Review of the existing maximum residue levels for *Streptomyces lydicus* strain WYEC 108 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 *Streptomyces lydicus* strain WYEC 108. Considering the information provided by Member States, neither EU uses nor import tolerances are currently authorised for *Streptomyces lydicus* strain WYEC 108 within the EU. Furthermore, no MRLs are established by the Codex Alimentarius Commission (codex maximum residue limits) for this active substance. Therefore, residues of *Streptomyces lydicus* strain WYEC 108 are not expected to occur in any plant or animal commodity and therefore a consumer risk assessment is not required. Nevertheless, the available information allowed EFSA to propose a marker residue definition noting that methods for identification and quantification of *Streptomyces lydicus* strain WYEC 108 are available; however, a method for enforcement fully validated at a specific limit of quantification (LOQ) was not provided. An inclusion of *Streptomyces lydicus* strain WYEC 108 in Annex IV of (EC) No 396/2005 is not recommended.

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Summary

*S. lydicus* strain WYEC 108 was approved on 1 January 2015 by means of Commission Implementing Regulation (EU) No 917/2014 under Regulation (EC) No 1107/2009 as amended by Commission Implementing Regulations (EU) No 540/2011 and 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 *Streptomyces lydicus* strain WYEC 108 in compliance with Article 12(1) of the aforementioned regulation.

As the basis for the MRL review, on 18 November 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 18 December 2019 their national Good Agricultural Practices (GAPs), in a standardised way, in the format of specific GAP forms. According to the information provided in the GAP forms, no uses are currently authorised for *Streptomyces lydicus* strain WYEC 108 in the Member States. Nevertheless, Member States were requested to provide any additional information that might be available, within a period of 1 month, by 13 February 2020. No additional information was submitted. Moreover, the RMS did not report any uses authorised in third countries that might have a significant impact on international trade.

Considering the data submitted by Member States, EFSA, according to the process, should in principle ask the Netherlands as the designated RMS, to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. Since neither the European Union (EU) uses nor import tolerances are currently authorised for *Streptomyces lydicus* strain WYEC 108, a GAP overview file and PROFile were not considered necessary and were not submitted. The evaluation report was provided by the RMS to EFSA on 14 April 2020. Subsequently, EFSA performed the completeness check with the RMS. The outcome of this exercise including the clarifications provided by the RMS was compiled in the completeness check report.

Based on the information provided by the RMS and Member States, and taking into account the conclusions derived by EFSA in the framework of Commission Regulation (EU) No 188/2011 and the subsequent Commission Review Report, EFSA prepared in June 2020 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 9 July 2020 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

Residues of *Streptomyces lydicus* strain WYEC 108 are not expected to occur in any plant commodity or in any animal product because no uses or import tolerances are currently authorised for *Streptomyces lydicus* strain WYEC 108 in the EU and no CXLs are available for this active substance. A consumer dietary risk assessment is therefore not required.

An inclusion of *Streptomyces lydicus* strain WYEC 108 in Annex IV of (EC) No 396/2005 is however not recommended based on an incomplete characterisation of *Streptomyces lydicus* strain WYEC 108, lack of information on potential formation of toxicologically relevant metabolites following use as flagged already during the EFSA peer review Conclusion of 2013 and considering that there are no authorised uses, conclusive information on its potential to form metabolites under GAP relevant conditions cannot be provided.

Nevertheless, to assist risk managers in applying the most appropriate enforcement measures (against potential illegal uses), EFSA assessed the available data on the analytical methods.

*Streptomyces lydicus* strain WYEC 108 is the most adequate marker for enforcement against the potential illegal uses of this active substance in plant commodities. This compound may be analysed in plant commodities; however, a method for enforcement fully validated at a specific LOQ was not provided.

