study accounted for 13.6 % AR and 16.7 % AR. Most of the radioactivity was present as bound residue to the sediment by the end of the study (73.8 % AR – 75.9 % AR).

Benfuracarb dissipates rapidly in water phase with a half life between 6 h to 15 h. Main dissipation process is transformation to carbofuran. Carbofuran dissipates from water phase with half life between 8.2 d to 10.8 d. Main dissipation process is partitioning into sediment. The whole system linear SFO DT_{50} of carbofuran was calculated to be 13.9-14.8 days, and the whole system linear SFO DT_{50} of carbofuran-phenol was calculated to be 4.8-20.5 days.

In the carbofuran dossier, dissipation of carbofuran in the water sediment was investigated in two studies with a total of three systems. In an acidic system at 25°C, carbofuran degraded in the whole system with a half life of 44.6 d. In the neutral or alkaline systems carbofuran degraded in the whole system with half lives of 7.8 – 11.6 d. These experiments seem to indicate that the degradation of carbofuran may be pH dependent in water sediment systems.

FOCUS PEC_{SW} and PEC_{SED} calculations were evaluated up to step 3 and step 4 for benfuracarb and carbofuran. In the step 4 calculations, there was no mitigation measurement applied, only the mode of application was set to furrow application to 2.5 cm depths, for the runoff scenarios. This modification is in line with opinion of the EFSA PPR Panel and with the applied for representative use of benfuracarb, as far as the granules are placed directly in the sowing row (to at least 2.5 cm below the soil surface) and that the furrows are covered by the soil. PEC_{SW} and PEC_{SED} calculations for carbofuran-phenol were based on the calculated PEC_{SW} and PEC_{SED} of carbofuran and the observed occurrence of carbofuran-phenol in water sediment studies.

PEC_{GW} (based on the applied for GAP) have been calculated for benfuracarb, carbofuran, 3-hydroxy-carbofuran and 3-keto-carbofuran with FOCUS PELMO and FOCUS PEARL models using the seven FOCUS scenarios relevant for cabbage. For some FOCUS scenarios, cabbage can be planted two times a year, spring and summer. For these scenarios separate simulations were perfomed, either for the spring or for the summer applications.

Annual average 80th percentiles of benfuracarb, 3-hydroxy-carbofuran and 3-keto-carbofuran were < 0.001 µg / L for all calculated scenarios.

Carbofuran exceed the 0.1 µg/L trigger for all the FOCUS simulations for Chateaudun, Hamburg Jokioinen, Kremsmuenster and Thiva scenarios. The calculated PEC_{GW} values were below the 0.1 µg/L trigger for two scenarios (Porto and Sevilla) out of the six, when spring application was simulated. For both spring and summer application, only Sevilla scenario resulted PEC_{GW} values below the trigger 0.1 µg/L. The table below summarises the calculated PEC_{GW} values of carbofuran, for all the simulations (values in bold are higher than the trigger of 0.1 µg/L).

The annual average 80th percentile PEC_{GW} values of carbofuran at 1 m depth below the soil surface

FOCUS	Time of	PEC_{GW} (µg/L)	PEC_{GW} (µg/L)

Scenario	application (spring/summer)	simulated by FOCUS PELMO	simulated by FOCUS PEARL
Chateaudun	Spring	**0.126**	**0.646**
Hamburg	Spring	**0.361**	**0.737**
Jokioinen	Spring	**0.294**	**0.741**
Kremsmuenster	Spring	**0.122**	**0.667**
Porto	Spring	0.007	0.013
Sevilla	Spring	<0.001	0.093
Thiva	Summer	**0.101**	**0.229**
Chateaudun	Summer	**0.134**	**0.574**
Hamburg	Summer	**2.664**	**3.127**
Kremsmuenster	Summer	**0.430**	**1.531**
Porto	Summer	0.032	**0.268**
Sevilla	Summer	<0.001	0.024
Sum of the safe (<0.1 µg/L) combinations of scenario and application time		4 out of 12	3 out of 12
No of safe (<0.1 µg/L) FOCUS scenario		2 out of 7	1 out of 7

Concentrations of benfuracarb in the air compartment are expected to be negligible, due to short persistence in the atmosphere.

Data gaps were identified to address further the risk to birds and mammals for the uptake of contaminated seedlings and earthworms. The granules need to be covered by soil to mitigate the risk to birds from uptake of granules. A high risk to the aquatic environment cannot be excluded for environmental conditions represented by the FOCUS scenarios D3, D4 stream and D6. Only the part scenario D4 (pond) resulted in TERs above the Annex VI trigger values. The risk from run-off (represented by the FOCUS scenarios R1, R2, R3, R4) was assessed as low if the granules were incorporated at a soil depth of at least 2.5 cm.

The risk to bees from exposure to residues in cabbage was assessed as low since cabbage has no flower in the production crop. A high risk to bees cannot be excluded if the product is to be applied on flowering brassicas attractive to bees (e.g. oilseed rape). The potential risk to bees from residues in flowering weeds should be assessed at Member State level, taking into account the agricultural practice (management of weeds in cabbage fields). The experts proposed labelling with SPe8 to avoid exposure from flowering weeds. Data gaps remain with regard to the risk to soil dwelling arthropods (*Aleochara bilineata*) and earthworms.

The risk to soil dwelling mites, non-target micro-organisms, non-target plants and biological methods of sewage treatment was assessed as low for the representative use.

Key words: benfuracarb, peer review, risk assessment, pesticide, insecticide, nematicide

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BACKGROUND

Commission Regulation (EC) No 451/2000 laying down the detailed rules for the implementation of the second and third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC, as amended by Commission Regulation (EC) No 1490/2002, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Benfuracarb is one of the 52 substances of the second stage covered by the amended Regulation (EC) No 451/2000 designating Belgium as rapporteur Member State.

In accordance with the provisions of Article 8(1) of the amended Regulation (EC) No 451/2000, Belgium submitted the report of its initial evaluation of the dossier on benfuracarb, hereafter referred to as the draft assessment report, to the EFSA on 2 August 2004. In accordance with Article 8(5) of the amended Regulation (EC) No 451/2000 the draft assessment report was distributed for consultation on 17 August 2004 to the Member States and the main applicant Otsuka Chemical Co., Ltd as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, representatives from Member States identified and agreed in an evaluation meeting on 7 March 2005 on data requirements to be addressed by the notifier as well as issues for further detailed discussion at expert level. A representative of the notifier attended this meeting.

Taking into account the information received from the notifier addressing the request for further data, a scientific discussion of the identified data requirements and/or issues took place in expert meetings organised on behalf of the EFSA by the EPCO-Team of the Pesticide Safety Directorate (PSD) in York, United Kingdom in September 2005. The reports of these meetings have been made available to the Member States electronically.

A discussion of the outcome of the consultation of experts following the procedure set out in Commission Regulation (EC) 451/2000 took place with representatives from the Member States on 8 June 2006 leading to the conclusions set out in the EFSA Conclusion issued on 28 July 2006 (EFSA Scientific Report (2006) 89).

Following the Commission Decision of 20 September 2007 (2007/615/EC)[8] concerning the non-inclusion of benfuracarb in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the notifier Otsuka Chemical Co., Ltd made a resubmission application for the inclusion of benfuracarb in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the areas of concern identified in the review report as follows:

- the toxicity of the substance and the high toxicity of some of its metabolites,

[8] OJ No L 246, 21.09.2007, p.47

- the presence of carcinogenic impurities in the technical substance,
- the consumer exposure which is regarded inconclusive and which indicated,
- mainly due to certain metabolites, a potential acute risk to certain vulnerable goups of consumers,
- the possible contamination of groundwater, especially by a number of relevant metabolites,
- the substantial lack of data for almost all groups in the ecotoxicological field.

Belgium, being the designated rapporteur Member State, submitted the additional report on benfuracarb to the EFSA on 20 August 2008. In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA dispatched the additional report to Member States and the notifier for consultation. The comments received were subsequently submitted to the Commission for evaluation. In accordance with Article 20 of Commission Regulation (EC) No. 33/2008, the Commission subsequently requested the EFSA, by letter received on 6 November 2008, to arrange a peer review of the evaluation, i.e. the additional report provided by the rapporteur Member State, and to deliver its conclusion on the risk assessment within 90 days.

The peer review was initiated on 6 November 2008 by dispatching the comments received on the additional report to the rapporteur Member State for examination. The rapporteur provided a response to the comments in the reporting table, which was subsequently evaluated by the EFSA to identify the remaining issues to be further considered in a series of scientific meetings and teleconferences with Member State experts in January 2009.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in February 2009. The EFSA conclusion has therefore been re-issued to update the risk assessment in the areas of methods of analysis, mammalian toxicology, residues, environmental fate and behaviour, and ecotoxicology.

The original conclusion from the review was reached on the basis of the evaluation of the representative uses presented in the DAR, i.e. use as an insecticide which comprises incorporation into soil (pre-plantation) to control soil and foliar insects, where brassica will be grown. A list of the relevant endpoints for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the resubmission peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's additional report:

- the comments received
- the resulting reporting table (rev. 1-1 of 5 December 2008)

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation
- the evaluation table (rev. 2-1 of 2 February 2009).

Given the importance of the additional report including its addendum (compiled version of February 2009), and the peer review report with respect to the examination of the active substance, these

documents are considered respectively as background documents A and B to this conclusion. The documents of the peer review report and the final addendum developed and prepared during the course of the initial review process are made publicly available as part of the background documentation to the original conclusion, EFSA Scientific Report (2006) 89, 1-81, finalised on 28 July 2006.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Benfuracarb is the ISO common name for ethyl *N*-[2,3-dihydro-2-2-dimethylbenzofuran-7-yloxycarbonyl(methyl)aminothio]-*N*-isopropyl-β-alaniate (IUPAC).

Benfuracarb belongs to the class of benzofuranyl methylcarbamate insecticides such as benfuracarb and carbofuran. It belongs also to the class of carbamate nematicides. Benfuracarb is a systemic insecticide with contact and stomach action. In soil application, benfuracarb is absorbed at root level and moves to the aerial parts of plants to control both soil and foliar pests. The biological activity is based on the transformation into carbofuran inside of the pest. Carbofuran inhibits the Acetyl-Choline Esterase (AChE) in the nervous system.

The representative formulated product for the evaluation was "Oncol 8.6G", a granule (GR), registered in France and Spain.

The evaluated representative uses as insecticide as proposed by the applicant comprises incorporation into soil (pre-plantation) to control soil and foliar insects, where brassicas will be grown. Benfuracarb can be used as insecticide and nematicide. It should be noted that during the peer review process only the use as an insecticide was evaluated.

SPECIFIC CONCLUSIONS OF THE EVALUATION

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

The minimum purity of benfuracarb as manufactured should not be less than 930 g/kg.
At the moment no FAO specification exists.

The technical material contains 1,2-dichloroethane (classified as toxic), which has to be regarded as a relevant impurity. The maximum content in the technical material should not be higher than 4 g/kg.

The content of benfuracarb in the representative formulation is 90 g/kg (pure).

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of benfuracarb or the respective formulation.

The main data regarding the identity of benfuracarb and its physical and chemical properties are given in appendix 1.

Sufficient test methods and data relating to physical, chemical and technical properties are available. Also adequate analytical methods are available for the determination of benfuracarb in the technical material and in the representative formulation as well as for the determination of the respective impurities in the technical material. An analytical method is available for the determination of the relevant impurity 1,2-dichloroethane in the formulation, the method is GC-FID. Enough data are available to ensure quality control measurements of the plant protection product are possible.

With respect to the residue analytical methods for enforcement purposes, adequate methods are available to monitor all compounds given in the respective residue definition, i.e. benfuracarb in food of plant origin; carbofuran (sum of carbofuran and 3-hydroxy-carbofuran[9]) in food of plant origin; benfuracarb and carbofuran in surface water and carbofuran in soil. Also validated methods for the determination of carbofuran, benfuracarb and 3- hydroxy-carbofuran in blood are available.

An analytical method for the determination of residues in air is not required according to SANCO/825/00, due to the application technique (i.e. granular formulation to be incorporated in soil) is such that no relevant exposure is likely to occur). However, a method for the determination of benfuracarb is available.

The methodology used for plants is LC-MS/MS analysing benfuracarb, carbofuran and 3-hydroxy-carbofuran with LOQs of 0.05, 0.0015 and 0.003 mg/kg respectively. A multi-residue method like the Dutch MM1 or the German S19 is not applicable to due the nature of the residues. An analytical method for food of animal origin is not required due to the fact that no residue definition is proposed (see 3.2).

The discussion in the meeting of experts (EPCO 35, September 2005) on identity, physical and chemical properties and analytical methods was limited to certain residue analytical methods, the identity and determination of impurities and some clarification with respect to certain physical and chemical properties of benfuracarb.

2. Mammalian toxicology

Benfuracarb was discussed at the EPCO experts' meeting for mammalian toxicology (EPCO 33) in September, 2005. It was re-discussed in the PRAPeR teleconference TC 04 in January 2009, based on the Additional Report (August 2008) and the addendum of January 2009. The re-discussion at the teleconference focused on the relevant metabolite of benfuracarb, carbofuran.[10]

[9]3-hydroxy-carbofuran; 3-hydroxy-2,2-dimethyl-2,3-dihydro-1-benzofuran-7-yl methylcarbamate
[10] Carbofuran: 2,3-dihydro-2,2-dimethylbenzofuran-7-yl methylcarbamate

2.1 ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

Benfuracarb is rapidly and nearly completely absorbed reaching 42-69 % of the dose within 24 h increasing to 70-81 % of the dose within 144 h. Benfuracarb is widely distributed and high levels are found in excretory organs and adrenals. No accumulation occurs after repeated oral exposure.
The main metabolite of benfuracarb is carbofuran. Carbofuran is further metabolized to 3-keto-carbofuran-phenol[11], 3-hydroxy-carbofuran[12], 3-hydroxy-carbofuran-phenol[13] and carbofuran-phenol[14]. Radioactivity in urine consisted of carbofuran hydrolytic derivatives. Excretion is high, almost 100 % within 7 days, 66-76 % of the oral administered dose is excreted within 48 h via urine and 10-12 % via faeces.

2.2 ACUTE TOXICITY

Overall, the toxic responses are typical for of effects on acetyl cholinesterase activity. The acute inhalatory toxicity is high (LC_{50} 0.3 mg/L) whereas the oral toxicity moderate (LD_{50} 205 mg/kg bw). However, the toxicity via dermal route is low (LD_{50} > 2000 mg/kg bw). It is neither a skin or an eye irritant nor a skin sensitizer. **Classification for acute toxicity is needed and the proposed risk phrases are: T, R23 "Toxic by inhalation" and R22 "Harmful if swallowed"**

2.3 SHORT TERM TOXICITY

The short term effects of benfuracarb were studied in 10 studies in the rat, mouse and dog for 4 weeks up to 2 years; at doses ranging from 0.6 up to 378 mg/kg bw/day as well as one dermal study in rat. No study on inhalation was submitted.

The critical effects are cholinesterase inhibition. Acetyl cholinesterase (AChE) activity was measured in red blood cells and plasma in the majority of the studies whereas the brain AChE activity was not measured in all studies. Mortality was rarely observed. The critical effects apart from clinical signs of neurotoxicity were haematological changes, thymus and spleen involution, enlarged lymph nodes, hypoplasia of prostate, regressive transformation of adrenal cortex. Some of these effects occurred at doses lower or equal to those producing inhibition of AChE. Dog appeared to be the most sensitive species.

<u>The rat</u>
In rats, increased motor activity, tremor, twitches, body temperature decrease and reduced pain sensitivity, atrophic seminal vesicle, hypoplasia of prostate, transformation of adrenal cortex were apparent at 20 mg/kg bw/day but no effects on AChE were noted.

In the 90-day rat studies, rough hair coat and urine stains appeared together with plasma AChE inhibition from 13 mg/kg bw/day. Brain AChE was not inhibited.

[11] 3-keto-carbofuran-phenol: 7-hydroxy-2,2-dimethyl-1-benzofuran-3(2*H*)-one
[12] 3-hydroxy-carbofuran: 3-hydroxy-2,2-dimethyl-2,3-dihydro-1-benzofuran-7-yl methylcarbamate
[13] 3-hydroxy-carbofuran-phenol: 2,2-dimethyl-2,3-dihydro-1-benzofuran-3,7-diol
[14] carbofuran-phenol: 2,2-dimethyl-2,3-dihydro-1-benzofuran-7-ol

A 1-year rat study was performed in which, at 25 mg/kg bw/day body weight was decreased and statistically significant changes in the clinical chemistry were observed in females. The incidence of cysts in ovaries was also enhanced. In this study, plasma AChE was inhibited at all dose levels, but there was no correlation with clinical signs of neurotoxicity. The NOAEL was 200 ppm i.e. 12 mg/kg bw/day.

The mouse

Contradictory results were seen in the mice studies, brain AChE was inhibited in the 49-day study at 111 mg/kg bw/day without clinical signs of neurotoxicity. However, in the 13-week study, where clinical signs of neurotoxicity were seen, brain AChE was not inhibited at the same dose level. These effects were mainly transient and recovery occurred within 24 h. The NOAEL is around 50 mg/kg bw/day.

The dog

Three studies were evaluated and the doses ranged from 0.625 mg/kg bw/day up to 10 mg/kg bw/day. After 90-day exposure, no clinical signs of cholinesterase inhibition were seen and plasma or RBC AChE was not inhibited. In this study, thymus involution was seen at 2.5 mg/kg bw/day, the NOAEL is thus 0.625 mg/kg bw/day. In the 6-month study, Inhibition of AChE in plasma and RBCs was apparent after administration of 5-mg/kg bw/day as well as hind limb ataxia. In the 1-2 year dog study, clinical signs of neurotoxicity as well as inhibition of plasma cholinesterase were observed from 5 mg/kg bw/day while RBCs- and brain AChE were not significantly affected.

The relevant oral NOAEL was discussed at the experts´ meeting and it was agreed to accept the rapporteur Member State proposal for an overall short term NOAEL of 1 mg/kg bw/day based on the dog studies. The NOAEL is based on the 90-day study (0.625 mg/kg bw/day) and the 6-month and 1-2 year study (2.5 mg/kg bw/day).

Dermal study, rat

In the 28-day dermal rat study, clinical signs of toxicity correlated with plasma cholinesterase inhibition at 25 mg/kg bw/day were noted. The NOAEL for systemic toxicity is 5 mg/kg bw/day and the NOAEL local effect is > 125 mg/kg bw/day.

2.4 GENOTOXICITY

In the DAR the genotoxic properties of benfuracarb were studied in five *in vitro* studies (of which two Ames tests) and three *in vivo* studies. The purity was between 93.4 % and 98.4 % (as well as pure grade).

In vitro tests

Benfuracarb was tested *in vitro* in the *Salmonella typhimurium* test with and without S9 mix, and in mouse lymphoma cells L5178Y for its ability to induce gene mutations. Negative responses were reported in both tests. Furthermore, benfuracarb did not induce chromosomal aberrations in human peripheral lymphocytes.

In vivo tests

Intraperitoneal injection of benfuracarb at doses ranging from 2.5 to 10 mg/kg bw/day did not induce micronuclei in mice bone marrow. Oral administration of benfuracarb did not produce significant increases in the frequency of micronuclei, but experimental deviations makes the results of one of the three studies not suitable for final evaluation. A rat bone marrow chromosome aberration test gave negative results.

The overall conclusion is that there is no mutagenic or genotoxic potential for benfuracarb.

2.5 LONG TERM TOXICITY

Three long term studies were evaluated, two in the rat (2-year) and one in the mouse (18 month). There was no evidence of carcinogenicity of benfuracarb in either rats or mice. These findings are supported by the absence of genotoxic activity for benfuracarb. The NOAEL is 5.5 mg/kg bw/day in the rat based on clinical signs and inhibition of brain acetylcholine esterase activity.

2.6 REPRODUCTIVE TOXICITY

One multigeneration study in the rat in order to determine the reproductive effects of benfuracarb is presented in the DAR (Schroeder, 1984).

The reproductive effects were discussed at the experts´ meeting. At the highest dose level (400 ppm) statistically significant effects on reproduction parameters were observed such as, decreased male fertility, number of live pups and pup weight was decreased, even the entire second generation was lost. The parental toxicity observed at this dose level was not severe, decreased body weight (around 10 %) and increased food consumption (around 20 %).

These effects were observed at the lower dose level (100 ppm) as well but to a lesser extent and in this case there are no adverse effects on paternal toxicity and the maternal toxicity observed is reduced body weight by less than 10 %. Thus, the parental as well as reproductive including embryotoxic NOAEL is 25 ppm i.e. 1.2 mg/kg bw/day. **The appropriate classification for reproduction toxicity was discussed by the experts but no agreement was reached and the question should be forwarded to ECB.**

EFSA note: Thus, Reproduction toxic category 3 **R62? "Possible risk of impaired fertility"** is highlighted in order to increase transparency. Benfuracarb has been discussed at ECB and R62 was concluded in November 2005; this decision was included in the Commission Directive 2009/2/EC of 15 January 2009.

The teratogenic or developmental effects of benfuracarb were studied in one study in one rat and one rabbit study (Schroeder, 1983a and b). In the rat, one dam in the 10 mg/kg bw/day dose level died at day 12 and one dam died at day 9 in the 40 mg/kg bw/day group, no abortions were registered. At these dose levels the body weight was decreased with 18 % and 36 %, respectively. At the 40 mg/kg bw/day dose, decreased foetal weight, delayed or incomplete ossification was observed in foetuses. The maternal toxicity observed at this dose level was reduced body weight. The NOAEL for maternal

toxicity for the rat is 2 mg/kg bw/day based on reduced body weight and the NOAEL for developmental toxicity is 10 mg/kg bw/day.

In the rabbit, mortality was also observed at the highest dose levels (10 and 15 mg/kg bw/day), 2 and 3 dams, respectively. Maternal body weight was not affected. At 15 mg/kg bw/day, embryotoxicity was evident such as reduced foetal weights; one dam aborted in the 5 and 10 mg/kg bw/day group.
The NOAEL for maternal toxicity in the rabbit is 15 mg/kg bw/day and the developmental NOAEL is 10 mg/kg bw/day.

2.7 NEUROTOXICITY

Delayed neurotoxicity

An acute toxicity was study performed initially in the hen. The oral LD_{50} is 92 mg/kg bw. A delayed neurotoxicity study was performed in the hen using tri ortho cresyl phosphate (TOCP) as positive control. Signs of acute neurotoxicity were seen at 160 mg/kg bw/day for up to 48-120 hours after dosing. Thereafter, the hens showed no signs of residual or delayed toxicity. No delayed neuromuscular impairment was seen. One hen exhibited mild focal axonal swelling at the lumbo-sacral cord; axonal degeneration was seen in the right sciatic nerve. These lesions were not comparable to lesions produced by TOCP, which were more severe, typically bilateral and usually multiple. Benfuracarb does not induce delayed neurotoxicity in hens.

Short term neurotoxicity study

A 28-day neurotoxicity study was performed in rats. Toxic signs related to inhibition of AChE were observed. There were no treatment related histopathological findings in the nervous system. The NOAEL is 25 ppm i.e. 1.81 mg/kg bw/day based on decreased brain acetyl cholinesterase activity of (30 %) at 125 ppm (i.e. 9.4 mg/kg bw/day).

2.8 FURTHER STUDIES

Metabolites

Carbofuran

The main metabolite of benfuracarb is carbofuran, an active substance on its own (rapporteur Member State: Belgium, applicants Dianica and FMC). The studies provided in the dossier and evaluated in the DAR are all from the open literature. Further studies on male reproductive system and comparative acute neurotoxicity studies conducted after the submission of the original DAR were evaluated and presented in the addendum of January 2009.

EFSA note: These results from the open literature are not always in accordance on the agreed values confirmed at the experts' meeting when carbofuran was discussed as active substance (EPCO 33). Thus, as carbofuran is a major metabolite in potential food feed, data gaps were identified for the applicant to get access to relevant studies for carbofuran. The rapporteur Member State informed that the applicant, after the experts´ meeting, has obtained access to the data set for carbofuran provided by Arysta/Dianica.

