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

European Food Safety Authority (EFSA),
Alba Brancato, Daniela Brocca, Luis Carrasco Cabrera, Chloe De Lentdecker, Zoltan Erdos, Lucien Ferreira, Luna Greco, Samira Jarrah, Dimitra Kardassi, Renata Leuschner, Alfonso Lostia, Christopher Lythgo, Paula Medina, Ileana Miron, Tunde Molnar, Ragnor Pedersen, Hermine Reich, Angela Sacchi, Miguel Santos, Alois Stanek, Juergen Sturma, Jose Tarazona, Anne Theobald, Benedicte Vagenende and Laura Villamar-Bouza

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 prochloraz. To assess the occurrence of prochloraz residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission as well as the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Some information required by the regulatory framework was missing and a possible acute risk to consumers was identified. Hence, the consumer risk assessment is considered indicative only, some MRL proposals derived by EFSA still require further consideration by risk managers and measures for reduction of the consumer exposure should also be considered.

© 2018 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: prochloraz, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, imidazole, fungicide, metabolites BTS 44595 (M201-04) and BTS 44596 (M201-03)

Requestor: European Commission
Question number: EFSA-Q-2009-00069
Correspondence: pesticides.mrl@efsa.europa.eu
Acknowledgement: EFSA wishes to thank the rapporteur Member State Ireland for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Brancato A, Brocca D, Carrasco Cabrera L, De Lentdecker C, Erdos Z, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Medina P, Miron I, Molnar T, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B and Villamar-Bouza L, 2018. Reasoned Opinion on the review of the existing maximum residue levels for prochloraz according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(8):5401, 70 pp. https://doi.org/10.2903/j.efsajournal.2018.5401

ISSN: 1831-4732

© 2018 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
Summary

Prochloraz was included in Annex I to Directive 91/414/EEC on 1 January 2012 by Commission Implementing Regulation No 1143/2011, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation. To collect the relevant pesticide residues data, EFSA asked Ireland, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period, which was initiated by EFSA on 23 May 2016 and finalised on 22 July 2016. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 6 October 2016.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS and Member States, EFSA prepared in April 2018 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 25 May 2018 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The nature of prochloraz in primary plants was investigated in more than three different crop groups (cereals, oilseeds/pulses, fruit crops and mushrooms). Furthermore, the available studies cover different types of applications (foliar applications, seed treatment and local applications). A similar metabolism was identified in all studies, allowing EFSA to derive a general residue definition in plant commodities. For enforcement purpose, the residue was defined as the sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz. Validated analytical methods for enforcement of this residue definition are available. The residue for risk assessment was defined as sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz. A similar residue pattern was observed in rotational crops and prochloraz was also found to be stable under standard hydrolysis conditions. Therefore, these residue definitions are also deemed valid for rotational crops and processed commodities.

The available residue trials were sufficient to derive MRL proposals, risk assessment values and conversion factors for all commodities under evaluation, except for citrus fruits, almonds, stone fruits and strawberries. Tentative MRLs were also derived for cereal straw, sugar beet tops, fodder beet (root and tops) and rape/canola forage in view of the future need to set MRLs in feed items.

Based on the confined rotational crops studies, it was concluded that significant residues may be expected in rotational crops. A risk mitigation measure (minimum plant-back interval of 365 days) was proposed on a tentative basis to limit this uptake. For food commodities, the proposed mitigation is expected to be sufficient to avoid significant uptake. For feed items, however, minor uptake cannot be avoided, even considering the proposed mitigation measure. No MRL proposals accommodating residues in rotational crops were needed as residue uptake would only occur in feed items. However, tentative risk assessment values to be considered in the livestock dietary burden could be derived.

Tentative processing factors were derived on the processed commodities of barley (brewing malt, beer, milled by-products) and wheat (milled by-products, flours and breads).

Prochloraz is authorised for use on several feed items and dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in all commodities of animal origin. The available metabolism studies on dairy ruminants and laying hens were sufficient to propose a common residue definition in all livestock commodities. For enforcement purpose, the residue was defined as the sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz. Validated analytical methods for enforcement of this residue definition are available. The residue for risk assessment was defined as sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz. Tentative conversion factors from enforcement to risk assessment were derived from the metabolism studies. However, as the available feeding studies do not provide analysis in accordance with the proposed residue definition for enforcement, only tentative MRLs could be derived in livestock commodities.
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 Pesticide Residues Intake Model (PRIMo). For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. An exceedance of the acute reference dose (ARfD) was identified for all citrus fruits (from 805% to 5,305% ARfD) and for bovine liver (222.7% ARfD). Excluding citrus fruits and all Good Agricultural Practices (GAPs) on commodities leading to an acute concern in bovine liver from the calculations, the highest chronic exposure represented 52.7% of the acceptable daily intake (ADI) (FR, toddler) and the highest acute exposure amounted to 60.3% of the ARfD (bovine liver).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for prochloraz (as sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety expressed as prochloraz). This residue definition for enforcement is not compatible with the residue for enforcement proposed by EFSA. Therefore, although no health concerns were identified for some of the existing CXLs, these values could not be reported in the EU MRL recommendations. Furthermore, potential risk to consumers were identified for the existing CXLs on oranges, grapefruits, pineapples, bananas, mangoes, mandarins, bovine liver, lemons and kiwi.
# Table of contents

| Section                                                                 | Page |
|------------------------------------------------------------------------|------|
| **Abstract**                                                           | 1    |
| **Summary**                                                            | 3    |
| **Background**                                                         | 6    |
| **Terms of Reference**                                                 | 7    |
| **The active substance and its use pattern**                          | 7    |
| **Assessment**                                                         | 8    |
| **1. Residues in plants**                                              | 8    |
| **1.1. Nature of residues and methods of analysis in plants**          | 8    |
| **1.1.1. Nature of residues in primary crops**                         | 8    |
| **1.1.2. Nature of residues in rotational crops**                      | 9    |
| **1.1.3. Nature of residues in processed commodities**                 | 9    |
| **1.1.4. Methods of analysis in plants**                               | 10   |
| **1.1.5. Stability of residues in plants**                             | 10   |
| **1.1.6. Proposed residue definitions**                               | 11   |
| **1.2. Magnitude of residues in plants**                               | 11   |
| **1.2.1. Magnitude of residues in primary crops**                      | 11   |
| **1.2.2. Magnitude of residues in rotational crops**                   | 13   |
| **1.2.3. Magnitude of residues in processed commodities**              | 15   |
| **1.2.4. Proposed MRLs**                                               | 15   |
| **2. Residues in livestock**                                           | 15   |
| **2.1. Nature of residues and methods of analysis in livestock**       | 15   |
| **2.2. Magnitude of residues in livestock**                            | 16   |
| **3. Consumer risk assessment**                                        | 17   |
| **3.1. Consumer risk assessment without consideration of the existing CXLs** | 17   |
| **3.2. Indicative consumer risk assessment of the existing CXLs**      | 19   |
| **Conclusions**                                                       | 20   |
| **Recommendations**                                                    | 21   |
| **References**                                                        | 24   |
| **Abbreviations**                                                      | 26   |
| **Appendix A – Summary of authorised uses considered for the review of MRLs** | 28   |
| **Appendix B – List of end points**                                   | 35   |
| **Appendix C – Pesticide Residue Intake Model (PRIMo)**                | 55   |
| **Appendix D – Input values for the exposure calculations**            | 61   |
| **Appendix E – Decision tree for deriving MRL recommendations**       | 68   |
| **Appendix F – Used compound codes**                                   | 70   |
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 prochloraz. As prochloraz was included in Annex I to Council Directive 91/414/EEC on 1 January 2012 by means of Commission Implementing Regulation No 1143/2011\(^3\), 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 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.

Ireland, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for prochloraz and to prepare a supporting evaluation report (Ireland, 2015). The PROFile and the supporting evaluation report were submitted to EFSA on 23 November 2015 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 May 2016 and finalised on 22 July 2016. Additional evaluation reports were submitted by Belgium, the Czech Republic, France, Germany, Greece, Italy, Spain, the United Kingdom and the European Union Reference Laboratories for Pesticide Residues (Belgium, 2016; Czech Republic, 2016; EURLs, 2016; France, 2016; Germany, 2016; Greece, 2016; Italy, 2016; Spain, 2016; United Kingdom, 2016) and, after having considered all the information provided by RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 6 October 2016. Further clarifications were sought from Member States via a written procedure in October 2016.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, 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 April 2018 a draft reasoned

---

1. Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
2. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.
3. Commission Implementing Regulation (EU) No 1143/2011 of 10 November 2011 approving the active substance prochloraz, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 and Commission Decision 2008/934/EC. OJ L 293, 11.11.2011, p. 26–30.
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.
opinion, which was submitted to Member States for commenting via a written procedure. All comments received by 25 May 2018 were considered by EFSA during the finalisation of the reasoned opinion.

Furthermore, during the finalisation of the assessment, additional clarifications were requested to France on the FR Good Agricultural Practices (GAPs) on barley and oats and Greece on summary trials for almonds and stone fruits. These clarifications, received in July 2018, were reported in the last column of the Member State consultation report (EFSA, 2018c) and were taken into account for the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Ireland, 2015) and the evaluation reports submitted by Member States (Belgium, 2016; Czech Republic, 2016; EURL, 2016; France, 2016; Germany, 2016; Greece, 2016; Italy, 2016; Spain, 2016; United Kingdom, 2016) 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, 2018b) and the Member States consultation report (EFSA, 2018c). 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(EU1 and EU2) is presented in Appendix C.

