Review of the existing maximum residue levels for myclobutanil 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 myclobutanil. To assess the occurrence of myclobutanil residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EC) No 33/2008, the MRLs established by the Codex Alimentarius Commission as well as the import tolerances and/or 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. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

Keywords: myclobutanil, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, triazole group, fungicide

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Summary

Myclobutanil was included in Annex I to Directive 91/414/EEC on 1 June 2011 by Commission Directive 2011/2/EU, 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 myclobutanil 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 Belgium, 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 23 June 2017 and finalised on 23 August 2017. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 11 October 2017.

Based on the conclusions derived by EFSA in the framework of Commission Regulation (EC) No 33/2008, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS and Member States, EFSA prepared in February 2018 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 3 April 2018 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of myclobutanil was assessed in fruits, root crops, cereals and sugar beet tops (tentatively addressing leafy vegetables). For fruits and root crops, a residue definition is proposed for risk assessment: myclobutanil and metabolite RH-9090 free and conjugated, expressed as myclobutanil. For enforcement, the residue definition should be myclobutanil (sum of constituent isomers). For leafy vegetables, pulses and oilseeds and post-harvest treatments the same residue definitions were proposed on a tentative basis. A validated analytical method for enforcement of the proposed residue definition in the four main analytical matrices is available; however, a validated analytical method is missing and is required for hops. The metabolism in rotational crops was found to be similar as the metabolism in primary crops, therefore the same residue definitions apply.

Myclobutanil and metabolite RH-9090 were stable to hydrolysis under standard conditions of pasteurisation, boiling/brewing/baking and sterilisation. Studies investigating the magnitude of residues in several processed commodities of bananas, plums, tomatoes, grapes, apples, currants, cherries, strawberries and hops are available and allowed to derive processing factors.

The available data are considered sufficient to derive appropriate MRL proposals as well as risk assessment values for permanent crops only (some fruits and stone fruits). For hazelnuts/cobnuts and walnuts, no MRLs could be derived. Due to the lack of data, EFSA was not able to propose MRLs which would allow considering the potential uptake of myclobutanil from previous applications in crops that may be grown in rotation. Therefore, the MRLs proposed for annual crops are tentative only. Furthermore, for the other annual crops for which no good agricultural practices (GAPs) are authorised, specific MRLs covering the potential uptake from previous treatment on other crops could not be derived. Tentative MRLs were also derived for feed crops (e.g. sugar beet tops) in view of the future need to set MRLs in feed items.

The dietary burdens of cattle, sheep and swine were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). The metabolism of myclobutanil was investigated in ruminants (lactating goats) and poultry (laying hens). Feeding studies performed on ruminants (lactating cow) and poultry (laying hens) were also available for this MRL review. The residue definition in livestock for both enforcement and risk assessment is proposed as follows: free and conjugated forms of RH-9090, expressed as myclobutanil. An analytical method for enforcement for milk, eggs, meat, liver and kidney is available (however, a confirmatory method and the extraction efficiency were not reported). The MRLs in commodities of animal origin (cattle, swine and sheep) are proposed to be set at the limit of quantification (LOQ) as no significant residues of myclobutanil and RH-9090 (free and conjugates) are expected to occur. The MRLs for animal products are tentative as extraction efficiency of the analytical methods was not reported and storage stability studies on kidney, fat and milk are missing. Based on the European uses, no MRLs are needed for poultry products.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA Pesticides Residues Intake model.
(PRIMo). For those commodities where data were insufficient to derive a MRL, EFSA considered the existing European Union (EU) MRL for an indicative calculation. The highest chronic exposure was calculated for DE children representing 17.5% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for table grapes representing 34.5% of the acute reference dose (ARfD). Although no risk to consumers was identified, the consumer risk assessment for the EU scenario did not take into consideration the potential uptake of myclobutanil and metabolites from previous applications in crops that can be grown in rotation. Therefore, the acute and chronic exposure should be considered as tentative only.

Apart from the MRLs evaluated in the framework of this review, internationally recommended codex maximum residue limits (CXLs) have also been established for myclobutanil. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and no exceedances of the ARfD were identified for DE children representing 17.3% of the ADI, and the highest acute exposure (after refinement) was calculated for peppers representing 48.8% of the ARfD. For some commodities, the highest residue level and median residue level from the field rotational crop study were used as input values according to the methodology employed by the JMPR. It is noted that this approach could not be confirmed by EFSA, since a full assessment of the rotational crop field study is needed.

It is noted by EFSA that the above risk assessment was performed disregarding the possible impact of the isomer ratios due to plant or livestock metabolism. Considering, however, that the isomer ratio of myclobutanil is specified as 50/50 and provided that the racemic mixture is stable then this concern is covered by the toxicological tests performed (EFSA, 2010); a change of isomer ratios in the residues might, in the worst-case situation, lead to a duplication of the toxicological burden of the residues. Since the exposure calculations represent less than 50% of the ADI or ARfD, EFSA concludes that the potential change of isomer ratios in the final residues will not be of concern for the authorised uses reported in the framework of this review. In case future uses of myclobutanil would lead to a higher consumer exposure, further information regarding the impact of plant and livestock metabolism on the isomer ratio might be required.

EFSA emphasises that the above assessment does not take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA was asked to perform a comprehensive dietary risk assessment for TDMs considering data for several triazole fungicides submitted in the framework of the confirmatory data assessment. However, currently, an overall consumer exposure assessment to relevant TDMs arising from all triazole fungicides could not be concluded on until the outstanding issues and general recommendations highlighted in the assessment are addressed.
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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 myclobutanil was included in Annex I to Council Directive 91/414/EEC on 1 June 2011 by means of Commission Directive 2011/2/EU\(^3\), 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.

Belgium, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC and Commission Regulation (EC) No 33/2008\(^7\) was asked to complete the PROFile for myclobutanil and to prepare a supporting evaluation report (Belgium, 2014). The PROFile and the supporting evaluation report were submitted to EFSA on 5 June 2014 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 23 June 2017 and finalised on 23 August 2017. Additional evaluation reports were submitted by Austria, Italy, the Czech Republic, Germany, Spain, Hungary, Greece, France, Belgium and the European Union Reference Laboratories for Pesticide Residues (Austria, 2017; Belgium, 2017a; Czech Republic, 2017; EURL, 2017; France, 2017, Germany, 2017a; Greece, 2017; Hungary, 2017; Italy, 2017; Spain, 2017a,b) and, after having considered all the information provided by the RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 11 October 2017. Further clarifications were sought from Member States via a written procedure in October 2017.

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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 Directive 2011/2/EU of 7 January 2011 amending Council Directive 91/414/EEC to include myclobutanil as active substance and amending Decision 2008/934/EC. OJ L 5, 8.1.2011, p. 7–10.

\(^4\) 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 (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 9(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.
Based on the conclusions derived by EFSA in the framework of Commission Regulation (EC) No 33/2008, the MRLs established by the Codex Alimentarius Commission (codex maximum residue limit; CXLs) and the additional information provided by the Member States, EFSA prepared in February 2018 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 3 April 2018 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Belgium, 2014) and the evaluation reports submitted by Member States Austria, Italy, the Czech Republic, Germany, Spain, Hungary, Greece, France, Belgium and the EURL (Austria, 2017; Belgium, 2017a,b; Czech Republic, 2017; EURL, 2017; France, 2017; Germany, 2017a,b; Greece, 2017; Hungary, 2017; Italy, 2017, Spain, 2017a,b) 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 and acute 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 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

Myclobutanil is the ISO common name for (RS)-2-(4-chlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl) hexanenitrile (IUPAC).

Myclobutanil belongs to the class of conazole fungicides. Myclobutanil is a systemic fungicide with preventive, curative and eradicant properties. It is a sterol biosynthesis inhibitor, inhibiting primarily the C-14 demethylation step in the fungal sterol biosynthesis pathway. The active substance is absorbed by the leaves and stems and is transported upward in the plant into areas of new growth via the xylem.

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

Myclobutanil was evaluated in the framework of Directive 91/414/EEC, under Commission Regulation (EC) No 1490/2002 as amended by Commission Regulation (EC) No 1095/2007, with Belgium designated as RMS. Following the Commission Decision of 5 December 2008 (2008/934/EC) concerning the non-inclusion of myclobutanil in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant Dow AgroScience made a resubmission application for the inclusion of myclobutanil in Annex I in accordance with the provisions laid down in Commission Regulation (EC) No 33/2008.

The representative uses evaluated under the resubmission process comprised foliar spraying against powdery mildew (Uncinula necator), and black rot (Guignardia bidwellii) in table and wine grapes, in all EU countries, up to a maximum of four applications at a maximum individual application rate per spray of 48 g a.s./ha, with an interval of 10 days between applications. In the resubmission dossier, the use in apples was no longer supported.

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8 Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000. OJ L 224, 21.8.2002, p. 23-48.
9 Commission Regulation (EC) No 1095/2007 of 20 September 2007 Amending Regulation (EC) No 1490/2002 Laying Down Further Detailed Rules for the Implementation of the Third Stage of the Programme of Work Referred to in Article 8(2) of Council Directive 91/414/EEC. OJ L246, 21.9.2007, p.19.
10 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.
Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2011/2/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, myclobutanil is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as fungicide only. Furthermore, in the approval directive submission of confirmatory information was set on the residues of myclobutanil and its metabolites in following growing seasons and information confirming that the available residue data cover all compounds of the residue definition. An EFSA Conclusion on the confirmatory data assessment is not available.

The EU MRLs for myclobutanil are established in Annexes II and IIIB of Regulation (EC) No 396/2005 and codex maximum residue limits (CXLs) for myclobutanil were also established by the Codex Alimentarius Commission (CAC). An overview of the MRL changes that occurred since the entry into force of the Regulation mentioned above is provided below (Table 1).

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

| Procedure                  | Legal implementation                  | Remarks                                                                 |
|----------------------------|---------------------------------------|-------------------------------------------------------------------------|
| Implementation of CAC, July 2015 | Commission Regulation (EU) 2016/567  | CXLs adopted by CAC for myclobutanil on 15 July 2015 following EFSA comments on the toxicological reference values and on the proposed Codex MRLs evaluated by JMPR in 2014 |

CXL: codex maximum residue limit; CAC: Codex Alimentarius Commission; MRL: maximum residue level.

For the purpose of this MRL review, the critical uses of myclobutanil currently authorised within the EU, as well as uses authorised in third countries that might have a significant impact on international trade 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 GAP(s) for myclobutanil are given in Appendix A.

Assessment

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Belgium, 2014), the draft assessment report (DAR) prepared under Council Directive 91/414/EEC (Belgium, 2007), the additional report and its addenda prepared under Commission Regulation (EC) No 33/2008 (Belgium, 2009, 2010), the review report on myclobutanil (European Commission, 2016), the conclusion on the peer review of the pesticide risk assessment of the active substance myclobutanil (EFSA, 2010), the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2014), as well as the evaluation reports submitted during the completeness check (Austria, 2017; Belgium, 2017a,b; Czech Republic, 2017; EURL, 2017; France, 2017, Germany, 2017a,b; Greece, 2017; Hungary, 2017; Italy, 2017; Spain, 2017a,b). 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 546/201111 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a-g, 2000, 2010a,b, 2017 and 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.

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11 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.
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 myclobutanil was investigated after foliar treatment in fruits (apples and grapes), cereals (EFSA, 2010) and root crops (Belgium, 2014), with myclobutanil radiolabelled in the phenyl or triazole ring of the molecule.

After 10 foliar applications at a weekly interval of 240 g a.s./ha on apples, at harvest the major component identified in the fruit was myclobutanil, representing 49% of the total radioactive residues (TRR) while the alcohol metabolite RH-9090 was present at 35% TRR (EFSA, 2010). Residue levels of myclobutanil and RH-9090 in the whole fruit were 0.48–0.32 mg eq/kg and 0.066–0.10 mg eq/kg in both labels, respectively. There was no cleavage of the triazole linkage of myclobutanil to give any of the triazole derivate metabolites (TDMs) referred to as triazole alanine (TA), triazole acetic acid (TAA) and 1,2,4-triazole (1,2,4-T) in apple portion (EFSA, 2010).

After five foliar applications at a weekly interval of 50 g a.s./ha on grapes, the major component identified in fruit was myclobutanil, representing 66% of the TRR, and metabolite RH-9090 observed at 15% TRR (EFSA, 2010). Residue levels of myclobutanil and RH-9090 in the whole fruit were 0.32–0.24 mg eq/kg and 0.029–0.047 mg eq/kg in both labels, respectively. There was no cleavage of the triazole linkage of myclobutanil that would lead to the generation of any TDMs (EFSA, 2010).

After one foliar application with myclobutanil labelled on the phenyl ring and two applications with myclobutanil labelled on the triazole ring of 240 g a.s./ha on wheat, myclobutanil was extensively metabolised in the grain, accounting to 25% of the TRR in the phenyl label (EFSA, 2010). The major metabolites recovered in grain treated with myclobutanil labelled in the triazole ring were identified as the triazole conjugates RH-3968 (TA) and RH-4098 (TAA), which amounted 51.3% and 25.4% of the TRR, respectively (1.83 and 0.906 mg eq/kg). In straw, myclobutanil remained the major compound (up to 46.9% of the TRR) while the other metabolites identified were RH-9090 and its conjugates. In wheat, there is a cleavage of myclobutanil at the triazole linkage which leads to the generation of TDMs (EFSA, 2010).

The metabolism of myclobutanil labelled in the phenyl and triazole ring was investigated in sugarbeet roots and tops (Belgium, 2014), but this study was not peer-reviewed. After one foliar application of either 150 or 1,500 g a.s./ha on sugarbeet, myclobutanil represented 50% of the TRR 15 days after treatment (DAT) in both tops and roots, and 25% of the TRR at maturity (30 DAT). At maturity (30 DAT), total residues of RH-9090 (free and conjugated) were 60% TRR in tops and 10–15% TRR in root samples. Residue levels of myclobutanil in sugarbeet roots 30 DAT were 0.081–0.044 mg eq/kg at the low dose and 0.871–1.19 mg eq/kg at the high dose in both labels, respectively. Residue levels of myclobutanil in sugarbeet tops were 0.53–0.69 mg eq/kg at the low dose and 5.32–4.65 mg eq/kg at the high dose 30 DAT in both labels, respectively. There was no cleavage of the triazole linkage and therefore no formation of TDMs. The metabolic pathway in root crops was similar to the metabolism observed in apples and grapes (fruit crops). The findings observed in sugarbeet tops were used to depict, on a tentative basis, the metabolism of myclobutanil in leafy vegetables.

1.1.2. Nature of residues in rotational crops

Myclobutanil is authorised on crops that may be grown in rotation. The field DT₉₀ reported in the soil degradation studies evaluated in the framework of the peer review was higher than the trigger value of 100 days (EFSA, 2010).

As a specific provision of the approval of myclobutanil, further data were requested in the form of confirmatory information on the residues of myclobutanil and its metabolites in following growing seasons and information confirming that the available residue data cover all compounds of the residue definition. Two confined rotational crop studies were assessed by the RMS in an addendum (confirmatory data) to the DAR (Belgium, 2013).

In the first study, myclobutanil labelled in the phenyl ring was applied three times at a rate of 224 g a.s./ha per application onto bare soil. One plot was treated in the spring and the other in early fall. Crops were planted into the treated plots at nominal plant-back intervals of 30, 120, 210 and 365 DAT. Crops planted at each interval consisted of a leafy vegetable (lettuce or mustard), a root crop (radish or turnips), a small grain (dwarf sorghum or wheat) and soybeans. Myclobutanil levels were
higher than 0.01 mg/kg in lettuce (0.013 mg eq/kg), sorghum stover (0.019 mg eq/kg) and soybean forage (0.027 mg eq/kg) at 30 DAT. Myclobutanil levels at 120 DAT were below 0.01 mg/kg in all crops with the exception of radish tops (0.014 mg eq/kg) which is a non-edible part of the crop. The main metabolite RH-9090 did not exceed 0.01 mg/kg in any crop, with the exception of sorghum forage (0.013 mg eq/kg) and soybean straw (0.03 mg eq/kg) at 30 DAT.

In the second study, myclobutanil labelled in the triazole ring was applied with a single dose of 360 g a.s./ha onto bare soil. Lettuce, radish and wheat were planted at plant-back intervals (PBIs) of 30, 120 and 365 days DAT. Residues in immature and mature lettuce and radish tops declined over time, while residues in radish roots increased over time. Residues in wheat hay, straw and grain did not show a consistent pattern over time. Highest myclobutanil levels were detected in lettuce (55% to 21% TRR; 0.432 to 0.195 mg eq/kg) and radish roots (27% TRR; 0.021 mg eq/kg) 30 DAT. Significant residues were observed up to 120 DAT in lettuce (0.013–0.014 mg eq/kg), radish roots (0.015 mg eq/kg), radish tops (0.016 mg eq/kg) and wheat forage and straw (0.029 mg eq/kg; 0.019 mg eq/kg). In 365 DAT, significant residues were observed only in radish roots (0.023 mg eq/kg) and wheat hay (0.046 mg eq/kg). In wheat, as it occurred in the primary crop study, there was cleavage of the triazole linkage and the formation of TDM. In wheat grain, TA and TAA represented the primary overall residues, each one with approximately 20–30% TRR (0.45 to 0.43 mg eq/kg) 120 DAT and 26% TRR (0.39 to 0.37 mg eq/kg) 365 DAT. However, TA was also detected at levels higher than 0.01 mg eq/kg in lettuce (immature and mature) and radish tops, 365 DAT. Therefore, it can be concluded that even after one year, significant residues of myclobutanil can be detected in edible parts of root crops (radish roots).

The metabolism and distribution of myclobutanil in rotational crops is similar to the metabolic pathway observed in primary crops. However, it should be noted that additional residues of TDMs may occur in all types of rotational crops due to uptake (and transformation) of residues from the soil (Belgium, 2013).

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues in processed commodities were assessed in the framework of the peer review (EFSA, 2010). Studies were conducted with radiolabelled myclobutanil and metabolite RH-9090 simulating 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). Myclobutanil and metabolite RH-9090 were stable to hydrolysis under standard conditions of pasteurisation, baking/brewing/boiling and sterilisation (EFSA, 2010).

The nature of residues was assessed in apple juice and apple wet pomace and in grape juice and grape wet pomace (EFSA, 2010). In apple juice, myclobutanil was present at 22–24% TRR (0.15–0.12 mg eq/kg), but was extensively metabolised into RH-9090 (including sugar conjugates), present at up to 68% of TRR (0.10 to 0.065 mg eq/kg). In apple wet pomace, myclobutanil was the major compound detected at 56% TRR (1.0 to 0.66 mg eq/kg). In grape juice, the parent compound was present at 26–33% TRR (0.0138 to 0.0088 mg eq/kg) and RH-9090 (including sugar conjugates) was present at up to 47% of TRR (0.455 to 0.009 mg eq/kg). In grape wet pomace, myclobutanil was the major compounds present at 72% TRR (0.97 to 0.91 mg eq/kg).

1.1.4. Methods of analysis in plants

During the peer review, a multiresidue analytical method using liquid chromatography with tandem mass spectrometry (LC-MS/MS) was validated for the determination of myclobutanil in high water content and high acid content commodities with a LOQ of 0.025 mg/kg (EFSA, 2010). A multiresidue analytical method using LC-MS/MS, validated for the determination of myclobutanil in all four plant matrices with a LOQ of 0.01 mg/kg was reported by France (2017). However, extraction efficiency of the method reported by France was not demonstrated. The EURLs reported a multiresidue analytical method using LC-MS/MS for the four main plant matrices with a LOQ of 0.01 mg/kg (EURL, 2017). Hence, it is concluded that myclobutanil can be enforced with a LOQ of 0.01 mg/kg in high water content, high acid content, high oil content and dry commodities. No fully validated methods were reported for the determination of myclobutanil in hops and therefore a data gap is identified for this commodity.

In addition, the EURLs reported that the metabolite RH-9090 can be enforced with a LOQ of 0.01 mg/kg in high water content, high acid content, and with a LOQ of 0.03 mg/kg in high oil and dry commodities. The EURLs have also reported that a Quick Polar Pesticides Method (QuPPe) developed for the four TDMs with a LOQ of 0.01 mg/kg for high water and high acid content, and a LOQ of 0.02 mg/kg for dry commodities is available (EURL, 2017).
1.1.5. Stability of residues in plants

In the framework of the peer review, storage stability of myclobutanil and its metabolite RH-9090 was demonstrated for a period of 36 months at \(-10^\circ C\) in high water content matrices and for a period of 18 months at \(-10^\circ C\) for high oil content matrices; the storage stability of myclobutanil only was demonstrated for a period of 24 months at \(-15^\circ C\) in high acid content matrices (EFSA, 2010). There is no data for the storage stability of metabolite RH-9090 in high acid matrices; however, since this will not affect the assessment (see Section 1.2.1), this lack of data is considered to be a minor deficiency only.

1.1.6. Proposed residue definitions

The metabolism of myclobutanil was not similar in all crops since in cereals there is a cleavage of myclobutanil at the triazole linkage which leads to the generation of TDMs which did not occur in fruits and roots. Although a metabolism study on leafy vegetables would be necessary to have a comprehensive view of the metabolic pathway on these crops, the metabolism observed on sugar beet tops was similar to fruits and roots. The metabolism in rotational crops is similar to the metabolism observed in primary crops and the processing of myclobutanil is not expected to modify the nature of residues.