EFSA note: Below follows the summary on carbofuran and for further information, see the EFSA conclusion report for carbofuran[15].

Carbofuran is rapidly and completely absorbed and excreted in the rat. It is very toxic by ingestion (LD_{50} 7 mg/kg bw) and by inhalation (LC_{50} 0.05 mg/L) whereas toxicity during dermal exposure is moderate. Carbofuran is not a skin irritant or eye irritant or skin sensitizer but mortality was reported after exposure to eyes. The proposed classification is T^{+}, R28/R26 "Very toxic if swallowed and via inhalation", Xn, R21 "Harmful in contact with skin" and T, 39/41 "Danger of very serious irreversible effects" and Risk for serious damage to eyes". The critical target is inhibition of brain and RBC acetyl cholinesterase. The overall relevant oral short term NOAEL is 0.1 mg/kg bw/day based on the 1-year dog studies. It is genotoxic *in vitro* but negative in *in vivo* studies. The relevant long term NOAEL is 0.462 mg/kg bw/day from the rat study. Carbofuran induced decreased body weight in pups as well as pup survival. Results from the open literature demonstrated that carbofuran caused testicular and spermatotoxicity in pups at dose levels of 0.4 mg/kg bw not associated with inducing general toxic effects. Therefore, a supplementary study was conducted to examine if these effects on the male reproductive system were reproducible. In this study, it was found that testicular findings were reproduced in the dietary administration; however, the effects were far less pronounced and occurred only at a systemically toxic dose (18 mg/kg bw/day). With gavage administration the histopathological effects were not replicated. Therefore the experts agreed that no classification was triggered related to this endpoint. In March 2006, the ECB classification meeting proposed that no classification for reproduction was required. This decision was included in the Commission Directive 2009/2/EC of 15 January 2009.

At the occasion of the resubmission of carbofuran, FMC notified the existence of comparative acute neurotoxicity studies, conducted after the submission of the original EU DAR. As the rapporteur Member State suspected that these studies could have an impact on the original reference doses of carbofuran, they were requested and evaluated. These studies were conducted to establish the lowest relevant neurotoxicity NOAEL in post natal day 11 (PND11) in rat pups or young adult rats. Overall, clinical signs were observed from 0.3 mg/kg bw onwards. But no NOAEL could be established in pups based on a significant inhibition of the brain cholinesterase (statistically significant decrease of 20 % compared to the controls), the LOAEL was 0.03 mg/kg bw. The rapporteur Member State proposed to apply a curve-fitting to estimate the NOAEL using the data in the dose-response curve, and to estimate the benchmark dose at the 10 % response level (BMD_{10}). This approach resulted in a value of 0.017-0.020 mg/kg bw which supports a 2x assessment factor on the LOAEL to derive a NOAEL.

The metabolites 3-hydroxy-carbofuran and 3-keto-carbofuran[16] are very toxic and toxic (LD_{50} of 8 and 107 mg/kg bw, respectively), the hydroxy metabolite is genotoxic as well (Ames test).

[15] Conclusion regarding the peer review of the pesticide risk assessment of the active substance carbofuran, EFSA Scientific Report (2006), 90, 1-88.
[16] 3-keto-carbofuran: 2,2-dimethyl-3-oxo-2,3-dihydro-1-benzofuran-7-yl methylcarbamate

The Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD) of carbofuran is 0.00015 mg/kg bw/day based on the LOAEL from the acute neurotoxicity study in rat and applying a safety factor of 200.

Impurity

The significant impurity (no 7) 1,2 dichlorotehane is present in the toxicological batches before 1995 in the range of 0.5-1.5 % while in batches after 1996 0.16-0.27 %. 1,2 dichlorotehane is classified (19th ATP) as **Carcinogenic Category 2 R45**, harmful via oral ingestion (**R22**) as well as irritating to eyes, lung and skin (**R36/37/38**). In the range 0.1-20 %, the classification is **T; R45**. The level tested in the Ames test, bone marrow *in vivo* was 0.5-1.5 % whereas in the *in vitro* tests it was the lower level. The applicant has proposed a maximum limit of 4 g/kg and the acceptability was discussed at the experts meeting. The experts agreed to the proposed limit since the higher level was tested in the Ames test in addition to the fact that benfuracarb was not carcinogenic in neither rat nor mouse.

2.9 MEDICAL DATA

Medical examination of workers participating in the manufacturing process of benfuracarb did not display any adverse signs or symptoms.

2.10 ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) and ACUTE REFERENCE DOSE (ARfD)

ADI

The ADI is based on the NOAELs of 1 mg/kg bw /day in the 13-week feeding study in dogs, and the NOAEL of 1.2 mg/kg bw/d in the 2-generation rat study.

The rounded ADI is 0.01 mg/kg bw/day, with the safety factor of 100 applied.

AOEL

The AOEL is based on the overall NOAEL of 1 mg/kg bw/d resulting from the sub chronic feeding studies in dogs, with a safety factor of 100. Correction for oral absorption is not needed.

The AOEL is 0.01 mg/kg bw/day, with the safety factor of 100 applied.

ARfD

The ARfD is based on the NOAEL of 1.81 mg/kg bw/day in the 28-day neurotoxicity study in rat where effects were observed at 125 ppm i.e. 9.4 mg/kg bw/day.

The rounded ARfD is 0.02 mg/kg bw/day, with the safety factor of 100 applied.

2.11 DERMAL ABSORPTION

No studies for the representative formulation Oncol 8.6 G were provided by the applicant. The default value of 100 % was agreed by the experts.

2.12 EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

The representative plant protection product Oncol 8.6 G is a granular formulation.

Operator exposure

According to the intended uses submitted by the applicant the maximum applied dose is 1 kg a.s./ha. The granules are mixed with the moving soil closing the seed furrow.

The operator exposure was estimated using the American Pesticide Handlers exposure Database (PHED) as well as the standard models UK-POEM and the German model. The latter models do not have scenarios representative for granular formulations and should therefore only be considered as supplemental. The calculations are based on the dermal absorption of 100 % and the assumption that the treatment is 20 ha/day the total amount handled is 20 kg/day. The estimated exposure is just the AOEL i.e. 86 % only if PPE and respiratory protective equipment (RPE) is worn and the 75th percentile is considered, see table below. Although it should be considered that PPE is solely gloves.

Estimated exposure presented as % of AOEL (0.01 mg/kg bw/day), according to calculations with the PHED model. The default for body weight of operator is 60 kg

Model	**No PPE**	**With PPE:**	**With PPE and RPE:**
PHED (75th percentile)	-	148 %	86 %
PHED (95th percentile)	-	371 %	235 %

PPE (personal protective equipment): gloves, RPE (respiratory protection equipment)

The UK-POEM and the German model are not appropriate for this representative use and several assumptions are needed. Anyhow for transparency, calculations are provided and these are the applied assumptions; tractor mounted hydraulic boom and nozzles model (UK POEM) and the tractor field crops (BBA model) and that the use of granular applicators distributing the granules by drilling reduces operator exposure to loading since no water is needed and eliminates mixing phase as well as application exposure. The work rate is 10 ha/day for tractor-mounted /drawn equipment at for tractor-mounted /drawn equipment and the estimated exposure of the unprotected operator is about 296 % and 3400 % of the systemic AOEL according to the German and POEM model respectively. Using gloves reduces operator exposure to 14 % of AOEL according to the German model and to 34 % according to the UK model.

Worker exposure

Oncol 8.6 G is normally used at times when it is not necessary to enter the field shortly after application. The product is incorporated into the soil by mechanical means and the low vapour pressure of benfuracarb makes any exposure very unlikely. It is therefore considered not necessary to determine a particular re-entry period for workers.

Bystander exposure

Considering the use of soil integration and the low vapour pressure of benfuracarb ($2x10^{-7}$ mmHg at 20°C) exposure to vapour is likely to be negligible, and it is accepted that bystander exposure will result primarily from airborne dust via the dermal and inhalation routes. Additionally, it is unlikely that a bystander would be present throughout the whole loading and application operation, and

exposure to drifting is, therefore, likely to be considerably lower than the estimated operator exposure value.

3. Residues

Benfuracarb was discussed in the experts' teleconference meeting for residues (TC 05) in January 2009. The representative use to be evaluated for inclusion of benfuracarb in Annex I of 91/414/EEC is a pre-planting granular application to brassicas (document D1). From the data submitted it is assumed the applicant applied for the use in brassica vegetables (head, leafy, flowering brassicas and kohlrabi) and not for the whole genus of brassica plants that includes also swedes, turnips, mustard and rape seeds etc. After the submission and review of new data received, substantial changes have been made in the residue section since the previous EFSA conclusion on benfuracarb, issued on 28 July 2006. Information outdated or no longer relevant to the assessment of the notified use has been deleted from this section and was replaced by text reflecting the most recent information and experts' conclusions.

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

3.1.1. PRIMARY CROPS

The metabolism, distribution and residue behaviour of benfuracarb was investigated in various crops, treated with different methods of application and at different timings. In a study on cotton, bush beans, and corn plants benfuracarb was applied by either foliar treatment or stem injection. In studies on potatoes and apples benfuracarb was directly sprayed onto potato plants and apple trees, respectively. As for the mode of application this data was considered less relevant for the evaluation of the representative use in brassicas. For details on the evaluation and the experts' discussions and conclusions concerning these metabolism studies with a direct application of the substance to aerial plant part, reference is made to the previous EFSA conclusion on benfuracarb issued on 28 July 2006.

In terms of the notified use under evaluation, the metabolism studies on cabbage and sugar beet with a treatment at sowing were closest to the proposed GAP for brassicas.

In the study on cabbage (2002), the identity of metabolites was not investigated. A more recent study with identification of metabolites on cabbage seedlings treated in furrow (2006) was provided in the resubmission dossier for benfuracarb.

Since in this study the identification of metabolites was only performed on interim samples (up to 4 weeks after application at the latest) and not on the mature crop at harvest, the experts in the meeting TC05 agreed to also consider the metabolism data on sugar beet leaves in the evaluation, as proposed in a previous discussion by experts on benfuracarb in the meeting EPCO 34 in September 2005.

In the study on cabbage seedlings up to 86.9 % of TRR could be identified. Benfuracarb was extensively metabolised as it was not found in the cabbage seedlings at any sampling time between 3 days and 4 weeks after treatment.

Upon chromatographic analysis of the extracted radioactivity, carbofuran, 3-keto-carbofuran, 3-hydroxy-carbofuran, carbofuran-phenol and 3-hydroxy-carbofuran-phenol could be identified. Acidic hydrolysis of the aqueous soluble phase (51.9 % of TRR) of the 4 week samples showed that up to 31% of the TRR consisted of organo-soluble metabolites. Theses were tentatively identified as 3-hydroxy-carbofuran (6.1 % TRR), 3-keto-carbofuran (2.7 % TRR) and carbofuran (17.2 % TRR) and were assumed to be present as conjugates.

Based on these findings the experts in TC05 agreed there was a clear indication for the presence of metabolites in their conjugated forms in significant amounts. The experts also noted an increase in amount of these conjugated metabolites between 1 week and 4 weeks (last sample taken). Results at later stages are not available.

The submitted metabolism study in sugar beet with an application rate equal to the proposed rate for brassicas considered leaf and root metabolism. In intermediate root and leaf samples benfuracarb was not found above levels of 0.004 mg/kg while carbofuran, 3-hydroxy-carbofuran and 3-keto-carbofuran were present in total at a level of 0.05 mg/kg (12% TRR) and 0.2 mg/kg (26% TRR) in theses samples, respectively. Neither benfuracarb nor one of the above mentioned metabolites was found above the LOQ (0.001-0.002 mg/kg) in sugar beet leaves and roots at harvest. The meeting EPCO 34 concluded at that time that, although this sugar beet study may have addressed metabolism in brassica vegetables following a soil application of benfuracarb, the study did not sufficiently identify potentially relevant metabolites for the supported uses in brassicas since a fraction T1 that made up 26% of TRR (0.08 mg/kg) in leaves at harvest was not identified. Therefore the applicant carried out further chromatographic analyses on fraction T1 and eventually concluded on the basis of molecular weight comparison that T1 contained compounds of high molecular weight but did not contain benfuracarb or its metabolites.

Based on the studies in sugar beet and cabbage seedlings the main metabolic transformation of benfuracarb consisted of the formation of carbofuran by cleavage of the N-S bond followed by hydrolysis and a benzylic hydroxylation to form the metabolites carbofuran-phenol and 3-hydroxy-carbofuran respectively. 3-hydroxy-carbofuran is reduced to 3-keto-carbofuran and further hydrolysed into 3-hydroxy-carbofuran-phenol. As a step of detoxification in plants these metabolites can also be present as conjugates.

The benfuracarb metabolite carbofuran is an active substance itself. It has a higher toxicity than benfuracarb. Also 3-hydroxy-carbofuran and 3-keto-carbofuran are of higher toxicity than benfuracarb (refer to chapter 4). The carbofuran-phenol metabolites were tested regarding their acute toxicity and based on that studies considered of lower toxicity than benfuracarb, carbofuran, 3-hydroxy-carbofuran and 3-keto-carbofuran.

It is noted that the toxicological information on 3-keto-carbofuran, 3-hydroxy-carbofuran the phenol metabolites carbofuran-phenol, 3-hydroxy-carbofuran-phenol and 3-keto-carbofuran-phenol was

gained based on studies provided with the carbofuran dossier by a different applicant (FMC). It is unclear to EFSA whether this information is accessible for the applicant for benfuracarb.

The applicant suggested the difference seen in the study on cabbage seedling and in sugar beet concerning the presence of conjugates was due to transformation of conjugates of carbofuran, 3-keto carbofuran and 3-hydroxy-carbofuran found at early sampling intervals (cabbage) into compounds of large molecular weight at harvest (sugar beet leaves).

However, the 1997 JMPR evaluation based on metabolism studies in maize, potato and soya plants with soil application showed that carbofuran, 3-keto-carbofuran, 3- hydroxy-carbofuran and the phenol metabolites and their conjugated forms were present at non negligible levels at later sampling intervals than considered in the sugar beet study and also at harvest. It was highlighted by the JMPR that in particular "conjugates of 3- hydroxy-carbofuran can constitute an appreciable proportion of the total residue" and thus the conjugates of 3-hydroxy-carbofuran were included in the residue definition for risk assessment by the JMPR.

The experts in TC05 agreed that this information cannot be ignored. Considering in addition the findings in the new study with cabbage seedlings the experts could not conclusively agree that conjugates of carbamate metabolites will not be present in mature brassica vegetable crops. Hence, as a precautionary approach the carbofuran and 3-hydroxy-carbofuran conjugates should be included in the residue definition for risk assessment for brassica vegetable crops.

Eventually the meeting TC05 agreed on the following residue definitions for soil applied uses on brassica vegetable crops:

> Risk assessment: 1) Benfuracarb; 2) sum of carbofuran and 3-hydroxy-carbofuran, both free and conjugated expressed as carbofuran equivalents.
>
> Monitoring: 1) Benfuracarb to be monitored separately from 2) Carbofuran defined as sum of carbofuran and 3-hydroxy-carbofuran expressed as carbofuran equivalents

Residue data under field conditions on cauliflower, broccoli, head cabbage, kale and leafy cabbage in accordance with the proposed GAP were submitted. The applicant followed the advice of EPCO 34 and attempted a lower LOQ for carbofuran and 3-hydroxy-carbofuran in the new residue trials submitted. It is however noted that the number of these new trials in leafy, flowering and head brassica is lower per crop and region than the minimum requirement set out in current guidance documents except for the submitted trials on head cabbage in southern Europe. No data were submitted for kohlrabi.

Benfuracarb, carbofuran and 3-hydroxy-carbofuran were the residues determined with an LOQ of 0.05 mg/kg, 0.0015 mg/kg and 0.003 mg/kg, respectively in the majority of trials. The used methods of analysis were sufficiently validated for all three analytes, but did not contain an analytical step that would have determined their conjugated forms. Acceptable storage stability data were provided to support the trial results.

In the submitted trials, residues of benfuracarb were always below the LOQ. Though residues of carbofuran and 3-hydroxy-carbofuran were merely below the LOQ at harvest, results above LOQ could be found at harvest in two trials in broccoli (flowering brassica) and kale (leafy brassica) in northern Europe.

In the available trials on head cabbage (three in the north, four in the south), residues at harvest were all below the LOQ for carbofuran and 3-hydroxy-carbofuran, respectively. However, considering the argument by the applicant that the picture seen in residue decline studies and residue trials with head cabbage and flowering and leafy brassica was very similar, the experts noted that the probability for occasional findings above the LOQ also in head cabbage may increase with a greater number of residue trials. Moreover, the applied method of analysis did not determine potentially present conjugates of carbofuran and 3-hydroxy-carbofuran and actual residue levels may be therefore underestimated.

The experts agreed that further residue trial data is required for all brassica vegetable crops to comply with the residue definition for risk assessment and to render the consumer exposure assessment more robust.

The available data allow the consumer exposure and consumer risk to only be provisionally assessed. Since this assessment indicates the ARfD of carbofuran and 3-hydroxy-carbofuran is exceeded for flowering and leafy brassica for adults and children, the experts noted that further trials on these categories of brassicia vegetable crops will probably not alter the conclusion of an identified acute consumer risk.

For head cabbage, depending on the variability factor used in the acute assessment, the consumer exposure is above (default factor of 5) or below (default factor of 3) the toxicological reference value for carbofuran and 3-hydroxy-carbofuran. As the default variability factor to be used in the assessment is a risk management decision as to how much uncertainty can be accepted in an exposure and risk assessment (see EFSA PPR Panel opinion issued in February 2005[17]), the use of benfuracarb on head cabbage might be considered a borderline case. It is however noted that potentially present conjugates of carbofuran and 3-hydroxy-carbofuran have not yet been considered in these estimates for head cabbage.

Eventually the experts agreed that the applicant should submit a robust data set with the full number of trials that analyse for the agreed residue definition for risk assessment and at a sufficiently low LOQ, possibly even lower than in the latest trials submitted though it was acknowledged that this might be extremely difficult to achieve. The experts also suggested that the applicant may consider the possibility of conducting trials in order to replace the default variability factor by an experimental variability factor that may be lower and result in a more favourable outcome. A higher application

[17] Opinion of the PPR Panel related to the appropriate variability factor(s) to be used for acute dietary exposure assessment of pesticide residues in fruit and vegetables. Question number: EFSA-Q-2004-124; (2005)

rate than the notified rate may be necessary in these trials to generate determinable residues and establish a robust factor.

No data on effects of industrial or household processing on the nature and level of residues was submitted as it was not triggered by current guidance.

3.1.2. SUCCEEDING AND ROTATIONAL CROPS

Since benfuracarb is degraded very rapidly in soil, the rapporteur Member State considered studies in succeeding crops or a waiting period for planting succeeding crops not necessary. However, benfuracarb is largely degraded to the more toxic carbofuran, which appears also more persistent in soil (refer to 4.1.2). Thus the experts' meeting for residues EPCO 34 concluded that there is a need to address residues of carbofuran in succeeding crops following application of benfuracarb. With the resubmission dossier no new data was submitted since the applicant considered that no such data is required.

According to information received by the meeting on environmental fate and behaviour (PRAPeR 62) on the DT_{90} of carbofuran in laboratory (>1 year) and field studies (91 days) it might be that 10% of the total pertinent residue (i.e. benfuracarb and all bio-available metabolites) can still be found in soil at 100 days. The experts in the meeting TC05 agreed that even if uptake by rotational crops probably occurred at very low levels, an exceedance of the ARfD for carbofuran and 3-hydroxy-carbofuran might be expected depending on the contribution of the crop in the human diet. The experts noted further that rotational crop data is also available in the JMPR evaluation of 1997. This data indicated that residues of carbofuran equivalents may occur above the current LOQ in all rotated crops tested. The experts therefore concluded that rotational crop studies according to the OECD guidelines should be provided (intervals of 30, 120 days and 1 year on leafy crop, small grain crop and root crop).

It is noted that after the TC05 meeting the rapporteur Member State expressed their disagreement with the experts' conclusions in the meeting. The rapporteur Member State believes a rotational crop study is not triggered. Therefore the rapporteur Member State proposed to waive the required rotational crop study and to consider metabolism studies performed with carbofuran soil application instead. Such data were not submitted by the applicant for benfuracarb but are available in a dossier submitted by a different applicant. Therefore this data were not considered in the review procedure for benfuracarb and hence not discussed in terms of whether they are suitable and acceptable to address the issue of residue levels expected in rotational crops.

EFSA still supports the decision that residues in rotational crops have to be addressed by data as agreed by the experts; however it will be the applicant to choose on the source of such data to address the issue.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

There was no new discussion on the nature and magnitude of residues in livestock upon resubmission of the dossier and thus the conclusion has not changed significantly to what was previously agreed.

In terms of the representative uses, brassica crops are considered potential feed items. Thus, the dietary burden of livestock animals from residues of concern (i.e. currently proposed as benfuracarb, carbofuran, 3-hydroxy-carbofuran including carbofuran and 3-hydroxy-carbofuran conjugates) in brassica crops needs to be estimated to conclude on whether metabolism and feeding studies are required. Based on the currently available residue data for the representative brassica use significant residues in the total diet of livestock animals are not expected. However, since benfuracarb is considered fat-soluble (log pow 4.2) the submitted metabolism study in ruminants is considered useful to indicate whether benfuracarb residues tend to accumulate in fat tissues and subsequently significant residues may occur in edible animal matrices.

In the study lactating goats were orally dosed with benfuracarb radio labelled in the phenyl-ring for 10 consecutive days. Even though the relevant residues on potential feeding stuff are besides benfuracarb also carbofuran and 3-hydroxy- carbofuran, it is noted that the referred to metabolites are not deemed as fat-soluble compounds based on their log pow values and thus their potential to accumulate is considered low. The chosen benfuracarb dose rates correspond to a theoretical overdosing factor of at least 5N and 50N, respectively, with regard to the estimated maximum residues level in the total diet of livestock animals. The majority of the administered radioactivity (94% of total dose) was rapidly excreted. Only a low amount (0.2% of total dose) was excreted with the milk. The TRR in tissues and organs were low and residues did not appear to accumulate in fat tissues. Identification of metabolites in edible tissues was not attempted due to the very low level of the recovered radioactivity.

The metabolic pattern was investigated only in urine and indicated an extensive metabolisation mainly into phenolic metabolites through oxidation and hydrolysis steps. Neither benfuracarb nor its primary metabolite carbofuran were present in urine.

The study is not appropriate to establish a complete picture of the metabolic pathway and pattern in ruminants including edible animal matrices and to conclude on potential relevant metabolites in order to define a residue for risk assessment purposes. However, no significant total residues (<0.01 mg/kg) are expected to occur in edible animal matrices taking into account the residue situation for the representative use indicated by the data currently available. Thus, no residue definition or MRLs for animal matrices are currently proposed, and no further data on livestock animals are required at this stage.

3.3. CONSUMER RISK ASSESSMENT

The consumer risk assessment cannot be finalised due to the uncertainties caused by a lack of data identified during the peer review (residue data on the full definition of residue including conjugates and data to estimate contribution of rotational crop residues). The risk assessment provided by the rapporteur Member State has to be considered a provisional assessment that is based on the currently available data.

To assess consumer risk the rapporteur Member State followed the approach of a separated intake assessment of benfuracarb on one hand and carbofuran plus 3-hydroxy-carbofuran residues on the other hand, applying the toxicological reference values of carbofuran also to 3- hydroxy -carbofuran.

The **chronic consumer exposure** was estimated based on a variety of diets in the EFSA PRIMo and the LOQ of the analytical method or the highest residue (HR) in the supervised trials with flowering, leafy and head brassica, respectively. The estimated dietary intake of benfuracarb is significantly below (<1%) the benfuracarb ADI of 0.01 mg/kg bw/day for all considered consumer groups. The estimated dietary intake of the benfuracarb metabolites carbofuran and 3-hydroxy-carbofuran was at the maximum 7% of the allocated ADI for carbofuran of 0.00015 mg/kg bw/day, for the considered consumer groups.