Considering the importance of the completeness check and consultation report, all documents are considered as background documents to this reasoned opinion and, thus, are made publicly available.

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

Prochloraz is the ISO common name for N-propyl-N-[2-(2,4,6-trichlorophenoxy)ethyl]imidazole-1-carboxamide (IUPAC).

Prochloraz belongs to the group of imidazole compounds which are used as fungicide and acts as an inhibitor of ergosterol biosynthesis. Prochloraz is recommended for the control of stem, leaf and ear diseases of cereals, including e.g. *Fusarium* spp. Prochloraz has negligible systemic activity, but it is readily absorbed into leaf tissue from plant surfaces at the sites of application.

The chemical structure of the active substance and its main metabolites are reported in Appendix F. Prochloraz was evaluated in the framework of Directive 91/414/EEC with Ireland designated as RMS. The representative uses supported for the peer review process were fungicide on cereals (foliar spray and seed treatment) and mushrooms. Following the peer review, which was carried out by EFSA (2011), a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Implementing Regulation No 1143/2011, which entered into force on 1 January 2012. According to Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011, prochloraz is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as a fungicide only. A restriction is set for the outdoor uses regarding the application rate which shall not exceed 450 g/ha per application.

The EU MRLs for prochloraz are established in Annexes II and IIIB of Regulation (EC) No 396/2005 and CXL for prochloraz 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 in Table 1.
For the purpose of this MRL review, the critical uses of prochloraz currently authorised within the EU, have been collected by the RMS and reported in the PROFile. The additional GAPs reported by Member States during the completeness check were also considered. The details of the authorised GAPs for prochloraz are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

**Assessment**

EFSA has based its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (Ireland, 2015), the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Ireland, 2010), the conclusion on the peer review of the pesticide risk assessment of the active substance prochloraz (EFSA, 2011), the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2001, 2004, 2009a,b), the previous reasoned opinion on prochloraz (EFSA, 2010, 2018a) as well as the evaluation reports submitted during the completeness check (Belgium, 2016; Czech Republic, 2016; EURL, 2016; France, 2016; Germany, 2016; Greece, 2016; Italy, 2016; Spain, 2016; United Kingdom, 2016). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a–g, 2000, 2010a,b; OECD, 2011, 2013).

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

1. **Residues in plants**

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

1.1.1. **Nature of residues in primary crops**

The nature of prochloraz in primary plants was investigated in cereals (foliar and seed treatment), in oilseeds/pulses (foliar treatment) and fruit crops (local application on the surface of apples). The metabolism of prochloraz was also investigated in mushroom after application to the surface of the compost bed. All these studies were evaluated the framework of the EU pesticides peer review (EFSA, 2011).

Following foliar and local applications, prochloraz is rapidly and extensively metabolised. The parent molecule is only detected at significant levels in the samples collected just after the treatment, but with a fast decrease and proportions below 10% of total radioactive residue (TRR) in the days following the application. In all plant groups, the metabolism proceeds first by the cleavage of the imidazole ring, leading to the metabolite BTS 44596 which is further degraded to the amide metabolite BTS 44595. Both compounds are the most common metabolites detected in all plant parts, representing together 15–45% of the TRR in immature plant samples and up to 13% TRR in wheat grains, 43% TRR in barley grains, 25% TRR in rape seeds and 40% TRR in apples at harvest. These two metabolites can undergo further degradation of the lateral side chain, leading to the generation of several additional metabolites, all accounting for low proportions, with the exception of the metabolites BTS 45186 (2,4,6-trichlorophenol) and BTS 9608 which represented 25% and 10% TRR in mature rape seeds.

---

7 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.
After seed treatment on wheat, low residue levels were found in grain (0.23 mg eq/kg) and straw (0.24 mg eq/kg). The extracted radioactivity in grain was very low (12% TRR), indicating important incorporation into or association with insoluble plant material. Therefore, no specific compounds were identified in grain. However, in the analysis performed in wheat forage and straw, only the parent compound (up to 17.2% TRR) and its metabolites BTS 44595 and BTS 44596 (< 1%TRR) could be identified. Based on these data, it was concluded that the metabolic pathway was qualitatively comparable for foliar and seed treatments.

Metabolism observed in mushroom was less extensive compared to the other crops, with prochloraz remaining by far the most abundant compound, representing more than 70% of the TRR 30 days after application. All other compounds identified in mushrooms represented less than 10% of the TRR and were also identified in the metabolism studies performed on other crop groups.

1.1.2. Nature of residues in rotational crops

Most of the crops reported in this review can be grown in a crop rotation. According to the soil degradation studies which were investigated in the framework of the peer review (EFSA, 2011), in laboratory studies prochloraz exhibited moderate to very high persistence, forming major soil metabolites BTS 44596 (max. 12.8% applied radioactivity (AR)) and BTS 40348 (max. 13.9% AR), which exhibited low to moderate and low to high persistence, respectively. The field studies indicate that most critical DT50 value is 73 days for prochloraz but considering that a biphasic decline is expected in soil, the DT50 value is 7,545 days. In addition, DT50 value of metabolite BTS 44596 (35.8 days) and metabolite BTS 44595 (266 days) also indicate slow degradation in soil. The DT50 value of metabolite BTS 40348 according to soil degradation studies accounts for a maximum of 402 days (EFSA, 2011). Consequently, the nature and magnitude of prochloraz and its metabolites in rotational crops was further investigated.

The nature of prochloraz in rotational crops was investigated in cereals (wheat and barley), leafy crops (lettuce, cabbage) and root crops (radish) after bare soil treatment. In addition, nature of residues in potatoes was also investigated after prochloraz field application on initial wheat crop (EFSA, 2011). Overall, these studies were all performed with an initial application rate of 1 kg a.s./ha and different plant-back intervals of 29/30, 120 and 365 days were investigated. These parameters are expected to cover all the GAPs reported in this review because the maximal annual rate authorised on crops that can be grown in rotation is 0.90 kg a.s./ha (i.e. 290.45 kg a.s./ha). This is confirmed by doing the comparison between accumulated PEC soil estimation (0.24 mg/kg soil8) with the residue concentrations in soil that were reached in the confined studies (ranging between 0.40 and 1.34 mg/kg soil).

These studies indicate that the metabolic profile in rotational crops is similar to that in primary crops, with extensive degradation of prochloraz and metabolites BTS 44595, BTS 44596, BTS 45186 (2,4,6-trichlorophenol), BTS40348 and BTS 9608 (2,4,6-trichlorophenoxyacetic acid) being identified as the major components of the residue. It is concluded that no specific metabolism is expected in rotational crops compared to primary crops (EFSA, 2011).

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of prochloraz residues was investigated in the framework of the EU pesticides peer review. It was concluded that prochloraz is stable under standard hydrolysis conditions simulating pasteurisation, baking/brewing/boiling and sterilisation (EFSA, 2011).

In principle, the effect of processing on the nature residues for the major metabolites observed in raw plant commodities (BTS 44595 and BTS 49596) should also be assessed. However, considering that an extensive degradation of prochloraz, which proceeds through the 2,4,6-trichlorophenol moiety, was observed in plant commodities, it is not expected that new metabolites are formed when BTS 44595 and BTS 49596 or any other metabolites including the 2,4,6-trichlorophenol moiety is subject to standard hydrolysis conditions. Consequently, further studies investigating the degradation of those metabolites through standard hydrolysis are not considered necessary.

---

8 Assumption for the calculation of the accumulated PEC soil estimation: consideration of a biphasic decline of prochloraz in soil with DT50 of 73.2 days, DT50 of 7,545 days, following FOMC kinetics alpha = 0.3593, beta = 12.45; considering a crop interception of 80% (at BBCH 49-69) for oilseed rape. Critical GAP: 2 applications at 14-day intervals at the single rate of 0.45 kg a.s./ha; considering a soil mixing depth of 20 cm and assuming a soil bulk density of 1.5 g/cm³.
It is noted that EUR-L-SRM informed EFSA that metabolite BTS 40348 was found in some samples of canned products (EFSA, 2018c). Considering the above, it is not expected that this presence was due to the degradation of the parent compound itself.

1.1.4. Methods of analysis in plants

Several analytical methods for enforcement of prochloraz and its metabolites BTS 44595 and BTS 44596 were fully validated in the four main plant matrices (high water content, high oil content, dry and acidic). In the framework of the EU pesticides peer review, it was concluded that prochloraz and metabolites BTS 44595 and BTS 44596 could be analysed in products of plant origin by liquid chromatography with tandem mass spectrometry (LC-MS/MS) with a limit of quantification (LOQ) of 0.01 mg/kg for each compound (EFSA, 2011). In the framework of the present review, additional methods also using high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) were reported and validated for the analysis of prochloraz, metabolites BTS 44595 and BTS 44596 in high water content, high acid content, high oil content and dry commodities (Ireland, 2015). The validated LOQ of 0.01 mg/kg for each compound was confirmed. These conclusions were also confirmed by the EURLs during the completeness check (EURLs, 2016).

It is noted that validated common moiety analytical methods are also available for the determination of prochloraz and the metabolites containing the 2,4,6-trichlorophenol moiety by analysing 2,4,6-trichlorophenol after hydrolysis. However, these methods are not specific to prochloraz.

1.1.5. Stability of residues in plants

The storage stability of prochloraz and its metabolites BTS 44595 (also referred to as M201-04) and BTS 44596 (also referred to as M201-03) was investigated in the framework of the EU pesticides peer review (EFSA, 2011) and in new studies submitted under this review (Ireland, 2015; France, 2016).

