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Review of the existing maximum residue levels for *Pseudomonas* sp. strain DSMZ 13134 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 *Pseudomonas* sp. strain DSMZ 13134. To assess the occurrence of *Pseudomonas* sp. strain DSMZ 13134 residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EU) No 188/2011, 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 cannot be derived and are deemed not to be necessary. A consumer risk assessment cannot be performed quantitatively. Although no apparent risk to consumers was identified, some information required by the regulatory framework would still be desirable. The outcome of the assessment was compared to the criteria defined by the European Commission for inclusion of pesticide active substances in Annex IV of the Regulation. A proposal for inclusion of *Pseudomonas* sp. strain DSMZ 13134 into Annex IV of Regulation (EC) No 396/2005 is derived by EFSA based on the authorised uses of this Art. 12 review.

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Summary

Pseudomonas sp. strain DSMZ 13134 has been approved under Regulation (EC) No 1107/2009 on 1 February 2014 by Commission Implementing Regulation (EU) No 829/2013.

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.

As the basis for the MRL review, on 14 August 2019 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 13 September 2019 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State (RMS) the Netherlands to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 5 December 2019. On the basis of all the data submitted by Member States, EFSA asked the RMS to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report, together with an updated GAP overview file were provided by the RMS to EFSA on 20 February 2020. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EU) No 188/2011, EFSA prepared in May 2020 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 29 May 2020 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

In conclusion, it remains supported and sustained by this review that *Pseudomonas* sp. strain DSMZ 13134 is not hazardous to consumers considering new information received on the fact that it produces the siderophore *enantio-pyochelin*.

The metabolites are not considered hazardous based on the available knowledge. Their respective magnitude in plants, determined according to sufficiently validated methods for their quantification, has not been addressed and it is still considered as desirable to comply with the current data requirements.

Considering the authorised uses, no significant levels of viable counts of *Pseudomonas* sp. strain DSMZ 13134 and/or of its metabolites are expected at the time of harvest and consumer exposure can be reasonably assumed to be negligible.

The consumer risk assessment with regard to the use of *Pseudomonas* sp. strain DSMZ 13134 according to the authorised uses can be finalised based on expert judgement, considering that the known metabolites have no identified hazardous properties and are also unlikely to be present in significant amounts at the time of harvest.

Following the assessment according to the criteria defined by the European Commission for inclusion of pesticide active substances into Annex IV of Regulation (EC) No 396/2005, an inclusion of *Pseudomonas* sp. strain DSMZ 13134 is recommended.

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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.

Pseudomonas sp. strain DSMZ 13134 has been approved under Regulation (EC) No 1107/2009[3] on 1 February 2014 by means of Commission Implementing Regulation (EU) No 829/2013[4]. Therefore, EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Commission Regulation (EU) No 188/2011[5] *Pseudomonas* sp. strain DSMZ 13134 was evaluated by the Netherlands, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2012). Furthermore, according to the provisions of the approval regulation, confirmatory information was requested, as regards effects on human health to confirm the absence of an acute intratracheal and intraperitoneal toxicity/infectivity/pathogenicity potential, to be submitted by 31 January 2016 and evaluated by the RMS and EFSA (2017).

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC repealed by Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, 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 Regulation (EC) No 1107/2009 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.

As the basis for the MRL review, on 14 August 2019 EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 13 September 2019 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation 18 Member States provided feedback on their national authorisations of *Pseudomonas* sp. strain DSMZ 13134. Based on the GAP data submitted, the designated RMS the Netherlands was asked to identify the critical GAPs to be further considered in the assessment, in the format of a specific GAP overview file. Subsequently, in a second step, Member States were requested to provide residue data supporting the critical GAPs by 5 December 2019.

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

[4] Commission Implementing Regulation (EU) No 829/2013 of 29 August 2013 approving the active substance *Pseudomonas sp.* strain DSMZ 13134, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/201. OJ L 232, 30.8.2013, p. 29–32.

[5] Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51–55.

On the basis of all the data submitted by Member States, EFSA asked the Netherlands to complete the PROFile and to prepare a supporting evaluation report. The PROFile and the supporting evaluation report, together with an updated GAP overview file, were submitted to EFSA on 20 February 2020. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information, EFSA prepared in May 2020 a draft reasoned opinion, which was circulated to Member States for commenting via a written procedure. All comments received by 29 May 2020 were considered by EFSA during the finalisation of the reasoned opinion.