An assessment of the TMDI with residue levels at the proposed MRL was not conducted, but is expected to differ only marginally from what is presented here above. An assessment with national models for chronic exposure estimates that consider higher percentiles of consumption data (e.g. UK Rees Day model) was not conducted by the rapporteur Member State.

In the updated **acute exposure and risk assessment** provided in the addendum of November 2008 and January 2009 the consumer exposure to benfuracarb and to carbofuran and 3-hydroxy-carbofuran, respectively, was calculated with the EFSA PRIMo for adults and children. This assessment considered lower reference values for carbofuran than initially used in the additional report of August 2008.

For the estimates of benfuracarb consumer exposure, again the LOQ in the residues trials on flowering, leafy and head brassica (0.05 mg/kg) was used as highest residue for all brassica vegetables except kohlrabi. For the estimates on carbofuran and 3-hydroxy-carbofuran the highest residue (HR) in the supervised trials with cauliflower (0.0065 mg/kg), broccoli (0.0103 mg/kg), kale (0.0086 mg/kg), head cabbage (0.0045 mg/kg) were applied. Moreover, the estimates were carried out with different variability factors.

According to these calculations, no exceedance of the ARfD of 0.02 mg/kg bw/day was identified for benfuracarb. For carbofuran and 3-hydroxy-carbofuran however the estimates indicated an **exceedance of the ARfD** of 0.00015 mg/kg bw/day for adults and children consuming cauliflower (137% and 286% ARfD, respectively), broccoli (145% to 396% ARfD), kale (87% to 387% ARfD), and Chinese cabbage (107% to 111% ARfD). As already indicated before (3.1.1) for head cabbage, depending on the variability factor used in the acute assessment, the exposure of children is above (158% with default factor of 5) or below (95% with default factor of 3) the toxicological reference value for carbofuran and 3-hydroxy-carbofuran. For adults no exceedance of the ARfD by the consumption of head cabbage was identified (57-95% ARfD). The default variability factor to be used in the assessment is a risk management decision as to how much uncertainty can be accepted by risk managers in an risk assessment. It should however be noted that the possible contribution from conjugates of carbofuran and 3-hydroxy-carbofuran has not been considered in the presented estimates for head cabbage, cauliflower, broccoli, kale and Chinese cabbage.

Moreover, estimates could not be carried with regard to exposure from residues in rotational crops. If residues occurred in following crops, even if at very low levels, an exceedance of the ARfD for carbofuran and 3-hydroxy-carbofuran might also be expected depending on the contribution of those crops in the human diet.

Finally, EFSA notes that, if there were no use restrictions imposed to mitigate groundwater exposure, the level of carbofuran in groundwater is expected to exceed 0.1 µg/L (refer to 4.2.2.); the highest predicted contamination in one of the scenarios resulted in >3 µg/L. In the assessment performed by the rapporteur Member State the possible **consumer intake** of carbofuran **through drinking water** derived from groundwater was not considered although a significant contribution to the acute and chronic exposure might be expected if any restrictions that might be considered were not effective.

To assess this situation EFSA estimated consumer exposure (not peer reviewed) with regard to carbofuran residues in ground water used as drinking water on the basis of the predicted PEC groundwater levels (FOCUS PEARL) in order to reflect the worst case.The estimates are based on the default assumptions laid down in the WHO Guidelines for drinking- water quality[18] for the consumer groups of adults (weighing 60 kg), toddlers (10 kg) and bottle-fed infants (5 kg) with a daily per capita consumption of 2 L, 1 L and 0.75 L, respectively.

The predicted carbofuran concentrations in the most vulnerable scenarios may lead to the exceedance of the toxicological reference values ADI and ARfD for toddlers and infants. In terms of the acute assessment it is noted that the used daily consumption figures might rather reflect a mean consumption than a high consumption that is normally considered for acute intake estimates, and thus the actual acute consumer exposure (single day event) might be even higher than estimated.

Estimated intakes of carbofuran through drinking water derived from groundwater expressed in µg/kg bw and as percent of the toxicological reference values (ADI and ARfD, both 0.00015 mg/kg bw/day)

FOCUS Scenario	PEC_{GW} (µg/L) simulated by FOCUS PEARL	Estimated consumer intake					
		Adult		Toddler		Infant	
Time of application: Spring		µg/kg bw	% tox. ref. val.	µg/ kg bw	% tox. ref. val.	µg/ kg bw	% tox. ref. val.
Chateaudun	0.646	0.022	14.4	0.065	43.1	0.097	64.6
Hamburg	0.737	0.025	16.4	0.074	49.1	0.111	73.7
Jokioinen	0.741	0.025	16.5	0.074	49.4	0.111	74.1
Kremsmuenster	0.667	0.022	14.8	0.067	44.5	0.100	66.7
Porto	0.013	0.000	0.3	0.001	0.9	0.002	1.3
Sevilla	0.093	0.003	2.1	0.009	6.2	0.014	9.3
Time of application: Summer							
Thiva	0.229	0.008	5.1	0.023	15.3	0.034	22.9

[18] Guidelines for drinking-water quality. 3rd edition, Volume 1: Recommendations. World health organisation (2006)

Chateaudun	0.574	0.019	12.8	0.057	38.3	0.086	57.4
Hamburg	3.127	0.104	69.5	0.313	**208.5**	0.469	**312.7**
Kremsmuenster	1.531	0.051	34.0	0.153	**102.1**	0.230	**153.1**
Porto	0.268	0.009	6.0	0.027	17.9	0.040	26.8
Sevilla	0.024	0.001	0.5	0.002	1.6	0.004	2.4

3.4. PROPOSED MRLS

Based on available data the following MRLs have been proposed by the rapporteur Member State:

1) Benfuracarb

Flowering brassica, head brassica, leafy brassica 0.05* mg/kg

2) Carbofuran (Carbofuran + 3-hydroxy-carbofuran expressed as carbofuran)

Flowering brassica, leafy brassica 0.01 mg/kg

Head brassica 0.01* mg/kg

It is noted that when an acute consumer risk assessment is conducted with the currently proposed MRLs for carbofuran (including 3-hydroxy-carbofuran) the ARfD will be exceeded.

Since the experts in the meeting TC05 concluded that further residue trials to address the notified use are necessary, the future results may lead to changes in the current proposal for carbofuran. Furthermore, if the applicant intended with their notification to support a use in the category of brassica vegetables, residue data on kohlrabi would also be necessary.

4. Environmental fate and behaviour

Benfuracarb fate and behaviour in the environment was discussed in the meeting of experts EPCO 31 (September 2005) on the basis of the benfuracarb DAR (July 2004) and the benfuracarb Reporting and Evaluation tables. The rapporteur Member State prepared an additional report (August 2008) that included summaries of new studies and relevant updated information, which was regarded as necessary for the proper finalization of the assessment of environmental fate and behaviour of benfuracarb in the environment. The assessment of this resubmission was discussed in the meeting of experts PRAPeR 62 (January 2009) on fate and behaviour in the environment. Two addendums were prepared by the rapporteur Member State to the additional report; addendum 1 was prepared before the meeting and addendum 2 after the meeting of experts. Note that both addenda are dated January 2009. Point 4(11) of the reporting table for benfuracarb (rev.1-0; 1 December 2008) was also used for the peer review. Some information, which was still missing or was not included in any of the addenda, was included in an addendum prepared by EFSA. This addendum is referred as the EFSA addendum for benfuracarb.

In parallel to the additional report of benfuracarb, the same rapporteur Member State prepared an additional report for carbofuran (November 2008) based on the resubmitted dossier of carbofuran, from which some data were used for the evaluation of benfuracarb.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

Metabolism of benfuracarb in soil under dark aerobic conditions at 20ºC (soil moisture content at 40% of the maximum water holding capacity) was investigated in two studies with four soils and with ^{14}C benfuracarb labelled at the ring position. The soils were in the range of pH values (5.8-7.1), clay contents (8.2 % - 42.3 %) and organic matter contents (2.3 % - 5.3 %).

In aerobic conditions degradation of benfuracarb in soil rapidly yields **carbofuran**[19] (maximum 84.6 % AR after 2 d). Two other major metabolites were reported in the DAR: **MVIII** (maximum = 16.7 % after one day) and **MVI** (maximum = 16.0 % after 0.24 day) that do not correspond to any of the known metabolites of benfuracarb or carbofuran. In the meeting of MS experts (EPCO 31), the rapporteur Member State clarified that MVIII and MVI corresponded to the same fraction. Identity of this fraction was investigated in a separated study with identical experimental conditions. In this second study, it was found that this single peak represented three individual compounds one of them tentatively characterized as desmethyl-benfuracarb and two other unknowns. The meeting of experts (EPCO 31) considered that whereas it can not be completely excluded that some of these metabolites reached the 10 % of applied radioactivity their short half life prevented any further characterization. Therefore, further investigation of the nature of these metabolites was not deemed necessary. Other minor metabolites were detected (maximum sum of them: 34.9 % AR after 0.24 d) that individually did not reach the 10 % AR. However, metabolites at levels between 5 % AR and 10 % AR were not reported. Mineralization was high at the end of the study (CO_2 = 27.7 % AR – 66.6 % AR). Amount of unextractable residues reached a maximum = 74.1 % at the end of the study in one of the soils. No effort to characterize bound residue was reported in the DAR. After the meeting of the experts (EPCO 31), the rapporteur Member State confirmed that no detailed characterization of bound residues had been performed in this study.

No soils were investigated in the range of alkaline soils that, according to hydrolysis study, could represent a worst case for chemical degradation. Therefore, a data gap was set to address the degradation of benfuracarb under alkaline soils in 2006. In order to address this requirement, the applicant submitted a new degradation study in one alkaline soil at temperatures of 10°C and 20°C that was summarized in the additional report of benfuracarb. The soil properties were: pH 7.9, clay content 30% and organic matter content 4.48%. In this new study in alkaline soil at 20°C, the mineralization to carbon dioxide was negligible (0.2% AR at the end of the study) and the amount of unextractable residues reached a maximum of 12.1% AR at the end of the study (93 hours). Other residues than benfuracarb were not investigated in this study. At 10°C, the mineralization and the amount of unextractable residues were similar.

Additionally, a degradation and metabolism study of carbofuran in four soils under aerobic conditions at 20 ºC is available. The soils covered a range of pH values (5.7-7.5), clay contents (9 % - 34.2 %) and organic carbon contents (1.3 % - 3.0 %). No metabolites > 10 % AR were found. One experiment

[19] carbofuran: 2,3-dihydro-2,2-dimethylbenzofuran-7-yl methylcarbamate

was repeated at 10ºC in which metabolite **3-keto-carbofuran**[20] reached a 7.7 % AR at the end of the study (56 d). Experts meeting (EPCO 31) agreed that 3-hydroxy-carbofuran (minor carbofuran metabolite containing the carbamate moiety) needs to be addressed, as potential benfuracarb soil metabolite, for ground water contamination**.** However, according the experts meeting (EPCO 31) the carbofuran metabolite carbofuran-phenol does not need to be addressed for benfuracarb.

No anaerobic soil degradation study has been provided.

No soil photolysis study has been provided for benfuracarb, however a soil photolysis study is available for the metabolite carbofuran in the carbofuran dossier that has been used to assess that this metabolite of benfuracarb is photollytically stable on soil surface.

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Degradation rate of benfuracarb in soil was investigated in the same degradation studies used for the metabolism elucidation. The available studies indicate that at 20ºC benfuracarb is very low persistent in soil (DT_{50} = 0.23 d – 0.83 d in neutral or acidic condition and DT_{50} = 0.13 day in alkaline soil. These DT_{50} values above were calculated by single first order kinetics (SFO)). For the resubmission of the dossier of carbofuran, one of the notifier of carbofuran reanalysed all of the available data for carbofuran and its precursors (pesticide molecules as parent of carbofuran from which carbofuran as metabolite can be formed in soil) benfuracarb and carbosulfan. In this reanalysis of the data, the residues of benfuracarb from the neutral or acidic soils were refitted by SFO and also by FOMC (first order multi compartment) kinetics. Since the fit by the FOMC model was found to be better, the resulting DT_{50}/DT_{90} values of these FOMC fits were normalized to FOCUS reference conditions (20°C and -10 kPa soil moisture). For modelling purposes, pseudo SFO DT_{50} values were calculated by dividing the FOMC DT_{90} values by the factor of 3.32 as recommended by the FOCUS kinetic guidance document.[21] The DT_{50} value from the alkaline soil was derived by EFSA using the same method as described above. The resulting range of these DT_{50} values was 0.23 – 1.17 days (normalized to FOCUS reference conditions, pseudo SFO derived from FOMC DT_{90}, n=5) and the geometric mean was 0.42 day. The meeting of experts (PRAPeR 62) found these values as appropriate to be used in the calculations of the exposure.

The metabolite carbofuran is low to moderate persistent in soil (DT_{50} = 6.1 d– 19.4 d). However, degradation of carbofuran seems to be very dependent of the temperature and at 10 ºC is highly persistent (DT_{50} = 110 d). The meeting of experts (EPCO 31) discussed the impact of this high temperature dependence on the risk assessment. The rapporteur Member State informed that the notifier had submitted a position paper and a new study to address the degradation of carbofuran at low temperatures (2006). The meeting of the experts (EPCO 31) agreed that this new study needs to be evaluated in an addendum. The study was not evaluated in an addendum; however it was included

[20] 3-keto-carbofuran: 2,2-dimethyl-3-oxo-2,3-dihydro-1-benzofuran-7-yl methylcarbamate
[21] FOCUS (2005) "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration" Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 1.0, 431 pp

in the additional report for benfuracarb (August 2008) and the position of the notifier was incorporated into the reporting table of benfuracarb (rev.1-0; 1 December 2008; point 4(11)). The new study is the new study conducted in one alkaline soil at temperatures of 10°C and 20°C, already mentioned in point 4.1.1 above. This study was conducted with benfuracarb, the formation and the degradation of carbofuran or other metabolites were not investigated. The experts at PRAPeR 62 meeting discussed this issue and did not support the argumentation from the applicant that evidence from one benfuracarb investigation might give an indication of what would occur for carbofuran. The meeting of experts agreed that in line with the PPR panel opinion on Q10,[22] evidence from more than a single soil at two different temperatures is required before it can be justified to go away from agreed default value for Q10 in modelling. Therefore the experts agreed that the default Q10 (2.2) applicable to be used in simulations of leaching of both benfuracarb and carbofuran.

Additionally, in the carbofuran dossier there are studies that indicate a potential high persistence of carbofuran in soil ($DT_{50\ lab\ 20°C}$ = 175 – 444 d). Further clarification on the acceptability of the different carbofuran degradation studies and the reasons for the high differences on the carbofuran half life was expected to be provided by the rapporteur Member State as an addendum to the carbofuran DAR in 2006. Relevance of this data for the assessment of benfuracarb was considered as necessary when this addendum became available (2006). This addendum was not available until the meeting of experts of PRAPeR 62 (January 2006) or at the time of updating this conclusion, however these long DT_{50} values were regarded by the rapporteur Member State as not valid anymore and they were not used in the estimation of the exposure of environmental compartments in the additional report of benfuracarb. The argumentation of the exclusion of these values was regarded as inappropriate; therefore the validity of these experiments was discussed at the meeting of experts of PRAPeR 62. The meeting of experts considered that there seemed to be no methodological reason to conclude that these experiments were not valid and the experts agreed that these long DT_{50} values should be used in the assessment of the exposure.

As mentioned above, for the resubmission of the dossier of carbofuran, one of the notifiers of carbofuran reanalysed and normalised (to FOCUS reference conditions) all of the available laboratory data for carbofuran and its precursors, carbosulfan and benfuracarb according to the FOCUS kinetic guidance document. This reanalysis for all the experiments, where the degradation of carbofuran was adequately investigated and the experiment was regarded as valid by the previous peer review of carbofuran, carbosulfan or benfuracarb was available for the meeting of experts of PRAPeR 62, except the three experiments that indicated a potential high persistence of carbofuran, as mentioned above. The carbofuran residues from these three experiments were refitted and normalised by EFSA before the meeting of experts. Taking into account all of these data, the resulting range of DT_{50} values for carbofuran was 5.7 – 387 days (normalized to FOCUS reference conditions, SFO, n=17). The experts at the meeting of PRAPeR 62 discussed the reanalysis of the data and the derivation of degradation endpoints for carbofuran. The meeting agreed with this data set and that the median of these DT_{50} values, which is 14 days, is appropriate to be used in the FOCUS modelling.

[22] Scientific Opinion of the Panel on Plant Protection Products and their Residues on a request from EFSA related to the default Q10 value used to describe the temperature effect on transformation rates of pesticides in soil. The EFSA Journal (2007) 622, 1-32

Unknown metabolites fraction (MVIII-MVI) is very low persistent and transient in nature.

No data on relevant soil metabolites 3-hydroxy-carbofuran and 3-keto-carbofuran were available in the carbofuran dossier for the original submission. The dossier prepared for the resubmission (2009) contained studies accepted by the peer review regarding the degradation of these metabolites in three aerobic soils (pH 5.7-6.9, OC content 1.02-2.29%, clay content 7.9-42%). Whilst there were some deficiencies with the experiments (few sampling times with reliable quantifiable residues), the experiments provide indications of low persistence. The DT_{50} of 3-hydroxy-carbofuran was less than one day in all the three soils. The geometric mean derived after the normalisation to FOCUS reference conditions (20°C and -10k Pa soil moisture) of these three uncertain SFO values was 0.41 of a day. The SFO DT_{50} values of 3-keto-carbofuran were between 1.54 and 4.41 days. After normalisation to FOCUS reference conditions, this range became 0.9-4.14 days and the geometric mean was 3.01 days. Additionally, the degradation of the minor soil metabolite carbofuran-phenol was also investigated in three soils. The results indicated that the DT_{50} of this metabolite is less than one day (an uncertain value, the applicant proposed rapid formation of unextracted residue accounted for these short DT_{50}).

Worst case laboratory half lives were used to calculate PEC soil of benfuracarb and its metabolite carbofuran. However, data from a different carbofuran notifier show that field worst case half life for carbofuran is 71.9 d in EU sites. Therefore, PECs soil were also calculated by the rapporteur Member State with this half life in the original DAR. However, according to the conclusion for carbofuran, further assessment and confirmation of the reliability of this value was deemed to be necessary in 2006. In the additional report of benfuracarb, the Rapportaur did not include summaries of the available field studies, but expressed that the study from which the field DT_{50} of 71.9 days come from is of limited quality and is not appropriate to derive accurate dissipation endpoint. Therefore, the rapporteur Member State was asked to include their assessment of this study in an addendum (for details see addendum 1). The meeting of experts (PRAPeR 62) discussed this evaluation and agreed that the study is not relied on. Therefore, the meeting agreed moreover, that from those available field DT_{50} values, which were not excluded, the longest value of 27 days should be used for PECsoil calculations.

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Due to the fast degradation of benfuracarb batch adsorption desorption studies failed to determine a reliable K_{Foc}. Nevertheless, by the HPLC method it was estimated that benfuracarb may be classified as immobile in soil (K_{doc} = 9100 mL / g).

A batch adsorption / desorption study is available for carbofuran in four soils. Carbofuran may be classified as very high mobile compound (K_{Foc} = 17 – 28 mL / g).

No data were available for minor carbofuran relevant soil metabolites 3-hydroxy-carbofuran and 3-keto-carbofuran in the original dossier. The additional report for benfuracarb (August 2008) included

batch adsorption/desorption studies for these metabolites in three soils. Due to the fast degradation observed in the experiments, reliable Freundlich isotherms were not established for these metabolites. The calculated K_{doc} values for 3-hydroxy-carbofuran were in the range of 43-62 mL/g (mean 55 mL/g) and the K_{doc} values for 3-keto-carbofuran were in the range of 47.5-504 mL/g (mean 330.5 mL/g) (note: the dataset of 3-keto-carbofuran is a mix of one K_{doc} value and two K_{Foc} values). Additionally, the adsorption/desorption of the minor soil metabolite carbofuran-phenol was also investigated in three soils. The calculated K_{Foc} values varied from 444 to 1810 mL/g (mean 1031 mL/g) (1/n 0.407-0.751).

A lysimeter study was available in the original DAR (2004), where two different lysimeters were investigated [with application in beets (furrow) and potatoes (spray)]. Both lysimeters were in the acidic range of soils (pH (0-30cm) = 5.1 – 5.4). Annual average amount of radioactivity leaching was in the range 1.3 – 2.5 µg / L. Only few samples were analyzed for individual components. Therefore, it was not possible to calculate annual average concentration for individual components. Benfuracarb was found at maximum amounts of 0.25 µg / L and carbofuran at maximum amounts of 0.16 µg / L. A new or available lysimeter study was required by the rapporteur Member State in the DAR. The meeting of the experts (EPCO 31) agreed that the new FOCUS GW modelling required can substitute the requirement for a new lysimeter at this stage. No new lysimeter study was included in the additional report of benfuracarb, but two studies are available in the updated dossier of carbofuran and included in the additional report of carbofuran (not yet peer reviewed).

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

In sterile aqueous buffer solutions, hydrolysis of benfuracarb is pH dependent. Half life is less than half hour at pH 4, 1.4 days at pH 7 and 26.9 d at pH 9. Major hydrolysis products were carbofuran and metabolites **MI** (maximum = 36.6 % AR after 30 d at pH = 7), **MIII** (maximum = 13.8 % AR after 23 d at pH 9) and **MIV** (maximum = 10.5 % after 30 d). Desethylbenfuracarb and carbofuran-phenol were identified in a separate study that failed to elucidate the chemical structure of the unknown components MI, MIII and MIV. The meeting of experts (EPCO 31) agreed that no further investigation of these metabolites was necessary since appear within a range of pHs already investigated in the more relevant water / sediment studies.

The rapporteur Member State stated in the DAR that benfuracarb is readily degradable by direct phototransformation in water. However, the potential contribution of aqueous photolysis to benfuracarb degradation may not be fully established due to the great contribution of hydrolysis at pH (6-7.5) chosen to perform the photolysis sterile study. In the natural water experiment (pH ≈ 7-8) photolysis seems not to contribute significantly to the aqueous degradation of benfuracarb. However, irradiation seems to enhance the degradation of the metabolite carbofuran to carbofuran-phenol.[23]

Benfuracarb is not readily biodegradable. The substance was found to have a slightly inhibitory effect on microbial activity.

[23] carbofuran-phenol: 2,2-dimethyl-2,3-dihydro-1-benzofuran-7-ol.

A study with two water sediment systems is available. Both systems are in the alkaline range (pH_{water} 7.8-8.04). Main compounds found in the water phase are benfuracarb and carbofuran (maximum = 58.26 % AR after 2d). Main compounds found in the sediment phase are carbofuran (maximum = 25.31 % after 14 d) and carbofuran-phenol (maximum = 13.6 % after 14 d). The cumulative amounts of CO_2 at the end of the study accounted for 13.6 % AR and 16.7 % AR. Most of the radioactivity was present as bounded residue to the sediment by the end of the study (73.8 % AR – 75.9 % AR).

Benfuracarb dissipates rapidly in water phase with a half life between 6 h to 15 h. Main dissipation process is transformation to carbofuran. Carbofuran dissipates from water phase with half life between 8.2 d to 10.8 d. Main dissipation process is partitioning into sediment. Whole system and sediment phase half lives for carbofuran and carbofuran-phenol had not been calculated, therefore the rapporteur Member State was expected to provide this evaluation in an addendum during the first peer review of benfuracarb. The results of the new calculations regarding the whole systems were included in the additional report of benfuracarb and details of the derivation of these values were included in the addendum 1 for the additional report. The whole system linear SFO DT_{50} of carbofuran was calculated to be 13.9-14.8 days, and the whole system linear SFO DT_{50} of carbofuran-phenol was calculated to be 4.8-20.5 days. These calculations were accepted by the meeting of experts of PRAPeR 62.

In the carbofuran dossier, dissipation of carbofuran in the water sediment was investigated in two studies with a total of three systems. In an acidic system at 25°C, carbofuran degraded in the whole system with a half life of 44.6 d. In the neutral or alkaline systems carbofuran degraded in the whole system with half lives of 7.8 – 11.6 d. From this study, the degradation of carbofuran-phenol in the whole system was also calculated. The DT_{50} values for these neutral and alkaline systems were 3.7 and 8.2 days (note: these values were not included in the original EFSA conclusion from 2006 and they were not used further in the assessment of the exposure). These experiments seem to indicate that the degradation of carbofuran may be pH dependent in water sediment systems.