Considering that the enforcement against potential illegal uses falls under the remit of risk managers, EFSA is not in a position to recommend whether the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005, or whether the setting of a MRL at a specific LOQ value, respectively, for plant and/or animal commodities should apply.
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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 *Streptomyces lydicus* strain WYEC 108 was approved on 1 January 2015 by means of Commission Implementing Regulation (EU) No 917/2014\(^3\) in the framework of Regulation (EC) No 1107/2009\(^4\) as amended by Commission Implementing Regulations (EU) No 540/2011\(^5\) and 541/2011\(^6\), 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\(^7\) *Streptomyces lydicus* strain WYEC 108 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, 2013).

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 18 November 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 18 December 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, none of the 10 Member States that provided feedback reported national authorisations of *Streptomyces lydicus* strain WYEC 108. Nevertheless, Member States were requested to provide any additional supporting data by 13 February 2020.

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\(^1\) 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 Regulation (EU) No 917/2014 of 22 August 2014 approving the active substance *Streptomyces lydicus* strain WYEC 108 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 540/2011. OJ L 251, 23.8.2014, p. 19–23.

\(^4\) 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.

\(^7\) 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 prepare a supporting evaluation report. The supporting evaluation report was submitted to EFSA on 14 April 2020. Subsequently, EFSA performed the completeness check 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 June 2020 a draft reasoned opinion, which was circulated to Member States and EURLs for commenting via a written procedure. All comments received by 9 July 2020 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Netherlands, 2020) is considered as the main supporting document to this reasoned opinion and, thus, is made publicly available. No EURL report on analytical methods was available. Noting that no GAPs were reported the exposure calculations performed using the EFSA Pesticide Residues Intake Model (PRIMo) and PROFILE were not required.

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.

**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**

The reference isolate of *Streptomyces lydicus* strain WYEC 108 is deposited at the USDA-American Type Culture Collection (ATCC) with the number 55445. *Streptomyces lydicus* strain WYEC 108 was isolated from an English agricultural soil (in the Downs of West Sussex). *Streptomyces lydicus* strain WYEC 108 is used to control seed, soil and foliar fungi pathogens such as *Fusarium*, *Pythium*, *Rhizoctonia* and *Phytophthora*.

For *Streptomyces lydicus* strain WYEC 108, a default MRL of 0.01 mg/kg is established according to Art 18(1)(b) of Regulation (EC) No 396/2005.

For the purpose of this MRL review, the GAP collection revealed that no uses of *Streptomyces lydicus* strain WYEC 108 currently authorised within the EU were submitted by the Member States. The RMS did not report any use authorised in third countries that might have a significant impact on international trade. Codex MRLs are not set for *Streptomyces lydicus* strain WYEC 108.

**Assessment**

EFSA has based its assessment on the following documents:

- the evaluation report (Netherlands, 2020);
- the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/ EEC (Netherlands, 2012, 2013);
- the conclusion on the peer review of the pesticide risk assessment of the active substance *Streptomyces lydicus* strain WYEC 108 (EFSA, 2013);
- the review report on *Streptomyces lydicus* strain WYEC 108 (European Commission, 2014);

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\(^8\) 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).

\(^8\) Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
Residues of *Streptomyces lydicus* strain WYEC 108 are not expected to occur in any plant commodity or in any animal product because no uses or import tolerances are currently authorised for *Streptomyces lydicus* strain WYEC 108 in the EU and no codex maximum residue limits (CXLs) are available for this active substance. A risk assessment is therefore in principle not required. EFSA nevertheless reviewed the available information for this Art. 12 review and assessed the available data with attention to the analytical methods to assist risk managers in applying the most appropriate enforcement measures (against potential illegal uses).

During the peer review, it was noted that *Streptomyces* species are known to produce many secondary metabolites. Strain-specific data on the production of secondary metabolites were not provided. The consumer risk assessment could not be finalised until the outstanding issues on toxins/secondary metabolites and the infectivity to humans are addressed and it is confirmed by the toxicological assessment that a quantitative consumer risk assessment is not necessary (EFSA, 2013).