In high oil content and dry/high starch content commodities, the studies assessed in the peer review demonstrated storage stability for each compound independently: prochloraz (8 months), metabolite BTS 44595 (8 months) and metabolite BTS 44596 (6 months). An additional study reported in the framework of this review demonstrates stability of prochloraz and metabolite BTS 44595 for a longer period (up to 25 months) in both matrices. For metabolite BTS 44596, however, the study does not show good recovery even after short storage periods (France, 2016). This confirms the outcome of the peer review where the stability of this compound was considered questionable in these matrices.

For high water and high acid content matrices, the new study reported by France demonstrates the storage stability of prochloraz, metabolite BTS 44595 and metabolite BTS 44596 (separately) for up to 19 and 12 months, respectively (France, 2016). It is considered that the results of this study should supersede the outcome of the peer review for high water and high acid content matrices.

In addition, the storage stability of the total residues analysed as 2,4,6-trichlorophenol moiety (i.e. sum of all metabolites containing the 2,4,6-trichlorophenol moiety) was investigated in high water content commodities, high oil content commodities and dry/starch commodities (EFSA, 2011; France, 2016). When spiked with prochloraz, metabolite BTS 44595 and metabolite BTS 44596 and then analysed for sum of all metabolites containing the 2,4,6-trichlorophenol moiety, longer storage stability periods were demonstrated in high oil content commodities (36 months) as well as in high water content commodities and dry/starch commodities (24 months).

Overall, the above results demonstrate that prochloraz and its metabolite BTS 44595 are stable for a long period in all plant matrices (up to 25 months) while the most limiting storage stability period for metabolite BTS 44596 is generally shorter (6–19 months). However, the results obtained on total residues analysed as 2,4,6-trichlorophenol moiety suggest that, if metabolite BTS 44596 is not stable for a long period in plant matrices, it is at least degraded into other metabolites containing the 2,4,6-trichlorophenol moiety during the storage. Considering that metabolite BTS 44596 is likely to degrade into its amide form (metabolite BTS 44595) in plants (see Section 1.1.1), it can reasonably be assumed that most of the degraded part of BTS 44596 is actually retrieved as BTS 44595. One additional storage stability study investigating the degradation of BTS 44596 would be desirable to confirm it (minor deficiency).

It is noted that no specific study is available for the storage stability in cereal straw. However, as storage stability was investigated and demonstrated in the four main plant matrices, the most limiting storage stability conditions demonstrated for general matrices are assumed to be applicable to cereal straw.
1.1.6. Proposed residue definitions

The available primary crop metabolism studies are sufficient to conclude on a similar metabolism of prochloraz in all plant commodities and following all investigated types of treatment. Furthermore, a similar metabolism was observed in rotational crops (EFSA, 2011).

As the parent compound is extensively degraded in plants it may not be a sufficient marker for enforcement. The available studies indicate that the two main metabolites, BTS 44595 (also referred to as M201-04) and BTS 44596 (also referred to as M201-03), are found in significant proportions in all plant commodities. Therefore, the residue for enforcement is proposed as the sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz. This proposal is in line with the conclusion of the peer review (EFSA, 2011). Validated analytical methods for enforcement of this residue definition are available (see Section 1.1.4). As each compound constituent of the residue definition can be analysed with an LOQ of 0.01 mg/kg, a combined LOQ of 0.03 mg/kg is considered for the proposed residue definition for enforcement. It is noted that the residue definition for enforcement currently in place in the EU MRL Regulation as well as at Codex level is the sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety expressed as prochloraz. However, this residue definition for enforcement of current MRLs and CXLs is not considered appropriate because, as discussed in the framework of the EU pesticides peer review, the common moiety residue definition is not specific to prochloraz (EFSA, 2011).

For risk assessment purpose, however, all degradation and reaction products containing the 2,4,6-trichlorophenol moiety are regarded as residues of concern. Therefore, it was agreed during the peer review to base the residue definition for risk assessment on the common moiety approach. Consequently, the residue for risk assessment was defined as sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz (EFSA, 2011). This proposal remains valid in the framework of the present review.

Considering that a similar metabolic pathway was observed in all studies, a general residue definition can be proposed for all crops. It is noted that all GAPs under consideration in this review are supported by the available metabolism studies, except the post-harvest treatment on citrus fruits. However, it is not expected that post-harvest treatment would present a different pathway than the one observed in the available studies. Therefore, the proposed residue definition is also expected to cover post-harvest treatment and additional study investigating the metabolism of prochloraz in post-harvest treatment is not required. Nevertheless, it is noted that no information is available on whether the degradation of prochloraz after post-harvest treatment is as extensive as the one observed with foliar treatment; this point should be addressed with GAP-compliant residue trials analysing for both residue definitions in citrus fruits (see Section 1.2.1).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of prochloraz residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Ireland, 2015), including residue trials evaluated in the framework of the peer review (Ireland, 2007, 2010) or in the framework of a previous MRL application (EFSA, 2010, 2018a) and additional data submitted during the completeness check (Belgium, 2016; France, 2016; Greece, 2016).

For high water content commodities (cultivated fungi, sugar beet and forage), all residue trial samples considered in this framework were stored in compliance with the conditions for which storage stability or residues was demonstrated. Decline of residues during storage of the trial samples is therefore not expected for these commodities. This is also the case for most of the residue trials performed on wheat and barley. In some of these studies, however, the maximal storage period of the samples was more than 6 months, which is the limiting storage period of metabolite BTS 44596 for dry commodities (see Section 1.1.5). For information, the residue trials taken from these studies were reported in italic in Appendix B.1.2.1. It is noted that the residue levels observed in these trials are similar to those that were stored for less than 6 months. In addition, as the total residue analysed as 2,4,6-trichlorophenyl moiety (i.e. residue definition for risk assessment) was found to be stable for 24 months, the residue data for risk assessment are not expected to be affected. Therefore, this is considered as a minor deficiency. For sake of completeness, further details on the storage conditions for the residue trials performed on wheat and barley and reported in italic (Table B.1.2.1) would be desirable. A similar reasoning applies to the residue trials supporting the GAPs on rapeseed and other...
Some of these samples seem to have been stored for more than 6 months. However, as the samples analysed for the total residue containing the 2,4,6-trichlorophenyl moiety show similar levels than those analysed for the sum of parent and metabolites BTS 44595 and BTS 44596, the possible degradation of metabolite BTS 44596 is expected to be covered by the other metabolite included in the residue definition for enforcement.

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).

Residue trials are not available to support the authorisations on citrus fruits, almonds, stone fruits and strawberries. Therefore, MRL or risk assessment values for these crops could not be derived by EFSA and the following data gaps were identified:

- Citrus fruits: four trials on oranges and four trials on mandarins compliant with the GAP (post-harvest use) are required;
- Almonds: four trials compliant with the southern outdoor GAP are required;
- Peaches and apricots: eight trials compliant with the southern outdoor GAP are required;
- Plums: eight trials compliant with the southern outdoor GAP are required;
- Cherries: four trials compliant with the southern outdoor GAP are required;
- Strawberries: eight trials compliant with the northern outdoor GAP and eight trials compliant with the indoor GAP are required. It is noted that considering the timing of application (just after planting), significant residues in fruits harvest at maturity may not be expected. Therefore, the required number of trials might be reduced in the case these data would confirm this assumption.

For all other crops, available residue trials are sufficient to derive MRL and risk assessment values, taking note of the following considerations:

- Cultivated fungi: out of 11 trials considered to derive the MRL, only 2 trials were analysed according to the residue definition for enforcement. The other nine trials were analysed for total residues expressed as 2,4,6-trichlorophenyl moiety (i.e. residue definition for risk assessment). However, this is considered acceptable because the metabolism study performed on mushroom has shown the residues to be almost exclusively composed of the parent compound (EFSA, 2011). Additional data are not deemed necessary.
- Barley: the critical GAP authorised in the northern zone is defined for last application at BBCH 61 (inflorescence fully emerged and beginning of flowering stage) and is fully supported by data. Therefore, appropriate MRL and risk assessment values can be derived from the northern data. A less critical GAP is authorised in the southern zone with application at BBCH 49 (end of booting stage, no awn visible). Therefore, MRL derived from the northern data is expected to cover the southern GAP. This is partially confirmed by two trials matching the southern GAP showing residue levels at least in the same range than the ones obtained with the northern GAP. Additional data are not deemed necessary.
- Barley and oat (seed treatment): a fall-back GAP was reported for these crops (Belgium, 2016). It is noted that this GAP is supported by a limited number of trials: only two trials in accordance with the residue definition for enforcement and five trials in accordance with the residue definition for risk assessment. These trials were performed at the overdosed rate of 0.21 g/100 kg (compared to 0.12 g/100 kg). However, these deviations are deemed acceptable considering that residues levels remained the below LOQ in grain and straw for both residue definition for enforcement and risk assessment. Therefore, additional data are not deemed necessary.
- Wheat: the critical GAPs authorised in northern and southern zones consist of two applications at the rate of 0.45 kg a.s./ha, with last application during flowering stage (BBCH 65-69). Therefore, these GAPs are considered equivalent. These GAPs are supported by sufficient datasets both presenting similar ranges and distribution of results. Furthermore, the MRL proposals derived from northern and southern data only differ from one MRL class for grain (0.3 and 0.2 mg/kg) and for straw (20 and 15 mg/kg). Therefore, it is proposed to merge the northern and southern datasets in order to derive MRL and risk assessment values for wheat grain and wheat straw.

