CONCLUSION ON PESTICIDE PEER REVIEW

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

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SUMMARY

Pencycuron is one of the 79 substances of the third stage part A of the review programme covered by Commission Regulation (EC) No 1490/2002[3], as amended by Commission Regulation (EC) No 1095/2007[4]. In accordance with the Regulation, at the request of the Commission of the European Communities (hereafter referred to as 'the Commission'), the EFSA organised a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the Netherlands, being the designated rapporteur Member State (RMS). The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of pencycuron in Annex I to Council Directive 91/414/EEC.

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

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, the Netherlands, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 4 November 2009.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 13 November 2009. The EFSA collated and forwarded all comments received to the Commission on 4 January 2010.

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

1 On request from the European Commission, Question No EFSA-Q-2010-00076, issued on 24 September 2010.

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3 OJ L224, 21.08.2002, p.25

4 OJ L 246, 21.9.2007, p. 19

5 OJ L 333, 11.12.2008, p.11

6 OJ L 15, 18.01.2008, p.5

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The conclusions laid down in this report were reached on the basis of the evaluation of the representative use of pencycuron as a fungicide on potatoes, as proposed by the applicant. Full details of the representative use can be found in Appendix A to this report.

A data gap is identified in the section physical and chemical properties of the formulation.

No data gaps or critical areas of concern are identified in the mammalian toxicology section.

In the residues area, for the specific use on potatoes at planting, the pertinent issues for consumer risk assessment have been reasonably addressed and no data gaps or critical areas of concern are identified.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative use, with the notable exception that information is missing regarding the fate and behaviour of the chlorophenyl and cyclopentyl portions of the molecule in soil, and the chlorophenyl and phenyl portions of the molecule in natural surface water and sediment systems. Consequently, the soil, groundwater, surface water and sediment exposure assessments for metabolites that have the potential to be formed from these portions of the molecule could not be finalised.

A high long-term risk to large omnivorous mammals (wild boar) was indicated in the refined risk assessment. This issue has been regarded as a critical area of concern and a data gap has been identified. The risk assessments for non-target organisms in relation to metabolites in soil, groundwater when it becomes surface water, surface water and sediment could not be finalised in view of the data gaps for further information on the nature and level of the metabolites in these environmental matrices.

KEY WORDS

Pencycuron, peer review, risk assessment, pesticide, fungicide

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BACKGROUND

Legislative framework

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

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

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

Pencycuron is one of the 79 substances of the third stage part A of the review programme covered by Commission Regulation (EC) No 1490/2002, as amended by Commission Regulation (EC) No 1095/2007. In accordance with the Regulation, at the request of the Commission, the EFSA organised a peer review of the DAR (The Netherlands, 2005) provided by the designated rapporteur Member State, the Netherlands, which was received by the EFSA on 20 February 2006.

The peer review was initiated on 31 May 2006 by dispatching the DAR to the applicant Bayer CropScience AG, and on 26 October 2006 to Member States for consultation and comments. In addition, the EFSA conducted a public consultation on the DAR. The comments received were collated by the EFSA and forwarded to the RMS for compilation and evaluation in the format of a Reporting Table.

The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 11e, to withdraw support for the inclusion of pencycuron in Annex I to Council Directive 91/414/EEC.

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

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

In accordance with Article 18, the Netherlands, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report (The Netherlands, 2009). The Additional Report was received by the EFSA on 4 November 2009.

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

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 13 November 2009. In addition, the EFSA conducted a public consultation on the Additional Report. The EFSA collated and forwarded all comments received to the Commission on 4 January 2010. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 1 February 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on pencycuron within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 4 February 2010; the applicant was also invited to give its view on the need for additional information. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the areas of mammalian toxicology, environmental fate and behaviour, and ecotoxicology, and that further information should be requested from the applicant in the areas of residues, environmental fate and behaviour, and ecotoxicology.

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

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

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

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a fungicide on potatoes, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report (EFSA, 2010), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report comprises the following documents:

- the comments received on the DAR and the Additional Report,
- the Reporting Tables (revision 1-1; 5 February 2010),
- the Evaluation Table (8 September 2010),
- the report(s) of the scientific consultation with Member State experts (where relevant).

Given the importance of the DAR and the Additional Report including its addendum (compiled version of August 2010 containing all individually submitted addenda) (The Netherlands, 2010) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Pencycuron is the ISO common name for 1-(4-chlorobenzyl)-1-cyclopentyl-3-phenylurea (IUPAC).

The representative formulated product for the evaluation was 'Monceren DS 12.5', a powder for dry seed treatment (DS), containing 125 g/kg pencycuron, registered under different trade names in Europe.

The representative use evaluated comprises seed treatment on potatoes to control *Rhizoctonia solani*. Full details of the representative use can be found in the list of end points in Appendix A.

CONCLUSIONS OF THE EVALUATION

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

The minimum purity of pencycuron technical material is 980 g/kg. No FAO specification exists. Although not peer reviewed, the specification as given in the revised Additional Report dated August 2010 (The Netherlands, 2010) can be accepted by EFSA.

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 pencycuron or the respective formulation, however a data gap is identified for a GLP study on particle size distribution. It should be noted that the seed loading will need to be addressed at Member State level as this is not a data requirement at EU level.

The main data regarding the identity of pencycuron and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of pencycuron and the impurities in the technical material and for the determination of the active substance in the representative formulation. Adequate analytical methods are available for monitoring the residues of pencycuron in food of plant and animal origin, and in the environmental matrices. It should be noted however that the residue definitions for soil and water are provisional. Analytical methods for the determination of residues in body fluids and tissues are not required as pencycuron is not classified as toxic or highly toxic.

2. Mammalian toxicity

Pencycuron is not acutely toxic via the oral, dermal or inhalation routes (oral LD_{50} > 5000 mg/kg bw, dermal LD_{50} > 2000 mg/kg bw, LC_{50} > 5.13 mg/L); it is not a skin or eye irritant, and it is not a skin sensitiser. The target organ after repeated exposures (both subchronic and chronic) is the liver: the relevant NOAELs are 65 mg/kg bw/day and 120 mg/kg bw/day in mice and rats, respectively (short-term studies), and 18 mg/kg bw/day in rats and 43 mg/kg bw/day in mice (long-term studies). Pencycuron does not show any genotoxic or carcinogenic potential. It is not a reproductive toxicant (the relevant parental and offspring NOAELs are 32 mg/kg bw/day, based on reduced pup weight at parentally toxic doses, and the reproductive toxicity NOAEL is 1000 mg/kg bw/day), and is not toxic for the development: the relevant maternal and developmental NOAELs are 1000 mg/kg bw/day (highest dose tested in rats) and 2000 mg/kg bw/day (highest dose tested in rabbits).
The Acceptable Daily Intake (ADI) of pencycuron is 0.2 mg/kg bw/day, based on the 2-year rat NOAEL with a safety factor of 100; the Acceptable Operator Exposure Level (AOEL) is 0.15 mg/kg bw/day, based on the NOAEL of the two-generation study in rats with a safety factor of 100, and corrected for 46 % oral absorption. Based on the toxicological profile of pencycuron, an Acute Reference Dose (ARfD) was not allocated. The reference values of the parent pencycuron can also apply to the metabolite pencycuron-BP-amine. The operator exposure assessed using a field study with the on-planter technique showed exposure levels below the AOEL (7 %, without the use of personal protective equipment); similarly, the estimated bystander exposure is below the AOEL (< 1%). No re-entry exposure is expected for the representative use.

3. Residues

The metabolism of pencycuron was investigated in potatoes and rice as well as in wheat, Swiss chard and turnip, grown as rotational crops. In potato foliage and root, pencycuron was the major residue. The additional data available for rice do not contradict the findings in potatoes. The metabolic pattern in rotational crop differs from the one in the primary crop, because the metabolite pencycuron-PB-amine was a major residue in almost all commodities found at significant levels in crops used for human and animal consumption after the three rotations performed. In the soil, pencycuron-PB-amine is slowly but continuously formed from the relatively persistent pencycuron, but pencycuron-PB-amine is much more available for uptake by plants. The residue definition in the primary crop for both monitoring and risk assessment is proposed to include pencycuron alone. Because of the differences between the residue pattern in primary and rotational crops, and the toxicological properties of pencycuron-PB-amine, the potential intake of pencycuron-PB-amine residues through rotational crops was included in the consumer risk assessment.

Metabolism data with pencycuron in lactating goats and laying hens indicate that in most tissues pencycuron is extensively metabolised. However, pencycuron is present in all edible tissues and reaches the highest relative concentration in fat. The animal residue definition for both monitoring and risk assessment is proposed to include pencycuron alone. Livestock intake of pencycuron exceeded 0.1 mg/kg dry feed for cattle and pigs. However, based on metabolism data, residues above the LOQ of 0.01 mg/kg are not expected in animal products, and therefore no MRLs have been proposed.

Based on 12 residue trials in potatoes from southern Europe and 25 northern European trials, the MRL for potato tubers is proposed at 0.05 mg/kg pencycuron. 11 field rotational crop studies were performed with spring wheat, spring barley, turnip, lettuce and carrot. Significant residues of pencycuron and pencycuron-PB-amine were found at plant back intervals of 30 days in turnip, cereal straw and forage. At longer plant back intervals (100 days and beyond) residues of pencycuron and pencycuron-PB-amine in rotational crops were both below the LOQ of 0.01 mg/kg. Moreover, it was shown that consumer exposure to residues in rotational crops was very low (0.3 % of the ADI). Therefore, it is not considered necessary to set specific MRLs for pencycuron or pencycuron-PB-amine in rotational crops. Processing studies were not required due to the low consumer intake.

Using the EFSA-PRIMo model, intake calculations of pencycuron and pencycuron-PB-amine by humans based on consumption of potatoes and rotational crops indicated that the maximum total intake was 0.4 % of the ADI. For pencycuron and pencycuron-PB-amine an acute risk assessment was not required since no ARfD was set.

