Modification of the existing maximum residue level for pencycuron in potatoes

European Food Safety Authority (EFSA)

Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience submitted an application to raise the existing maximum residue limit (MRL) for the active substance pencycuron in potatoes from 0.1 to 0.2 mg/kg. The competent authority in the Netherlands drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA. According to EFSA, the submitted data on the residue behaviour of pencycuron provide evidence that for the intended use of the active substance a MRL of 0.2 mg/kg would be required. An indicative risk assessment for residues of parent pencycuron did not identify a consumer health risk. However, the available data did not sufficiently elucidate the degradation products formed in processed products. Since a reliable dietary risk assessment for processed potatoes could not be performed, EFSA does not propose a modification of the existing MRL for potatoes.

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Keywords: pencycuron, fungicide, potatoes, MRL application, consumer risk assessment

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Correspondence: pesticides.mrl@efsa.europa.eu
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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the competent national authorities in the Netherlands, hereafter referred to as the evaluating Member State (EMS), received an application from the company Bayer CropScience to modify the existing MRLs for the active substance pencycuron in potatoes. In order to accommodate for the intended EU uses of pencycuron, the EMS proposed to raise the existing MRL for potatoes from 0.1 to 0.2 mg/kg. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 5 February 2016.

EFSA bases its assessment on the evaluation report submitted by the Netherlands, the DAR and the Additional Reports prepared under Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance pencycuron as well as the conclusions from a previous EFSA opinion on pencycuron.

The metabolism of pencycuron in primary crops was evaluated in the framework of the peer review in potatoes following seed treatment and in rice following foliar treatment. The peer review agreed to set parent pencycuron as the relevant residue for monitoring and risk assessment. In the framework of the current application, new metabolism studies on potatoes (in-furrow application) and lettuce (foliar application) were submitted. The new studies indicate that in tubers pencycuron is the major residue; in addition, the metabolite pencycuron-PB-amine, a cleavage product of parent pencycuron which was also identified in soil and in rotational crop studies. Aniline and a precursor molecule were identified, but only after applying a microwave-assisted extraction procedure which involved elevated temperature. These studies suggest that aniline is most likely not a major primary plant metabolite, but an artefact. However, the study gives an indication that aniline is a potential degradation product relevant for processed products. Considering that pencycuron-PB-amine was not found in residue trials, EFSA decided not to amend the previously agreed residue definition for primary crops for this MRL application. However, in the framework of the MRL review the residue definitions should be reconsidered, taking into account the new metabolism data and residue data for all supported uses.

The applicant submitted residue trials reflecting the use in NEU and SEU. Based on the more critical NEU data set a MRL proposal of 0.2 mg/kg was derived. Adequate analytical enforcement methods are available to monitor the residues of pencycuron in potatoes.

Standard hydrolysis studies on the nature of pencycuron residues formed under standardised processing conditions are not available. From studies investigating the nature of residues in processed potatoes, it became evident that pencycuron degrades at temperatures that are representative of food processing. Although the nature of the degradation products is not fully elucidated, aniline is likely to be formed. Given the toxicological concerns related to aniline, the applicant submitted a study where the formation and bioavailability of aniline from boiled/baked potatoes that were treated with pencycuron was investigated. This study does not allow quantifying the amount of bioavailable aniline after digestion. EFSA concludes that the information available suggests that parent pencycuron is not an appropriate residue definition for processed products. However, no alternative residue definition can be proposed, lacking more detailed information on the nature and magnitude of residues in processed products.

A number of processing studies were submitted where the magnitude of pencycuron and pencycuron-PB-amine was investigated in various potato processed products; the magnitude of aniline was not tested. A concentration of residues was observed only in peel (fresh and dried), dried waste from flake production and dried pulp from starch production. However, since no residue definition for processed products could be derived, EFSA does not propose any processing factors for potato products.

Based on the available rotational crop field studies, EFSA concludes that significant pencycuron residues are unlikely to occur in rotational crops, provided that the active substance is used on potatoes according to the intended use.

Potatoes are used as feed product and therefore a potential carryover into food of animal origin had to be assessed. Considering the intended use on potatoes submitted in the framework of this application, the calculated livestock dietary burden exceeds the trigger value of 0.1 mg/kg dry matter (DM) for all relevant species, except poultry. The nature of pencycuron residues in livestock has been investigated during the peer review and the residue definition for enforcement and risk assessment was proposed as pencycuron. Based on the estimated dietary burden resulting from residues in potatoes and the results of metabolism studies, EFSA concludes that pencycuron residues are not expected to occur in animal commodities above the LOQ of 0.01 mg/kg. A comprehensive assessment
of the dietary exposure of livestock, taking into account all authorised uses of pencycuron on potential feed crops, needs to be performed in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of pencycuron was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.2 mg/kg bw per day. No acute reference dose (ARfD) was deemed necessary. For pencycuron-PB-amine the same toxicological reference values as established for pencycuron are applicable. For aniline no ADI or ARfD value has been established at EU level. However, in the framework of a previous assessment, the CEF Panel of EFSA calculated the benchmark dose level causing a 10% increase in tumour incidence (BMDL10) that ranged from 29 to 35 mg/kg bw per day.

An indicative consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) for parent pencycuron. The calculations were performed for unprocessed potatoes. However, since potatoes are exclusively consumed after processing, and no appropriate residue definition for processed products could be derived, the results of this assessment are considered purely indicative. EFSA did not identify a long-term consumer intake concern for parent pencycuron. The highest calculated chronic intake was 2% of the ADI (NL child). The contribution of residues in potatoes to the total consumer exposure accounted for a maximum of 0.05% of the ADI (NL child). An acute consumer exposure assessment was not performed, since the setting of an ARfD was not deemed necessary when the active substance was approved at the EU level.

Since no residue definition could be derived for processed products, the dietary risk assessment could not be completed for the intended use of pencycuron in potatoes.

EFSA shares the opinion of JMPR who recommended that for aniline a hazard characterisation and comprehensive exposure assessment should be performed which takes into account different sources of aniline exposure, including the use of pesticides such as pencycuron.