---

9 NEU and SEU data non-significantly different, using a U-test (Mann–Whitney).
- Rye: the combined data set of northern and southern trials performed on wheat can be extrapolated to rye for which the same GAP is authorised in the northern zone, allowing to derive appropriate MRL and risk assessment values for this crop. It is noted that the southern GAP on rye (with last application at BBCH 49) is less critical than the northern GAP (with last application at BBCH 65). No trials are available to support the southern GAP. However, the MRL derived from the combined data set (NEU/SEU) obtained on wheat at a more critical GAP is expected to also cover the southern GAP on rye. Additional data are not deemed necessary.

- Rape/Canola forage: one additional trial compliant with the southern outdoor GAP is desirable (minor deficiency).

Considering that different residue definitions are proposed for enforcement and risk assessment, conversion factors (CF) were derived for all commodities. Several residue trials including simultaneous analysis according to the residue definition for enforcement and risk assessment are available. The results for both residue definitions are reported by pairs in Appendix B.1.2.1, using the same order for the results expressed according to enforcement and risk assessment residue definitions. Based on these trials and considering the median CF derived from all available pairs of data, EFSA is proposing a CF of 1 in oilseeds, 2 in sugar/fodder beet root, 2.8 in sugar/fodder beet tops and 4 in rape/canola forage. The same principle was applied to small grain cereals for which harmonised CFs were derived for wheat, barley, rye and oat grains (1.7), barley/oat straw (1.8) and wheat/rye straw (1.5), based on the overall data. These CFs are consistent with the proportion of parent, metabolite BTS 44595 and BTS 44596 observed in the metabolism studies performed on cereals. For cultivated fungi, a CF of 1 is deemed sufficient as the metabolism study performed on mushroom indicate the residues to be almost exclusively composed of the parent compound (EFSA, 2011).

### 1.2.2. Magnitude of residues in rotational crops

Field studies investigating the residues of prochloraz in rotational crops are not available. Therefore, a tentative assessment of the magnitude of residues in rotational crops was performed based on the confined rotational crops studies. It is noted that in Commission Implementing Regulation No 1143/2011 a restriction is set for the outdoor uses regarding the application rate which shall not exceed 0.45 kg a.s./ha per application. However, as two applications per year are authorised in many annual crops (e.g. rapeseeds, cereals, sugar beets), the maximum annual application rate is 0.90 kg a.s./ha. Therefore, the confined studies performed on bare soil or primary plants treated with prochloraz at rates 0.94–1.1 kg a.s./ha are deemed representative of the more critical GAPs authorised in the EU. This is confirmed by doing the comparison between the accumulated PEC soil estimation with the residue concentrations in soil that were reached in the confined studies (see Section 1.1.2 for details).

In the confined rotational crop studies, total radioactivity remained below 0.03 mg eq/kg in leafy crops and cereal grains; the maximal TRR of 0.03 mg eq/kg was observed at plant-back interval (PBI) of 30 days in lettuce and barley grain. Therefore, no residues above the combined LOQ are expected in leafy crops and cereal grains grown in rotation.

In cereal straw and root crops however, significant residues uptakes were observed. In wheat and barley straw, high TTR levels were observed at all PBIs: maximum observed at PBI 30 day (1.14 mg eq/kg) and still significant at PBI 365 days (0.43 mg eq/kg). In radish root, significant residues (i.e. 0.05 mg eq/kg) were only found at 30 days PBI but clearly decrease below the LOQ with longer PBI of 120 or 365 days. In radish tops, TTR levels of 0.05 mg eq/kg were still observed at PBI 365 days. Therefore, when considering the total residues as defined for risk assessment, significant residues in rotational crops can be expected in cereal straw and root crops tops (up to PBI 365 days) and in roots (at PBI 30 days).

Considering the above, EFSA is of the opinion that a mitigation measure could be set to limit the residue uptakes in rotational crops. The available data indicate that a restriction such as ‘crop not to be rotated with a PBI shorter than 365 days’ would allow limiting the residue uptake to the maximum of 0.43 mg/kg in cereal straw, 0.05 mg/kg in radish tops and below the LOQ in radish roots. As these levels are significantly lower than the ones from primary crops in wheat, rye, barley and oats straw as well as in sugar and fodder beet (roots and tops), such a mitigation measure should be sufficient to avoid any concerns in these crops. However, it highlighted that this remains an indicative assessment.

---

10 Overall estimation considering the median CFs calculated in barley grain (1.54–1.67) and wheat grain (1.67).

11 Overall estimation from all individual CFs calculated in barley straw (NEU and SEU data).

12 Overall estimation from all individual CFs calculated in wheat straw (NEU and SEU data).
based on the confined rotational crop studies. In order to confirm or refine this proposed mitigation measures, field rotational crop studies covering the plateau level may still be required at national level.

For all other cereals (straw) and root crops (tops) for which no GAPs are currently authorised (i.e. millet straw, rice straw, maize stover, sorghum stover and turnip tops), the possible uptake expected at PBI 365 days (0.05–0.43 mg/kg) should be considered in the risk assessment as the proposed mitigation measures cannot ensure the total absence of residue uptake in these crops. This was considered in the calculation of the livestock dietary burden (see Section 2).

Regarding the residue definition for enforcement, cereal straw is the only commodity for which residues can exceed the LOQ. Therefore, if the proposed mitigation measures are applied, the MRLs derived on food commodities based on primary crops data are expected to cover any potential residue uptakes from previous applications.

In the absence of field studies investigating the residues of prochloraz in rotational crops, EFSA was not able to assess further scenarios.

It is noted that in the absence of data for fruit crops, no conclusion was drawn on whether residue uptake might be expected in fruits grown in rotation. However, it is generally expected that residue uptakes in fruits commodities are lower than the ones observed in leaves, roots and straw. Therefore, if the proposed restriction measures would be applied to annual fruit crops as well, no concern concerns should be expected for fruit crops. In addition, it is highlighted that residue trials compliant with the authorised GAP on strawberries (‘application just after planting’) were required (see Section 1.2.1). These trials should provide further information on the potential uptake from soil to fruit. Depending on the results of these trials, this point may be either deemed addressed or to be reconsidered in the future.

1.2.3. Magnitude of residues in processed commodities

Studies investigating the magnitude of prochloraz residues in processed commodities were assessed during the peer review (Ireland, 2007; EFSA, 2011) and by the RMS in the framework of the MRL review (Ireland, 2015). An overview of all available processing studies is available in Appendix B.1.2.3.

In these studies, specific analysis for parent and metabolites BTS 44595 (M201-04) and BTS 44596 (M201-03) was not carried out but residues levels were directly determined as total residues containing the 2,4,6-trichlorophenol moiety. Therefore, processing factors derived from these studies do not match with the proposed residue definition for enforcement (restricted to the sum of parent and metabolites BTS 44595 and BTS 44596). Although not appropriate, these studies are expected to provide good indication on the possible concentration or dilution of the total residues in processed commodities. Therefore, these studies were used to derive tentative processing factors on the processed commodities of barley (brewing malt, beer, milled by-products) and wheat (milled by-products, flours and breads).

Conversion factors (CFp) for risk assessment in the processed commodity should normally be calculated. However, since separate analysis for enforcement and risk assessment residue definitions were not performed in processed commodities, CFs for processed commodities could not be derived. However, considering that processing does not affect the nature of residues for the parent compound (see Section 1.1.3) and assuming that the same would occur for metabolites BTS 44595 and BTS 44596, the CFs derived for raw plant commodities can tentatively be used for processed commodities. It is noted that additional studies investigating the magnitude of residues in wheat and barley processed commodities were reported by France during the completeness check (France, 2016). However, as these studies were neither evaluated by France nor by any other Member State, they are only considered for information. These studies include separate analysis of parent and metabolites BTS 44595 and BTS 44596 and indicate that the processing factors derived from the total residues containing the 2,4,6-trichlorophenol moiety may be slightly overestimated.

Considering the above, the absence of processing studies including separate analysis for residue definitions for enforcement and risk assessment is only considered as a minor deficiency. However, if robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies including separate analysis for residue definitions for enforcement and risk assessment would be needed. In this view, a complete assessment of the studies reported by France would be desirable (minor deficiency).
1.2.4. Proposed MRLs

Consequently, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for citrus fruits, almonds, stone fruits and strawberries. Tentative MRLs were also derived for cereal straw, sugar beet tops, fodder beet (root and tops) and rape/canola forage in view of the future need to set MRLs in feed items.

It was noted that significant residues may be expected in rotational crops. A risk mitigation measure (minimum PBI of 365 days) was tentatively proposed by EFSA to limit this uptake. This proposal may need to be confirmed or refined by additional field rotational crops studies. In the meanwhile, it is assumed that the proposed mitigation would be sufficient to avoid significant uptake in food commodities. Therefore, it was not deemed necessary to derive MRL proposals accommodating residues in rotational crops. For certain feed items, however (in particular cereal straw and sugar beet/fodder beet/turnips tops), there were indications that minor residue uptake cannot be totally avoided, even considering the proposed mitigation measure. Indicative risk assessment values based on the TRR levels observed in the confined rotational crops studies were derived in order to be considered in the livestock dietary burden.

It was noted that fall-back MRLs and risk assessment values could also be derived from less critical GAPs reported for barley and oat (seed treatment; fully supported by data).

2. Residues in livestock

Prochloraz is authorised for use on citrus fruits, oilseeds, cereals, sugar/fodder beet and rape seed for forage that might be fed to livestock. Livestock dietary burdens were therefore calculated for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. Livestock dietary burdens were calculated residues levels resulting from the critical uses on primary crops as well as the possible uptake in rotational crops. A tentative estimate of the residue levels expected in rotational crops (maize/sorghum stover, millet straw, rice straw and turnip tops) was made using the TRR levels measured in the confined rotational crops studies, considering a PBI of 365 days (see also Section 1.2.2). The input values for all relevant commodities are summarised in Appendix D. The dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in all commodities of animal origin.