4. Environmental fate and behaviour

In soil laboratory incubations under aerobic conditions in the dark, pencycuron exhibited moderate to high persistence, forming the major (>10 % applied radioactivity (AR)) metabolite pencycuron-PB-amine (max. 45 % AR), which exhibited low to medium persistence. The metabolites pencycuron-phenyl-cyclopentyl-urea (max. 6.6 % AR, exhibiting low persistence) and pencycuron-ketone (max. 9.9 % AR, exhibiting medium to high persistence) were formed at levels that triggered groundwater exposure assessments in accordance with European Commission (2003) guidance. Mineralisation of the methylene and phenyl ring radiolabels to carbon dioxide accounted for 4.7 – 46.3 % AR after 104-120 days, and 21 - 29.4 % AR after 104 days respectively. The formation of unextractable[11] residues for these radiolabels accounted for 11 - 24 % AR after 100 - 120 days, and 34.1 - 44.5 % AR after 104 days respectively. A data gap was identified for soil incubations where the chlorophenyl and cyclopentyl rings were radiolabelled, as the results from the available investigated radiolabelling do not preclude that metabolites from the other rings could reach levels that would trigger further consideration (for example groundwater exposure assessment). Pencycuron was immobile or exhibited

[11] not extracted by acetonitrile followed by methylene chloride, or water followed by acetonitrile then dichloromethane, or water then acetonitrile or acetonitrile/water followed by microwave extraction with acetonitrile/water.

slight mobility in soil. Pencycuron-PB-amine exhibited medium to slight mobility, pencycuron-phenyl-cyclopentyl-urea exhibited high to medium mobility, while pencycuron-ketone exhibited low soil mobility. It was concluded that the adsorption of pencycuron and these metabolites was not pH dependent. For the metabolite pencycuron-ketone, the available batch soil adsorption investigations only investigated a single soil solution concentration, therefore the effect of concentration on soil adsorption was not investigated. Further investigation of this would be warranted if a reduction in the uncertainty would be required to finalise the leaching assessment. It was concluded that this was not necessary in this case for the representative use assessed, provided a 1/n value of 1 was selected for use in FOCUS leaching simulations. However, it was concluded that a data gap should be identified in relation to this core Annex II requirement in the context of other use patterns needing to be assessed. In satisfactory field dissipation studies carried out at 6 sites in Germany, 1 in the UK, 1 in northern France, 1 in southern France and 1 in Italy (spray application to the soil surface on bare soil plots in late spring) pencycuron exhibited moderate to medium persistence. Sample analyses were only carried out for the parent pencycuron and pencycuron-PB-amine. With the aim of enabling field degradation rates for pencycuron and pencycuron-PB-amine to be used in leaching modelling, the field trials were normalised to FOCUS reference conditions[12] using the time step normalisation method as recommended by FOCUS (FOCUS, 2006). The UV visible absorption spectrum of pencycuron indicated that direct soil photolysis would not be expected to be a process contributing to the degradation measured in field trials where the test substance was sprayed on the soil surface. This is an important consideration when considering if it is appropriate to use field degradation rates in leaching modelling, as significant photolytic breakdown has to be excluded. As the weather stations utilised for the normalisation to FOCUS reference conditions (source of the required daily temperature and precipitation data) were not necessarily at the experimental trial sites, a data gap was identified for further clarification of how representative the used weather stations were for the trial sites.

In laboratory incubations in dark aerobic natural sediment water systems, pencycuron exhibited medium to high persistence, forming no major metabolites in the water or sediment compartments of the test systems. As would be expected, the test substance partitioned from the water to the sediment phase of the test system reaching its maximum in the sediment (55 - 79 % AR) after 30 days. The unextractable sediment fraction (not extracted by ethyl acetate) was the major sink for the cyclopentyl ring radiolabel, accounting for 23.9 – 29.5 % AR at study end (91 days). Mineralisation of this radiolabel accounted for 11.5 – 21.7 % AR at the end of the study. A data gap was identified for aerobic sediment water system incubations where the chlorophenyl and phenyl rings were radiolabelled, as the cleavage pattern in the available incubations does not preclude that metabolites from these rings might reach levels that would trigger further consideration. The necessary surface water and sediment exposure assessments (Predicted environmental concentrations (PEC)) were carried out for the active substance pencycuron and the metabolite pencycuron-PB-amine up to FOCUS surface water step 3 (FOCUS, 2001)[13].

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (FOCUS, 2000) scenarios and the PEARL 3.3.3 model[14] for the active substance pencycuron, and for the metabolites pencycuron-PB-amine, pencycuron-ketone and pencycuron-phenyl-cyclopentyl-urea. A data gap was identified that needs to be filled before the normalisation of the field trials to FOCUS reference conditions can be relied on. Consequently, the relied on groundwater modelling assessment used soil DT_{50} and kinetic formation fractions derived from the laboratory incubations, with the exception that for the metabolite leaching assessments the DT_{50} for the precursor in the modelling (pencycuron) came from the normalised field trials. This approach was considered acceptable in this case even though there was uncertainty in the normalised pencycuron field values, as the shorter pencycuron DT_{50} value from the field trial database (median of 38.3 days, compared to laboratory incubation database, median value of 90.7 days) would increase the mass simulated for the metabolites

[12] 20ºC and pF 2 soil moisture, the normalisation assumed the Walker equation coefficient of 0.7 and Q10 of 2.58 (following EFSA, 2007)
[13] Simulations appropriately utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7.
[14] Simulations correctly utilised the agreed Q10 of 2.58 (following EFSA, 2007) and Walker equation coefficient of 0.7

that were available for leaching. The potential for groundwater exposure from the representative use by all these compounds above the parametric drinking water limit of 0.1 µg/L was concluded to be low in geoclimatic situations that are represented by all 9 FOCUS groundwater scenarios.

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

5. Ecotoxicology

Taking into account the representative use of pencycuron, dietary exposure of herbivorous birds was not considered relevant. Although geese potentially feed on potato tubers during winter after harvest of potatoes, it was considered unlikely that they would feed on potatoes in spring when treated potatoes are sown and covered by soil. The risk assessment via uptake of contaminated drinking water was based on the PECsw, since no source of contaminated drinking water was expected to be available in field. A standard risk assessment for birds and mammals was conducted for secondary poisoning via uptake of contaminated earthworms and fish. The TERs for fish-eating birds and mammals exceeded the Annex VI trigger of 5, indicating a low risk. The first-tier TER for earthworm-eating birds and mammals was below the trigger, indicating a potential high risk. The PECsoil in the first-tier risk assessment was based on the concentration of pencycuron for the area of 5 cm around the potato. A refined risk assessment was based on the maximum plateau PECsoil of 0.26 mg/kg for an even distribution of pencycuron in the upper 20 cm soil layer. The resulting TERs were above the Annex VI trigger of 5 for earthworm-eating birds and mammals, indicating a low risk. The suggested refinement was agreed in the PRAPeR 77 meeting of experts.

The acute risk to mammals was assessed as low, but the long-term risk to wild boar (*Sus scrofa*) from uptake of potato tubers was assessed as high in the first-tier risk assessment. It was suggested to refine the risk assessment with a higher end point from the two-generation rat study (32 mg pencycuron/kg bw/day instead of 3.2 mg pencycuron/kg bw/day); a dose-response relationship was observed but the magnitude of effects was low (< 5 %). A suggested PD refinement of 0.26 was not agreed, since the submitted literature gave an indication that the proportion of potato in the diet during the relevant period of time would be much higher and an appropriate PD would be 0.63. Based on the end point of 32 mg pencycuron/kg bw/day and a PD of 0.63, the resulting TER was 4.27. It was noted in the meeting that other contaminated food items and contaminated soil, which are also taken up by wild boars, were not considered in the TER calculation. The majority of experts considered the long-term risk to mammals as not sufficiently addressed, since the refined TER of 4.27 was below the Annex VI trigger of 5, however no consensus could be reached. EFSA is of the opinion that the long-term risk to mammals needs to be addressed further since the trigger was not met, the risk assessment is based on an end point which is not conservative, and the suggested PD refinement does not consider all food items. Therefore a data gap has been identified to refine further the long-term risk to large omnivorous mammals. The risk of secondary poisoning from the major soil metabolite pencycuron-PB-amine was considered to be low for birds and mammals, since its $\log P_{ow}$ is < 3.

No toxic effects were observed in tests with fish, daphnids or algae within the aqueous solubility of pencycuron of about 0.3 mg/L. The acute and chronic TERs were above the Annex VI trigger values for all FOCUS step 3 scenarios, indicating a low risk. The toxicity of the major soil metabolite pencycuron-PB-amine was tested with fish, daphnids and algae, and the respective TERs based on FOCUS step 3 PEC_{sw} were above the Annex VI triggers of 100 and 10, indicating a low risk. It should be noted that uncertainty remains with regard to classification and labelling. No studies with the formulation (where a higher solubility of the active substance was achieved) were available for aquatic invertebrates and no reliable information with studies with increased solubility of the active substance was available for invertebrates and fish. The proposal of R52/R53 may be appropriate on the basis of the algae study and the formulation. A bioconcentration study was performed since the $\log P_{ow}$ of pencycuron is 4.7. The whole body bioconcentration factor (BCF) value was determined to be 226 in a study with *Cyprinus carpio*. Based only on the lipid content the BCF was 5650. Although the Annex VI trigger of 100 is breached, the risk of bioaccumulation in the food chain was considered to be low,

because pencycuron was rapidly excreted (about 90 % of pencycuron was excreted within 3 days), and after 7 days of depuration the concentration in fish was below the limit of detection (0.01 mg/L). Overall, the risk to aquatic organisms was considered to be low for the representative use from the active substance, the metabolite pencycuron-PB-amine, and the unknown metabolites that might be formed in natural sediment water systems from the low levels of parent pencycuron that are calculated to reach surface water via drainage (short-term and long-term aquatic TER values are significantly more than an order of magnitude greater than the Annex VI triggers, using the exposure values for the active substance, see Appendix A). However, with the available information the aquatic risk assessment cannot be finalised in respect of possible, as yet unknown soil metabolites that might reach surface water via drainage (consequent to one of the data gaps identified in section 4).

Exposure of bees is unlikely, since pencycuron is used as a seed treatment on potatoes and it is non-systemic. The risk to bees from the representative use was considered to be low.

The risk to non-target arthropods was considered to be low for the representative use.

The acute toxicity of technical pencycuron and the major soil metabolite pencycuron-PB-amine to earthworms was low, with the acute TERs being far above the Annex VI trigger of 10. The chronic toxicity of pencycuron was tested with the formulations 'Pencycuron DS 12.5' and 'Pencycuron FS 250'. The 56-day NOEC of 100 mg pencycuron/kg soil d.w. was used in the risk assessment, leading to a chronic TER of 10.5. However, with the available information the risk assessment for earthworms cannot be finalised in respect of possible, as yet unknown, soil metabolites that might be formed (see data gaps identified in section 4).

The formulation 'Pencycuron 12.5 DS' and the major soil metabolite pencycuron-PB-amine were tested with collembola (*Folsomia candida*). The TER based on a worst-case PEC of 9.5 mg pencycuron/kg soil and a NOEC of 30 mg pencycuron/kg soil (60 mg pencycuron/kg soil corrected by a factor 2) resulted in a long-term TER of 3.2. The 28-day NOEC for the metabolite pencycuron-PB-amine was 125 mg/kg (corrected by a factor of 2). The resulting TER was 46, with a PECsoil of 2.7266 mg/kg soil. An older study with technical pencycuron, which resulted in a lower end point (NOEC of 1 mg pencycuron/kg soil), was considered as less reliable than the formulation study, since it was not conducted according to test guidelines for collembola, and a very flat dose-response curve was observed. The risk to collembola was assumed to be low by the experts since the worst-case soil PEC in the 5 cm potato tuber sphere was used in the TER calculation, and only a part of the in-field population would be affected. If the maximum plateau PECsoil of 0.26 mg pencycuron/kg soil would be used in the risk assessment then the TERs would clearly exceed the trigger of 5. In addition, no effect on organic matter breakdown was observed in two litterbag studies. However, with the available information the risk assessment for other soil non-target macro-organisms cannot be finalised in respect of possible, as yet unknown, soil metabolites that might be formed (see data gaps identified in section 4).

The risk of adverse effects on soil microbial processes was considered to be low. However the risk assessment cannot be finalised in respect of possible, as yet unknown, soil metabolites that might be formed (see data gaps identified in section 4).

The risk to non-target plants from exposure to pencycuron and pencycuron-PB-amine was assessed as low for the representative use. The risk to biological methods of sewage treatment was considered to be low.