In conclusion, EFSA does not propose to amend the existing MRL for pencycuron in potatoes since the data were not sufficient to perform a dietary risk assessment for processed potatoes. Further information on the nature and magnitude of residues expected in processed products is required to finalise the dietary risk assessment.
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Background

Regulation (EC) No 396/2005\(^1\) establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at the European Union (EU) level. Article 6 of the Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC,\(^2\) repealed by Regulation (EC) No 1107/2009\(^3\), shall submit to a Member State an application to set or to modify a MRL in accordance with the provisions of Article 7 of the Regulation.

The Netherlands, hereafter referred to as the evaluating Member State (EMS), received an application from the company Bayer CropScience\(^4\) to modify the existing MRLs for the active substance pencycuron in potatoes. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission and to EFSA on 5 February 2016.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00125 and the following subject:

Pencycuron: Modification of existing MRLs in potato.

The EMS Netherlands proposed to raise the existing MRL of pencycuron in potatoes from 0.1 to 0.2 mg/kg.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the EMS, provide a reasoned opinion on the risks to the consumer associated with the application.

In accordance with Article 11 of the Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months (which may be extended to 6 months if more detailed evaluations need to be carried out) from the date of receipt of the application. If EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

The active substance and its use pattern

The details of the intended GAPs for pencycuron on potatoes in the NEU and SEU triggering the MRL application are given in Appendix A.\(^5\)

Pencycuron is the ISO common name for 1-(4-chlorobenzyl)-1-cyclopentyl-3-phenylurea (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix B.

Pencycuron was evaluated in the framework of Council Directive 91/414/EEC with the Netherlands designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2011/49/EU\(^6\) which entered into force on 1 June 2011 for use as a fungicide. In accordance with Regulation (EU) No 540/2011\(^7\), pencycuron is approved under Regulation (EC) No 1107/2009.

The representative use evaluated in the peer review was seed treatment of potatoes. The draft assessment report (DAR) of pencycuron has been peer reviewed by EFSA (EFSA, 2010). The review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 is in progress.

The EU MRLs for pencycuron are established in Annex III of Regulation (EC) No 396/2005. Since the entry into force of this regulation, EFSA has issued one reasoned opinion on the modification of MRLs for pencycuron in potatoes; due to data gaps identified in the dossier submitted in support of

\(^{1}\) Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

\(^{2}\) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.

\(^{3}\) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

\(^{4}\) Bayer CropScience, Rue Jean Marie Leclair 16 CP 106, 69266, Lyon, France.

\(^{5}\) The line with the critical GAP assessed in this reasoned opinion is highlighted in grey in Appendix A.

\(^{6}\) Commission Implementing Directive 2011/49/EU of 18 April 2011 amending Council Directive 91/414/EEC to include pencycuron as active substance and amending Commission Decision 2008/934/EC. OJ L 103, 19.4.2011, p. 109–112.

\(^{7}\) Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 Implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.
the application, no MRL proposal was derived by EFSA (EFSA, 2012). Codex Alimentarius has not established maximum residue limits (CXL) for pencycuron.

**Assessment**

EFSA bases its assessment on the evaluation report submitted by the EMS (Netherlands, 2015), the DAR and the Additional Reports prepared under Directive 91/414/EEC (Netherlands, 2005, 2009, 2010), the conclusion on the peer review of the pesticide risk assessment of the active substance pencycuron (EFSA, 2010) as well as the conclusions from a previous EFSA opinion on pencycuron (EFSA, 2012). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a,b, 2015; OECD, 2011, 2013).

1. **Method of analysis**

1.1. **Methods for enforcement of residues in food of plant origin**

   Analytical methods for the determination of pencycuron residues in plant commodities were assessed during the peer review under Directive 91/414/EEC for the enforcement residue definition set as pencycuron (EFSA, 2010). An HPLC method using MS/MS detection is sufficiently validated for the determination of pencycuron residues in high water/starch (potato, turnip), high water (lettuce, tomato), high acid (orange, pineapple), high oil (oilseed rape, sunflower) and high protein (beans) content commodities and in dry/starch (wheat) commodities with an LOQ of 0.01 mg/kg.

   EFSA concludes that sufficiently validated analytical methods for enforcing the MRLs for pencycuron in different crop types, including potatoes, are available.

1.2. **Methods for enforcement of residues in food of animal origin**

   The multi-residue DFG S19 method using HPLC-MS/MS was previously assessed; the method is sufficiently validated to control and monitor pencycuron residues in matrices of animal origin (meat, fat, liver, kidney, milk and eggs) with an LOQ of 0.01 mg/kg (EFSA, 2010).

2. **Mammalian toxicology**

2.1. **Toxicological profile of the active substance**

   The toxicological profile of the active substance pencycuron was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2010). The data were sufficient to derive toxicological reference values compiled in Table 1.

   | Source | Year | Value | Study | Safety factor |
   |--------|------|-------|-------|--------------|
   | ADI    | EFSA | 2010  | 0.2 mg/kg bw per day | 2 year rat | 100          |
   | ARfD   | EFSA | 2010  | Not allocated, not necessary |             |              |

   ADI: acceptable daily intake; ARfD: acute reference dose.

2.2. **Toxicological profile of metabolites and degradation products**

2.2.1. **Pencycuron-PB-amine**

   Pencycuron-PB-amine is the main soil metabolite that was also found in rotational crops. The toxicological reference values established for pencycuron are applicable to the metabolite (EFSA, 2010).

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8 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
2.2.2. Aniline

Aniline is a degradation product that is expected to be formed under conditions representative of processing. According to Annex VI of Regulation (EC) No 1272/2008\(^9\), aniline is classified as a Category 2 mutagen (H341, suspected of causing genetic defects) and as a Category 2 carcinogen (H351, suspected of causing cancer).

In 2007, the EFSA Scientific Panel of Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (CEF Panel) performed a risk assessment of aniline in the framework of the evaluation of the food colour Red 2G (EFSA, 2007b). The CEF Panel concluded that aniline should be considered as a carcinogen for which a genotoxic mechanism cannot be excluded. Based on the available data, the CEF Panel calculated BMDL10 (benchmark dose level causing a 10% increase in tumour incidence) values that ranged from 29 to 35 mg/kg bw per day.