The **evaluation report** submitted by the RMS (Netherlands, 2020), taking into account also the information provided by Member States during the collection of data, is considered as main supporting document to this reasoned opinion and, thus, made publicly available. No **EURL report on analytical methods** was available.

In addition, further supporting documents to this reasoned opinion are the **completeness check report** (EFSA, 2020a) and the **Member States consultation report** (EFSA, 2020b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, **PROFile** and the **GAP overview file** listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion.

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 general principles for the establishment and update of Annex IV are laid down in Article 5 of Regulation (EC) No 396/2005, which requires that for an active substance which shall be included in Annex IV account should be taken of:

- the use of the active substance;
- the scientific and technical knowledge available;
- the result of an assessment of any potential risks to consumers with a high intake and high vulnerability and, where appropriate, to animals;
- the results of any evaluations and decisions to modify the use of plant protection products.

Criteria for inclusion of active substances into Annex IV of Regulation (EC) No 396/2005 were defined in a guidance document of the European Commission (2015). As outlined in the guidance document, an active substance should comply with one of the following criteria in order to be recommended for inclusion in Annex IV of Regulation (EC) No 396/2005:

- Criterion 1: The active substance is approved as a basic substance under Regulation (EC) No 1107/2009;
- Criterion 2: The compound is listed in Annex I of Regulation (EC) No 396/2005;
- Criterion 3: The compound has no identified hazardous properties;
- Criterion 4: Natural exposure is higher than the one linked to the use of PPP;
- Criterion 5: No consumer exposure is forecasted linked to the mode of application of the PPP.

The active substance and its use pattern

The reference isolate of *Pseudomonas* sp. strain DSMZ 13134 is deposited at the culture collection of the German Collection of Micro-organisms and Cell Cultures (DSMZ) under the reference number DSMZ 13134. *Pseudomonas* sp. strain DSMZ 13134 was isolated from soil from a lettuce field in Germany.

Uses evaluated comprised fungicide uses for seed treatment on potatoes to control *Rhizoctonia solani* and *Helminthosporium solani* as well as outdoor uses on various crops. Full details of the GAP can be found in the list of end points in Appendix A.

Pseudomonas sp. strain DSMZ 13134 produces four metabolites, referring to pyochelin, indole-2-acetic acid, salicylic acid methylether and deferoxamine as reported in the assessment section and Appendix B.

For *Pseudomonas* sp. strain DSMZ 13134 the default MRL of 0.01 mg/kg is established according to Art 18(1)(b) of Regulation (EC) No 396/2005. There are no MRL changes since the entry into force of the Regulation mentioned above.

For the purpose of this MRL review, all the uses of *Pseudomonas* sp. strain DSMZ 13134 currently authorised within the EU as submitted by the Member States during the GAP collection, have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were subsequently summarised in the PROFile and considered in the assessment. The details of the authorised critical GAPs for *Pseudomonas* sp. strain DSMZ 13134 are given in Appendix A. The RMS did not report uses authorised in third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Netherlands, 2020);
- the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Netherlands, 2009, 2012);
- the conclusion on the peer review of the pesticide risk assessment of the active substance *Pseudomonas* sp. strain DSMZ 13134 (EFSA, 2012);
- the review report on *Pseudomonas* sp. strain DSMZ 13134 (European Commission, 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[6] 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).

During the peer review, it was concluded that *Pseudomonas* sp. strain DSMZ 13134 is not toxic and not expected to be pathogenic to humans by the oral route (EFSA, 2012). Furthermore, confirmatory data also demonstrated absence of acute intratracheal toxicity, infectivity and pathogenicity potential of *Pseudomonas* sp. strain DSMZ 13134 (EFSA, 2017).

It was further noted during the peer review that *Pseudomonas* sp. strain DSMZ 13134 produces four metabolites (*pyochelin*, indole-2-acetic acid, salicylic acid methylether, deferoxamine) and that their toxicological profiles are unknown (EFSA, 2012). The peer review however also mentioned that the metabolites detected in the culture filtrate are naturally occurring compounds, of no toxicological concern and that there are no indications that *Pseudomonas* sp. strain DSMZ 13134 produces toxic metabolites. Furthermore, while these metabolites have been identified in the culture medium, it was concluded that they are unlikely to be present in the product due to removal of the bacteria from the medium (EFSA, 2012; European Commission, 2018).

