REASONED OPINION

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Review of the existing maximum residue levels for pencycuron according to Article 12 of Regulation (EC) No 396/2005

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance pencycuron. To assess the occurrence of pencycuron residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EC) No 33/2008 as well as the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Some information required by the regulatory framework was missing and a possible risk to consumers was identified. Hence, the consumer risk assessment is considered indicative only and no MRL proposals were derived by EFSA. Further consideration by risk managers are needed and measures for reduction of the consumer exposure should also be considered.

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Summary

Pencycuron was included in Annex I to Directive 91/414/EEC on 1 June 2011 by Commission Directive 2011/49/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked the Netherlands, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 21 November 2016 and finalised on 21 January 2017. Furthermore, additional data were also considered and evaluated by the RMS in an updated report also prepared in the frame of the Article 12 (Netherlands, 2017). After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 6 March 2018.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the RMS and Member States, EFSA prepared in July 2018 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 29 August 2018 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of pencycuron in plants was investigated in primary and rotational crops. Although different types of crops were investigated, several authorised Good Agricultural Practices (GAPs) that were reported in this review are not covered by a metabolism study. As a consequence, no residue definition could be derived for fruit crops and pulses/oilseeds. The available studies allowed defining the residue for enforcement as pencycuron. Validated analytical methods are available for the enforcement of the proposed residue definition in different plant matrices at the limit of quantification (LOQ) of 0.01 mg/kg. Considering that pencycuron is not stable through processing conditions, a specific residue definition for enforcement in processed commodities was proposed as the sum of pencycuron and pencycuron-PB-amine, expressed as pencycuron. As the metabolite pencycuron-PB-amine may be relevant in certain primary crops (root and leafy), which is predominant in rotational crops and may also be formed in processed commodities, the residue for risk assessment was defined as sum of pencycuron and pencycuron-PB-amine, expressed as pencycuron. It is noted that the toxicological reference values of pencycuron also apply to pencycuron-PB-amine.

The available residue trials were only sufficient to derive an MRL and risk assessment values for potatoes. Furthermore, considering that no data were available for the metabolite pencycuron-PB-amine, these MRL and risk assessment values were derived on a tentative basis only. In the absence of data for all other commodities under assessment, it was not possible to derive other MRLs. The assessment of residue levels in rotational crops indicated that significant residue uptakes in succeeding crops can be avoided. Therefore, specific MRLs and risk assessment were not derived for rotational crops.

The available processing trials performed on potatoes with different standard processes allowed deriving processing factors for potato waste (wet peel) and dried pulp, which could be used to refine the dietary burden calculation. In addition, indicative processing factors were also derived for cooked, microwaved and fried potatoes, crisps, flakes and starch.

Pencycuron is authorised for use on potatoes, head cabbages and cotton seeds that might be fed to livestock. A tentative estimate of the dietary burden was calculated considering the available data on potatoes. It was found to exceed the trigger value of 0.1 mg/kg dry matter (DM) for all relevant groups of livestock except for poultry. Considering the results of the available metabolism study performed on lactating goat and scaling the total radioactivity levels with the calculated dietary burdens, residues are expected to remain below the LOQ of 0.01 mg/kg in all animal products. For poultry tissues, no MRLs are needed considering that the calculated dietary burden are bellows the trigger value.

An indicative consumer risk assessment for pencycuron was performed considering the residue definition for risk assessment including the sum of pencycuron and pencycuron-PB-amine, expressed pencycuron. Chronic consumer exposure resulting from the authorised uses reported in the framework

of this review was calculated using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). For the plant commodities for which no data were available to derive MRL and risk assessment values, EFSA considered the existing EU MRL defined for pencycuron. Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance. The indicative calculations resulted in a highest chronic exposure of 0.6% of the acceptable daily intake (ADI) (Spanish adults). Although this is not indicating a risk to consumers, this assessment was not sufficient to conclude on the impact of the pesticide use of pencycuron on the consumer dietary exposure.

The studies on the nature of residues indicated that aniline, a highly toxic compound, may be formed when pencycuron is subject to processes including hydrolysis conditions and in minor extent in the leafy crop primary metabolism. All commodities assessed in this review are (or can be) consumed after processing. Therefore, it is highly expected that the pesticide uses of pencycuron lead to consumer exposure to aniline. Aniline is classified a Category 2 mutagen (H341, suspected of causing genetic defects) and as a Category 2 carcinogen (H351, suspected of causing cancer). Furthermore, it is considered as a carcinogen for which a genotoxic mechanism cannot be excluded, meaning that a risk to consumer cannot be excluded. In the absence of further residue data for aniline and toxicological reference values, and considering that the use of the Margin of Exposure approach is not recommended for considering the risk of genotoxic metabolites, EFSA was not in a position to fully assess or refine the consumer exposure to aniline due to the pesticide use of pencycuron. Thus, the impact of the pesticide use of pencycuron on the consumer dietary exposure was not addressed. This was deemed as a major uncertainty, which prevented EFSA from recommending any MRLs for pencycuron.

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Background

Regulation (EC) No 396/2005[1] (hereinafter referred to as 'the Regulation') establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide, within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC[2] a reasoned opinion on the review of the existing MRLs for that active substance. As pencycuron was included in Annex I to Council Directive 91/414/EEC on 1 June 2011 by means of Commission Directive 2011/49/EC[3], and has been deemed to be approved under Regulation (EC) No 1107/2009[4], in accordance with Commission Implementing Regulation (EU) No 540/2011[5], as amended by Commission Implementing Regulation (EU) No 541/2011[6], EFSA initiated the review of all existing MRLs for that active substance.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that, in the framework of Directive 91/414/EEC, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

To gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;
- the analytical methods for enforcement of the proposed MRLs.

The Netherlands, the designated rapporteur Member State (RMS) in the framework in the framework of Commission Regulation (EC) No 33/2008, was asked to complete the PROFile for pencycuron and to prepare a supporting evaluation report (Netherlands, 2011). The PROFile and the supporting evaluation report were submitted to EFSA on 1 July 2011 and made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 21 November 2016 and finalised on 21 January 2017. Additional evaluation reports were submitted by the Czech Republic, Germany, Italy, Portugal and the European Union Reference Laboratories for Pesticide Residues (Czech Republic, 2017; Germany, 2017; Italy, 2017; EURLs, 2018; Portugal, 2018).

Based on the Evaluation Report prepared by the United Kingdom (2012) and evaluating Member State (EMS) the Netherlands (2015) and conclusions made by EFSA (2012, 2017), Bayer Division Crop Science has submitted studies on hydrolysis and processing. In agreement with the Commission and EFSA, RMS the Netherlands evaluated these studies in an Evaluation Report (Netherlands, 2017) and these new data were considered in the Article 12 Reasoned Opinion. After having considered all the information provided by RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 6 March 2018. Further clarifications were sought from Member States via a written procedure in April 2018. Additional evaluation reports were provided during

[1] Regulation (EC) No 396/2005 of the European 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, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.

[3] 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.

[4] 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.

[5] Commission Implementing Regulation (EU) No 540/2011 of 25 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.

[6] Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 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. 187–188.

the clarifications requests on the completeness check report (Belgium, 2018; EURLs, 2018; Lithuania, 2018; Portugal, 2018).

Based on the conclusions derived by EFSA in the framework of Commission Regulation (EC) No 33/2008, and the additional information provided by the Member States, EFSA prepared in July 2018 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 29 August 2018 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation reports submitted by the RMS (Netherlands, 2011, 2017) and the evaluation reports submitted by Member States Belgium, the Czech Republic, Germany, Italy, Lithuania, Portugal and the European Union Reference Laboratories for Pesticide Residues (Czech Republic, 2017; Germany, 2017; Italy, 2017; Belgium, 2018; EURLs, 2018; Lithuania, 2018; Portugal, 2018) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2018a) and the Member States consultation report (EFSA, 2018b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo excel file) and the PROFile are key supporting documents and made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo(EU) is presented in Appendix C.

Terms of Reference

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

The active substance and its use pattern

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

Pencycuron belongs to the group of phenylurea compounds which are used as fungicide with protective action. It can be used as a foliar spray or as a seed treatment for the control of diseases caused by *Rhizoctonia solani* and *Pellicularia* spp.

The chemical structure of the active substance and its main metabolites are reported in Appendix F.

Pencycuron was evaluated in the framework of Directive 91/414/EEC with Netherlands designated as RMS. Following the Commission Decision of 5 December 2008 (2008/934/EC)[7] 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 Commission Regulation (EC) No 33/2008[8].

The representative use supported for the peer review process was a seed treatment of potatoes (DS formulation) against basidiomycete fungus *Rhizoctonia solani*. Following the peer review, which was carried out by EFSA (2010), a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2011/49/EU, which entered into force on 1 June 2011. According to Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, pencycuron is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses fungicide only. Furthermore, in the approval directive submission of confirmatory data was set in the areas of ecotoxicology and fate and behaviour to be submitted by 31 May 2013. An EFSA conclusion on the confirmatory data assessment is not available.

[7] Commission Decision of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances (notified under document number C(2008) 7637). OJ L 333, 11.12.2008, p. 11–14.

[8] Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.

The EU MRLs for pencycuron are established in Annexes IIIA of Regulation (EC) No 396/2005. No MRL changes occurred since the entry into force of the Regulation mentioned above.

For the purpose of this MRL review, the critical uses of pencycuron currently authorised within the EU have been collected by the RMS and reported in the PROFile. The additional good agricultural practices (GAPs) reported by Member States during the completeness check were also considered. The details of the authorised GAPs for pencycuron are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS and the evaluation report accompanying the PROFile (Netherlands, 2011, which was updated in 2017). The draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Netherlands, 2005, 2009) and the conclusion on the peer review of the pesticide risk assessment of the active substance pencycuron (EFSA, 2010) were also considered. The previous reasoned opinions on pencycuron (EFSA, 2012, 2017) and the evaluation report prepared by the EMS for the opinion of 2017 were taken into account. Finally, EFSA considered the evaluation reports submitted during the completeness check (Czech Republic, 2017, Germany, 2017; Italy, 2017; Belgium, 2018; EURLs, 2018; Lithuania, 2018; Portugal, 2018). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011[9] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of pencycuron in primary crops was assessed in potatoes following seed treatment, using two different types of applications: powdering/soaking of tubers before sowing and spraying of tuber simultaneously to planting (in-furrow application). In addition, the metabolism of pencycuron was also investigated for foliar application in lettuce and rice. These studies were assessed during the peer review (Netherlands, 2009; EFSA, 2010) and in a recent MRL application (Netherlands, 2015; EFSA, 2017).

In potatoes following seed treatment of tubers before planting, the total radioactivity was relatively low in tubers (0.02–0.06 mg eq./kg). Most of the radioactivity was associated with starch and the main component identified in roots and foliage is the parent compound (8–40% total radioactive residue (TRR) in tubers). No other compounds were found in significant levels in tubers. The studies performed with rice also indicates parent compound to be the main and unique relevant residue component, representing 77–92% of the TRR. Both studies showed limited metabolic transformation under the investigated conditions.

The recent metabolism studies performed with in furrow spraying on potatoes tubers and with foliar application on lettuce depicted a more extensive degradation (EFSA, 2017).