The presence of aniline as part of the pesticide residue is not specific for pencycuron; aniline was also observed as metabolite/degradation product for other pesticides, e.g. buprofezin (EFSA, 2015). In the 2010 JMPR monograph on buprofezin, aniline was identified as a processing metabolite of buprofezin. Aniline was considered to be toxicologically relevant. Since it can occur naturally in some foods and may also originate from many chemicals, including buprofezin and other pesticides, aniline was not included in the residue definition for buprofezin (FAO, 2009). In 2015, JMPR recommended that JECFA should place aniline on the agenda for an evaluation to both characterize hazard and estimate exposure from the diet, including exposure from the use of pesticides (FAO, 2015).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of pencycuron in primary crops was evaluated in the framework of the peer review under Directive 91/414/EEC in potatoes following seed treatment and in rice following foliar treatment (Netherlands, 2009; EFSA, 2010). In the framework of the current application, the applicant submitted new metabolism studies in potatoes following in-furrow application of phenyl- and methylene-labelled pencycuron and following a foliar spray application on lettuce (Netherlands, 2015).

An overview of the available metabolism studies is presented in Table 2.

| Crop group | Crops | Label position | Application | Sampling\(^{(a)}\) |
|------------|-------|----------------|-------------|-------------------|
| Root       | Potato| phenyl-methylene-\(^{14}\)C | Seed tuber powdering | a) 132 DAT |
|            |       |                 | a) 0.2 g/kg seed | b) metabolite structure elucidation study |
|            |       | phenyl-(U)-\(^{14}\)C | Seed tuber soaking (1 x 0.25 g/kg seed) | 14, 56, 133 (harvest) DAT |
|            |       | methylene-\(^{14}\)C | 1.547 kg/ha in-furrow spray at planting | 78 and 89 DAT (immature leaves only; 125 DAT (maturity) |
|            |       | phenyl-\(^{14}\)C | 1.369 kg/ha in-furrow spray at planting | |

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, p. 1-1355.
The two potato metabolism studies following seed treatment were assessed in a previous reasoned opinion of EFSA (EFSA, 2012). Following seed treatment, the parent compound was the major residue component in foliage and root. The toxicologically relevant metabolite pencycuron-PB-amine was not detected in tubers but represented about 3% of the total radioactive residue (TRR) in foliage and roots after the soaking treatment.

Potatoes (in-furrow application)

Following the in-furrow treatment of potatoes, the total TRR in tubers accounted for 0.054–0.056 mg eq/kg. In the study with the methylene-labelled active substance, 78.6% of the TRR was extracted using conventional extraction conditions; to complete the extraction, the solids remaining after conventional extraction were subject to a second extraction step (microwave extraction at higher temperature (≤ 120°C)). Under these conditions, additional 10.0% TRR was extracted. The combined extracts comprised as major component parent pencycuron (49.2% TRR, 0.027 mg eq/kg) and pencycuron-PB-amine (15% TRR, 0.008 mg eq/kg). In addition, a number of unidentified compounds were reported (in total 35.8% of TRR), none of which individually exceeded 5% of TRR.

In potato leaves (PHI 78 days) the TRR was significantly higher than in tubers (0.36 mg eq/kg). 74.2% of the TRR were extracted with the conventional extraction. Parent compound was not detected. In total, 18 different minor metabolites were characterised (together 72.6% of TRR). One compound accounted for 14.7% of the TRR but was not further investigated. Pencycuron-PB-amine accounted for 5.8% (0.015 mg(eq/kg)) of the TRR in leaves (Netherlands, 2015).

In the study with phenyl-labelled active substance, the conventional extraction yielded in 64.2% of the TRR. The subsequent extraction of the tuber samples (microwave-assisted extraction with methanol at elevated temperature) released additional 7.9% of the TRR. The post-extraction solids were subject to a third extraction (microwave-assisted extraction with a mixture of acetonitrile/water) which resulted in additional 16.9% of TRR. The major residues were identified as parent pencycuron (42.8%, 0.024 mg eq/kg), pencycuron-PB-amine (3.1%, 0.002 mg eq/kg) and 10 unidentified compounds (in total 49.3% of TRR, none of them individually exceeding 6%, 0.003 mg eq/kg). In addition, aniline and an aniline precursor (pencycuron-carbamic acid-methyl ester) were identified (4.8% of TRR and 3.1% of TRR, respectively). It is noted that these two metabolites were only found in the methanol extract. Comparable results were obtained in a second assay, where the potato tuber samples were subject to a different extraction scheme using dichloromethane/ethylacetate in the first conventional extraction, followed by microwave-assisted extraction with methanol and acetonitrile/water (Netherlands, 2015).

In the conventional extract PB-amine accounted for 9% of TRR, 0.005 mg eq/kg.
In potato leaves, eight metabolites were extracted, representing 67.9% of TRR, individually not being above 0.003 mg eq/kg. Parent pencycuron was not observed.

These studies demonstrate that following in-furrow treatment, pencycuron is the major residue in potato tuber; metabolite pencycuron-PB-amine is present at low levels.

Aniline and its precursor (pencycuron-carbamic acid) were not detected after conventional extraction of potato tuber or leaves. Thus, it is probably not a primary plant metabolite but a degradation product formed after hydrolytic cleavage of the molecule, leading to pencycuron-PB-amine and pencycuron-carbamic acid. The latter is unstable in the presence of water and degrades to aniline via decarboxylation while in the presence of methanol, pencycuron-carbamic acid-methyl ester is formed. Thus, in the primary crop metabolism study aniline is most likely an artefact that was formed in potatoes due to hydrolytic processes during microwave-assisted extraction and is the complementary cleavage product to pencycuron-PB-amine. The stability of pencycuron and the possible formation of aniline under processing conditions is further discussed in Section 3.1.1.3.

Pencycuron-PB-amine is a soil metabolite of pencycuron that was also identified in a confined rotational crop study. These findings suggest that pencycuron-PB-amine is formed in soil and taken up by the roots and distributed within the potato plants (EFSA, 2010; Netherlands, 2015).