During the peer review, information on viable counts (colony-forming units (CFUs)) of *Streptomyces lydicus* strain WYEC 108 on tomato seedling was provided (Netherlands, 2012). The population dynamics of *Streptomyces lydicus* WYEC108 on tomato seedlings was monitored up to 14 days after the spray application with a water suspension containing approximately $10^{6}$ CFU/mL. Enumeration was performed by plating on water-yeast-extract-cellulose (WYEC) agar. The population of *Streptomyces lydicus* WYEC108 dropped approximately 10-fold after 4 days and remained stable at a population density around $10^{3}$ CFU/g leaf until the end of the 14-day incubation period (Netherlands, 2020).

It is to be noted that the applied concentration of the representative use on tomato seedlings was $2 \times 10^{6}$ CFU/g of seedlings which was performed by dipping (EFSA, 2013). Therefore, the results of the study on tomato seeds can be used indicatively to demonstrate decline of viable residues following application. Nevertheless, from the provided data, it can be concluded that *Streptomyces lydicus* strain WYEC 108 does not multiply on tomato seedlings or persists at the initial levels following treatment.

In the European Commission review report, it was outlined with reference to the EFSA Conclusion, that additional information on the possible production of metabolites are considered as not relevant. *Streptomyces lydicus* strain WYEC 108 is a microorganism isolated from a European soil and does not contain additional genetic elements. The genetic stability of this organism, including the risk for transfer of genetic material, is not expected to be noticeably influenced under the proposed conditions of use. Due to the absence of toxicity, infectivity and pathogenicity indications, it was considered not necessary to derive toxicological reference values for *Streptomyces lydicus* strain WYEC 108 (European Commission, 2014).

With particular regard to residues, the review report concluded that a quantitative consumer risk assessment was not deemed necessary, as the microorganism is not pathogenic to humans and no toxins or toxic metabolites are expected to occur in food following the use of *Streptomyces lydicus* strain WYEC 108 (European Commission, 2014).

For this Art. 12 review, the applicant conducted a new literature search in line with the recommendations made by the EFSA Guidance on the submission of scientific peer-reviewed open literature (EFSA, 2011). The updated literature search conducted for this MRL review did not show any indication of a toxicologically relevant metabolite being produced (EFSA, 2020a). However, the RMS clarified that *Streptomyces lydicus* strain WYEC 108 produces hydroxamate siderophores which enhance plant growth and uptake of metals from soil and at least one chitinase (chitin degrading enzymes) and one polypeptide fungicide (Chandramycin) (EFSA, 2020a). Toxicological information on these products and metabolites was not provided.

Although the literature searches provided during the peer review and the updated search provided for this Art. 12 review did not show evidence of any toxicologically relevant metabolite being formed by *Streptomyces lydicus* strain WYEC 108, notably literature searches for individual metabolites as assessed during the peer review were not provided (Netherlands, 2012, 2020; EFSA, 2020a). This leaves uncertainties with regard to completeness of the provided information as retrieved from the literature.

The applicant also submitted a genome report which, however, was not carried out according to GLP and was not peer reviewed. Based on this report, 30 predicted proteins associated with degradation and metabolism of chitin and/or chitooligosaccharides were found and 33 gene clusters are implicated in the synthesis of secondary metabolites.

Numerous genes were identified; however, the presence of specific genes does not necessarily mean that these genes are expressed and that the corresponding compounds/metabolites are produced (EFSA 2020a; Netherlands, 2020). In addition, for a characterisation of *Streptomyces lydicus*
strain WYEC 108 conclusive information on its potential to form metabolites under GAP relevant conditions was not provided because there are no authorised uses in Europe.