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

It is noted that until data gaps have been filled, it cannot be excluded that further compounds might need to be added to the residue definitions for all environmental compartments, except air.

6.1. Soil

Compound (name and/or code)	**Persistence**	**Ecotoxicology**
pencycuron	moderate to medium persistence (based on field studies) Biphasic DT_{50} 36.4-188 days (DT_{90} 159–625 days, 20°C, 40-55% MWHC soil moisture) Field studies: Biphasic DT_{50} 10-68.2 days (DT_{90} 98–373 days)	The risk for earthworms and soil micro-organisms was assessed as low. The chronic TER for collembola was below the trigger of 5 based on local concentrations of pencycuron. However, the TERs would clearly exceed the trigger if plateau PECsoil were used.
pencycuron-PB-amine	low to medium persistence Biphasic DT_{50} 2.2 to around 100 days (DT_{90} 24–upward of 224 days, 20°C, 45% MWHC soil moisture)	The risk to earthworms, collembola, and soil micro-organisms was assessed as low.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
pencycuron	slight mobility to immobile K_{Foc} 2414-10441 mL/g	No	Yes	Yes	No toxicity observed in fish, daphnids or algae up to the limit of solubility of 0.3 mg a.s./L. The risk to aquatic organisms in surface water was assessed as low.
pencycuron-PB-amine	medium to slight mobility K_{Foc} 158-2057 mL/g	No	No	No data available, not needed	The lowest end point was observed for algae (EC_{50} > 0.00892 mg a.s./L). The risk to aquatic organisms was assessed as low.
pencycuron-phenyl-cyclopentyl-urea	high to medium mobility K_{Foc} 96-153 mL/g	No	No data submitted, No data required	No data available, not needed	No data submitted, No data required
pencycuron-ketone	low mobility K_{doc} 1283-1394 mL/g	No	No data submitted, No data required	No data available, not needed	No data submitted, No data required

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
pencycuron	No toxic effects on fish, daphnids or algae were observed up to the limit of solubility in water (0.3 mg a.s./L). The risk to aquatic organisms was assessed as low.
pencycuron-PB-amine	The lowest end point was observed for algae (EC_{50} > 0.00892 mg a.s./L). The risk to aquatic organisms was assessed as low.

6.4. Air

Compound (name and/or code)	Toxicology
pencycuron	Not acutely toxic via inhalation.

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

- GLP study on particle size distribution of the formulation (relevant for the representative use evaluated; submission date proposed by the applicant: unknown, see section 1).

- Satisfactory information on the fate of the chlorophenyl and cyclopentyl moieties of pencycuron in soil was not available. With the available studies (methylene and phenyl ring radiolabels) the results do not preclude that metabolites from the other rings would reach levels that would trigger further consideration (for example groundwater exposure assessment) (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see section 4).

- The available batch adsorption study on pencycuron-ketone only investigated adsorption at a single solution concentration. A guideline batch adsorption study that would enable the Freundlich slope to be estimated was not available. The results of such a study would be needed to reduce uncertainty in leaching modelling assessments in situations where the margins of safety for the risk assessment might be reduced (i.e. higher application rates or different seasons of application needed to be assessed) (not essential for the representative use evaluated in this conclusion; submission date proposed by the applicant: unknown; see section 4).

- Satisfactory information on the fate of the chlorophenyl and phenyl moieties of pencycuron in aerobic sediment water systems was not available. The cleavage pattern in the available incubations does not preclude that metabolites from these rings might reach levels that would trigger further consideration (relevant for all representative use evaluated; submission date proposed by the applicant: unknown; see section 4).

- Sufficient details on how representative 'the nearest weather station' is to each field dissipation trial site, to enable the precipitation measured at the weather stations to be used for normalising the field dissipation studies to FOCUS soil moisture reference conditions (with the necessary degree of certainty) were not available. Altitude/topographical comparisons/direction of prevailing wind at the trial sites and the weather stations should have been compared (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see section 4).

- The long-term risk assessment for large omnivorous mammals feeding on potato tubers needs to be further refined (relevant for the representative use evaluated; submission date proposed by the applicant: unknown; see section 5).

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

None.

ISSUES THAT COULD NOT BE FINALISED

- Information is missing regarding the fate and behaviour of the chlorophenyl and cyclopentyl portions of the molecule in soil, and the chlorophenyl and phenyl portions of the molecule in natural surface water and sediment systems. The soil, groundwater, surface water and sediment exposure assessments for metabolites that have the potential to be formed from these portions of the molecule could not be finalised. Consequently, the possible levels of groundwater exposure and environmental risk assessments to non-target organisms in these compartments from metabolites were not finalised (see sections 4 and 5).

CRITICAL AREAS OF CONCERN

- A high long-term risk is identified to large omnivorous mammals (wild boar) feeding on recently planted treated potato tubers.

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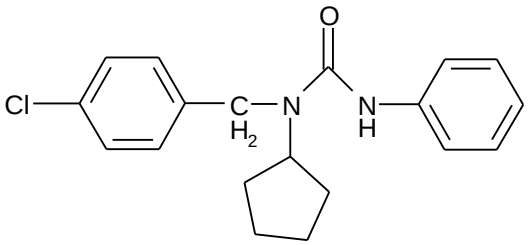
APPENDICES

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

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

Active substance (ISO Common Name)	Pencycuron
Function (*e.g.* fungicide)	fungicide for use as seed treatment in potato
Rapporteur Member State	The Netherlands

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	1-(4-chlorobenzyl)-1-cyclopentyl-3-phenylurea
Chemical name (CA)	*N*-[(4-chlorophenyl)methyl]-*N*-cyclopentyl-*N'*-phenylurea
CIPAC No	402
CAS No	66063-05-6
EEC No (EINECS or ELINCS)	ELINCS no. 266-096-3
FAO Specification (including year of publication)	not indicated
Minimum purity of the active substance as manufactured (g/kg)	≥ 980 g/kg (technical material)
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	none
Molecular formula	$C_{19}H_{21}ClN_2O$
Molecular mass	328.8
Structural formula	

Physical-chemical properties (Annex IIA, point 2)

Melting point	132 °C (active substance after re-crystallisation (99.5%))
Boiling point	283 - 289 °C (pure active substance (98.7%); atmospheric pressure) 283 - 288 °C (technical grade active substance (98.7%); atmospheric pressure)
Temperature of decomposition	weight loss (thermogravimetric measurement) starts above 140 °C and continues until a mass loss of 98% at 250 °C (99.5%) exothermic effect at 300-400°C (pure active substance (98.7%)) or at 310-400°C (technical grade active substance (98.7%))
Appearance	colourless crystals (99.5%) colourless powder (99.6%) white powder (both pure active substance (98.7%) and technical grade active substance (98.7%))
Relative density	1.22 g/cm^3 at 20 °C (99.5%) D^{20}_4: 1.24 (pure active substance (98.7%) D^{20}_4: 1.23 (technical grade active substance (98.7%))
Surface tension	72.1 mN/m of a 90% saturated aqueous solution at 20°C (98.7%)
Vapour pressure (in Pa, state temperature)	4.10^{-7} / 5.10^{-10} Pa at 20 °C (extrapolated; 98.7% / 99.5%) $9.3.10^{-7}$ / 2.10^{-9} Pa at 25 °C (extrapolated; 98.7% / 99.5%)
Henry's law constant (Pa m^3 mol $^{-1}$)	5.10^{-4} / 5.10^{-7} Pa.m^3.mol^{-1} at 20 °C (98.7% / 99.5%)
Solubility in water (g/l or mg/l at 20 °C)	Water solubility at 20 °C (98.7%): 0.35 mg/L at pH 4.0 0.26 mg/L at pH 6.8 0.29 mg/L at pH 9.0 0.3 mg/L at 20 °C, no influence of pH in the range of 4 to 9
Solubility in organic solvents (in g/L or mg/L)	Solubility at 20 °C (98.7 & 99.5%): n-heptane 0.23-0.26 g/L xylene 11.5 g/L dichloromethane >250 g/L 2-propanol 15.6 g/L 1-octanol 16.7 g/L polyethyleneglycol 25.7 g/L acetone 89.4-95 g/L ethylacetate 43.8-45 g/L acetonitrile 24.9 g/L dimethylsulfoxide 152.9 - >250 g/L methanol 27 g/L toluene 24 g/L
Partition co-efficient (log P_{OW}) (state temperature)	logPow = 4.7 at 20 °C (shake flask method)-(99.8%) Log P_{ow} at 25°C (HPLC method): 4.0 at pH 4 (pH of buffered eluent) 4.0 at pH 7 (pH of buffered eluent) 4.0 at pH 9 (pH of buffered eluent) (98.7%)

Hydrolytic stability (DT_{50}) (state pH and temperature)	at 20°C: pH 4: DT_{50} = 29.9 days pH 7: DT_{50} = 289 days pH 9: DT_{50} = 256 days (>98%)
Dissociation constant	Pencycuron exhibits neither basic nor acidic properties in aqueous systems. It is not possible to specify a pK for water. No pKa in the pKa range of 2 to 12.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	molar absorptivity 19720 L.mol-1.cm-1 at 240 nm absorption of Pencycuron ends at a wavelength of 291 nm with molar absorptivity < 10 L.mol-1.cm-1 UV-spectrum: MeOH or MeOH/buffer solution (ratio not specified):

pH	λmax	E L/(molxcm)
2	201	38818
	227	16627
	240	19112
MeOH	203	35910
	228	16644
	240	19506
10	203	35204
	229	16270
	240	19240

Photostability (DT_{50}) (aqueous, sunlight, state pH)	no UV absorption at a wavelength > 295 nm: test substance is not considered to be directly photodegradable in the environment
Quantum yield of direct phototransformation in water at λ > 290 nm	not available and not required (as addressed before)
Flammability	Not highly flammable (tech. a.s. 98.7% (w/w)
Explosive properties	not explosive (98.7%)
Oxidizing properties	not oxidizing (tech. a.s. 98.7% (w/w))

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical and chemical data	No classification is proposed

List of representative uses evaluated (pencycuron)*

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
potato	EU North South	MONCE-REN DS 12.5	F	Rhizoctonia solani	DS	125 g / kg	powdering of tubers	pre /during planting	1	not applicable		-	25 g as / dt seed potato*	n.a.	*700 g a.s./ha, approx. 2800 kg tubers /ha [I] [II]

[I] The environmental risk assessment from exposure to metabolites and the groundwater exposure assessment for metabolites could not be finalised due to data gaps relating to the route of degradation of pencycuron in soil.
[II] A high risk to large omnivorous mammals feeding on potato tubers was identified with the available long-term risk assessment.