It is highlighted that residue data were not available to support the post-harvest treatment reported on citrus fruits. The animal intake of prochloraz residues via these commodities has therefore not been assessed. Considering that post-harvest treatment may potentially lead to high residue levels and also considering the assumption on the effect of the proposed PBI are only tentative, the calculated dietary burden is potentially under-estimated and is therefore considered on a tentative basis only.

2.1. Nature of residues and methods of analysis in livestock

The nature of prochloraz in livestock was investigated in lactating cows, goats and in laying hens at levels covering the maximum dietary burden calculated in this review. The metabolism studies were evaluated the framework of the EU pesticides peer review (EFSA, 2011). These studies were all performed with parent prochloraz, although the metabolism studies have shown the parent to be extensively metabolised and not present in plants. However, these studies were considered acceptable during the peer review since the main metabolites identified in plants are also the major metabolites in animal matrices.

These studies show that prochloraz is extensively degraded as it was only detected in goat liver and fat (< 6% TRR). Radioactive residues were composed of many different degradation compounds. It should be noted that the metabolites BTS 44596 (5-66% TRR), BTS 44595 (5-19% TRR) and BTS 9608 (5-22% TRR) were almost present in all matrices and in significant proportions. Metabolite 2,4,6-trichlorophenol was also identified as a major metabolite but only in cow liver (19% TRR) where the compounds mentioned above were in similar proportions. In milk, the metabolite BTS 54906 was observed as the most abundant component (58% TRR), but only in the cow study where metabolite BTS 44596 was also significantly present (23% TRR). The presence of metabolite BTS 54906 was not
confirmed in the cow feeding study, even at the highest dose rate (2.5N; see also Section 2.2) and it was finally concluded that this compound should not be considered as a significant metabolite in milk (EFSA, 2011).

In laying hens, the highest TRR were identified in liver (max 0.88 mg eq/kg) and eggs yolk (max 1.68 mg eq/kg). Lower levels were found in fat and muscle (< 0.08 mg eq/kg). The main compound identified was metabolite BTS 44596 (15–55% TRR in all hens tissues) and BTS 9608 (14–39% TRR in muscle, fat and liver). Other metabolites BTS 44595, BTS 44770 and BTS 3037 were also present at lower levels.

Considering that BTS 44595 and BTS 44596 can be relevant markers for the residues in all animal matrices, the peer review has defined the residue for enforcement as sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz (EFSA, 2011). This proposal is still valid under the present review. A method using HPLC–MS/MS was fully validated in all animal matrices for the analysis of prochloraz, BTS 44595, BTS 44596 with a combined LOQ of 0.03 mg/kg (Ireland, 2015). This information was confirmed by the EURLs (2016). It is noted that the residue definition for enforcement currently in place in the EU MRL Regulation as well as at the Codex level is the sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety expressed as prochloraz. It is noted that validated analytical methods are also available for the determination of prochloraz and all metabolites containing the 2,4,6-trichlorophenol moiety. However, the residue definition for enforcement of current MRLs and CXLs is not considered appropriate because the common moiety residue definition is not specific to prochloraz (EFSA, 2011).

For risk assessment purpose, however, all degradation and reaction products containing the 2,4,6-trichlorophenol moiety are regarded as residues of concern. Therefore, it was agreed during the peer review to base the residue definition for risk assessment on the common moiety approach. Consequently, the residue for risk assessment was defined as sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz (EFSA, 2011). This proposal remains valid in the framework of the present review.

Considering that prochloraz and its main metabolites BTS 44595 and BTS 44596 are fat soluble and that residues levels retrieved in fat were significantly higher compared to muscle, the proposed residue definition is fat soluble (EFSA, 2011).

The storage stability of prochloraz and its metabolites BTS 44595 and BTS 44596 was investigated in the framework of the peer review (EFSA, 2011) and in new studies submitted under this review (Ireland, 2015; France, 2016). Each compound taken separately is stable for a period of 3 months in all matrices. In addition, the total residues analysed as 2,4,6-trichlorophenol moiety was demonstrated stable for a period of 12 months in all matrices.

Tentative CFs from enforcement to risk assessment were derived from the metabolism studies. For ruminant tissues, an overall CF of 2 was derived from the cow and goat metabolism studies, considering the respective ratios of the relevant metabolites in the different tissues (EFSA, 2011). For milk, a tentative CF of 4 can be proposed considering that metabolite BTS 44596 (only relevant compound in milk) accounted for 23% of the TRR in the cow metabolism study. Similarly, tentative CFs can be proposed for poultry muscle (9), fat (6), liver (6) and eggs (2) based on the ratio between TRR levels and residues levels relevant for enforcement according to the metabolism study performed on laying hens.

2.2. Magnitude of residues in livestock

The magnitude of prochloraz residues in animal matrices was investigated in two feeding studies performed with cows. These studies were assessed in the framework of the EU pesticides peer review (EFSA, 2011).

In the first study, dairy cows were dosed with prochloraz for 28 days at a level of 0.31, 0.92 and 3.1 mg/kg bw per day, whereby covering the maximum dietary burdens calculated for all ruminants. The four main tissues (muscle, fat, liver and kidney) were sampled and analysed for the total residues containing the 2,4,6-trichlorophenol moiety, which is matching with the residue definition for risk assessment. Therefore, this study can be used to derive risk assessment values in all ruminant tissues. However, it is not appropriate to derive MRLs according to the residue definition for enforcement. In

---

13 Highest dose rate is 3.1 mg/kg body weight (bw) per day is 2.5N compared to the highest DB calculated for dairy ruminants (1.2 mg/kg bw per day for sheep ewe).

14 Dose rate of 200, 600 and 2,000 mg prochloraz per day (Ireland, 2007) recalculated assuming body weight of 650 kg for dairy cattle (OECD, 2013).
the absence of appropriate data, a tentative estimation of the MRL expressed according to the residue definition for enforcement was done by dividing residue levels analysed for the total 2,4,6-trichlorophenol moiety by the CF (enforcement to risk assessment) of 2, previously derived from the metabolism studies (see also Section 2.1). As the metabolic pathways are expected to be similar in ruminants and pigs, the same approach was followed for swine commodities. Nevertheless, it is highlighted that for livestock a feeding study analysing for both enforcement and risk assessment residue definitions would remain the only appropriate approach to derive robust MRL in ruminant and swine tissues. Considering the outcome of the risk assessment (see Section 3), risk managers may require robust MRLs for enforcement purpose in ruminant tissues. Should it be the case, an additional feeding study as defined above would be needed. Alternatively, MRLs for ruminant and swine tissues based on the common 2,4,6-trichlorophenol moiety might still be considered, taking into account however that these MRLs would not be specific to prochloraz (see Section 2.1).

In the second study, dairy cows were dosed with prochloraz using the same feeding levels as in the first study but focused on milk samples analysis. Milk samples were analysed for prochloraz and for the main individual metabolites found in the metabolism studies (BTS 44596, BTS 54906 and BTS 54908). The results confirmed the absence of prochloraz and showed that metabolites BTS 54906 and BTS 54908 were not present at any feeding levels. The metabolite BTS 44596 was only retrieved at low levels (< 0.05–0.013 mg/kg) at the highest administered dose. Considering that parent and metabolite BTS 44595 were not found in milk, this study is deemed appropriate to derive MRL and risk assessment values in milk.

For laying hens, there is no feeding study available. Considering that need for MRLs is triggered in poultry, a livestock a feeding study analysing for both enforcement and risk assessment residue definitions should be required. A tentative assessment of residue levels expected in poultry products was proposed using the metabolism study as surrogate of feeding studies. The results of total TRR were used to estimate the residues for risk assessment. The residues levels according to the residue definition for enforcement were calculated considering the sum of individual levels for parent (not present), metabolite BTS 44595 (max 0.023 mg eq/kg) and BTS 44596 (between 0.008 and 0.381 mg eq/kg). The residue levels according to the residue definition for risk assessment were approached considering the total radioactivity levels. These results allowed deriving tentative MRL, risk assessment values and CFs for poultry products.

The results of these three studies (feeding study for ruminant tissues, feeding study for ruminant milk and poultry metabolism) were scaled according to the dietary burdens calculated under the two different scenarios (EU1 considering all authorised GAPs and EU2 considering risk mitigation measures, see also Section 3.1). Therefore, two different sets for MRLs and risk assessment values were derived according to these scenarios (see Appendix B.2.2.1).

### 3. Consumer risk assessment

In the framework of this review, only the uses of prochloraz reported by the RMS in Appendix A were considered; however, the use of prochloraz was previously also assessed by the JMPR (FAO, 2001, 2004, 2009a,b). The CXLs, resulting from these assessments by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. However, it is highlighted that the existing CXLs are expressed according to a residue definition for enforcement different than the one proposed by EFSA. As the residue definition of the CXLs (sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety expressed as prochloraz) is not compatible with the definition proposed by EFSA, it was not possible to compare the CXLs with the EU MRLs derived under this review. Therefore, it was not possible to perform a consumer exposure calculation combining both EU MRLs proposals and existing CXLs. Therefore, the first round of calculations, performed without the CXLs (Section 3.1), should be used as a basis for MRL recommendations. For information purpose, an indicative risk assessment considering CXLs only was performed separately (Section 3.2).