The currently available studies indicate that the metabolic pathway of pencycuron in potatoes following seed treatment and in-furrow application is not completely comparable; the metabolite pencycuron-PB-amine was only found in the study investigating in-furrow application.

The new metabolism study on lettuce submitted in the framework of this application is not relevant for the assessment of the residues in potatoes. Briefly summarised, the TRR in lettuce following foliar treatment was high, accounting for 18.9–19.6 mg eq/kg and in both studies consisted mostly from unchanged parent compound (93–96% TRR). Only small amounts of metabolites were detected, not being individually above 1% TRR. Pencycuron-PB-amine accounted for 2.4% TRR (0.47 mg eq/kg). In the study with phenyl-labelled active substance, aniline was detected at 0.6% TRR (0.11 mg/kg), giving an indication that aniline is also a plant metabolite in leafy crops.

In brown rice and foliage, pencycuron was the major residue of the TRR at maturity. Based on the studies available to the peer review (metabolism study in rice (foliar application) and potatoes (seed treatment)), the residue definitions for the monitoring and risk assessment in primary crops were agreed as parent pencycuron only (EFSA, 2010). The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review.

The new metabolism studies give an indication that pencycuron-PB-amine should be considered for inclusion in the residue definition for risk assessment. However, considering the results of the submitted residue trials in potatoes, pencycuron-PB-amine was not found in concentrations above the LOQ (only data from SEU), a revision of the previously agreed residue definition is not suggested now. However, the need to revise the residue definitions established in the framework of the peer review should be discussed in detail in the framework of the MRL review under Art. 12 of Regulation (EC) No 396/2005. In particular, the inclusion of pencycuron-PB-amine for root and tuber crops and aniline for leafy crops should be considered.

Aniline was found in one of the potato metabolism studies in samples that underwent a treatment reflecting conditions that typically occur during processing. Thus, the relevance of aniline in processed products is further discussed in Section 3.1.1.3 on the nature of residues in processed products.

3.1.1.2. Magnitude of residues

**Potatoes** (GAP SEU/NEU: 1 × 1200 g/ha, in-furrow spray at BBCH 00-03)

The residue trials supporting the NEU outdoor use have been already assessed in the previous EFSA reasoned opinion on pencycuron (EFSA, 2012). Nine GAP-compliant residue trials on potatoes were available, with pencycuron residues ranging from < 0.01 to 0.10 mg/kg. The trial samples have not been analysed for pencycuron-PB-amine residues.

Under the current MRL application, eight GAP-compliant trials on potatoes for the SEU outdoor use were submitted, performed over the 2013–2014 growing season in Spain, France, Italy, Greece and Portugal. The samples were analysed for pencycuron and pencycuron-PB-amine. While pencycuron-PB-amine was not measured in any of the samples (all results below the LOQ of 0.01 mg/kg), residues of parent pencycuron ranged from < 0.01 to 0.04 mg/kg.

According to the U-test, both residue data populations are similar. However, since the calculated MRL proposals using the OECD calculator differed by more than one MRL class, it is not appropriate to combine the data sets. Based on the NEU residue data set, a MRL proposal of 0.2 mg/kg is derived.
The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposal are summarised in Table 3.

The stability of pencycuron and pencycuron-PB-amine residues in plant matrices under storage conditions prior to analysis was assessed during the peer review under Directive 91/414/EEC (EFSA, 2010). Residues of both compounds were found to be stable at ≤18°C for up to 24 months in matrices with high water content (lettuce), high water/starch content (turnips, potatoes) as well as in dry/starch matrices (wheat grain). As the supervised residue trial samples were stored under conditions (up to 19 months) for which integrity of the samples was demonstrated, it is concluded that the studies are valid with regard to storage stability.

Table 3: Overview of the available residue trials data

| Crop (GAPs) | Region/Indoor(a) | Residue levels observed in the supervised residue trials(b) (mg/kg) | Recommendations/comments(c) | MRL proposal (mg/kg) | HR(d) (mg/kg) | STMR(e) (mg/kg) |
|-------------|------------------|---------------------------------------------------------------|-----------------------------|---------------------|---------------|----------------|
| Potatoes (1 × 1200 g/ha; in-furrow) | NEU/outdoor | Pencycuron: 5 × < 0.01; 2 × 0.02; 0.08; 0.10 Pencycuron-PB-amine: not analysed | MRLOECD: 0.17/0.20 | 0.20 | 0.10 | 0.01 |
| | SEU/outdoor | Pencycuron: <0.01; 0.012; 0.013; 0.015; 0.016; 2 × 0.017; 0.04 Pencycuron-PB-amine: 8 × < 0.01 | MRLOECD: 0.06/0.06 | 0.06 | 0.04 | 0.0155 |

(a): NEU: outdoor trials conducted in northern Europe; SEU: outdoor trials conducted in southern Europe; Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Individual residue levels considered for MRL calculation are reported in ascending order.
(c): Any information/comment; result of OECD MRL calculation (unrounded/rounded values).
(d): HR: highest residue level according to the residue definition for risk assessment.
(e): STMR: median residue level according to residue definition for risk assessment.

3.1.1.3. Effect of industrial processing and/or household preparation

3.1.1.3.1. Effect of processing on the nature of residues

Standard hydrolysis studies simulating the effect on the nature of pencycuron residues under processing conditions representative of pasteurisation, boiling and sterilisation are not available.

In the metabolism studies in potatoes (in-furrow treatment) submitted in the framework of the current application (see Section 3.1.1.1), potato tuber samples were subject to conventional extraction using acetonitrile/water or dichloromethane/ethylacetate followed by high-temperature microwave extractions at elevated temperature (≤120°C). Under these extraction conditions that are considered comparable to conditions that occur under food processing (boiling, sterilisation), aniline and an aniline precursor compound (pencycuron-carbamic acid) were identified as degradation products (aniline: 4.8% of TRR; 0.003 mg eq/kg; pencycuron-carbamic acid: 3.1% TRR; 0.002 mg eq/kg) (Netherlands, 2015). Considering that the major amount of parent pencycuron was removed with the first conventional extraction step, the aniline formed during the harsh extraction conditions is not reflecting the quantitative degradation of pencycuron under processing conditions; in this study aniline was generated by hydrolytic cleavage from pencycuron metabolites that were not extracted with the conventional extraction using acetonitrile/water or dichloromethane/ethylacetate. This study however gives an indication that pencycuron is not stable under hydrolytic conditions.