PEC_{SW} and PEC_{SED} calculations for benfuracarb, carbofuran and carbofuran-phenol was not adequately performed for the first submission of benfuracarb. For its resubmission, FOCUS surface water modelling was evaluated in the additional report up to step 3 and step 4 for benfuracarb and in separated runs for carbofuran. Step 4 calculations were made only for the so called 'runoff' FOCUS scenarios (R1, R2, R3 and R4). In these step 4 calculations there was no mitigation measurement applied, but the mode of application was modified from the default soil incorporation of granules to furrow application to 2.5 cm depths. This modification is in line with opinion of the EFSA PPR Panel[24] and with the applied for representative use of benfuracarb, as far as the granules are placed directly in the sowing row (to at least 2.5 cm below the soil surface) and than the furrows are covered by the soil. PEC_{SW} and PEC_{SED} calculations for carbofuran-phenol were based on the calculated PEC_{SW} and PEC_{SED} of carbofuran and the observed occurrence of carbofuran-phenol in water sediment studies, as carbofuran-phenol is formed (from carbofuran) predominantly in the aquatic

[24] Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS sw scenarios. The EFSA Journal (2004)145, 1-31

environment. However, the input parameters of these calculations were discussed and a new set of input parameters was agreed in the meeting of experts of PRAPeR 62. After the meeting, the FOCUS step 3 and step 4 calculations were repeated with the agreed input parameters and were included in addendum 2 by the rapporteur Member State (for the discussions and the agreed input parameters see the Report of PRAPeR expert meeting 62, 15 January 2009). These calculations are included in appendix 1 of this conclusion.

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

For the original submission, FOCUS PEC_{GW} calculations were performed for benfuracarb and its soil metabolites, but the potential contamination of the ground water by the metabolites was regarded as not being adequately addressed by the finalisation of the EFSA conclusion (2006) of the peer review on this original submission. For the resubmission of benfuracarb, the required FOCUS groundwater simulations for the applied for representative use were included and evaluated in the additional report by the rapporteur Member State. FOCUS PEARL (version 3.3.3) modelling were conducted for benfuracarb, carbofuran, 3-hydroxy-carbofuran, 3-keto-carbofuran and additionally for carbofuran-phenol. FOCUS PELMO (version 3.3.2) modelling was conducted only for benfuracarb and carbofuran. Additionally, for benfuracarb and carbofuran biennial applications were also simulated. For some FOCUS scenarios, cabbage can be planted two times a year, spring and summer. For these scenarios separate simulations were done, either for the spring or for the summer applications.

Some important input parameters (soil DT_{50} of benfuracarb and carbofuran, formation fraction of carbofuran, Q10 value to be applied for carbofuran, 1/n value of benfuracarb, 3-hydroxy-carbofuran and 3-keto-carbofuran) of these calculations were discussed in the meeting of experts of PRAPeR 62 (for the discussions and the agreed input parameters see the Report of PRAPeR expert meeting 62; 15 January 2009). After the meeting, the calculations for benfuracarb and carbofuran were repeated with FOCUS PELMO using the agreed input parameters and were included in the addendum 2 by the rapporteur Member State. These input parameters for benfuracarb were: pseudo first order (from FOMC kinetics) DT_{50} 0.42 days, K_{doc} 9100 mL/g , 1/n=1 and for carbofuran: single first order DT_{50} 14 days, formation fraction from benfuracarb 1 (100%), K_{Foc} 22 mL/g, 1/n=0.96.

No simulations for benfuracarb and carbofuran with FOCUS PEARL model program were included in the addendum 2. However based on the opinion of the PPR panel,[25] simulations with a second model are necessary. EFSA conducted simulations for benfuracarb and carbofuran with FOCUS PEARL model program using the same, agreed input parameters (for details see EFSA addendum for benfuracarb, January 2009).

For the biennial applications adequate information only for one scenario for both application time were available, therefore and because of the applied for representative use assumes application in every year, results only for the yearly application are included in this conclusion.

[25] Opinion of the Scientific Panel on Plant Health, Plant Protection Products and their Residues on a request of EFSA related to FOCUS groundwater models. The EFSA Journal (2004) 93, 1-20.

PEC_{GW} calculations for the metabolites 3-hydroxy-carbofuran and 3-keto-carbofuran were not included in the addendum 2, but reports (output files) of updated FOCUS PEARL simulations were available (submitted by the notifier directly to EFSA and also to the rapporteur Member State and Member States in December 2008). The input parameters of these calculations were the same as what was required later on by the meeting of experts PRAPeR 62 in January 2009 (3-hydroxy-carbofuran: SFO DT_{50} 0.41 day, formation fraction from carbofuran 0.1, K_{doc} 55 mL/g, 1/n=1; 3-keto-carbofuran: SFO DT_{50} 3.01 day, formation fraction from carbofuran 0.1, K_{doc} 330.5 mL/g, 1/n=1). Examples from these FOCUS PEARL reports are included in the EFSA addendum for benfuracarb (January 2009).

The results of these FOCUS simulations indicated that the annual average 80th percentile PEC_{GW} (at 1 m depth below the soil surface) for benfuracarb, 3-hydroxy-carbofuran and 3-keto-carbofuran were <0.001 µg/L for all the simulated scenario (six scenario for cabbage plantation in spring and six scenario for cabbage plantation in summer).

Carbofuran exceed the 0.1 µg/L trigger for all the FOCUS simulations for Chateaudun, Hamburg Jokioinen, Kremsmuenster and Thiva scenarios. The calculated PEC_{GW} values were below the 0.1 µg/L trigger for two scenarios (Porto and Sevilla) out of the six, when spring application was simulated. For both spring and summer application, only Sevilla scenario resulted PEC_{GW} values below the trigger 0.1 µg/L. The table below summarises the calculated PEC_{GW} values of carbofuran, for all the simulations (values in bold are higher than the trigger of 0.1 µg/L).

The annual average 80th percentile PEC_{GW} values of carbofuran at 1 m depth below the soil surface

FOCUS Scenario	Time of application (spring/summer)	PEC_{GW} (µg/L) simulated by FOCUS PELMO	PEC_{GW} (µg/L) simulated by FOCUS PEARL
Chateaudun	Spring	**0.126**	**0.646**
Hamburg	Spring	**0.361**	**0.737**
Jokioinen	Spring	**0.294**	**0.741**
Kremsmuenster	Spring	**0.122**	**0.667**
Porto	Spring	0.007	0.013
Sevilla	Spring	<0.001	0.093
Thiva	Summer	**0.101**	**0.229**
Chateaudun	Summer	**0.134**	**0.574**
Hamburg	Summer	**2.664**	**3.127**
Kremsmuenster	Summer	**0.430**	**1.531**
Porto	Summer	0.032	**0.268**
Sevilla	Summer	<0.001	0.024
Sum of the safe (<0.1 µg/L) combinations of scenario and application time		4 out of 12	3 out of 12
No of safe (<0.1 µg/L) FOCUS scenario		2 out of 7	1 out of 7

5. Ecotoxicology

Benfuracarb was discussed at the EPCO experts' meeting for ecotoxicology (EPCO 32) in September 2005. The discussion focused on confirming the data requirements originally proposed by the rapporteur Member State and on identifying additional data gaps for the proposed representative uses, since no additional information or studies provided had been evaluated by the rapporteur Member State. An addendum to the chapter on ecotoxicology has been provided on 18 May 2006. When reported, the information in the addendum has been summarized too briefly to draw any conclusion on its reliability. Benfuracarb was resubmitted and peer-reviewed and discussed in the PRAPeR experts' meeting for ecotoxicology (PRAPeR 63) in January 2009 on the basis of the additional report from August 2008 and the addendum to Volume 3, B9 from January 2009.

5.1. RISK TO TERRESTRIAL VERTEBRATES

A risk assessment for birds and mammals was conducted according to SANCO/4145/2000. The number of granules to reach the acute and dietary LD_{50} dose was calculated to be 54 and 41 granules for a 15 g bird. To reach a dose equivalent to the reproductive NOEC an amount of 24 granules would be required for a 15 g bird. The need for further information on the acceptance of granules was identified in the DAR to assess the risk from uptake of granules. A study on the acceptance of granules was submitted in April 2005. An addendum was provided by the rapporteur Member State in May 2006. The addendum was not peer reviewed. The rapporteur Member State noted in the additional report that it was not possible to derive any avoidance factor to be used in a refined risk assessment.

A new risk assessment for the uptake of granules was provided in the addendum to the additional report. The experts agreed to the risk assessment according to the EPPO scheme.[26] The risk to birds and mammals from accidental ingestion of granules was assessed as low. Concerns were raised with regard to the use of a DT_{50} value of 0.44 days in soil as a surrogate for the DT_{50} of granules to derive the time weighted average factor (ftwa) used in the long-term exposure calculation. According to the EPPO scheme an uncertain risk was identified for acute exposure of birds from uptake of granules as grit. The experts proposed a new risk calculation without considering degradation of the granules (without ftwa) and further clarification of the GAP. The rapporteur Member State provided a new long-term exposure toxicity calculation in the updated addendum of January 2009. The new long-term exposure toxicity values (ETR) indicate a high long-term risk to birds from uptake of granules as grit. The granules need to be covered by soil in order to mitigate the acute and long-term risk to birds.

A data requirement was set in the DAR for the applicant to address the risk from ingestion of treated seedlings. Residue studies and a risk assessment were submitted in August 2005. An addendum was submitted in May 2006. The risk from uptake of contaminated seedlings was considered by the rapporteur Member State as low for benfuracarb but was considered as high for the metabolite carbofuran. However the information provided in the addendum was not peer reviewed.

[26] EPPO-Standards (2003). "Environmental risk assessment scheme for plant protection products. Chapter 11: Terrestrial Vertebrates." EPPO Bulletin(33): 211 - 238.

The refined risk assessment for birds and mammals in the additional report was based on residue studies. The experts agreed to use the second highest residue value of 3.92 mg carbofuran/kg from eight trials as suggested by the rapporteur Member State. The risk assessment was not based on the highest measured value of 10.566 mg carbofuron/kg since it was considered an outlier according to Dixon's test and the trial was conducted late in the growing season which could have caused unusual high residues due to slow growth.

The refined risk assessment for birds was based on crested lark (*Galerida cristata*), wood pigeon (*Columba palumbus*) and black-headed gull (*Chroicocephalus ridibundus*). The PD values suggested in the refined risk assessment for crested lark and wood pigeon were rejected by the experts for a quantitative refinement of the exposure calculation since the relevance of the data collected in different habitats was unclear in relation to the food composition of birds foraging in brassica fields. It was noticed that the information provided in the additional report indicated that the proportion of cabbage leaves can be up to 51% of the food items of wood pigeon instead of the suggested 33%. Furthermore, the food composition of skylark was used as a surrogate for data on crested lark. It was also pointed out by the experts that PD refinement is problematic to refine the acute risk assessment. Further information would be necessary to support the assumption that birds would not feed only on one feed item on the acute time scale.

The experts discussed whether the provided data could be used to refine the PT values. The data provide some information about the home-range of birds and the composition of the agricultural landscape. The experts agreed that more robust data would be needed (i.e. radio-tracking data) in order to derive reliable PT values.

The risk assessment for secondary poisoning from uptake of contaminated earthworms was based on a study with blackbirds and earthworms treated with benfuracarb. The experts' meeting concluded that the study was conducted to investigate whether blackbirds would consume contaminated earthworms and whether they would be affected but it was not designed to determine a NOEC in line with the NOECs from dietary studies. It was noted that the exposure period was sufficiently long because the active substance acts as an acute toxin. However, the meeting concluded that the study has certain deficiencies (e.g. birds were not particularly motivated to feed, the relevance of the concentration of benfuracarb to the representative use is not known). An open point was set for the rapporteur Member State to reconsider the study in the light of the discussion at the expert meeting. The risk of secondary poisoning to birds is not finally concluded. Poisoning incidents from uptake of contaminated earthworms were reported by France. A new risk assessment for the uptake of contaminated earthworms was submitted in August 2005. An addendum was submitted in May 2006. The information provided in the addendum was not peer reviewed.

A risk assessment was provided for black-headed gull as a representative of earthworm-eating birds occurring in brassica fields. The refined PD value for earthworms of 0.92 was a based on the highest proportions of earthworms in the diet observed in agricultural landscape in Switzerland. The experts agreed to use the suggested PD value to refine the short-term and long-term risk. The experts considered the data not sufficient to exclude that bird could feed only on earthworms to satisfy its

daily energy demand. The risk assessment was refined further by using measured residue values of carbofuran in earthworms. The acute TER is still below the trigger of 10 indicating a high acute risk for earthworm-eating birds.

The LC_{50} for the dietary toxicity to mallard duck (*Anas platyrhynchus*) was based on an average food intake for all doses. The meeting did not accept this as food avoidance was observed at all concentrations. Adverse effects were observed at all dose levels and no NOEC could be derived from this particular study. Since the primary concern is the acute risk it was proposed by the meeting to base the first tier risk assessment on the acute endpoint. Ecological parameters, toxicological data or avoidance studies could be used for refinement of the risk assessment.
The reproductive NOEC for birds was discussed in the expert meeting. A statistically significant lower weight of 14 day old survivors was observed in the reproduction study with bobwhite quail (*Colinus virginianus*). Since the difference was only 5% the experts did not reach a conclusion on the ecological relevance of the effect. Therefore a data gap was identified for the applicant to compare the key endpoints on hatchling body weights with historical control data. This information was provided and evaluated in the additional report. The long-term NOEC of 115 mg benfuracarb/kg diet (8.93 mg benfuracarb/kg bw/d) was accepted.

No agreement was reached on the long-term endpoint of carbofuran for birds. Since the studies with carbofuran were not evaluated in the additional report for benfuracarb it was decided to update the endpoint after the peer review of the re-submission of carbofuran.

A data gap was identified to further address the risk to birds from uptake of residues in contaminated food items.

The acute risk to mammals from direct uptake of granules was assessed as low. As regards the long-term risk, the experts suggested an open point for the rapporteur Member State to recalculate the risk without refinement (ftwa) (see discussion above).

The rapporteur Member State identified the following data requirements in the DAR to address the risk to mammals: a long-term risk assessment for uptake of granules, the risk from consumption of contaminated earthworms and the risk from ingestion of residues in seedlings. Further data and a new risk assessment were submitted by the applicant in August 2005. An addendum was submitted in May 2006. The information provided in the addendum was not peer reviewed.

A new risk assessment was provided in the additional report. The refined risk assessment was based on common shrew (*Sorex araneus*) and hare (*Lepus europaeus*). The risk assessment was refined using measured residue values in earthworms and in cabbage seedlings. The suggested PD refinement was accepted by the experts to refine the long-term risk but not the acute risk assessment since the data provided no evidence to exclude that hare or shrew feed only on one food item on the acute time scale. The experts agreed that the acute risk should be recalculated by the rapporteur Member State without PD refinement. The acute TERs are below the Annex VI trigger of 10 without PD refinement

indicating a high risk. Therefore a data gap remains to address the risk to mammals from uptake of contaminated earthworms and residues in seedlings.

It was unclear on how the long-term NOAEL for carbofuran for the mammals risk assessment was derived. Since the studies were not summarized in the additional report it was decided in the meeting of experts that the long-term endpoint for mammals should be updated after the peer-review of carbofuran.

The experts considered it necessary that the risk from carbofuran from uptake of contaminated drinking water from puddles should be addressed since caburoan is very toxic and also longer persistent in soil than benfuracarb. It was suggested to follow the risk assessment scheme provided in the panel opinion on the science behind the new guidance document on birds and mammals.[27] The rapporteur Member State provided a first-tier risk assessment in the updated addendum from January 2009. The acute TERs were calculated as 1.62 for birds and 22 for mammals indicating the need for further refinement of the risk to birds.

5.2. RISK TO AQUATIC ORGANISMS

Since Oncol 10 8.6 G is a granular formulation direct entry into surface is not expected to be a major route of entry. Due to the rapid conversion of benfuracarb to carbofuran the PECsw water and TER values were calculated for carbofuran.

Two out of 3 scenarios resulted in TER values below the relevant Annex VI trigger of 100 and 10 for the acute and chronic risk to fish and aquatic invertebrates. Hence a need for a refined risk assessment was identified in the DAR. The applicant submitted a new juvenile fish growth test and a refined risk assessment for aquatic organism in April 2005. In the addendum of May 2006 two NOEC values from a juvenile growth test with rainbow trout were mentioned. No study summaries and no risk assessment were provided in the addendum. The new juvenile growth test with carbofuran was included in the additional report.

The risk of bioaccumulation was assessed as low since the BCF_{ss} for the whole fish was below the trigger of 100

A rapid shift of benfuracarb and carbofuran to the sediment phase was observed in the water-sediment study but no risk assessment for sediment dwelling organisms was presented. EFSA is of the opinion that the risk to sediment dwelling organisms needs to be addressed and suggests a data gap. In the addendum of May 2006 the rapporteur Member State identified the need for a study with carbofuran and sediment dwelling organisms as a prerequisite to conduct a risk assessment.
An open point was set for the rapporteur Member State to amend the risk assessment taking into account potential changes in the PECsw calculation following from the data requirement on the

[27] PPR-Panel (2008). "Scientific Opinion of the Panel on Plant protection products and their Residues (PPR) on the Science behind the Guidance Document on Risk Assessment for birds and mammals." The EFSA Journal(734): 1-181. http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902014630.htm

degradation of benfuracarb under alkaline pH in soil. Data were submitted by the applicant but not evaluated.

No PECsw calculation and no risk assessment were performed for the metabolite carbofuran-phenol. The risk from carbofuran-phenol is expected to be covered by the risk assessment for carbofuran because of its much lower toxicity (about 4 orders of magnitude). The PECsw for carbofuran-phenol would need to be more than 4 orders of magnitude higher than the PECsw for carbofuran to pose a higher risk to aquatic organisms than carbofuran.

A new aquatic risk assessment was included in the additional report from August 2008. TER values were calculated only for carbofuran since benfuracarb is very rapidly degraded to carbofuran in the aquatic environment. The risk assessment for sediment dwelling organisms (*Chironomus riparius*) was based on an endpoint derived from a study with benfuracarb. This was considered appropriate because it is very likely that benfuracarb was rapidly converted into carbofuran in the test system. No full FOCUS step 3 drainage scenario (D3, D4 stream, D6) resulted in TERs above the Annex VI trigger values for zooplankton and sediment dwelling insects. Only in the part scenario D4 (pond) the TERs exceeded the trigger values. No FOCUS step 3 calculations were provided for the the run-off scenarios. FOCUS step 4 calculations were based on an incorporation depth of 2.5 cm of the granules. The resulting TERs for all run-off scenarios were far above the trigger values indicating a low risk. Overall it can be concluded that a high risk to the aquatic environment cannot be excluded for environmental conditions represented by the FOCUS scenarios D3, D4 stream and D6. The risk from run-off was assessed as low if the granules were incorporated at a soil depth of at least 2.5 cm.

5.3. RISK TO BEES

The exposure of bees was assumed to be negligible since the granules are applied in the sowing bed and cabbage has no flower in the production crop. The expert's meeting agreed that the risk to bees is low for the exposure to residues in cabbage but that there could be a potential exposure of bees foraging on weeds that are present in the field. It was argued by the rapporteur Member State that weeds are controlled and no flowering weeds are present in cabbage fields. Therefore, it is concluded that the risk is considered as low in cabbage fields if no flowering weeds are present. The potential risk to bees foraging on flowering weeds should be assessed at Member State level taking into account the agricultural practice.
It was discussed whether the product is applied only in cabbage or also in other (flowering) brassica species since the GAP table only states brassicas. In case that the product is applied to flowering brassica crops (e.g. oilseed rape) a high risk to bees cannot be excluded due to the systemic properties of benfuracarb and carbofuran. Therefore it was decided by the experts that the use should be restricted to brassica crops which are not attractive for bees. In addition labelling with SPe8 was proposed to avoid exposure from flowering weeds.

5.4. RISK TO OTHER ARTHROPOD SPECIES

The effects of benfuracarb on survival were tested with *Aphidius rhopalosiphi*, *Typhlodromus pyri*, *Coccinella septempunctata*, *Chrysoperla carnea*, *Poecilus cupreus* and *Aleochara bilineata*. The LD_{50} for *A. rhopalosiphi* and *T. pyri* were determined as 43 mL Oncol 20 EC/ha and 42.4 mL Oncol

20 EC/ha. Exposure of ground dwelling arthropods was considered as more relevant because of the suggested use. Tests with the ground dwelling beetles *P. cupreus* and *A. bilineata* and the granular formulation Oncol 8.6 G revealed high mortality rates (59.5%) for *A. bilineata* at the suggested GAP (a dose rate equivalent to 12 kg Oncol 8.6 G/ha). Therefore, a data requirement to address the risk to ground dwelling non-target arthropods was identified in the DAR. An extended lab study with *A. bilineata* and a new risk assessment was submitted by the applicant in August 2005. In the addendum of May 2006 an endpoint from a study with *Aleochara bilineata* from an extended laboratory test was given. The rapporteur Member State concluded in the addendum that the risk to non-target arthropods is low. However no study summary or evaluation of the study was provided in the addendum. The new data need to be evaluated before a final conclusion on the risk to non-target arthropods can be drawn.

No significant effects were observed in new standard laboratory studies with *Hypoaspis aculeifer* and *Pardosa sp.* at an application rate of 1 kg a.s./ha. However, relatively high levels of mortality were observed in the aged residue test with *A. bilineata*. Effects on reproduction increased until 119 days of ageing and exceeded the trigger of 50%. The applicant suggested that these effects would not be treatment related since benfuracarb and carbofuran degrade too fast to see effects after such a long time of ageing of residues. The experts were of the opinion that it cannot be excluded that the observed effects are treatment related since the carbamate moiety is also present in the degradation products of carbofuran. A data gap was identified to address the risk to *Aleochara bilineata* further.

5.5. RISK TO EARTHWORMS

The TER for the acute risk to earthworms was calculated as 7 based on an endpoint from a study with the formulation Oncol 20 EC. A field study with the formulation Oncol 10 G was submitted but several deficiencies were noted by the rapporteur Member State (e.g. not enough samples were taken and the study does not cover the proposed use rate). An acute study with the active substance and an earthworm field study with appropriate dose levels were identified as data requirements in the DAR. New acute toxicity studies with benfuracarb and the formulation Oncol 8.6 G were submitted in April 2005 together with a new acute risk assessment. The studies were not evaluated by the rapporteur Member State and not peer reviewed. The applicant submitted also a justification why a field study with earthworms is not triggered based on the results of the new toxicity studies. The justification was not evaluated by the rapporteur Member State and is not peer reviewed. In the addendum of May 2006 the acute risk to earthworms from benfuracarb was assessed as low. A reliable study to assess the acute risk to earthworms was not available for carbofuran. A field study was considered necessary to address the long-term risk to earthworms from benfuracarb and its metabolite carbofuran. The addendum of May 2006 is not peer reviewed.

The above mentioned earthworm field study with the formulation Oncol 10 G was discussed again in the expert meeting. The study had several deficiencies and the experts agreed to the assessment of the rapporteur Member State that the results of the study are not reliable. The risk to earthworms was considered as not fully addressed and the data gap remains open. The rapporteur Member State informed in a written comment on the conclusion about concerns regarding sublethal effects observed

in the acute studies with benfuracarb and the formulation Oncol 8.6G. According to the rapporteur Member State these effects should also be taken into account in the final risk assessment.

5.6. RISK TO OTHER SOIL NON-TARGET ORGANISMS

A study with other soil non-target organisms is not triggered since the DT_{90}(field) for benfuracarb and carbofuran are <100 days. In the addendum of May 2006 the rapporteur Member State suggested a field study to assess the risk to soil macro-organisms. The addendum is not peer reviewed.