Remarks:

*	Uses for which risk assessment could not been concluded due to lack of essential data are marked grey	(h)	Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)	(i)	g/kg or g/l
(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(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
(c)	*e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds		
(d)	*e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
(f)	Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
(g)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restrictions

Methods of Analysis

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

Technical as (principle of the method)	HPLC/DAD (validated)
Impurities in technical as (principle of the method)	HPLC/DAD, HPLC/ UV(validated), titration
Plant protection product (principle of the method)	HPLC/UV (validated)

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		pencycuron
Food of animal origin		pencycuron
Soil		Provisionally pencycuron as data gaps need to be filled before it can be finalised.
Water	surface	Provisionally pencycuron as data gaps need to be filled before it can be finalised.
	drinking/ground	Provisionally pencycuron as data gaps need to be filled before it can be finalised.
Air		pencycuron

Monitoring/Enforcement methods

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	LC/MS/MS LOQ = 0.01 mg/kg (potato tubers) ILV available Crops with high water content (potato tubers, lettuce, tomato, turnip, pineaple) Dry crops (wheat, dry beans), crops with high acid content (orange), crops with high fat content (oilseed rape, sunflower)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	HPLC/MS/MS, LOQ = 0.01 mg/kg
Soil (principle of the method and LOQ)	HPLC/UV - LOQ = 0.05 mg/kg HPLC/MS - LOQ = 0.01 mg/kg
Water (principle of the method and LOQ)	HPLC/FLU LOQ = 0.05 µg/L (surface water)
Air (principle of the method and LOQ)	HPLC/UV LOQ = 0.54 µg/m³
Body fluids and tissues (principle of the method and LOQ)	Not required as the active substance is not classified as toxic or highly toxic.

Impact on Human and Animal Health

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

Rate and extent of absorption:	Absorption from the gut after single oral low dose 46% within 48 h, based on radiolabel recovered from bile, urine, tissues and organs
Distribution:	72 h after administration highest in the liver
Potential for accumulation:	No evidence of accumulation
Rate and extent of excretion:	within 24 h 76-83% of the administered dose (males-females), after repeated low dose, mainly via faeces (ca. 80% or more of total excretion) within 72 h 76-91% of the administered dose (males-females), mainly via faeces (ca. 80% or more of total excretion)
Metabolism in animals	extensively metabolised once absorbed (virtually no parent compound in urine)
Toxicologically relevant compounds (animals and plants)	Parent compound and metabolites.
Toxicologically relevant compounds (environment)	Parent compound and metabolites.

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	>5000 mg/kg bw
Rat LD_{50} dermal	>2000 mg/kg bw
Rat LC_{50} inhalation	>5.13 mg/L
Skin irritation	not irritating
Eye irritation	not irritating
Skin sensitisation	not sensitising (Maximisation test)

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Liver
Lowest relevant oral NOAEL / NOEL	90-day mouse: 65 mg/kg bw/day 90-day rat: 120 mg/kg bw/day 1-year dog: 277 mg/kg bw/day (highest dose tested)
Lowest relevant dermal NOAEL / NOEL	21d rabbit: 1000 mg/kg bw/day (highest dose tested)
Lowest relevant inhalation NOAEL / NOEL	No data – not required

Genotoxicity (Annex IIA, point 5.4)	No genotoxic potential

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

Target/critical effect	Liver
Lowest relevant NOAEL / NOEL	2-year rat: 18 mg/kg bw/day 2-year mouse: 43 mg/kg bw/day
Carcinogenicity	No carcinogenic potential

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction target / critical effect	Reduced pup weight at parentally toxic doses
Relevant parental NOAEL	Rat: 32 mg/kg bw/day
Relevant repoductive NOAEL	Rat: 1000 mg/kg bw/day
Relevant offspring NOAEL	Rat: 32 mg/kg bw/day

Developmental toxicity

Developmental target / critical effect	No adverse effects observed
Relevant maternal NOAEL	Rat: 1000 mg/kg bw/day Rabbit : 2000 mg/kg bw/day
Lowest relevant developmental NOAEL	Rabbit: 2000 mg/kg bw/day (highest dose tested) Rat: 1000 mg/kg bw/day (highest dose tested)

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 5.7)

acute neurotoxicity NOAEL	No data – not required
semi-chronic neurotoxicity NOAEL	Rat: 181 mg/kg bw/day in males and 275 mg/kg bw/day in females based on increased motor and locomotor activities (marginal)

Other toxicological studies (Annex IIA, point 5.8)

oral LD_{50} (Pencycuron-PB-amine):	>200-2000 mg/kg bw Ames test negative

Medical data (Annex IIA, point 5.9)

Records are kept on file; no adverse effects reported so far.

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI	0.2 mg/kg bw/day	2-year rat	100
AOEL (semi-chronic, internal)	0.15 mg/kg bw/day	2-generation rat	100 46% oral absorption
ARfD (acute reference dose)	Not allocated – not necessary		

Dermal absorption (Annex IIIA, point 7.3)

Monceren DS 12.5 (undiluted): 0.2% based on *in vitro* (human) study

Acceptable exposure scenarios (including method of calculation)

Operator	7 % of the AOEL without PPE for the on-planter technique (field study)
Workers	Not relevant - not exposed
Bystanders	<1 % AOEL for the on-planter technique (field study)

Classification and proposed labelling (Annex IIA, point 10)

with regard to toxicological data	none

Residues

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

Plant groups covered	potatoes, rice
Rotational crops	Cereals (wheat), leafy crops (Swiss chard) and root vegetables (turnip)
Plant residue definition for monitoring	pencycuron
Plant residue definition for risk assessment	Primary crop: pencycuron Rotational crops: pencycuron and pencycuron-PB-amine
Conversion factor (monitoring to risk assessment)	None. No MRLs are proposed for rotational crops; no monitoring is required. For pre-registration consumer RA levels of pencycuron-PB-amine residues in rotational crops are available and they were used in the intake assessments.

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

Animals covered	lactating goat, laying hen
Animal residue definition for monitoring	pencycuron
Animal residue definition for risk assessment	pencycuron
Conversion factor (monitoring to risk assessment)	none
Metabolism in rat and ruminant similar (yes/no)	yes
Fat soluble residue: (yes/no)	yes

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

- Confined rotational crop study: Pencycuron-PB-amine found at relevant levels (>0.05 mg/kg) in various plant parts used for human and animal consumption. - Field rotational crop study: At PBI of 30 days residues of pencycuron and pencycuron-PB-amine max. 0.02 mg/kg. At longer PBI (following potatoes), residues of pencycuron and pencycuron-PB-amine individually <LOQ (0.01 mg/kg).

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

Pencycuron and pencycuron-PB-amine are stable in potato (tuber), wheat grain and straw, turnip, and lettuce (leaf) for at least 24 months when stored frozen at temperatures ≤ -18°C. No storage stability study in animal products was submitted (not required).

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

Residues in animal matrices were estimated based on metabolism data with pencycuron. No feeding studies are available.

Intakes by livestock ≥ 0.1 mg/kg diet/day:	**Ruminant:** Pencycuron: Yes PB-amine: Yes*	**Poultry:** Pencycuron: No PB-amine: No	**Pig:** Pencycuron: Yes PB-amine: No
Muscle	<LOQ	-	<LOQ
Liver	<LOQ	-	<LOQ
Kidney	<LOQ	-	<LOQ
Fat	<LOQ	-	<LOQ
Milk	<LOQ		
Eggs		-	

LOQ for pencycuron = 0.01 mg/kg

*: No studies in animals were required with pencycuron-PB-amine. The calculated maximum dietary burden (dry weight) for meat and dairy ruminants is calculated to be 0.1 mg/kg dry weight, the agreed trigger for a livestock feeding study. However, the calculated intake of 0.1 mg PB-amine/kg dry weight by cattle is considered as a rare event, resulting from an accumulation of worst-cases: potato crop failure followed by grasses after a plant back interval of 30 days, HR of 0.02 mg/kg with a diet of 100% grasses. Therefore no livestock feeding studies were considered necessary.

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Southern Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)
Potato (tuber)	N & S	North: 14x <0.01, 0.011, 3x 0.02, 2x 0.03, 4x <0.05, 0.06 South: 9x <0.01, 0.02, 0.03, 0.04	Since the observed residue levels in potato trials performed in northern and southern European zones are showing comparable residue levels, the results are taken together	0.05	0.01

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

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

ADI	Pencycuron: 0.2 mg/kg bw/day Pencycuron-PB-amine: ADI of parent pencycuron can be applied.
TMDI (EFSA-PRIMo model, % ADI)	Maximum intakes: 0.4% (UK toddler) 0.3% (WHO Cluster diet B)
NEDI (% ADI)	not applicable
Factors included in NEDI	not applicable
ARfD	Pencycuron: no ARfD Pencycuron-PB-amine: no ARfD
Acute exposure (EFSA-PRIMo) (% ARfD)	not applicable

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

Not required. TMDI of pencycuron/pencycuron-PB-amine accounts for less than 10 % of the ADI.

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

Potatoes	0.05 mg/kg

Fate and Behaviour in the Environment

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

Mineralisation after 100 days	methylene-label: 6.5-40.9% AR on day 84-91 (5 soils) and 4.7-46.3% AR on day 104-120 (12 soils). phenyl-UL-label: 19.3-27.4% AR on day 91 and 21.0-29.4% AR on day 104 (4 soils).
Non-extractable residues after 100 days	methylene-label: 11.2-24.0% AR after 100-120 days (12 soils). phenyl-UL-label: 34.1-44.5% AR after 104 days (4 soils).
Relevant metabolites - name and/or code, % of applied (range and maximum)	THS 3995 = (N-[(4-chlorophenyl)-methyl]-N-cyclopentylamide) (*M16*) = pencycuron-PB-amine: max. 45.0% AR on day 100 pencycuron-phenyl-cyclopentyl-urea: max 6.6% AR on day 91 pencycuron-ketone: max 9.9% AR on day 84

Data gap: Satisfactory information on the fate of the chlorophenyl and cyclopentyl moieties of pencycuron in soil is still not available, as the new study provided in the resubmission application only investigated the methylene and phenyl ring, and the cleavage pattern in these experiments does not preclude that metabolites from the other rings would not reach levels that would trigger further consideration (for example groundwater exposure assessment).

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

Anaerobic degradation	No data submitted. Data considered not relevant due to the intended application pattern.
Soil photolysis	No data submitted. Data considered not relevant due to the intended application pattern.