The applicant submitted two studies investigating the formation of aniline in potatoes under conditions representative of processing.

In the first study, unpeeled potatoes obtained from the primary crop metabolism study (in-furrow application of 1.369 kg pencycuron radiolabelled in the phenyl ring; TRR in unprocessed potato tuber: 0.031 mg eq/kg) were boiled in salted water for 25 min. The boiled potatoes were extracted at ambient temperature with acetonitrile/water. Since the extraction efficiency was low (only 23.6% of TRR were extracted), the extraction solids were subject to two additional, microwave-assisted extraction steps with methanol and acetonitrile/water, respectively.
The cooking water contained 33% of the TRR; TRR in the boiled tuber accounted for 67% of TRR. Parent pencycuron was the only compound that was identified in the potato tuber extract derived with conventional extraction, but occurred in low amounts (1% of TRR, < 0.001 mg/kg). In addition, 12 unidentified compounds were isolated accounting for in total 23.1% of TRR. Aniline and pencycuron-carbamic acid methyl ester were only found in the methanol extract (microwave-assisted extraction). Overall, in this study only 4.6% of the TRR was identified. A significant high amount of the TRR was not extractable (26.9% of TRR) or not identified (Netherlands, 2015).

This study confirmed previous findings that pencycuron is not stable under conditions that are typical for food processing. The molecule is likely to be cleaved hydrolytically, leading to the unstable cleavage product pencycuron-carbamic acid; in the presence of water this compound degrades to aniline. The complementary cleavage product is pencycuron-PB-amine. Since aniline and its precursor were not identified in the extract derived with conventional extraction methods, it is likely that additional degradation products other than aniline are present in boiled potatoes. The processing study does not elucidate any of these additional degradation products.

EFSA concludes that this study does not allow deriving a robust residue definition for processed products. In a second supportive study, the applicant investigated the potential formation of aniline in processed potatoes during cooking and oven-baking in peel and its bioavailability following digestion. Potatoes with incurred residues (from the potato metabolism study with phenyl-UL-14C-pencycuron) described previously and potato samples spiked with radiolabelled pencycuron equivalent to 0.10 mg/kg were processed: the unpeeled potatoes were boiled (100°C, 25 min) or oven-baked (220°C for 50 min). The initial TRR in boiled potatoes (incl. cooking water) was 0.07 mg eq/kg and in baked potatoes 0.054 mg eq/kg. In spiked samples, the TRR accounted for 0.105 mg eq/kg in boiled potatoes (incl. cooking water) and 0.048 mg eq/kg in baked potatoes.

After boiling, a part of the TRR was found in cooking water; 56.9% of TRR (0.06 mg eq/kg) were recovered in the boiled potatoes (spiked sample), 67.8% of TRR (0.05 mg eq/kg) in the boiled potatoes derived from the incurred sample. In the oven-baked potatoes derived from the spiked potatoes, ca. 50% were lost, probably due to volatilisation.

After processing potatoes were submitted to digestion with artificial gastric juice (incubation for 4 h at 37°C in 0.1 N hydrochloric acid). Following ingestion, the samples were centrifuged and the supernatant decanted. The bioavailability was calculated as percentage of the released TRR determined in the gastric acid after digestion compared to the initial TRR value.

The percentage of bioavailable residues was 11% and 18% of TRR for boiled potatoes with incurred and spiked residues, respectively. For oven potatoes, the bioavailability was slightly higher (26% and 19% of TRR for potatoes with incurred and spiked residues).

Parent pencycuron was not detected in any of the gastric acid samples after digestion. Seven minor metabolites were detected, but individually not exceeding 0.004 mg eq/kg. Aniline was detected: according to the EMS, the concentration of aniline was 0.002 and 0.003 mg/kg gastric juice (Netherlands, 2015).

According to EFSA, this study provides evidence that consumption of processed potatoes treated with pencycuron leads to dietary exposure to aniline. However, since the ratio of processed potatoes and the volume of gastric juice is not clearly reported, the aniline concentration measured in the gastric juice cannot be used directly for an exposure calculation.

To summarise, EFSA is of the opinion that in the light of the new information provided with this application, the residue definition derived in the peer review for unprocessed products (i.e. parent pencycuron) seems to be not appropriate for processed products as there is evidence that the parent compound is almost completely degraded during processing. A hydrolytic cleavage of the parent compound is likely to occur. The formation of aniline in processed products or during digestion cannot be completely ruled out. The available data however, do not sufficiently elucidate the nature of degradation products that would allow deriving residue definitions for processed products. Thus, for processed products no residue definitions can be proposed.

3.1.1.3.2. Effect of processing on the magnitude of residues

Potato samples from two field trials performed in Spain and France in 2013 according to the intended use (in furrow-spray application) and from two field trials performed in Belgium and Germany (spray application, 2.5 kg/ha, 2 N intended application rate) were taken at harvest and processed into a wide range of potato-processed commodities (peeled/unpeeled boiled, fried, oven baked, microwaved potatoes, French fries, flakes, crisps and starch). Various intermediate processing products...
were analysed. The processed products were analysed for pencycuron; in the processing study performed with in-furrow treatment (potatoes from the Spanish and French field trial), in addition, residues of pencycuron-PB-amine were determined separately. Samples were not analysed for aniline (Netherlands, 2015).

Overall, the results indicate the peeling and washing significantly reduces residues in the crop. In all edible processed commodities, residues of pencycuron or pencycuron-PB-amine were below the LOQ of 0.01 mg/kg, except in one sample of microwaved potatoes (pencycuron residues of 0.01 mg/kg) and in cooked potatoes with peel (residues of pencycuron-PB-amine of 0.01 and 0.011 mg/kg). Increased residue concentrations were observed in peel (fresh and dried), dried waste from flake production and dried pulp from starch production, compared with the unprocessed potatoes.