An extended laboratory study (14 day exposure period) with the soil dwelling mite *Hypoaspis aculeifer* was included in the additional report. No significant effects on mortality or reproduction were observed at a treatment rate equivalent to 12 kg formulation/ha. Therefore the risk to soil dwelling mites was considered low.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

The submitted studies were assessed as not acceptable because the soil used in the studies was not representative for European soils, the sand content was too low, no data on its organic carbon content and the microbial biomass were given and formulations different from Oncol 6.8 G were tested. Therefore a data requirement was set by the rapporteur Member State to submit soil nitrification and respiration studies with benfuracarb or carbofuran to address the risk to soil non-target micro-organisms. Studies investigating the effects of carbofuran on soil nitrification and respiration were submitted in April 2005. The rapporteur Member State assessed the risk to soil non-target micro-organisms as low in the addendum of May 2006. The addendum is not peer reviewed.

Studies with carbofuran were included in the additional report. The effects on soil respiration and nitrification were less than 25% after 28 days at concentrations of up to 3.5 mg carbofuran/kg soil. The risk to soil micro-organisms was assessed as low.

5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

A data requirement was identified in the DAR since no information was provided to address the risk to non-target organisms. Studies on phytotoxic effects with formulations containing benfuracarb were submitted. The studies were listed in the addendum of May 2006. The rapporteur Member State assessed the risk as low. However no study summaries were provided to support the suggested assessment. The addendum is not peer reviewed. The studies with non-target plants were presented in the additional report and the risk to non-target plants in the off-field area was assessed as low.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

No effects on respiration of activated sewage sludge were observed at the tested dose of 100 mg benfuracarb/L. Therefore it is concluded that the risk from the representative use to biological methods of sewage treatment is low.

6. Residue definitions

Soil

Definitions for risk assessment: benfuracarb, carbofuran, 3-hydroxy-carbofuran, 3-keto-carbofuran
Definitions for monitoring: carbofuran

Water

Ground water

Definitions for exposure assessment: benfuracarb, carbofuran, 3-hydroxy-carbofuran, 3-keto-carbofuran
Definitions for monitoring: carbofuran

Surface water

Definitions for risk assessment: benfuracarb (only water phase), carbofuran (water and sediment), Carbofuran-phenol (only in sediment).
Definitions for monitoring: benfuracarb (only water phase), carbofuran (water and sediment)

Air

Definitions for risk assessment: benfuracarb, carbofuran.
Definitions for monitoring: benfuracarb, carbofuran.

Food of plant origin

Definitions for risk assessment: benfuracarb; carbofuran and 3-hydroxy-carbofuran, both free and conjugated
Definitions for monitoring: two separate definitions to be monitored for: 1) benfuracarb; 2) carbofuran (sum of carbofuran and 3-hydroxy-carbofuran expressed as carbofuran)

Food of animal origin

Definitions for risk assessment: not proposed due to limited data, however the study demonstrates that no bioaccumulation occurs
Definitions for monitoring: not required for representative use

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

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
Benfuracarb	Very low to low persistent pseudo SFO (derived from FOMC DT_{90}) DT_{50} = 0.23 – 1.17 day, normalized to 20°C and -10kPa soil moisture	The first tier risk assessment indicates a high acute risk to earthworms. Further studies are required to finalise the risk assessment.
Carbofuran	Low to very high persistent SFO DT_{50} = 5.7 – 387 days, normalized to 20°C and -10kPa soil moisture	The risk form carbofuran was not assessed in the DAR for benfuracarb. The first tier risk assessment conducted in the DAR for carbofuran indicated a high long-term risk to earthworms.
3-keto-carbofuran	Very low to low persistent SFO DT_{50} = 0.9 - 4.14 days, normalized to 20°C and -10kPa soil moisture	No studies with soil dwelling organisms available. No data required because of the rapid degradation and the risk is considered to be covered by the risk assessment for carbofuran.
3-hydroxy-carbofuran	Very low persistent SFO DT_{50} = 0.22 – <1.0 day, normalized to 20°C and -10kPa soil moisture	No studies with soil dwelling organisms available. No data required due to the transient nature of the molecule.

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

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
Benfuracarb	Estimated to be immobile (K_{doc} ~ 9100 mL/g)	FOCUS: No Lysimeter: Yes (individual samples, annual average concentration not available)	Yes	Yes	Benfuracarb is very toxic to fish and aquatic invertebrates (the toxicity is similar to carbofuran). Due to the rapid conversion to carbofuran the aquatic risk assessment is based on the PECsw for carbofuran.
Carbofuran	Very high mobile (K_{Foc} = 17–28 mL/g)	FOCUS: Yes, trigger 0.1 µg/L exceeded for 5 of 7 scenarios (PELMO), or 6 of 7 scenarios (PEARL), trigger 0.75 µg/L exceeded for 1 of 7 scenarios (PELMO), or 3 of 7 scenarios (PEARL). Lysimeter: Yes (individual samples, annual average concentration not available)	Yes	More toxic than benfuracarb (30 times) Very toxic by oral and inhalatory exposure ADI: 0.00015 mg/kg bw/day	Carbofuran is very toxic to fish and aquatic invertebrates. A high risk for aquatic invertebrates and was identified on the basis of the peer reviewed data for evironmental situations represented by FOCUS drainage scenarios D3, D4(stream), D6.
3-keto-carbofuran	Very high to low mobility (K_{doc} = 47.5–504 mL/g)	FOCUS: No	No data available No data needed	Relevant More toxic than benfuracarb (3-fold) Toxic via oral exposure No exposure expected	No data available No data needed

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
3-hydroxy-carbofuran	Very high to high mobility (K_{doc} = 43–62 mL/g)	FOCUS: No	No data available No data needed	Relevant More toxic than benfuracarb (10 times) Very toxic via oral exposure Genotoxic *in vitro* No exposure expected	No data available No data needed

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
Benfuracarb (only water phase)	Benfuracarb is very toxic to fish and aquatic invertebrates (the toxicity is similar to carbofuran). Due to the rapid conversion to carbofuran the aquatic risk assessment is based on the PEC_{SW} for carbofuran.
Carbofuran (water and sediment)	Carbofuran is very toxic to fish and aquatic invertebrates. A high risk for aquatic invertebrates and was identified on the basis of the peer reviewed data for evironmental situations represented by FOCUS drainage scenarios D3, D4(stream), D6.
Carbofuran-phenol (only in sediment)	Carbofuran-phenol is markedly less toxic to aquatic organisms compared to benfuracarb and carbofuran. No PECsw calculation and no risk assessment was performed. However, only in case that the PEC_{SW} would be 4 orders of magnitude higher than the PEC_{SW} for carbofuran the resulting TERs would be higher than the TERs for carbofuran.

Air

Compound	Toxicology

(name and/or code)	
Benfuracarb	Toxic inhalatory exposure: rat LC_{50} 0.3 mg/L (T; R23)
Carbofuran	Very toxic via inhalatory exposure: rat LC_{50} 0.05 mg/L (T^{+}; R26)

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

- A complete residue trial database for brassica vegetable crops in compliance with the new residue definition for risk assessment has to be submitted (relevant for all representative uses; date of submission unknown; data gap identified by the meeting of experts TC05 in January 2009; refer to point 3.1.1).
- Rotational crop studies according to the OECD guidelines should be provided (intervals of 30, 120 days and 1 year on leafy crop, small grain crop and root crop) (relevant for all representative uses; date of submission unknown; data gap identified by the meeting of experts TC05 in January 2009; refer to point 3.1.2).
- The acute risk to birds from uptake of residues in seedlings and contaminated earthworms needs to be addressed further (relevant for all representative uses evaluated; data gap identified in the meeting of experts (PRAPeR 63) in January 2009; no submission date indicated by the applicant; refer to point 5.1).
- The risk to birds from uptake of granules as grit (an open point for the rapporteur Member State was identified in the meeting of experts (PRAPeR 63) in January 2009; a data gap may result from the open point depending on the clarification on the GAP (if granules are covered after the application this data gap becomes obsolete); no submission date indicated by the rapporteur Member State or applicant; refer to point 5.1).
- The risk to mammals from uptake of contaminated earthworms and seedlings (relevant for all representative uses; data gap identified in the meeting of experts (PRAPeR 63) in January 2009; no submission date indicated by the applicant; refer to point 5.1).
- The risk to birds from uptake of contaminated drinking water needs to be addressed (relevant for all representative uses evaluated; data gap identified in the meeting of experts (PRAPeR 63) in January 2009; no submission date indicated by the applicant; refer to point 5.1).
- The risk to ground dwelling non-target arthropods (*Aleochara bilineata*) needs to be addressed (relevant for all representative uses; data gap identified in the meeting of experts (PRAPeR 63) in January 2009; no submission date indicated by the applicant; refer to point 5.4).
- A field study with earthworms at appropriate dose rates (relevant for all representative uses; data gap identified in the meeting of experts (PRAPeR 63) in January 2009; no submission date indicated by the applicant; refer to point 5.5).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

The conclusion was reached on the basis of the evaluation of the representative uses as insecticide as proposed by the applicant which comprises incorporation into soil (pre-plantation) to control soil and foliar insects, where brassica will be grown. Benfuracarb can be used as insecticide and nematicide. It should be noted that during the peer review process only the use as insecticide was evaluated.

The representative formulated product for the evaluation was "Oncol 8.6G", a granule (GR), registered in France and Spain.

Adequate methods are available to monitor all compounds given in the respective residue definition for food of plant origin, soil and water.
Only single methods for the determination of residues are available since a multi-residue-method like the German S19 or the Dutch MM1 is not applicable due to the nature of the residues.
Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible.

Benfuracarb is rapidly and nearly completely absorbed in the rat. The main metabolite of benfuracarb is carbofuran (approximately 30 %). The acute inhalatory toxicity is high (LC_{50} 0.3 mg/L) whereas the oral toxicity moderate (LD_{50} 205 mg/kg bw). However, the toxicity via dermal route was low (LD_{50} > 2000 mg/kg bw). It is neither a skin nor an eye irritant nor a skin sensitizer, proposed risk phrases are: T, R23 "Toxic by inhalation" and R22 "Harmful if swallowed" The critical effects are cholinesterase inhibition. And the dog was the most sensitive species. The relevant short term NOAEL is 1 mg/kg bw/day. It is not mutagenic, genotoxic or carcinogenic. The long term NOAEL is 5.5 mg/kg bw/day in the rat based on clinical signs and inhibition of brain acetylcholine esterase activity.

Effects on reproduction parameters were observed such as, decreased male fertility, number of live pups and pup weight was decreased, even the entire second generation was lost The parental toxicity observed at this dose level was not severe, decreased body weight (around 10 %) and increased food consumption (around 20 %).The parental as well as reproductive including embryotoxic NOAEL is 25 ppm i.e. 1.2 mg/kg bw/day. The appropriate classification for reproduction toxicity could not be agreed and the question should be forwarded to ECB, R62 is high lighted. ECB has concluded R62 "possible risk of impaired fertility" and this decision was included in the Commission Directive 2009/2/EC of 15 January 2009.

The main metabolite of benfuracarb is the active ingredient carbofuran which is more toxic than benfuracarb and presents a lower ADI and ARfD of 0.00015 mg/kg bw/day. The relevant impurity 1,2 dichloroethane, is classified as toxic, Carcinogenic Category 2 (T; R45).

The Acceptable Daily Intake (ADI) of benfuracarb is 0.01 mg/kg bw/day, based on the NOAELs of 1.2 mg/kg bw /day in the 13-week feeding study in dogs, and the NOAEL of 1.2 mg/kg bw/d in the 2-generation rat study mean 1 mg/kg bw/d, with the safety factor of 100 applied.

The Acceptable Operator Exposure Level (AOEL) is 0.01 mg/kg bw/day based on the overall NOAEL of 1 mg/kg bw/d dogs, with a safety factor of 100.

The Acute Reference Dose (ARfD) is 0.02 mg/kg bw/day based on the NOAEL of 1.81 mg/kg bw/day in the 28-day neurotoxicity study in rat, with the safety factor of 100 applied**.**

The default value of 100 % was agreed on for the granular formulation Oncol 8.6 G no studies were provided by the applicant.

The estimated operator exposure according to the US PHED model is below the AOEL (86 %) if personal protective equipment as well as respiratory equipment is used.

The metabolism, distribution and residue behaviour of benfuracarb was investigated in various crops with different methods of application and at different timings.

As for the evaluation of the notified use in brassicas the studies on cabbage and sugar beet with soil application were the most relevant metabolism data. On the basis of these studies it could be concluded that the degradation of benfuracarb in plants with soil treatment consisted primarily of the N-S bond cleavage into carbofuran followed by hydroxylation or hydrolysis and oxidation steps to yield 3-hydroxy-carbofuran and phenol metabolites of carbofuran. All metabolites may also be present as conjugates. However, differences were noted with regard to the amounts of conjugates of metabolites in cabbage and sugar beet. Upon consideration of an evaluation by the JMPR 1997 on other soil treated crops, the experts agreed to include also conjugates of carbofuran and 3-hydroxy-carbofuran in the residue definition for consumer risk assessment. Thus, benfuracarb, carbofuran and 3-hydroxy-carbofuran, both free and conjugated were considered the relevant residues to assess consumer exposure and consumer risk.

In residue trials under field conditions, the residue levels of benfuracarb, carbofuran and 3-hydroxy-carbofuran were determined in cauliflower, broccoli, head cabbage, leafy cabbage and kale. However, given occasional findings of residues above the LOQ in flowering and leafy brassicas, and the fact that the applied method of analysis did not analyse for the full residue definition for risk assessment, the experts in the meeting TC05 agreed that further residue trial data is required for a robust data base and a conclusive exposure assessment. If with their notification on brassicas the applicant intended a use in the category of brassica vegetables, residue trials on kohlrabi will also be required.

Furthermore the experts concluded that it is necessary to also address residues in succeeding crops, due to the behaviour of carbofuran in soil and due to indication from the JMPR evaluation 1997 that residues above LOQ could occur in rotated crops.

Sound occurrence data are considered particularly relevant in the light of very low toxicological reference values for carbofuran and 3-hydroxy-carbofuran, because even very low residues of these compounds in crops may result in an intake concern for the consumer.

From a study with lactating goats it was concluded that benfuracarb and its metabolites are unlikely to accumulate in edible animal tissues and no significant total residues are expected to occur when brassica crops are fed to livestock.

Due to their different toxicological endpoints the consumer risk has been separately assessed for benfuracarb residues and for carbofuran and 3-hydroxy-carbofuran residues. The estimated chronic and acute dietary intake of benfuracarb was found to be below the toxicological reference values for benfuracarb. Since residue data on the full residue definition for risk assessment and on rotated crops are still required with regard to carbofuran and 3-hydroxy-carbofuran residues, the consumer risk assessment cannot be finalised.

In a provisional assessment, the estimated chronic dietary intake of the benfuracarb metabolites carbofuran and 3-hydroxy-carbofuran was found to be below the ADI of carbofuran. However, an acute exposure concern was identified for adults and children (up to 396% of carbofuran ARfD) consuming leafy and flowering brassica. These estimates are based on residue values obtained in residue trials. Also for head brassica it is difficult to demonstrate conclusively that there is no risk for the consumer even though residues in the available trials were below the LOQ. Depending on the variability factor used in the estimates the ARfD may be exceeded for head cabbage. Furthermore, the number of available trials in head cabbage is limited and conjugates of carbofuran and 3-hydroxy-carbofuran were not determined. Further data has been considered necessary to enable a more robust consumer exposure assessment and eventually consumer risk assessment.

It should also be noted that with the predicted concentrations of carbofuran in groundwater a significant acute and chronic exposure of the consumer is expected through the consumption of drinking water derived from groundwater, if any restriction to mitigate groundwater exposure were not effective. The predicted concentrations in the most vulnerable scenarios may even lead to the exceedance of the toxicological reference values.

The information available on the fate and behaviour in the environment (including the information available only in the EFSA addendum) is sufficient to carry out an appropriate environmental exposure assessment at the EU level. For the applied for intended uses, the potential for groundwater exposure by benfuracarb and the minor soil metabolites 3-hydroxy-carbofuran and 3-keto-carbofuran above the parametric drinking water limit of 0.1 µg/L, is low. However, for the metabolite carbofuran (which is a pesticide itself and therefore considered as relevant for groundwater), in geoclimatic regions represented by the FOCUS groundwater scenarios available for cabbage, contamination of groundwater above the 0.1 µg/L limit cannot be excluded. The only exception is FOCUS Sevilla scenario, where the simulated PEC_{GW} was <0.1 µg/L.

Carbofuran is > 0.1 µg/L in six out of seven FOCUS ground water scenarios from the applied for intended use assessed. Predicted concentration is up to 3.1 µg/L.

Data gaps were identified to address further the risk to birds and mammals for the uptake of contaminated seedlings and earthworms. The granules need to be covered by soil to mitigate the risk to birds from uptake of granules. A high risk to the aquatic environment cannot be excluded for environmental conditions represented by the FOCUS scenarios D3, D4 stream and D6. Only the part scenario D4 (pond) resulted in TERs above the Annex VI trigger values. The risk from run-off

(represented by the FOCUS scenarios R1, R2, R3, R4) was assessed as low if the granules were incorporated at a soil depth of at least 2.5 cm.

The risk to bees from exposure to residues in cabbage was assessed as low since cabbage has no flower in the production crop. A high risk to bees cannot be excluded if the product is to be applied on flowering brassicas attractive to bees (e.g. oilseed rape). The potential risk to bees from residues in flowering weeds should be assessed at Member State level taking into account the agricultural practice (management of weeds in cabbage fields). The experts proposed labelling with SPe8 to avoid exposure from flowering weeds. Data gaps remain with regard to the risk to soil dwelling arthropods (*Aleochara bilineata*) and earthworms.

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

- Personal as well as respiratory protective equipment is needed for operators (20 ha/day is considered), see 2.12.
- The method of application should be restricted to furrow application, where the granules are placed directly in the planting row (to at least 2.5 cm below the soil surface) and then the furrows are covered by the soil (in order to mitigate the risk to aquatic organisms and birds).
- The potential risk to bees from residues in flowering volunteer plants should be assessed at Member State level taking into account the agricultural practice (management of weeds in cabbage fields). Labelling with SPe8 was proposed (refer to point 5.3).

Critical areas of concern

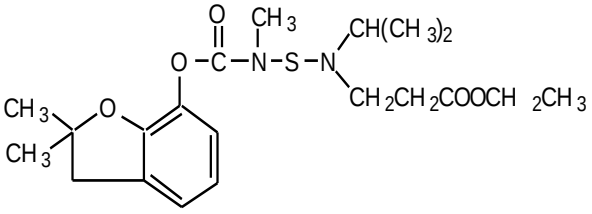
- The consumer risk assessment can not be finalised due to a lack of data.
  - Residue data according to the residue definition for risk assessment i.e. including conjugates of carbofuran and 3-hydroxy-carbofuran are not available and the submitted residue trial data may therefore underestimate exposure. With the available data, an acute intake concern has been identified for the representative use in brassicas.
  - Moreover, residues are not addressed in succeeding crops. There are indications that residues may occur in those crops and lead to an exceedance of the acute reference dose depending on the contribution of the crop in the human diet.
- Very high potential for groundwater contamination by the relevant benfuracarb metabolite carbofuran over a broad range of geoclimatic conditions (as represented by six out of seven FOCUS groundwater scenarios).
- If consumers were exposed to the predicted levels of carbofuran in ground water because any restriction to mitigate groundwater contamination were not effective, this could result in a significant consumer intake which may even exceed the allocated toxicological reference values (in two of the presented FOCUS groundwater scenarios).
- A high risk to birds and mammals from uptake of contaminated seedlings and earthworms.
- The risk to birds from uptake of contaminated drinking water needs to be addressed further (the first-tier TER was calculated as 1.62).
- Data gaps remain with regard to the risk assessment for earthworms and soil dwelling arthropods (*Aleochara bilineata*).

APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

(Abbreviations used in this list are explained in appendix 2)

Appendix 1 - List of end points (based on EPCO Manual D4, rev. 0, 21.11.2003)

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

Active substance (ISO Common Name) ‡	Benfuracarb
Function (*e.g.* fungicide)	Insecticide, nematicide
Rapporteur Member State	Belgium
Co-rapporteur Member State	none
Identity (Annex IIA, point 1)	
Chemical name (IUPAC) ‡	Ethyl *N*-[2,3-dihydro-2,2-dimethylbenzofuran-7-yloxycarbonyl(methyl)aminothio]-*N*-isopropyl-β-alaninate
Chemical name (CA) ‡	2,3-dihydro-2,2-dimethyl-7-benzofuranyl 2-methyl-4-(1-methylethyl)-7-oxo-8-oxa-3-thia-2,4-diazadecanoate
CIPAC No ‡	501
CAS No ‡	82560-54-1
EC No (EINECS or ELINCS) ‡	Not assigned
FAO Specification (including year of publication) ‡	Not available
Minimum purity of the active substance as manufactured ‡	930 g/kg (commercial plant)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	1,2-dichloroethane (EDC) - max. 4 g/kg
Molecular formula ‡	$C_{20}H_{30}N_2O_5S$
Molecular mass ‡	410.5 u
Structural formula ‡	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	No freezing point/freezing range can be determined (98.1%)
Boiling point (state purity) ‡	No boiling point below 190 °C (98.7%)
Temperature of decomposition (state purity)	Thermal decomposition above 200 °C (98.7%)
Appearance (state purity) ‡	Pale yellow, slightly viscous oil; no characteristic odour (98.7%)
Vapour pressure (state temperature, state purity) ‡	4.2×10^{-6} Pa at 25 °C (98.1%)
Henry's law constant ‡	2.1×10^{-4} $Pa.m^3.mol^{-1}$ at 20 - 25 °C
Solubility in water (state temperature, state purity and pH) ‡	pH 4, 20 °C: ca 8 mg/L (no accurate measurement due to hydrolytical instability) (98.3%)
	pH 7, 20 °C: 8.4 mg/L pH 10, 20 °C: 8.4 mg/L
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20 °C (g/L) (98.7%) hexane > 1000 xylene > 1000 dichloromethane > 1000 ethanol > 1000 acetone > 1000 ethyl acetate > 1000
Surface tension ‡ (state concentration and temperature, state purity)	52.4 mN/m at 20 °C (90% saturated solution) (93.3%)
Partition co-efficient ‡ (state temperature, pH and purity)	Determined value : pH ≈ 6.3, 25 °C: 4.22 (99.9%) no effect of pH calculated values : 4.37 (ClogP software) 4.06 (EPISUITE model, version 3.11)
Dissociation constant (state purity) ‡	Not applicable (no dissociation in water)
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	(98.7%) In neutral methanol: λ_{max} 277.5 - 281.5 nm; $\varepsilon = 3.36 \times 10^3$ $L.mol^{-1}.cm^{-1}$ at λ 290 nm : $\varepsilon = 6.14 \times 10^2$ $L.mol^{-1}.cm^{-1}$ in acidic and basic methanol: no significant difference in spectra
Flammability ‡ (state purity)	Flash point = 154.5 °C (93.4%) auto-ignition temperature = 370 °C (93.3%)
Explosive properties ‡ (state purity)	No explosive properties (theoretical consideration)
Oxidising properties ‡ (state purity)	No oxidising properties (theoretical consideration)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Summary of representative uses evaluated (*benfuracarb*)*

Crop and/ or situation (a)	Member State, Country or Region	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 (l) min – max	water L/ha min – max	kg as/ha (l) min – max		
Brassicas [1]	EU Member States	ONCOL 8.6G	*F*	*Plutella xylostella* and *Brevicoryne brassicae*	*GR*	86 g/kg	**	at transplan-ting	1	not applicable	not applica-ble	not applica ble	1.0	not applica ble	** Apply the granules homogeneously distributed over the planting row with microgranule applicator (in furrow application and soil incorporation) [2]

[1] Data was submitted on head, flowering and leafy brassica vegetables and this was evaluated in the DAR.
[2] A high risk was identified in sections 3 and 5.

* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).	(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(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)	(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
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)	(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds	(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
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(m) PHI - minimum pre-harvest interval
(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	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Methods of Analysis

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

Technical as (analytical technique)	CIPAC Method 501/TC/(M)/3: HPLC-UV (ISTD)
Impurities in technical as (analytical technique)	HPLC-UV 1,2-dichloroethane by GC-MS
Plant protection product (analytical technique)	HPLC-UV; CIPAC Method 501/GR/(M)/3: HPLC-UV (ISTD) 1,2-dichloroethane by GC-FID

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Benfuracarb Carbofuran + 3-hydroxy-carbofuran (expressed as carbofuran equivalents)
Food of animal origin		Not applicable
Soil (and sediment)		Carbofuran
Water	surface	Benfuracarb, carbofuran
	drinking/ground	Carbofuran
Air		Benfuracarb, carbofuran

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	UPLC-MS/MS <u>Brassica:</u> LOQ = 0.05 mg/kg (benfuracarb) LOQ = 0.0015 mg/kg (carbofuran) LOQ = 0.003 mg/kg (3-hydroxy-carbofuran)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not required (no MRL's proposed)
Soil (analytical technique and LOQ)	LC-MS/MS (carbofuran, 3-hydroxy-carbofuran, 3-keto-carbofuran, carbofuran-phenol); LOQ = 0.01 mg/kg
Water (analytical technique and LOQ)	GC-MS (benfuracarb) and LC-MS/MS (carbofuran, carbofuran-phenol); LOQ = 0.1 µg/L (for each analyte)
Air (analytical technique and LOQ)	Not required (vapour pressure is very low and application techniques (i.e. granular formulation to be incorporated in soil) are such that no relevant exposure is likely to occur)
Body fluids and tissues (analytical technique and LOQ)	LC-MS/MS (carbofuran); LOQ = 50 µg/L (fluids), 0.1 mg/kg (tissues)

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

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Active substance	None

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Impact on Human and Animal Health

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

Rate and extent of oral absorption ‡	Relatively rapid, 70-81 % based on levels in urine within 144 h (rats, 6.7 or 40 mg/kg bw)
Distribution ‡	Large, highest level in excretory organs and carcass
Potential for accumulation ‡	No evidence of accumulation
Rate and extent of excretion ‡	Extensively excreted, 66-76 % in urines; 10-12 % in faeces within 48 h
Metabolism in animals ‡	Extensive; Benfuracarb breaks down to carbofuran, which is further hydroxylated/oxidated into 3-keto-carbofuran-phenol, 3-hydroxy-carbofuran, 3-hydroxy-carbofuran-phenol, carbofuran-phenol
Toxicologically relevant compounds ‡ (animals and plants)	Benfuracarb and metabolites with the carbamate moiety, such as carbofuran
Toxicologically relevant compounds ‡ (environment)	Benfuracarb and metabolites with the carbamate moiety, such as carbofuran and 3-hydroxy-carbofuran

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	205 mg/kg bw	**Xn; R22**
Rat LD_{50} dermal ‡	> 2000 mg/kg bw	
Rat LC_{50} inhalation ‡	0.344 mg/L air/4 h (nose only as liquid droplet aerosol)	**T; R23**
Skin irritation ‡	Non-irritant	
Eye irritation ‡	Non-irritant	
Skin sensitisation ‡	Non-sensitizer (M&K test)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Clinical signs of neurotoxicity, inhibition of acetyl cholinesterase, thymus involution (dogs)	
Relevant oral NOAEL ‡	Overall: 1 mg/kg bw/day (13-week ; 6-month and 12-24 month dog)	
Relevant dermal NOAEL ‡	5 mg/kg bw/day (28-day, rat)	
Relevant inhalation NOAEL ‡	No data - not relevant	

Genotoxicity ‡ (Annex IIA, point 5.4)

Negative *in vitro* and *in vivo*	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

Target / critical effect ‡	Clinical signs of neurotoxicity, acetylcholinesterase inhibition (rat)	
Relevant NOAEL ‡	5.5 mg/kg bw/day, 104-week, rat	
Carcinogenicity ‡	No carcinogenic potential	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Reduced pregnancy rate and male fertility indices, reduced pup survival.	**Repr. Cat. 3, R62**
Relevant parental NOAEL ‡	1.2 mg/kg bw/day	
Relevant reproductive NOAEL ‡	1.2 mg/kg bw/day	
Relevant offspring NOAEL ‡	1.2 mg/kg bw/day	

Developmental toxicity

Developmental target / critical effect ‡	Delayed or incomplete ossification and delayed foetal weight (rat). Reduced foetal weight and abortions (rabbit)	
Relevant maternal NOAEL ‡	Rabbit: 15 mg/kg bw/day Rat: 2 mg/kg bw/day	
Relevant developmental NOAEL ‡	Rabbit: 10 mg/kg bw/day Rat: 10 mg/kg bw/day	

Neurotoxicity (Annex IIA, point 5.7)

Short term neurotoxicity ‡	1.81 mg/kg bw/day, 28-day rat	
Delayed neurotoxicity ‡	No delayed neuropathy in hens LD_{50} 92 mg/kg bw	

Other toxicological studies (Annex IIA, point 5.8)

Metabolites

The information presented on carbofuran and other metabolites was agreed on in the context of the assessment of the active substance carbofuran (peer review 2005), and revised in the Peer review in January 2009. Further details are given in the EFSA conclusion on carbofuran

Carbofuran

Acute toxicity	Rat LD_{50} oral: 7 mg/kg bw	**T+; R28**
	Rabbit LD_{50} dermal: 1000 - 2000 mg/kg bw	**Xn; R21**

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	Rat LC_{50} inhalation: 0.05 mg/L air/4 h (nose only)	**T+; R26**
	Skin irritation: non- irritant	
	Eye irritation: non- irritant, but mortality reported (rabbits)	**T; R39/41**
	Skin sensitization: Non-sensitizer (Buehler and M&K)	
Short term toxicity (carbofuran)	Target / critical effect: testicular degeneration (dog, – not reproducible in a more recent study in rat), clinical signs of neurotoxicity related to AChE inhibition (rat and dogs) Relevant oral NOAEL: 0.1 mg/kg bw/day, 1-year dog and 60-day, rat Relevant dermal NOAEL: 25 mg/kg bw/day, 21-day rabbit Relevant inhalation NOAEL: No study available	
Genotoxicity (carbofuran)	Positive results in bacterial tests; negative in *in vivo* tests	
Long term toxicity and carcinogenicity (carbofuran)	Target / critical effect: Body weight and AChE inhibition Relevant NOAEL: 0.462 mg/kg bw/day, 2-year rat Carcinogenicity: No carcinogenic potential	
Reproductive toxicity (carbofuran)	Reproduction target / critical effect: Reduced litter parameters in rat multigeneration study; Testicular and sperm toxicity at parental toxic doses. Relevant parental, reproductive and offspring NOAEL: 1.2 mg/kg bw/day	
	Developmental target / critical effect: Foetotoxicity and developmental neurotoxicity at maternal toxic doses (rat). Relevant maternal NOAEL: Rat: 0.1 mg/kg bw/day Rabbit: 0.5 mg/kg bw/day Relevant developmental NOAEL: Rat: 1 mg/kg bw/day Rabbit: 0.5 mg/kg bw/day	

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Neurotoxicity / delayed neurotoxicity (carbofuran)	Delayed neurotoxicity: No delayed neuropathy in hens NOAEL neurotoxicity 0.5 mg/kg bw Subchronic neurotoxicity test: 3.2 mg/kg bw/day, 13-week rat Acute neurotoxicity studies in rats (add Jan 2009): brain AChE inhibition, LOAEL pups 0.03 mg/kg bw, NOAEL adults 0.03 mg/kg bw	
ADI (carbofuran)	0.00015 mg/kg bw/day (acute neurotoxicity study in rat (pups), SF: 200)	
ARfD (carbofuran)	0.00015 mg/kg bw (acute neurotoxicity study in rat (pups), SF: 200)	
3-hydroxy-carbofuran:	Rat LD_{50} oral: 8.3 mg/kg bw Positive in Ames test strain TA1537 with S9 mix Positive in TK locus in L5178Y mouse lymphoma cells with and without S9 mix	**T+, R28**
3-keto-carbofuran:	Rat LD_{50} oral: 107 mg/kg bw	**T, R25**
3-hydroxy-carbofuran-phenol:	Rat LD_{50} oral: 1654 mg/kg bw	**Xn, R22**
3-keto-carbofuran-phenol:	Rat LD_{50} oral: > 800 mg/kg bw	**Xn, R22**
Carbofuran-phenol:	Rat LD_{50} oral: 1743 mg/kg bw Negative in Ames test	**Xn, R22**

Medical data ‡ (Annex IIA, point 5.9)

Medical examination of workers participating in the manufacturing process of benfuracarb did not display any adverse signs or symptoms.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI benfuracarb ‡	0.01 mg/kg bw/day	Overall NOAEL in dogs, 2-generation rat studies	100
AOEL benfuracarb ‡	0.01 mg/kg bw/day	Overall NOAEL in dogs, 2-generation rat studies	100
ARfD benfuracarb‡	0.02 mg/kg bw	28-day, rat neurotoxicity study	100

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Dermal absorption ‡ (Annex IIIA, point 7.3)

Oncol 8.6G	No studies are available. Default value of 100% based on physical chemical properties applied.

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Estimated exposure (% of the AOEL) is performed with the PHED model. The maximum application rate is 1 kg/ha, work rate 20 ha/day and body weight 60 kg.

	PPE (gloves)	PPE+RPE
75th percentile	148 %	86 %
95th percentile	371 %	235 %

Workers	Soil incorporation: no worker exposure
Bystanders	Soil incorporation : no exposure

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

	RMS/peer review proposal
Substance classified (benfuracarb)	**T** "Toxic **R22** "Harmful if swallowed **R23** "Toxic by inhalation **Repr. Cat. 3; R62** "Possible risk of impaired fertility"

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

Plant groups covered	Additional report 2008: Cabbage, sugar beet (soil application) JMPR report 1997: Potatoes, soya beans and maize(soil application). Metabolism data provided for information -Cotton, bush beans, corn (leaf painting and stem injection) -Potatoes, apples (foliar application)
Rotational crops	No data submitted – Based on laboratory and field studies 10% of the total pertinent residue (bio available from soil) could still be present in soil at 100 days. Adverse information was also found in the JMPR evaluation 1997. Further data are required.
Metabolism in rotational crops similar to metabolism in primary crops?	Open
Processed commodities	No data - Not required according to current guidance
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Not applicable
Plant residue definition for monitoring	-Benfuracarb, -Carbofuran + 3-hydroxy-carbofuran expressed as carbofuran equivalents.
Plant residue definition for risk assessment	-Benfuracarb, -Carbofuran + 3-hydroxy-carbofuran, both free and conjugated expressed as carbofuran.
Conversion factor (monitoring to risk assessment)	To be determined according to new residue trials performed in compliance with the new DOR for risk assessment.

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

Animals covered	Lactating goats
Time needed to reach a plateau concentration in milk and eggs	2 days after first dosing.
Animal residue definition for monitoring	No residue definition in animal matrices could be drawn based on the available metabolism data in ruminants.
Animal residue definition for risk assessment	No residue definition in animal matrices could be drawn based on the available metabolism data in ruminants.
Conversion factor (monitoring to risk assessment)	None

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Metabolism in rat and ruminant similar (yes/no)	No conclusion could be drawn due to a lack of metabolites identification in the metabolism study on lactating goats.
Fat soluble residue: (yes/no)	Yes.

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

No data submitted– however adverse data provided in the JMPR report 1997 that indicate residues of carbofuran above the LOQ may occur in all rotational crops. Further data are required.

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

Benfuracarb residues: 306 days in cauliflower and cabbage, 177 days in maize (frozen storage conditions, -20°C). Carbofuran: 306 days in cauliflower and cabbage, 177 days in maize (frozen storage conditions, -20°C). 3-hydroxy-carbofuran: 300-302 days in cauliflower and cabbage, 176 days in maize (frozen storage conditions, -20°C). All the trials used for MRL setting were characterized by a maximum period of frozen storage of 56 days.

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* only for Benfuracarb residues assumed at LOQ in cabbage. (0.126 mg/kg diet DM)	No	No
Muscle	-	-	-
Liver	-	-	-
Kidney	-	-	-
Fat	-	-	-
Milk	-	-	-
Eggs	-	-	-

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

*: No ruminant feeding study was provided and was not required even if the first criterion to require a feeding
study was fulfilled (significant residues ≥ 0.1 mg/kg of total diet – occurred in the crops fed to animals). In fact,
the metabolism study in lactating goats demonstrated that no significant total residues (<0.01 mg/kg) occurred in milk and edible tissues taking into account the calculated dietary burden.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

Crop	Northern or Mediterranean Region, field or glasshouse, and any other useful information	Trials results relevant to the representative uses [1] (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
Cauliflower (Flowering brassica)	NE	*Benfuracarb :* 3x<0.05 *Carbofuran:* 3x 0.0015 *3-hydroxy-carbofuran:* 3x<0.003 *Carbofuran + 3-hydroxy-carbofuran expressed as carbofuran:*3X<0.0045 mg/kg	Trials performed in accordance with the critical GAP. Not performed according to DOR for risk assessment. Data gap for further trials	*Flowering brassica* *Benfuracarb*: 0.05* mg/kg *Carbofuran + 3-hydroxy-carbofuran expressed as carbofuran:* 0.01 mg/kg.	*Benfuracarb*: 0.05 mg/kg *Carbofuran + 3-OH-carbo-furan expressed as carbofuran:* 0.01 mg/kg	-
	SE	*Benfuracarb :2x* <0.005; <0.05 *Carbofuran:* 2x 0.0015 *3-hydroxy-carbofuran:*-<0.003; <0.005 *Carbofuran + 3-hydroxy-carbofuran expressed as carbofuran:* <0.0045; <0.065 mg/kg				
Broccoli (Flowering brassica)	NE	*Benfuracarb :* 2x<0.05 *Carbofuran:*<0.0015, 0.0071 *3-hydroxy-carbofuran:* <0.003; 0.0032 *Carbofuran + 3-hydroxy-carbofuran expressed as carbofuran:* <0.0045; <0.0101 mg/kg	Trials performed in accordance with the critical GAP. Not performed		*Benfuracarb*: 0.05 mg/kg *Carbofuran + 3-OH-carbo-furan*	-

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	SE	*Benfuracarb :* 2x<0.05 *Carbofuran* 2x <0.0015 *3-hydroxy-carbofuran* 2x <0.003 *Carbofuran + 3-hydroxy-carbofuran expressed as carbofuran:*2x<0.0045 mg/kg	according to DOR for risk assessment. Data gap for further trials		*expressed as carbofuran:* 0.0101 mg/kg	
Head cabbage (Head brassica)	NE	Findings : *Benfuracarb :* 3x<0.05 mg/kg *Carbofuran* 3x <0.0015 *3-hydroxy-carbofuran* 3x <0.003 *Carbofuran + 3-hydroxy-carbofuran expressed as carbofuran:* 3x<0.0045 mg/kg	Trials performed in accordance with the critical GAP. Not performed according to DOR for risk assessment. Data gap for further trials	*Head brassica* *Benfuracarb*: 0.05* mg/kg *Carbofuran + 3-hydroxy-carbofuran expressed as carbofuran:* 0.01* mg/kg.	*Benfuracarb*: 0.05 mg/kg *Carbofuran + 3-OH-carbo-furan expressed as carbofuran:* 0.0043 mg/kg	-
	SE	*Benfuracarb :* 4x<0.05 mg/kg *Carbofuran* 4x <0.0015 *3-hydroxy-carbofuran* 4x <0.003 *Carbofuran + 3-hydroxy-carbofuran expressed as carbofuran:* 4x<0.0045 mg/kg				
Kale (Leafy Brassica)	NE	*Benfuracarb :* 3x<0.05mg/kg *Carbofuran* 3x <0.0015 *3-hydroxy-carbofuran* 2x <0.003; 0.0072 *Carbofuran + 3-hydroxy-carbofuran expressed as carbofuran:* 2x<0.0045, 0.0082 mg/kg	Trials performed in accordance with the critical GAP. Not performed according to DOR for risk assessment. Data gap for further trials in leafy brassica.	*Kale* *Benfuracarb*: 0.05* mg/kg *Carbofuran + 3-hydroxy-carbofuran expressed as carbofuran:* 0.01 mg/kg.	*Benfuracarb*: 0.05 mg/kg *Carbofuran + 3-OH-carbo-furan expressed as carbofuran:* 0.0082 mg/kg	-
	SE	No trial was submitted.	Data gap for further trials in leafy brassica.			

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Leafy cabbage (Leafy brassica)	NE	No trial was submitted.	Data gap for further trials in leafy brassica.	*Leafy cabbage* *Benfuracarb*: 0.05* mg/kg *Carbofuran + 3-hydroxy-carbofuran expressed as carbofuran:* 0.01 mg/kg.	*Benfuracarb*: 0.05 mg/kg *Carbofuran + 3-OH-carbo-furan expressed as carbofuran:* 0.0043 mg/kg	-
	SE	*Benfuracarb :* 3x<0.05mg/kg *Carbofuran* 3x <0.0015 *3-hydroxy-carbofuran* 3x <0.003 *Carbofuran + 3-hydroxy-carbofuran expressed as carbofuran:* 3x<0.0045 mg/kg	Trials performed in accordance with the critical GAP. Not performed according to DOR for risk assessment. Data gap for further trials in leafy brassica.			
No trials available on kohlrabi. If the applicant intended a use in the whole category of brassica vegetables, residue trials on kohlrabi will be required.						

(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

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

a) Benfuracarb

ADI	0.01mg/kg bw/day
TMDI (% ADI) according to WHO European diet	/
TMDI (% ADI) according to national (to be specified) diets	/
IEDI (WHO European Diet) (% ADI)	/
NEDI (specify diet) (% ADI)	/
Factors included in IEDI and NEDI	/
ArfD	0.02 mg/kg bw/day
IESTI (% ARfD)	/
NESTI (% ARfD) according to national (to be specified) large portion consumption data	/
Factors included in IESTI and NESTI	/
TMDI (% ADI) according to EFSA model rev.2a	**The highest calculated TMDI value in % of the ADI is 0.6 % for the NL child.**
IESTI (% ARfD) according to EFSA model rev.2a	There is no commodity for which the ARfD value is exceeded (highest % of the ARfD : 16.9 % of the ARfD for kale).

b) Carbofuran and 3-hydroxy-carbofuran expressed as carbofuran equivalents

Note: Provisional assessment. Consumer risk assessment can not be finalised due to lack of data (definition of residue including conjugates and contribution of the rotational crops not taken into account).

ADI	0.00015 mg/kg bw/day
TMDI (% ADI) according to WHO European diet	/
TMDI (% ADI) according to national (to be specified) diets	/
IEDI (WHO European Diet) (% ADI)	/
NEDI (specify diet) (% ADI)	/
Factors included in IEDI and NEDI	/
ArfD	0.00015 mg/kg bw/day
IESTI (% ARfD)	/
NESTI (% ARfD) according to national (to be specified) large portion consumption data	/

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Factors included in IESTI and NESTI	/
TMDI (% ADI) according to EFSA model rev.2a	**The highest calculated TMDI value in % of the ADI is 5.7 % for the NL child.**
IESTI (% ARfD) according to EFSA model rev.2a	-Broccoli: 396 % ARfD (children) -Kale:387 % ARfD (children) -Cauliflower: 286 % ARfD (children) -Head cabbage: 157 % ARfD (children) (variability factor : 5) -Head cabbage: 95 % ARfD (children) (variability factor : 3) **Note:** The chronic and acute risk assessments were performed using the LOQ/HR according to the previous residue definition for risk assessment, i.e. Sum of carbofuran and 3-hydroxy-carbofuran expressed as carbofuran equiv.

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)
Not applicable..

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

Note: With this MRL proposal for **Carbofuran** an acute risk for consumers will be identified.

Crops	**Expression of the residue**	**MRLs (mg/kg)**
Flowering brassica	**Benfuracarb**	0.05*
	Carbofuran (Carbofuran + 3-hydroxy-carbofuran expressed as Carbofuran equivalents)	0.01

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Head brassica	**Benfuracarb**	0.05*
	Carbofuran (Carbofuran + 3-hydroxy-carbofuran expressed as Carbofuran equivalents)	0.01*
Leafy brassica	**Benfuracarb**	0.05*
	Carbofuran (Carbofuran + 3-hydroxy-carbofuran expressed as Carbofuran equivalents)	0.01

No data available to propose an MRL for kohlrabi.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

Benfuracarb	
Mineralization after 100 days ‡	27.7-66.6% % after 120 d, [^{14}C-ring]-label (n= 4) (20°C)
Non-extractable residues after 100 days ‡	37.6-74.1% after 120 d, [^{14}C-ring]-label (n= 4) (20°C)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Carbofuran: max level of 84.6 % at 2 d [^{14}C-ring]-label (n = 4) (20°C)
Carbofuran	
Mineralization after 100 days ‡	26.9-66.3% after 120 d, [14C-ring]-label (n= 4) (20°C)
Non-extractable residues after 100 days ‡	23.9-57.7% after 120 d, [14C-ring]-label (n= 4) (20°C)
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	EPCO 31 agreed that the minor (< 10% AR) metabolites of 3-hydroxy-carbofuran and 3-keto-carbofuran need to be further assessed as carbofuran metabolites containing the active carbamate moiety.

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

Anaerobic degradation ‡	Benfuracarb: not required Carbofuran : Mineralisation 2.4-6.1 % after 120 d Non-extractable residues 56.4-62.7% after 120 d Major metabolite: carbofuran-phenol, max level of 62.9 % at 28 d Minor metabolites: M4 (was shown to be highly polar and to contain several fractions), M9, M11 and M12. [^{14}C-ring]-label
Soil photolysis ‡	Benfuracarb: no data available and not required. Carbofuran: photolytically stable on soil surface. No photodegradation product.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

Laboratory studies ‡

Benfuracarb	Aerobic conditions						
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d)** 20°C pF2/10kPa	St. (χ^2)	Method of calculation
Sandy loam		5.8*	20/40	0.04/1.46	0.44	-	FOMC
Loam		7.1*	20/40	0.14/0.85	0.23	-	FOMC
Clay		6.7*	20/40	0.54/3.05	0.46	-	FOMC
Clay loam§		7.9#	20/45	2.2/20	0.24	0.7	FOMC
Sandy loam		6.5*	20/40	0.38/4.57	1.17	-	FOMC
Clay loam§		7.9#	10/45	0.44/1.47	-	-	SFO
Geometric mean					0.42		

* in $CaCl_2$; # in water; § performed in same soil during the same experiment.
** values calculated by dividing the FOMC DT_{90} by the factor of 3.32

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

Laboratory studies

Carbofuran	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50} (d)	f. f. k_f/k_{dp}	DT_{50} (d) 20°C pF2/10kPa	St. (X^2)	Method of calculation
Carbofuran as test item								
Sandy loam		5.7	25/75% FC	13.72	-	17.87	7.9	SFO
Silt loam		5.8	20/40	14.75	-	14.01	10.3	SFO
Silt loam			10/40	86.36	-	-	3.1	SFO
Sandy loam		6.5	20/40	8.97	-	7.71	14.8	SFO
Clay loam		7.5	20/40	14.12	-	13.56	8.5	SFO
Loam		5.7	20/40	19.17	-	17.25	2.1	SFO
Sandy loam		5.7	25/75% FC at 1/3 bar	307	-	151	2.6	SFO
Sandy loam		7.7	25/75% FC at 1/3 bar	111	-	54.6	9.1	SFO
Sandy loam		7.1	25/82% FC	362	-	387	1.4	SFO
Carbofuran as metabolite of carbosulfan								
Sandy loam		5.8	20/40	6.92	-	6.92	13.8	SFO
Silt loam		7.1	20/40	11.61	-	9.39	21.1	SFO
Loam		7.3	20/40	13.04	-	11.46	7.8	SFO
Loam		7.2	20/40	25.99	-	22.54	14.8	SFO
Silt loam		6.1	23/(60% FC)	17.47	-	22.19	4.4	SFO

[1] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.
‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Carbofuran as metabolite of benfuracarb								
Sandy loam	-	6.5	20/40	6.70	0.91	5.70	20.1	SFO
Sandy loam	-	5.8	20/40	20.39	0.79	20.39	15.9	SFO
Loam	-	7.1	20/40	11.42	0.83	10.39	15.7	SFO
Clay	-	6.7	20/40	23.38	0.91	11.69	16.8	SFO
Overall median						14.01		

3-hydroxy-carbofuran	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
loamy sand			20/40	<1/<1		<1	na	graphical
sandy loam		6.3*	20/40	0.27/0.88	-	0.22	1.0	SFO
sandy clay		6.9*	20/40	0.51/1.70	-	0.3	1.0	SFO
Geometric mean						0.41		

* in $CaCl_2$

3-keto-Carbofuran	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation
loamy sand			20/40	4.41/14.6		4.41	0.994	SFO
sandy loam		6.3*	20/40	8.12/27.0	-	6.65	0.984	SFO
sandy clay		6.9*	20/40	1.54/5.13	-	0.9	0.998	SFO
Geometric mean						3.01		

* in $CaCl_2$

Carbofuran-phenol	Aerobic conditions							
Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20°C pF2/10kPa	St. (r^2)	Method of calculation

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

loamy sand			20/40	<1/<1		<1	na	graphical
sandy loam		6.3*	20/40	<1/<1	-	<1	na	graphical
sandy clay		6.9*	20/40	<1/<1	-	<1	na	graphical
Geometric mean						1		

* in $CaCl_2$

Field studies ‡

Benfuracarb	Not required
Carbofuran	European sites (NL, ES, IT): DT50f: 1.3-27 days, DT90f: 4.4-91 days (SFO kinetics, n=5) Notes: these field dissipation studies, where carbosulfan was applied as parent and carbofuran appears as metabolite, are available in the carbofuran dossier. US sites (CA, KS, IL, AR): DT50f : 5-121 days (n=7), values were not used further in the risk assessment.