As the parent compound is found to be a sufficient marker in fruit and root crops, the residue definition for enforcement is proposed as myclobutanil (sum of constituent isomers) for all crops. An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all matrices is available. The toxicity of metabolite RH-9090 is presumed to be covered by the toxicity of myclobutanil (EFSA, 2010). Therefore, the residue definition for risk assessment is proposed as: sum of myclobutanil and metabolite RH-9090 (free and conjugated), expressed as myclobutanil.

The proposed residue definition is applied on a tentative basis to leafy vegetables and pulses and oilseeds. In addition, the residue definition was also tentatively applied to post-harvest treatments (to cover the import tolerance of bananas). Consequently, additional metabolism studies investigating the nature of residues in leafy vegetables (foliar treatment), pulses and oilseeds (foliar treatment) and fruits (post-harvest treatment) are required.

EFSA emphasises that the above residue definitions do not yet take into consideration TDMs. Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Directive 91/414/EEC have been evaluated and a general methodology on the risk assessment of triazole compounds and their TDMs is available.

1.2. Magnitude of residues in plants

In the framework of the peer review it was noted that myclobutanil consists of two optical isomers (enantiomers) and that the methods of analysis used in the residue studies were not stereoselective (EFSA, 2010). Thus, there was no information on the behaviour of each individual myclobutanil enantiomer in plants and livestock. Therefore, all residues reported as myclobutanil in the framework of the peer review were for the sum of the two enantiomers. It is not known if either isomer is metabolised or degraded more quickly than the other in the matrices studied in all residue trials reported in this MRL review.

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of myclobutanil residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Belgium, 2014), including residue trials evaluated in the framework of the peer review (EFSA, 2010) and additional data submitted during the completeness check (France, 2017; Germany, 2017a; Greece, 2017; Italy, 2017) All residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions.

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).

Sufficient residue trials are not available to support the authorisations on hazelnuts/cobnuts, raspberries (red and yellow), beans (with pods), asparagus and borage seeds. Therefore, MRL or risk assessment values for this crop could not be derived by EFSA and the following data gaps were identified:
Hazelnuts/cobnuts; walnuts: Four trials on hazelnuts/cobnuts and walnuts compliant with the southern GAP are required (although four trials are available, these trials lacked a validity report).

Raspberries (red and yellow): Four trials on raspberries (red and yellow) compliant with the indoor GAP are required.

Beans (with pods): Five trials on beans (with pods) compliant with the import tolerance GAP are required.

Borage seeds: Four trials on borage seeds compliant with the southern GAP are required.

Asparagus: Four trials on asparagus compliant with the southern GAP are required.

For some crops, the available residue trials are sufficient to derive (tentative) MRL and risk assessment values, taking note of the following considerations:

Cherries (sweet): Although tentative MRL and risk assessment values can be derived from the northern data performed with a more critical GAP, eight trials compliant with the northern GAP and four trials compliant with the southern GAP are still required.

Plums: Although tentative MRL and risk assessment values can be derived from the northern data, eight trials compliant with the northern GAP and three trials compliant with the southern GAP are still required.

Apricots: Although tentative MRL and risk assessment values can be derived from the southern data, four trials on apricots compliant with the northern GAP and two trials on apricots compliant with the southern GAP are still required.

Peaches: Although MRL and risk assessment values can be derived from the southern data, four trials compliant with the northern GAP are still required.

Strawberries: Two additional trials compliant with the southern GAP and eight trials compliant with the indoor GAP are in principle still required. However, the reduced number of residue trials is considered acceptable in this case because the northern GAP is clearly more critical than the southern and indoor GAPs. Further residue trials are therefore not required.

Blackberries: Although tentative MRL and risk assessment values can be derived from the northern data, four additional trials compliant with the northern GAP, three additional trials compliant with the southern GAP and four additional trials compliant with the indoor GAP are still required.

Currants and gooseberries: Although tentative MRL and risk assessment values can be derived from the northern data, four additional trials on currants and gooseberries compliant with the northern GAP and four additional trials compliant with the southern GAP are still required.

Tomatoes: Although tentative MRL and risk assessment values can be derived from the indoor data, four additional trials compliant with the indoor GAP and four additional trials compliant with the southern GAP are still required.

Aubergines/eggplants: Although tentative MRL and risk assessment values can be derived from the indoor data, four additional trials compliant with the southern GAP are still required.

Cucumbers: Although tentative MRL and risk assessment values can be derived from the indoor data, four additional trials compliant with the indoor GAP, four additional trials on courgettes compliant with the northern GAP and four additional trials compliant with the southern GAP are still required.

Gherkins, courgettes: Although tentative MRL and risk assessment values can be derived from the indoor data, four additional trials compliant with the indoor GAP, four additional trials on courgettes compliant with the northern GAP and eight additional trials compliant with the southern GAP are still required.

Melons, pumpkins and watermelons: Although tentative MRL and risk assessment values can be derived from the southern data, three additional trials compliant with the southern GAP are still required. For melons, four trials compliant with the indoor GAP are still required, and for pumpkins and watermelons, eight trials compliant with the indoor GAP are still required.

Lamb's lettuce/corn salads: Although tentative MRL and risk assessment values can be derived from the indoor data (not analysed with a method that covers the residue definition for risk assessment), four additional trials compliant with the northern GAP and four additional trials compliant with the indoor GAP are still required. Additional trials should be analysed according to the residue definition for risk assessment, with a method that allows the release of RH-9090 conjugates.
Review of the existing MRLs for myclobutanil

- Globe artichokes: Although tentative MRL and risk assessment values can be derived for the northern data (not analysed with a method that covers the residue definition for risk assessment), four additional trials compliant with the northern GAP and four additional trials compliant with the southern GAP are still required. Additional trials should be analysed according to the residue definition for risk assessment, with a method that allows the release of RH-9090 conjugates.

- Hops: Although tentative MRL and risk assessment values can be derived from the overdosed northern data (not analysed with a method that covers the residue definition for risk assessment), four additional trials compliant with the northern GAP are still required. Additional trials should be analysed according to the residue definition for risk assessment, with a method that allows the release of RH-9090 conjugates.

- Sugarbeet root: The number of residue trials supporting the southern outdoor GAPs is not compliant with the data requirements for these crops (four trials instead of eight). However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and a no-residue situation is expected. Further residue trials are therefore not required.

Residue trials were analysed according to the residue definition for risk assessment in several fruits. The conversion factors varied between 1.04 and 1.60. EFSA is proposing a robust conversion factor of 1.50 based on the residue data on cherries (sweet). This conversion factor is considered consistent with the proportion between myclobutanil and RH-9090 (free and conjugated) observed in the fruits metabolism studies. A tentative conversion factor of 2.0 is proposed for leafy vegetables based on the residue trials performed with witloof (GAP disregarded from this MRL review) reported with an analytical method that covered the residue definition for risk assessment. Finally, for root crops, a robust conversion factor of 2.0 is proposed based on the proportion between myclobutanil and RH-9090 conjugates observed in the metabolism study performed with sugarbeet roots and the residue trials made on sugarbeet root analysed according to the residue definition for risk assessment. Since there are no metabolism studies on pulses and oilseeds, a tentative conversion factor applied to borage seeds and beans (with pods) is based on the conversion factor derived from sugarbeet root (CF = 2), as roots reflected the worst-case scenario for conversion factors.

1.2.2. Magnitude of residues in rotational crops

A field rotational study was assessed by JMPR (FAO, 2014), but was not assessed by the RMS. Myclobutanil was applied at 6 x 140 g a.s./ha to courgettes. Within 2 days after the last application, courgette fruit were harvested and removed from the plots. The remaining plant parts were incorporated into the soil 7–10 days after harvest and then rotational crops (soya bean, radish and wheat) were planted 30 DAT. Rotational crops were sampled ranging between 71 and 258 DAT. Myclobutanil and RH-9090 levels were higher in vegetative matrices (forage, hay and straw) than the respective seed or grain crop matrix. Residues of myclobutanil and RH-9090 in soya bean seed and wheat grains were all below LOQ (0.01 mg/kg). Residues of myclobutanil and RH-9090 occurred up to 0.36 and 0.15 mg/kg in soya bean forage, 0.093 and 0.19 mg/kg in soya bean hay, 0.052 and below 0.01 mg/kg in radish root, 0.044 and 0.12 mg/kg in radish tops, 0.071 and 0.11 mg/kg in wheat forage, 0.18 and 0.63 mg/kg in wheat straw, respectively. The median residue levels of myclobutanil in soybean forage and hay were 0.195 and 0.055 mg/kg; in radish root and tops, the median residue levels were 0.039 and 0.030 mg/kg and in wheat forage and hay the median residue levels were 0.047 and 0.098 mg/kg. Therefore, it can be concluded that significant amounts of myclobutanil and RH-9090 are expected to occur in rotational crops even 258 days after treatment.

The rotational crop field study evaluated by the JMPR was not assessed by the RMS or by any other MS before or during the completeness check. EFSA could not retrieve the full report of the field rotational crop study, but rather only the summary presented by JMPR, and as such it was not possible to fully assess or validate the data and conclusions presented by JMPR. Since previous applications of myclobutanil may cause an impact on the levels of residues in crops that can be grown in rotation, this represents a data gap that will render the consumer risk assessment as tentative only for crops that can be rotated. As residues were still present even 258 days after treatment and did not show a decline (e.g. radish roots), it is not possible for EFSA to suggest adequate mitigation measures such as deriving MRL and risk assessment values that could cover the residue levels of previous applications. As a consequence, a general data gap for crops that can be grown in rotation is identified and the full report of the field rotational crop study presented by JMPR (detailed assessment) should be provided.
Field trials on grapes covering multiple growing seasons (trials conducted in 2010 and 2011) and analysed for TDMs were assessed by the RMS in an addendum to the DAR (Belgium, 2013). Myclobutanil was applied three times at 10 days interval at the nominal rate of 72 g a.s./ha in southern Europe and at 48 g a.s./ha in northern Europe. The third and final application was made 14 days before harvest. Residues of 1,2,4-T and TAA were in most cases below the LOQ (< 0.01 mg/kg). There were positive findings in the control samples probably related to the use of other triazole fungicides on the plots in previous seasons, confirming the widespread presence of TDMs in the environment. Levels of TAA were observed at a maximum of 0.013 mg/kg, while 1,2,4-T was in most cases below 0.01 mg/kg with the exception of one trial where its levels ranged from 0.015-0.026 mg/kg in grape samples. TA and triazole lactic acid (TLA) were found more frequently in both treated and control samples, with highest vales detected at 0.019 mg/kg (TA) and 0.053 mg/kg (TLA). On the basis of the result residues from five vineyard plots treated during two successive years with myclobutanil, no significant or consistent increase of residues – neither of myclobutanil and RH-9090, nor of TDMs – in grapes were observed (Belgium, 2013). The overall application rate used in the trials for the southern zone (216 g a.s./ha) cover the intended use for wine/table grapes GAPs in the southern zone; however, the application rate used in the northern trials (144 g a.s./ha) was less than half the application rate intended for wine/table grapes GAPs for the northern zone. In addition, the presence of TDMs in the control plots indicates that the occurrence of these substances cannot be excluded on permanent crops.

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on studies conducted on apples, bananas, grapes, cherries, plums, currants, strawberry, tomato and hops (EFSA, 2010; Belgium 2014). An overview of all available processing studies is available in Appendix B.1.2.3. Robust processing factors (fully supported by data) could be derived for plums (dried), tomatoes (juice, canned and puree), wine grapes (juice and red mature wine), citrus (juice and pulp), apple (juice and wet pomace) and currants (juice) and bananas (peeled), while limited processing factors (not fully supported by data) were derived for hops (beer), strawberries (jam, canned), cherries (juice), apples (dry pomace) and currants (canned).

Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive appropriate MRL proposals as well as risk assessment values for permanent crops only (pome fruits and stone fruits). For hazelnuts/cobnuts and walnuts, no MRLs could be derived.

Due to the lack of data, EFSA was not able to propose MRLs which would allow considering the potential uptake of myclobutanil from previous applications in crops that may be grown in rotation (see also Section 1.2.2). Therefore, the MRLs proposed for annual crops are tentative only. Furthermore, for the other annual crops for which no GAPs are authorised, specific MRLs covering the potential uptake from previous treatment on other crops were not derived.

Tentative MRLs were also derived for feed crops (e.g. sugar beet tops) in view of the future need to set MRLs in feed items.

2. Residues in livestock

Myclobutanil is authorised for use on apples and sugarbeet that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for cattle, swine and sheep were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in these groups of livestock. It should be noted that residues from rotational crops were not considered in the dietary burden calculations.
2.1. Nature of residues and methods of analysis in livestock

Studies to investigate metabolism in livestock were conducted on lactating goat (Belgium, 2014) and laying hens (Belgium, 2009).

A ruminant metabolism study, performed with lactating goats, was assessed by the RMS (Belgium, 2014). Myclobutanil labelled in the triazole and phenyl rings was administered for five consecutive days at a nominal dose level of 24.2 mg/kg feed and 14.2 mg/kg feed, respectively. Myclobutanil was extensively metabolised in goat and was not detected in milk, kidney, muscle and fat, and was only present in liver at 2.1–6.0% TRR (0.019–0.029 mg/kg). Metabolite RH-9090 was detected at 45–59% TRR in milk (0.02–0.012 mg eq/kg) on day 1 and at 28–49% TRR on day 5 (0.022 to 0.016 eq/kg) in each label, respectively. No other metabolite was present at levels higher than 0.01 mg/kg in milk. In liver, metabolite RH-9090 was present at 15% TRR (0.147 to 0.122 eq/kg) and metabolite RH-9089 was detected at 15% TRR (0.136 mg eq/kg) in the triazole label, whereas RH-9090 conjugates were observed at 43 to 35% TRR (0.395 to 0.169 mg/kg). In kidney, metabolite RH-9090 was present at 14–17% TRR (0.07 to 0.035 mg eq/kg) and metabolite RH-9089 was detected at 13–24% TRR (0.065 to 0.05 mg eq/kg), whereas RH-9090 conjugates were observed at max 44% TRR (0.228 to 0.099 mg eq/kg). In muscle, metabolite RH-9090 was present at 44–80% TRR (0.028 to 0.018 mg eq/kg), and in fat, metabolite RH-9090 was present at 35–39% TRR (0.014 to 0.007 mg eq/kg), while metabolite RH-9089 and RH-9090 conjugates were below 0.01 mg/kg in both muscle and fat. The only metabolite apart from RH-9090 to be detected above 10% TRR was metabolite RH-9089 and only in liver and kidney. However, reanalysis of these extracts in another system or by LC-MS often showed only very low levels of RH-9089 and confirmed that the radioactivity appeared to be additional RH-9090 or conjugates of RH-9090 (Belgium, 2014). Therefore, metabolite RH-9090 appears to be the only metabolite present at relevant levels in all tissues.

Laying hens received daily oral doses of myclobutanil labelled on the phenyl label and metabolites RH-9090/RH-9089 labelled on the triazole ring at a dose level of 110 mg/kg in the feed for seven consecutive days. Total radioactive residues were observed in the liver (0.52 mg eq/kg) and the kidney (0.32 mg eq/kg), while lower residues were found in muscle (0.06 mg eq/kg) and fat (0.02 mg eq/kg). Parent myclobutanil was a main residue in fat (67% TRR), kidney (12% TRR), liver (4.8% TRR), and in muscle (up to 4% TRR). Metabolites RH-9090/RH-9089 and hydroxyl-lactone accounted for 15% TRR in kidney. The major component of the residue in muscle was RH-9089 (61–72% TRR). The major component of the residue in eggs was RH-9090 accounting for 36% TRR. No parent compound was observed in eggs.

The following considerations should be made regarding the residue definition for livestock: the parent compound (myclobutanil) is not a good marker since it is not found in all tissues at significant levels; metabolite RH-9090 is a good marker since it was detected in significant levels in all animal matrices (free and in conjugated forms); the toxicity of metabolites RH-9090 and RH-9089 is considered to be in the same range of toxicity as the parent compound (EFSA, 2010).

Therefore, EFSA is proposing a residue definition for animal commodities for risk assessment and enforcement as follows: free and conjugated forms of RH-9090, expressed as myclobutanil.

In the framework of the peer review, a multi-residue method DGF S19 was reported for the detection of metabolite RH-9090 in matrices of animal origin (milk, eggs, meat, liver and kidney) with a LOQ of 0.01 mg/kg and a single-method DGF ER 58.13 was reported for the detection of metabolite RH-9090 in fat (EFSA, 2010). The EURLs reported screening data indicating that RH-9090 can be enforced in commodities of animal origin with a LOQ of 0.005 mg/kg in meat, eggs and milk, and with a LOQ of 0.01 mg/kg in honey (EURL, 2017). However, extraction efficiency of the methods reported by EFSA and the EURLs was not demonstrated. Therefore, a data gap is identified for analytical methods in animal products according to the proposed residue definition for enforcement.

Storage stability studies demonstrated that myclobutanil and its metabolite RH-9090 are stable in beef liver and muscle for at least 80 days (EFSA, 2010). There was no information on the storage stability in other animal matrices such as kidney, fat and milk, and therefore, a data gap is identified.

2.2. Magnitude of residues in livestock

Feeding studies performed with lactating cows and laying hens were available for this review (Belgium, 2009, 2014).

Lactating cows were fed with 1.6, 4.8 or 16 mg/kg in diet (equivalent to 0.058, 0.17 and 0.58 mg/kg body weight per day based on the default value of 550 kg for the body weight) for 28 days. The highest
dose level is 44 N for dairy ruminant and 39 N for meat ruminant. Residues of myclobutanil and its alcohol metabolite, RH-9090, were not quantifiable (< 0.01 mg/kg) in milk, muscle, fat or kidney even at the high dose level. Residues of RH-9090 were higher than 0.01 mg/kg only in liver (0.015–0.020 mg/kg). Residue levels in milk reached plateau after 2–3 days.

Laying hens were fed with oral daily doses of myclobutanil for 28 consecutive days at nominal dose levels of 1, 3, 10 and 30 mg/kg in diet (equivalent to 0.06, 0.19, 0.6 and 1.9 mg/kg body weight (bw) per day based on the default value of 1.9 kg for the body weight). The highest level is 633 N for poultry. After 7 days, residue levels reached a plateau for eggs. At sacrifice, within 24 h of the last dosing, residue levels were below the respective LOQs in all sampled tissues in the lowest dose tested (equivalent to 20 N for poultry).

MRLs in livestock were derived in compliance with the latest recommendations on this matter (FAO, 2009) and are summarised in Appendix B.2.2. Since the calculated dietary burdens for poultry were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in poultry products is unnecessary and no MRL were derived for these commodities. For other animals (ruminants, swine), significant residues of myclobutanil or its metabolite RH-9090 (free and conjugates) are not expected and therefore MRLs for these commodities can be established at the LOQ. Due to the data gaps for analytical methods and storage stability all MRLs for animal products are considered tentative only. In addition, it should be noted that in rotational crops that are feed items, residues from previous applications of myclobutanil were also not taken into account.

3. Consumer risk assessment

In the framework of this review, only the uses of myclobutanil reported by the RMS in Appendix A were considered; however, the use of myclobutanil was previously also assessed by the JMPR (FAO, 2014). The CXLs, resulting from this assessment by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. To facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs.

It is noted that the metabolism studies were not studied with regard to the two isomers of myclobutanil. Thus, it is not known if either isomer is metabolised or degraded more quickly and to which ratio of isomers consumers and livestock may be exposed. As a consequence, the consumer risk assessment does not take into account the isomers of myclobutanil.

3.1. Consumer risk assessment without consideration of the existing CXLs

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a (tentative) MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). For those commodities where data were insufficient to derive a MRL in Section 1, EFSA considered the existing EU MRL for an indicative calculation. All input values included in the exposure calculations are summarised in Appendix D. The relevant peeling factor was applied to bananas.

The exposure values calculated were compared with the toxicological reference values for myclobutanil derived by EFSA (2010) under Commission Regulation (EC) No 33/2008. The highest chronic exposure was calculated for DE children representing 17.5% of the acceptable daily intake (ADI), and the highest acute exposure was calculated for table grapes representing 34.5% of the acute reference dose (ARID). It should be noted that the potential uptake of myclobutanil and metabolite RH-9090 from previous applications in crops that can be grown in rotation was not taken into account in this consumer risk assessment. Chronic exposure calculations are not considering all potential residues, to which consumers can be exposed; therefore the exposure calculations may be underestimated. Therefore, major uncertainties remain due to the data gaps identified in the previous sections. Although there were major uncertainties identified this indicative exposure calculation did not indicate a risk to consumers.

It is noted by EFSA that the above risk assessment was performed disregarding the possible impact of the isomer ratios due to plant or livestock metabolism. Considering, however, that the isomer ratio of myclobutanil is specified as 50/50 and provided that the racemic mixture is stable then this concern
is covered by the toxicological tests performed (EFSA, 2010); a change of isomer ratios in the residues might, in the worst case situation, lead to a duplication of the toxicological burden of the residues. Since the exposure calculations represent less than 50% of the ADI or ARfD, EFSA concludes that the potential change of isomer ratios in the final residues will not be of concern for the authorised uses reported in the framework of this review. In case future uses of myclobutanil would lead to a higher consumer exposure, further information regarding the impact of plant and livestock metabolism on the isomer ratio might be required.

EFSA emphasises that the above assessment does not take into consideration TDMs. Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA was asked to perform a comprehensive dietary risk assessment for TDMs considering data for several triazole fungicides submitted in the framework of the confirmatory data assessment. However, currently, an overall consumer exposure assessment to relevant TDMs arising from all triazole fungicides could not be concluded on until the outstanding issues and general recommendations highlighted in the assessment are addressed (EFSA, 2018c).