Although the applicant provided processing studies for a wide range of potato products, EFSA is of the opinion that no definitive processing factors can be derived at the moment due to the lack of an agreed residue definition for processed products. The effects of processing on the nature of pencycuron residues and the issues regarding the magnitude of aniline in processed commodities need to be addressed. However, indicative processing factors were derived for processed products relevant for animal feed; the results for these processed products are summarised in Table 4.

### Table 4: Indicative processing factors to be used for dietary burden calculation in livestock

| Crop (RAC)/edible part or crop (RAC)/processed product | Number of studies(a) | Indicative processing factor (PF) | Median PF |
|--------------------------------------------------------|----------------------|----------------------------------|-----------|
| Enforcement residue definition: Pencycuron             |                      |                                  |           |
| Potato/potato peel                                     | 2(a); 4(b)           | 1.5(a); 2.1(b); 2.5(a); 3.4(h); 4(b); 5.4(b) | 2.9       |
| Potato/potato dried pulp from starch prod production   | 2(a)                 | 4.2(a); 16.4(a)                  | 10.3      |

(a): Studies (SEU) with in-furrow treatment at 1 × 1.2 kg/ha; (b): Studies (NEU) with foliar spray at 1 × 2.5 kg/ha

### 3.1.2. Rotational crops

Potatoes can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed.

The soil degradation studies demonstrated that the degradation rate of pencycuron is moderate; the maximum DT90 field was about 373 days (EFSA, 2010). Metabolite pencycuron-PB-amine is formed as a major metabolite of pencycuron in soil (> 45% of the applied radioactivity). According to a laboratory soil degradation study, the metabolite is of low to medium persistence (DT90 lab of 224.8 days). Thus, further studies investigating the nature and magnitude of the compound uptake in rotational crops are required (European Commission, 1997c).

#### 3.1.2.1. Nature of residues

The metabolism of pencycuron residues in rotational crops was assessed during the peer review (Netherlands, 2009; EFSA, 2010). The key parameters of the studies are presented in the table below (Table 5).

### Table 5: Overview of the available confined rotational crop studies

| Crop group | Rotational crops | Application Method | Rate (g/ha) | PBI(a) (days) | Sampling |
|------------|------------------|--------------------|-------------|---------------|----------|
| Leafy crops | Swiss chard      | Spray application to bare soil | 1 × 2.5 kg a.s./ha | 30, 132, 278 | 69, 180, 345 DAT |
| Roots/tubers | Turnips         | Wheat              |             |               | 111, 211, 355 DAT |
| Cereals    | Wheat            |                    |             |               | Forage: 61, 161, 306 DAT |
|            |                  |                    |             |               | Hay: 100, 225, 371 DAT |
|            |                  |                    |             |               | Straw, grain: 132, 278, 411 DAT |

(a): Plant back interval (interval between the application of the a.s. and the sowing/planting of the rotational crop).
The metabolic pattern of pencycuron in rotational crop differs from the one in the primary crop, since 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 peer review agreed on the residue definition for monitoring as pencycuron alone. For risk assessment, the residue definition for rotational crops was established as pencycuron and pencycuron-PB-amine (EFSA, 2010).

The residue definition for rotational crops may need to be reconsidered in the light of additional information provided in the framework of confirmatory data requested for the section on environmental fate and behaviour (European Commission, 2014).

3.1.2.2. Magnitude of residues

Rotational crop field studies were assessed in the framework of the peer review (Netherlands, 2009; EFSA, 2010). Eleven field trials in total were performed in Europe. Spring wheat, barley, turnip, lettuce and carrot were planted/sown 30, 120 and 365 days following the treatment of a bare soil or of potatoes (in-furrow) with pencycuron at dose rates ranging from 0.7 to 2.5 kg/ha. The PBI following soil treatment was 28–30 days. Residues at 0.02 mg/kg or lower were found at 30 PBI days in turnip, cereal straw, wheat grain and forage after application of active substance on bare soil.

Based on the available information, EFSA concludes that significant residue levels are unlikely to occur in rotational crops provided that pencycuron is used on potatoes according to the proposed GAPs.

3.2. Nature and magnitude of residues in livestock

Potatoes are normally fed to livestock and therefore the nature and magnitude of pencycuron residues in livestock has to be further investigated in the framework of this application (European Commission, 1996).

3.2.1. Dietary burden of livestock

The median and maximum dietary burden related to pencycuron\textsuperscript{11} was calculated for livestock using the OECD methodology (OECD, 2013). Only potatoes and their by-products were considered since for other potential feed items the existing EU MRLs are set below the LOQ of 0.05 mg/kg.

The input values for the dietary burden calculation are summarised in Table 6.

The processing factors as derived for process waste (wet peel) and dried pulp (from starch production) in the processing studies submitted under the current MRL application and referred to in the Table 4 were applied.

Table 6: Input values for the dietary burden calculation (parent pencycuron)

| Feed commodity                              | Median dietary burden | Maximum dietary burden |
|---------------------------------------------|-----------------------|------------------------|
|                                            | Input (mg/kg)         | Comment                | Input (mg/kg) | Comment                |
| Potato culls                                | 0.02                  | STMR (Table 3)         | 0.10          | HR (Table 3)           |
| Potato process waste (i.e. wet peel)        | 0.06                  | STMR (Table 3) $\times$ PF (2.9) (Table 4) | 0.06          | STMR (Table 3) $\times$ PF (2.9) (Table 4) |
| Potato dried pulp (from starch production) | 0.21                  | STMR (Table 3) $\times$ PF (10.3) (Table 4) | 0.21          | STMR (Table 3) $\times$ PF (10.3) (Table 4) |

Results of the dietary burden calculation are summarized in the table below (Table 7).

\textsuperscript{11} In the framework of the peer review it was agreed that no feeding studies are required for pencycuron-PB-amine since significant intake of PB-amine ($<0.1$ mg PB-amine/kg dry weight by cattle) is considered as a rare event (EFSA, 2010). For the current application, EFSA considered the calculation of the dietary burden for parent pencycuron sufficient to estimate the potential carryover of residues in food of animal origin.
The maximum dietary animal intake exceeded the trigger value (> 0.1 mg/kg dry matter (DM)) for all relevant livestock species except for poultry. Therefore, the occurrence of pencycuron residues in products of animal origin has to be investigated.