In the review report, the derivation of consumer reference values for *Pseudomonas* sp. strain DSMZ 13134 was considered as not needed because the metabolites are naturally occurring, of no known toxicological concern and there are no indications that *Pseudomonas* sp. strain DSMZ 13134 produces toxic metabolites. With regard to residues, a quantitative consumer risk assessment was not deemed necessary, as *Pseudomonas* sp. strain DSMZ 13134 is not toxic and is not expected to be pathogenic to humans by the oral route (European Commission, 2018).

In the identity section of the peer review, it was highlighted that the taxonomy at the time might change following scientific progress and that the identification of *Pseudomonas* sp. strain DSMZ 13134 at strain level is ensured by a ribotyping method. It was highlighted that there is no direct evidence of a relationship to known animal or human pathogens and only distant relationship to some plant pathogens (EFSA, 2012).

Additional information was made available during this Art. 12 review regarding the identity of *Pseudomonas* sp. strain DSMZ 13134. Based on the available data, it can be reasonably assumed that *Pseudomonas* sp. strain DSMZ 13134 belongs to the species *Pseudomonas protegens*; however, it was not possible to verify all available whole genome sequencing data (Netherlands, 2020). It is considered

[6] 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.

desirable that the assignment of *Pseudomonas* sp. strain DSMZ 13134 to this species is confirmed and readily updated in light that the taxonomy evolves in the future.

During the peer review, EFSA obtained information concerning the production of different *pyochelin* isomers by different *Pseudomonas* species from published studies and identified consequently a data gap regarding information on the stereochemistry of the siderophore *pyochelin* (EFSA, 2012). This data gap was addressed during this Art. 12 review, where it was demonstrated on a genomic level that *Pseudomonas* sp. strain DSMZ 13134 produces the siderophore *enantio-pyochelin* and not *pyochelin* which is produced by *Pseudomonas aeruginosa* (Netherlands, 2020).

Furthermore, in the literature the siderophore *enantio-pyochelin* is not described as a virulence factor or its producers as mammalian pathogens. However, studies in compliance with the current data requirements were not provided to characterise and to assess the toxicology of *enantio-pyochelin*. Noting that *enantio-pyochelin* producing organisms are ubiquitous in soil as plant growth-promoting bacteria and that there are no reports indicating that this metabolite represents a virulence factor, it can be concluded that its association is not related to known human pathogens.

Since the strain *Pseudomonas* sp. strain DSMZ 13134 has been confirmed as non-pathogenic to humans, further data are not deemed necessary whereby a continuously updated body of knowledge following available guidance would be recommended.

Classical microbiological methods are available to determine colony forming units (CFUs) of *Pseudomonas* sp. strain DSMZ 13134. A new and validated method was provided for this Art. 12 review to distinguish *Pseudomonas* sp. strain DSMZ 13134 from *Pseudomonas aeruginosa* which includes a quantitative determination within the defined linear working ranges. However, the specificity of the quantitative polymerase chain reaction (qPCR) method for *Pseudomonas* sp. strain DSMZ 13134 cannot be determined as no *Pseudomonas* strains other than *Pseudomonas aeruginosa* were included in the validation (Netherlands, 2020). Nevertheless, *Pseudomonas* sp. strain DSMZ 13134 can also be identified by ribotyping (EFSA, 2012).

Analytical methods to identify and quantify the known metabolites as mentioned above in plant matrices are not provided. The presence and concentrations in plants of the metabolites produced by *Pseudomonas* sp. strain DSMZ 13134 after application under GAP relevant conditions are not known.

Noting that methods for monitoring are not required at present, sufficiently validated qualitative and quantitative methods for verification of viable counts, for identification and quantification of *Pseudomonas* sp. strain DSMZ 13134 and of its metabolites post application (after treatment) on plant commodities would be considered as desirable for verification purposes in cases of need.