3.2. Consumer risk assessment with consideration of the existing CXLs

The residue definition for enforcement for plants in the EU and CXL is the same (myclobutanil). The residue definitions for risk assessment in the EU and CXL are comparable (sum of myclobutanil, metabolite RH-9090 and its conjugates, expressed as myclobutanil). Conversion factors were applied on a tentative basis to the CXL in the consumer risk assessment.

The residue definition for enforcement for animals in CXLs is not comparable to the residue definition for enforcement proposed by EFSA. Although parent and metabolites are found in tissues of animal metabolism study, no residues of parent compound and metabolites were expected above LOQ on the basis of dietary burden calculation and animal feeding studies (FAO, 2014). Therefore, the CXLs for poultry products were included in the assessment since residues of parent and metabolites are not expected to be present above the LOQ.

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix E and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. An overview of the input values used for this exposure calculation is also provided in Appendix D.

Chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and the exposure values calculated were compared with the toxicological reference values derived for myclobutanil. The CXLs for annual crops were not considered fully supported by data as it was not possible to confirm if these values accommodate the potential uptake of residues of myclobutanil from previous applications. The relevant peeling factor was applied to bananas.

For some commodities, the highest residue level and median residue level from the field rotational crop study were used as input values according to the methodology employed by the JMPR, although this approach was not confirmed by EFSA since a full assessment of the field rotational crop study is needed. The highest chronic exposure was calculated for DE children representing 17.3% of the ADI, and the highest acute exposure was calculated for peppers, representing 61.9% of the ARfD. Considering that the isomer ratio of myclobutanil is specified as 50/50, this would mean that, in a worst case scenario, a change of isomers ratio may lead to a duplication of the toxicological burden of the residues and an exceedance of the ARfD would be observed (123.8% ARfD). Therefore, a refined consumer risk assessment was carried out by EFSA. The value of 61.9% of the ARfD is obtained when using as input value the highest residue calculated for myclobutanil only (2.03 mg/kg) multiplied by the conversion factor for fruits (1.5). However, when the highest residue expressed according to the residue definition for risk assessment is directly used as input value (2.40 mg/kg), the highest acute exposure calculated for peppers represented 48.8% of the ARfD. Therefore, even in a worst case scenario (a change of isomer ratio leading to a duplication of the toxicological burden of the residues), no exceedance of the ARfD would be observed (97.6% ARfD). It is noted that this approach (selection of the highest total residue calculated according to the residue definition for risk assessment as input value for the risk assessment) was already taken by EFSA when preparing an EU position for the Codex Committee on Pesticide Residues (CCPR) meeting where the CXLs for myclobutanil were discussed (EFSA, 2015).

It should be noted that the potential uptake of myclobutanil and metabolite RH-9090 from previous applications in crops that can be grown in rotation was not taken into account in this consumer risk assessment. In addition, chronic exposure calculations are not considering all potential residues to
which consumers can be exposed and as such the exposure calculations may be underestimated. Therefore, major uncertainties remain due to the data gaps identified for a certain number of these CXLs. Although there were major uncertainties identified, this indicative exposure calculation did not indicate a risk to consumers.

It is noted by EFSA that the above risk assessment was performed disregarding the possible impact of the isomer ratios due to plant or livestock metabolism. Considering, however, that the isomer ratio of myclobutanil is specified as 50/50 and provided that the racemic mixture is stable then this concern is covered by the toxicological tests performed (EFSA, 2010); a change of isomer ratios in the residues might, in the worst case situation, lead to a duplication of the toxicological burden of the residues. Since the exposure calculations after refinement represent less than 50% of the ADI or ARfD, EFSA concludes that the potential change of isomer ratios in the final residues will not be of concern for the authorised uses reported in the framework of this review. In case future uses of myclobutanil would lead to a higher consumer exposure, further information regarding the impact of plant and livestock metabolism on the isomer ratio might be required.

EFSA emphasises that the above assessment does not take into consideration TDMs. Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA was asked to perform a comprehensive dietary risk assessment for TDMs considering data for several triazole fungicides submitted in the framework of the confirmatory data assessment. However, currently, an overall consumer exposure assessment to relevant TDMs arising from all triazole fungicides could not be concluded on until the outstanding issues and general recommendations highlighted in the assessment are addressed (EFSA, 2018c).

Conclusions

The metabolism of myclobutanil was assessed in fruits, root crops, cereals and sugar beet tops (tentatively addressing leafy vegetables). For fruits and root crops, a residue definition is proposed for risk assessment: myclobutanil and metabolite RH-9090 free and conjugated, expressed as myclobutanil. For enforcement, the residue definition should be myclobutanil (sum of constituent isomers). For leafy vegetables, pulses and oilseeds and post-harvest treatments the same residue definitions were proposed on a tentative basis. A validated analytical method for enforcement of the proposed residue definition in the four main analytical matrices is available; however, a validated analytical method is missing and is required for hops. The metabolism in rotational crops was found to be similar as the metabolism in primary crops, therefore the same residue definitions apply.

Myclobutanil and metabolite RH-9090 were stable to hydrolysis under standard conditions of pasteurisation, boiling/brewing/baking and sterilisation. Studies investigating the magnitude of residues in several processed commodities of bananas, plums, tomatoes, grapes, apples, currants, cherries, strawberries and hops are available and allowed to derive processing factors.

The available data are considered sufficient to derive appropriate MRL proposals as well as risk assessment values for permanent crops only (pome fruits and stone fruits). For hazelnuts/cobnuts and walnuts no MRLs could be derived. Due to the lack of data, EFSA was not able to propose MRLs which would allow considering the potential uptake of myclobutanil from previous applications in crops that may be grown in rotation. Therefore, the MRLs proposed for annual crops are tentative only. Furthermore, for the other annual crops for which no GAPs are authorised, specific MRLs covering the potential uptake from previous treatment on other crops could not be derived. Tentative MRLs were also derived for feed crops (e.g. sugar beet tops) in view of the future need to set MRLs in feed items.

The dietary burdens of cattle, sheep and swine were found to exceed the trigger value of 0.1 mg/kg DM. The metabolism of myclobutanil was investigated in ruminants (lactating goats) and poultry (laying hens). Feeding studies performed on ruminants (lactating cow) and poultry (laying hens) were also available for this MRL review. The residue definition in livestock for both enforcement and risk assessment is proposed as follows: free and conjugated forms of RH-9090, expressed as myclobutanil. An analytical method for enforcement for milk, eggs, meat, liver and kidney is available (however, a confirmatory method and the extraction efficiency were not reported). The MRLs in commodities of animal origin (cattle, swine and sheep) are proposed to be set at the LOQ as no significant residues of myclobutanil and RH-9090 (free and conjugates) are expected to occur. The MRLs for animal products are tentative as extraction efficiency of the analytical methods was not reported and storage stability studies on kidney, fat and milk are missing. Based on the European uses, no MRLs are needed for poultry products.
Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure was calculated for DE children representing 17.5% of the ADI, and the highest acute exposure was calculated for table grapes representing 34.5% of the ARfD. Although no risk to consumers was identified, the consumer risk assessment for the EU scenario did not take into consideration the potential uptake of myclobutanil and metabolites from previous applications in crops that can be grown in rotation. Therefore, the acute and chronic exposure should be considered as tentative only.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for myclobutanil. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and no exceedances of the ARfD were identified for the existing CXLs. The highest chronic exposure was calculated for DE children representing 17.3% of the ADI, and the highest acute exposure (after refinement) was calculated for peppers representing 48.8% of the ARfD. For some commodities, the highest residue level and median residue level from the field rotational crop study were used as input values according to the methodology employed by the JMPR. It is noted that this approach could not be confirmed by EFSA, since a full assessment of the rotational crop field study is needed.

It is noted by EFSA that the above risk assessment was performed disregarding the possible impact of the isomer ratios due to plant or livestock metabolism. Considering, however, that the isomer ratio of myclobutanil is specified as 50/50 and provided that the racemic mixture is stable then this concern is covered by the toxicological tests performed (EFSA, 2010); a change of isomer ratios in the residues might, in the worst case situation, lead to a duplication of the toxicological burden of the residues. Since the exposure calculations represent less than 50% of the ADI or ARfD, EFSA concludes that the potential change of isomer ratios in the final residues will not be of concern for the authorised uses reported in the framework of this review. In case future uses of myclobutanil would lead to a higher consumer exposure, further information regarding the impact of plant and livestock metabolism on the isomer ratio might be required.

EFSA emphasises that the above assessment does not take into consideration TDMs. Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA was asked to perform a comprehensive dietary risk assessment for TDMs considering data for several triazole fungicides submitted in the framework of this review. However, an overall consumer exposure assessment to relevant TDMs arising from all triazole fungicides could not be concluded on until the outstanding issues and general recommendations highlighted in the assessment are addressed (EFSA et al., 2018c).

**Recommendations**

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 2 footnotes for details).

Significant residues of myclobutanil and its metabolites occurred in the confined rotational crop studies and in the rotational crop field study. Therefore, it is not possible to propose a pre-planting interval that would avoid MRL exceedance in annual crops that can be grown in rotation. Member States should consider that the MRLs for annual crops that are proposed on a tentative basis might not be sufficient to prevent an exceedance due the application of myclobutanil in previous seasons. As a consequence, rotational crop field studies should address the potential uptake of myclobutanil in all type of crops. The MRLs proposed by EFSA do not take into account the potential uptake of myclobutanil from previous applications. Therefore, all tentative MRLs and/or existing EU MRLs related to crops that can be grown in rotation need to be confirmed by the following data:

- A representative rotational crop field study to address the uptake of residues of myclobutanil and metabolites from previous applications (it is noted that a study was reported by JMPR, but a detailed assessment of this study was not available for this review).

Member States where GAPs on annual crops are authorised should provide rotational crop field studies to derive MRLs accommodating the uptake of residues from previous application or should
modify the authorisations with refined mitigation measures to ensure that no residue uptake will occur. As the available data does not allow an assessment of the potential uptake of residues from previous applications, Member States are recommended to withdraw or modify the relevant authorisations at national level.

In addition, some tentative MRLs and/or existing EU MRLs need to be confirmed by the following data:

- A representative study investigating the metabolism in leafy vegetables;
- A representative study investigating the metabolism in pulses and oilseeds;
- A representative study investigating the metabolism in fruits following post-harvest treatment (to cover the important tolerance for bananas);
- Hazelnuts/cobnuts; walnuts: four trials on hazelnuts/cobnuts and walnuts compliant with the southern GAP are required.
- Raspberries (red and yellow): four trials on raspberries (red and yellow) compliant with the indoor GAP are required.
- Blackberries: four additional trials compliant with the northern GAP, three additional trials compliant with the southern GAP and four additional trials compliant with the indoor GAP are still required.
- Gooseberries: four additional trials on currants and gooseberries compliant with the northern GAP and four additional trials compliant with the southern GAP are still required.
- Tomatoes: four additional trials compliant with the indoor GAP and four additional trials compliant with the southern GAP are still required.
- Melons, pumpkins and watermelons: three additional trials compliant with the southern GAP are still required. For melons, four trials compliant with the indoor GAP are still required, and for pumpkins and watermelons, eight trials compliant with the indoor GAP are still required.
- Beans (with pods): five trials on beans (with pods) compliant with the import tolerance GAP are required.
- Borage seeds: four trials on borage seeds compliant with the southern GAP are required.
- Asparagus: four trials on asparagus compliant with the southern GAP are required.
- Lamb’s lettuce/corn salads: four additional trials compliant with the northern and indoor GAP analysed with a method that allows the release of RH-9090 conjugates are required.
- Globe artichokes: four additional trials compliant with the northern and southern GAP analysed with a method that allows the release of RH-9090 conjugates are required.
- Hops: four additional trials compliant with the northern GAP analysed with a method that allows the release of RH-9090 conjugates are required.
- A fully validated analytical method for the determination of myclobutanil in hops is required.
- A confirmatory method for the analytical methods for animal matrices is required.
- A report demonstrating the extraction efficiency of the analytical methods for animal matrices is required.
- A storage stability study on animal matrices (kidney, fat and milk) is required.

It is highlighted that some of the MRLs derived result from a GAP in one climatic zone only or CXL, whereas other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- Additional residue trials supporting the GAPs on cherries (sweet), apricots, peaches, plums, currants, aubergines/eggplants, cucumbers, gherkins and courgettes.

If the above-reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

It is highlighted that the consumer risk assessment for TDMs was not addressed in this review. However, several data gaps which were identified during the peer review (EFSA, 2010; see also European Commission, 2016) were not addressed so far. In the view of a comprehensive dietary risk assessment for TDMs considering data for several triazole fungicides, the following data are still missing:

- Field rotation trials performed with myclobutanil and analysing for TDMs residue levels (data gap relevant for annual crops).
- Residue trials following growing seasons performed with myclobutanil and analysing for TDMs residue levels (data gap relevant for permanent crops).
A minor deficiency was also identified in the assessment but this deficiency is not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data is therefore considered desirable but not essential:

- A storage stability study of metabolite RH-9090 in high acid content matrices.

### Table 2: Summary table

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|-------------------------|----------------------|-----------------------|---------|
| 120060      | Hazelnuts/cobnuts | 0.05* | – | 0.05 | Further consideration needed(a) |
| 120110      | Walnuts | 0.05* | – | 0.05 | Further consideration needed(a) |
| 130010      | Apples | 0.6 | 0.6 | 0.6 | Recommended(b) |
| 130020      | Pears | 0.6 | 0.6 | 0.6 | Recommended(b) |
| 130030      | Quinces | 0.6 | 0.6 | 0.6 | Recommended(b) |
| 130040      | Medlars | 0.6 | 0.6 | 0.6 | Recommended(b) |
| 130050      | Loquats/Japanese medlars | 0.6 | 0.6 | 0.6 | Recommended(b) |
| 140010      | Apricots | 0.3 | 3 | 3 | Recommended(c) |
| 140020      | Cherries (sweet) | 3 | 3 | 3 | Recommended(c) |
| 140030      | Peaches | 0.5 | 3 | 3 | Recommended(b) |
| 140040      | Plums | 2 | 2 | 2 | Recommended(c) |
| 151010      | Table grapes | 1 | 0.9 | 1.5 | Recommended(d) |
| 151020      | Wine grapes | 1 | 0.9 | 1.5 | Recommended(d) |
| 152000      | Strawberries | 1 | 0.8 | 1.5 | Further consideration needed(e) |
| 153010      | Blackberries | 1 | – | 0.8 | Further consideration needed(f) |
| 153030      | Raspberries (red and yellow) | 1 | – | 1 | Further consideration needed(g) |
| 154030      | Currants (black, red and white) | 1 | 0.9 | 0.9 | Further consideration needed(g) |
| 154040      | Gooseberries (green, red and yellow) | 1 | – | 0.8 | Further consideration needed(f) |
| 163020      | Bananas | 2 | – | 3 | Further consideration needed(f) |
| 211000      | Potatoes | 0.06 | 0.06 | 0.06 | Further consideration needed(h) |
| 212010      | Cassava | 0.06 | 0.06 | 0.06 | Further consideration needed(h) |
| 212020      | Sweet potatoes | 0.06 | 0.06 | 0.06 | Further consideration needed(h) |
| 212030      | Yams | 0.06 | 0.06 | 0.06 | Further consideration needed(h) |
| 212040      | Arrowroot | 0.06 | 0.06 | 0.06 | Further consideration needed(h) |
| 213010      | Beetroot | 0.06 | 0.06 | 0.06 | Further consideration needed(h) |
| 213020      | Carrots | 0.2 | 0.06 | 0.06 | Further consideration needed(h) |
| 213030      | Celeriac | 0.06 | 0.06 | 0.06 | Further consideration needed(h) |
| 213040      | Horseradish | 0.2 | 0.06 | 0.06 | Further consideration needed(h) |
| 213050      | Jerusalem artichokes | 0.06 | 0.06 | 0.06 | Further consideration needed(h) |
| 213060      | Parsnips | 0.2 | 0.06 | 0.06 | Further consideration needed(h) |
| 213070      | Parsley root | 0.2 | 0.06 | 0.06 | Further consideration needed(h) |
| 213080      | Radishes | 0.06 | 0.06 | 0.06 | Further consideration needed(h) |
| 213090      | Salsify | 0.06 | 0.06 | 0.06 | Further consideration needed(h) |
| 213100      | Swedes | 0.06 | 0.06 | 0.06 | Further consideration needed(h) |
| 213110      | Turnips | 0.06 | 0.06 | 0.06 | Further consideration needed(h) |
| 220010      | Garlic | 0.06 | 0.06 | 0.06 | Further consideration needed(h) |
| 220020      | Onions | 0.06 | 0.06 | 0.06 | Further consideration needed(h) |
| 220030      | Shallots | 0.06 | 0.06 | 0.06 | Further consideration needed(h) |
| Code number | Commodity                        | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review (mg/kg) | Comment                        |
|-------------|----------------------------------|-------------------------|----------------------|-----------------------------|--------------------------------|
| 220040      | Spring onions                    | 0.06                    | 0.06                 | 0.06                         | Further consideration needed(h) |
| 231010      | Tomatoes                         | 0.3                     | 0.3                  | 0.6                          | Further consideration needed(e) |
| 231020      | Sweet peppers/bell peppers       | 0.5                     | 3                    | 3                            | Further consideration needed(g) |
| 231030      | Aubergines/eggplants              | 0.3                     | –                    | 0.2                          | Further consideration needed(f) |
| 232010      | Cucumbers                        | 0.2                     | 0.2                  | 0.2                          | Further consideration needed(g) |
| 232020      | Gherkins                         | 0.2                     | 0.2                  | 0.2                          | Further consideration needed(g) |
| 232030      | Courgettes                       | 0.2                     | 0.2                  | 0.2                          | Further consideration needed(g) |
| 233010      | Aubergines/eggplants              | 0.2                     | 0.2                  | 0.3                          | Further consideration needed(e) |
| 233020      | Pumpkins                         | 0.2                     | 0.2                  | 0.3                          | Further consideration needed(e) |
| 233030      | Watermelons                      | 0.2                     | 0.2                  | 0.3                          | Further consideration needed(e) |
| 241010      | Broccoli                         | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 241020      | Cauliflower                      | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 242010      | Brussels sprouts                 | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 242020      | Head cabbage                     | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 243010      | Chinese cabbage                  | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 243020      | Kale                             | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 244000      | Kohlrabi                         | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 251010      | Lamb’s lettuces/corn salads       | 5                       | 0.5                  | 9                            | Further consideration needed(c) |
| 251020      | Lettuce                          | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 251030      | Scarole (broad-leaf endive)       | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 251040      | Cress                            | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 251050      | Land cress                       | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 251060      | Rocket, Rucola                   | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 251070      | Red mustard                      | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 251080      | Leaves and sprouts of *Brassica*  | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 252010      | Spinach                          | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 252020      | Purslane                         | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 252030      | Beet leaves (chard)              | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 253000      | Vine leaves (grape leaves)       | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 254000      | Water cress                      | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 255000      | Witloof                          | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 256010      | Chervil                          | 0.05                    | 0.05                 | 0.05                         | Further consideration needed(b) |
| 260010      | Beans (with pods)                | 0.8                     | 0.8                  | 0.8                          | Further consideration needed(i) |
| 270010      | Asparagus                        | 0.02*                   | –                    | 0.02                         | Further consideration needed(s) |
| 270040      | Fennel                           | 0.02*                   | 0.06                 | 0.06                         | Further consideration needed(b) |
| 270050      | Globe artichokes                 | 0.5                     | –                    | 0.8                          | Further consideration needed(d) |
| 270060      | Leek                             | 0.02*                   | 0.06                 | 0.06                         | Further consideration needed(b) |
| 401120      | Borage seeds                     | 0.05*                   | –                    | 0.05                         | Further consideration needed(s) |
| 700000      | Hops                             | 5                       | 5                    | 6                            | Further consideration needed(e) |
| 900010      | Sugar beet roots                 | 0.02*                   | –                    | 0.01*                        | Further consideration needed(f) |
|             | Other commodities of plant origin (annual crops) | – | – | – | Further consideration needed(i) |
|             | Other commodities of plant origin | See Reg. 2016/567 | – | – | Further consideration needed(i) |
### Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment
---|---|---|---|---|---
1011010 | Swine muscle | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1011020 | Swine fat tissue | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1011030 | Swine liver | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1011040 | Swine kidney | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1012010 | Bovine muscle | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1012020 | Bovine fat tissue | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1012030 | Bovine liver | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1012040 | Bovine kidney | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1013010 | Sheep muscle | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1013020 | Sheep fat tissue | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1013030 | Sheep liver | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1013040 | Sheep kidney | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1014010 | Goat muscle | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1014020 | Goat fat tissue | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1014030 | Goat liver | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1014040 | Goat kidney | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1015010 | Equine muscle | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1015020 | Equine fat tissue | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1015030 | Equine liver | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1015040 | Equine kidney | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1016010 | Poultry muscle | 0.01* | 0.01* | 0.01* | Further consideration needed (b)
1016020 | Poultry fat tissue | 0.01* | 0.01* | 0.01* | Further consideration needed (b)
1016030 | Poultry liver | 0.01* | 0.01* | 0.01* | Further consideration needed (b)
1020100 | Cattle milk | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1020200 | Sheep milk | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1020300 | Goat milk | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1020400 | Horse milk | 0.01* | 0.01* | 0.01* | Further consideration needed (e)
1030000 | Birds eggs | 0.01* | 0.01* | 0.01* | Further consideration needed (b)

- Other commodities of animal origin | See Reg. 2016/567 | – | – | Further consideration needed (b)

**MRL**: maximum residue level; **CXL**: codex maximum residue limit.

*: Indicates that the MRL is set at the limit of quantification.