In the provided genome report, a data gap identified in the EFSA conclusion regarding the possible transfer of genetic material coding for the resistance of antibiotics was addressed. Actinomycetes to which the species Streptomyces lydicus belongs are known to have the capacity to transfer genetic material through the exchange of plasmids. Based on genome analysis, no plasmids were identified for Streptomyces lydicus strain WYEC 108, although the presence of low copy number, linear plasmids cannot be excluded (Netherlands, 2020). This leaves again room for uncertainty of the presented results regarding potential presence of low numbers of uncharacterised linear plasmids.

There are in conclusion considerable uncertainties with regard to the characterisation of Streptomyces lydicus strain WYEC 108 and while viable counts were shown to decline on tomato seedlings during the peer review, it is still recommended to provide conclusive genetic data on (acquired) antimicrobial resistance and information on toxicologically relevant metabolites in combination with their potential expression under GAP relevant conditions in accordance with available EFSA Panel guidance such as ‘on characterisation of microorganisms used in the food chain’ and ‘on the characterisation of microorganisms used as feed additives or as production organisms’ in case that authorisations were to be sought in the future (EFSA FEEDAP Panel, 2018; EFSA CEP Panel, 2019). A lack of guidance on the transfer of genetic material in the context of antimicrobial resistance specifically in the area of pesticide risk assessment is flagged by the RMS. The RMS does not consider any additional genome data necessary for the assessment of metabolites for the strain (EFSA, 2020b). It is, however, to be noted that the updated literature search does not cover searches for individual metabolites as outlined above.

An inclusion of Streptomyces lydicus strain WYEC 108 in Annex IV of (EC) No 396/2005 is not recommended considering the outlined uncertainties and shortcomings regarding the characterisation of Streptomyces lydicus strain WYEC 108, a lack of information on potential formation of toxicologically relevant metabolites as flagged already during the EFSA peer review Conclusions of 2013 and since there are no authorised uses, conclusive information on its potential to form metabolites under GAP relevant conditions cannot be provided. Therefore, a qualitative consumer risk assessment cannot be finalised.

Available methods of analysis are those provided during the peer review and new information was not made available during this review. Streptomyces lydicus strain WYEC 108 can be quantified by a plate count method. However, molecular tools need to be used to specifically identify and differentiate Streptomyces lydicus strain WYEC 108 from other Streptomyces strains since this would not be possible by morphological identification methods. Randomly amplified polymorphic DNA (RAPD) methods and DNA fingerprinting techniques using polymerase chain reaction (PCR) are available. A 0.3 kDa probe is available (assigned Genbank number F239669) which can be used for strain-specific identification of the Streptomyces lydicus strain WYEC 108 by PCR (Netherlands, 2012; EFSA 2020a). However, a validation for any of the methods was not performed.

To assist risk managers in applying the most appropriate enforcement measures (against potential illegal uses), EFSA assessed the available data and particularly the analytical methods. Streptomyces lydicus strain WYEC 108 is the most adequate marker for enforcement against the potential illegal uses of this active substance in plant commodities. This compound may be identified and quantified in plant commodities; however, a method for enforcement fully validated at a specific LOQ was not provided.

Considering that the enforcement against potential illegal uses falls under the remit of risk managers, EFSA is not in a position to recommend whether the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005, or whether the setting of an MRL at a specific LOQ value, respectively, for plant and/or animal commodities should apply.

Conclusions and recommendation

Residues of Streptomyces lydicus strain WYEC 108 are not expected to occur in any plant or animal commodity because no uses or import tolerances are currently authorised for Streptomyces lydicus strain WYEC 108 in the EU and no CXLs are available for this active substance. A consumer dietary risk assessment is therefore in principle not required.

An inclusion of Streptomyces lydicus strain WYEC 108 in Annex IV of (EC) No 396/2005 is, however, not recommended based on an incomplete characterisation of Streptomyces lydicus strain WYEC 108, lack of information on potential formation of toxicologically relevant metabolites following use as flagged already during the EFSA peer review Conclusion of 2013 and considering that there are no
authorised uses, conclusive information on its potential to form metabolites under GAP relevant conditions cannot be provided.