The authorised GAPs of this Art. 12 review are not more critical than the representative uses assessed during the peer review (EFSA, 2012). Authorised uses are characterised by seed treatments, soil treatments or local soil treatments (drip irrigation). Applied viable counts of *Pseudomonas* sp. strain DSMZ 13134 are equivalent to those assessed during the peer review. Plant preharvest intervals of 65 days are indicated for several GAPs and where this information was indicated as not applicable, the pre-harvest time interval for potatoes, yams and Jerusalem artichokes can be anticipated to be around nine weeks after treatment.

Concerning residues, it could not be excluded during the peer review that consumers might be exposed to *Pseudomonas* sp. strain DSMZ 13134 and to its metabolites (EFSA, 2012). During this Art. 12 review, a study on the persistence of *Pseudomonas* sp. strain DSMZ 13134 in the rhizosphere in soil was made available in which barley seeds were treated at a rate of 8 $\times$ 10E10 CFU/kg seed under greenhouse conditions which can be considered representative for the authorised uses of this Art. 12 review. Following application, the *Pseudomonas* sp. strain DSMZ 13134 initially successfully colonised the root and was detected in all root parts. However, it only transiently influenced the composition of indigenous rhizosphere bacteria and did not establish itself as a predominant member of the root community. In the absence of competing microorganisms, in monoxenic cultures, viable counts of *Pseudomonas* sp. strain DSMZ 13134 decreased after 3 weeks. Plants were harvested at 1, 2, 3, 4, 6, 8 and 10 weeks after planting. The available study demonstrated that *Pseudomonas* sp. strain DSMZ 13134 could still be detected 4 weeks after planting, however, not any longer after 8 weeks (Netherlands, 2020).

Considering the authorised uses and the strain specific information that is available regarding the decrease of *Pseudomonas* sp. strain DSMZ 13134 after application, significant amounts of metabolites are not expected at the time of harvest.

Based on expert judgement, the consumer risk assessment can be considered as finalised because the metabolites do not have identified or known hazardous properties and while noting that a verification of the magnitude of residues of the metabolites on plant commodities following application

of *Pseudomonas* sp. strain DSMZ 13134 in compliance with the authorised GAPs would be desirable, at the time of harvest significant amounts are not expected.

With regard to the five assessment criteria according to the Commission guidance (European Commission, 2015) for potential inclusion of *Pseudomonas* sp. strain DSMZ 13134 in Annex IV of Regulation (EC) No 396/2005, criteria three and five are considered as met for the following reasons:

- *Pseudomonas* sp. strain DSMZ 13134 is not approved as a basic substance under Regulation (EC) No 1107/2009;
- *Pseudomonas* sp. strain DSMZ 13134 is not included into Annex I of Regulation (EC) No 396/2005;
- *Pseudomonas* sp. strain DSMZ 13134 and metabolites of *Pseudomonas* sp. strain DSMZ 13134 have no identified hazardous properties. However, the determination of the concentrations of the residues of metabolites at the time of harvest in the plant commodities according to a sufficiently validated method including a LOQ is still considered as desirable;
- It has not been demonstrated that *Pseudomonas* sp. strain DSMZ 13134 and its metabolites were below natural background levels. However, as long as hazardous properties are not identified for *Pseudomonas* sp. strain DSMZ 13134 and the formed metabolites are not expected in significant amounts at harvest this is not considered as a concern;
- While consumer exposure cannot be excluded based on the mode of application of the PPP and therefore criterion 5 is not met *in sensu strictu*, the consumer exposure to residues of *Pseudomonas* sp. strain DSMZ 13134 and its metabolites following application in accordance with the authorised GAPs can be considered as highly unlikely.

Considering the overall assessment of the available data and based on expert judgement, it is proposed to include *Pseudomonas* sp. strain DSMZ 13134 in Annex IV of Regulation (EC) No 396/2005 since criteria three and five of the guidance document on criteria for the inclusion of active substances into Annex IV of Regulation (EC) No 396/2005 (European Commission, 2015) are considered fulfilled. Therefore, it can be concluded that while criteria 1, 2 and 4 are not applicable or demonstrated, it can be reasonably assumed that the consumer exposure to residues of *Pseudomonas* sp. strain DSMZ 13134 and its metabolites is negligible.