#### 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, 2009a,b).

For plant commodities, poultry commodities and milk, the CFs derived in this review were used to express the residues according to the definition for risk assessment. For ruminant tissues, the risk assessment values derived from the feeding studies were directly used as they were already expressed according to the definition for risk assessment (see Section 2.2). For those commodities where data were insufficient to derive an MRL in Section 3, EFSA considered the existing EU MRL for an indicative calculation, noting that the existing residue definition is equivalent to the proposed residue definition for risk assessment.

The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation, assuming that the proposed mitigation measure (minimum PBI of 365 days for rotational crops) would be applied; there are indications that such a mitigation measure would be sufficient to avoid significant residue uptakes in non-treated food commodities (see Section 1.2.2).

All input values included in the exposure calculations are summarised in Appendix D.

The exposures calculated were compared with the toxicological reference values for prochloraz, derived by EFSA (2011) under Directive 91/414/EEC. The highest chronic exposure was calculated for German children, representing 483.8% of the acceptable daily intake (ADI). With regard to the acute exposure, an exceedance of the acute reference dose (ARfD) was identified for all citrus fruits (from 805% to 5,305% acute reference dose (ARfD)) and for bovine liver (222.7% ARfD).

In order to assist risk managers in the view of potential risk mitigation measures, EFSA made an attempt to identify a scenario where the toxicological reference values (ADI and ARfD) would not be exceeded.

For citrus fruits, no fall-back GAPs were provided by Member States; Greece was the only MS to report a GAP for these crops. Therefore, there was no other option than excluding these crops from the calculation.

With regard to bovine liver, EFSA identified the main contributors to the maximum dietary burden of cattle (all diets) in order to investigate the different possibilities to reduce the livestock exposure. In this first scenario (EU1), the main contributor was barley straw, followed by oat straw, fodder beet tops and sugar beet tops.

Therefore, different scenarios considering less critical GAPs (seed treatment) on barley and oat and with and without the uses on fodder and sugar beets were assessed. A summary of these different scenarios is reported in Table 2. The only scenario leading to a short-term exposure to bovine liver below the ARfD is the scenario considering the seed treatment GAPs on barley and oat and excluding any uses on sugar and fodder beets (see scenario EU2 Table 2). All those intermediate scenarios including GAP(s) with foliar treatment on at least one of these crops led to acute exposure concern for bovine liver (see scenarios Int1, Int2, Int3 and Int4 in Table 2).

It is noted that some fall-back GAPs using foliar applications for barley and oat were reported during the completeness check. An attempt to consider these GAPs in an additional scenario was performed by EFSA. However, none of these GAPs was suitable to derive a fall back MRL. These GAPs were either not supported by data, either not enough less critical to result in an acute exposure below the ARfD for bovine liver. It is noted that this conclusion was confirmed by Member States during the Member States consultation (EFSA, 2018c). As a matter of example, the southern GAP authorised on barley and oats consists of two applications no later than BBCH 49 and is expected to be less critical than the northern GAPs (BBCH 59-61). The available data supporting the southern GAP are very limited (see Appendix B.1.2.1). Furthermore, it indicates that high residue levels can still be expected in barley and oat straw after such a treatment (HR_{ag} = 20.6 mg/kg). Therefore, considering these GAPs on barley and/or oat is also expected to lead to acute exposure concern in bovine liver (see scenario Int4 in Table 2). For fodder and sugar beets, no fall-back GAPs were reported to EFSA.

Finally, it is noted that a risk mitigation consisting on not feeding livestock with cereal straw or beet tops previously treated with prochloraz was not considered in this reasoned opinion. There are indications that such measures may significantly reduce the livestock exposure to an acceptable level. However, as there is currently no indication on how these measures could be implemented in practice, such scenarios were not assessed in the present review.
A second calculation of the consumer exposure was performed under the scenario EU2 in which the livestock dietary burden was significantly lower (see also dietary burden calculated under scenario EU2 in Appendix B.2). MRLs and risk assessment values in livestock commodities were recalculated accordingly (see scenario EU2 in Appendix B.2.1). A detailed overview of the values included in the exposure calculations under scenario EU2 is available in Appendix D.2.2. According to the results of the second calculation, the highest chronic exposure decreased to 52.7% of the ADI (FR, toddler); the highest acute exposure calculated for bovine liver, represented 60.3% of the ARfD.

Based on these calculations, a risk to consumers was identified for the critical GAPs reported on citrus fruits, barley, oats, fodder beet and sugar beet. A fall-back GAP (seed treatment) was identified for barley and oat for which a second risk assessment did not result in an exceedance of the toxicological reference values. For citrus fruits, sugar beet and fodder beet however, no fall-back GAPs could be identified. For the remaining commodities, although the uncertainties due to the data gaps identified in Sections 1 and 2 still remain, the indicative exposure calculation performed under this second risk assessment did not indicate a risk to consumers.

### 3.2. Indicative consumer risk assessment of the existing CXLs

As the residue definition for enforcement of the CXLs is not compatible with the residue definition for enforcement proposed by EFSA, it was not possible to include the CXLs directly in the calculation performed in Section 3.1. For information purposes, EFSA has performed an indicative risk assessment with the existing CXLs only, considering the relevant data from JMPR evaluations (FAO, 2001, 2004, 2009a,b). As the CXLs and the risk assessment values from JMPR were derived according to the sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety expressed as prochloraz, the available values could directly be considered for an indicative risk assessment, without the use of a CF. For citrus fruits as well as for the subgroup of tropical and subtropical fruits with inedible peel, the highest residue values measured in pulp were considered in the calculations. An overview of the input values used for this exposure calculation is also provided in Appendix D.

**Table 2:** Overview of the different scenarios of feed diets and impact on the acute exposure for bovine liver

| No | Assumption(s) | Max DB for cattle (all diets) (mg/kg bw per d) | HR bovine liver (mg/kg) (a) | Acute exposure for bovine liver (% ARfD) |
|----|---------------|-----------------------------------------------|----------------------------|----------------------------------------|
| EU1 | All critical GAPs currently authorised (Appendix A) | 0.6965 | 6.90 | 222.7% |
| Int1 | EU1 excluding the foliar GAPs on barley (NEU and SEU) and considering the seed treatment instead(b) | 0.4664 | 4.98 | 160.7% |
| Int2 | Int1 excluding the foliar GAPs on oats (NEU and SEU) and considering the seed treatment instead(b) | 0.3064 | 3.81 | 122.9% |
| Int3 | Int2 excluding GAPs on fodder beet(c) | 0.2439 | 3.35 | 108.1% |
| EU2 | Int3 excluding GAPs on sugar beet(c) | 0.1742 | 1.87 | 60.3% |
| Int4 | EU2 + fall-back GAP on barley/oat (foliar treatment: 2 applications before BBCH 49)(d) | 0.2710 | 3.55 | 114.5% |

DB: dietary burden; HR: highest residue; bw: body weight; ARfD: acute reference dose; GAP: Good Agricultural Practice; NEU: northern Europe; SEU: southern Europe; BBCH: growth stages of mono- and dicotyledonous plants.

(a): HR expressed according to the residue definition for risk assessment calculated according to the method defined in Section 2.2.

(b): When excluding the foliar GAPs on barley or oats, residues are expected to remain below LOQ in grain (with seed treatment) and the minimal residue level from rotational crops was considered for straw (0.43 mg/kg; see also Section 1.2.2).

(c): When excluding the GAPs on sugar or fodder beets, no residues are expected in roots and the minimal residue level from rotational crops was considered for tops (0.05 mg/kg; see also Section 1.2.2).

(d): Fall back GAP with 2 applications before BBCH 49, during the completeness check (HR risk assessment in barley straw is 20.6 mg/kg).

A second calculation of the consumer exposure was performed under the scenario EU2 in which the livestock dietary burden was significantly lower (see also dietary burden calculated under scenario EU2 in Appendix B.2). MRLs and risk assessment values in livestock commodities were recalculated accordingly (see scenario EU2 in Appendix B.2.2.1). A detailed overview of the values included in the exposure calculations under scenario EU2 is available in Appendix D.2.2. According to the results of the second calculation, the highest chronic exposure decreased to 52.7% of the ADI (FR, toddler); the highest acute exposure calculated for bovine liver, represented 60.3% of the ARfD.
Chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and the exposures calculated were compared with the toxicological reference values derived for prochloraz. The highest chronic exposure was calculated for WHO Cluster diet B, representing 18.8% of the ADI. With regard to the acute exposure, an exceedance of the ARfD was identified for oranges, grapefruits, pineapples, bananas, mangoes, mandarins, bovine liver, lemons and kiwi, representing 488%, 328%, 283%, 234%, 220%, 205%, 200%, 127% and 113% of the ARfD, respectively. No further refinements of the risk assessment were possible.

These calculations indicate a potential risk to consumers for the existing CXLs on oranges, grapefruits, pineapples, bananas, mangoes, mandarins, bovine liver, lemons and kiwi. Considering that a CXL on an animal commodity (bovine liver) may lead to acute concern, the CXLs on the plant commodities that can be fed to livestock are also deemed of concern; this includes the CXLs on citrus fruits, oilseeds and cereals.

No health concerns were identified for the CXLs on kumquats, lychee, passion fruits, prickly pear, star apple, American persimmon, avocados, papaya, pomegranate, cherimoya, guava, breadfruit, durian, soursop, cultivated fungi, buckwheat grain and spices (fruits and berries). However, considering that CXLs are currently expressed according to a residue definition for enforcement not compatible with the one proposed by EFSA, it was not possible to consider them into the EU MRL recommendations.