Following in furrow application of potato tubers, the total radioactivity accounted for 0.054–0.056 mg/kg in tubers. In both studies, performed with phenyl- and methylene-labelled active substance, pencycuron remain the major residue (42.8–49.2% TRR; 0.024–0.027 mg/kg). However, other compounds were also identified. Metabolite pencycuron-PB-amine is the only one retrieved in significant proportions (up to 15% TRR; 0.008 mg eq./kg). A number of unidentified compounds were also reported, representing 36–49% of the TRR in total but none of them individually exceeding 6% of the TRR (≤ 0.003 mg eq./kg). It is noted that aniline and its precursor (pencycuron-carbamic acid) were identified in the study performed with phenyl label (3.1–4.8% TRR). However, it is highlighted that these compounds were only detected after a specific extraction process using microwave

[9] 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.

assistance with methanol at elevated temperature whilst totally absent after conventional extraction. Thus, it was concluded that this observation may probably be an artefact that was formed in potatoes due to the hydrolytic process during microwaved-assisted extraction (EFSA, 2017). This is consistent with the finding of the hydrolysis studies where aniline was found to be released under different process conditions (see also Section 1.1.3).

In lettuce following foliar application, total radioactivity was very high (18.9–19.6 mg eq./kg) and in both studies consisted mostly of unchanged parent compound (93–96% TRR). Pencycuron-PB-amine was identified and accounted for 2.4% of TRR (0.47 mg eq./kg). Other metabolites were detected in very small amounts (individually ≤ 1% TRR). In the study with phenyl-labelled active substance, aniline was detected at 0.6% TRR (0.11 mg eq./kg), giving an indication of the formation of aniline in leafy crops.

1.1.2. Nature of residues in rotational crops

Pencycuron is authorised on crops that may be grown in rotation. The field DT_{90} reported in the soil degradation studies evaluated in the framework of the peer review was 373 days (EFSA, 2010). In addition, pencycuron-PB-amine is formed as a major soil metabolite (> 45% of the applied radioactivity). According to a laboratory soil degradation study, this metabolite is of low to medium persistence (DT_{90lab} of 224.8 days). Therefore, investigation on the nature of residues in rotational crops is required.

The metabolism of pencycuron residues in rotational crops was assessed during the European peer review (Netherlands, 2009; EFSA, 2010). The available study investigated residue uptake in root crops (turnips), leafy crops (Swiss chard) and cereals (wheat) planted after three different plant-back intervals (PBI): 30, 132 and 278 days after treatment.

The metabolite pencycuron-PB-amine is a major residue in almost all commodities at any PBI: 19–45% TRR in wheat forage/hay/straw, 29–46% TRR in Swiss chard and 6–16% in turnip roots. Parent compound is, among others, a minor component of the residues (0.5–13% TRR). As in primary crops, pencycuron and its PB-amine metabolite were the only significant compounds observed rotational crops. Therefore, no specific metabolic pathway is observed in rotational crops.

Pencycuron-PB-amine is a soil metabolite. The above results indicate that this compound is more available than parent compound for uptake by plants. As a consequence, this metabolite is found in higher concentrations in rotational crops and in a minor extent following agricultural practices where parent compound is degraded in soil before potential uptake into plants (e.g. in-furrow application on potato tubers).

It is noted that after the assessment of confirmatory data requested for the section on environmental fate and behaviour, the possible formation of an additional metabolite (cyclopentilamine) in soil was not fully addressed[10] (European Commission, 2014). Therefore, the conclusion on the nature of residues in rotational crops remains tentative pending a full clarification of this point.

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities were reported to RMS in the framework of the MRL review. The RMS assessed these studies (Netherlands, 2017) which were not peer reviewed.

The studies were conducted, one with pencycuron radiolabelled on the chlorophenyl ring and one with pencycuron radiolabelled on the phenyl ring. Both studies simulated the representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6).

Two studies demonstrated that pencycuron is readily degraded when subject to hydrolytic conditions. The level of degradation increases with temperature/pH: 59–64% degradation under pasteurisation, 97% degradation under boiling/brewing/baking and 100% degradation under sterilisation. The main degradation products are pencycuron-PB-amine (56.4–95.9% of the applied radioactivity) and aniline (57.6–92.9% of the applied radioactivity). Other unidentified metabolites were also observed but in very low proportions (< 3% of the applied radioactivity).

It is also noted that additional supportive studies investigating the formation of aniline in potatoes under different processing conditions were reported and evaluated in the framework of a previous MRL

[10] In the context of the assessment of confirmatory data, it was noted that additional information were still needed regarding the fate and behaviour in soil of the cyclopentyl portion of pencycuron. The theoretically possible formation in soil, and consequently occurrence in groundwater, surface water and sediment, of the metabolite cyclopentylamine could not be excluded (European Commission, 2014).

application (Netherlands, 2015, considered in EFSA, 2017). In those studies, unpeeled potato samples containing incurred residues were submitted to specific household process of potatoes (boiling in salted water, microwave, cooking, oven-baking) as well as to simulation of digestion with artificial gastric juice. Detailed results were reported in the previous EFSA opinion on the modification of the existing MRL for pencycuron in potatoes (2017). Overall, these studies confirm the finding of the in-vitro hydrolysis studies, providing additional evidence that consumption of processed potatoes treated with pencycuron may lead to dietary exposure to aniline.

Consequently, the metabolite pencycuron-PB-amine and the aniline compound are the major degradation products in processed commodities. Therefore, the residue pattern in processed commodities cannot be considered identical to the one of raw agricultural commodities.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of pencycuron in plant commodities were assessed during the European peer review. An high-performance liquid chromatography (HPLC) method using tandem mass spectrometry detection (MS/MS) is sufficiently validated for the determination of pencycuron residues in high water content, high acid content and high oil content commodities as well as in dry commodities, with an LOQ of 0.01 mg/kg.

During the completeness check, the EURLs provided QuEChERS multi-residue analytical methods using liquid chromatography with tandem mass spectrometry (LC–MS/MS) and gas chromatography with tandem mass spectrometry (GC–MS/MS), with a LOQ of 0.01 mg/kg for the routine analysis of pencycuron in commodities with high water, high acid and high oil content as well as dry commodities (EURLs, 2018).

In addition, the EURL also provided validation data demonstrating that pencycuron-PB-amine could be enforced using LC–MS/MS with an LOQ of 0.01 mg/kg in high water content, high acid content and high oil content commodities as well as in dry commodities (EURLs, 2018). Based on this report and on the complementary information received during the Member States consultation (EFSA, 2018b), this methods were successfully validated for the analysis of pencycuron-PB-amine on courgettes, cucumber, oranges, blueberries, wheat, rice and cashew nuts.

1.1.5. Stability of residues in plants

The storage stability of pencycuron and its metabolite pencycuron-PB-amine was investigated in the framework of the peer review (Netherlands, 2009; EFSA, 2010).

In high water content commodities, in high starch content commodities and in dry commodities, the available studies the demonstrated the storage stability for pencycuron and pencycuron-PB-amine (separately) for a period of 24 months when stored at –18°C. The same was also demonstrated for cereals straw.

It is noted that no study is available to cover the storage stability in commodities with high oil content and high acid content. If in the future residue trials would be generated on crops belonging to these categories, such studies may be required.

1.1.6. Proposed residue definitions

It is firstly highlighted that metabolism studies on fruit crops (soil and seed treatment), leafy crops (seed treatment) and pulses/oilseeds (seed treatment) were not available although GAPs were reported for crops belonging to these categories. Therefore, the corresponding GAPs are not supported by a primary crop metabolism study. As a consequence, data gaps are identified regarding the nature of residues in primary crops for fruit crops (soil and seed treatment), leafy crops (seed treatment) and pulses/oilseeds (seed treatment). In the meanwhile, no residue definitions for enforcement and risk assessment can be proposed for the corresponding commodities.

According to the available primary crop metabolism studies, pencycuron should be a sufficient marker for monitoring in root crops (seed treatment and in furrow spray at planting), leafy crops (foliar treatment) and cereals (foliar treatment). Therefore, the residue definition for enforcement in raw agricultural commodities can be set a pencycuron; this proposal is restricted to the above investigated crop categories. Sufficiently validated analytical methods for enforcement of pencycuron in the four main plant matrices are available (see Section 1.1.4).

Considering that pencycuron is not stable through processing conditions (see Section 1.1.3), a specific residue definition is needed for enforcement in processed commodities. The proposed

definition is the sum of pencycuron and pencycuron-PB-amine, expressed as pencycuron. There are indications, according to the EURLs, that pencycuron-PB-amine can be enforced in different plant matrices (EURLs, 2018). However, this information should also be demonstrated for processed commodities and detailed validation data should be reported in an evaluation report (data gap). It is noted that this proposal is appropriate as long as the residue definition in raw commodities remain unchanged. If metabolites other than the parent compound and its PB-amine metabolite would be observed in significant concentrations in future metabolism studies (e.g. fruit crops or pulses/oilseeds), the hydrolytic stability of those metabolites would also need to be addressed. Thus, the proposed residue definition is deemed tentative.

For a limited number of crops and uses, parent compound may be sufficient for risk assessment. This is the case for seed treatment on root crops as well as cereals. However, for several GAPs reported in this review, pencycuron-PB-amine should also be considered for risk assessment purpose. This compound was observed in root crops (after seed treatment with application in furrow) and in leafy crops. In addition, this compound is also relevant in rotational crops and in processed commodities subject to hydrolysis. During the peer review of pencycuron (EFSA, 2010), it was concluded that the toxicological reference values of pencycuron also apply to pencycuron-PB-amine since this latter was found in significant proportion in the rat metabolism. Therefore, the residue for risk assessment can be defined as sum of pencycuron and pencycuron-PB-amine, expressed as pencycuron. This residue definition applies to all commodities belonging to the investigated crop categories, noting, however, that in some particular cases (cereals and root crops with seed treatment before planting), the presence of PB-amine metabolite is not expected.

Further to the above, it should be considered that another compound, aniline, can also be released in two different situations: when pencycuron is subject to hydrolysis conditions and in minor extents in the leafy crop primary metabolism. Thus, consumers may be exposed to aniline after pesticide use of pencycuron on plant commodities. Aniline is a highly toxic compound. It is classified as a Category 2 mutagen (H341, suspected of causing genetic defects) and as a Category 2 carcinogen (H351, suspected of causing cancer). Furthermore, it is considered as a carcinogen for which a genotoxic mechanism cannot be excluded (EFSA, 2007b). Therefore, a separate risk assessment should in theory be performed for aniline. This residue definition for risk assessment would be relevant for leafy crops and for processed commodities (subject to any hydrolysis constraints). However, considering the toxicological properties of aniline, no toxicological reference values could be derived for this compound and as aniline should be considered as a metabolite, not an impurity, EFSA has not included in this Reasoned Opinion a risk assessment based on the Margin of Exposure approach for this compound.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of pencycuron residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Netherlands, 2011), including residue trials evaluated in the framework of the peer review (Netherlands, 2009) or in the framework of a previous MRL applications (EFSA, 2012, 2017). All residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability of residues was demonstrated. Decline of residues during storage of the trial samples is therefore not expected.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

It is noted that among all GAPs reported in this review, only the GAPs on potatoes are supported by residue trials. For this crop, two types of seed treatments are authorised:

- Seed treatment simultaneously to planting (in-furrow spraying): only reported by Member States of the northern zone.
- Seed treatment before planting: reported by Member States of both northern and southern zones.