Conclusions and Recommendations

The conclusion of the peer review that *Pseudomonas* sp. strain DSMZ 13134 is not hazardous to humans remains supported and sustained by this review together with the new information received on the fact that it produces the siderophore *enantio-pyochelin*.

The metabolites are not considered hazardous based on the available knowledge. Their respective magnitude in plants determined according to sufficiently validated methods for their quantification has not been addressed and it is still considered as data requirements.

Considering the authorised uses, no significant levels of viable counts of *Pseudomonas* sp. strain DSMZ 13134 and/or of its metabolites are expected at the time of harvest and consumer exposure can be reasonably assumed to be negligible.

The consumer risk assessment with regard to the use of *Pseudomonas* sp. strain DSMZ 13134 according to the authorised uses can be finalised based on expert judgement, considering that the known metabolites have no identified hazardous properties and are also unlikely to be present in significant amounts at the time of harvest.

Following the assessment according to the criteria defined by the European Commission for inclusion of pesticide active substances into Annex IV of Regulation (EC) No 396/2005 an inclusion of *Pseudomonas* sp. strain DSMZ 13134 is recommended.

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CFU	colony forming units
CXL	codex maximum residue limit
DAR	draft assessment report
DSMZ	German Collection of Micro-organisms and Cell Cultures

EURLs	European Union Reference Laboratories for Pesticide Residues (former CRLs)
GAP	Good Agricultural Practice
InChiKey	International Chemical Identifier Key
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
OECD	Organisation for Economic Co-operation and Development
PHI	preharvest interval
PROFile	(EFSA) Pesticide Residues Overview File
qPCR	quantitative polymerase chain reaction
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RMS	rapporteur Member State
SANCO	Directorate-General for Health and Consumers
SMILES	simplified molecular-input line-entry system
TRR	total radioactive residue
WP	wettable powder

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

A.1. Authorised outdoor uses in northern EU

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)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Potatoes	NL	F	*Rhizoctonia*, *Helminthosporium*	WP	6.6 × 10E 10 CFU/g	Seed treatment – general (see also comment field)	00-00	1	–	–	–	4 × 10E 12 CFU/ha	n.a.	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 4 × 10E12 CFU/ha; Different pests are claimed by different countries and some MSs did not specify the formulation. Therefore, the NL GAP was selected which covers all other GAPs in terms of application rate

MS: Member State; a.s.: active substance; WP: wettable powder; CFU: colony forming unit; GAP: Good Agricultural Practice.
(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. Authorised outdoor uses in southern EU