3.2.2. Nature of residues

The metabolism of pencycuron in livestock was investigated in lactating cows and laying hens in the framework of the peer review under Directive 91/414/EEC (Netherlands, 2009; EFSA, 2010). For three consecutive days, goat was administered 14C- pencycuron at a dose of 9.9 mg/kg bw day (800 N the calculated maximum dietary burden for dairy cattle and sheep); laying hens were administered pencycuron at a dose of 20 mg/kg bw day (2800 N) for three consecutive days (Netherlands, 2009).

Metabolism data 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 was proposed to include pencycuron alone (EFSA, 2010).

3.2.3. Magnitude of residues

Livestock feeding studies have not been submitted and assessed in the framework of the peer review. Based on metabolism study results, the peer review concluded that residues above the LOQ of 0.01 mg/kg are not expected in animal products, and therefore proposed no MRLs (EFSA, 2010).

Considering that the livestock dietary burden calculated in the framework of the current application is significantly lower than the dose rates investigated in the metabolism studies, EFSA concludes that significant residues of pencycuron will not occur in animal commodities following the intake of potatoes treated with pencycuron according to the intended use pattern. A comprehensive assessment of the possible transfer of pencycuron-related residues to food of animal origin will be performed in the framework of the Art. 12 MRL review, taking into account all sources of exposure for livestock.

4. Consumer risk assessment

4.1. Pencycuron

An indicative consumer risk assessment for parent pencycuron was performed with revision 2 of the EFSA PRIMo. This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population12 (EFSA, 2007a).

To calculate the chronic exposure, EFSA used median residue value (STMR) for parent pencycuron derived from the residue trials conducted on potatoes and reported in Table 3. For the

12 The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus one regional and four cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from Member State surveys are used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007a).

Table 7: Results of the dietary burden calculation (parent pencycuron)

| Animals            | Median burden (mg/kg bw) | Maximum burden (mg/kg bw) | Above 0.1 mg/kg DM | Maximum burden (mg/kg DM) | Highest contributing commodities |
|--------------------|--------------------------|---------------------------|--------------------|---------------------------|---------------------------------|
| Beef cattle        | 0.006                    | 0.008                     | Yes                | 0.35                      | Potato culls                   |
| Dairy cattle       | 0.007                    | 0.012                     | Yes                | 0.30                      | Potato culls                   |
| Ram/ewe            | 0.008                    | 0.012                     | Yes                | 0.35                      | Potato culls                   |
| Lamb               | 0.005                    | 0.009                     | Yes                | 0.20                      | Potato culls                   |
| Pig (breeding)     | 0.003                    | 0.008                     | Yes                | 0.35                      | Potato culls                   |
| Pig (finishing)    | 0.003                    | 0.009                     | Yes                | 0.30                      | Potato culls                   |
| Poultry broiler    | 0.004                    | 0.007                     | No                 | 0.10                      | Potato culls                   |
| Poultry layer      | 0.003                    | 0.006                     | No                 | 0.09                      | Potato culls                   |
| Turkey             | 0.001                    | 0.007                     | No                 | 0.10                      | Potato culls                   |
remaining commodities of plant and animal origin, the existing MRLs as established in Regulation (EU) No 149/2008\textsuperscript{13} were used as input values. The calculations were performed for unprocessed potatoes. However, since potatoes are exclusively consumed after processing, and no appropriate residue definition for processed products could be derived the results of this assessment are considered purely indicative.

An acute consumer exposure assessment was not performed, since no ARfD was established for pencycuron due to the low acute toxicity.

The input values used for the dietary exposure calculation are summarised in Table 8. The estimated exposure was then compared with the toxicological reference value derived for pencycuron (Table 1).

Table 8: Input values for the consumer dietary exposure assessment

| Commodity                      | Chronic exposure assessment | Acute exposure assessment |
|--------------------------------|-----------------------------|---------------------------|
|                                | Input (mg/kg) | Comment | Input (mg/kg) | Comment |
| Risk assessment residue definition: Pencycuron |
| Potatoes                       | 0.02 STMR (Table 3) | Acute exposure not calculated as the setting of an ARfD was not necessary. |
| Other plant and animal commodities | MRL | Regulation (EC) 396/2005 | |

The results of the intake calculation using the EFSA Pesticide Residues Intake Model (PRIMo) is a key supporting document and is made publicly available as a background document to this reasoned opinion.

In this indicative scenario, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The highest calculated chronic intake was 2% of the ADI (NL child). The contribution of residues in potatoes to the total consumer exposure accounted for a maximum of 0.05% of the ADI (NL child).

Considering that potatoes are consumed only after processing, the risk assessment based on the residue definition for unprocessed products is not sufficient to conclude that the intended use of pencycuron will not pose a consumer health risk.

Lacking data to derive a reliable residue definition for processed products, the dietary risk assessment cannot be completed.

4.2. Aniline

The identification of aniline in the primary crop metabolism study indicated that aniline is a relevant degradation product formed under processing conditions.

In the framework of the assessment of confirmatory data for buprofezin (EFSA, 2015), a provisional consumer risk was performed for aniline expected in processed tomatoes that were treated with buprofezin; using the BMDL10 for aniline that was calculated by the CEF Panel in 2007 (EFSA, 2007b). The margin of exposure (MoE) was calculated for aniline resulting from the use of buprofezin in tomatoes, using consumption data for processed and unprocessed tomatoes reported in the EFSA PRIMo rev. 2 (EFSA, 2007a). For tomato juice the lowest MoE was identified (29,700). Although the MoE exceeded the threshold value of 10,000, EFSA highlighted that other sources and routes of exposure need to be taken into account to come to a final conclusion on the risks related to the exposure to aniline. In the EFSA conclusion on buprofezin, it was highlighted that the Scientific Committee (EFSA Scientific Committee, 2005) is of the opinion that ‘substances which are both genotoxic and carcinogenic should not be approved for deliberate addition to foods or for use earlier in the food chain, if they leave residues which are both genotoxic and carcinogenic in food’.