(a): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix E).

(b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix E). The possible impact of TDMs on the validity of the MRL proposal was not considered in the assessment.

(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix E). The possible impact of TDMs on the validity of the MRL proposal was not considered in the assessment.

(d): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix E). The possible impact of TDMs on the validity of the MRL proposal was not considered in the assessment.

(e): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); existing CXL is covered by the tentative MRL (combination E-III in Appendix E).

(f): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).

(g): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the existing residue definition); GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix E).
MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).

GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); existing CXL is covered by the existing EU MRL (combination C-III in Appendix E).

For annual crops for which no GAPs are authorised, MRLs above the LOQ due to the potential uptake from previous application in rotational crops may be needed. However, due to the lack of information on residue levels in rotational crops, no proposal could be derived in this review.

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).

References

Austria, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for myclobutanil, August 2017. Available online: www.efsa.europa.eu

Belgium, 2007. Draft assessment report on the active substance myclobutanil prepared by the rapporteur Member State Belgium in the framework of Council Directive 91/414/EEC, July 2007. Available online: www.efsa.europa.eu

Belgium, 2009. Additional report to the draft assessment report on the active substance myclobutanil prepared by the rapporteur Member State Belgium in the framework of Commission Regulation (EC) No 33/2008, September 2009. Available online: www.efsa.europa.eu

Belgium, 2010. Final addendum to the draft assessment report on the active substance myclobutanil prepared by the rapporteur Member State Belgium in the framework of Commission Regulation (EC) No 33/2008, compiled by EFSA, May 2010. Available online: www.efsa.europa.eu

Belgium, 2013. Myclobutanil. Addendum to Volume 3 B7 of the DAR. Confirmatory data. July 2013. Available online: www.efsa.europa.eu

Belgium, 2014. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for myclobutanil, June 2014. Available online: www.efsa.europa.eu

Belgium, 2017a. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing MRLs for myclobutanil, August 2017. Available online: www.efsa.europa.eu

Belgium, 2017b. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing MRLs for myclobutanil - clarifications, October 2017. Available online: www.efsa.europa.eu

Czech Republic, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for myclobutanil, August 2017. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs. EFSA Journal 2007;5(3):32r, 1141 pp. https://doi.org/10.2903/j.efsa.2007.32r

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance myclobutanil. EFSA Journal 2010;8(10):1682, 83 pp. https://doi.org/10.2903/j.efsa.2009.298r

EFSA (European Food Safety Authority), 2015. Scientific support for preparing an EU position in the 46th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2015;13(7):4208, 178 pp. https://doi.org/10.2903/j.efsa.2015

EFSA (European Food Safety Authority), 2018a. Completeness check report on the review of the existing MRLs of myclobutanil prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 18 June 2018. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2018b. Member States consultation report on the review of the existing MRLs of myclobutanil prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 18 June 2018. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), Brancato A, Brocca D, Carrasco Cabrera L, Chiusolo A, Civitella C, Court Marques D, Crivellente F, De Lentdecker C, Erdos Z, Ferreira L, Goumenou M, Greco L, Istaçe F, Jarrah S, Kardasi D, Leuschner R, Medina P, Mineo D, Miron I, Molnar T, Nave S, Parra Morte JM, Pedersen R, Reich H, Sacchi A, Santos M, Staneck A, Sturma J, Tarazona J, Terron A, Theobald A, Vagenende B and Villamar-Bouza L, 2018c. Conclusion on the peer review of the pesticide risk assessment for the triazole derivative metabolites in light of confirmatory data. EFSA Journal 2018;16(7):5376, 74 pp. https://doi.org/10.2903/j.efsa.2018.5376

EURL (European Union Reference Laboratories for Pesticide Residues), 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Analytical methods validated by the EURLs and overall capability of official laboratories to be considered for the review of the existing MRLs for myclobutanil. July 2017. Available online: www.efsa.europa.eu

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. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

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

European Commission, 1997f. Appendix H. 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-rev. 2, 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 on 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, 2016. Review report for the active substance myclobutanil. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 23 November 2010 in view of the inclusion of myclobutanil in Annex I of Council Directive 91/414/EEC. SANCO/13039/2010-Final rev.1, 29 January 2016.

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.

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

FAO (Food and Agriculture Organization of the United Nations), 2014. Myclobutanil. In: Pesticide residues in food – 2014. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticides Residues. FAO Plant Production and Protection Paper 221.

France, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for myclobutanil, August 2017. Available online: www.efsa.europa.eu

Germany, 2017a. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for myclobutanil, August 2017. Available online: www.efsa.europa.eu

Germany, 2017b. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for myclobutanil, October 2017. Available online: www.efsa.europa.eu

Greece, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for myclobutanil, August 2017, updated during clarifications. Available online: www.efsa.europa.eu

Hungary, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for myclobutanil, August 2017. Available online: www.efsa.europa.eu

Italy, 2017. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for myclobutanil, August 2017. 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, 04 September 2013.

Spain, 2017a. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for myclobutanil, August 2017. Available online: www.efsa.europa.eu

Spain, 2017b. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing EU MRLs for myclobutanil, October 2017. Available online: www.efsa.europa.eu
Abbreviations

1,2,4-T 1,2,4-triazole
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
CAC Codex Alimentarius Commission
CAS Chemical Abstract Service
CCPR Codex Committee on Pesticide Residues
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
DT90 period required for 90% dissipation (define method of estimation)
dw dry weight
EC emulsifiable concentrate
eq residue expressed as a.s. equivalent
EURLs European Union Reference Laboratories for Pesticide Residues (former CRLs)
EW emulsion, oil in water
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
GC-ECD gas chromatography with electron capture detector
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardization
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
LC-MS/MS liquid chromatography with tandem mass spectrometry
LOQ limit of quantification
Mo monitoring
MRL maximum residue level
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
QuPPe Quick Polar Pesticides Method
Rmax 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
| Acronym | Term                                      |
|---------|-------------------------------------------|
| SEU     | southern European Union                   |
| SMILES  | simplified molecular-input line-entry system |
| STMR    | supervised trials median residue          |
| TA      | triazole alanine                          |
| TAA     | triazole acetic acid                      |
| TLA     | triazole lactic acid                      |
| TRR     | total radioactive residue                  |
| WHO     | World Health Organization                  |
### Appendix A – Summary of authorised uses considered for the review of MRLs

#### A.1. Authorised uses in northern outdoor EU

| Crop and/or situation | NEU, SEU, MS or country | F G or I | Pests or Group of pests controlled | Preparation | Method kind | Range of growth stages & season | Number min-max | Interval between application (min) | Water L/ha min-max | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|--------|------------------------------------|-------------|------------|---------------------------------|----------------|-----------------------------------|-------------------|-------------------------------|------------|---------|
| Apples                | UK, CZ                  | F      |                                    | EW 200 g/L  | Foliar treatment – spraying | 10 – 7          | – –                              | – –              | 90 g a.i./ha                  | 14         |         |
| Pears                 | IE, UK, CZ              | F      |                                    | EW 60 g/L   | Foliar treatment – spraying | 4 to 10         | 7 – –                            | – –              | 90 g a.i./ha                  | 14         |         |
| Quinces               | UK                      | F      |                                    | EW 200 g/L  | Foliar treatment – spraying | 10 – 7          | – –                              | – –              | 90 g a.i./ha                  | 14         |         |
| Medlars               | FR                      | F      | Antrachnoses                        | EW 45 g/L   | Foliar treatment – spraying | 51 – 80         | 3 – 10                           | – –              | 85 g a.i./ha                  | 14         |         |
| Loquats               | FR                      | F      | Antrachnoses                        | EW 45 g/L   | Foliar treatment – spraying | 51 – 80         | 3 – 10                           | – –              | 85 g a.i./ha                  | 14         |         |
| Apricots              | CZ                      | F      | Apiognomonia erythrostrona, Monilinia laxa | EW 200 g/L | Foliar treatment – spraying | 3                | – –                              | – –              | 140 g a.i./ha                | 14         |         |
| Cherries              | UK                      | F      | Monilinia                           | EW 200 g/L  | Foliar treatment – spraying | 60 – 69         | 3 – 10                           | – –              | 140 g a.i./ha                | 21         |         |
| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|--------------------------|-----------------------------------|-------------|-------------|-----------------------------|---------|
|                       |                          |                                   |             |             |                             |         |
| Peaches               | DE                       | Gumspot of stone fruit (*Stigmina carpophila*), scab (*Venturia* spp.); brown fruit rot of Japan (*Monilinia fructigena*); powdery mildew of rose (*Sphaerotheca pannosa*) | EW 200 g/L | Foliar treatment – spraying | 2 | 10 | 135 g a.i./ha | 14 | Different GAP is authorised in CZ (3 x 140 g a.s./ha; PHI 21 days). No residue trials are available to support this GAP |
| Plums                 | UK                       | Rust                              | EW 200 g/L | Foliar treatment – spraying | 5 | 11 | 110 g a.i./ha | 3 | |
| Table grapes          | SK, AT, DE, UK           | Powdery mildew                    | EW 200 g/L | Foliar treatment – spraying | 4 | 10 | 48 g a.i./ha | 14 | |
| Wine grapes           | UK, HU                   | Powdery mildew                    | EW 200 g/L | Foliar treatment – spraying | 8 | 10 | 48 g a.i./ha | 14 | |
| Strawberries          | UK                       | Powdery mildew                    | EW 200 g/L | Foliar treatment – spraying | 6 | 7 | 90 g a.i./ha | 3 | |
| Blackberries         | BE                       | Powdery mildew                    | EW 200 g/L | Foliar treatment – spraying | 13–87 | 1–3 | 90 g a.i./ha | 14 | |
| Currants             | IE, UK                   | Powdery mildew                    | EW 60 g/L  | Foliar treatment – spraying | 6 | 7 | 90 g a.i./ha | 14 | |
| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | Remark |
|-----------------------|-------------------------|-----------------------------------|-------------|-------------|-------------------------------|--------|
|                       |                         |                                   | Type(b) | Conc. a.s. | Method kind | Range of growth stages & season | Number min-max | Interval between application (min) | g a.s./hL min-max | g a.s./ha min-max | PHI (days) (d) |
| Gooseberries          | IE, UK                  | Powdery mildew                   | EW       | 60 g/L     | Foliar treatment – spraying  | 6 – 7   | –                  | –                  | 90 g a.i./ha   | 15         |
| Courgettes            | BE                      | EW                                | 200 g/L  |            | Foliar treatment – spraying  | 13–87   | 4–11               | –                  | 30 g a.i./ha   | 3          |
| Lamb’s lettuces       | BE                      | EW                                | 200 g/L  |            | Foliar treatment – spraying  | 2–10    | –                  | –                  | 60 g a.i./ha   | 14         |
| Globe artichokes      | UK                      | Powdery mildew                   | EW       | 200 g/L    | Foliar treatment – spraying  | 3–14    | –                  | –                  | 80 g a.i./ha   | 3          |
| Hops                  | BE                      | Powdery mildew                   | EW       | 200 g/L    | Foliar treatment – spraying  | 4–10    | –                  | –                  | 320 g a.i./ha  | 14         |

(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 uses in southern outdoor EU

| Crop and/or situation | NEU, SEU, MS or country | F G or T | Pests or Group of pests controlled | Preparation Type(a) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | g a.s./ha min-max | Water L/ha min-max | g a.s./ha min-max | PHI (days) | Remarks |
|-----------------------|-------------------------|----------|-----------------------------------|---------------------|------------|------------|--------------------------|----------------|------------------------|----------------|----------------|----------------|------------|---------|
| Hazelnuts EL F        | Powdery mildew          | EW 45 g/L | Foliar treatment – spraying       | 55–80               | 3          | 8          | –                        | –              | –                      | 75 g a.i./ha    | –                      | 60          | A different GAP (3 × 85 g a.s./ha; PHI 14 days) is authorised in FR and EL. No residue trials are available to support this GAP. |
| Walnuts EL F          | Powdery mildew          | EW 45 g/L | Foliar treatment – spraying       | 55–80               | 3          | 8          | –                        | –              | –                      | 75 g a.i./ha    | –                      | 60          | |
| Apples IT F           | EC 42 g/L               | Foliar treatment – spraying       | 2–4                    | 8          | –          | –                        | –              | –                      | 75 g a.i./ha    | –                      | 14          | |
| Pears IT F            | EC 43 g/L               | Foliar treatment – spraying       | 2–4                    | 8          | –          | –                        | –              | –                      | 75 g a.i./ha    | –                      | 14          | A different GAP (3 × 85 g a.s./ha; PHI 14 days) is authorised in FR and EL. No residue trials are available to support this GAP. |
| Quinces FR F          | Oidium                  | EW 45 g/L | Foliar treatment – spraying       | 51–80               | 3          | 10         | –                        | –              | –                      | 85 g a.i./ha    | –                      | 14          | |
| Medlars FR F          | Oidium                  | EW 45 g/L | Foliar treatment – spraying       | 51–80               | 3          | 10         | –                        | –              | –                      | 85 g a.i./ha    | –                      | 14          | |
| Crop and/or situation | NEU, SEU, MS or country | F G or I(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|------------|------------------------------------|-------------|------------|-------------------------------|------------|---------|
| Loquats               | FR                      | F          | Oidium                             | EW 45 g/L  | Foliar treatment – spraying  | 51-80  | 3 10 – – | 85 g a.i./ha | 14 |
| Apricots              | ES                      | F          | Powdery mildew                    | EC 125 g/L | Foliar treatment – spraying | 1-5   | 10 – – | 7.5 g a.i./L | 7 |
| Cherries              | ES                      | F          | Powdery mildew                    | EC 125 g/L | Foliar treatment – spraying | 1-5   | 10 – – | 7.5 g a.i./L | 7 |
| Peaches               | ES                      | F          | Powdery mildew                    | EC 125 g/L | Foliar treatment – spraying | 1-5   | 10 – – | 7.5 g a.i./L | 7 |
| Plums                 | ES                      | F          | Powdery mildew                    | EC 125 g/L | Foliar treatment – spraying | 1-5   | 10 – – | 7.5 g a.i./L | 7 |
| Table grapes          | EL                      | F          | Oidium                             | EC 240 g/L | Foliar treatment – spraying | 68    | 2 10 – – | 75 g a.i./ha | 15 |
| Wine grapes           | EL                      | F          | Oidium                             | EC 240 g/L | Foliar treatment – spraying | 68    | 2 10 – – | 75 g a.i./ha | 15 |
| Strawberries          | ES                      | F          | EC 125 g/L                         | Foliar treatment – spraying | 1-4   | 7 – – | 75 g a.i./ha | 3 |
| Blackberries          | FR                      | F          | EW 45 g/L                          | Foliar treatment – spraying | 13-88 | 3 10 – – | 60 g a.i./ha | 14 |

(a) A different GAP is authorised in ES (3 × 72 g a.s./ha; PHI 14 days). No residue trials are available to support this GAP.
| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------------------|-----------------------------------|-------------|-------------|-----------------------------|-----------|---------|
|                       |                          |                                   |             | Method kind | Range of growth stages & season (c) | Number min-max | Interval between application (min) | g a.s./hL min-max | g a.s./ha min-max |
| Gooseberries          | ES                       | F                                 | EC 125 g/L  | Foliar treatment – spraying | 3–7 | – | – | 59 g a.i./ha |
| Tomatoes              | EL, IT                   | F                                 | EC 125 g/L  | Foliar treatment – spraying | 3–7 | – | – | 75 g a.i./ha |
| Sweet peppers         | ES                       | F                                 | EC 125 g/L  | Foliar treatment – spraying | 1–4 | 10 | – | 10 g a.i./hL |
| Aubergines            | IT                       | F Powdery mildew                  | EC 125 g/L  | Foliar treatment – spraying | 1–3 | 7 | – | 75 g a.i./ha |
| Cucumbers             | ES                       | F                                 | EC 125 g/L  | Foliar treatment – spraying | 1–4 | 10 | – | 10 g a.i./hL |
| Gherkins              | ES                       | F                                 | EC 125 g/L  | Foliar treatment – spraying | 1–4 | 10 | – | 10 g a.i./hL |
| Courgettes            | ES                       | F                                 | EC 125 g/L  | Foliar treatment – spraying | 1–4 | 10 | – | 10 g a.i./hL |
| Melons                | IT                       | F                                 | EC 240 g/L  | Foliar treatment – spraying | 2–4 | 8 | – | 70 g a.i./ha |
| Pumpkins              | IT                       | F                                 | EC 240 g/L  | Foliar treatment – spraying | 2–4 | 8 | – | 70 g a.i./ha |
| Watermelons           | IT                       | F                                 | EC 240 g/L  | Foliar treatment – spraying | 2–4 | 8 | – | 70 g a.i./ha |
| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|----------------------|------------------------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
|                      |                        |                                   | Type(b)     | Conc. a.s. | Method kind                   |            |         |
| Asparagus            | ES F                   | EC 125 g/L Foliar treatment – spraying |            | 5          | 10                             | 10 g a.i./hL | n.a.    |
|                      |                        |                                   |             |            |                               |            |         |
|                      |                        |                                   |             |            |                               |            |         |
|                      |                        |                                   |             |            |                               |            |         |
| Globe artichokes     | IT F                   | EC 240 g/L Foliar treatment – spraying |            | 2-4        | 8                              | 70 g a.i./ha | 3       |
|                      |                        |                                   |             |            |                               |            |         |
|                      |                        |                                   |             |            |                               |            |         |
| Borage seeds         | ES F                   | EC 125 g/L Foliar treatment – spraying |            | 2-3        | 10                             | 100 g a.i./ha | 15      |
|                      |                        |                                   |             |            |                               |            |         |
| Sugar beets          | ES F                   | EC 125 g/L Foliar treatment – spraying |            | 1          | –                              | 63 g a.i./ha | 28      |

(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 the EU

| Crop and/or situation | NEU, SEU, MS or country | Pegs or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|-----------------------------------|-------------|-------------|---------------------------|------------|---------|
|                       | F G or T(a)             |                                    |             |             |                           |            |         |
| Strawberries          | FR, HU, BE              | I                                  | Foliar      | Treatment – spraying | 3   –   7   –   –   60 g a.i./ha | 3          |         |
| Blackberries          | UK                      | I                                  | EW          | 200 g/L     | Foliar treatment – spraying | 6   –   7   –   –   9 g a.i./hL | 3          |         |
| Raspberries           | UK                      | I                                  | EW          | 200 g/L     | Foliar treatment – spraying | 6   –   7   –   –   9 g a.i./hL | 3          |         |
| Tomatoes              | DE                      | I                                  | EW          | 200 g/L     | Foliar treatment – spraying | 5   –   –   100 g a.i./ha | 3          |         |
| Sweet peppers         | IT, ES, EL, HU          | I                                  | EW          | 200 g/L     | Foliar treatment – spraying | 3   –   –   75 g a.i./ha | 3          |         |
| Aubergines            | IT, EL, ES, FR          | I                                  | EW          | 200 g/L     | Foliar treatment – spraying | 3   –   –   75 g a.i./ha | 3          |         |
| Cucumbers             | DE                      | I                                  | EW          | 200 g/L     | Foliar treatment – spraying | 5   –   –   80 g a.i./ha | 3          |         |
| Gherkins              | FR, HU                  | I                                  | EW          | 200 g/L     | Foliar treatment – spraying | 13–88 1–3 7   –   –   75 g a.i./ha | 3          |         |
| Courgettes            | EL, FR, HU              | I                                  | EW          | 200 g/L     | Foliar treatment – spraying | 13–88 1–3 7   –   –   75 g a.i./ha | 3          |         |
| Melons                | EL                      | I                                  | Powdery     | Mildew      | EW 25 g/L                | Foliar treatment – spraying | 13–88 3   8   –   –   75 g a.i./ha | 3          |         |
| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|-----------------------------------|-------------|-------------|-------------------------------|------------|---------|
|                       |                         |                                   | Type(b)     | Conc. a.s.  | Range of growth stages & season(c) | Number min-max | Interval between application (min) | g a.s./hL min-max | Water L/ha min-max | g a.s./ha min-max | (d) |
| Pumpkins              | EL                      | I                                 | SC          | 62.5 g/L   | Foliar treatment – spraying    | 4-5        | 10                  | –               | –                 | 60 g a.i./ha    | 7   |
| Watermelons           | EL                      | I                                 | SC          | 63.5 g/L   | Foliar treatment – spraying    | 4-5        | 10                  | –               | –                 | 60 g a.i./ha    | 7   |
| Lamb’s lettuces       | BE                      | I                                 | EW          | 200 g/L    | Foliar treatment – spraying    | 2          | 10                  | –               | –                 | 60 g a.i./ha    | 14  |

(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.4. Authorised import tolerances in the EU

| Crop and/or situation | NEU, SEU, MS or country | F G or I<sup>(a)</sup> | Pests or Group of pests controlled | Preparation Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages & season<sup>(c)</sup> | Number min-max | Interval between application (min) | Application rate per treatment g a.s./ha min-max | Water L/ha min-max | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|-------------------------|------------------------|-----------------------------------|-----------------------------|-----------|------------|-----------------------------------|--------------|-------------------------------|-------------------------------|----------------|------------|---------|
| Bananas | USA & Costa Rica | I | | Post-harvest treatment – dipping | 81 | 1 | – | – | 400 g a.i./ton | n.a. | Either spraying to run-off or running under cascade |
| Beans (with pods) | Kenya & Senegal | F | | Foliar treatment – spraying | 1–2 | – | – | 100 g a.i./ha | 3 |

a.s.: active substance; a.i.: active ingredient; EW: emulsion, oil in water; EC: emulsifiable concentrate; NEU: northern European Union; SEU: southern European Union; MS: Member State; GAP: Good Agricultural Practice; SC: suspension concentrate.