These GAPs are supported by a sufficient number of trials. Based on these data, the GAP with seed treatment before planting (northern European Union (NEU) and southern European Union (SEU)) is less critical than the northern GAP with in-furrow application. It is noted that none of the reported trials provide residue analysis for the metabolite pencycuron-PB-amine. For the GAPs with seed treatment

before planting, this is not deemed as a deficiency since pencycuron-PB-amine is not expected to be formed under this type of treatment (see also Section 1.1.1). However, for the northern GAP with in-furrow spraying, such data are missing (data gap). It is noted that southern trials performed with in-furrow applications with similar GAP parameters were reported and assessed in a previous MRL application (EFSA, 2017). These data indicate the metabolite pencycuron-PB-amine to be absent (all results below the LOQ of 0.01 mg/kg). Based on this information, a tentative conversion factor of 1 can proposed for the critical northern GAP with in-furrow application. However, this conversion factor (CF) should in principle be confirmed by GAP-compliant trials analysing simultaneously for residue definitions for enforcement and risk assessment.

For all other crops than potatoes, no residue trials were available and thus, MRL or risk assessment values could not be derived by EFSA. The following data gaps were identified:

- Strawberries: eight trials compliant with the southern outdoor GAP and eight trials compliant with the indoor GAP are required;
- Beetroots: four trials compliant with the southern outdoor GAP are required;
- Tomatoes and aubergines: eight trials compliant with the southern outdoor GAP are required;
- Sweet peppers: eight trials compliant with the southern outdoor GAP are required;
- Head cabbages: eight trials compliant with the southern outdoor GAP are required;
- Lettuces: eight trials compliant with the southern outdoor GAP and eight trials compliant with the indoor GAP are required;
- Beans and peas (with pods): eight trials compliant with the southern outdoor GAP are required;
- Beans and peas (without pods): eight trials compliant with the southern outdoor GAP are required;
- Asparagus: four trials compliant with the southern outdoor GAP and four trials compliant with the indoor GAP are required;
- Globe artichoke: four trials compliant with the southern outdoor GAP are required;
- Cottons seeds: eight trials compliant with the southern outdoor GAP are required.

It is noted that for none of the commodities reported above (except beetroots), a residue definition could be derived (see Section 1.1.1). Therefore, before generating new residue trials on strawberries, tomatoes, aubergines, sweet peppers, head cabbages, lettuces, beans and peas, asparagus, globe artichoke and cottons seeds, the data gaps on the nature of residues in fruit crops, leafy crops (with seed treatment) and pulses/oilseeds should be addressed in order to properly define the relevant residues to be measured in the trials.

1.2.2. Magnitude of residues in rotational crops

The confined rotational crops studies indicate that residue uptakes may occur in succeeding crops. Significant total radioactivity levels (partially incorporated to the plant matrix) were found in wheat grain (up to 0.18 mg eq./kg), turnip leaves and roots (up to 0.28 mg eq./kg) and Swiss chard (up to 0.27 mg eq./kg). Residue levels were even higher in wheat hay and straw (up to 2.8–4.2 mg eq./kg in the shortest rotation).

Rotational crop field trials were reported and assessed in the framework of the peer review (Netherlands, 2009; EFSA, 2010). A total of 11 field trials were performed in Europe: spring wheat, barley, turnip, lettuce and carrot were planted/sown 30, 120 and 365 days after treatment (DAT) of a bare soil or of potatoes (in-furrow) with pencycuron at dose rates ranging from 0.7 to 2.5 kg/ha, therefore simulating conditions that cover the critical GAPs reported in this review. The harvested samples were analysed for pencycuron and pencycuron-PB-amine. The residue levels of pencycuron and pencycuron-PB-amine found in these trials never exceed 0.02 mg/kg, which corresponds to the maximum levels retrieved in turnips, cereal straw and forage at PBI 30 day. With PBI longer than 100 days, residue levels were found to remain below the LOQ of 0.01 mg/kg.

These results indicate that the relevant components of the residue are likely to remain in low concentration (< 0.02 mg/kg) in rotational crops provided that pencycuron is used according to the authorised GAPs. However, as residue above 0.01 mg/kg cannot totally be excluded, Member States may prefer to consider mitigation measures to ensure that no residue uptakes occur. Based on the above data, there are indications that residue uptakes in rotational crops can totally be avoided with a minimum PBI of 100 days.

1.2.3. Magnitude of residues in processed commodities

In the framework of the peer review, processing studies were not reported and are not required. It is noted that residue levels in the available trials on primary crops (only potatoes) are below or equal to 0.10 mg/kg. However, considering that the parent compound is likely to degrade into aniline when subject to standard process conditions (see Section 1.1.3), further data on the magnitude of residues in processed commodities are deemed essential to assess the consumer exposure.

Several processing trials performed on potatoes with different standard processes were reported and assessed in the framework of the last MRL application (Netherlands, 2015, assessed in EFSA, 2017). In this opinion, processing factors (PF) were derived only considering the level of parent compound because a specific residue definition for processed commodities was not available in this framework.

Considering that specific residue definitions are now proposed for processed commodities (sum of pencycuron and pencycuron-PB-amine, expressed as pencycuron, see Section 1.1.6), EFSA reconsidered the available data to derive processing factors. EFSA considered only the available trials where samples of processed products were analysed for both pencycuron and for pencycuron-PB-amine (i.e. only 2 studies out of 6, representing 10 different trials). Based on these data, processing factors were recalculated considering the proposed residue definition for enforcement in raw commodities (pencycuron) and in processed commodities (sum of pencycuron and pencycuron-PB-amine, expressed as pencycuron). Consequently, the values derived in the present opinion differ from the one reported in the previous EFSA opinion (EFSA, 2017).

Overall, increased residue concentrations are observed in waste (peel) and dried pulp from starch production, compared with the unprocessed potatoes. Robust processing factors could be derived for processed waste (wet peel) based on four trials analysing for residues in wet peel (reported as 'peel rest' and 'waste'). It is noted that the two trials providing analysis in washed peel were disregarded since they are expected to underestimate the residue levels. Tentative processing factors could be derived for dried pulp, which can also be used to perform an indicative calculation of the dietary burden (see Section 2).

In addition, analysis performed in cooked, microwaved and fried potatoes, crisps, flakes and starch indicated that both pencycuron and pencycuron-PB-amine are expected to be close or below the LOQ in these processed fractions. Positive findings were only found in microwaved sample (pencycuron residues of 0.01 mg/kg) and in one sample of cooked potato with peel (0.011 mg/kg of pencycuron-PB-amine). Processing factors slightly above 1 are derived for the above mentioned processed items (ranging from 1 to 1.48 mg/kg), except in peeled microwaved potatoes (0.82 mg/kg). It is noted that validity of these processing factors is limited because in most of the available studies, residue concentrations measured in the raw and processed commodities were generally quite low (ranging between 0.01 and 0.03 mg/kg).

It is highlighted that samples were not analysed for aniline. The potential level of aniline that might be released in processed commodities remains an essential issue that could not be addressed with the available data.

1.2.4. Proposed MRLs

The available data are only sufficient to derive an MRL and risk assessment values for one food commodity (potatoes). For this commodity, an MRL can be derived from the critical GAP (NEU: seed treatment in-furrow). However, considering that the metabolite pencycuron-PB-amine is expected to be formed under these conditions of use and since the available trials do not provide information on the pencycuron-PB-amine residue levels, this MRL and the associated risk assessment values are derived on a tentative basis only. In the absence of data for all other commodities under assessment, it was not possible to derive other MRLs.

The assessment of residue levels in rotational crops indicates that significant residue uptakes in succeeding crops can be avoided. Therefore, specific MRLs and risk assessment were not derived for rotational crops.

2. Residues in livestock

Pencycuron is authorised for use on potatoes, head cabbages and cotton seeds that might be fed to livestock. Livestock dietary burdens were therefore calculated for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level.

2.1. Pencycuron and pencycuron-PB-amine

An indicative dietary exposure was calculated for the residue definition for risk assessment including the sum of pencycuron and pencycuron-PB-amine, expressed as pencycuron. Considering that no residue data were available for head cabbages and cottons seeds, this calculation was based on the estimated residues in potatoes only. Consequently, the dietary burden calculation is considered indicative only. The processing factors derived for potato waste (wet peel) and dried pulp (from starch production) (see Section 1.2.3) were applied to consider potential concentration of pencycuron and/or pencycuron-PB-amine in these commodities. The input values for all relevant commodities are summarised in Appendix D.2. The dietary burdens calculated were found to exceed the trigger value of 0.1 mg/kg dry matter (DM) for all relevant groups of livestock except for poultry. Therefore, behaviour of residues needs to be assessed in cattle, sheep and swine.

The metabolism of pencycuron in livestock was investigated in lactating cows and laying hens in the framework of the peer review (Netherlands, 2009; EFSA, 2010). Lactating goat and laying hens were administered with pencycuron at the dose of 9.9 and 20 mg/kg body weight (bw) per day, respectively. These feeding levels are largely covering the calculated dietary burdens (500 N and 2,800 N respectively).

In the edible matrices of lactating goat, total radioactive residues ranged from 0.08 mg eq./kg (muscle) to 3.0 mg eq./kg (liver). The available results indicate that in most tissues pencycuron is extensively metabolised. However, pencycuron remains present in all edible tissues, with absolute levels ranging from 0.01 mg/kg (13% TRR in muscle) and 0.18 mg/kg (65% TRR in fat; 6% TRR in liver). Similar results were found in poultry tissues where total radioactivity ranged between 0.24 mg eq./kg (muscle) and 3.4 mg eq./kg (liver).

Considering that the dietary burden calculated in this review is much lower than the feeding levels used in the metabolism studies, the absolute levels of the single identified metabolites are not expected to be significant. Therefore, the residue definition for both monitoring and risk assessment proposed during the peer review (i.e. parent pencycuron alone) is still relevant (EFSA, 2010). Considering the proportion of pencycuron found in fat, the proposed residue definition is considered as fat soluble.

Analytical methods for the determination of pencycuron in commodities of animal origin were assessed during the European peer review (EFSA, 2010). An HPLC method using MS/MS detection is sufficiently validated for the determination of pencycuron residues in muscle, fat, liver, kidney, milk and eggs, with an LOQ of 0.01 mg/kg (EFSA, 2010). In addition, screening data generated by EURLs for commodities of animal origin show that pencycuron can be monitored in meat, eggs, milk and honey with a screening detection limit (SLD) of 0.005 mg/kg (EURLs, 2018).

Livestock feeding studies are not available. Considering the total radioactivity levels found in the metabolism studies and scaling these figures with the calculated dietary burdens, total residues are expected to remain below the LOQ of 0.01 mg/kg in all animal products. Therefore, MRLs and risk assessment values can be proposed at the LOQ for all animal tissues. For poultry tissues, no MRLs are needed considering that the calculated dietary burden is below the trigger value. It is highlighted that the above conclusion may need to be updated when additional residue data would be available for the other relevant feed items (head cabbages, cotton seeds).

2.2. Aniline

In the absence of residue data for aniline, EFSA could not assess the animal exposure to this compound. However, considering that aniline might be present in raw agricultural feed items (in particular in leafy crops) and is likely to be formed under processing, it is expected that livestock are also exposed to this compound through their diet. Considering this remaining issue, the impact of the pesticide use of pencycuron on the residues in livestock is not fully addressed.