**Conclusions**

The nature of prochloraz in primary plants was investigated in more than three different crop groups (cereals, oilseeds/pulses, fruit crops and mushrooms). Furthermore, the available studies cover different types of applications (foliar applications, seed treatment and local applications). A similar metabolism was identified in all studies, allowing EFSA to derive a general residue definition in plant commodities. For enforcement purpose, the residue was defined as the sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz. Validated analytical methods for enforcement of this residue definition are available. The residue for risk assessment was defined as sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz. A similar residue pattern was observed in rotational crops and prochloraz was also found to be stable under standard hydrolysis conditions. Therefore, these residue definitions are also deemed valid for rotational crops and processed commodities.

The available residue trials were sufficient to derive MRL proposals, risk assessment values and CFs for all commodities under evaluation, except for citrus fruits, almonds, stone fruits and strawberries. Tentative MRLs were also derived for cereal straw, sugar beet tops, fodder beet (root and tops) and rape/canola forage in view of the future need to set MRLs in feed items.

Based on the confined rotational crops studies, it was concluded that significant residues may be expected in rotational crops. A risk mitigation measure (minimum PBI of 365 days) was proposed on a tentative basis to limit this uptake. For food commodities, the proposed mitigation is expected to be sufficient to avoid significant uptake. For feed items, however, minor uptake cannot be avoided, even considering the proposed mitigation measure. No MRL proposals accommodating residues in rotational crops were needed as residue uptake would only occur in feed items. However, tentative risk assessment values to be considered in the livestock dietary burden could be derived.

Tentative processing factors were derived on the processed commodities of barley (brewing malt, beer, milled by-products) and wheat (milled by-products, flours and breads). Prochloraz is authorised for use on several feed items and dietary burdens calculated for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in all commodities of animal origin. The available metabolism studies on dairy ruminants and laying hens were sufficient to propose a common residue definition in all livestock commodities. For enforcement purpose, the residue was defined as the sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz. Validated analytical methods for enforcement of this residue definition are available. The residue for risk assessment was defined as sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz. Tentative CFs from enforcement to risk assessment were derived from the metabolism studies. However, as the available feeding studies do not provide analysis in accordance with the proposed residue definition for enforcement, only tentative MRLs could be derived in livestock commodities.

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 an MRL, EFSA considered the existing EU MRL for an indicative
calculation. An exceedance of the ARfD was identified for all citrus fruits (from 805% to 5,305% ARfD) and for bovine liver (222.7% ARfD). Excluding citrus fruits and the GAPs leading to an acute concern in bovine liver from the calculations, the highest chronic exposure represented 52.7% of the ADI (FR, toddler) and the highest acute exposure amounted to 60.3% of the ARfD (bovine liver).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for prochloraz (as sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety expressed as prochloraz). This residue definition for enforcement is not compatible with the residue for enforcement proposed by EFSA. Therefore, although no health concerns were identified for some of the existing CXLs, these values could not be reported in the EU MRL recommendations. Furthermore, potential risk to consumers were identified for the existing CXLs on oranges, grapefruits, pineapples, bananas, mangoes, mandarins, bovine liver, lemons and kiwi.

**Recommendations**

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see summary table). 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 summary table footnotes for details in Table 3). In particular, some existing EU MRLs on plant commodities need to be confirmed by the following data:

- Additional residue trials on citrus fruits, almonds, peaches, apricots, plums, cherries and strawberries.

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 noted that Greece informed EFSA that the uses reported on almonds, peaches, apricots, plums and cherries would no longer be supported by the authorisation holder in the future (EFSA, 2018c).

Regarding citrus fruits, it is also highlighted that an exceedance of the ARfD was identified when considering the existing MRL in the risk assessment. As no residue trials were available, no further refinement was possible and thus the existing MRL was deemed of concern. Therefore, no MRL proposal was reported for grapefruits, oranges, lemons, limes and mandarins.

Furthermore, the critical GAPs reported for barley, oat, sugar beet and fodder beet (foliar treatments) were found to lead to an exceedance of the ARfD in bovine liver. A fall-back GAP was identified for barley and oat, allowing deriving an MRL for these commodities. Member States are therefore recommended to reconsider or withdraw their national authorisations on barley and oats in order to ensure that the fall-back MRLs derived for these crops are not exceeded. For sugar beet and fodder beet, no fall-back GAPs were identified, thus either a specific LOQ or the default MRL of 0.01 mg/kg may be considered by risk managers for these corresponding commodities. Member States are therefore recommended to reconsider or withdraw their national authorisations on sugar beet and fodder beet consequently.

In addition, it was noted that significant residues may be expected in rotational crops. Considering that residue uptakes are more likely to occur in feed items (cereal straw and sugar beet/fodder beet/turnips tops) and since acute concerns were identified for a commodity of animal origin (bovine liver), risk mitigation measures should be implemented in order to limit the residue uptakes in rotational crops. Based on the available data, there are indications that a mitigation measure such as ‘crop not to be rotated with a PBI shorter than 365 days’ would be sufficient to limit the residue uptake to the maximum of 0.43 mg/kg in cereal straw, 0.05 mg/kg in radish tops and below the LOQ in radish roots. Furthermore, it would allow limiting the residue uptakes to levels below the LOQ in all other food crops that can be grown in rotation. Therefore, the MRLs for plant commodities derived in this review do not take into account any potential residues from rotational crops.

When granting authorisations, Member States and risk managers are recommended to consider the suggested mitigation measure to limit the residue uptakes in rotational crops. However, this proposal is indicative only as it is based on the results of the confined rotational crop study. Any proposal of mitigation measures may need to be confirmed by the following data:

- Field studies investigating the magnitude of residues in rotational crops.
The MRL proposals in commodities of animal origin were derived in accordance with all above considerations, i.e. taking into account the fall-back GAPs on barley and oats and excluding GAPs on citrus fruits, sugar beet and fodder beet. In addition, it was assumed that the proposed risk mitigation measure for rotational crops would be sufficient and applied. These MRLs may need to be reconsidered if:

- Further data would be provided for citrus fruits;
- Different fall-back GAPs would be identified for barley and oat;
- Fall-back GAPs would be identified for sugar beet and fodder beet;
- Risk mitigation measures on rotational crops would not be confirmed and/or implemented.

Regarding the MRL proposals derived for animal commodities, it is highlighted that only tentative estimates could be proposed on the basis of the available livestock feeding and metabolism studies. Considering the outcome of the risk assessment (possible acute concerns with bovine liver), robust MRLs for enforcement purpose should be needed. Therefore, the following data should be required:

- Livestock feeding studies analysing for both enforcement and risk assessment residue definitions (relevant for ruminants and poultry commodities).

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following actions and data are therefore considered desirable but not essential:

- One additional residue trial on rape/canola forage;
- Processing studies including separate analysis for residue definitions for enforcement and risk assessment;
- A storage stability study investigating the degradation of BTS 44596 in plant commodities;
- Detailed identification of the residue trials for which samples may have been stored for more than 6 months (wheat, barley and rapeseed).

Regarding the CXLs, it is noted that the residue definition for enforcement used at the Codex level is not compatible with the residue for enforcement proposed by EFSA. The residue definition for enforcement currently in place at the Codex level is the sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety expressed as prochloraz. This residue definition for enforcement is not considered appropriate because the 2,4,6-trichlorophenol moiety is not specific to prochloraz. Therefore, although no health concerns were identified for some of the existing CXLs, these values could not be reported in the EU MRL recommendations. Furthermore, it is highlighted that potential risk to consumers were identified for the existing CXLs on oranges, grapefruits, pineapples, bananas, mangos, mandarins, bovine liver, lemons and kiwi.