<sup>(a)</sup> Outdoor or field use (F), greenhouse application (G) or indoor application (I).

<sup>(b)</sup> CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.

<sup>(c)</sup> 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.

<sup>(d)</sup> 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)\(^{(a)}\) | Sampling (DAT) |
|----------------------------------|-------------|---------|--------------------------|---------------|
| Fruit crops                      | Apples      | Foliar, 10 x 240 g a.s./ha at 7 days interval between applications | Fruits: 7, 16 |
|                                  | Grapes      | Foliar, 5 x 50 g a.s./ha at 7 days interval between applications | Fruits: 7, 16 |
| Root crops                       | Sugar beet  | Foliar, 1 x 150 g a.s./ha or 1 x 1,500 g a.s./ha | Roots: 0, 15, 30, Tops: 0, 15, 30 |
| Cereals                          | Wheat       | Foliar, 1 x 240 g a.s./ha | Grain, straw: at maturity after application done at BBCH 30-45 |

Sources: EFSA (2010); Belgium (2014)

(a): Studies with myclobutanil labelled on the phenyl and triazole labels.

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) |
|-------------------------------------|-------------|---------|----------------|-----------|
| Root/tuber crops                    | Radish; turnip | Bare soil, 3 x 224 g a.s./ha (phenyl label) | 30, 120, 210, 365 |
|                                     | Radish      | Bare soil, 1 x 360 g a.s./ha (triazole label) | 30, 120, 365 |
| Leafy crops                         | Lettuce; mustard | Bare soil, 3 x 224 g a.s./ha (phenyl label) | 30, 120, 210, 365 |
|                                     | Lettuce     | Bare soil, 1 x 360 g a.s./ha (triazole label) | 30, 120, 365 |
| Pulses and oilseeds                | Soybean     | Bare soil, 3 x 224 g a.s./ha (phenyl label) | 30, 120, 210, 365 |
| Cereal (small grain)               | Dwarf sorghum; wheat | Bare soil, 3 x 224 g a.s./ha (phenyl label) | 30, 120, 210, 365 |
|                                     | Wheat       | Bare soil, 1 x 360 g a.s./ha (triazole label) | 30, 120, 365 |

Source: Belgium (2013)

| Processed commodities (hydrolysis study) | Conditions | Investigated?\(^{(a)}\) |
|-------------------------------------------|------------|--------------------------|
|                                           | 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 |

Sources: EFSA (2010); Belgium (2014)

(a): Studies performed with myclobutanil and metabolite RH-9090.
Can a general residue definition be proposed for primary crops? | No
---|---
Rotational crop and primary crop metabolism similar? | Yes
Residue pattern in processed commodities similar to residue pattern in raw commodities? | Yes
Plant residue definition for monitoring (RD-Mo) | Myclobutanil (sum of constituent isomers) (tentative for leafy vegetables, pulses and oilseeds and post-harvest treatment)
Plant residue definition for risk assessment (RD-RA) | sum Of myclobutanil and metabolite RH-9090 (free and conjugated), expressed as myclobutanil (tentative for leafy vegetables, pulses and oilseeds and post-harvest treatment)
Conversion factor (monitoring to risk assessment) | Fruits: 1.5
| Roots: 2.0
| Leafy vegetables: 2.0 (tentative)
| Pulses and oilseeds: 2 (tentative, based on the highest CF that was derived)
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) | LC-MS/MS (EURL, 2017):
| Method EN 15662:2008 validated in high water and high acid and dry content commodities
| Method EN 15662:2008 validated in high oil content commodities
| LOQ: 0.01 mg/kg (for high water and high acid content commodities even a LOQ of 0.005 mg/kg would be feasible)
| LC-MS/MS (EFSA, 2010):
| Method EN 15662:2008
| LOQ: 0.025 mg/kg (high water and high acid content commodities)
| LC-MS/MS (France, 2017):
| LOQ: 0.01 mg/kg
| Validated in high water, high acid and high oil and dry content commodities
| Extraction efficiency not demonstrated

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; LC-MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.

### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability (months) |
|---|---|---|---|---|
| High water content | Tomato<sup>(a)</sup> Cucumber<sup>(a)</sup> | –10 | 36 |
| High acid content | Grapes<sup>(b)</sup> | –15 | 24 |
| High oil content | Almond<sup>(a)</sup> | –10 | 18 |

Source: EFSA (2010)

<sup>(a)</sup> Stability demonstrated for myclobutanil and metabolite RH-9090.

<sup>(b)</sup> Stability demonstrated for myclobutanil only.
B.1.2. Magnitude of residues in plants

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

| Crop                      | Region(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HRMo (mg/kg)(b) | STMRMo (mg/kg)(c) | CF     |
|---------------------------|-----------|------------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|-----------------|-------------------|--------|
| Hazelnuts/cobnuts         | SEU       | Mo: –                                                                                         | No data available                           | –                     | –               | –                 | 1.5(d) |
| Walnuts                   |           | RA: –                                                                                         |                                             |                       |                 |                   |        |
| Apples                    | NEU       | Mo: 0.13; 0.19; 0.12; 0.38; 0.15; 0.14; 0.12; 0.09; 0.089; 0.145; 0.113; 0.348; 0.16; 0.16; 0.06; 0.18 | Trials on apples with 12 applications deemed acceptable (Belgium, 2009). Extrapolation to pears, quinces, medlars and loquats is applicable. MRL_{OECD} = 0.51 | 0.5       | 0.38             | 0.14              | 1.5(d) |
| Pears                     |           | RA: 0.14; 0.21; 0.14; 0.40; 0.17; 0.15; 0.15; 0.10; 0.099; 0.155; 0.123; 0.358; 0.18; 0.18; 0.07; 0.21 |                                             |                       |                 |                   |        |
| Quinces                   |           |                                                                                               |                                             |                       |                 |                   |        |
| Medlars                   |           |                                                                                               |                                             |                       |                 |                   |        |
| Loquats/Japanese medlars   | SEU       | Mo: 0.129; 0.10; 0.04; 0.05; 0.04; 0.18; 0.11; 0.09; 0.03; 0.14; 0.09; 0.13; 0.10; 0.06; 0.07; 0.07; 0.05 | Trials on apples with 4–6 applications deemed acceptable (Belgium, 2009). Extrapolation to pears, quinces, medlars and loquats is applicable. MRL_{OECD} = 0.26 | 0.3       | 0.18             | 0.09              | 1.5(d) |
| Apricots                  | NEU       | No data available                                                                               |                                             |                       |                 |                   |        |
|                           | SEU       | Mo: 0.026; 0.05; 0.15; 0.098; 0.13; 0.04; 0.06; 0.11                                                                                               | Combined data set of trial on apricots (first 2 trials) and peaches compliant with GAP (Belgium, 2014). MRL_{OECD} = 0.26 | 0.3       | 0.15             | 0.08              | 1.5(d) |
|                           |           | RA: 0.04; 0.06; 0.178; 0.146; 0.041; 0.08; 0.14                                                                                               |                                             |                       |                 |                   |        |
| Cherries (sweet)          | NEU       | Mo: 0.08; 3 × < 0.01; 2 × 0.02; 2 × 0.03; 0.054                                                                 | Trials made with 3 × 135 g a.s./ha, but intervals of 3–17 days and then 35–72 days are used on a tentative basis (Belgium, 2014). MRL_{OECD} = 0.12 | 0.15      | 0.08             | 0.02              | 1.5(d) |
|                           |           | RA: < 0.089; < 0.01; < 0.03; < 0.02; < 0.04; < 0.04; < 0.03; < 0.02; 0.794                                                                 |                                             |                       |                 |                   |        |
|                           | SEU       | No data available                                                                               |                                             |                       |                 |                   |        |
| Crop                  | Region(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_{M0} (mg/kg)(b) | STMR_{M0} (mg/kg)(c) | CF  |
|----------------------|-----------|-----------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|-------------------|---------------------|-----|
| Peaches              | NEU       | Mo: –                                                                                          | No data available                           | –                    | –                 | –                   | –   |
|                      | SEU       | Mo: 0.026; 0.05; 0.15; 0.098; 0.13; 0.04; 0.06; 0.11; RA: 0.04; 0.06; 0.178; 0.146; 0.041; 0.08; 0.14 | Combined data set of trial on apricots (first 2 trials) and peaches compliant with GAP (Belgium, 2014). MR_{OECD} = 0.26 | 0.3                  | 0.15              | 0.08                | 1.5(d) |
| Plums                | NEU       | Mo: 0.20; 0.10; 0.13; 0.08; 0.05; 0.04; 0.11; 0.09; 0.64; 0.12; 0.43; 0.05                  | Trials performed at 80–130 g a.s./ha (first 8 trials) or 22.5 g/hl (4 last trials) are used on a tentative basis (Belgium, 2014). Analytical method does not cover residue definition for risk assessment (no release of RH-9090 conjugates). MR_{OECD} = 0.9 | 0.9                  | 0.64              | 0.11                | 1.5(d) |
|                      | SEU       | Mo: 0.05; 0.08; 0.09; 0.14; 0.28                                                                 | Trials compliant with GAP (Belgium, 2014). MR_{OECD} = 0.49 R_{max} = 0.51 | 0.6                  | 0.28              | 0.09                | 1.5(d) |
| Table grapes/Wine grapes | NEU | Mo: 0.03; 0.66; 0.10; 0.28; 0.34; 1.09; 0.29; 0.41; 0.34; 0.28; 0.47; 0.27; 0.25; 0.21; 0.07; 0.07; 0.14; 0.08; 0.07; 0.08 | Trials with 4–8 applications (Belgium, 2014; France, 2017). MR_{OECD} = 1.28 | 1.5                  | 1.09              | 0.26                | 1.5(d) |
|                      | SEU       | Mo: < 0.01; 0.01; 0.06; 0.08; 0.14; 0.17; 0.18; 0.28                                                                 | Trials compliant with GAP (Greece, 2017). Extrapolation to wine grapes is applicable. MR_{OECD} = 0.49 | 0.5                  | 0.28              | 0.11                | 1.5(d) |
| Crop | Region<sup>(a)</sup> | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR_<sub>M0</sub> (mg/kg)<sup>(b)</sup> | STMR_<sub>M0</sub> (mg/kg)<sup>(c)</sup> | CF |
|------|-----------------|-------------------------------------------------|-----------------------------------------------|----------------------|------------------------|------------------------|----|
| Strawberries | NEU | **Mo**: 2 × 0.08; 0.19; 2 × 0.20; 0.22; 0.48; 0.69 | Trials compliant with GAP (Belgium, 2014). MRL<sub>OECD</sub> = 1.11 | 1.5 (tentative)<sup>(h)</sup> | 0.69 | 0.20 | 1.5<sup>(d)</sup> |
| | SEU | **Mo**: 0.05; 0.07; 0.14; 0.18; 0.22; 0.26 | Trials compliant with GAP (Belgium, 2014). SEU data set is sufficient to confirm that NEU GAP is more critical. MRL<sub>OECD</sub> = 0.48 | 0.5 (tentative)<sup>(h)</sup> | 0.26 | 0.16 | 1.5<sup>(d)</sup> |
| | EU | **Mo**: 0.13; 0.16; 0.18; 0.19; 0.20; 0.24; 0.37; 0.46 | Overdosed trials are considered on a tentative basis (France, 2017; Greece, 2017). Indoor data set is sufficient to confirm that NEU GAP is more critical. MRL<sub>OECD</sub> = 0.72 | 0.8 (tentative)<sup>(h)</sup> | 0.46 | 0.20 | 1.5<sup>(d)</sup> |
| Blackberries | NEU | **Mo**: 0.43; 0.30; 0.31; 0.26; 0.126; 0.199; 0.158 | Trials on raspberries conducted with 6 × 18 g a.s./hL (approximately 90 g a.s./ha) at 11–17 days interval (Belgium, 2014) are considered on a tentative basis. Extrapolation to currants (black, red and white), blackberries and gooseberries (green, red and yellow) is applicable. GAP authorised only for blackberries. MRL<sub>OECD</sub> = 0.76 | 0.8 (tentative)<sup>(g),(h)</sup> | 0.43 | 0.26 | 1.5<sup>(d)</sup> |
| Raspberry (red and yellow) | SEU | **Mo**: 0.07 | Trial on red currant compliant with GAP (France, 2017). GAP authorised only for blackberries. | – | – | – | – |
| | EU | – | No data available | – | – | – | – |
| Crop                  | Region | 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) | STMR_{Mo} (mg/kg) | CF  |
|----------------------|--------|---------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|----------------------|----------------|------------------|-----|
| Currants (black, red and white) | NEU    | **Mo**: 0.43; 0.30; 0.31; 0.26; 0.126; 0.199; 0.158<br>**RA**: –                                                                 | Trials on raspberries conducted with 6 × 18 g a.s./hl (approximately 90 g a.s./ha) at 11–17 days interval (Belgium, 2014) are considered on a tentative basis. Extrapolation to currants (black, red and white) and gooseberries (green, red and yellow) is applicable. MRL_{OECD} = 0.76 | 0.8 (tentative)(g),(h) | 0.43           | 0.26             | 1.5(d) |
| Gooseberries (green, red and yellow) | SEU    | No data available. GAP authorised only for gooseberries. | | | | | |
| Bananas              | USA, Costa Rica | **Mo**: 0.048; 0.271; 0.284; 0.58; 0.84; 0.90; 1.04; 1.25; 1.32; 1.34; 1.57; 1.61<br>**RA**: – | First five values were corrected for pulp/peel ratio (assuming 65% pulp and 35% peel and total weight 150 g) (Belgium, 2014). MRL_{OECD} = 3.03 | 3 (tentative)(i) | 1.61           | 0.97             | 1.5(d) |
| Tomatoes             | SEU    | **Mo**: < 0.01; 2 × 0.02; 0.07<br>**RA**: –                                                                 | Trials compliant with GAP (Italy, 2017). Extrapolation to aubergines/eggplants is applicable. MRL_{OECD} = 0.14 R_{max} =0.17 | 0.2 (tentative)(g),(h) | 0.07           | 0.02             | 1.5(d) |
|                      | EU     | **Mo**: 0.04; 0.05; 2 × 0.18<br>**RA**: –                                                                 | Trials with 6 trials of ca 100 g a.s./ha instead of 5 applications are deemed acceptable (Belgium, 2014). GAP for tomatoes only. MRL_{OECD} = 0.6 | 0.6 (tentative)(g),(h) | 0.18           | 0.12             | 1.5(d) |
| Aubergines/eggplants | SEU    | **Mo**: < 0.01; 2 × 0.02; 0.07<br>**RA**: –                                                                 | Direct extrapolation from tomatoes SEU. MRL_{OECD} = 0.14 R_{max} =0.17 | 0.2 (tentative)(g),(h) | 0.07           | 0.02             | 1.5(d) |
|                      | EU     | **Mo**: 0.02; 0.03; 0.04; 0.06; 0.06; 0.07; 0.08; 0.09<br>**RA**: –                                                                      | Trials on tomatoes compliant with GAP (Belgium, 2014). Extrapolation to aubergines is applicable. MRL_{OECD} = 0.2 | 0.2 (tentative)(h) | 0.09           | 0.06             | 1.5(d) |
| Crop                | Region<sup>(a)</sup> | 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)<sup>(b)</sup> | STMR<sub>Mo</sub> (mg/kg)<sup>(c)</sup> | CF |
|---------------------|-----------------------|---------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|-------------------------------|---------------------------------|----|
| Sweet peppers/bell peppers | SEU      | Mo: 0.11; 0.14; 0.15; 0.16; 0.17; 0.28; 0.44<br>Ra: – | Trials performed with 6 applications instead of 4 deemed acceptable (Belgium, 2014). $MRL_{OECD} = 0.66$ | 0.7<br>(tentative)<sup>(h)</sup> | 0.44 | 0.16 | 1.5<sup>(d)</sup> |
|                     | EU        | Mo: 0.02; 0.04; 0.07; 0.10; 0.11; 0.12; 0.13; 0.29<br>Ra: – | Trials compliant with GAP (Italy, 2017). $MRL_{OECD} = 0.44$ | 0.5<br>(tentative)<sup>(h)</sup> | 0.29 | 0.11 | 1.5<sup>(d)</sup> |
| Cucumbers           | SEU      | Mo: – | No data available | – | – | – | – |
|                     | EU        | Mo: 0.020; 0.03; 0.038; 0.04; 0.043; 0.06<br>Ra: – | Trials on cucumbers with 6–8 applications of ca 100 g a.s./ha are used on a tentative basis (Belgium, 2014). $MRL_{OECD} = 0.15$ | 0.15<br>(tentative)<sup>(g),(h)</sup> | 0.06 | 0.04 | 1.5<sup>(d)</sup> |
| Gherkins Courgettes | NEU      | Mo: – | No data available. GAP authorised for courgettes only | – | – | – | – |
|                     | SEU      | Mo: – | No data available | – | – | – | – |
|                     | EU        | Mo: < 0.01; 0.02; 2 × 0.03<br>Ra: – | Trials on cucumbers (3) and courgettes (1) compliant with GAP (Italy, 2017). Extrapolation to gherkins is applicable. $MRL_{OECD} = 0.06$ $R_{max} = 0.07$ | 0.08<br>(tentative)<sup>(g),(h)</sup> | 0.03 | 0.03 | 1.5<sup>(d)</sup> |
| Crop                   | Region | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations)                                                                 | MRL proposals (mg/kg) | $\text{HR}_{\text{Mo}}$ (mg/kg) | $\text{STMR}_{\text{Mo}}$ (mg/kg) | CF |
|-----------------------|--------|---------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|----------------------|---------------------------------|----------------------------------|----|
| Melons                | SEU    | **Mo**: 0.139; 0.079; 0.027; 0.04; 0.02<br>**RA**: 0.140; 0.080; 0.040; 0.0425 | Trials on melons done with 3 applications instead of 4 are considered on a tentative basis (Belgium, 2014). Extrapolation to pumpkins and watermelons is applicable. $\text{MRL}_{\text{OECD}} = 0.26$ | 0.3 (tentative)<sup>(g),(h)</sup> | 0.14                            | 0.04                             | 1.5<sup>(d)</sup> |
|                       | EU     | **Mo**: 0.01; 0.01; 0.01; 0.01; 0.01; 0.02; 0.04<br>**RA**: – | First 4 trials at PHI 7 days instead of PHI 3 days are considered on a tentative basis. Four last trials compliant with GAP (Greece, 2017). $\text{MRL}_{\text{OECD}} = 0.06$ | 0.06 (tentative)<sup>(g),(h)</sup> | 0.04                            | 0.01                             | 1.5<sup>(d)</sup> |
| Pumpkins<br>Watermelons | SEU    | **Mo**: 0.139; 0.079; 0.027; 0.04; 0.02<br>**RA**: – | Direct extrapolation from melons SEU GAP. $\text{MRL}_{\text{OECD}} = 0.26$ | 0.3 (tentative)<sup>(g),(h)</sup> | 0.14                            | 0.04                             | 1.5<sup>(d)</sup> |
|                       | EU     | **Mo**: 0.02; 0.02; 0.04<br>**RA**: 0.0225; 0.0225; 0.0425 | Overdosed trials on melons are considered on a tentative basis (Belgium, 2014). Extrapolation to pumpkins and watermelons is applicable | – | – | – | – |
| Lamb’s lettuces/<br>corn salads | NEU   | **Mo**: 0.055; 0.28<br>**RA**: – | Trials performed on lamb’s lettuce compliant with GAP (Belgium, 2014). Analytical method does not cover residue definition for risk assessment (no release of RH-9090 conjugates) | – | – | – | – |
|                       | EU     | **Mo**: 0.10; 0.865; 1.38; 3.47<br>**RA**: – | Trials performed on lamb’s lettuce compliant with GAP (Belgium, 2014). Analytical method does not cover residue definition for risk assessment (no release of RH-9090 conjugates). $\text{MRL}_{\text{OECD}} = 7.23$<br>\(\text{R}_{\text{max}} = 8.88\) | 9 (tentative)<sup>(g),(h),(i)</sup> | 3.47                            | 1.12                             | 2.0<sup>(e)</sup> |
| Beans (with pods)     | Kenya, Senegal | **Mo**: 0.05; 0.08; 0.18<br>**RA**: – | Trials compliant with GAP. Only myclobutanil was measured. (Belgium, 2014). | – | – | – | 2.0<sup>(e)</sup> |
| Crop                  | Region | Region(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) | STMR_{Mo} (mg/kg) | CF |
|----------------------|--------|-----------|---------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|----------------------|----------------|------------------|----|
| Asparagus            | SEU    | –         | Treatment after harvesting not expected to result in measurable residues in a crop harvested the following year. Trials are needed to confirm a no-residue situation. |                                                                                                             | –                    | –              | –                | –  |
| Globe artichokes     | NEU    | Mo: 0.22; 0.23; 0.27 RA: – | Trials performed on globe artichokes at 6 × 75–80 g a.s./ha at 10–12 days interval are considered on a tentative basis (Belgium, 2014). Analytical method does not cover residue definition for risk assessment (no release of RH-9090 conjugates). MRL_{OECD} = 0.72 | 0.8 (tentative)(g),(h),(i) | 0.27 | 0.23 | 2.0(e) |
|                      | SEU    | Mo: 0.16; 0.2 RA: – | Two trials performed on globe artichokes at 6 × 78–85 g a.s./ha at 7–10 days interval are considered on a tentative basis (Belgium, 2014). Analytical method does not cover residue definition for risk assessment (no release of RH-9090 conjugates) | –                                                                                                             | –                    | –              | –                | –  |
| Borage seeds         | SEU    | –         | No data available                                                                                              |                                                                                                             | –                    | –              | –                | –  |
| Hops                 | NEU    | Mo: 0.50; 0.63; 0.73; 1.06; 1.14; 1.54; 1.8; 3.5 RA: – | Combined data set of trials with 4 × 180–308 g a.s./ha and 2 trials with 6 × 300 g a.s./ha (last two values) are considered on a tentative basis (Belgium, 2014). Analytical method does not cover residue definition for risk assessment (no release of RH-9090 conjugates). MRL_{OECD} = 5.25 | 6 (tentative)(g),(h),(i),(k) | 3.50 | 1.10 | 2.0(e) |
| Crop                  | Region(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 |
|----------------------|-----------|---------------------------------------------------------------------------------|---------------------------------------------|-----------------------|----------------|----------------|------|
| Sugar beet roots     | SEU       | Mo: $4 \times < 0.01$<br>RA: $4 \times < 0.02$<br><br>Trials with two applications at 20–21 days interval are considered acceptable (Belgium, 2014).<br>MRL_{OECD} = 0.01 | 0.01*<br>(tentative)(h) | < 0.01 | < 0.01 | 2.0(i) |
| Sugar beet tops      | SEU       | Mo: $0.011; 0.022; 0.035; 0.093$<br>RA: $0.029; 0.027; 0.015; 0.030$<br><br>Trials with two applications instead of one at 20–21 days interval are considered acceptable (Belgium, 2014).<br>MRL_{OECD} = 0.19<br>R_{\text{max}} = 0.23 | 0.3<br>(tentative)(h) | 0.09 | 0.03 | 2.0(e) |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; Mo: monitoring; RA: risk assessment; a.s.: active substance.<br>