3. Consumer risk assessment

3.1. Pencycuron and pencycuron-PB-amine

An indicative consumer risk assessment for pencycuron was performed considering the residue definition for risk assessment including the sum of pencycuron and pencycuron-PB-amine, expressed pencycuron. Chronic exposure calculations considering the crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007a). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E.

Input values were derived according to the internationally agreed methodologies (FAO, 2009). It is noted that potatoes is the only plant commodity for which MRL and risk assessment values could be derived in the framework of this review. The chronic exposure was assessed considering the median residue value (STMR) derived for parent pencycuron based on the most critical GAP. A tentative CF of 1 was applied (see Section 1.2.1). For the other plant commodities, no data were available to derive an MRL and risk assessment values in Section 1.2.1. For those commodities, EFSA considered the existing EU MRL (defined for pencycuron) for an indicative calculation. For livestock commodities, EFSA considered the LOQ as derived in Section 2.1. All input values included in the exposure calculations are summarised in Appendix D.2. Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

The indicative exposures calculated were compared with the toxicological reference value for pencycuron, derived by EFSA (2010) under the peer review. The highest chronic exposure was calculated for Spanish adults, representing 0.6% of the acceptable daily intake (ADI). Although this is not indicating a risk to consumers, this assessment only took into account the unprocessed commodities and residue data were only available for potatoes. Therefore, this is not sufficient to conclude on the impact of the pesticide use of pencycuron on the consumer dietary exposure.

3.2. Aniline

All plant commodities assessed in this review are (or can be) consumed after processing. In particular, potatoes are exclusively consumed after processing. It was demonstrated that pencycuron is likely to release aniline during industrial and household processes (see Section 1.1.3). Furthermore, this compound may also be formed in minor extents in leafy crop primary metabolism. Therefore, it is highly expected that the pesticide uses of pencycuron lead to consumer exposure to aniline.

Aniline is classified a Category 2 mutagen (H341, suspected of causing genetic defects) and as a Category 2 carcinogen (H351, suspected of causing cancer). Furthermore, it is considered as a carcinogen for which a genotoxic mechanism cannot be excluded (EFSA, 2007b), meaning that no toxicological reference values can be derived. Considering the above toxicological properties however, a risk to consumer's health cannot be excluded if aniline enter in the food chain.

In the absence of further residue data for aniline and toxicological reference values, and considering that the use of the Margin of Exposure approach is not recommended for considering the risk of genotoxic metabolites, EFSA is not in position to perform a full dietary risk assessment for this substance. This is deemed as a major uncertainty, which prevent EFSA from recommending any MRLs for pencycuron.

Conclusions

The metabolism of pencycuron in plants was investigated in primary and rotational crops. Although different types of crops were investigated, several authorised GAPs that were reported in this review are not covered by a metabolism study. As a consequence, no residue definition could be derived for fruit crops and pulses/oilseeds. The available studies allowed defining the residue for enforcement as pencycuron. Validated analytical methods are available for the enforcement of the proposed residue definition in different plant matrices at the LOQ of 0.01 mg/kg. Considering that pencycuron is not stable through processing conditions, a specific residue definition for enforcement in processed commodities was proposed as the sum of pencycuron and pencycuron-PB-amine, expressed as pencycuron. As the metabolite pencycuron-PB-amine may be relevant in certain primary crops (root and leafy), which is predominant in rotational crops and may also be formed in processed commodities, the residue for risk assessment was defined as sum of pencycuron and pencycuron-PB-amine, expressed as pencycuron. It is noted that the toxicological reference values of pencycuron also apply to pencycuron-PB-amine.

The available residue trials were only sufficient to derive an MRL and risk assessment values for potatoes. Furthermore, considering that no data were available for the metabolite pencycuron-PB-amine, these MRL and risk assessment values were derived on a tentative basis only. In the absence of data for all other commodities under assessment, it was not possible to derive other MRLs. The assessment of residue levels in rotational crops indicated that significant residue uptakes in succeeding crops can be avoided. Therefore, specific MRLs and risk assessment were not derived for rotational crops.

The available processing trials performed on potatoes with different standard processes allowed deriving processing factors for potato waste (wet peel) and dried pulp, which could be used to refine

the dietary burden calculation. In addition, indicative processing factors were also derived for cooked, microwaved and fried potatoes, crisps, flakes and starch.

Pencycuron is authorised for use on potatoes, head cabbages and cotton seeds that might be fed to livestock. A tentative estimate of the dietary burden was calculated considering the available data on potatoes. It was found to exceed the trigger value of 0.1 mg/kg DM for all relevant groups of livestock except for poultry. Considering the results of the available metabolism study performed on lactating goat and scaling the total radioactivity levels with the calculated dietary burdens, residues are expected to remain below the LOQ of 0.01 mg/kg in all animal products. For poultry tissues, no MRLs are needed considering that the calculated dietary burden are bellows the trigger value.

An indicative consumer risk assessment for pencycuron was performed considering the residue definition for risk assessment including the sum of pencycuron and pencycuron-PB-amine, expressed pencycuron. Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For the plant commodities for which no data were available to derive MRL and risk assessment values, EFSA considered the existing EU MRL defined for pencycuron. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance. The indicative calculations resulted in a highest chronic exposure of 0.6% of the ADI (Spanish adults). Although this is not indicating a risk to consumers, this assessment was not sufficient to conclude on the impact of the pesticide use of pencycuron on the consumer dietary exposure.

The studies on the nature of residues indicated that aniline, a highly toxic compound, may be formed when pencycuron is subject to processes including hydrolysis conditions and in minor extent in the leafy crop primary metabolism. All commodities assessed in this review are (or can be) consumed after processing. Therefore, it is highly expected that the pesticide uses of pencycuron lead to consumer exposure to aniline. Aniline is classified a Category 2 mutagen (H341, suspected of causing genetic defects) and as a Category 2 carcinogen (H351, suspected of causing cancer). Furthermore, it is considered as a carcinogen for which a genotoxic mechanism cannot be excluded, meaning that a risk to consumer cannot be excluded. In the absence of further residue data for aniline and toxicological reference values, and considering that the use of the Margin of Exposure approach is not recommended for considering the risk of genotoxic metabolites, EFSA was not in a position to fully assess or refine the consumer exposure to aniline due to the pesticide use of pencycuron. Thus, the impact of the pesticide use of pencycuron on the consumer dietary exposure was not addressed. This was deemed as a major uncertainty, which prevented EFSA from recommending any MRLs for pencycuron.

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 1).

It was demonstrated that aniline may be released in the food chain following any pesticide use of pencycuron. This compound is classified a Category 2 mutagen (H341, suspected of causing genetic defects) and as a Category 2 carcinogen (H351, suspected of causing cancer). Furthermore, it is considered as a carcinogen for which a genotoxic mechanism cannot be excluded, meaning that a risk to consumer cannot be excluded. Consequently, no MRL values could be recommended for inclusion in Annex II and further consideration by risk managers are still required (see Table 1 footnotes for details).

It is highlighted that the existing uses could not be fully assessed in the absence of the following data:

- a representative study investigating primary crop metabolism in fruit crops (soil and seed treatment);
- a representative study investigating primary crop metabolism in leafy crops (seed treatment);
- a representative study investigating primary crop metabolism in pulses/oilseeds (seed treatment);
- a validated analytical method for enforcement of pencycuron-PB-amine in processed commodities (it is noted that according to the EURLs, some methods were successfully validated analysis of this compound in courgettes, cucumber, oranges, blueberries, wheat, rice and cashew nuts);
- rotational crops residue trials providing information on the potential level of soil metabolite cyclopentilamine in plant;

- Residue trials supporting the northern GAP on potatoes (in-furrow spraying) analysing simultaneously for residue definitions for enforcement and risk assessment;
- Residue trials supporting the GAPs on strawberries, beetroots, tomatoes, aubergines, sweet peppers, head cabbages, lettuces, beans and peas (with and without pods), asparagus, globe artichoke and cotton seeds;
- Studies covering the storage stability of pencycuron and pencycuron-PB-amine in commodities with high oil content and in commodities with high acid content;
- Processing trials with quantitative analysis of aniline in processed items which can be produced from the authorised uses.

Considering the major uncertainties identified during the assessment (in particular the data gaps linked the nature of residues and to the presence of aniline in processed commodities) and since a risk to consumers cannot be excluded for the existing uses, Member States are recommended to withdraw the relevant authorisations at national level. In addition, in order to ensure that no residue uptakes above the LOQ occur in rotational crops, Member States may also consider mitigation measures in the fields previously treated with pencycuron. The available data indicated that a minimum plant back interval of 100 days is expected to be sufficient.

Table 1: Summary table

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: pencycuron(F)				
152000	Strawberries	0.05*	–	Further consideration needed(a)
211000	Potatoes	0.1	–	Further consideration needed(b)
213010	Beetroots	0.05*	–	Further consideration needed(a)
231010	Tomatoes	0.05*	–	Further consideration needed(a)
231020	Sweet peppers/bell peppers	0.05*	–	Further consideration needed(a)
231030	Aubergines/eggplants	0.05*	–	Further consideration needed(a)
242020	Head cabbages	0.05*	–	Further consideration needed(a)
251020	Lettuces	2	–	Further consideration needed(a)
260010	Beans (with pods)	0.05*	–	Further consideration needed(a)
260020	Beans (without pods)	0.05*	–	Further consideration needed(a)
260030	Peas (with pods)	0.05*	–	Further consideration needed(a)
260040	Peas (without pods)	0.05*	–	Further consideration needed(a)
270010	Asparagus	0.05*	–	Further consideration needed(a)
270050	Globe artichokes	0.05*	–	Further consideration needed(a)
401090	Cotton seeds	0.05*	–	Further consideration needed(a)
1011010	Swine muscle	0.05*	–	Further consideration needed(b)
1011020	Swine fat tissue	0.05*	–	Further consideration needed(b)
1011030	Swine liver	0.05*	–	Further consideration needed(b)
1011040	Swine kidney	0.05*	–	Further consideration needed(b)
1012010	Bovine muscle	0.05*	–	Further consideration needed(b)
1012020	Bovine fat tissue	0.05*	–	Further consideration needed(b)
1012030	Bovine liver	0.05*	–	Further consideration needed(b)
1012040	Bovine kidney	0.05*	–	Further consideration needed(b)
1013010	Sheep muscle	0.05*	–	Further consideration needed(b)
1013020	Sheep fat tissue	0.05*	–	Further consideration needed(b)
1013030	Sheep liver	0.05*	–	Further consideration needed(b)
1013040	Sheep kidney	0.05*	–	Further consideration needed(b)
1014010	Goat muscle	0.05*	–	Further consideration needed(b)
1014020	Goat fat tissue	0.05*	–	Further consideration needed(b)
1014030	Goat liver	0.05*	–	Further consideration needed(b)

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
1014040	Goat kidney	0.05*	–	Further consideration needed[(b)]
1015010	Equine muscle	0.05*	–	Further consideration needed[(b)]
1015020	Equine fat tissue	0.05*	–	Further consideration needed[(b)]
1015030	Equine liver	0.05*	–	Further consideration needed[(b)]
1015040	Equine kidney	0.05*	–	Further consideration needed[(b)]
1020010	Cattle milk	0.05*	–	Further consideration needed[(b)]
1020020	Sheep milk	0.05*	–	Further consideration needed[(b)]
1020030	Goat milk	0.05*	–	Further consideration needed[(b)]
1020040	Horse milk	0.05*	–	Further consideration needed[(b)]
–	Other commodities of plant and/or animal origin	See Reg. (EC) No 149/2008	–	Further consideration needed[(c)]