Nevertheless, to assist risk managers in applying the most appropriate enforcement measures (against potential illegal uses), EFSA assessed the available data as regards to the analytical methods. *Streptomyces lydicus* strain WYEC 108 is the most adequate marker for enforcement against the potential illegal uses of this active substance in plant commodities. This compound may be identified and quantified in plant commodities; however, a method for enforcement fully validated at a specific LOQ was not provided.

Considering that the enforcement against potential illegal uses falls under the remit of risk managers, EFSA is not in a position to recommend whether the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005, or whether the setting of an MRL at a specific LOQ value, respectively, for plant and/or animal commodities should apply.

**References**

EFSA (European Food Safety Authority), 2011. Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009. EFSA Journal 2011;9(2):2092. https://doi.org/10.2903/j.efsa.2011.2092

EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment of the active substance *Streptomyces lydicus* WYEC 108. EFSA Journal 2013;11(11):3425, 30 pp. https://doi.org/10.2903/j.efsa.2013.3425

EFSA (European Food Safety Authority), 2020a. Completeness check report on the review of the existing MRLs of *Streptomyces lydicus* WYEC 108 prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 10 June 2020. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2020b. Member States consultation report on the review of the existing MRLs of *Streptomyces lydicus* WYEC 108 prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 19 August 2020. Available online: www.efsa.europa.eu

EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids), Silano V, Barat Baviera JM, Bolognesi C, Bruschweiler BJ, Cocconcelli PS, Crebelli R, Gott DM, Grob K, Lampi E, Mortensen A, Riviere G, Steffensen I-L, Tiustos C, Van Loveren H, Vernis L, Zom H, Glandorf B, Herman L, Aguilera J and Chesson A, 2019. Statement on the characterisation of microorganisms used for the production of food enzymes. EFSA Journal 2019;17(6):5741, 13 pp. https://doi.org/10.2903/j.efsa.2019.5741

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aguilera J, Anguita M, Brozzi R and Galobart J, 2018. Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206, 24 pp. https://doi.org/10.2903/j.efsa.2018.5206

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Metabolism and distribution in plants. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix A. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix A. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals.7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev. 4.

European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.
European Commission, 2014. Review report for the active substance Streptomyces lydicus strain WYEC 108. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 11 June 2014 in view of the approval of Streptomyces lydicus strain WYEC 108 as active substance in accordance with Regulation (EC) No 1107/2009. SANCO/11427/2014.

European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.10.3, June 2017.

Netherlands, 2012. Draft assessment report on the active substance Streptomyces lydicus WYEC 108 prepared by the rapporteur Member State the Netherlands in the framework of Council Directive 91/414/EEC, May 2012. Available online: www.efsa.europa.eu

Netherlands, 2013. Final addendum to the draft assessment report on the active substance Streptomyces lydicus WYEC 108, compiled by EFSA, June 2013. Available online: www.efsa.europa.eu

Netherlands, 2020. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for Streptomyces lydicus WYEC 108, 14 April 2020. Available online: www.efsa.europa.eu

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 4 September 2013.

Abbreviations

a.i. active ingredient
a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
CAC Codex Alimentarius Commission
CAS Chemical Abstract Service
CCPR Codex Committee on Pesticide Residues
DAR draft assessment report
EMS evaluating Member State
GAP Good Agricultural Practice
ISO International Organisation for Standardization
LOQ limit of quantification
MRL maximum residue level
MS Member States
MS mass spectrometry detector
MS/MS tandem mass spectrometry detector
MW molecular weight
OECD Organisation for Economic Co-operation and Development
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
PROFile (EFSA) Pesticide Residues Overview File
RMS rapporteur Member State
WHO World Health Organization
Appendix A – Summary of authorised uses considered for the review of MRLs

**A.1. Authorised outdoor uses in Europe and import tolerances**

| 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 | | |
| No authorised uses were reported | | | | | | | |

**MS:** Member State.
(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.