*: Indicates that the MRL is proposed at the limit of quantification.<br>
(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.<br>
(b): Highest residue according to the residue definition for monitoring.<br>
(c): Residue levels relevant to the supported GAPs.<br>
(d): Conversion factor derived from residue trials on cherries (sweet) analysed according to the residue definition for risk assessment (CF = 1.5) were applied to all fruit commodities.<br>
(e): Conversion factor derived from residue trials on witloof (from a GAP disregarded from the MRL review) analysed according to the residue definition for risk assessment (CF = 2.0) was applied on a tentative basis to leafy vegetables. This conversion factor (CF = 2) was applied to pulses and oilseed on a tentative basis.<br>
(f): Conversion factor derived from residue trials on sugar beet roots analysed according to the residue definition for risk assessment (CF = 2.0) were applied to root crops.<br>
(g): MRL is tentative because residue trials compliant with GAP are needed.<br>
(h): MRL is tentative because field rotational crop trials are needed to confirm the uptake and level of residues from previous applications in crops that can be rotated.<br>
(i): MRL is tentative because a metabolism study on leafy vegetables is needed.<br>
(j): MRL is tentative because a metabolism study on fruits (post-harvest) is needed.<br>
(k): MRL is tentative because analytical methods for hops are needed.
B.1.2.2. Residues in succeeding crops

| Confined rotational crop study (quantitative aspect) | Phenyl label: Myclobutanil levels were lower than 0.01 mg/kg in all crops except in lettuce (0.013 mg eq/kg, 30 DAT), sorghum stover (0.019 mg eq/kg, 30 DAT), soya bean forage (0.027 mg eq/kg) and radish tops (0.014 mg eq/kg, 120 DAT). Levels of RH-9090 were higher than 0.01 mg/kg only in sorghum forage and soybean straw 30 DAT. Triazole label: Up to 120 DAT, there were significant levels of myclobutanil and of RH-9090 in all crops except wheat grain. At 365 DAT, significant residues of myclobutanil were only in radish roots (0.023 mg eq/kg) and of RH-9090 in wheat hay (0.046 mg eq/kg). |
|---|---|
| Field rotational crop study | Significant residues were detected in radish roots, soya bean forage and straw and wheat forage and straw up to 258 DAT. A general data gap for crops that can be grown in rotation is identified and the full report of the field rotational crop study (detailed assessment) should be provided. |

Source: Belgium (2013)
Source: FAO (2014)

eq: residue expressed as a.s. equivalent; DAT: days after treatment.

B.1.2.3. Processing factors

| Processed commodity | Number of studies(a) | Processing factor (PF) | CF<sub>r</sub>(b) |
|---|---|---|---|
| **Robust processing factors (sufficiently supported by data)** | | | |
| Bananas/peeled | 11 | Individual values: 0.03, 0.03, 0.08, 0.11, 0.13, 0.13, 0.16, 0.19, 0.21, 0.23, 0.24 | Median PF: 0.13 | |
| Plums/prunes (dried) | 4 | 0.98, 2.10, 2.92, 3.15 | 2.51 | 1.33 |
| Tomatoes/juice | 4 | 0.033, 0.20, 0.25, 1.0 | 0.23 | < 1.23 |
| Tomatoes/peeled and canned (preserves) | 4 | 0.2, 0.25, 0.33, 0.5 | 0.29 | < 1.23 |
| Tomatoes/paste (puree) | 4 | 0.8, 1.0, 2.0, 3.0 | 1.5 | < 1.04 |
| Citrus/juice | 4 | 0.07, 0.09; 0.10; 0.10 | 0.01 | – |
| Citrus/pulp | 4 | < 0.01; < 0.01; < 0.01; < 0.01 | < 0.01 | – |
| Wine grapes/juice | 3 | 0.156, 0.205, 0.219 | 0.21 | 1.12 |
| Wine grapes/red mature wine | 3 | 0.098, 0.117, 0.170 | 0.12 | 1.23 |
| Apple/juice | 4 | 0.106, 0.117, 0.125, 0.165 | 0.12 | 1.35 |
| Apple/wet pomace | 4 | 0.55, 0.646, 2.87, 3.07 | 1.76 | 3.69 |
| Currants/juice | 3 | < 0.01; 0.039; 0.071 | 0.04 | 5.73 |
| **Indicative processing factors (limited data set)** | | | |
| Hops/beer | 2 | 0.03, 0.11 | 0.07 | < 1.05 |
| Strawberries/jam | 2 | 0.5, 0.5 | 0.5 | < 1.23 |
| Strawberries/canned | 2 | 0.75, 0.875 | 0.81 | < 1.15 |
| Cherries/juice | 2 | 0.3, 0.91 | 0.6 | < 2.02 |
| Apples/dry pomace | 2 | 11.76, 12.37 | 12.1 | 1.05 |
| Currants/preserves (canned) | 1 | 0.2 | 0.2 | 6.56 |

(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 (Belgium, 2014).
### B.2. Residues in livestock

| Relevant groups | Dietary burden expressed in mg/kg bw per day | Most critical diet\(^{(a)}\) | Most critical commodity\(^{(a)}\) | Trigger exceeded (Y/N) |
|-----------------|---------------------------------------------|-----------------------------|----------------------------------|------------------------|
| **Cattle**      |                                             |                             |                                  |                        |
| (all diets)     | 0.0123 0.0182                               | Cattle (dairy)              | Apple, pomace, wet               | Yes                    |
| (dairy only)    | 0.0118 0.0182                               | Cattle (dairy)              | Apple, pomace, wet               | Yes                    |
| **Sheep**       |                                             |                             |                                  |                        |
| (all diets)     | 0.0119 0.0167                               | Sheep (lamb)                | Apple, pomace, wet               | Yes                    |
| (ewe only)      | 0.0094 0.0131                               | Sheep (ram/ewe)             | Apple, pomace, wet               | Yes                    |
| **Swine**       |                                             |                             |                                  |                        |
| (all diets)     | 0.0025 0.0038                               | Swine (breeding)            | Beet, sugar, tops                | Yes                    |
| **Poultry**     |                                             |                             |                                  |                        |
| (all diets)     | 0.0008 0.0028                               | Poultry (layer)             | Beet, sugar, tops                | No                     |
| (layer only)    | 0.0008 0.0028                               | Poultry (layer)             | Beet, sugar, tops                | No                     |

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

| Livestock (available studies) | Animal \(^{(a)}\)     | Dose (mg/kg bw per day) | Duration (days) | N rate/comment                                      |
|-------------------------------|-----------------------|-------------------------|-----------------|-----------------------------------------------------|
| Laying hen                   | 6.9                   | 7                       | > 2000N (compared to poultry) |
| Lactating goat \(^{(b)}\)    | 0.4–0.7               | 5                       | 22–38N (compared to cattle) |

\(a\): Study conducted with myclobutanil and metabolites RH-9090 and RH-9089 (TZ-labelling; ratio of metabolites 82:18 w/w).
\(b\): Study conducted with myclobutanil only.
### Time needed to reach a plateau concentration in milk and eggs (days)

- **Milk**: 2–3 days
- **Eggs**: 7 days

### Metabolism in rat and ruminant similar (Yes/No)
- Yes

### Animal residue definition for monitoring (RD-Mo)
- Free and conjugated forms of RH-9090, expressed as myclobutanil

### Animal residue definition for risk assessment (RD-RA)
- Free and conjugated forms of RH-9090, expressed as myclobutanil

### Conversion factor (monitoring to risk assessment)
- Not applicable

### Fat soluble residues (Yes/No)
- No

### Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

#### Multimethod DGF S19/GC-ECD (EFSA, 2010):
- LOQ: 0.01 mg/kg (milk, eggs, meat, kidney, liver)
- Confirmatory method missing
- ILV available
- Extraction efficiency not reported.

#### Single method DGF ER 58.13/GC-ECD (EFSA, 2010):
- LOQ: 0.01 mg/kg (fat)
- Confirmatory method missing
- ILV available
- Extraction efficiency not reported.

#### LC-MS/MS (EURL, 2017):
- Validation screening data with LOQ of 0.005 mg/kg in meat, eggs, milk, and LOQ of 0.01 mg/kg in honey
- Extraction efficiency not demonstrated.

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bw: body weight; GC-ECD: gas chromatography with electron capture detector; LOQ: limit of quantification; ILV: independent laboratory validation.

#### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability (Days) |
|------------------------------------|--------|-----------|--------|------------------|
| Beef Muscle                        | Beef   | Muscle    | −10    | 80               |
| Beef Liver                         | Beef   | Liver     | −10    | 80               |
| Beef Kidney                        | Beef   | Kidney    | −      | −                |
| Beef Fat                           | Beef   | Fat       | −      | −                |
| Dairy Fat                          | Dairy  | Fat       | −      | −                |
| Dairy Milk                         | Dairy  | Milk      | −      | −                |

(a): Stability demonstrated for myclobutanil and metabolite RH-9090.  
Source: EFSA (2010)
## B.2.2. Magnitude of residues in livestock

### B.2.2.1. Summary of the residue data from livestock feeding studies

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N (mg/kg) | MRL proposal (mg/kg) |
|------------------|---------------------------------------------|-------------------------------|----------------------|
|                  | Mean | Highest | STMR\(^{(a)}\) | HR\(^{(b)}\) |
| **Cattle (all diets)** – Closest feeding level (0.058 mg/kg bw per day; 3 N rate)\(^{(c)}\) | | | |
| Muscle           | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01* (tentative) |
| Fat              | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01* (tentative) |
| Liver            | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01* (tentative) |
| Kidney           | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01* (tentative) |
| **Cattle (dairy only)** – Closest feeding level (0.058 mg/kg bw per day; 3 N rate)\(^{(c)}\) | | | |
| Milk\(^{(d)}\)   | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01* (tentative) |
| **Sheep (all diets)**\(^{(e)}\) – Closest feeding level (0.058 mg/kg bw per day; 3 N rate)\(^{(c)}\) | | | |
| Muscle           | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01* (tentative) |
| Fat              | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01* (tentative) |
| Liver            | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01* (tentative) |
| Kidney           | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01* (tentative) |
| **Sheep (dairy only)**\(^{(e)}\) – Closest feeding level (0.058 mg/kg bw per day; 4 N rate)\(^{(c)}\) | | | |
| Milk\(^{(d)}\)   | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01* (tentative) |
| **Swine**\(^{(e)}\) – Closest feeding level (0.058 mg/kg bw; 15 N rate)\(^{(c)}\) | | | |
| Muscle           | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01* (tentative) |
| Fat              | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01* (tentative) |
| Liver            | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01* (tentative) |
| Kidney           | < 0.01 | < 0.01 | 0.01 | 0.01 | 0.01* (tentative) |
| **Poultry (all diets)** – Dietary burden is below the trigger value, no MRLs are needed | | | |
| Muscle           | n.a. | n.a. | n.a. | n.a. | – |
| Fat              | n.a. | n.a. | n.a. | n.a. | – |
| Liver            | n.a. | n.a. | n.a. | n.a. | – |
| **Poultry (layer only)** – Dietary burden is below the trigger value, no MRLs are needed | | | |
| Egg              | n.a. | n.a. | n.a. | n.a. | – |

MRL: maximum residue level; bw: body weight; n.a.: not applicable; n.r.: not reported.

\(^{(a)}\): As the mean residue levels were not reported for tissues and eggs (minor deficiency), the mean residue level for milk and the highest residue levels for eggs and tissues were recalculated at the 1N rate for the median dietary burden.

\(^{(b)}\): The mean residue level in milk and the highest residue levels in eggs and tissues were recalculated at the 1N rate for the maximum dietary burden.

\(^{(c)}\): Closest feeding level and N dose rate related to the maximum dietary burden.

\(^{(d)}\): Highest residue level from day 1 to day 28 (daily mean of 3 cows).

\(^{*}\): Indicates that the MRL is proposed at the limit of quantification.

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(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.
(f): MRLs for animal products are tentative due to uncertainties regarding the lack of analytical methods and stability studies in animal matrices.

B.3. Consumer risk assessment

B.3.1. Consumer risk assessment without consideration of the existing CXLs

| ADI | 0.025 mg/kg bw per day (EFSA, 2010) |
|-----|----------------------------------|
| Highest IEDI, according to EFSA PRIMO | 17.5% ADI (DE, child) |
| Assumptions made for the calculations | The calculation is based on the median residue levels in the raw agricultural commodities. For those commodities where data were insufficient to derive a MRL, EFSA considered the existing EU MRL for an indicative calculation. The possible uptake of myclobutanil in crops that can be rotated from previous applications was not taken into consideration. Peeling factor (PF = 0.13) was applied to bananas. Conversion factors were applied to fruits and roots (fully supported by data) and to other crops (on a tentative basis). The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation. |

| ARfD | 0.31 mg/kg bw (EFSA, 2010) |
|------|---------------------------|
| Highest IESTI, according to EFSA PRIMO | 34.5% ARfD (table grapes) |
| Assumptions made for the calculations | The calculation is based on the highest residue levels in the raw agricultural commodities. The possible uptake of myclobutanil in crops that can be rotated from previous applications was not taken into consideration. Peeling factor (PF = 0.13) was applied to bananas. Conversion factors were applied to fruits and roots (fully supported by data) and to other crops (on a tentative basis). For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. |

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMO: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; ARfD: acute reference dose; IESTI: international estimated short-term intake.

B.3.2. Consumer risk assessment with consideration of the existing CXLs

| ADI | 0.025 mg/kg bw per day (EFSA, 2010) |
|-----|----------------------------------|
| Highest IEDI, according to EFSA PRIMO | 17.3% ADI (DE, child) |
| Assumptions made for the calculations | The calculation is based on the median residue levels in the raw agricultural commodities. For those commodities having a CXL higher than the EU MRL proposal, median residue levels applied in the EU scenario were replaced by the median residue levels derived by JMPR. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. For some commodities (roots and leafy vegetables including Brassicas), the median residue level in the rotational crop field study derived by JMPR were used as input value. It is noted that this is a tentative approach and that the values were not confirmed by EFSA (full assessment of the rotational crop field study is needed). Peeling factor (PF = 0.13) was applied to bananas. Conversion factors were applied on a tentative basis. The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation. |

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ARfD 0.31 mg/kg bw (EFSA, 2010)

Highest IESTI, according to EFSA PRIMo

Scenario 1: 61.9% ARfD (peppers); 35.3% ARfD (peaches)
Scenario 2: 48.8% (peppers)

Assumptions made for the calculations

Scenario 1: The calculation is based on the highest residue levels in the raw agricultural commodities. For some commodities (roots and leafy vegetables including Brassicas), the highest residue levels detected in the rotational field study derived by JMPR were used as input value. It is noted that this is a tentative approach and that the values derived by JMPR were not confirmed by EFSA (full assessment of the rotational crop field study is needed). Peeling factor (PF = 0.13) was applied to bananas. Conversion factors were applied on a tentative basis. For peppers, the highest residue calculated by JMPR for myclobutanil only (2.03 mg/kg) multiplied by the worst case tentative conversion factor for fruits (1.5) is used. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation.

Scenario 2 (refined risk assessment): The calculation is based on the highest residue levels in the raw agricultural commodities. For some commodities (roots and leafy vegetables including brassicas), the highest residue levels detected in the rotational field study derived by JMPR were used as input value. It is noted that this is a tentative approach and that the values derived by JMPR were not confirmed by EFSA (full assessment of the rotational crop field study is needed). Peeling factor (PF = 0.13) was applied to bananas. Conversion factors were applied on a tentative basis. For peppers, the highest residue derived by JMPR according to the residue definition for risk assessment (2.40 mg/kg) is used. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation.