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(F): Residue definition is fat soluble.
(a): GAP evaluated at EU level is not supported by data and a risk to consumers cannot be excluded for the existing EU MRL; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination B-I in Appendix E).
(b): GAP evaluated at EU level is not fully supported by data and a risk to consumers cannot be excluded; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination D-I in Appendix E).
(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

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Abbreviations

a.i.	active ingredient
a.s.	active substance

ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
DAR	draft assessment report
DAT	days after treatment
DB	dietary burden
DM	dry matter
DS	powder for dry seed treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
eq.	residue expressed as a.s. equivalent
EURLs	European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC-MS/MS	gas chromatography with tandem mass spectrometry
HPLC–MS/MS	high-performance liquid chromatography with tandem mass spectrometry
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
InChiKey	International Chemical Identifier Key
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC–MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
Mo	monitoring
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
MS/MS	tandem mass spectrometry detector
MW	molecular weight
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PBI	plant-back interval
PF	processing factor
PHI	preharvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RA	risk assessment
RD	residue definition
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SC	suspension concentrate
SEU	southern European Union
SMILES	simplified molecular-input line-entry system
SLD	screening detection limit
STMR	supervised trials median residue
TRR	total radioactive residue

Appendix A – Summary of authorised uses considered for the review of MRLs

A.1. Northern outdoor GAPs

Crop and/or situation	MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./ hL min–max	Water L/ha min–max	Rate and unit		
Potatoes	CZ	F	Various, including aphids	–	–	Seed treatment – general (see also comment field)	0–3	1		–	–	1,000 g a.i./ha	n.a.	Spraying on tubers and soil during planting ('in furrow application'). Less critical GAPs authorised in DE, LV, BE (rate of 375 g a.s./ha; but not supported by GAP-compliant trials) and AT, FR, HU, NL, BE: Seed treatment before planting (20–25 g a.s./100 kg seed)

GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; a.i.: active ingredient.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to 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.
(d): PHI: minimum preharvest interval.

A.2. Southern outdoor GAPs

Crop and/or situation	MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between appli-cation (min)	g a.s./ hL min–max	Water L/ha min–max	Rate and unit		
Strawberries	ES	F	*Rhizoctonia* spp.	SC	250 g/L	Soil treatment – general (see also comment field)	0–0	1–1		–	–	2 kg a.i./ ha	n.a.	Soil application before sowing. Also authorised with drip irrigation before or at sowing. Also authorised as a dipping (seed treatment): 500 g a.s./hL
Potatoes	IT, PT	F	*Rhizoctonia* spp.	SC	250 g/L	Seed treatment – spraying	0–3	1–1		–	–	25 g a.i./ 100 kg	n.a.	Spraying of potatoes seed before sowing
Beetroots	IT	F	*Thanatephorus cucumeris*	SC	250 g/L	Seed treatment – general (see also comment field)	0–0	1–1		–	–	8.75 g a.i./ 100 kg	n.a.	Also authorised as a dipping (seed treatment) against rhizoctonia: 87 g a.s./hL
Tomatoes	IT	F	*Thanatephorus cucumeris*	SC	250 g/L	Seed treatment – general (see also comment field)	0–0	1–1		–	–	8.75 g a.i./ 100 kg	n.a.	Also authorised as a dipping (seed treatment) against rhizoctonia: 87 g a.s./hL
Sweet peppers	IT	F	*Thanatephorus cucumeris*	SC	250 g/L	Seed treatment – general (see also comment field)	0–0	1–1		–	–	8.75 g a.i./ 100 kg	n.a.	Also authorised as a dipping (seed treatment) against rhizoctonia: 87 g a.s./hL

Crop and/or situation	MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between appli-cation (min)	g a.s./ hL min–max	Water L/ha min–max	Rate and unit		
Aubergines	IT	F	*Thanatephorus cucumeris*	SC	250 g/L	Seed treatment – general (see also comment field)	0–0	1–1		–	–	8.75 g a.i./ 100 kg	n.a.	Also authorised as a dipping (seed treatment) against rhizoctonia: 87 g a.s./hL
Head cabbages	IT	F	*Thanatephorus cucumeris*	SC	250 g/L	Seed treatment – general (see also comment field)	0–0	1–1		–	–	8.75 g a.i./ 100 kg	n.a.	Also authorised as a dipping (seed treatment) against rhizoctonia: 87 g a.s./hL
Lettuces	IT	F	*Thanatephorus cucumeris*	SC	250 g/L	Seed treatment – general (see also comment field)	0–0	1–1		–	–	8.75 g a.i./ 100 kg	n.a.	Also authorised as a dipping (seed treatment) against rhizoctonia: 87 g a.s./hL
Beans (with pods)	IT	F	*Thanatephorus cucumeris*	SC	250 g/L	Seed treatment – general (see also comment field)	0–0	1–1		–	–	8.75 g a.i./ 100 kg	n.a.	Also authorised as a dipping (seed treatment) against rhizoctonia: 87 g a.s./hL
Beans (without pods)	IT	F	*Thanatephorus cucumeris*	SC	250 g/L	Seed treatment – general (see also comment field)	0–0	1–1		–	–	8.75 g a.i./ 100 kg	n.a.	Also authorised as a dipping (seed treatment) against rhizoctonia: 87 g a.s./hL

Crop and/or situation	MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between appli-cation (min)	g a.s./ hL min–max	Water L/ha min–max	Rate and unit		
Peas (with pods)	IT	F	*Thanatephorus cucumeris*	SC	250 g/L	Seed treatment – general (see also comment field)	0–0	1–1		–	–	8.75 g a.i./ 100 kg	n.a.	Also authorised as a dipping (seed treatment) against rhizoctonia: 87 g a.s./hL
Peas (without pods)	IT	F	*Thanatephorus cucumeris*	SC	250 g/L	Seed treatment – general (see also comment field)	0–0	1–1		–	–	8.75 g a.i./ 100 kg	n.a.	Also authorised as a dipping (seed treatment) against rhizoctonia: 87 g a.s./hL
Asparagus	IT	F	*Thanatephorus cucumeris*	SC	250 g/L	Seed treatment – general (see also comment field)	0–0	1–1		–	–	25 g a.i./ 100 kg	n.a.	20 kg of seed to produce the vegetative part (root) then used for the sowing (max. 33,000 plant/ha). Also authorised as a dipping (seed treatment) against rhizoctonia: 25 g a.s./hL
Globe artichokes	IT	F	*Thanatephorus cucumeris, Rhizoctonia* spp.	SC	250 g/L	Seed treatment – general (see also comment field)	0–0	1–1		–	–	25 g a.i./ 100 kg	n.a.	Also authorised as a dipping (seed treatment) against rhizoctonia: 500 g a.s./hL - Density 10,500 plant/ha

Crop and/or situation	MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between application (min)	g a.s./hL min–max	Water L/ha min–max	Rate and unit		
Cotton seeds	IT	F	*Thanatephorus cucumeris*	SC	250 g/L	Seed treatment – general (see also comment field)	0–0	1–1		–	–	8.75 g a.i./100 kg	n.a.	Also authorised as a dipping (seed treatment) against rhizoctonia: 87 g a.s./hL

GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; a.i.: active ingredient; SC: suspension concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to 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.
(d): PHI: minimum preharvest interval.

A.3. Indoor GAPs

Crop and/or situation	MS or country	F G or I[a]	Pests or group of pests controlled	Preparation		Application				Application rate per treatment			PHI (days)[d]	Remarks
				Type[b]	Conc. a.s.	Method kind	Range of growth stages & season[c]	Number min–max	Interval between appli-cation (min)	g a.s./hL min–max	Water L/ha min–max	Rate and unit		
Strawberries	ES	I	*Rhizoctonia* spp.	SC	250 g/L	Soil treatment – general (see also comment field)	0–0	1	–	–	–	2 kg a.i./ha	n.a.	Soil applications before sowing. Also authorised with drip irrigation before or at sowing. Also authorised as a dipping (seed treatment): 500 g a.s./hL
Lettuces	IT	I	*Thanatephorus cucumeris*	SC	250 g/L	Seed treatment – general (see also comment field)	0–0	1	–	–	–	8.75 g a.i./ 100 kg	n.a.	Also authorised as a dipping (seed treatment) against rhizoctonia: 87 g a.s./hL
Asparagus	IT	I	*Thanatephorus cucumeris*	SC	250 g/L	Seed treatment – general (see also comment field)	0–0	1	–	–	–	25 g a.i./100 kg	n.a.	20 kg of seed to produce the vegetative part (root) then used for the sowing (max. 33,000 plant/ha). Also authorised as a dipping (seed treatment) against rhizoctonia: 25 g a.s./hL

GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; a.i.: active ingredient; SC: suspension concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to 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.
(d): PHI: minimum preharvest interval.

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**
	Root crops	Potatoes	Seed tuber powdering: a) 1 × 0.2 g a.s./kg seed b) 1 × 1.6 g/kg seed (supportive only)	a) 132 b) not reported
		Potatoes	Seed tuber soaking: 1 × 0.25 g a.s./kg seed	14, 56, 133
		Potatoes	In-furrow spray at planting: 1.55 kg a.s./ha	78, 89, 126
		Potatoes	In-furrow spray at planting: 1.37 kg a.s./ha	78, 89, 126
	Leafy crops	Lettuce	Foliar: 3 × 750 g a.s./ha	21 DAT_3
	Cereals/grass crops	Rice	Foliar treatment: 2 × 1,400 g a.s./ha	0, 22 DAT_2
		Rice	Foliar treatment: 2 × 280 g a.s./ha	0 DAT_1, 27 DAT_1, 36 DAT_2
		Rice	Absorption and translocation studies using a solution containing 2 mg a.s./L: a) Root treatment: seedlings (4th leaf stage) inserted in solution; b) Water treatment: seedlings (5th leaf stage) planted in flooded soil irrigated with the solution 3 days after	a) 1, 4 DAT (eq. 6, 24, 96 h) b) 5-10 DAT
		Rice	Absorption and translocation study using a solution containing 0.2 g a.s./L Foliar: 20 µg a.s./leaf	1, 10, 20, 30, 40 (leaves only)
	In the studies performed with potatoes, phenyl and methylene radiolabels were used: seed tuber treatments assessed in 'Netherlands (2009)' and in-furrow spray at planting assessed in 'Netherlands (2015)' and considered in 'EFSA (2017)'. In the studies performed with lettuces, phenyl and chlorobenzyl radiolabels were used (Netherlands, 2015, considered in EFSA, 2017). In the studies performed with rice, phenyl and methylene radiolabels were used (Netherlands, 2009). No studies available for fruit crops (soil and seed treatment), leafy crops (seed treatment) and pulses/oilseeds (seed treatment) (data gaps). DAT_X: days after treatment x.			

Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**
	Root/tuber crops	Turnips	Bare soil, 1 × 2.5 kg a.s./ha	30, 132, 278
	Leafy crops	Swiss chard	Bare soil, 1 × 2.5 kg a.s./ha	30, 132, 278
	Cereal (small grain)	Wheat	Bare soil, 1 × 2.5 kg a.s./ha	30, 132, 278
	Study performed with methylene-radiolabelled pencycuron (Netherlands, 2009)			

Processed commodities (hydrolysis study)	**Conditions**	**Investigated?**
	Pasteurisation (20 min, 90 °C, pH 4)	Yes
	Baking, brewing and boiling (60 min, 100 °C, pH 5)	Yes
	Sterilisation (20 min, 120 °C, pH 6)	Yes
	Standard hydrolysis studies performed with chlorophenyl- and phenyl- radiolabelled pencycuron (Netherlands, 2017). It is noted that additional supportive studies investigating the formation of aniline in potatoes under different conditions are also available: boiled in salted water, microwave, cooking, oven-baking, bioavailability following digestion (Netherlands, 2015, considered in EFSA, 2017)	

Can a general residue definition be proposed for primary crops?	No (available studies not covering all crops and types of treatments; specific compounds (aniline and PB-amine) are observed in particular conditions)
Rotational crop and primary crop metabolism similar?	Yes (noting that pencycuron-PB-amine is the major residue in rotational crops while just a secondary metabolite in primary crops; assessment of the nature of residues in rotational crops is tentative pending upon the uncertainty regarding the possible formation of cyclopentilamine in soil (see EFSA, 2010 and European Commission, 2014)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	No (cleavage of the parent compound releasing aniline in significant proportions: parent is degraded from 60 to 100% depending on the hydrolytic conditions)
Plant residue definition for monitoring (RD-Mo)	**RD-Mo 1:** – [Raw agricultural commodities: root crops, leafy crops[(a)] and cereals]: pencycuron[(b)] **RD-Mo 2:** – [processed commodities]: sum of pencycuron and pencycuron-PB-amine, expressed as pencycuron (tentative)
Plant residue definition for risk assessment (RD-RA)	**RD-RA 1:** – [Root crops, leafy crops[(a)], cereals, rotational crops and processed commodities]: sum of pencycuron and pencycuron-PB-amine, expressed as pencycuron **RD-RA 2** (separated risk assessment): – [leafy crops and processed commodities]: aniline
Conversion factor (monitoring to risk assessment)	Not derived from metabolism study (see Table B.1.2.1).
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	**Pencycuron:** High water and high acid content commodities: • HPLC–MS/MS • LOQ: 0.01 mg/kg • Fully validated on potato tubers, lettuce, tomatoes, turnips, pineapple and orange • Netherlands (2009) considered in EFSA (2010) High oil content commodities: • HPLC–MS/MS • LOQ: 0.01 mg/kg • Fully validated on oilseed rape and sunflower • Netherlands (2009) considered in EFSA (2010) Dry commodities: • HPLC–MS/MS • LOQ: 0.01 mg/kg • Fully validated on wheat grain and dry beans • Netherlands (2009) considered in EFSA (2010) EURLs indicated that pencycuron can be monitored in high water content, high acid content, high oil content and dry commodities with a LOQ of 0.01 mg/kg (EURLs, 2018)

	Pencycuron-PB-amine: EURLs indicated that pencycuron-PB-amine can be monitored using LC–MS/MS in high water content, high acid content, high oil content and dry commodities with a LOQ of 0.01 mg/kg (EURLs, 2018). Still to fully demonstrate for processed commodities (data gap)

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.
(a): It is noted leafy crops subject to seed treatment are not covered by metabolism study.
(b): No residue definition can be derived for fruit crops and pulses/oilseeds.

B.1.1.2. Stability of residues in plants

Plant products (available studies)	**Category**	**Commodity**	**T (°C)**	**Stability (months)**
	High water content	Lettuce	−18	24
	High water/starch	Potatoes	−18	24
	High water/starch	Turnips	−18	24
	Dry/high starch	Wheat grain	−18	24
	Specific matrix	What straw	−18	24
	High oil content	–	–	–
	High acid content	–	–	–
	Storage stability was demonstrated for pencycuron and pencycuron-PB-amine, separately (Netherlands, 2009) High oil content and high acid content commodities: no study available (data gap)			

B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

Crop	Region/indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Strawberries	SEU	–	No trials available	–	–	–	
	Indoor	–	No trials available	–	–	–	
Potatoes	NEU (seed treatment spraying in furrow: 1 kg a.s./ha)	**Monitoring:** Application rate 1 kg a.s./ha: < 0.01; 0.02; 0.02; 0.09 Application rate 1.2 kg a.s./ha: 5 × < 0.01; 2 × 0.02; 0.08; 0.10 **Risk assessment:** –	Trials compliant with GAP (seed treatment performed simultaneously to seedling, 'in-furrow application'; Netherlands, 2009). Missing data for metabolite PB-amine which is relevant for risk assessment MRL_{OECD} = 0.17	0.2 (tentative)[e]	0.10	0.02	1[f]
	NEU (seed treatment before planting: 25 g a.s./100 kg)	5 × < 0.01; 0.011; 2 × 0.02; 0.03; 4 × < 0.05; 0.06	Trials compliant with GAP (powdering/dusting/flowable spray of seed potatoes before planting; Netherlands, 2009). Metabolite PB-amine is not relevant for seed treatment before planting MRL_{OECD} = 0.11	0.15	0.06	0.02	n.r.
	SEU (seed treatment before planting: 25 g a.s./100 kg)	Dry seed treatment: 8 × < 0.01 Flowable seed treatment: < 0.01; 0.02; 0.03; 0.04	Trials compliant with GAP (dry treatment and flowable spraying of seed potatoes before planting; Netherlands, (2009) considered in EFSA, 2010). Metabolite PB-amine is not relevant for seed treatment before planting MRL_{OECD} = 0.06	0.06	0.04	< 0.01	n.r.
Beetroots	SEU	–	No trials available	–	–	–	
Tomatoes Aubergines	SEU	–	No trials available	–	–	–	
Sweet peppers	SEU	–	No trials available	–	–	–	
Head cabbages	SEU	–	No trials available	–	–	–	

Crop	Region/indoor[a]	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR_{Mo} (mg/kg)[b]	$STMR_{Mo}$ (mg/kg)[c]	CF[d]
Lettuces	SEU	–	No trials available	–	–	–	
	Indoor	–	No trials available	–	–	–	
Beans and peas (with pods)	SEU	–	No trials available	–	–	–	
Beans and peas (without pods)	SEU	–	No trials available	–	–	–	
Asparagus	SEU	–	No trials available	–	–	–	
	Indoor	–	No trials available	–	–	–	
Globe artichokes	SEU	–	No trials available	–	–	–	
Cottons seeds	SEU	–	No trials available	–	–	–	

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.
n.r.: not relevant (conversion factor is not relevant for seed treatment before planting because parent compound is the only relevant component of the residues under this type of treatment).
(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): Highest residue according to the residue definition for monitoring.
(c): Supervised trials median residue according to the residue definition for monitoring.
(d): Conversion factor for risk assessment; median of the individual conversion factors at the supported PHI for each residues trial.
(e): MRL is tentative because the available trials only provide analysis for the residue definition for enforcement (no data for metabolite PB-amine).
(f): A tentative conversion factor of 1 is proposed based on residue trials performed in the southern zone with similar GAP parameters (SEU : 1 × 1.2 kg a.s./ha; in-furrow spraying at BBCH 00-03), reported and assessed in a previous MRL application (EFSA, 2017).

B.1.2.2. Residues in succeeding crops

Confined rotational crop study (quantitative aspect)	Significant TRR (partially incorporated to the plant matrix) was found in: • Wheat grain: up to 0.18 mg eq./kg • Turnip leaves and roots: up to 0.28 mg eq./kg • Swiss chard: up to 0.27 mg eq./kg • Wheat hay and straw: up to 2.8–4.2 mg eq./kg
Field rotational crop study	A total of 11 field rotational crops trials were performed on spring wheat, barley, turnip, lettuce and carrot using PBI of 30, 120 and 365 DAT in conditions simulating the most critical GAPs reported in this review (Netherlands, 2009). The harvested samples were analysed for pencycuron and pencycuron-PB-amine: • At PBI 30 DAT: Maximum level of 0.02 mg/kg observed for the sum of pencycuron and pencycuron-PB-amine (turnips, cereal straw and forage). • PBI > 100 DAT: Residue levels remain below 0.01 mg/kg (LOQ). Residue levels are likely to remain low (< 0.02 mg/kg) in rotational crops provided that pencycuron is used according to the authorised GAPs. Furthermore, based on the above data, there are indications that residue uptakes in rotational crops can totally be avoided with a minimum PBI of 100 days

TRR: total radioactive residue; eq.: residue expressed as a.s. equivalent; PBI: plant-back interval; DAT: days after treatment; GAP: Good Agricultural Practice; LOQ: limit of quantification.

B.1.2.3. Processing factors

Processed commodity	Number of studies[a]	Processing factor (PF)		CF_P[b]
		Individual values	Median PF	
Processing factors calculated for the main residue definitions: pencycuron (raw agricultural commodities); sum of pencycuron and pencycuron-PB-amine, expressed as pencycuron (processed commodities)				
Robust processing factors (fully supported by data)				
Potatoes, peel (waste)[c]	4	2.32; 2.61; 11.0; 15.6	6.81	n.r.
Indicative processing factors (insufficient number of data)				
Potatoes, dried pulp	2	5.11; 18.1	11.6	n.r.
Potatoes, peeled and microwaved	1	0.82	0.82	n.r.
Potatoes, unpeeled cooked	2	0.86; 1.60	1.23	n.r.
Potatoes, fried	2	0.37; 1.38	1.02	n.r.
Potatoes, crisps	2	1.21; 1.74	1.48	n.r.
Potatoes, flakes	2	0.63; 2.0	1.32	n.r.
Potatoes, starch	2	1.21; 1.48	1.35	n.r.
Aniline: no studies investigating residue levels of aniline in processed products (data gap)				
–	–	–	–	n.r.

n.r.: CF are not relevant since residue definitions for enforcement and risk assessment are the same for processed commodities.
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each residues trial.
(c): The reported data referred to "peel rest" and potato "waste" (Netherlands, 2015). 2 data obtained on washed peel were disregarded.

B.2. Residues in livestock

Relevant groups	Dietary burden expressed in				Most critical diet[(a)]	Most critical commodity[(a)]	Trigger exceeded (Y/N)
	mg/kg bw per day		mg/kg DM				
	Med.	Max.	Med.	Max.			
Cattle (all diets)	0.0143	0.0189	0.48	0.60	Cattle (dairy)	Potato, process waste	Y
Cattle (dairy only)	0.0143	0.0189	0.37	0.49	Cattle (dairy)	Potato, process waste	Y
Sheep (all diets)	0.0161	0.0201	0.48	0.60	Sheep (ram/ewe)	Potato, process waste	Y
Sheep (ewe only)	0.0161	0.0201	0.48	0.60	Sheep (ram/ewe)	Potato, process waste	Y
Swine (all diets)	0.0064	0.0110	0.28	0.48	Swine (breeding)	Potato, process waste	Y
Poultry (all diets)	0.0044	0.0072	0.06	0.10	Poultry (broiler)	Potato, culls	N
Poultry (layer only)	0.0034	0.0061	0.05	0.09	Poultry (layer)	Potato, culls	N

bw: body weight; DM: dry matter.
(a): Calculated for the maximum dietary burden.