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

Laboratory studies ‡									
Parent	Aerobic conditions - **persistence endpoints**								
soil	pH[A]	% oc	% MWHC	temp. (°C)	DT_{50} (d)	DT_{90} (d)	kinetics	**DT_{50} (20°C, d)**	**DT_{90} (20°C, d)**
Loam A	6.4	1.98	40	20	121	477	DFOP	121	477
Sandy loam A	6.7	1.12	40	20	167	554	SFO	167	554
Silt	7.8	2.62	40	20	99.1	410	DFOP	99.1	410
Sandy loam B	7.0	1.8	40	20	188	625	SFO	188	625
Sandy loam C[B]	6.6	1.5	55	20	43.1	199	DFOP	43.1	199
Sandy loam C[C]	6.6	1.5	55	20	40.8	210	DFOP	40.8	210
Sandy loam C							*mean*	42.0	205
Clay loam	7.4	3.8	55	20	60.2	211	DFOP	60.2	211
Clay loam	7.4	3.8	55	20	60.0	215	DFOP	60.0	215
Clay loam							*Mean*	60.1	213
Sandy loam D[A]	7.3	1.5	55	20	38.5	150	DFOP	38.5	150
Sandy loam D[B]	7.3	1.5	55	20	34.3	168	DFOP	34.3	168
Sandy loam D							*Mean*	36.4	159
Loam B[B]	6.3	1.2	55	20	58.7	279	DFOP	58.7	279
Loam B[C]	6.3	1.2	55	20	52.7	198	DFOP	52.7	198
Loam B							*mean*	55.7	239

							Min	**36.4**	**159**
							Max	**188**	**625**

SFO = Single First-Order model
DFOP = Double-First-Order in Parallel model
(A) pH in water
(B) Treatment with methylene-14C-labelled pencycuron
(C) Treatment with phenyl-UL-labeled 14C-pencycuron

Laboratory studies ‡							
Parent	Aerobic conditions - **modelling endpoints**						
soil	pH (A)	% oc	% MWHC	temp. (°C)	DT_{50} (d)	kine-tics	**DT_{50} (20°C, d) pF 2/10 kPa**
Loam A	6.4	1.98	40	20	139	SFO	139
Sandy loam A	6.7	1.12	40	20	167	SFO	155
Silt	7.8	2.62	40	20	118	SFO	118
Sandy loam B	7.0	1.8	40	20	188	SFO	175
Sandy loam C(B)	6.6	1.5	55	20	53.2	SFO	
Sandy loam C(C)	6.6	1.5	55	20	53.7	SFO	
Sandy loam C				*mean*	53.5	SFO	53.5
Clay loam	7.4	3.8	55	20	62.8	SFO	
Clay loam	7.4	3.8	55	20	63.7	SFO	
Clay loam				*mean*	63.3	SFO	63.3
Sandy loam D(B)	7.3	1.5	55	20	42.2	SFO	
Sandy loam D(C)	7.3	1.5	55	20	42.8	SFO	
Sandy loam D				*mean*	42.5	SFO	42.5
Loam B(A)	6.3	1.2	55	20	67.8	SFO	
Loam B(B)	6.3	1.2	55	20	57.7	SFO	
Loam B				*mean*	62.8	SFO	62.8
						geometric mean	**89.2**
						median	**90.7**

SFO = Single First-Order model
DFOP = Double-First-Order in Parallel model
(A) pH in water
(B) Treatment with methylene-14C-labelled pencycuron
(C) Treatment with phenyl-UL-labeled 14C-pencycuron

Laboratory studies ‡									
Pencycuron-PB-amine	Aerobic conditions - **persistence endpoints**								
soil	pH(A)	% oc	% MWHC	temp. (°C)	DT_{50} (d)	DT_{90} (d)	kinetics	**DT_{50} (20°C, d)**	**DT_{90} (20°C, d)**
Sand	5.9	0.7	45	20	~100	n.a.	Graph	~100	n.a.
Loamy sand	6.0	2.48	45	20	19.4	94.3	DFOP	19.4	94.3
Silt loam	8.1	0.86	45	20	2.2	24.4	DFOP	2.2	24.4
Sandy loam	6.6	1.5	55	20	67.7	224.8	SFO	67.7	224.8
							Min	**2.2**	**24.4**
							Max	**~100**	224.8

FOMC = First Order Multi-Compartment model
DFOP = Double-First-Order in Parallel model
Graph = graphical estimation, no acceptable fit could be obtained by any model.
n.a. = not applicable
(A) pH in water

Laboratory studies ‡	
Pencycuron-PB-amine	Aerobic conditions - **modelling endpoints**

Soil	pH(A)	% oc	% MWHC	temp. (°C)	DT_{50} (d)	kine-tics	DT_{50} (20°C, d) pF 2/10 kPa	Formation fraction
Loam	6.4	1.98	40	20	102	SFO	102	0.664346

Silt	7.8	2.62	40	20	69.1	SFO	69.1	0.620186
Loamy sand	6.0	2.48	45	20	32.2	DFOP	32.2	n.a.
Silt loam	8.1	0.86	45	20	7.7	FOMC	5.6	n.a.
Sandy loam	6.6	1.5	55	20	67.7	SFO	67.7	0.413
						geometric mean	**38.6**	
						median	**67.7**	
						arithmetic mean		**0.566**

SFO = Single First-Order model
FOMC = First Order Multi-Compartment model
DFOP = Double-First-Order in Parallel model
n.a. = not applicable
(A) pH in water

Laboratory studies ‡									
pencycuron-phenyl-cyclopentyl-urea	Aerobic conditions - **persistence endpoints**								
soil	pH[(A)]	% oc	% MWHC	temp. (°C)	DT_{50} (d)	DT_{90} (d)	kinetics	**DT_{50} (20°C, d)**	**DT_{90} (20°C, d)**
Sandy loam	6.7	1.7	54	20	4.5	15.1	SFO	4.5	15.1
Silt loam	6.9	2.4	55	20	3.4	11.4	SFO	3.4	11.4
Clay loam	7.4	4.8	55	20	2.9	9.6	SFO	2.9	9.6
Loam	5.7	2.3	54	20	5.8	19.3	SFO	5.8	19.3
							Min	2.9	9.6
							Max	5.8	19.3

SFO = Single First-Order model
(A) pH in water

Laboratory studies ‡	
pencycuron-phenyl-cyclopentyl-urea	Aerobic conditions - **modelling endpoints**

Soil	pH[(A)]	% oc	% MWHC	temp. (°C)	DT_{50} (d)	kine-tics	DT_{50} (20°C, d) pF 2/10 kPa	Forma-tion fraction
Sandy loam	6.7	1.7	54	20	4.5	SFO	4.5	n.a.
Silt loam	6.9	2.4	55	20	3.4	SFO	3.4	n.a.
Clay loam	7.4	4.8	55	20	2.9	SFO	2.9	n.a.
Loam	5.7	2.3	54	20	5.8	SFO	5.8	n.a.
						geometric mean	4.0	
						median	4.0	

SFO = Single First-Order model
n.a. = not applicable
(A) pH in water

Laboratory studies ‡	
pencycuron-ketone	Aerobic conditions - **modelling endpoints** (Note these are fitted observed decline values from the maximum observed in studies dosed with pencycuron)

soil	pH [(A)]	% oc	% moisture	dose (mg/kg)	temp. (°C)	DT_{50} (d)	kine-tics	**DT_{50} (20°C, d) pF 2/10 kPa**	Forma-tion fraction
Clay loam	7.4	3.8	41.1	1.33	20	105.0	SFO		
Clay loam	7.4	3.8	41.1	1.33	20	60.8	SFO		
				geometric mean		79.9	SFO	**79.9**	n.a.
Sandy loam D[(B)]	7.3	1.5	28.2	1.33	20	52.5	SFO		
Sandy loam D[(C)]	7.3	1.5	28.2	1.33	20	73.7	SFO		

				geometric mean		62.2	SFO	**62.2**	n.a.
Loam B[(A)]	6.3	1.2	33.5	1.33	20	119.5	DFOP		
Loam B[(B)]	6.3	1.2	33.5	1.33	20	150.7	SFO		
				geometric mean		134.2	SFO	**134.2**	n.a.
							geometric mean	**87.4**	
							median	**79.9**	

SFO = Single First-Order model
DFOP = Double-First-Order in Parallel model
(A) pH in water
(B) Treatment with methylene-14C-labelled pencycuron
(C) Treatment with phenyl-UL-labeled 14C-pencycuron

Field studies ‡								
Parent	**persistence endpoints**							
Region	location	soil	pH	% oc	dose (kg a.s./ha)	**DT_{50} (d)**	**DT_{90} (d)**	kine-tics
Europe-N	Laacher Hof (D)	Sandy loam	6.32	0.89	2.5	34.6	165.8	DFOP
	Höfchen (D)	Silt loam	6.25	0.97	2.5	10.6	98.2	FOMC
	Le Thil en Vexin (north F)	Silt loam	7.45	0.95	2.5	29.9	206.1	FOMC
	Bury St. Edmunds (UK)	Sandy loam	7.45	0.86	2.5	64.9	372.9	DFOP
	Maasen (D)	Sandy loam	5.3	0.84	0.45	55.1	251.0	FOMC
	Swisstal Hohn(D)	Silt loam	6.8	1.00	0.45	44.2	209.4	FOMC
	Höfchen	Silt loam	6.8	1.11	0.45	35.9	187.0	DFOP
	Laacher Hof(D)	Sandy loam	6.7	1.26	0.45	68.2	318.1	FOMC
					Min	**10.6**	**98.2**	
					Max	**68.2**	**372.9**	
Europe-S	Nogarole Rocca (IT)	Loam	7.4	0.73	0.75	31.7	108.1	DFOP
	Marsonnas (south F)	Loam	5.5	1.07	0.75	43.7	171.5	DFOP
					Min	**31.7**	**108.1**	
					Max	**43.7**	**171.5**	

FOMC = First Order Multi-Compartment model
DFOP = Double-First-Order in Parallel model
Note: for the data set with the worst case DT_{50} value (Laacherhof, FOMC, DT_{50} 68.2 days) the optimised model parameters were as follows: $\alpha = 2.592$, $\beta = 222.27$; for the data set with the worst case DT_{90} value (Bury St. Edmunds, DFOP, DT_{90} 372.9 days) the optimised model parameters were as follows: k1 = 0.0377 day-1, k2 = 0.005 day-1, g = 0.3495.

Soil accumulation and plateau concentration	No experimental data available, for calculated values see PEC soil plateau concentration entries.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

Parent ‡							
Soil Type	Soil pH	OC %	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sand	4.3	0.526	-	-	55.0	10441	1.1770
Sandy loam	6.6	0.577	-	-	28.4	4912	1.0519
Silt loam	5.9	1.53	-	-	36.9	2414	0.9058
Clay loam	6.4	1.16	-	-	56.7	4899	1.2058
				Arithmetic mean	**44.3**	**5667**	**1.09**
				median	46.0	4906	1.11
pH dependence, Yes or No	No						
pencycuron-PB-amine ‡							
Soil Type	Soil pH	OC %	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n

sandy loam	7.0	1.80	-	-	8.12	451.3	0.80
loamy sand	6.0	2.48	-	-	5.12	206.6	0.85
sand	5.9	0.70	-	-	1.11	158.3	0.84
loam	6.4	1.98	-	-	40.72	2056.6	0.91
				Arithmetic mean	**13.8**	**718**	**0.85**
				median	6.6	329	0.85
pH dependence, Yes or No	No						
pencycuron-phenyl-cyclopentyl-urea ‡							
Soil Type	Soil pH	OC %	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
Sandy loam	6.4	1.7	-	-	1.955	115.0	0.8978
Silt loam	6.7	2.4	-	-	2.837	118.2	0.8802
Clay loam	7.2	4.8	-	-	4.626	96.4	0.8717
Loam	5.4	2.3	-	-	3.515	152.8	0.9092
				Arithmetic mean	**3.2**	**121**	**0.89**
				median	3.2	117	0.89
pH dependence, Yes or No	No						
pencycuron-ketone ‡							
Soil Type	Soil pH	OC %	Kd (mL/g)	Koc (mL/g)	Kf (mL/g)	Kfoc (mL/g)	1/n
sandy loam	6.4	1.7	22.1	1301	-	-	-
silt loam	6.7	2.4	30.8	1283	-	-	-
Sandy clay loam	5.7	1.8	25.1	1394	-	-	-
	Arithmetic mean		**26.0**	**1326**			
	median		25.1	1301			
pH dependence, Yes or No	No						

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

Column leaching	No data submitted and no data required.
Aged residues leaching	No data submitted and no data required.
Lysimeter/ field leaching studies	No data submitted and no data required.