B.4. Proposed MRLs

| Code number | Commodity            | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment               |
|-------------|----------------------|-------------------------|----------------------|-----------------------|-----------------------|
|             | **Enforcement residue definition (existing):** myclobutanil |                         |                      |                       |                       |
|             | **Enforcement residue definition (proposed):** myclobutanil (sum of constituent isomers) |                         |                      |                       |                       |
| 120060      | Hazelnuts/cobnuts    | 0.05*                   | –                    | 0.05                  | Further consideration needed(a) |
| 120110      | Walnuts              | 0.05*                   | –                    | 0.05                  | Further consideration needed(a) |
| 130010      | Apples               | 0.6                     | 0.6                  | 0.6                   | Recommended(b)        |
| 130020      | Pears                | 0.6                     | 0.6                  | 0.6                   | Recommended(b)        |
| 130030      | Quinces              | 0.6                     | 0.6                  | 0.6                   | Recommended(b)        |
| 130040      | Medlars              | 0.6                     | 0.6                  | 0.6                   | Recommended(b)        |
| 130050      | Loquats/Japanese medlars | 0.6                     | 0.6                  | 0.6                   | Recommended(b)        |
| 140010      | Apricots             | 0.3                     | 3                    | 3                     | Recommended(c)        |
| 140020      | Cherries (sweet)     | 3                       | 3                    | 3                     | Recommended(c)        |
| 140030      | Peaches              | 0.5                     | 3                    | 3                     | Recommended(b)        |
| 140040      | Plums                | 2                       | 2                    | 2                     | Recommended(c)        |
| 151010      | Table grapes         | 1                       | 0.9                  | 1.5                   | Recommended(d)        |
| 151020      | Wine grapes          | 1                       | 0.9                  | 1.5                   | Recommended(d)        |
| 152000      | Strawberries         | 1                       | 0.8                  | 1.5                   | Further consideration needed(e) |
| 153010      | Blackberries         | 1                       | –                    | 0.8                   | Further consideration needed(f) |
| 153030      | Raspberries (red and yellow) | 1                       | –                    | 1                     | Further consideration needed(a) |
| Code number | Commodity                                      | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review MRL (mg/kg) | Comment                |
|-------------|-----------------------------------------------|-------------------------|---------------------|----------------------------------|------------------------|
| 154030      | Currants (black, red and white)               | 1                       | 0.9                 | 0.9                              | Further consideration  |
| 154040      | Gooseberries (green, red and yellow)          | 1                       | –                   | 0.8                              | Further consideration  |
| 163020      | Bananas                                       | 2                       | –                   | 3                                | Further consideration  |
| 211000      | Potatoes                                      | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 212010      | Cassava                                       | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 212020      | Sweet potatoes                                | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 212030      | Yams                                          | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 212040      | Arrowroot                                     | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 213010      | Beetroot                                      | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 213020      | Carrots                                       | 0.2                     | 0.06                | 0.06                             | Further consideration  |
| 213030      | Celeriac                                      | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 213040      | Horseradish                                   | 0.2                     | 0.06                | 0.06                             | Further consideration  |
| 213050      | Jerusalem artichokes                          | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 213060      | Parsnips                                      | 0.2                     | 0.06                | 0.06                             | Further consideration  |
| 213070      | Parsley root                                  | 0.2                     | 0.06                | 0.06                             | Further consideration  |
| 213080      | Radishes                                      | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 213090      | Salsify                                       | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 213100      | Sweeds                                        | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 213110      | Turnips                                       | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 220010      | Garlic                                        | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 220020      | Onions                                        | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 220030      | Shallots                                      | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 220040      | Spring onions                                 | 0.06                    | 0.06                | 0.06                             | Further consideration  |
| 231010      | Tomatoes                                      | 0.3                     | 0.3                 | 0.6                              | Further consideration  |
| 231020      | Sweet peppers/bell peppers                   | 0.5                     | 3                   | 3                                | Further consideration  |
| 231030      | Aubergines/eggplants                          | 0.3                     | –                   | 0.2                              | Further consideration  |
| 232010      | Cucumbers                                     | 0.2                     | 0.2                 | 0.2                              | Further consideration  |
| 232020      | Gherkins                                      | 0.2                     | 0.2                 | 0.2                              | Further consideration  |
| 232030      | Courgettes                                    | 0.2                     | 0.2                 | 0.2                              | Further consideration  |
| 233010      | Melons                                        | 0.2                     | 0.2                 | 0.3                              | Further consideration  |
| 233020      | Pumpkins                                      | 0.2                     | 0.2                 | 0.3                              | Further consideration  |
| 233030      | Watermelons                                   | 0.2                     | 0.2                 | 0.3                              | Further consideration  |
| 241010      | Broccoli                                      | 0.05                    | 0.05                | 0.05                             | Further consideration  |
| 241020      | Cauliflower                                   | 0.05                    | 0.05                | 0.05                             | Further consideration  |
| 242010      | Brussels sprouts                              | 0.05                    | 0.05                | 0.05                             | Further consideration  |
| 242020      | Head cabbage                                  | 0.05                    | 0.05                | 0.05                             | Further consideration  |
| 243010      | Chinese cabbage                               | 0.05                    | 0.05                | 0.05                             | Further consideration  |
| 243020      | Kale                                           | 0.05                    | 0.05                | 0.05                             | Further consideration  |
| 244000      | Kohlrabi                                       | 0.05                    | 0.05                | 0.05                             | Further consideration  |
| 251010      | Lamb’s lettuces/corn salads                    | 5                       | 0.5                 | 9                                | Further consideration  |
| 251020      | Lettuce                                       | 0.05                    | 0.05                | 0.05                             | Further consideration  |
| 251030      | Scarole (broad-leaf endive)                   | 0.05                    | 0.05                | 0.05                             | Further consideration  |
| 251040      | Cress                                          | 0.05                    | 0.05                | 0.05                             | Further consideration  |
| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|------------------------|---------------------|-----------------------|---------|
| 251050      | Land cress | 0.05                   | 0.05                | Further consideration needed |
| 251060      | Rocket, Rucola | 0.05               | 0.05                | Further consideration needed |
| 251070      | Red mustard | 0.05                  | 0.05                | Further consideration needed |
| 251080      | Leaves and sprouts of *Brassica* spp. | 0.05          | 0.05                | Further consideration needed |
| 252010      | Spinach    | 0.05                   | 0.05                | Further consideration needed |
| 252020      | Purslane   | 0.05                   | 0.05                | Further consideration needed |
| 252030      | Beet leaves (chard) | 0.05             | 0.05                | Further consideration needed |
| 253000      | Vine leaves (grape leaves) | 0.05        | 0.05                | Further consideration needed |
| 254000      | Water cress | 0.05                   | 0.05                | Further consideration needed |
| 255000      | Witloof    | 0.05                   | 0.05                | Further consideration needed |
| 256010      | Chervil    | 0.05                   | 0.05                | Further consideration needed |
| 260010      | Beans (with pods) | 0.8              | 0.8                 | Further consideration needed |
| 270010      | Asparagus  | 0.02*                  | –                   | Further consideration needed |
| 270040      | Fennel     | 0.02*                  | 0.06                | Further consideration needed |
| 270050      | Globe artichokes | 0.5             | 0.8                 | Further consideration needed |
| 270060      | Leek       | 0.02*                  | 0.06                | Further consideration needed |
| 401120      | Borage seeds | 0.05*           | –                   | Further consideration needed |
| 700000      | Hops       | 5                      | 6                   | Further consideration needed |
| 900010      | Sugar beet roots | 0.02*         | –                   | Further consideration needed |
| –           | Other commodities of plant origin (annual crops) | See Reg. 2016/567 | –                   | Further consideration needed |
| –           | Other commodities of plant origin | See Reg. 2016/567 | –                   | Further consideration needed |

Enforcement residue definition (existing): not available
Enforcement residue definition (proposed): free and conjugated forms of RH-9090, expressed as myclobutanil

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------|------------------------|---------------------|-----------------------|---------|
| 1011010     | Swine muscle | 0.01*               | 0.01*               | Further consideration needed |
| 1011020     | Swine fat tissue | 0.01*            | 0.01*               | Further consideration needed |
| 1011030     | Swine liver | 0.01*                 | 0.01*               | Further consideration needed |
| 1011040     | Swine kidney | 0.01*              | 0.01*               | Further consideration needed |
| 1012010     | Bovine muscle | 0.01*            | 0.01*               | Further consideration needed |
| 1012020     | Bovine fat tissue | 0.01*         | 0.01*               | Further consideration needed |
| 1012030     | Bovine liver | 0.01*                | 0.01*               | Further consideration needed |
| 1012040     | Bovine kidney | 0.01*            | 0.01*               | Further consideration needed |
| 1013010     | Sheep muscle | 0.01*              | 0.01*               | Further consideration needed |
| 1013020     | Sheep fat tissue | 0.01*           | 0.01*               | Further consideration needed |
| 1013030     | Sheep liver | 0.01*                | 0.01*               | Further consideration needed |
| 1013040     | Sheep kidney | 0.01*             | 0.01*               | Further consideration needed |
| 1014010     | Goat muscle | 0.01*                | 0.01*               | Further consideration needed |
| 1014020     | Goat fat tissue | 0.01*           | 0.01*               | Further consideration needed |
| 1014030     | Goat liver | 0.01*                 | 0.01*               | Further consideration needed |
| 1014040     | Goat kidney | 0.01*                | 0.01*               | Further consideration needed |
| 1015010     | Equine muscle | 0.01*             | 0.01*               | Further consideration needed |
| 1015020     | Equine fat tissue | 0.01*         | 0.01*               | Further consideration needed |
| 1015030     | Equine liver | 0.01*                | 0.01*               | Further consideration needed |
| Code number | Commodity          | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                                      |
|-------------|--------------------|-------------------------|----------------------|-------------|----------------------------------------------|
| 1015040     | Equine kidney      | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(e)}\)       |
| 1016010     | Poultry muscle     | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(h)}\)       |
| 1016020     | Poultry fat tissue | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(h)}\)       |
| 1016030     | Poultry liver      | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(h)}\)       |
| 1020010     | Cattle milk        | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(e)}\)       |
| 1020020     | Sheep milk         | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(e)}\)       |
| 1020030     | Goat milk          | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(e)}\)       |
| 1020040     | Horse milk         | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(e)}\)       |
| 1030000     | Birds eggs         | 0.01*                   | 0.01*                | 0.01*       | Further consideration needed\(^{(h)}\)       |
| –           | Other commodities  |                         |                      |             | Further consideration needed\(^{(k)}\)       |
|             | of animal origin   |                         |                      |             |                                              |

MRL: maximum residue level; CXL: codex maximum residue limit.

*: Indicates that the MRL is set at the limit of quantification.

\(^{(a)}\): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); no CXL is available (combination C-I in Appendix E).

\(^{(b)}\): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix E). The possible impact of TDMs on the validity of the MRL proposal was not considered in the assessment.

\(^{(c)}\): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix E). The possible impact of TDMs on the validity of the MRL proposal was not considered in the assessment.

\(^{(d)}\): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix E). The possible impact of TDMs on the validity of the MRL proposal was not considered in the assessment.

\(^{(e)}\): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); existing CXL is covered by the tentative MRL (combination E-III in Appendix E).

\(^{(f)}\): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination E-I in Appendix E).

\(^{(g)}\): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the existing residue definition); GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix E).

\(^{(h)}\): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).

\(^{(i)}\): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL (also assuming the existing residue definition); existing CXL is covered by the existing EU MRL (combination C-III in Appendix E).

\(^{(j)}\): For annual crops for which no GAPs are authorised, MRLs above the LOQ due to the potential uptake from previous application in rotational crops may be needed. However, due to the lack of information on residue levels in rotational crops, no proposal could be derived in this review.

\(^{(k)}\): 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(EU1)

### Myclobutanil

| Toxicological endpoints | ADI (mg/kg bw per day) | LOQ (mg/kg bw) | Proposed LOQ | ADI (mg/kg bw) | LOQ (mg/kg bw) |
|-------------------------|------------------------|----------------|--------------|----------------|----------------|
| Source of ADI | EFSA | Year of evaluation | 2010 | | EFSA | Year of evaluation | 2010 |

| Status of the active substance | Code no. |
|--------------------------------|-----------|
| LOQ (mg/kg bw) | Proposed LOQ |

| ARfD (mg/kg bw) | Source of ADI | Year of evaluation |
|----------------|--------------|--------------------|
| 0.31 | EFSA | 2010 |

| Year of evaluation | 2010 |
|--------------------|------|

| No of diets exceeding ADI | TMDI (range) in % of ADI | minimum – maximum |
|---------------------------|--------------------------|--------------------|

| Highest calculated TMDI values in % of ADI | MS Diet | 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) |
|-------------------------------------------|---------|---------------------------------|--------------------------------------|---------------------------------|--------------------------------------|---------------------------------|--------------------------|
| 10.3 | Apples | 2.0 | Table grapes | 0.8 | Bananas |
| 14.6 | NL child | 5.4 | Apples | 3.2 | Beans (with pods) |
| 13.6 | FR toddler | 7.1 | Beans (with pods) | 2.2 | Apples |
| 11.4 | WHO Cluster diet B | 2.8 | Wine grapes | 2.1 | Beans (with pods) |
| 10.3 | FR infant | 5.4 | Beans (with pods) | 2.1 | Apples |
| 9.0 | FR all population | 6.2 | Wine grapes | 0.9 | Beans (with pods) |
| 7.4 | IE adult | 2.0 | Wine grapes | 1.1 | Beans (with pods) |
| 7.2 | UK Toddler | 1.8 | Sugar beet (root) | 1.5 | Apples |
| 7.0 | WHO cluster diet E | 2.5 | Wine grapes | 1.8 | Beans (with pods) |
| 6.8 | PT General population | 3.9 | Wine grapes | 0.9 | Apples |
| 5.8 | UK infant | 1.5 | Milk and cream | 1.3 | Apples |
| 5.4 | NL general | 1.6 | Beans (with pods) | 1.0 | Apples |
| 5.4 | ES child | 1.5 | Beans (with pods) | 1.0 | Apples |
| 5.3 | DK child | 2.0 | Apples | 0.6 | Pears |
| 4.8 | WHO regional European diet | 1.3 | Beans (with pods) | 0.8 | Tomatoes |
| 4.8 | ES adult | 1.5 | Beans (with pods) | 0.7 | Apples |
| 4.6 | SE general population 90th percentile | 0.9 | Apples | 0.9 | Bananas |
| 4.3 | OK adult | 2.2 | Wine grapes | 0.7 | Apples |
| 3.8 | UK vegetarian | 1.3 | Wine grapes | 0.5 | Apples |
| 3.7 | IT kids/toddler | 1.0 | Tomatoes | 0.8 | Apples |
| 3.7 | UK adult | 1.7 | Wine grapes | 0.4 | Apples |
| 3.6 | IT adult | 1.0 | Beans (with pods) | 0.8 | Tomatoes |
| 3.6 | PL general population | 1.7 | Apples | 0.6 | Tomatoes |
| 3.5 | WHO cluster diet D | 0.7 | Tomatoes | 0.6 | Beans (with pods) |
| 3.2 | WHO Cluster diet F | 0.9 | Wine grapes | 0.6 | Apples |
| 2.7 | LT adult | 1.6 | Tomatoes | 0.4 | Apples |
| 2.2 | FI adult | 0.5 | Wine grapes | 0.3 | Apples |

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

**Review of the existing MRLs for myclobutanil**

www.efsa.europa.eu/efsajournal 57 EFSA Journal 2018;16(8):5392
### Acute risk assessment/children – refined calculations

The acute risk assessment is based on the ARfD.

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 variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

#### No of critical MRLs (IESTI 1)

| Commodity | pTMRL (mg/kg) |
|-----------|---------------|
| Table grapes | 1.635/- |
| Apples | 0.57/- |
| Pears | 0.57/- |
| Peppers | 0.6525/- |
| Melons | 0.2085/- |

#### No of critical MRLs (IESTI 2)

| Commodity | pTMRL (mg/kg) |
|-----------|---------------|
| Table grapes | 1.635/- |
| Apples | 0.57/- |
| Pears | 0.57/- |
| Peppers | 0.6525/- |
| Melons | 0.2085/- |

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

The acute risk assessment is based on the ARfD.

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 variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

#### No of critical MRLs (IESTI 1)

| Commodity | pTMRL (mg/kg) |
|-----------|---------------|
| Table grapes | 1.635/- |
| Apples | 0.57/- |
| Raspberries | 0.27/- |
| Quince | 0.57/- |
| Tomato (preserved) | 0.27/- |

#### No of critical MRLs (IESTI 2)

| Commodity | pTMRL (mg/kg) |
|-----------|---------------|
| Table grapes | 1.635/- |
| Apples | 0.57/- |
| Raspberries | 0.27/- |
| Quince | 0.57/- |
| Tomato (preserved) | 0.27/- |

### Conclusion:

For myclobutanil, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

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1. **pTMRL**: provisional temporary MRL.
2. **pTMRL**: provisional temporary MRL for unprocessed commodity.
3. No exceedance of the ARfD/ADI was identified for any unprocessed commodity.
4. The results of the IESTI calculations are reported for at least 5 commodities. If the ARD is exceeded for more than 5 commodities, all IESTI values > 90% of ARD are reported.
5. For processed commodities, no exceedance of the ARfD/ADI was identified.

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![Graph showing acute risk assessment/children – refined calculations](image1)

![Graph showing acute risk assessment/adults/general population – refined calculations](image2)
### Myclobutanil

**Status of the active substance:** Code no. 00487

**LOQ (mg/kg bw):** Proposed LOQ: 0.025 mg/kg bw

**ADI (mg/kg bw per day):** 0.025 mg/kg bw

**ARfD (mg/kg bw):** 0.31 mg/kg bw

**Source of ADI:** EFSA

**Source of ARfD:** EFSA

**Year of evaluation:** 2010

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

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 variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For myclobutanil, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

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 variability factor of 3.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

Conclusion:
For myclobutanil, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

For processed commodities, no exceedance of the ARfD/ADI was identified.
### Chronic risk assessment – refined calculations

| TMDI (range) in % of ADI | Minimum – Maximum |
|-------------------------|-------------------|
| MS Diet                 | 3 – 17            |

| Commodity/group of commodities | 1st contributor to MS diet | 2nd contributor to MS diet | 3rd contributor to MS diet |
|-------------------------------|---------------------------|---------------------------|----------------------------|
| Caribbean                     | 10.0                      | 9.0                       | 8.0                        |
| Potatoes                      | 10.0                      | 9.0                       | 8.0                        |
| Sweet potatoes                | 10.0                      | 9.0                       | 8.0                        |
| Tomatoes                      | 10.0                      | 9.0                       | 8.0                        |

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of myclobutanil is unlikely to present a public health concern.
## Acute risk assessment/children – refined calculations

The acute risk assessment is based on the ARfD.

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 variability factor of 3.

Threshold MRL is the calculated residue level which leads to an exposure equivalent to 100% of the ARfD.

### Commodity List

| Commodity          | pTMRL/Threshold MRL (mg/kg) |
|--------------------|-----------------------------|
| Peppers            | 17.8                         |
| Peaches            | 35.3                         |
| Table grapes       | 16.7                         |
| Apricots           | 18.4                         |
| Plums              | 17.8                         |
| Grape juice        | 17.4                         |
| Peach juice        | 8.4                          |
| Plum juice         | 7.6                          |
| Raspberries juice  | 5.6                          |
| Wine               | 12.7                         |
| Peach preserved    | 10.7                         |
| Apple juice        | 8.4                          |
| Quince jelly       | 5.6                          |
| Raisins            | 7.6                          |
| Apple juice        | 8.4                          |
| Quince jelly       | 5.6                          |

### Table

| Commodity          | pTMRL/Threshold MRL (mg/kg) |
|--------------------|-----------------------------|
| Peppers            | 2.4                          |
| Peaches            | 1.845                        |
| Table grapes       | 1.635                        |
| Apricots           | 1.845                        |
| Plums              | 1.68                         |
| Grape juice        | 1.635                        |
| Peach juice        | 0.51                         |
| Plum juice         | 1.68                         |
| Raspberries juice  | 1.5                          |
| Wine               | 1.635                        |
| Peach preserved    | 1.845                        |
| Apple juice        | 0.51                         |
| Raisins            | 1.635                        |
| Quince jelly       | 0.51                         |

### Conclusion

For myclobutanil, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.
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 |
| Apple, pomace, wet | 0.93 STMR x PF (1.76) x CF (3.69) | 0.93 STMR x PF (1.76) x CF (3.69) |
| Beet, sugar, dried pulp | 0.36 STMR x default PF (18) x CF (2) | 0.36 STMR x default PF (18) x CF (2) |
| Beet, sugar, ensiled pulp | 0.06 STMR x default PF (3) x CF (2) | 0.06 STMR x default PF (3) x CF (2) |
| Beet, sugar, molasses | 0.56 STMR x default PF (28) x CF (2) | 0.56 STMR x default PF (28) x CF (2) |
| Beet, sugar, tops | 0.06 STMR x CF (2) | 0.19 HR x CF (2) |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CF: conversion factor.
*: Indicates that the input value is proposed at the limit of quantification.
(a): For sugar beet pulps and molasses, in the absence of processing factors supported by data, default processing factors of were respectively included in the calculation to consider the potential concentration of residues in these commodities.

D.2. Consumer risk assessment without consideration of the existing CXLs

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| Hazelnuts/cobnuts          | 0.08 EU MRL x CF (tentative) | 0.08 EU MRL x CF (tentative) |
| Walnuts                    | 0.08 EU MRL x CF (tentative) | 0.08 EU MRL x CF (tentative) |
| Apples                     | 0.21 STMR x CF          | 0.57 HR x CF          |
| Pears                      | 0.21 STMR x CF          | 0.57 HR x CF          |
| Quinces                    | 0.21 STMR x CF          | 0.57 HR x CF          |
| Medlars                    | 0.21 STMR x CF          | 0.57 HR x CF          |
| Loquats/Japanese medlars   | 0.21 STMR x CF          | 0.57 HR x CF          |
| Apricots                   | 0.12 STMR x CF (tentative) | 0.23 HR x CF (tentative) |
| Cherries (sweet)           | 0.03 STMR x CF (tentative) | 0.12 HR x CF (tentative) |
| Peaches                    | 0.12 STMR x CF          | 0.23 HR x CF          |
| Plums                      | 0.16 STMR x CF (tentative) | 0.96 HR x CF (tentative) |
| Table grapes               | 0.39 STMR x CF          | 1.64 HR x CF          |
| Wine grapes                | 0.39 STMR x CF          | 1.64 HR x CF          |
| Strawberries               | 0.30 STMR x CF (tentative) | 1.04 HR x CF (tentative) |
| Blackberries               | 0.39 STMR x CF (tentative) | 0.65 HR x CF (tentative) |
| Raspberries (red and yellow)| 1.50 EU MRL x CF (tentative) | 1.50 EU MRL x CF (tentative) |
| Currants (black, red and white) | 0.39 STMR x CF (tentative) | 0.65 HR x CF (tentative) |

Risk assessment residue definition (plants): sum of myclobutanil and metabolite RH-9090 (free and conjugated), expressed as myclobutanil.
| Commodity                          | Chronic risk assessment | Acute risk assessment |
|-----------------------------------|-------------------------|-----------------------|
| Gooseberries (green, red and yellow) | 0.39 STMR x CF (tentative) | 0.65 HR x CF (tentative) |
| Bananas                           | 0.12 STMR x CF x PF (tentative) | 0.21 HR x CF x PF (tentative) |
| Tomatoes                           | 0.17 STMR x CF (tentative) | 0.27 HR x CF (tentative) |
| Sweet peppers/bell peppers        | 0.24 STMR x CF (tentative) | 0.65 HR x CF (tentative) |
| Aubergines/eggplants              | 0.09 STMR x CF (tentative) | 0.14 HR x CF (tentative) |
| Cucumbers                          | 0.06 STMR x CF (tentative) | 0.09 HR x CF (tentative) |
| Gherkins                           | 0.04 STMR x CF (tentative) | 0.05 HR x CF (tentative) |
| Courgettes                         | 0.04 STMR x CF (tentative) | 0.05 HR x CF (tentative) |
| Melons                             | 0.06 STMR x CF (tentative) | 0.21 HR x CF (tentative) |
| Pumpkins                           | 0.06 STMR x CF (tentative) | 0.21 HR x CF (tentative) |
| Watermelons                        | 0.06 STMR x CF (tentative) | 0.21 HR x CF (tentative) |
| Lamb's lettuces/corn salads       | 2.25 STMR x CF (tentative) | 6.94 HR x CF (tentative) |
| Beans (with pods)                 | 1.60 EU MRL x CF (tentative) | 1.60 EU MRL x CF (tentative) |
| Asparagus                          | 0.04 EU MRL x CF (tentative) | 0.04 EU MRL x CF (tentative) |
| Globe artichokes                  | 0.46 STMR x CF (tentative) | 0.54 HR x CF (tentative) |
| Borage seeds                      | 0.10 EU MRL x CF (tentative) | 0.10 EU MRL x CF (tentative) |
| Hops                              | 2.20 STMR x CF (tentative) | 7.00 HR x CF (tentative) |
| Sugar beet roots                  | 0.02 STMR x CF (tentative) | 0.02 HR x CF (tentative) |