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)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Potatoes	EL	F	*Rhizoctonia*, *Helminthosporium*	WP	6.6 × 10E 10 CFU/g	Soil treatment – spraying		1	–	–	–	4 × 10E 12 CFU/ha	65	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 4 × 10E12 CFU/ha; Different pests are claimed by different countries and some MSs did not specify the formulation. Therefore, the EL GAP was selected which covers all other GAPs in terms of application rat
Sweet potatoes	HR	F	*Rhizoctonia solani*	WP	6.6 × 10E 10 CFU/g	Local treatment – general (see also comment field)	00-00	1	–	–	–	4 × 10E 12 CFU/ha	n.a.	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 4 × 10E12 CFU/ha; Method: drip irrigation/manual water system immediately after planting
Yams	HR	F	*Rhizoctonia solani*	WP	6.6 × 10E 10 CFU/g	Local treatment – general (see also comment field)	00-00	1	–	–	–	4 × 10E 12 CFU/ha	n.a.	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 4 × 10E12 CFU/ha; Method: drip irrigation/manual water system immediately after planting
Beetroots	IT	F	*Rhizoctonia solani*; *Helminthosporium solani*	WP	6.6 × 10E 10 CFU/g	Seed treatment – general (see also comment field)		1				1.2 × 10E 11 CFU/ha	65	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 1.2 × 10E11 CFU/ha
Carrots	IT	F	*Rhizoctonia solani*; *Helminthosporium solani*	WP	6.6 × 10E 10 CFU/g	Seed treatment – general (see also comment field)		1				1.2 × 10E 11 CFU/ha	65	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 1.2 × 10E11 CFU/ha
Celeriacs	IT	F	*Rhizoctonia solani*; *Helminthosporium solani*	WP	6.6 × 10E 10 CFU/g	Seed treatment – general (see also comment field)		1				1.2 × 10E 11 CFU/ha	65	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 1.2 × 10E11 CFU/ha
Horseradishes	IT	F	*Rhizoctonia solani*; *Helminthosporium solani*	WP	6.6 × 10E 10 CFU/g	Seed treatment – general (see also comment field)	00-00	1	–	–	–	1.2 × 10E 11 CFU/ha	65	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 1.2 × 10E11 CFU/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)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Jerusalem artichokes	HR	F	*Rhizoctonia solani*	WP	6.6 × 10E 10 CFU/g	Local treatment – general (see also comment field)	00-00	1	–	–	–	4 × 10E 12 CFU/ha	n.a.	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 4 × 10E12 CFU/ha; Method: drip irrigation/manual water system immediately after planting
Parsnips	IT	F	*Rhizoctonia solani*; *Helminthosporium solani*	WP	6.6 × 10E 10 CFU/g	Seed treatment – general (see also comment field)	00-00	1	–	–	–	1.2 × 10E 11 CFU/ha	65	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 1.2 × 10E11 CFU/ha
Parsley roots	IT	F	*Rhizoctonia solani*; *Helminthosporium solani*	WP	6.6 × 10E 10 CFU/g	Seed treatment – general (see also comment field)	00-00	1	–	–	–	1.2 × 10E11 CFU/ha	65	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 1.2 × 10E11 CFU/ha
Radishes	IT	F	*Rhizoctonia solani*; *Helminthosporium solani*	WP	6.6 × 10E 10 CFU/g	Seed treatment – general (see also comment field)	00-00	1	–	–	–	1.2 × 10E11 CFU/ha	65	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 1.2 × 10E11 CFU/ha
Salsifies	IT	F	*Rhizoctonia solani*; *Helminthosporium solani*	WP	6.6 × 10E 10 CFU/g	Seed treatment – general (see also comment field)	00-00	1	–	–	–	1.2 × 10E11 CFU/ha	65	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 1.2 × 10E11 CFU/ha
Swedes	IT	F	*Rhizoctonia solani*; *Helminthosporium solani*	WP	6.6 × 10E 10 CFU/g	Seed treatment – general (see also comment field)	00-00	1	–	–	–	1.2 × 10E11 CFU/ha	65	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 1.2 × 10E11 CFU/ha
Turnips	IT	F	*Rhizoctonia solani*; *Helminthosporium solani*	WP	6.6 × 10E 10 CFU/g	Seed treatment – general (see also comment field)	00-00	1	–	–	–	1.2 × 10E11 CFU/ha	65	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 1.2 × 10E11 CFU/ha

MS: Member State; a.s.: active substance; WP: wettable powder; CFU: colony forming unit; GAP: Good Agricultural Practice.
(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. Authorised indoor uses in EU

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)	a.s./hL min–max	Water L/ha min–max	Rate and unit		
Potatoes	HR	I	*Rhizoctonia solani*; *Helminthosporium solani*	WP	6.6 × 10E 10 CFU/g	Seed treatment – general (see also comment field)	00-00	1	–	–	–	4 × 10E 12 CFU/ha	65	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 4 × 10E12 CFU/ha; Different pests are claimed by different countries and some MSs did not specify the formulation. Therefore, the NL GAP was selected which covers all other GAPs in terms of application rate
Sweet potatoes	HR	I	*Rhizoctonia solani*	WP	6.6 × 10E 10 CFU/g	Local treatment – general (see also comment field)	00-00	1	–	–	–	4 × 10E 12 CFU/ha	n.a.	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 4 × 10E12 CFU/ha; Method: drip irrigation/manual water system immediately after planting
Yams	HR	I	*Rhizoctonia solani*	WP	6.6 × 10E 10 CFU/g	Local treatment – general (see also comment field)	00-00	1	–	–	–	4 × 10E 12 CFU/ha	n.a.	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 4 × 10E12 CFU/ha; Method: drip irrigation/manual water system immediately after planting
Jerusalem artichokes	HR	I	*Rhizoctonia solani*	WP	6.6 × 10E 10 CFU/g	Local treatment - general (see also comment field)	00-00	1	–	–	–	4 × 10E 12 CFU/ha	n.a.	Formulation: 6.6 × 10E10 CFU/g; Appl rate: 4 × 10E12 CFU/ha; Method: drip irrigation/manual water system immediately after planting