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

Laboratory studies ‡

Benfuracarb	Anaerobic conditions: no data available and not required Degradation in saturated zone: not required
Carbofuran	Anaerobic conditions: Carbofuran: DT_{50}lab (20°C): 7.6 d (n= 1, r^2 = 0.99318)

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Benfuracarb ‡	
log Koc = 3.96; Koc = 9.1 * 10^3 (by HPLC method)	
pH dependence, Yes or No	No

Carbofuran ‡							
Soil Type	OC %	Soil pH*	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy sand	2.19	5.8	-	-	0.425	19	0.94
Loam	1.22	7.27	-	-	0.299	24	0.92

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Silty clay loam	2.67	5.42	-	-	0.456	17	1.01
Silt loam	1.97	5.8	-	-	0.549	28	0.95
Arithmetic mean					0.432	22	0.96
pH dependence (yes or no)			No				

* in $CaCl_2$

3-hydroxy-carbofuran ‡							
Soil Type	OC %	Soil pH*	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy sand	2.29	5.7	1.4	62	-	-	-
Sandy loam	1.02	6.3	0.4	43	-	-	-
Sandy clay	1.9	6.9	1.1	60	-	-	-
Arithmetic mean			0.97	55	-	-	-
pH dependence (yes or no)			No				

* in $CaCl_2$

3-keto-Carbofuran ‡							
Soil Type	OC %	Soil pH*	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy sand	2.29	5.7	1.1	47.5	-	-	-
Sandy loam	1.02	6.3	-	-	4.59	440	1.144
Sandy clay	1.9	6.9	-	-	9.65	504	0.489
Arithmetic mean			Koc: 330.5				
pH dependence (yes or no)			No				

* in $CaCl_2$

Carbofuran-phenol ‡							
Soil Type	OC %	Soil pH*	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Loamy sand	2.29	5.7	-	-	10.0	444	0.407
Sandy loam	1.02	6.3	-	-	18.9	1810	0.516
Sandy clay	1.9	6.9	-	-	16.0	838	0.751
Arithmetic mean					14.97	1031	
pH dependence (yes or no)			No				

* in $CaCl_2$

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

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Column leaching ‡	No data available and not required
Aged residues leaching ‡	No data available and not required

Lysimeter/ field leaching studies ‡	BBA guideline, outdoor lysimeter study performed in Hamburg, Germany. The soil was a light sandy loam. Crop : 1st year, beets; 2nd year, potato, 3rd year, wheat Lysimeter 1: 1st year, furrow appl. of 1290 g a.s./ha Lysimeter 2 : 1st year, furrow appl. of 1290 g a.s./ha 2nd year, spray appl. of 411 g a.s./ha Precipitation (mm): 1012 mm/year Time period (d): 1200 d Mean annual concentration in the leachate: 1.3-2.5 µg a.s. equivalent /L Benfuracarb and carbofuran transiently leached at level above 0.1 µg/L. Due to the short number of samples it is not possible to calculate annual average concentrations. Radioactivity mainly in upper soil layer, due to the mode of application, the radioactivity is not distributed homogeneously

PEC (soil) (Annex IIIA, point 9.1.3)

Benfuracarb Method of calculation	DT_{50} (benfuracarb): 0.83 days Kinetics: 1st order worst case lab DT_{50}
Application data	Crop: brassicas 0% plant interception: granular application in the sowing bed, soil layer: 5 cm, soil density : 1.5 kg/dm^3 Number of applications: 1 Application rate(s): 1000 g a.s./ha

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	1.333		x	
Short term 24h	0.578	0.904	x	x
2d	0.250	0.648	x	x

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	4d	0.047	0.385	x	x
Long term	7d	0.004	0.227	x	x
	28d	<0.001	0.057	x	x
	50d	<0.001	0.031	x	x
	100d	<0.001	0.015	x	x
Plateau concentration		not relevant			

Method of calculation	DT_{50} (carbofuran): 27 days Kinetics: 1st order worst case field DT_{50} (worst case FMC study)
Application rate	Crop: brassicas 0% plant interception: granular application in the sowing bed, soil layer: 5 cm, soil density: 1.5 kg/dm^3 Number of applications: 1 Application rate(s): 540 g/ha (assumed carbofuran is formed at a maximum of 100% of the applied dose, molecular mass of benfuracarb is 410.5; molecular mass of carbofuran is 221.3)

PEC$_{(s)}$		Single application Actual (mg/kg soil)	Single application Time weighted average (mg/kg soil)	Multiple application Actual (mg/kg soil)	Multiple application Time weighted average (mg/kg soil)
Initial		0.720	0.720	-	-
Short term	24h	0.702	0.711	-	-
	2d	0.683	0.702		
	4d	0.650	0.684		
Long term	7d	0.602	0.659	-	-
	28d	0.351	0.513		
	50d	0.199	0.406		
	100d	0.055	0.259		

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	pH 4: 20°C DT_{50} <0.5 hr (1st order) carbofuran: 100 %AR (0.5 hr) Carbofuran: pH 5: hydrolytically stable

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	pH 7: 20°C DT_{50} 1.4 d (1st order) carbofuran: max 73.9% AR (15 d) Metabolite MI: 36.6% AR (30 d) carbofuran: pH 7, 25°C : DT_{50} = 45.7 d (1st order) carbofuran-phenol or 7-phenol: 55.6 % AR (51 d)
	pH 9: 20°C DT_{50} 26.9 d (1st order) carbofuran: max 16.6 %AR (30 d) 3 unknown (groups of) metabolites : M I (up to 28.2% after 30 d) (possibly desethyl benfuracarb and carbofuran-phenol) M III (max. 13.8% after 23 d, unstable under lab cond.) M IV (observed only after 30 d at 10.5%, artefact) desethyl benfuracarb and carbofuran-phenol present at pH 7 and 9 carbofuran: pH 9, 25°C : DT_{50} = 0.1 d (1st order) carbofuran-phenol or 7-phenol : 98.3% AR (5 d)
Photolytic degradation of active substance and metabolites above 10 % ‡	Xenon light source with UV filter, continuous irradiation DT_{50} 15.6 days (irradiated, river water) DT_{50} 4.7 days (dark, river water) DT_{50} 15.3 hr (irradiated, purified water) DT_{50} 30.4 hr (dark, purified water) The potential contribution of aqueous photolysis to benfuracarb degradation may not be fully established due to the great contribution of hydrolysis at pH (6-7.5) chosen to perform the photolysis sterile study. Major degradates river water: carbofuran (27.6% after 20 d) and carbofuran-phenol (19.7% after 20 d) in irradiated samples; carbofuran (91.7% after 20 d) in dark controls purified water: carbofuran (93.6% after 72 hrs in irradiated samples; 80.1% after 72 hrs in dark controls) carbofuran: Xenon arc lamp with UV filter cut, DT_{50} : 33 days No major metabolite Estimated DT_{50} at 50°N : 108 days
Quantum yield of direct phototransformation in water at Σ > 290 nm	Φ = 0.106
Readily biodegradable ‡ (yes/no)	Not readily biodegradable

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Degradation in water / sediment

Benfuracarb	Distribution (<5% AR in water after 6 d. Max. sed 5.42 % after 0.25 d)									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	St. (r^2)	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
OVP	8.04	8.3	20	0.25-3	-	0.25-3	-	-	-	graphical
SW	7.8	7.9	20	0.625-5	-	0.625-5	-	-	-	graphical
Geometric mean/median			-	-		-		-		-

Carbofuran	Distribution (max in water 45.6-58.3% after 2-6 d. Max. sed 19.8-25.3% after 2-14 d)*									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
OVP	8.04	8.3	20	13.9-46.3	0.96	8.2-27.2#	0.99	-	-	SFO
SW	7.8	7.9	20	14.8-49.2	0.97	10.8-35.8#	0.99	-	-	SFO
A (River)[1]			20	7.8-25.9						SFO
B (Pond)[1]			20	11.6-38.5						SFO
C[1]			25	44.6-148.3						SFO
Geometric mean of values for 20-25°C				15.3						

$DT_{50/90}$ for dissipation
* taken from the relevant study with benfuracarb
[1] taken from studies with carbofuran as presented in EFSA conclusion on carbofuran (2006). The RMS agreed with the notifier's proposal to consider the entire database in order to produce a more robust endpoint. However these values may require re-evaluation and normalisation to 20°C, which can lead to different values after the peer review of carbofuran.
Note: three additional values referring to whole systems are available in the carbofuran additional report (2008), where carbofuran appears as metabolite of carbosulfan. These values have neither been peer reviewed.

Carbofuran-phenol	Distribution (max in water 0% at all d. Max. sed 13.6% after 14 d)*									
Water / sediment system	pH water phase	pH sed	t. °C	DT_{50}-DT_{90} whole sys.	St. (r^2)	DT_{50}-DT_{90} water	r^2	DT_{50}- DT_{90} sed	St. (r^2)	Method of calculation
OVP	8.04	8.3	20	20.5-68.1	0.99	-	-	20.5-68.1	0.99	SFO
SW	7.8	7.9	20	4.8-16.1	0.89	-	-	4.8-16.1	0.89	SFO
A (River)[1]	8.2	7.45	20	3.7-12.3	0.98	4.8-15.8#	0.99	-	-	SFO
B (Pond)[1]	7.0	7.08	20	8.2-27.3	0.84	7.3-24.2#	0.81	-	-	SFO
Geometric mean				7.39				9.92		

* taken from the relevant study with benfuracarb

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

[1] taken from studies with carbofuran. The RMS agreed with the notifier's proposal to consider the entire database in order to produce a more robust endpoint. However these values may require re-evaluation and normalisation to 20°C, which can lead to different values after the peer review of carbofuran.

$DT_{50/90}$ for dissipation

Mineralization and non extractable residues					
Water / sediment system	pH water phase	pH sed	Mineralization x % after n d. (end of the study).	Non-extractable residues in sed. Max x % after n d	Non-extractable residues in sed. Max x % after n d (end of the study)
OVP	8.04	8.3	16.7% after 103 d	75.94% after 103 d	75.94% after 103 d
SW	7.8	7.9	13.65% after 103 d	73.81% after 103 d	73.81% after 103 d

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

Selected input values for FOCUS STEP 1, 2 and 3/STEP 4 calculations for Benfuracarb

Parameter	**Value**	**Source**
water solubility	8.4 mg/L (20°C) at pH 7	(LoEP)
vapour pressure	4.2E-6 Pa (25°C)	(LoEP)
geometric mean soil DT_{50}	0.42 d (20°C, pF 2.0 normalised)	PRAPeR 62
Mean Koc soil	9.1E+3 L/kg	(LoEP)
1/n	1.0	PRAPeR 62
DT_{50} water/sediment whole system	6-15 hours (estimation). Calculations performed with DT_{50} of 15 hours (0.625 d).	(LoEP)
Application	1000 g a.i./ha	representative use Oncol 8.6G
Type of application	Granular application (PRZM, CAM=8, DEPI=2.5) Soil incorporated (MACRO) (according to guidance published in the EFSA journal (2004) 145, 1-31)	representative use Oncol 8.6G
Crop	Vegetables, leafy (cabbage)	representative use Oncol 8.6G
Scenarios	Relevant FOCUS scenarios: D3, D4, D6, R1, R2, R3, R4 (for the D3 scenario and all R scenarios, two application dates are possible)	FOCUS
Run-off	PRZM model (FOCUS)	FOCUS

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Drainage	MACRO model (FOCUS)	FOCUS
PECsw	TOXSWA (FOCUS)	FOCUS

Summary of maximum and 28 days TWA PEC_{SW} and PEC_{SED} concentrations for Benfuracarb (FOCUS STEP1/STEP2/STEP3/STEP4)

Scenario	System	Relevant for		Application date	Water		Sediment	
		NE	SE		Max PECsw (µg/L)	TWA 28 days (µg/L)	Max PECsed (µg/kg)	TWA 28 days (µg/kg)
D3 (STEP3)	ditch	X		April 10	0.000	0.000	0.000	0.000
	ditch	X		July 25	0.000	0.000	0.000	0.000
D4 (STEP3)	pond	X		May 16	0.000	0.000	0.000	0.000
	stream	X		May 16	0.000	0.000	0.000	0.000
D6 (STEP3)	ditch		X	Aug 04	0.000	0.000	0.000	0.000
R1 (STEP4)	pond	X		April 26	0.000	0.000	0.000	0.000
	pond	X		July 28	0.000	0.000	0.000	0.000
	stream	X		April 26	0.000	0.000	0.000	0.000
	stream	X		July 28	0.000	0.000	0.000	0.000
R2 (STEP4)	stream		X	March 06	0.000	0.000	0.000	0.000
	stream		X	Aug 05	0.000	0.000	0.000	0.000
R3 (STEP4)	stream		X	Feb 19	0.000	0.000	0.000	0.000
	stream		X	June 02	0.000	0.000	0.000	0.000
R4 (STEP4)	stream		X	March 01	0.000	0.000	0.000	0.000
	stream		X	June 01	0.000	0.000	0.000	0.000
STEP1	na	na	na	na	25.381	0.8782	2310	79.9196
STEP2	na		X	March-May Aug-Sep	0.0161	0.0000	1.4633	0.0522
STEP2	na	X		March-May Aug-Sep	0.0080	0.0000	0.7316	0.0261

na = not applicable

[1] The run-off scenarios are referred to as STEP 4 calculations because the defaults for CAM and DEPI were adjusted (see description above)

Selected input values for FOCUS STEP 3/STEP 4 calculations for Carbofuran

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Parameter	Value	Source
water solubility	318.5 mg/L (20°C)	mean value LoEP
vapour pressure	8E-5 Pa (25°C)	LoEP
geometric mean soil DT_{50}	14 d (normalised to pF2 and 20°C)	PRAPeR 62
mean Koc soil	22 L/kg	LoEP
1/n	0.96	LoEP
DT_{50} water/sediment whole system	BFC study: 13.9 d, 14.8 d CF study: 7.8 d, 11.6 d, 44.6 d geometric mean: 15.3 d	Calculated from BFC and CF studies[1] (LoEP)
Application	As if 100% application of CF with MW correction: 540 g/ha	PRAPeR 62 (ff =1)
Type of application	Granular application (PRZM, CAM=8, DEPI=2.5) Soil incorporated (MACRO) (according to guidance published in the EFSA journal (2004) 145, 1-31)	representative use Oncol 8.6G
Crop	Vegetables, leafy (cabbage)	representative use Oncol 8.6G
Scenarios	Relevant FOCUS scenarios: D3, D4, D6, R1, R2, R3, R4 (for the D3 scenario and all R scenarios, two application dates are possible)	FOCUS
Run-off	PRZM model (FOCUS)	FOCUS
Drainage	MACRO model (FOCUS)	FOCUS
PECsw	TOXSWA (FOCUS)	FOCUS

[1] Calculated from the data presented in the DAR of benfuracarb (1st order log-linear regression using the data points from the maximum occurrence of carbofuran until the end of the study (r^2 0.96-0.97)).

BFC = from benfuracarb dossier

CF = from carbofuran dossier

Summary of maximum and 28 days TWA PEC_{SW} and PEC_{SED} concentrations for Carbofuran (FOCUS STEP3/STEP4)

Scenario	System	Relevant for		Application date	Water		Sediment	
		NE	SE		Max PECsw (µg/L)	TWA 28 days (µg/L)	Max PECsed (µg/kg)	TWA 28 days (µg/kg)
D3 (STEP3)	Ditch	X		April 10	0.0110	0.0110	0.0191	0.0191
	Ditch	X		July 25	0.159	0.158	0.241	0.241

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

D4 (STEP3)	Pond	X		May 16	0.0522	0.0468	0.0650	0.0644
	Stream	X		May 16	0.163	0.0791	0.0918	0.0756
D6 (STEP3)	Ditch		X	Aug 04	0.163	0.0283	0.0246	0.0205
R1 (STEP4)[1]	Pond	X		April 26	0.000	0.000	0.000	0.000
	pond	X		July 28	0.000	0.000	0.000	0.000
	stream	X		April 26	0.000	0.000	0.000	0.000
	stream	X		July 28	0.000	0.000	0.000	0.000
R2 (STEP4)[1]	stream		X	March 06	0.000	0.000	0.000	0.000
	stream		X	Aug 05	0.000	0.000	0.000	0.000
R3 (STEP4)[1]	stream		X	Feb 19	0.000	0.000	0.000	0.000
	stream		X	June 02	0.000	0.000	0.000	0.000
R4 (STEP4)[1]	stream		X	March 01	0.000	0.000	0.000	0.000
	stream		X	June 01	0.000	0.000	0.000	0.000

[1] The run-off scenarios are referred to as STEP 4 calculations because the defaults for CAM and DEPI were adjusted (see description above)

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

Input values for PECgw calculations for Benfuracarb

Parameter	Value	Source
water solubility	8.4 mg/L (20°C) at pH 7	(LoEP)
vapour pressure	4.2E-6 Pa (25°C)	(LoEP)
geometric mean soil DT_{50}	0.42 d (20°C, moisture corrected)	PRAPeR 62
mean Koc soil	9.1E+3 L/kg	(LoEP)
1/n	1	PRAPeR 62
Application	1000 g a.i./ha	representative use Oncol 8.6G
Type of application	Soil incorporated (2.5 cm)	representative use Oncol 8.6G
Crop	Cabbage, 2 crop sequences	representative use Oncol 8.6G
Scenarios	Relevant FOCUS scenarios	FOCUS
MW	410.5	-

Input values for PECgw calculations for Carbofuran

Parameter	Value	Source
water solubility	318.5 mg/L (20°C)	(mean value LoEP)
vapour pressure	8E-5 Pa (25°C)	(LoEP)
median soil DT_{50}	14 d (20°C, moisture corrected)	PRAPeR 62

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

mean Koc soil	22 L/kg	(LoEP)
mean 1/n	0.96	(LoEP)
Formation fraction	1	PRAPeR 62
MW	221.3	-

Input values for PECgw calculations for 3-keto-carbofuran and 3-hydroxy-carbofuran

Parameter	3-keto-carbofuran	3-hydroxy-carbofuran
median soil DT_{50}	3.01	0.41
mean Koc soil	330.5	55
mean 1/n	1	1
Formation fraction	0.1	0.1

FOCUS-PELMO estimations of concentrations in groundwater (80th percentile, µg/L) of benfuracarb and carbofuran (yearly applications)

FOCUS Crop	scenario	Application date	80th percentile concentration in groundwater [µg/L] of:	
			Benfuracarb	Carbofuran
Cabbage	Chateaudun	April 27	<0.001	0.126
(seq 1)	Hamburg	April 27	<0.001	0.361
	Jokioinen	May 27	<0.001	0.294
	Kremsmunster	April 27	<0.001	0.122
	Porto	March 07	<0.001	0.007
	Sevilla	March 08	<0.001	<0.001
	Thiva	Aug 22	<0.001	0.101
Cabbage	Chateaudun	August 07	<0.001	0.134
(seq 2)	Hamburg	August 07	<0.001	2.664
	Kremsmunster	August 07	<0.001	0.430
	Porto	August 07	<0.001	0.032
	Sevilla	June 22	<0.001	<0.001

FOCUS-PEARL estimations of concentrations in groundwater (80th percentile, µg/L) of benfuracarb and carbofuran (yearly applications)

FOCUS Crop	scenario	Application date	80th percentile concentration in groundwater [µg/L] of:	
			Benfuracarb	Carbofuran
Cabbage	Chateaudun	April 27	<0.001	0.646
(seq 1)	Hamburg	April 27	<0.001	0.737
	Jokioinen	May 27	<0.001	0.741

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	Kremsmunster	April 27	<0.001	0.667
	Porto	March 07	<0.001	0.013
	Sevilla	March 08	<0.001	0.0093
	Thiva	Aug 22	<0.001	0.229
Cabbage	Chateaudun	August 07	<0.001	0.574
(seq 2)	Hamburg	August 07	<0.001	3.127
	Kremsmunster	August 07	<0.001	1.531
	Porto	August 07	<0.001	0.268
	Sevilla	June 22	<0.001	0.0024

FOCUS-PELMO estimations of concentrations in groundwater (80th percentile, µg/L) of 3-keto-carbofuran and 3-hydroxy-carbofuran (yearly applications)

FOCUS	scenario	Application date	80th percentile concentration in groundwater [µg/L] of:	
Crop			3-keto-carbofuran	3-hydroxy-carbofuran
Cabbage	Chateaudun	April 27	<0.001	<0.001
(seq 1)	Hamburg	April 27	<0.001	<0.001
	Jokioinen	May 27	<0.001	<0.001
	Kremsmunster	April 27	<0.001	<0.001
	Porto	March 07	<0.001	<0.001
	Sevilla	March 08	<0.001	<0.001
	Thiva	Aug 22	<0.001	<0.001
Cabbage	Chateaudun	August 07	<0.001	<0.001
(seq 2)	Hamburg	August 07	<0.001	<0.001
	Kremsmunster	August 07	<0.001	<0.001
	Porto	August 07	<0.001	<0.001
	Sevilla	June 22	<0.001	<0.001

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

Direct photolysis in air ‡	No data available, not required
Quantum yield of direct phototransformation	No data available, not required
Photochemical oxidative degradation in air ‡	Atkinson method : overall OH rate constant KOH = 1.589 x 10^{-10} cm^3/molecule.sec → estimated lifetime in atmosphere = 3.5 hr or 0.15 d (using global OH-concentration of 5.0 x 10^5 OH

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

	radicals/cm^3)
Volatilisation ‡	From plant surfaces: Not required
	From soil: Not required
Metabolites	No metabolites relevant for air

PEC (air)

Method of calculation	Not required

$PEC_{(a)}$

Maximum concentration	Not required. Expected negligible

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: benfuracarb, carbofuran, 3-keto-carbofuran, 3-hydroxy-carbofuran Ground water: benfuracarb, carbofuran, 3-keto-carbofuran, 3-hydroxy-carbofuran Surface water: benfuracarb, carbofuran Sediment: carbofuran, carbofuran-7-phenol Air: benfuracarb, carbofuran.