**Risk assessment residue definition (livestock):** free and conjugated forms of RH-9090, expressed as myclobutanil

| Commodity | Chronic risk assessment | Acute risk assessment |
|-----------|-------------------------|-----------------------|
| Swine meat                          | 0.01* | 0.8 x STMR muscle + 0.2 x STMR fat (tentative) | 0.01* | 0.8 x HR muscle + 0.2 x HR fat (tentative) |
| Swine fat tissue                     | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
| Swine liver                           | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
| Swine kidney                          | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
| Bovine meat                           | 0.01* | 0.8 x STMR muscle + 0.2 x STMR fat (tentative) | 0.01* | 0.8 x HR muscle + 0.2 x HR fat (tentative) |
| Bovine fat tissue                     | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
| Bovine liver                          | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
| Bovine kidney                         | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
| Sheep meat                            | 0.01* | 0.8 x STMR muscle + 0.2 x STMR fat (tentative) | 0.01* | 0.8 x HR muscle + 0.2 x HR fat (tentative) |
| Sheep fat tissue                      | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
| Sheep liver                           | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
| Sheep kidney                          | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
| Goat meat                             | 0.01* | 0.8 x STMR muscle + 0.2 x STMR fat (tentative) | 0.01* | 0.8 x HR muscle + 0.2 x HR fat (tentative) |
| Goat fat tissue                       | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
| Goat liver                            | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
| Goat kidney                           | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
| Equine meat                           | 0.01* | 0.8 x STMR muscle + 0.2 x STMR fat (tentative) | 0.01* | 0.8 x HR muscle + 0.2 x HR fat (tentative) |
| Equine fat tissue                     | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
| Equine liver                          | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
| Equine kidney                         | 0.01* | STMR (tentative) | 0.01* | HR (tentative) |
| Commodity          | Chronic risk assessment                        | Acute risk assessment                              |
|--------------------|------------------------------------------------|---------------------------------------------------|
|                    | Input value (mg/kg) | Comment                                      | Input value (mg/kg) | Comment                                      |
| Poultry meat       | 0.01*              | 0.9 x STMR muscle + 0.1 x STMR fat (tentative) | 0.01*              | 0.9 x HR muscle + 0.1 x HR fat (tentative)   |
| Poultry fat tissue | 0.01*              | STMR (tentative)                             | 0.01*              | HR (tentative)                              |
| Poultry liver      | 0.01*              | STMR (tentative)                             | 0.01*              | HR (tentative)                              |
| Cattle milk        | 0.01*              | STMR (tentative)                             | 0.01*              | HR (tentative)                              |
| Sheep milk         | 0.01*              | STMR (tentative)                             | 0.01*              | HR (tentative)                              |
| Goat milk          | 0.01*              | STMR (tentative)                             | 0.01*              | HR (tentative)                              |
| Horse milk         | 0.01*              | STMR (tentative)                             | 0.01*              | HR (tentative)                              |
| Birds eggs         | 0.01*              | STMR (tentative)                             | 0.01*              | HR (tentative)                              |

MRL: maximum residue level; CF: conversion factor; STMR: supervised trials median residue; HR: highest residue.
*: Indicates that the input value is proposed at the limit of quantification.

D.3. Consumer risk assessment with consideration of the existing CXLs

| Commodity          | Chronic risk assessment                        | Acute risk assessment                              |
|--------------------|------------------------------------------------|---------------------------------------------------|
|                    | Input value (mg/kg) | Comment                                      | Input value (mg/kg) | Comment                                      |
| Hazelnuts/cobnuts  | 0.08               | EU MRL x CF (tentative)                      | 0.08               | EU MRL x CF (tentative)                      |
| Walnuts            | 0.08               | EU MRL x CF (tentative)                      | 0.08               | EU MRL x CF (tentative)                      |
| Apples             | 0.09               | STMR (CXL) x CF                              | 0.51               | HR (CXL) x CF                               |
| Pears              | 0.09               | STMR (CXL) x CF                              | 0.51               | HR (CXL) x CF                               |
| Quinces            | 0.09               | STMR (CXL) x CF                              | 0.51               | HR (CXL) x CF                               |
| Medlars            | 0.09               | STMR (CXL) x CF                              | 0.51               | HR (CXL) x CF                               |
| Loquats/Japanese medlars | 0.09       | STMR (CXL) x CF                              | 0.51               | HR (CXL) x CF                               |
| Apricots           | 1.07               | STMR (CXL) x CF                              | 1.85               | HR (CXL) x CF                               |
| Cherries (sweet)   | 1.34               | STMR (CXL) x CF                              | 2.16               | HR (CXL) x CF                               |
| Peaches            | 1.07               | STMR (CXL) x CF                              | 1.85               | HR (CXL) x CF                               |
| Plums              | 0.41               | STMR (CXL) x CF                              | 1.68               | HR (CXL) x CF                               |
| Table grapes       | 0.39               | STMR x CF                                    | 1.64               | HR x CF                                     |
| Wine grapes        | 0.39               | STMR x CF                                    | 1.64               | HR x CF                                     |
| Strawberries       | 0.30               | STMR x CF (tentative)                        | 1.04               | HR x CF (tentative)                         |
| Blackberries       | 0.39               | STMR x CF (tentative)                        | 0.65               | HR x CF (tentative)                         |
| Raspberries (red and yellow) | 1.50       | EU MRL x CF (tentative)                      | 1.50               | EU MRL x CF (tentative)                      |
| Currants (black, red and white) | 0.45      | STMR (CXL) x CF (tentative)                  | 0.65               | HR (CXL) x CF (tentative)                   |
| Gooseberries (green, red and yellow) | 0.39      | STMR x CF (tentative)                        | 0.65               | HR x CF (tentative)                         |
| Bananas            | 0.12               | STMR x CF x PF (tentative)                   | 0.21               | HR x CF x PF (tentative)                    |
| Tomatoes           | 0.17               | STMR (CXL) x CF (tentative)                  | 0.27               | HR (CXL) x CF (tentative)                   |

Risk assessment residue definition (plants): sum of myclobutanil and metabolite RH-9090 (free and conjugated), expressed as myclobutanil.
| Commodity                      | Chronic risk assessment            | Acute risk assessment            |
|-------------------------------|-----------------------------------|----------------------------------|
|                               | Input value (mg/kg)                | Comment                          | Input value (mg/kg) | Comment                          |
| Sweet peppers/bell peppers    | 0.49                              | STMRMo (CXL) x CF (tentative)    | 3.05                | HRMo (CXL) x CF (tentative)      |
|                               | 0.44                              | Refined risk assessment value based on the STMR according to the residue definition for RA derived by JMPR (tentative) | 2.40                | Refined risk assessment value based on the HR according to the residue definition for RA derived by JMPR (tentative) |
| Aubergines/eggplants          | 0.09                              | STMR x CF (tentative)            | 0.14                | HR x CF (tentative)              |
| Cucumbers                     | 0.06                              | STMR (CXL) x CF (tentative)      | 0.24                | HR (CXL) x CF (tentative)        |
| Gherkins                      | 0.06                              | STMR (CXL) x CF (tentative)      | 0.24                | HR (CXL) x CF (tentative)        |
| Courgettes                    | 0.06                              | STMR (CXL) x CF (tentative)      | 0.24                | HR (CXL) x CF (tentative)        |
| Melons                        | 0.06                              | STMR x CF (tentative)            | 0.21                | HR x CF (tentative)              |
| Pumpkins                      | 0.06                              | STMR x CF (tentative)            | 0.21                | HR x CF (tentative)              |
| Watermelons                   | 0.06                              | STMR x CF (tentative)            | 0.21                | HR x CF (tentative)              |
| Lamb’s lettuces/corn salads   | 2.25                              | STMR x CF (tentative)            | 6.94                | HR x CF (tentative)              |
| Beans (with pods)             | 1.60                              | EU MRL x CF (tentative)          | 1.60                | EU MRL x CF (tentative)          |
| Asparagus                     | 0.04                              | EU MRL x CF (tentative)          | 0.04                | EU MRL x CF (tentative)          |
| Globe artichokes              | 0.46                              | STMR x CF (tentative)            | 0.54                | HR x CF (tentative)              |
| Borage seeds                  | 0.10                              | EU MRL x CF (tentative)          | 0.10                | EU MRL x CF (tentative)          |
| Hops                          | 2.20                              | STMR x CF (tentative)            | 7.00                | HR x CF (tentative)              |
| Sugar beet roots              | 0.02                              | STMR x CF (tentative)            | 0.02                | HR x CF (tentative)              |
| Potatoes                      | 0.08                              | STMR (CXL) x CF (tentative)      | 0.10                | HR x CF (tentative)              |
| Cassava                       | 0.08                              | STMR (CXL) x CF (tentative)      | 0.10                | HR x CF (tentative)              |
| Sweet potatoes                | 0.08                              | STMR (CXL) x CF (tentative)      | 0.10                | HR x CF (tentative)              |
| Yams                          | 0.08                              | STMR (CXL) x CF (tentative)      | 0.10                | HR x CF (tentative)              |
| Arrowroot                     | 0.08                              | STMR (CXL) x CF (tentative)      | 0.10                | HR x CF (tentative)              |
| Beetroot                      | 0.08                              | STMR (CXL) x CF (tentative)      | 0.10                | HR x CF (tentative)              |
| Carrots                       | 0.08                              | STMR (CXL) x CF (tentative)      | 0.10                | HR x CF (tentative)              |
| Celeriac                      | 0.08                              | STMR (CXL) x CF (tentative)      | 0.10                | HR x CF (tentative)              |
| Horseradish                   | 0.08                              | STMR (CXL) x CF (tentative)      | 0.10                | HR x CF (tentative)              |
| Jerusalem artichokes          | 0.08                              | STMR (CXL) x CF (tentative)      | 0.10                | HR x CF (tentative)              |
| Parsnips                      | 0.08                              | STMR (CXL) x CF (tentative)      | 0.10                | HR x CF (tentative)              |
| Parsley root                  | 0.08                              | STMR (CXL) x CF (tentative)      | 0.10                | HR x CF (tentative)              |
| Commodity                     | Chronic risk assessment | Acute risk assessment |
|-------------------------------|-------------------------|-----------------------|
|                               | Input value (mg/kg)     | Comment                |
| Radishes                      | 0.08 STMR (CXL) x CF (tentative) | 0.10 HR x CF (tentative) |
| Salsify                       | 0.08 STMR (CXL) x CF (tentative) | 0.10 HR x CF (tentative) |
| Swedes                        | 0.08 STMR (CXL) x CF (tentative) | 0.10 HR x CF (tentative) |
| Turnips                       | 0.08 STMR (CXL) x CF (tentative) | 0.10 HR x CF (tentative) |
| Garlic                        | 0.08 STMR (CXL) x CF (tentative) | 0.10 HR x CF (tentative) |
| Onions                        | 0.08 STMR (CXL) x CF (tentative) | 0.10 HR x CF (tentative) |
| Shallots                      | 0.08 STMR (CXL) x CF (tentative) | 0.10 HR x CF (tentative) |
| Spring onions                 | 0.08 STMR (CXL) x CF (tentative) | 0.10 HR x CF (tentative) |
| Broccoli                      | 0.06 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Cauliflower                   | 0.06 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Brussels sprouts              | 0.06 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Head cabbage                  | 0.06 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Chinese cabbage               | 0.06 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Kale                          | 0.06 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Kohlrabi                      | 0.06 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Lettuce                       | 0.06 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Scarole (broad-leaf endive)   | 0.06 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Cress                         | 0.09 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Land cress                    | 0.09 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Rocket, Rucola                | 0.06 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Red mustard                   | 0.06 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Leaves and sprouts of Brassica spp. | 0.06 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Spinach                       | 0.06 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Purslane                      | 0.09 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Beet leaves (chard)           | 0.09 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Vine leaves (grape leaves)     | 0.09 STMR (CXL) x CF (tentative) | 0.09 HR x CF (tentative) |
| Commodity     | Chronic risk assessment                                                                 | Acute risk assessment                                                                 |
|---------------|-----------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|
|               | **Input value (mg/kg)** | **Comment**                                                                                       | **Input value (mg/kg)** | **Comment**                                                                                       |
| Water cress   | 0.06 STMR (CXL) x CF (tentative)                                                   | 0.09 HR x CF (tentative)                                                                     |
| Witloof       | 0.06 STMR (CXL) x CF (tentative)                                                   | 0.09 HR x CF (tentative)                                                                     |
| Chervil       | 0.06 STMR (CXL) x CF (tentative)                                                   | 0.09 HR x CF (tentative)                                                                     |
| Fennel        | 0.08 STMR (CXL) x CF (tentative)                                                   | 0.10 HR x CF (tentative)                                                                     |
| Leek          | 0.08 STMR (CXL) x CF (tentative)                                                   | 0.10 HR x CF (tentative)                                                                     |

**Risk assessment residue definition (animals):** free and conjugated forms of RH-9090, expressed as myclobutanil

| Commodity  | Chronic risk assessment                                                                                      | Acute risk assessment                                                                 |
|------------|--------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| Swine meat | 0.01* 0.8 x STMR muscle + 0.2 x STMR fat (tentative)                                                      | 0.01* 0.8 x HR muscle + 0.2 x HR fat (tentative)                                       |
| Swine fat tissue | 0.01* STMR (tentative)                                                                                   | 0.01* HR (tentative)                                                                  |
| Swine liver | 0.01* STMR (tentative)                                                                                   | 0.01* HR (tentative)                                                                  |
| Swine kidney | 0.01* STMR (tentative)                                                                                   | 0.01* HR (tentative)                                                                  |
| Bovine meat | 0.01* 0.8 x STMR muscle + 0.2 x STMR fat (tentative)                                                      | 0.01* 0.8 x HR muscle + 0.2 x HR fat (tentative)                                       |
| Bovine fat tissue | 0.01* STMR (tentative)                                                                                  | 0.01* HR (tentative)                                                                  |
| Bovine liver | 0.01* STMR (tentative)                                                                                   | 0.01* HR (tentative)                                                                  |
| Bovine kidney | 0.01* STMR (tentative)                                                                                   | 0.01* HR (tentative)                                                                  |
| Sheep meat | 0.01* 0.8 x STMR muscle + 0.2 x STMR fat (tentative)                                                      | 0.01* 0.8 x HR muscle + 0.2 x HR fat (tentative)                                       |
| Sheep fat tissue | 0.01* STMR (tentative)                                                                                  | 0.01* HR (tentative)                                                                  |
| Sheep liver | 0.01* STMR (tentative)                                                                                   | 0.01* HR (tentative)                                                                  |
| Sheep kidney | 0.01* STMR (tentative)                                                                                   | 0.01* HR (tentative)                                                                  |
| Goat meat | 0.01* 0.8 x STMR muscle + 0.2 x STMR fat (tentative)                                                      | 0.01* 0.8 x HR muscle + 0.2 x HR fat (tentative)                                       |
| Goat fat tissue | 0.01* STMR (tentative)                                                                                  | 0.01* HR (tentative)                                                                  |
| Goat liver | 0.01* STMR (tentative)                                                                                   | 0.01* HR (tentative)                                                                  |
| Goat kidney | 0.01* STMR (tentative)                                                                                   | 0.01* HR (tentative)                                                                  |
| Equine meat | 0.01* 0.8 x STMR muscle + 0.2 x STMR fat (tentative)                                                      | 0.01* 0.8 x HR muscle + 0.2 x HR fat (tentative)                                       |
| Equine fat tissue | 0.01* STMR (tentative)                                                                                  | 0.01* HR (tentative)                                                                  |
| Equine liver | 0.01* STMR (tentative)                                                                                   | 0.01* HR (tentative)                                                                  |
| Equine kidney | 0.01* STMR (tentative)                                                                                  | 0.01* HR (tentative)                                                                  |
| Poultry muscle | 0.01* 0.9 x STMR muscle + 0.1 x STMR fat (CXL, tentative)                                                | 0.01* 0.9 x HR muscle + 0.1 x HR fat (CXL, tentative)                                  |
| Poultry fat tissue | 0.01* STMR (CXL, tentative)                                                                             | 0.01* HR (CXL, tentative)                                                             |
| Poultry liver | 0.01* STMR (CXL, tentative)                                                                             | 0.01* HR (CXL, tentative)                                                             |
| Cattle milk | 0.01* STMR (tentative)                                                                                   | 0.01* HR (tentative)                                                                  |
| Sheep milk | 0.01* STMR (tentative)                                                                                   | 0.01* HR (tentative)                                                                  |
| Goat milk | 0.01* STMR (tentative)                                                                                   | 0.01* HR (tentative)                                                                  |
| Horse milk | 0.01* STMR (tentative)                                                                                   | 0.01* HR (tentative)                                                                  |
| Birds eggs | 0.01* STMR (CXL, tentative)                                                                             | 0.01* HR (CXL, tentative)                                                             |

MRL: maximum residue level; CF: conversion factor; STMR: supervised trials median residue; HR: highest residue; PF: processing factor; CXL: codex maximum residue limit.
*: Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

Consumer risk assessment for GAPs evaluated at EU level – EU scenarios

Recommendations resulting from EU authorisations and import tolerances

(A) Specific LOQ or default MRL?
(B) Specific LOQ or default MRL?
(C) Maintain current EU MRL?
(D) Specific LOQ or default MRL?
(E) Establish tentative EU MRL?
(F) Specific LOQ or default MRL?
(G) MRL is recommended.

Comparison with CXLs
Review of the existing MRLs for myclobutanil

Comparison of the EU recommendation with the existing CXL

- CXL available?
  - Yes
    - RD comparable?
      - Yes
        - CXL higher?
          - Yes
            - Maintain EU recommendation; higher CXL is not safe for consumer.
          - No
            - CXL higher?
              - No
                - CXL is included in the RA.
                  - Codex median/ highest residues are included in the RA.
                  - Risk identified?
                    - Yes
                      - CXL is recommended; EU recommendation is covered as well.
                    - No
                      - Input values for the RA remain unchanged.
            - No
              - Input values for the RA remain unchanged.
      - No
        - Input values for the RA remain unchanged.
  - No
    - Input values for the RA remain unchanged.

Consumer risk assessment with consideration of the existing CXL

- CXL supported by data?
  - Yes
    - Input values for the RA remain unchanged.
  - No
    - Risk identified?
      - Yes
        - CXL is included in the RA.
          - Codex median/ highest residues are included in the RA.
          - Risk identified?
            - Yes
              - CXL is recommended; EU recommendation is covered as well.
            - No
              - Input values for the RA remain unchanged.
      - No
        - Input values for the RA remain unchanged.

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 | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|-------------------|-----------------------------------------------|---------------------------------|
| myclobutanil      | (RS)-2-(4-chlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl) hexanenitrile  
                    Clc1ccc(cc1)C(CCCC)(Cn2ccnc2)C#N  
                    HZJKXKUJVESEFU-UHFFFAOYSA-N | ![Structural formula for myclobutanil](image1) |
| RH-9090           | (2RS,5RS)-2-(4-chlorophenyl)-5-hydroxy-2-(1H-1,2,4-triazol-1-ylmethyl)hexanenitrile  
                    Clc1ccc(cc1)C(CCC(O)(Cn2ccnc2)C#N  
                    HIUOATAFAFIXAL-UHFFFAOYSA-N | ![Structural formula for RH-9090](image2) |
| RH-9089           | (2RS)-2-(4-chlorophenyl)-5-oxo-2-(1H-1,2,4-triazol-1-ylmethyl)hexanenitrile  
                    Clc1ccc(cc1)C(CCC(=O)(Cn2ccnc2)C#N  
                    WIXZNHGNDVBXMF-UHFFFAOYSA-N | ![Structural formula for RH-9089](image3) |
| hydroxyl-lactone  | (3RS,5RS)-3-(4-chlorophenyl)-5-[(1RS)-1-hydroxyethyl]-3-[(1H-1,2,4-triazol-1-yl)methyl]oxolan-2-one  
                    OC(C)C2CC(Cn1ccnc1)(C(=O)O2)c3ccc(Cl)cc3  
                    DKJZTLROWRQET-UHFFFAOYSA-N | ![Structural formula for hydroxyl-lactone](image4) |

### Triazole derivative metabolites

| 1,2,4-triazole  | 1H-1,2,4-triazole  
                1cnccn1  
                NSPMIYGKQJPBQR-UHFFFAOYSA-N |
| Triazole alanine | (TA)  
                  (RH-3968)  
                  3-(1H-1,2,4-triazol-1-yl)-D,L-alanine  
                  NC(Cn1ccnc1)(C(=O)O)  
                  XVWFTOJHOHIJMQ-UHFFFAOYSA-N |
| Triazole acetic acid  | (TAA)  
                         (RH-4098)  
                         (1H-1,2,4-triazol-1-yl)acetic acid  
                         O=C(O)Cn1ccnc1  
                         RXDBSQXFIWBJSR-UHFFFAOYSA-N |
| Triazole lactic acid  or Triazolohydroxyproponic acid  | (TLA)  
                                              (2RS)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propanoic acid  
                                              OC(Cn1ccnc1)(C(=O)O)  
                                              KJRGHGWTVMENC-UHFFFAOYSA-N |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system.

<sup>(a)</sup> ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).

<sup>(b)</sup> ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).