MS: Member State; a.s.: active substance; WP: wettable powder; CFU: colony forming unit; GAP: Good Agricultural Practice.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
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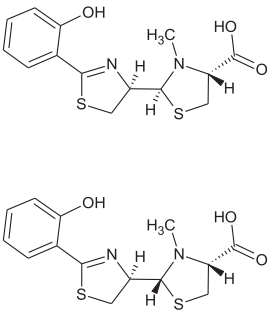
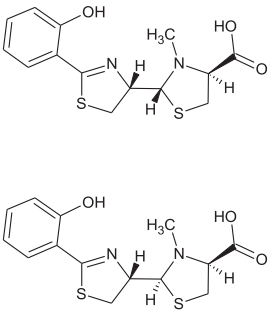
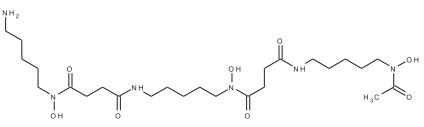
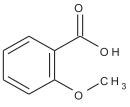
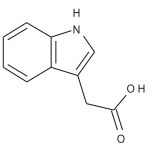
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI – minimum pre-harvest interval.

Appendix B – Used compound codes

Code/Trivial name[a]	Chemical name/SMILES notation/ InChiKey[b]	Structural formula[c]
pyochelin	Equilibrium mixture of the following two tautomer (2*S*,4*R*)-2-[(4*R*)-2-(2-hydroxyphenyl)-4,5-dihydro-1,3-thiazol-4-yl]-3-methyl-1,3-thiazolidine-4-carboxylic acid CN1[C@@H](SC[C@H]1C(O)=O)[C@H]1CSC(=N1)c1ccccc1O NYBZAGXTZXPYND-NRUUGDAUSA-N (2*R*,4*R*)-2-[(4*R*)-2-(2-hydroxyphenyl)-4,5-dihydro-1,3-thiazol-4-yl]-3-methyl-1,3-thiazolidine-4-carboxylic acid CN1[C@H](SC[C@H]1C(O)=O)[C@H]1CSC(=N1)c1ccccc1O NYBZAGXTZXPYND-GBIKHYSHSA-N	
enantio-pyochelin	Equilibrium mixture of the following two tautomer (2*R*,4*S*)-2-[(4*S*)-2-(2-hydroxyphenyl)-4,5-dihydro-1,3-thiazol-4-yl]-3-methyl-1,3-thiazolidine-4-carboxylic acid CN1[C@H](SC[C@@H]1C(O)=O)[C@@H]1CSC(=N1)c1ccccc1O NYBZAGXTZXPYND-OPQQBVKSSA-N (2*S*,4*S*)-2-[(4*S*)-2-(2-hydroxyphenyl)-4,5-dihydro-1,3-thiazol-4-yl]-3-methyl-1,3-thiazolidine-4-carboxylic acid CN1[C@@H](SC[C@@H]1C(O)=O)[C@@H]1CSC(=N1)c1ccccc1O NYBZAGXTZXPYND-CWSCBRNRSA-N	
deferoxamine	*N*′-{5-[acetyl(hydroxy)amino]pentyl}-*N*-[5-({4-[(5-aminopentyl)(hydroxy)amino]-4-oxobutanoyl}amino)pentyl]-*N*-hydroxysuccinamide CC(=O)N(O)CCCCCNC(=O)CCC(=O)N(O)CCCCCNC(=O)CCC(=O)N(O)CCCCCN UBQYURCVBFRUQT-UHFFFAOYSA-N	
salicylic acid methylether	2-methoxybenzoic acid COc1ccccc1C(=O)O ILUJQPXNXACGAN-UHFFFAOYSA-N	
indole-3-acetic acid	1*H*-indol-3-ylacetic acid O=C(O)Cc1c[NH]c2ccccc21 SEOVTRFCIGRIMH-UHFFFAOYSA-N	

SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.
(a): The metabolite name in bold is the name used in the reasoned opinion.
(b): ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).
(c): ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).