PEC (soil) (Annex IIIA, point 9.1.3)

"hot spots" approach

Parent		
Method of calculation	The initial concentration in "hot spots" around the treated tubers was calculated assuming that 38000 potatoes/ha are planted, that each tuber has a radius of 1.8 cm, that 5 cm of soil around the tuber are affected, and that the effective application rate is 700 g/ha. FOMC kinetics was worst case up to and including day 77, thereafter DFOP kinetics was worst case. Hence, for all time points except day 100, FOMC kinetics was used, but the PECsoil after 100 days was estimated using DFOP kinetics. FOMC, DT_{50} 68.2 days, DT_{90} 318.1 days; optimised model parameters $\alpha = 2.592$, $\beta = 222.27$ DFOP, DT_{50} 64.9 days, DT_{90} 372.9 days; optimised model parameters $k_1 = 0.0377$ day^{-1}, $k_2 = 0.005$ day^{-1}, $g = 0.3495$ Plateau concentration: Worst-case DT_{90}field: DFOP, DT_{50} 64.9 days, DT_{90} 372.9 days; optimised model parameters $k_1 = 0.0377$ day^{-1}, $k_2 = 0.005$ day^{-1}, $g = 0.3495$	
Application data	Crop:	potato (NE & SE)
	Depth of soil layer:	5 cm (for plateau concn: 20 cm)
	Soil bulk density:	1.5 g/cm^3
	% plant interception:	0% (Incorporation)
	Application rate(s):	700 g a.s./ha (based on 25 g a.s./dt potato and approximately 2800 kg tubers/ha).

Potato (Northern and Southern Europe)

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial		9.500	-	x	-
Short term	24h	9.390	9.445	x	x
	2d	9.282	9.391	x	x
	4d	9.071	9.284	x	x
Long term	7d	8.767	9.127	x	x
	21d	8.109	8.783	x	x
	28d	7.518	8.460	x	x
	50d	6.985	8.158	x	x
	100d	5.615	7.340	x	x
Plateau concentration (before max)		0.029			
Plateau concentration (max)		0.26			

Metabolite pencycuron-PB-amine

Method of calculation

Molecular weight relative to the parent: 0.64
Maximum % of occurrence: 45.0%

The initial PECsoil of the metabolite was calculated by multiplying the initial PECsoil of parent pencycuron with the maximum percentage of occurrence of the metabolite and the MW correction factor. Short- and long-term PECs values were not calculated.

Plateau concentration:

Based on the worst-case DT_{50}lab (100 days, graphically estimated). In the calculations, it was assumed that dissipation followed first order kinetics: $PEC_t = PIEC*e^{-kt}$, where $k_1 = \ln(2)/100 = 0.006931\ day^{-1}$. The incorporation depth was 20 cm. The contribution of each application year represented the PECsoil of the metabolite (0.0670 mg/kg), which was calculated by multiplying the PECsoil of the parent (0.233 mg/kg) with the maximum percentage of occurrence of the metabolite and the MW correction factor.

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
potato				
Initial	2.7266	-	x	-
Plateau concentration (before max)	0.0058			
Plateau concentration (max)	0.073			

homogeneous approach

Parent and metabolite pencycuron-PB-amine Method of calculation	Initial PEC_S values were calculated under the following assumptions: homogeneous distribution in the top 5 cm layer; a soil bulk density of 1.5 g/cm3. Initial PEC_S values of the metabolites were derived from that of the active substance, with corrections for the difference in molecular mass and the maximum percentage at which the metabolite was formed from the parent substance during laboratory studies. DT_{50} values for pencycuron were available from field trials. DT_{50} (lab) values for pencycuron-PB-amine were available in 3 soils.

Parameter	Pencycuron	Pencycuron-PB-amine
molecular mass	328.8	209.7
MMR	1.00	0.638
max. %	100	45
max. DT_{50} (d)	68.2#	100##

#(field FOMC; non normalised)

##(lab Graph; non normalised)

Application data	
Crop:	potato (NE & SE)
Depth of soil layer:	5 cm (for plateau concn: 20 cm)
Soil bulk density:	1.5 g/cm^3
% plant interception:	0% (Incorporation)
Application rate(s):	700 g a.s./ha (based on 25 g a.s./dt potato and approximately 2800 kg tubers/ha).

Potato (Northern and Southern Europe)

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
		Pencycuron		Metabolite pencycuron-PB-amine	
Initial		0.933	-	0.268	-
Short term	24h	0.924	0.929	0.266	x
	2d	0.915	0.924	0.264	x
	4d	0.896	0.915	0.261	x
Long term	7d	0.869	0.901	0.255	x
	21d	0.810	0.870	0.232	x
	28d	0.754	0.840	0.221	x
	50d	0.561	0.732	0.189	x
	100d	0.338	0.586	0.134	x
Plateau concentration (before max)		0.004		0.00003	
Plateau concentration (max)		0.23		0.067	

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

Hydrolysis of active substance and relevant metabolites	At 50°C: DT_{50} 4.7, 14.5 and 15.4 days at pH 5, 7 and 9, respectively. At 50, 25°C and 20°C, respectively: DT_{50} 20.5 hours, 20.2 days and 29.9 days at pH 4; At pH 7-9, DT_{50} 8.2-9.1 days at 50°C, and 194-289 days at 20°C or 25°C.
	Metabolite pencycuron-PB-amine at 50ºC pH 5: stable pH 7: stable pH 9: approximately 70 days
Photolytic degradation of active substance and relevant metabolites	UV absorption data at a wavelength > 291 nm showed that pencycuron is not considered to be directly photodegradable
Readily biodegradable (yes/no)	No data (not required)

Degradation in water / sediment

Parent pencycuron

Parent	Distribution: Water: 25% after 14 d. Maximum of 55-79% AR in sediment after 30 d							
Level	Compartment	sys-tem	model	DT_{50} at 22°C	DT_{90} at 22°C	Q10 factor	DT_{50} at 20°C	DT_{90} at 20°C
I	whole system(A)	A B	SFO SFO	139.0 82.6	461.7 274.3	2.58 2.58	166.7 99.1	553.8 329.0
						geometric mean	*128.5*	*426.8*
	water(B)	A B	FOMC FOMC	0.11 3.8	2.6 54.6	2.58 2.58	0.13 4.6	3.1 65.5
						geometric mean	*0.77*	*14*
	sediment(B)	A B	SFO SFO	152.5 87.0	506.6 289.1	2.58 2.58	182.9 104.3	607.6 346.7
						geometric mean	*138.1*	*459.0*
II	water(A)	A B	SFO SFO	30.7 25.8	101.8 85.5	2.58 2.58	36.8 30.9	122.1 102.5
						geometric mean	*33.7*	*111.9*
	sediment(A)	A B	SFO SFO	139.7 182.5	464.1 606.4	2.58 2.58	167.6 218.9	556.6 727.3
						geometric mean	*191.5*	*636.3*

(A) Half-lives for degradation.
(B) Half-lives for dissipation.

Mineralisation	Cyclopentyl-label: 11.50 – 21.70% AR (at 91d, study end, n = 2)
Non-extractable residues	Cyclopentyl-label: 23.9 – 29.5% AR (at 91d, study end, n = 2)
Distribution in water / sediment systems (metabolites)	Cyclopentyl-label: Water and sediment: not relevant, no metabolites > 10%

Data gap: Satisfactory information on the fate of the chlorophenyl and phenyl moieties of pencycuron in aerobic sediment water systems is not available; the cleavage pattern in the available incubations does not preclude that metabolites from these rings might reach levels that would trigger further consideration.

Pencycuron-PB-amine: no data

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

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: vs 1.1 Molecular weight (g/mol): 328.8 Water solubility (mg/L): 0.26 mg/L (20°C) K_{OC} (L/kg): 5667 DT_{50} soil (d): 35.9 (geomean fieldDT_{50} normalised)* DT_{50} water/sediment system (d): 1000 (worst case) DT_{50} water (d): 289 (i.e. worst case DT_{50} hydrolysis) DT_{50} sediment (d): 1000 (worst case)

Parameters used in FOCUSsw step 3 (if performed)	MACRO in FOCUS vs 4.3b; PRZM in FOCUS vs 3.21b; TOXSWA in FOCUS vs 2.2.1; Q10 factor 2.58, Arrhenius activation energy 65400 J/mol, alpha factor 0.0948 K^{-1}. A 30-day application window was defined starting 30 days prior to the emergence day proposed by FOCUS. Substance parameters as for STEP 1-2, and in addition: Vp (Pa, 20°C): 5E-10 Pa; Freundlich 1/n: 1.09

*Normalised field geomean values originate from an addendum (updated revised DAR) dated May 2010 Table B.8.1.4j. Accepted for use in this calculation for EU level assessment, but not an agreed endpoint due to a data gap to demonstrate that the normalisation to FOCUS reference conditions was valid.

Application rate	Crop: potato. Application type: no drift (incorporation or seed treatment) Number of applications: 1 Application rate: 700 g as/ha Crop interception: 0% (STEP 2) Region of application: Northern or Southern Europe (STEP 2) Runoff + drainage: 2% (Europe-N) or 4% (Europe-S) (STEP 2) Application window: March-May (STEP 2); as proposed by FOCUS for STEP 3 Multiple and single application was calculated and the application pattern resulting in the highest PECsw and PECsed values was selected.

FOCUS STEP 1 Scenario	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
		Actual	TWA	Actual	TWA
Potato, NE & SE GAP	0 h	27.2713	-	1.55E+03	-

FOCUS STEP 2 Scenario	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
		Actual	TWA	Actual	TWA
Potato, NE GAP	0 h	5.0489	---	286.12	---

FOCUS STEP 2 Scenario	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
		Actual	TWA	Actual	TWA
Potato, SE GAP	0 h	10.0978	---	572.2401	---

FOCUS STEP 3 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
D3 ditch	0 h	0.000000	-	0.000001	-
D4 pond	0 h	0.000380	-	0.003170	-
D4 stream	0 h	0.001430	-	0.000996	-
D6 ditch 1st application	0 h	0.000128	-	0.000127	-
D6 ditch 2nd application	0 h	0.001100	-	0.000751	-
R1 pond	0 h	0.000000	-	0.000001	-

R1 stream	0 h	0.000000	-	0.000001	-
R2 stream	0 h	0.000000	-	0.000001	-
R3 stream	0 h	0.000000	-	0.000001	-

Metabolite pencycuron-PB-amine	
Parameters used in FOCUSsw step 1 and 2	Molecular weight relative to the parent: 0.64 Maximum % of occurrence in water: no data Maximum % of occurrence in soil: 45% Molecular weight (g/mol): 209.70 Water solubility (mg/L): 0.26 mg/L (20°C) K_{OC} (L/kg): 718 DT_{50} soil (d): 42.8 DT_{50} water/sediment system (d): 1000 days DT_{50} water (d): 1000 DT_{50} sediment (d): 1000
Parameters used in FOCUSsw step 3 (if performed)	Substance parameters as for STEP 1-2, and in addition: Vp (Pa, 20°C): 5E-10 Pa Freundlich 1/n: 0.85
Application rate	The dose for pencycuron-PB-amine was obtained by multiplying the dose for the parent with the maximum % of occurrence in soil and the MW correction factor (209.70/328.8). The calculated dose was 0.2009 kg/ha for pencycuron-PB-amine. The simulations for pencycuron-PB-amine were then performed as if the metabolite was applied to soil at a dose of 0.2009 kg/ha. Formation of pencycuron-PB-amine in water from pencycuron was not simulated, since there is no acceptable evidence that pencycuron-PB-amine is formed in the water of water-sediment systems at >10% AR.
Main routes of entry	As for parent