B.2.1. Nature of residues and methods of analysis in livestock

B.2.2.1. Metabolism studies, methods of analysis and residue definitions in livestock

Livestock (available studies)	Animal	Dose (mg/kg bw per day)	Duration (days)	Comment
	Lactating goat	9.9	3	Dose level largely covering the calculated dietary burden
	Laying hen	20	3	Dose level largely covering the calculated dietary burden
	Metabolism studies performed with pencycuron reported and assessed during the peer review (Netherlands, 2009, considered in EFSA, 2010). Goat: phenylmethylene-radiolabelled pencycuron Hens phenylurea-radiolabelled pencycuron			

bw: body weight.

Time needed to reach a plateau concentration in milk and eggs (days)	Milk: 1 day Eggs: Not determined
Metabolism in rat and ruminant similar (Yes/No)	Yes
Animal residue definition for monitoring (RD-Mo)	Pencycuron (tentative)
Animal residue definition for risk assessment (RD-RA)	Pencycuron (tentative)
Conversion factor (monitoring to risk assessment)	Not relevant
Fat soluble residues (Yes/No)	Yes
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	Muscle, fat, liver, kidney, milk and eggs: • HPLC–MS/MS • LOQ: 0.01 mg/kg • Fully validated • Netherlands (2009) considered in EFSA (2010) Screening data generated by EURLs show that pencycuron can be monitored in meat, eggs, milk and honey with a screening detection limit (SLD) of 0.005 mg/kg (EURLs, 2018)

HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.

B.2.1.2. Stability of residues in livestock

Animal products (available studies)	Animal	Commodity	T (°C)	Stability (months/years)
	–	–	–	–
	No studies available (not required)			

B.2.2. Magnitude of residues in livestock

Based on the metabolism studies and the dietary burden tentatively calculated for the sum pencycuron and pencycuron-PB-amine, expressed as pencycuron, there are indication that total residue levels should remain below LOQ for enforcement.

However, it is noted that the animal exposure to all relevant residues was not calculated since contribution of aniline could not be considered in the dietary burden calculation. Therefore, MRLs derived for livestock commodities are tentative only.

B.3. Consumer risk assessment

B.3.1. Pencycuron and pencycuron-PB-amine

ADI	0.2 mg/kg bw per day (EFSA, 2010)
Highest IEDI, according to EFSA PRIMo	0.6% ADI (Spanish adult)
Assumptions made for the calculations	Indicative consumer risk assessment based on pencycuron residue levels only, considering the median residue levels in raw potatoes, derived from the most critical GAP. For the other commodities for which authorised GAPs were reported, data were insufficient to derive an MRL. Thus, EFSA considered the existing EU MRL (defined for pencycuron) for an indicative calculation. The contributions of commodities where no GAP was reported in the framework of this review, were not included in the calculation

ARfD	Not necessary (EFSA, 2010)
Highest IESTI, according to EFSA PRIMo	–
Assumptions made for the calculations	–

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ARfD: acute reference dose; IESTI: international estimated short-term intake; MRL: maximum residue level; GAP: Good Agricultural Practice.

B.3.2. Aniline

ADI/ARfD	Aniline is classified a Category 2 mutagen and as a Category 2 carcinogen. Furthermore, it is considered as a carcinogen for which a genotoxic mechanism cannot be excluded (EFSA, 2007b). Therefore, no toxicological reference values could be derived for this compound
Assessment and conclusion	All plant commodities assessed in this review are (or can be) consumed after processing. It was demonstrated that pencycuron is likely to release aniline during industrial and household processes. Therefore, it is expected that the pesticide uses of pencycuron lead to consumer exposure to aniline. Considering the toxicological properties of aniline (see above), a risk to consumer cannot be excluded. In the absence of further residue data for aniline, EFSA was not in position to fully assess or refine the consumer exposure to aniline due to the pesticide use of pencycuron

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

B.4. Proposed MRLs

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: pencycuron(F)				
152000	Strawberries	0.05*	–	Further consideration needed(a)
211000	Potatoes	0.1	–	Further consideration needed(b)
213010	Beetroots	0.05*	–	Further consideration needed(a)
231010	Tomatoes	0.05*	–	Further consideration needed(a)
231020	Sweet peppers/bell peppers	0.05*	–	Further consideration needed(a)
231030	Aubergines/eggplants	0.05*	–	Further consideration needed(a)
242020	Head cabbages	0.05*	–	Further consideration needed(a)
251020	Lettuces	2	–	Further consideration needed(a)
260010	Beans (with pods)	0.05*	–	Further consideration needed(a)
260020	Beans (without pods)	0.05*	–	Further consideration needed(a)
260030	Peas (with pods)	0.05*	–	Further consideration needed(a)
260040	Peas (without pods)	0.05*	–	Further consideration needed(a)
270010	Asparagus	0.05*	–	Further consideration needed(a)
270050	Globe artichokes	0.05*	–	Further consideration needed(a)
401090	Cotton seeds	0.05*	–	Further consideration needed(a)
1011010	Swine muscle	0.05*	–	Further consideration needed(b)
1011020	Swine fat tissue	0.05*	–	Further consideration needed(b)
1011030	Swine liver	0.05*	–	Further consideration needed(b)
1011040	Swine kidney	0.05*	–	Further consideration needed(b)
1012010	Bovine muscle	0.05*	–	Further consideration needed(b)
1012020	Bovine fat tissue	0.05*	–	Further consideration needed(b)
1012030	Bovine liver	0.05*	–	Further consideration needed(b)
1012040	Bovine kidney	0.05*	–	Further consideration needed(b)
1013010	Sheep muscle	0.05*	–	Further consideration needed(b)
1013020	Sheep fat tissue	0.05*	–	Further consideration needed(b)
1013030	Sheep liver	0.05*	–	Further consideration needed(b)
1013040	Sheep kidney	0.05*	–	Further consideration needed(b)
1014010	Goat muscle	0.05*	–	Further consideration needed(b)
1014020	Goat fat tissue	0.05*	–	Further consideration needed(b)
1014030	Goat liver	0.05*	–	Further consideration needed(b)
1014040	Goat kidney	0.05*	–	Further consideration needed(b)
1015010	Equine muscle	0.05*	–	Further consideration needed(b)
1015020	Equine fat tissue	0.05*	–	Further consideration needed(b)
1015030	Equine liver	0.05*	–	Further consideration needed(b)
1015040	Equine kidney	0.05*	–	Further consideration needed(b)
1020010	Cattle milk	0.05*	–	Further consideration needed(b)
1020020	Sheep milk	0.05*	–	Further consideration needed(b)
1020030	Goat milk	0.05*	–	Further consideration needed(b)
1020040	Horse milk	0.05*	–	Further consideration needed(b)

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
–	Other commodities of plant and/or animal origin	See Reg. (EC) No 149/2008	–	Further consideration needed[(c)]

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(F): Residue definition is fat soluble.
(a): GAP evaluated at EU level is not supported by data and a risk to consumers cannot be excluded for the existing EU MRL; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination B-I in Appendix E).
(b): GAP evaluated at EU level is not fully supported by data and a risk to consumers cannot be excluded; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination D-I in Appendix E)
(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

Appendix C – Pesticide Residue Intake Model (PRIMo)

- PRIMo(EU)

Pencycuron			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):		Proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw per day):	**0.2**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

Chronic risk assessment – refined calculations

	TMDI (range) in % of ADI minimum – maximum
	0 1
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	pTMRLs at LOQ (in % of ADI)
0.6	ES adult	0.5	Lettuce	0.0	Milk and cream	0.0	Tomatoes	
0.6	WHO Cluster diet B	0.4	Lettuce	0.1	Tomatoes	0.0	Potatoes	
0.6	ES child	0.4	Lettuce	0.1	Milk and cream	0.0	Tomatoes	
0.5	WHO regional European diet	0.4	Lettuce	0.0	Potatoes	0.0	Tomatoes	
0.4	IT adult	0.4	Lettuce	0.0	Tomatoes	0.0	Potatoes	
0.4	WHO Cluster diet F	0.3	Lettuce	0.0	Potatoes	0.0	Milk and cream	
0.4	NL child	0.1	Milk and cream	0.1	Lettuce	0.1	Potatoes	
0.3	IT kids/toddler	0.3	Lettuce	0.0	Tomatoes	0.0	Potatoes	
0.3	FR toddler	0.2	Milk and cream	0.1	Potatoes	0.0	Beans (with pods)	
0.3	UK Infant	0.2	Milk and cream	0.0	Potatoes	0.0	Peas (without pods)	
0.3	DK child	0.1	Lettuce	0.1	Milk and cream	0.0	Potatoes	
0.2	NL general	0.1	Lettuce	0.0	Milk and cream	0.0	Potatoes	
0.2	FR infant	0.1	Milk and cream	0.0	Potatoes	0.0	Beans (with pods)	
0.2	DE child	0.1	Milk and cream	0.1	Lettuce	0.0	Potatoes	
0.2	WHO cluster diet E	0.1	Lettuce	0.0	Potatoes	0.0	Milk and cream	
0.2	UK vegetarian	0.1	Lettuce	0.0	Milk and cream	0.0	Tomatoes	
0.2	UK Toddler	0.1	Milk and cream	0.0	Potatoes	0.0	Lettuce	
0.2	IE adult	0.1	Lettuce	0.0	Potatoes	0.0	Milk and cream	
0.2	UK Adult	0.1	Lettuce	0.0	Milk and cream	0.0	Potatoes	
0.2	SE general population 90th percentile	0.1	Milk and cream	0.0	Potatoes	0.0	Tomatoes	
0.2	LT adult	0.1	Lettuce	0.0	Potatoes	0.0	Milk and cream	
0.1	FR all population	0.1	Lettuce	0.0	Milk and cream	0.0	Potatoes	
0.1	FI adult	0.1	Lettuce	0.0	Milk and cream	0.0	Potatoes	
0.1	WHO cluster diet D	0.0	Potatoes	0.0	Tomatoes	0.0	Milk and cream	
0.1	PT General population	0.1	Potatoes	0.0	Tomatoes	0.0	Beans (without pods)	
0.1	PL general population	0.0	Potatoes	0.0	Tomatoes	0.0	Lettuce	
0.1	DK adult	0.0	Milk and cream	0.0	Potatoes	0.0	Tomatoes	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of pencycuron is unlikely to present a public health concern.

Acute risk assessment/children – refined calculations	Acute risk assessment/adults/general population – refined calculations

Acute risk assessment is not necessary.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.
In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variabilty factor of 3.
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100% of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---		
IESTI 1	*)	**)	IESTI 2	*)	**)	IESTI 1	*)	**)	IESTI 2	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
No of critical MRLs (IESTI 1)		---				**No of critical MRLs (IESTI 2)**		---			

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---						No of commodities for which ARfD/ADI is exceeded: ---					
		***)						***)			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL.
***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:
As no ARfD was considered necessary, it is concluded that the short-term intake of pencycuron residues is unlikely to present a pulbic health concern.

Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of pencycuron and pencycuron-PB-amine, expressed as pencycuron				
Potato, culls	0.02	STMR × CF (1)	0.10	HR × CF (1)
Potato, process waste (wet peel)	0.14	STMR × PF (6.81)	0.14	STMR × PF (6.81)
Potato, dried pulp	0.23	STMR × PF (11.6)	0.23	STMR × PF (11.6)

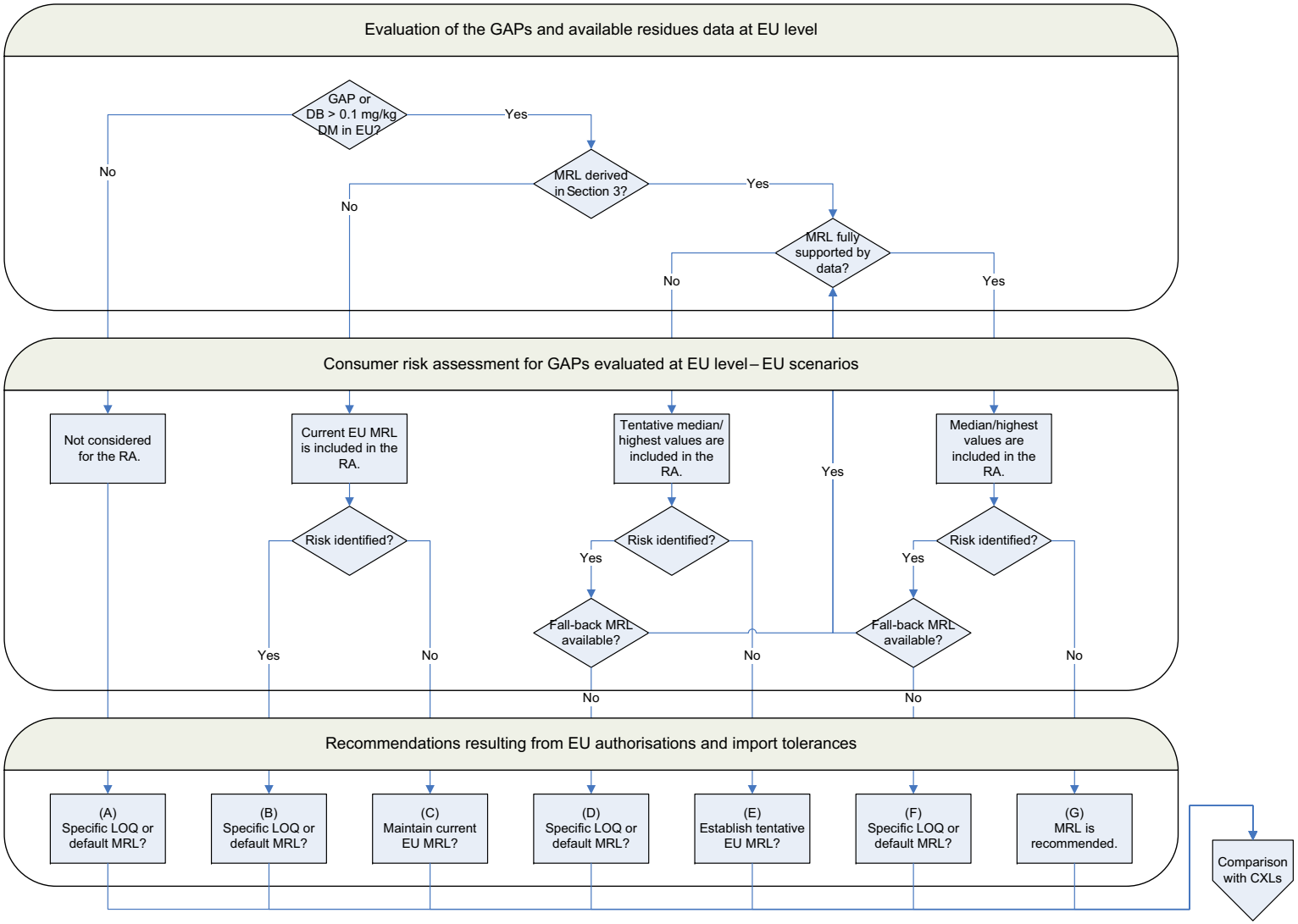
STMR: supervised trials median residue; HR: highest residue; PF: processing factor.

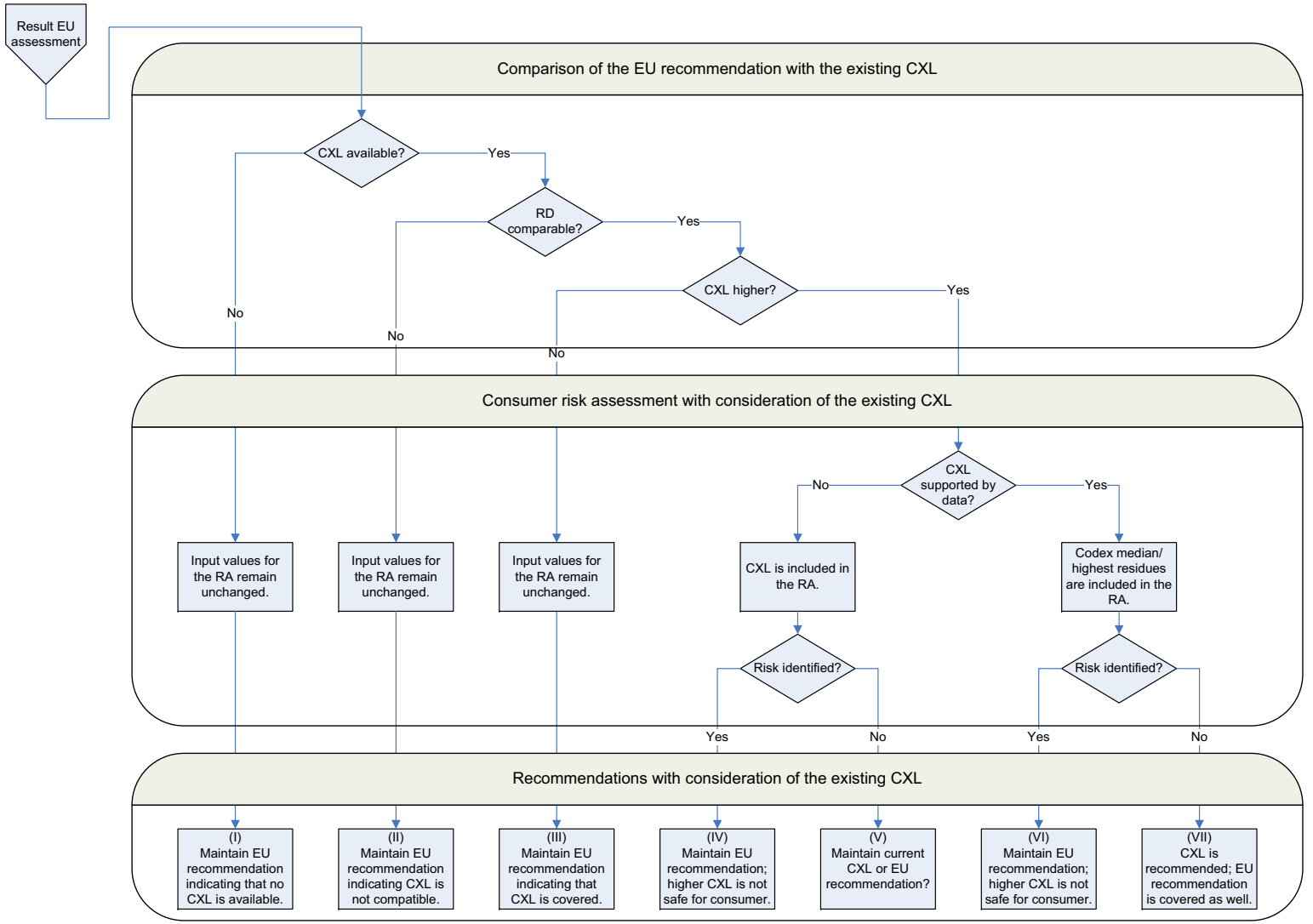
D.2. Consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of pencycuron and pencycuron-PB-amine, expressed as pencycuron		
Strawberries	0.05	EU MRL[(a)]
Potatoes	0.02	STMR (tentative)
Beetroots	0.05	EU MRL[(a)]
Tomatoes	0.05	EU MRL[(a)]
Sweet peppers	0.05	EU MRL[(a)]
Aubergines	0.05	EU MRL[(a)]
Head cabbages	0.05	EU MRL[(a)]
Lettuces	2.0	EU MRL[(a)]
Beans (with pods)	0.05	EU MRL[(a)]
Beans (without pods)	0.05	EU MRL[(a)]
Peas (with pods)	0.05	EU MRL[(a)]
Peas (without pods)	0.05	EU MRL[(a)]
Asparagus	0.05	EU MRL[(a)]
Globe artichokes	0.05	EU MRL[(a)]
Cottons seeds	0.05	EU MRL[(a)]
Swine muscle	0.01*	STMR (tentative)
Swine fat tissue	0.01*	STMR (tentative)
Swine liver	0.01*	STMR (tentative)
Swine kidney	0.01*	STMR (tentative)
Bovine and equine muscle	0.01*	STMR (tentative)
Bovine and equine fat tissue	0.01*	STMR (tentative)
Bovine and equine liver	0.01*	STMR (tentative)
Bovine and equine kidney	0.01*	STMR (tentative)
Sheep and goat muscle	0.01*	STMR (tentative)
Sheep and goat fat tissue	0.01*	STMR (tentative)
Sheep and goat liver	0.01*	STMR (tentative)
Sheep and goat kidney	0.01*	STMR (tentative)
Cattle and horse milk	0.01*	STMR (tentative)
Sheep and goat milk	0.01*	STMR (tentative)

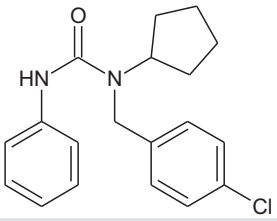
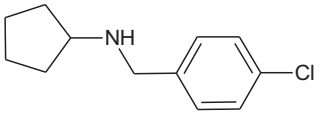
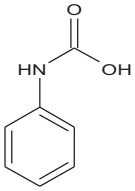
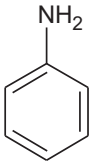
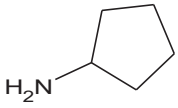
STMR: supervised trials median residue; MRL: maximum residue level.
*: Indicates that the input value is proposed at the limit of quantification.
(a): Use reported by the RMS is not supported by data; the existing EU MRL is used for indicative exposure calculations (considering the residue definition for pencycuron only but without data for metabolite pencycuron-PB-amine).

Appendix E – Decision tree for deriving MRL recommendations




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

Appendix F – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Pencycuron	1-(4-chlorobenzyl)-1-cyclopentyl-3-phenylurea Clc1ccc(cc1)CN(C(=O)Nc1ccccc1)C1CCCC1 OGYFATSSENRIKG-UHFFFAOYSA-N	
Pencycuron-PB-amine	*N*-(4-chlorobenzyl)cyclopentanamine Clc1ccc(cc1)CNC1CCCC1 XIXHUNCZQIRQOG-UHFFFAOYSA-N	
Pencycuron-carbamic acid	phenylcarbamic acid OC(=O)Nc1ccccc1 PWXJULSLLONQHY-UHFFFAOYSA-N	
Aniline	aniline Nc1ccccc1 PAYRUJLWNCNPSJ-UHFFFAOYSA-N	
Cyclopentilamine	cyclopentanamine NC1CCCC1 NISGSNTVMOOSJQ-UHFFFAOYSA-N	

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).