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

Soil (indicate location and type of study)	No data available - none requested
Surface water (indicate location and type of study)	No data available - none requested
Ground water (indicate location and type of study)	No data available - none requested
Air (indicate location and type of study)	No data available - none requested

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

Candidate for R 53: May cause long-term adverse effect to the aquatic environment

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Coturnix coturnix japonica	benfuracarb	Acute	48.3 (male) 39.9 (female)	- -
Anas platyrhynchos	benfuracarb	Acute	**19.8**	-
Colinus virginianus	benfuracarb	Short-term	179	558
Anas platyrhynchos	benfuracarb	Short-term	**15**	195
Colinus virginianus	benfuracarb	Long-term	**8.93**	115
Mammals ‡				
rat	benfuracarb	Acute	**205**	-
rat	benfuracarb	Long-term	**1.2**	-
Additional higher tier studies ‡				
An avoidance study from seed scattered on granules containing Oncol 8.6G with *Coturnix coturnix japonica* was conducted. Under the conditons of this test, no avoiding behaviour of the Japanse quail during 24 hours was observed.				

Carbofuran

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Anas platyrhynchos	carbofuran	Acute	**0.76**	-
Anas platyrhynchos	carbofuran	Short-term	**1.6**	-
Anas platyrhynchos	carbofuran	Long-term	**0.64**	-
Mammals ‡				
rat	carbofuran	Acute	**5.3**	-
rat	carbofuran	Long-term	**0.71**	-
Additional higher tier studies ‡				
Not available.				

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)
Benfuracarb is applied in brassicas as granules (Oncol 8.6G) in the sowing bed at a single application rate of 1 kg a.s./ha.

Exposure route for the active substance :

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Birds are exposed to benfuracarb via the consumption of granules (accidental or as grit).
Since the residue levels of benfuracarb in cabbage seedlings and earthworms are negligible, no TER calculation is necessary for benfuracarb in those food matrices.

Exposure route for the metabolites :
Since residue levels of the metabolites carbofuran and 3-hydroxy-carbofuran in cabbage seedlings and earthworms were relevant and since these metabolites are both more toxic than the active substance, the risk to birds from exposure to these metabolites has been assessed.

Birds - Benfuracarb – granules

LD_{50}, LC_{50} and NOEC of benfuracarb expressed in number of granules for different sizes of birds

Time scale	Number of granules for a 15 g bird	Number of granules for a 50 g bird	Number of granules for a 200 g bird	Number of granules for a 500 g bird
Acute LD_{50}	54	180	720	1800
Dietary LC_{50}	41	136	545	1364
Reproductive NOEC	24	81	325	812

Risk assessment according to EPPO scheme :

Accidental ingestion of Oncol 8.6G granules (as part of soil ingestion) :

Calculated exposure toxicity ratios for accidental ingestion of granules for small birds (25 g body weight)

Scenario	$DDSD_{RWC}$ (mg a.s./kg b.w./day)	5th percentile toxicity value (mg a.s./kg b.w./day)	ETR_{RWC}
Short-term	0.473	1.43	0.330
Medium-term	0.095	2.64	0.036
Long-term	0.095	0.27	0.350

Intentional ingestion of Oncol 8.6G granules (as part of grit ingestion) :

Calculated exposure toxicity ratios for intentional ingestion of granules for small birds as part of grit ingestion, RWC scenario

Scenario	DGI_{RWC} (granules/kg b.w./day)	$G_{sruface}$ (granules /m²)	TWA_{factor}	DGD_{RWC} (mg a.s./kg b.w./day)	5th percentile toxicity value (mg a.s./kg b.w.)	ETR_{RWC}
Short-term	651	18182	-	1.95	1.43	1.36
Medium-term	651	18182	-	1.95	2.64	0.74
	651	18182	1	1.95	0.27	7.18

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Long-term						

Calculated exposure toxicity ratios for intentional ingestion of granules for small birds as part of grit ingestion, MLC scenario

Scenario	**DGI_{MLC} (granules/ kg b.w./day)**	**$G_{sruface}$ (granules/m^2)**	**TWA_{factor}**	**DGD_{MLC} (mg a.s./kg b.w./day)**	**5^{th} percentile toxicity value (mg a.s./kg b.w.)**	**ETR_{MLC}**
Short-term	386	18182	-	0.58	1.43	0.40
Long-term	386	18182	1	0.58	0.27	2.13

Birds - Carbofuran (+ 3-hydroxy-carbofuran) – cabbage seedlings and earthworms

Indicator species/Category	Time scale	Route	ETE	TER	Annex VI Trigger
Tier 1 (worst case toxicological endpoints, measured residue in seedlings)					
medium herbivorous bird	Acute	leafy crop/early cabbage seedlings (PD = 100 %)	2.98	**0.255**	10
	Short-term		2.34	**0.684**	10
	Long-term		0.87	**0.739**	5
small granivorous bird	Acute	drinking water	0.47	**1.62**	10
Tier 2 (worst case toxicological endpoints, measured residue in seedlings and earthworms, focal species determined in monitoring studies, no food avoidance considered, PT =100%).					
Black-headed gull	Acute	earthworms (PD = 92 %), for acute TER the PD was 100 %	0.47	**1.62**	10
	Short-term		0.12	13.6	10
	Long-term		0.074	8.69	5

Mammals - Benfuracarb – granules

LD_{50} and NOAEL of benfuracarb expressed in number of granules for different sizes of mammals

Time scale	**Number of granules for a 10 g mammal**	**Number of granules for a 25 g mammal**	**Number of granules for a 100 g mammal**
Acute oral LD_{50}	373	932	3727
Two generation NOAEL	2	5	22

Risk assessment according to EPPO scheme :

Accidental ingestion of Oncol 8.6G granules (as part of soil ingestion) :

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Calculated exposure toxicity ratio for accidental ingestion of granules for small mammals (25 g body weight)

Scenario	**$DDSD_{RWC}$ (mg a.s./kg b.w./day)**	**5^{th} percentile toxicity value (mg a.s./kg b.w./day)**	**ETR_{RWC}**
Long-term	0.023	0.081	0.286

Mammals - Carbofuran (+ 3-hydroxy-carbofuran) – cabbage seedlings and earthworms

Indicator species/Category	Time scale	Route	ETE	TER	Annex VI Trigger
Tier 1 (worst case toxicological endpoints, measured residue in seedlings)					
vermivorous mammal	Acute	earthworms (PD = 100 %)	0.78	**6.78**	10
	Long-term		0.13	5.32	5
herbivorous mammal	Acute	leafy crop/early cabbage seedlings (PD = 100 %)	1.10	**4.83**	10
	Long-term		0.32	**2.23**	5
small granivorous mammal	Acute	drinking water	0.24	22	10
Tier 2 (worst case toxicological endpoints, measured residue in seedlings and earthworms, focal species determined in monitoring studies, no food avoidance considered, PT =100%)					
Common shrew	Acute refinement not accepted	80 % earthworms			
	Long-term		0.141	6.42	5
Hare	Acute refinement not accepted	cabbage seedlings (PD = 25 %)			
	Long-term		0.08	9.42	5

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg/L)
Laboratory tests				
Fish				
Oncorhynchus mykiss	benfuracarb	96 h (semi-static)	LC_{50}	0.083 mg a.s./L (m)
Lepomis macrochirus	benfuracarb	96 h (semi-static)	LC_{50}	0.017 mg a.s./L (m)
Lepomis macrochirus	carbofuran	96 h (semi-static)	LC_{50}	0.82 mg/L (nom)
Lepomis macrochirus	carbofuran	96 h (semi-static)	LC_{50}	**0.18 mg/L** (nom)
Oncorhynchus mykiss	carbofuran	28 d juvenile growth test	EC_{10}	**0.00655 mg/L** (nom)
Oncorhynchus mykiss	carbofuran	28 d juvenile growth	NOEC	0.022 mg/L (nom)
Lepomis macrochirus	7-phenol	96 h (semi-static)	LC_{50}	75 mg/L (nom)
Aquatic invertebrate				
Daphnia magna	benfuracarb	48 h (static)	EC_{50}	0.0099 mg a.s./L (m)
Daphnia magna	carbofuran	48 h (static)	EC_{50}	**0.0094 mg/L** (nom)
Daphnia magna	carbofuran	21 d (semi-static)	NOEC	**0.008 mg/L** (nom)
Daphnia magna	7-phenol	48 h (static)	EC_{50}	25 mg/L (nom)
Sediment dwelling organisms				
Chironomus riparius	benfuracarb	28 d (static)	EC_{50} NOEC	0.0041 mg a.s./L **0.001 mg a.s./L (*)** (nom)
Algae				
Pseudokirchneriella subcapitata	benfuracarb	72 h (static)	EC_{50}	> 2.2 mg a.s./L (m)
Pseudokirchneriella subcapitata	carbofuran	72 h (static)	E_bC_{50} E_rC_{50}	**6.5 mg/L** (m) 19 mg/L (m)
Pseudokirchneriella subcapitata	7-phenol	72 h (static)	E_bC_{50} E_rC_{50}	63 mg/L (nom) > 100 mg/L (nom)
Microcosm or mesocosm tests				
Not required				

(*) used for the carbofuran assessement

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

FOCUS Step 3

Carbofuran

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PECsw (µg/L) (max)	TER	Annex VI trigger
D3	Ditch	*Lepomis macrochirus*	96 h	180	0.159	1132	100
D4	Pond				0.0522	3448	100
D4	Stream				0.163	1104	100
D6	Ditch				0.163	1104	100
D3	Ditch	*Daphnia magna*	48 h	9.4	0.159	**59**	100
D4	Pond				0.0522	180	100
D4	Stream				0.163	**58**	100
D6	Ditch				0.163	**58**	100
D3	Ditch	*Pseudokirchneriella subcapitata*	72 h	6500	0.159	40881	10
D4	Pond				0.0522	124521	10
D4	Stream				0.163	39877	10
D6	Ditch				0.163	39877	10
D3	Ditch	*Oncorhynchus mykiss*	28 d	6.55	0.159	41	10
D4	Pond				0.0522	125	10
D4	Stream				0.163	40	10
D6	Ditch				0.163	40	10
D3	Ditch	*Daphnia magna*	21 d	8.0	0.159	50	10
D4	Pond				0.0522	153	10
D4	Stream				0.163	49	10
D6	Ditch				0.163	49	10
D3	Ditch	*Chironomus riparius*	28 d	1.0	0.159	**6**	10
D4	Pond				0.0522	19	10
D4	Stream				0.163	**6**	10
D6	Ditch				0.163	**6**	10

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

FOCUS Step 4 (*)

Carbofuran

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PECsw (µg/L)	TER	Annex VI trigger
R1	Pond	*Lepomis macrochirus*	96 h	180	<0.001	>180000	100
R1	Stream				<0.001	>180000	100
R2	Stream				<0.001	>180000	100
R3	Stream				<0.001	>180000	100
R4	Stream				<0.001	>180000	100
R1	Pond	*Daphnia magna*	48 h	9.4	<0.001	>9400	100
R1	Stream				<0.001	>9400	100
R2	Stream				<0.001	>9400	100
R3	Stream				<0.001	>9400	100
R4	Stream				<0.001	>9400	100
R1	Pond	*Pseudokirchneriella subcapitata*	72 h	6500	<0.001	>6500000	10
R1	Stream				<0.001	>6500000	10
R2	Stream				<0.001	>6500000	10
R3	Stream				<0.001	>6500000	10
R4	Stream				<0.001	>6500000	10
R1	Pond	*Oncorhynchus mykiss*	28 d	6.55	<0.001	>6550	10
R1	Stream				<0.001	>6550	10
R2	Stream				<0.001	>6550	10
R3	Stream				<0.001	>6550	10
R4	Stream				<0.001	>6550	10
R1	Pond	*Daphnia magna*	21 d	8.0	<0.001	>8000	10
R1	Stream				<0.001	>8000	10
R2	Stream				<0.001	>8000	10
R3	Stream				<0.001	>8000	10
R4	Stream				<0.001	>8000	10
R1	Pond	*Chironomus riparius*	28 d	1.0	<0.001	>1000	10
R1	Stream				<0.001	>1000	10
R2	Stream				<0.001	>1000	10

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Scenario	Water body type	Test organism	Time scale	Toxicity end point (µg/L)	PECsw (µg/L)	TER	Annex VI trigger
R3	Stream				<0.001	>1000	10
R4	Stream				<0.001	>1000	10

(*) Referred to as STEP 4 calculations because defaults for CAM and DEPI were adjusted to reflect granule incorporation at exactly 2.5 cm

Bioconcentration	
	benfuracarb
$logP_{O/W}$	4.22
Bioconcentration factor (BCF) ‡	48 (fillet); 172 (viscera); 90 (whole fish)
Annex VI Trigger for the bioconcentration factor	100
Clearance time (days) (CT_{50})	CT_{50} (1) = 0.44 days; CT_{50} (2) = 10 days (biphasic depuration curve)
(CT_{90})	CT_{90} (1) = 1.46 days; CT_{90} (2) = 33.2 days (biphasic depuration curve)
Level and nature of residues (%) in organisms after the 14 day depuration phase	< 0.5 % after 12 days (whole fish)

* 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)
benfuracarb ‡	2.1	0.19
benfuracarb ‡	0.92	-
Field or semi-field tests		
Not required.		

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

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Hazard quotients for honey bees (Annex IIIA, point 10.4)
Crop and application rate : brassicas, 1 x 1.0 kg a.s./ha

Test substance	Route	Hazard quotient	Annex VI Trigger
benfuracarb	Contact	Not applicable	50
benfuracarb	oral	Not applicable	50

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

Species	Life stage	Test substance, substrate and duration	Dose	Endpoint	% effect	Trigger value
Laboratory tests						
Coccinella septempunc-tata	larvae	Oncol 20EC, glass plates	216 g a.s./ha	Corrected mortality	100 %	50 %
Extended laboratory tests						
Aphidius rhopalosiphi	adult female s	Oncol 20EC, oat plants, 48 h + 11 d	0.69 g a.s./ha	Corrected mortality Reproduction	10 % -58 %	50 % 50 %
			2.16 g a.s./ha	Corrected mortality Reproduction	13 % -60 %	50 % 50 %
			6.9 g a.s./ha	Corrected mortality Reproduction	10 % -64 %	50 % 50 %
			21.6 g a.s./ha	Corrected mortality Reproduction	100 % -	50 % 50 %
			69.1 g a.s./ha	Corrected mortality Reproduction	100 % -	50 % 50 %
			LD_{50} = 9.3 g a.s./ha			
Typhlodromu s pyri	proto-nymph s	Oncol 20EC, apple tree leaves,	3.46 g a.s./ha	Corrected mortality Reproduction	14 % -8.7 %	50 % 50 %

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Species	Life stage	Test substance, substrate and duration	Dose	Endpoint	% effect	Trigger value
		7 d + 7 d	5.40 g a.s./ha	Corrected mortality Reproduction	36 % -38 %	50 % 50 %
			8.64 g a.s./ha	Corrected mortality Reproduction	52 % -72 %	50 % 50 %
			13.6 g a.s./ha	Corrected mortality Reproduction	73 % -	50 % 50 %
			21.6 g a.s./ha	Corrected mortality Reproduction	91 % -	50 % 50 %
			LD_{50} = 9.2 g a.s./ha			
Chrysoperla carnea	larvae	Oncol 20EC, apple tree leaves	2.16 g a.s./ha	Corrected mortality Reproduction	7.4 % -6.7 %	50 % 50 %
			6.91 g a.s./ha	Corrected mortality Reproduction	39 % -20 %	50 % 50 %
			21.6 g a.s./ha	Corrected mortality Reproduction	100 % -	50 % 50 %
			69.1 g a.s./ha	Corrected mortality Reproduction	100 % -	50 % 50 %
			216 g a.s./ha	Corrected mortality Reproduction	100 % -	50 % 50 %
			LD_{50} = 5.2 g a.s./ha			
Poecilus cupreus	adults	Oncol 8.6G, sand, 14 d	1.0 kg a.s./ha	Corrected mortality Food consumption	-3.4 % 0 %	50 % 50 %
Aleochara bilineata	adults	Oncol 8.6G, soil	1.0 kg a.s./ha	Corrected mortality Reproduction	59.5 % -58 %	50 % 50 %

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Species	Life stage	Test substance, substrate and duration	Dose	Endpoint	% effect	Trigger value
Hypoaspis aculeifer	adults	Oncol 8.6G, sand, 14 d	1 kg a.s./ha	Corrected mortality Reproduction	7 % -2 %	50 % 50 %
Pardosa	adults	Oncol 8.6G, sand, 14 d	1 kg a.s./ha	Corrected mortality Food consumption	0 % 6 %	50 % 50 %
Aged residue laboratory test						
Aleochara bilineata	adults	Oncol 8.6G, soil	1.0 kg a.s./ha, 0 DAT	Corrected mortality Reproduction	8.5 % -8.5 %	50 % 50 %
			1.0 kg a.s./ha, 7 DAT	Corrected mortality Reproduction	7.0 % -2.7 %	50 % 50 %
			1.0 kg a.s./ha, 14 DAT	Corrected mortality Reproduction	31.8 % -19.8 %	50 % 50 %
			1.0 kg a.s./ha 21 DAT	Corrected mortality Reproduction	18.3 % -0.8%	50 % 50 %
			1.0 kg a.s./ha, 28 DAT	Corrected mortality Reproduction	42.0 % -23.0 %	50 % 50 %
			1.0 kg a.s./ha, 56 DAT	Corrected mortality Reproduction	17.6 % -23.7 %	50 % 50 %
			1.0 kg a.s./ha, 119 DAT *	Corrected mortality Reproduction	20.8 % -57.8 %	50 % 50 %

Oncol 20EC : formulation containing 216 g/L benfuracarb

Oncol 8.6G : formulation containing 8.9 - 9.14 % benfuracarb

* the effect on reproduction at 119 DAT is not treatment-related

Corrected mortality : positive values : adverse effects; negative values : no adverse effects

Effect on reproduction, food consumption : negative values : adverse effects; positive values : no adverse effects

Field or semi-field tests

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Not required.

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

Test organism	Test substance	Time scale	End point[1]
Earthworms			
Eisenia fetida	benfuracarb ‡	14 d acute	LC_{50} = 58 mg a.s./kg substrate **$LC_{50\ corr}$ = 29 mg a.s./kg substrate** NOEC < 10 mg a.s./kg substrate, due to important biomass reduction and symptoms at all treatment doses
Eisenia fetida	Oncol 20EC	14 d acute	LC_{50} = 46.58 mg/kg substrate (9.3 mg a.s./kg substrate)
Eisenia fetida	Oncol 8.6G	14 d acute	LC_{50} = 730 mg/kg substrate (69 mg a.s./kg substrate) **$LC_{50\ corr}$ = 34.5 mg a.s./kg substrate** NOEC < 100 mg Oncol 8.6G/kg substrate (50 mg a.s./kg substrate), due to important biomass reduction and symptoms at all treatment doses
Other soil macro-organisms			
Not required according to the Guidance Document on Terrestrial ecotoxicology, since the maximum DT_{90} in field of carbofuran is < 100 days. However, a study with *Hypoaspis aculeifer* is reported under point B.9.5.2.			
Soil micro-organisms			
Nitrogen mineralisation	benfuracarb ‡	60 d	+1.37 % effect at day 60 at 2 mg a.s./kg d.w. soil (7.5 L formulation/ha) -5.38 % effect at day 60 at 20 mg a.s./kg d.w. soil (75 L formulation/ha)
Nitrogen mineralisation	Carbofuran	28 d	-2.9 % effect at day 28 at 0.7 mg/kg d.w. soil -1.9 % effect at day 28 at 3.5 mg/kg d.w. soil
Carbon mineralisation	Carbofuran	28 d	+5.5 % effect at day 28 at 0.7 mg/kg d.w. soil +13 % effect at day 28 at 3.5 mg/kg d.w. soil
Field studies[2]			

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Test organism	Test substance	Time scale	End point[1]
The important biomass reduction and symptoms that have been observed in the acute studies are susceptible to lead to chronic/reproduction effects.) The sublethal effects should be evaluated in a laboratory study or a field study performed according to the supported use conditions. Moreover the effects of carbofuran and other metabolites would be completely assessed in this type of studies.			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})

[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

Toxicity/exposure ratios for soil organisms

Crop and application rate : brasssicas, 1 x 1.0 kg a.s./ha

Test organism	Test substance	Time scale	Endpoint (mg/kg)	Max PECsoil (mg/kg)	TER	Trigger
Earthworms						
Eisenia fetida	benfuracarb	14 d	29	1.33	22	10
Eisenia fetida	Oncol 8.6G	14 d	34.5	1.33	26	10
Other soil macro-organisms						
See above						

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

Benfuracarb is applied in brassicas as granules (Oncol 8.6G) in the sowing bed at a single application rate of 1 kg a.s./ha.

Based on 11 reports of efficacy trials with formulations containing benfuracarb in a number of crop plant species (vegetable brassicas, cabbage, cauliflower and Brussels sprouts, brassica, carrot, sugar beet, maize, winter wheat and potato), it can be concluded that no phytotoxicity occurred at dose rates of 1.0-1.2 kg a.s./ha, the maximum proposed application rate. In addition, according to the Terrestrial Ecotoxicology guidance document (SANCO/10329/2002), the risk to non-target terrestrial plants applies to the off-crop area. The method of application of benfuracarb as an in-furrow granular formulation means that in this case the relevant exposure (primarily by drift) will be extremely low. Accordingly, it can be concluded that the risk to non-target terrestrial plants from the recommended use of benfuracarb will be low.

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

Test type/organism	end point
Activated sludge	NOEC = 100 mg a.s./L

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

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

Compartment	
Soil	benfuracarb, carbofuran, 3-keto-carbofuran (*)
Water	benfuracarb, carbofuran
Sediment	carbofuran, carbofuran-7-phenol (**)
groundwater	benfuracarb, carbofuran

(*): 3-keto-carbofuran is expected to be present in the experiments on soil organisms at levels relevant to the GAP

(**) carbofuran-phenol is 4 orders of magnitude less toxic than carbofuran to aquatic organisms

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 (benfuracarb)	N, dangerous for the environment R50/53, Very toxic to aquatic organisms, may cause long-term adverse effects to the aquatic environment

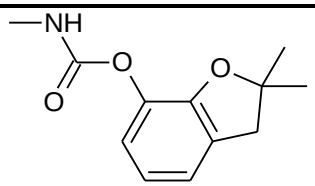
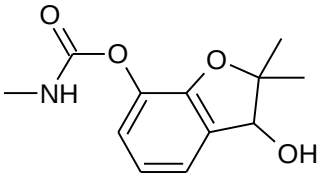
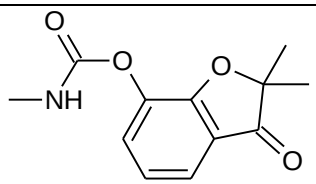
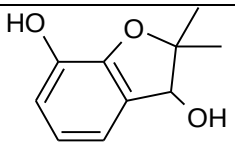
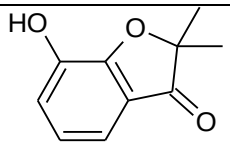
‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

APPENDIX 2 – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
d	day
DAR	draft assessment report
DM	dry matter
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
ε	decadic molar extinction coefficient
EC_{50}	effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GS	growth stage
h	hour(s)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
IEDI	international estimated daily intake
IESTI	international estimated short term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry

LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
µg	microgram
mN	milli-Newton
MRL	maximum residue limit or level
MS	mass spectrometry
NESTI	national estimated short term intake
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
r^2	coefficient of determination
RPE	respiratory protective equipment
STMR	supervised trials median residue
TER	toxicity exposure ratio
TMDI	theoretical maximum daily intake
UV	ultraviolet
WHO	World Health Organisation
WG	water dispersible granule
yr	year

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name	Structural formula
carbofuran	2,3-dihydro-2,2-dimethylbenzofuran-7-yl methylcarbamate	
3-hydroxy-carbofuran 3-OH-carbofuran	3-hydroxy-2,2-dimethyl-2,3-dihydro-1-benzofuran-7-yl methylcarbamate	
3-keto-carbofuran	2,2-dimethyl-3-oxo-2,3-dihydro-1-benzofuran-7-yl methylcarbamate	
3-hydroxy-carbofuran-phenol	2,2-dimethyl-2,3-dihydro-1-benzofuran-3,7-diol	
3-keto-carbofuran-phenol	7-hydroxy-2,2-dimethyl-1-benzofuran-3(2*H*)-one	
carbofuran-phenol	2,2-dimethyl-2,3-dihydro-1-benzofuran-7-ol