FOCUS STEP 1 Scenario	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
		Actual	TWA	Actual	TWA
Potato, NE & SE GAP	0 h	34.2132	-	245.6509	-

FOCUS STEP 2 Scenario	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
		Actual	TWA	Actual	TWA
Potato, NE GAP	0 h	6.4134	---	46.0484	---

FOCUS STEP 2 Scenario	Day after overall maximum	PECSW (µg/L)		PECSED (µg/kg)	
		Actual	TWA	Actual	TWA
Potato, SE GAP	0 h	12.8269	---	92.0968	---

FOCUS STEP 3 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
D3 ditch	0 h	0.000000	-	0.000000	-
D4 pond	0 h	0.000139	-	0.002020	-
D4 stream	0 h	0.000910	-	0.000766	-
D6 ditch 1st application	0 h	0.000028	-	0.000017	-

D6 ditch 2nd application	0 h	0.000380	-	0.000143	-
R1 pond	0 h	0.000000	-	0.000001	-
R1 stream	0 h	0.000000	-	0.000001	-
R2 stream	0 h	0.000000	-	0.000001	-
R3 stream	0 h	0.000000	-	0.000001	-

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

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model used: FOCUS-PEARL 3.3.3 Arrhenius activation energy was set at 65400 J/mol Scenarios: All FOCUS scenarios Crop: potato Median parent DT_{50lab} 90.7 d (normalised to pF2, 20°C). K_{OC}: parent, arithmetic mean 5667 L/kg, $^1/_n$ = 1.09. Plant uptake factor: 0.5 (default)
Application rate	Application rate: 700 g a.s./ha Time of application: The application date was set at 14 days prior to emergence of the crop. The treated potatoes are planted and therefore the entire dose is assumed to be incorporated to a depth of 20 cm.

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration in (µg/L at 1 m)

FOCUS-PEARL 3.3.3 potato NE & SE GAP	Scenario	Parent			
	Chateaudun	0.000509			
	Hamburg	0.001341			
	Jokioinen	0.000153			
	Kremsmunster	0.001663			
	Okehampton	0.002905			
	Piacenza	0.006297			
	Porto	0.000001			
	Sevilla	0.000005			
	Thiva	0.000122			

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model used: FOCUS-PEARL 3.3.3 Arrhenius activation energy was set at 65400 J/mol Scenarios: All FOCUS scenarios Crop: potato

Compound	DT50[a)] (days)	ff	K_{oc} (mL/g)	K_{om} (mL/g)	1/n
Pencycuron	38.3[b)]	n.a.	5667	3287	1.09
Pencycuron-ketone	87.4	0.267	1326	769	1.00
Pencycuron-PB-Amine	38.3 / 47.2[b)]	0.566/0.196[b)]	718	416	0.85
Pencycuron-phenyl-cyclopentyl-urea	4.0	1.000	120.6	70.0	0.89

[a)] referenced to 20 °C and 100 % of field capacity, [b)] field value

[b)] Normalised field geomean values originate from an addendum (updated revised DAR) dated May 2010 Table B.8.1.4j. Accepted for use in this calculation for metabolite groundwater concentrations for the precursor pencycuron for EU level assessment, but the value of 38.3 days is not an agreed endpoint due to a data gap to demonstrate that the normalisation to FOCUS reference conditions was valid. Similarly, the pencycuron-PB-amine values of 47.2 days and 0.196 (ff) from field studies are not agreed values.

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration in (µg/L at 1 m)

	Scenario	Parent	pencycuron-PB-amine	pencycuron-phenyl-cyclopentyl-urea	pencycuron-ketone
FOCUS-PEARL 3.3.3 potato NE & SE GAP	Chateaudun	-	< 0.001	< 0.001	0.005
	Hamburg	-	< 0.001	< 0.001	0.010
	Jokioinen	-	< 0.001	< 0.001	0.001
	Kremsmunster	-	< 0.001	< 0.001	0.013
	Okehampton	-	< 0.001	0.002	0.020
	Piacenza	-	< 0.001	0.003	0.049
	Porto	-	< 0.001	< 0.001	< 0.001
	Sevilla	-	< 0.001	< 0.001	< 0.001
	Thiva	-	< 0.001	< 0.001	< 0.001

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

Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	Not available and not required
Photochemical oxidative degradation in air	Atkinson calculation: DT_{50} 2.1 hours (assumptions: reaction with hydroxyl radicals, $1.5x10^6$ OH radicals/cm^3 in atmosphere).
Volatilisation	Vapour pressure: : 5 x 10^{-10} Pa (at 20 °C, extrapolated), 2 x 10^{-9} Pa (at 25 °C, extrapolated) Henry's Law constant: 5 x 10^{-7} $Pa.m^3.mol^{-1}$ (calculated)

PEC_A (air)

Method of calculation	Expert judgement, based on DT_{50}

PEC_A

Maximum concentration	Negligible (DT_{50}: 4.2h)

Definition of the Residue (Annex IIA, point 7.3)

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology) or for which a groundwater exposure assessment is triggered.	**Soil**: pencycuron and pencycuron-PB-amine **Surface water**: pencycuron and pencycuron-PB-amine **Aquatic sediment**: pencycuron and pencycuron-PB-amine **Groundwater**: pencycuron, pencycuron-PB-amine, pencycuron-phenyl-cyclopentyl-urea, pencycuron-ketone Note all the above definitions are provisional pending data gaps on route of degradation being filled. **Air**: pencycuron (by default)

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

Soil (indicate location and type of study)	not available
Surface water (indicate location and type of study)	not available
Ground water (indicate location and type of study)	not available
Air (indicate location and type of study)	not available

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	Candidate for R53

Ecotoxicology

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

Acute toxicity to mammals	LD_{50}: >5000 mg a.s./kg bw
Reproductive toxicity to mammals	NOAEL: 32 mg a.s./kg bw/day
Acute oral toxicity to birds	14d-LD_{50} > 2000 mg a.s./kg bw (bobwhite quail)
Dietary toxicity to birds	LC_{50} > 1750 mg a.s./kg bw/day
Reproductive toxicity to birds	8w-NOEL ≥ 122.1 mg a.s./kg bw/day (Japanese quail)

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

Application rate (kg as/ha)	Route	Category	Time-scale	TER	Annex VI Trigger
0.700	water	small bird	acute	>3E+05	10
0.700	earthworm	earthworm-eating bird	long-term	94	5
0.700	fish	fish-eating bird	long-term	97	5
0.700	potato tubers	omnivorous mammal (wild boar)	acute	420	10
0.700	water	small mammal	acute	>1E+06	10
0.700	potato tubers	omnivorous mammal (wild boar)	long-term	**2.7**	5
0.700	potato tubers	omnivorous mammal (wild boar)	long-term – **refined**	4.27[1]	5
0.700	earthworm	earthworm-eating mammal	long-term	20	5
	fish	fish-eating mammal	long-term	40	5

[1] Refinement of NOAEL to 32 mg as/ kg bw/d and refinement of ETE based on PD = 63%. Because some effects on bodyweight (<5%) were observed at the end point chosen in the risk assessment, attention should be paid to the margin of safety, indicated by the TER calculations (PT still 1, no ftwa used, PD 0.63).

Toxicity data for aquatic species (most sensitive species of each group)

Toxicity data of the active substance for aquatic organisms (most sensitive species of each group)

species	Test substance	Time scale	Endpoint	Toxicity value in mg a.s./L
Acute toxicity to fish				
Rainbow trout (*Salmo gairdneri, Oncorhynchus mykiss)*, Bluegill	Pencycuron techn	96h-LC_{50}	mortality	> 0.3*
Rainbow trout	Monceren FS 250	96h-LC_{50}	mortality	> 0.3*
Rainbow trout	Pencycuron 25 SC	96h-LC_{50}	mortality	> 0.3*
Rainbow trout	Pencycuron-PB-amine	96h-LC_{50}	mortality	29.8
Acute toxicity to invertebrates				
Water flea *Daphnia magna*	Pencycuron techn	48h-EC_{50}	mobility	> 0.3*
Water flea *Daphnia magna*	Pencycuron-PB-amine	48h-EC_{50}	mobility	17
Toxicity to algae				
Scenedesmus subspicatus	Pencycuron techn	72h-EC_{50} 72h-NOEC	growth rate	> 0.3* ≥ 0.3*
Scenedesmus subspicatus	Monceren FS 250	72h-EC_{50} 72h-NOEC	growth rate	15.7 138
Scenedesmus subspicatus	Pencycuron-PB amine	72h-EC_{50} 72h-NOEC	growth rate	>0.00892 0.00175
Chronic toxicity to fish				
Rainbow trout *Salmo gairdneri*	Pencycuron techn	21d-NOEC	growth	≥ 0.3*
Rainbow trout *Oncorhynchus mykiss*	Pencycuron techn	94d-NOEC	overall hatching, survival and growth	0.0832
Chronic toxicity to invertebrates				
Water flea *Daphnia magna*	Pencycuron (tech.),	21d-NOEC (overall value)	overall survival, reproduction and growth	0.0496
Water flea *Daphnia magna*	Pencycuron (tech.),	21d-NOEC (overall value)	overall survival, reproduction and growth	0.0992
Water flea *Daphnia magna*	Monceren FS 250	21d-NOEC (overall value)	overall survival, reproduction and growth	0.062
Midge *Chironomus riparius*	Pencycuron techn.	26d-NOEC	emergence	≥ 0.300

* Water solubility is 0.3 mg a.s./L. In acute fish, daphnia and algae tests with pencycuron there was no toxicity within the aqueous solubility of the test substance.

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

Acute TERs for pencycuron at different FOCUSsw step 3 scenarios, following seed treatment of potatoes in the North and South of Europe.

Crop	Scenario	LC/EC_{50} (µg a.s./L)			Actual PECsw	TER		
		fish	daphnia	Algae	(µg a.s./L)	fish	daphnia	algae
Potatoes (seed treatment)	D3 ditch	>300	>300	>300	0.000000	>3E+08	>3E+08	>3E+08
	D4 stream	>300	>300	>300	0.000380	>8E+05	>8E+05	>8E+05
	D4 pond	>300	>300	>300	0.001430	>2E+05	>2E+05	>2E+05
	D6 ditch	>300	>300	>300	0.000128	>2E+06	>2E+06	>2E+06
	R1 stream	>300	>300	>300	0.001100	>3E+05	>3E+05	>3E+05
	R1 pond	>300	>300	>300	0.000000	>3E+08	>3E+08	>3E+08
	R2 stream	>300	>300	>300	0.000000	>3E+08	>3E+08	>3E+08
	R3 stream	>300	>300	>300	0.000000	>3E+08	>3E+08	>3E+08

Chronic TERs for seed treatment of potatoes with pencycuron.