Lacking reliable information on the amount of aniline in processed potatoes, EFSA is not in a position to update the previously performed risk assessment for buprofezin, including the additional source of aniline.

EFSA shares the view of JMPR that it is necessary to characterise the hazard of aniline and to estimate exposure to aniline via the diet, including exposure from the use of pesticides and other sources.

\textsuperscript{13} Commission Regulation (EC) No 149/2008 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto OJ L 58, 1.3.2008, p. 1–398.
Conclusions and recommendations

In conclusion, EFSA does not propose to amend the existing MRL for pencycuron in potatoes since the data were not sufficient to perform a dietary risk assessment for processed potatoes. Further information on the nature and magnitude of residues expected in processed products is required to finalise the dietary risk assessment.

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Abbreviations

a.s.  active substance  
ADI  acceptable daily intake  
AR  applied radioactivity  
ARfD  acute reference dose  
BBCH  growth stages of mono- and dicotyledonous plants  
BMDL  benchmark dose level  
bw  body weight  
cGAP  critical GAP  
CXL  Codex maximum residue limit  
DAR  draft assessment report  
DAT  days after treatment  
DM  dry matter  
DS  powder for dry seed treatment  
DT₉₀  period required for 90% dissipation (laboratory/field)  
EMS  evaluating Member State  
eq  residue expressed as a.s. equivalent  
FS  flowable concentrate for seed treatment  
GAP  Good Agricultural Practice  
GS  growth stage  
HPLC  high performance liquid chromatography  
HPLC-MS/MS  high performance liquid chromatography with tandem mass spectrometry  
ISO  International Organisation for Standardisation  
IUPAC  International Union of Pure and Applied Chemistry  
LOQ  limit of quantification  
MoE  margin of exposure  
MRL  maximum residue level  
MS  Member States  
MS/MS  tandem mass spectrometry detector  
MW  molecular weight  
NEU  northern Europe  
OECD  Organisation for Economic Co-operation and Development  
PAFF  Standing Committee on Plants, Animals, Food and Feed  
PBI  plant back interval  
PF  processing factor  
PHI  pre-harvest interval  
PRIMo  (EFSA) Pesticide Residues Intake Model  
RAC  raw agricultural commodity  
RD  residue definition  
RMS  rapporteur Member State  
SC  suspension concentrate  
SEU  southern Europe  
STMR  supervised trials median residue  
TMDI  theoretical maximum daily intake  
TRR  total radioactive residue  
WHO  World Health Organization
## Appendix A – Good Agricultural Practice (GAPs)

| Crop and/or situation(a) | MS or NEU/SEU or country | Pest or group of pests controlled(c) | Formulation | Application | Application rate per treatment | PHI (days)(l) | Remarks(m) |
|--------------------------|--------------------------|-------------------------------------|-------------|------------|-------------------|--------------|------------|
|                          |                          |                                     | Type(d-f)   | Conc. a.s.(i) | Method kind(f-h)  | Number min–max (k) | Water L/ha min–max | g/ha min–max |
| **Potato**               |                          |                                     | DS          | 125        | Seed treatment (roller table, in-planter) | BBCH 00-03 | 1 | 250 kg a.s./t | 700 | n.a. | Based on a max density of 2.8 tonnes of tubers/ha for food consumption |
| **EU**                   | I                        | Rhizoctonia solani                  | FS          | 250        | Seed treatment (roller table) | BBCH 00-03 | 1 | 0.15–0.188 kg a.s./t | 420–525 | n.a. | |
| **SEU/NEU**              | F                        |                                     | In-furrow spray | 258 | Seed treatment (in-planter) | BBCH 00-03 | 1 | – | – | 150 | n.a. | Based on 2.8 tonnes of tubers/ha for food consumption |
| **EU**                   | I                        |                                     | FS          | 258        | Seed treatment (roller table) | BBCH 00-03 | 1 | – | – | 150 | n.a. | |
| **SEU/NEU**              | F                        |                                     | FS          | 258        | Seed treatment (in-planter) | BBCH 00-03 | 1 | – | – | 150 | n.a. | |
| **SEU/NEU**              | F                        |                                     | FS          | 370        | Seed treatment (in-planter) | BBCH 00-03 | 1 | – | – | 150 | n.a. | |
| **SEU/NEU**              | F                        |                                     | FS          | 258        | In-furrow | BBCH 00-03 | 1 | – | – | 150 | n.a. | |
| **SEU/NEU**              | F                        |                                     | SC          | 530        | In-furrow | BBCH 00-03 | 1 | 0.48–0.8 kg a.s./ha | 150–250 | 1,200 | n.a. | 3 L of formulated product/ha |

(a): For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the usage situation should be described (e.g. fumigation of a structure).

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

(c): e.g. biting and sucking insects, soil-born insects, foliar fungi, weeds.

(d): e.g. wettable powder (WP), water soluble granule (WG).

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

(f): All abbreviations must be explained.

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

(h): Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants. Type of equipment used must be indicated.

(i): g/kg or µg/L

(j): Growth stage at last treatment (Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forestry, Braunschweig, Germany, 2001), including where relevant, information on season at the time of application.

(k): The minimum and maximum number of application possible under practical conditions of use must be provided.

(l): PHI – minimum pre-harvest interval.

(m): Remarks may include: Extent of use/economic importance/restrictions.
## Appendix B – Used compound codes

| Code/trivial name       | Chemical name                                           | Structural formula |
|-------------------------|---------------------------------------------------------|--------------------|
| Pencycuron              | 1-(4-chlorobenzyl)-1-cyclopentyl-3-phenylurea           | ![Structural formula for Pencycuron](image) |
|                         | Clc1ccc(cc1)CN(C(=O)Nc2cccccc2)C3CCCC3                  |                    |
| Pencycuron-PB-amine     | N-(4-chlorobenzyl)cyclopentanamine                       | ![Structural formula for Pencycuron-PB-amine](image) |
|                         | Clc1ccc(cc1)CNC2CCCC2                                   |                    |
| Aniline                 | aniline                                                 | ![Structural formula for Aniline](image) |
|                         | Nc1cccccc1                                              |                    |