Crop	Scenario	NOEC (µg a.s./L)	NOEC (µg a.s./L)	NOEC (µg a.s./L)	Actual PECsw	TER	TER	TER
		fish	daphnia	*C. riparius*	(µg a.s./L)	fish	daphnia	*C. riparius*
Potatoes (seed treatment)	D3 ditch	83.2	49.6	300	>8E+07	>1E+08	>3E+08	>8E+07
	D4 stream	83.2	49.6	300	2E+05	1E+05	8E+05	2E+05
	D4 pond	83.2	49.6	300	6E+04	3E+04	2E+05	6E+04
	D6 ditch	83.2	49.6	300	7E+05	4E+05	2E+06	7E+05
	R1 stream	83.2	49.6	300	8E+04	5E+04	3E+05	8E+04
	R1 pond	83.2	49.6	300	>8E+07	>1E+08	>3E+08	>8E+07
	R2 stream	83.2	49.6	300	>8E+07	>1E+08	>3E+08	>8E+07
	R3 stream	83.2	49.6	300	>8E+07	>1E+08	>3E+08	>8E+07

Metabolites

Acute TERs for the minor metabolite **pencycuron-PB-amine** at different FOCUSsw step 3 scenarios, following seed treatment of potatoes in the North and South of Europe

Crop	Scenario	LC/EC_{50} (µg p.m../L)			Actual PECsw	TER		
		fish	daphnia	algae	(µg p.m./L)	fish	daphnia	algae
Potatoes (seed treatment)	D3 ditch	29800	17000	8.92	0.000000	>3E+10	>2E+10	>9E+06
	D4 stream	29800	17000	8.92	0.000139	2E+08	1E+08	6E+04
	D4 pond	29800	17000	8.92	0.000910	3E+07	2E+07	1E+04
	D6 ditch	29800	17000	8.92	0.000028	1E+09	6E+08	3E+05
	R1 stream	29800	17000	8.92	0.00038	8E+07	4E+07	2E+04
	R1 pond	29800	17000	8.92	0.000000	>3E+10	>2E+10	>9E+06
	R2 stream	29800	17000	8.92	0.000000	>3E+10	>2E+10	>9E+06
	R3 stream	29800	17000	8.92	0.000000	>3E+10	>2E+10	>9E+06

Bioconcentration

Bioconcentration factor (BCF)	In carp the BCF was 226L/kg at a 28d exposure period
Annex VI Trigger for the bioconcentration factor (BCF)	100
Clearance time	90% excreted within 3 days
Level of residues (%) in organisms after the 14 day depuration phase	no residues after 7 days depuration

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

Acute oral toxicity bees	active substance 48h LD_{50} > 98.50 µg a.s. per bee
Acute contact toxicity bees	active substance 48h LD_{50} > 100.00 µg a.s./bee

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

Not relevant

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

Species	Stage	Test substance	Substrate	Dose g a.s./ha	Endpoint	Adverse effect[1] (%)	ESCORT 2 trigger
Poecilus cupreus	adults	DS 12.5	potatoes in natural soil	2160.7 2160.7	mortality food consumption	0 + 81	50 50
Poecilus cupreus	not reported	FS 250	quartz sand	2465 2465	mortality food consumption	0 23	50 50
Poecilus cupreus	5 - 8 weeks	FS 250	quartz sand	565 565	mortality food consumption	0 + 23	50 50
Aleochara bilineata	3 - 6 weeks	DS 12.5	extended test/potatoes	2160.7	reproduction	7	50
Aleochara bilineata	1- 5 days	FS 250	potatoes	375 375	mortality reproduction	27.6 +2	50 50
Pardosa spp	adult; 15.7 mg	DS 12.5	potatoes	1790 1790	mortality food consumption	0 +19	50 50
Pardosa spp	not reported	FS 250	seed furrow with potato	367.5 376.5	mortality food consumption	-1.2 +11	50 50
Chrysoperla carnea	2 – 3 days old	SC 250	glass plate	300 6250 12500 300 6250 12500 300 6250 12500	mortality number of eggs Number of viable eggs	8.9 -6.7 -2.0 24 42 92 12 34 73	50 50 50
Typhlodromus pyri	protonymphs 2 – 3 days old	SC 250	glass plate	310 620 1240 2480 6200 310 620 1240 2480 6200	mortality LR_{50} reproduction	3.2 11.8 11.8 19.4 11.8 > 6200 g a.s./ha 26 7 8 38 58	HQ < 2

Species	Stage	Test substance	Substrate	Dose g a.s./ha	Endpoint	Adverse effect[1] (%)	ESCORT 2 trigger
Aphidius rhopalosiphi	< 24h	SC 250	glass plate	500 1000 1500 2000 2500 500 1000	mortality LR_{50} reproduction	34.5 50.6 73.6 80.5 96.5 685 g a.s./ha 42 18	HQ < 2

[1] Adverse effect means:
x % effect on mortality = x % increase of mortality compared to control
y % effect on a sublethal parameter = y % decrease of sublethal paramether compared to control

(sublethal parameters are e.g. reproduction, parasitism, food consumption)
When effects are favourable for the test organisms, a + sign is used for the sublethal effect percentages (i.e. increase of e.g. reproduction) and a – sign for mortality effect percentages (i.e. decrease of mortality).

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity	pencycuron LC_{50} > 10000 mg a.s./kg soil d.w. (5% OM) metabolite pencucuron-PB-amine LC_{50} > 1000 mg a.s./kg soil d.w. (10% OM)
Reproductive toxicity	formulation 'Pencycuron DS 12.5' 56-d NOEC reproduction > 10.000kg dressed potatoes (0.25 g a.s./kg potatoes), corresponding with 3.3 mg a.s./kg soil d.w. (5% OM) formulation 'Pencycuron FS 250' 56-d NOEC reproduction 100 mg a.s./kg soil d.w. (5% OM)

Toxicity/exposure ratios for earthworms (Annex IIIA, point 10.6)

Acute risk

pencycuron:

Scenario	LC_{50} (mg a.s./kg)	PECs (mg a.s./kg)	Acute TER	Annex VI trigger 91/414 EEC
Potato tubers	> 10000	9.5	>1053	10

pencycuron-PB-amine:

Scenario	LC_{50} (mg p.m./kg)	PECs (mg p.m./kg)	Acute TER	Annex VI trigger 91/414 EEC
Potato tubers	> 500 [1]	2.7266	>183	10

[1] corrected for organic matter content of test soil (divided by factor 2)

Long term exposure ratios for exposure of earthworms

Scenario	NOEC (mg a.s./kg)	PECs (mg a.s./kg)	Chronic TER	Annex VI trigger 91/414 EEC
Potato tubers	100	9.5	10.5	5

Effects on other soil non-target organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Collembola	formulation 'Pencycuron 12.5 DS' 28-d overall NOEC 60 mg a.s./kg soil d.w. ($NOEC_{corr}$ (5% OM) = 30 mg a.s./kg soil) metabolite pencycuron-PB-amine NOEC reproduction 250 mg a.s. /kg soil d.w. ($NOEC_{corr}$ (5% OM) = 125 mg a.s./kg soil)
Litterbag	In a litter-bag study, soil litter degradation was not inhibited 1, 3 and 6 months after two spray applications in spring with Pencycuron FS 250 G at a total nominal soil concentration of 2.35 mg a.s./kg soil d.w. (1^{st} application incorporated to a depth of 10 cm to give a nominal concentration of pencycuron of 0.27 mg a.s./kg soil d.w., 2^{nd} application applied in-furrow at planting of potato tubers at 2.08 mg a.s./kg soil d.w.). In a second study, soil litter degradation was not inhibited 1, 3 and 6 months after two applications in spring with pencycuron, the first one at the plateau PEC (incorporated to a depth of 10 cm to give a nominal concentration of pencycuron of 0.27 mg a.s./kg soil d.w.), and the second one at the maximum annual application rate dressed on potato tubers (400 mg a.s./kg potatoes, equivalent to 1000 g a.s./ha).

Toxicity/exposure ratios for other soil non-target macro-organisms (Annex IIIA, point 10.6.2)

Test organism	Test substance	Time-scale	TER	Annex VI trigger
Formulated product				
Folsomia candida	Pencycuron 12.5 DS	chronic	3.2	5
Folsomia candida	Pencycuron-PB-amine	chronic	46	**5**

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralization	active substance No effects up to 3.44 kg a.s./ha (4.4 mg pencycuron/kg soil) metabolite pencycuron-PB-amine No effects up to 2.19 kg metabolite/ha
Carbon mineralization	No effects up to 3.44 kg a.s./ha

Effects on no-target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Screening data on terrestrial plants	pencycuron : EC_{50} > 7500 g a.s./ha pencycuron-PB-amine: EC_{50} > 7500 g a.s./ha active substance No phytotoxic effects up to 7500 g a.s./ha (pre- and post-emergence) metabolite pencycuron-PB-amine no effects up to 625 g metabolite./ha (pre-emergence)

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

Inhibition of activated sludge	3h-EC_{50} (respiration inhibition) > 0.3 mg a.s./L.

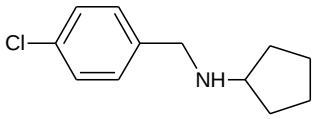
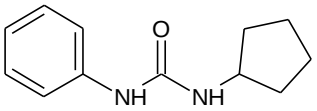
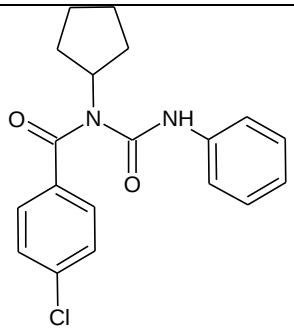
Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	Pencycuron
water	Pencycuron
sediment	Pencycuron
groundwater	Pencycuron

Classification and proposed labelling (Annex IIA, point 10)

with regard to the ecotoxicological data Annex I of the Council Directive 67/548/EEC:	R52/R53

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name*	Chemical name**	Structural formula**
pencycuron-PB-amine THS 3995 M16	*N*-(4-chlorobenzyl)cyclopentanamine	
pencycuron-phenyl-cyclopentyl-urea	1-cyclopentyl-3-phenylurea	
pencycuron-ketone	4-chloro-*N*-cyclopentyl-*N*-(phenylcarbamoyl)benzamide	

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

** ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

ABBREVIATIONS

1/n	slope of Freundlich isotherm
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
AChE	acetylcholinesterase
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DFOP	double first order in parallel kinetics
DM	dry matter
DS	powder for dry seed treatment
dt	decitonne
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FOMC	first order multi-compartment

g	gram
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GGT	gamma glutamyl transferase
GM	geometric mean
GS	growth stage
h	hour(s)
ha	hectare
Hb	haemoglobin
Hct	haematocrit
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-DAD	high pressure liquid chromatography with diode array detector
HPLC-FLU	high performance liquid chromatography florescence detector
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPLC-UV	high pressure liquid chromatography with ultraviolet detector
HQ	hazard quotient
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	inter laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NE	northern Europe

NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
PTT	partial thromboplastin time
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RPE	respiratory protective equipment
RUD	residue per unit dose
SC	suspension concentrate
SD	standard deviation
SE	southern Europe
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WHO	World Health Organisation
wk	week
yr	year