### Table 3: Summary table

| Code number | Commodity   | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review MRL (mg/kg) | Comment                                      |
|-------------|-------------|-------------------------|----------------------|----------------------------------|----------------------------------------------|
| 110010      | Grapefruit  | 10                      | 10                   | –                                 | Further consideration needed                 |
| 110020      | Oranges     | 10                      | 10                   | –                                 | Further consideration needed                 |
| 110030      | Lemons      | 10                      | 10                   | –                                 | Further consideration needed                 |
| 110040      | Limes       | 10                      | 10                   | –                                 | Further consideration needed                 |
| 110050      | Mandarins   | 10                      | 10                   | –                                 | Further consideration needed                 |
| 120010      | Almonds     | 0.1*                    | –                    | 0.1                               | Further consideration needed                 |
| 140010      | Apricots    | 0.05*                   | –                    | 0.05                              | Further consideration needed                 |
| 140020      | Cherries (sweet) | 0.05*   | –                    | 0.05                              | Further consideration needed                 |
| 140030      | Peaches     | 0.05*                   | –                    | 0.05                              | Further consideration needed                 |
| 140040      | Plums       | 0.05*                   | –                    | 0.05                              | Further consideration needed                 |
| Code number | Commodity                    | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review MRL (mg/kg) | Comment                  |
|-------------|------------------------------|-------------------------|----------------------|----------------------------------|--------------------------|
| 152000      | Strawberries                 | 0.05*                   | –                    | 0.05                             | Further consideration needed(6) |
| 161040      | Kumquats                     | 0.05*                   | 10                   | –                                | Further consideration needed(6) |
| 162010      | Kiwi                         | 0.05*                   | 7                    | –                                | Further consideration needed(6) |
| 162020      | Lychee (Litchi)              | 0.05*                   | 7                    | –                                | Further consideration needed(6) |
| 162030      | Passion fruit                | 0.05*                   | 7                    | –                                | Further consideration needed(6) |
| 162040      | Prickly pear (cactus fruit)  | 0.05*                   | 7                    | –                                | Further consideration needed(6) |
| 162050      | Star apple                   | 0.05*                   | 7                    | –                                | Further consideration needed(6) |
| 162060      | American persimmon (Virginia kaki) | 0.05*                   | 7                    | –                                | Further consideration needed(6) |
| 163010      | Avocados                     | 5                       | 7                    | –                                | Further consideration needed(6) |
| 163020      | Bananas                      | 0.05*                   | 7                    | –                                | Further consideration needed(6) |
| 163030      | Mangoes                      | 5                       | 7                    | –                                | Further consideration needed(6) |
| 163040      | Papaya                       | 5                       | 7                    | –                                | Further consideration needed(6) |
| 163050      | Pomegranate                  | 0.05*                   | 7                    | –                                | Further consideration needed(6) |
| 163060      | Cherimoya                    | 0.05*                   | 7                    | –                                | Further consideration needed(6) |
| 163070      | Guava                        | 0.05*                   | 7                    | –                                | Further consideration needed(6) |
| 163080      | Pineapples                   | 5                       | 7                    | –                                | Further consideration needed(6) |
| 163090      | Bread fruit                  | 0.05*                   | 7                    | –                                | Further consideration needed(6) |
| 163100      | Durian                       | 0.05*                   | 7                    | –                                | Further consideration needed(6) |
| 163110      | Soursop (guanabana)         | 0.05*                   | 7                    | –                                | Further consideration needed(6) |
| 280010      | Cultivated fungi            | 3                       | 3                    | 3                                | Recommended(6)             |
| 401010      | Linseeds                     | 0.5                     | 0.05*                | 0.3                              | Recommended(6)             |
| 401030      | Poppy seeds                  | 0.1*                    | –                    | 0.3                              | Recommended(6)             |
| 401050      | Sunflower seeds              | 0.5                     | 0.5                  | 0.3                              | Recommended(6)             |
| 401060      | Rapeseeds/canola seeds       | 0.5                     | 0.7                  | 0.3                              | Recommended(6)             |
| 500010      | Barley grains                | 1                       | 2                    | 0.03*                            | Recommended(6)             |
| 500020      | Buckwheat grain              | 0.05*                   | 2                    | –                                | Further consideration needed(6) |
| 500030      | Maize grain                  | 0.05*                   | 2                    | –                                | Further consideration needed(6) |
| 500040      | Millet grain                 | 0.05*                   | 2                    | –                                | Further consideration needed(6) |
| 500050      | Oat grains                   | 1                       | 2                    | 0.03*                            | Recommended(6)             |
| 500060      | Rice grain                   | 1                       | 2                    | –                                | Further consideration needed(6) |
| 500070      | Rye grains                   | 0.5                     | 2                    | 0.2                              | Recommended(6)             |
| 500080      | Sorghum grain                | 0.05*                   | 2                    | –                                | Further consideration needed(6) |
| 500090      | Wheat grains                 | 0.5                     | 2                    | 0.2                              | Recommended(6)             |
| 820000      | Spices (fruits and berries)  | 0.2                     | 10                   | –                                | Further consideration needed(6) |
| 900010      | Sugar beet roots             | 0.1*                    | –                    | –                                | Further consideration needed(6) |
| 1011010     | Swine muscle                 | 0.1*                    | 0.5                  | 0.03*                            | Further consideration needed(6) |
| 1011020     | Swine fat tissue             | 0.1*                    | 0.5                  | 0.03*                            | Further consideration needed(6) |
| 1011030     | Swine liver                  | 0.1*                    | 10                   | 0.3                              | Further consideration needed(6) |
| 1011040     | Swine kidney                 | 0.1*                    | 10                   | 0.05                             | Further consideration needed(6) |
| 1012010     | Bovine muscle                | 0.1*                    | 0.5                  | 0.03*                            | Further consideration needed(6) |
| 1012020     | Bovine fat tissue            | 0.2                     | 0.5                  | 0.07                             | Further consideration needed(6) |
| 1012030     | Bovine liver                 | 2                       | 10                   | 1                                | Further consideration needed(6) |
| 1012040     | Bovine kidney                | 0.5                     | 10                   | 0.2                              | Further consideration needed(6) |
| 1013010     | Sheep muscle                 | 0.1*                    | 0.5                  | 0.03*                            | Further consideration needed(6) |
| Code number | Commodity               | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-------------------------|-------------------------|----------------------|-----------------------|---------|
| 1013020     | Sheep fat tissue        | 0.1*                    | 0.5                  | 0.15                  | Further consideration needed (f) |
| 1013030     | Sheep liver             | 0.1*                    | 0.1                  | 0.5                   | Further consideration needed (f) |
| 1013040     | Sheep kidney            | 0.1*                    | 0.1                  | 0.15                  | Further consideration needed (f) |
| 1014010     | Goat muscle             | 0.1*                    | 0.05*                | 0.03*                 | Further consideration needed (f) |
| 1014020     | Goat fat tissue         | 0.1*                    | 0.05*                | 0.03*                 | Further consideration needed (f) |
| 1014030     | Goat liver              | 0.1*                    | 0.1                  | 0.1                   | Further consideration needed (f) |
| 1014040     | Goat kidney             | 0.1*                    | 0.1                  | 0.15                  | Further consideration needed (f) |
| 1015010     | Equine muscle           | 0.1*                    | 0.5                  | 0.03*                 | Further consideration needed (f) |
| 1015020     | Equine fat tissue       | 0.1*                    | 0.5                  | 0.07                  | Further consideration needed (f) |
| 1015030     | Equine liver            | 0.1*                    | 0.1                  | 1                     | Further consideration needed (f) |
| 1015040     | Equine kidney           | 0.1*                    | 0.1                  | 0.2                   | Further consideration needed (f) |
| 1016010     | Poultry muscle          | 0.1*                    | 0.05*                | 0.03*                 | Further consideration needed (f) |
| 1016020     | Poultry fat tissue      | 0.1*                    | 0.05*                | 0.03*                 | Further consideration needed (f) |
| 1016030     | Poultry liver           | 0.1*                    | 0.2                  | 0.04                  | Further consideration needed (f) |
| 1020010     | Cattle milk             | 0.02*                   | 0.05*                | 0.03*                 | Further consideration needed (f) |
| 1020020     | Sheep milk              | 0.02*                   | 0.05*                | 0.03*                 | Further consideration needed (f) |
| 1020030     | Goat milk               | 0.02*                   | 0.05*                | 0.03*                 | Further consideration needed (f) |
| 1020040     | Horse milk              | 0.02*                   | 0.05*                | 0.03*                 | Further consideration needed (f) |
| 1030000     | Birds eggs              | 0.1*                    | 0.1                  | 0.1                   | Further consideration needed (f) |
|             | Other commodities of plant and animal origin | See Reg. 520/2011 | –                   | –                     | Further consideration needed (f) |

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

References

Belgium, 2016. 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 prochloraz, June 2016. Available online: www.efsa.europa.eu

Czech Republic, 2016. 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 prochloraz, June 2016. 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

www.efsa.europa.eu/efsajournal 24
EFSA Journal 2018;16(8):5401
Review of the existing MRLs for prochloraz

EFSA (European Food Safety Authority), 2010. Reasoned opinion on the modification of the existing MRL(s) for prochloraz in rice. EFSA Journal 2010;8(4):1580, 27 pp. https://doi.org/10.2903/j.efsa.2010.1580

EFSA (European Food Safety Authority), 2011. Conclusion on the peer review of the pesticide risk assessment of the active substance prochloraz. EFSA Journal 2011;9(7):2323, 120 pp. https://doi.org/10.2903/j.efsa.2011.2323

EFSA (European Food Safety Authority), 2018a. Completeness check report on the review of the existing MRLs of active substance prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 26 April 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 active substance prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 27 July 2018. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), Brancato A, Brocca D, Carrasco Cabrera L, De Lentdecker C, Ferreira L, Greco L, Janossy J, Jarrah S, Kardassi D, Leuschner R, Lythgo C, Medina P, Miron I, Molnar T, Nougadere A, Pedersen R, Reich H, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2018c. Reasoned Opinion on the modification of the existing maximum residue levels for prochloraz in various commodities. EFSA Journal 2018;16(4):5241, 28 pp. https://doi.org/10.2903/j.efsa.2018.5241

EURL, 2016. 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 Prochloraz, July 2016. 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, 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 10634/2010-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, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.3, July 2017.

FAO (Food and Agriculture Organization of the United Nations), 2001. Prochloraz. In: Pesticide residues in food – 2001. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 167.

FAO (Food and Agriculture Organization of the United Nations), 2004. Prochloraz. In: Pesticide residues in food – 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 178.

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

FAO (Food and Agriculture Organization of the United Nations), 2009b. Prochloraz. In: Pesticide residues in food – 2009. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 196.

France, 2016. 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 prochloraz, July 2016. Available online: www.efsa.europa.eu

Germany, 2016. 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 prochloraz, July 2016. Available online: www.efsa.europa.eu

Greece, 2016. 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 prochloraz, July 2016. Available online: www.efsa.europa.eu

www.efsa.europa.eu/efsajournal 25 EFSA Journal 2018;16(8):5401
Ireland, 2007. Draft assessment report on the active substance prochloraz prepared by the rapporteur Member State Ireland in the framework of Council Directive 91/414/EEC, January 2007. Available online: www.efsa.europa.eu

Ireland, 2010. Additional report to the draft assessment report on the active substance prochloraz prepared by the rapporteur Member State Ireland in the framework of Commission Regulation (EC) No 33/2008, July 2010. Available online: www.efsa.europa.eu

Ireland, 2015. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing MRLs for prochloraz, November 2015. Available online: www.efsa.europa.eu

Italy, 2016. 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 prochloraz, July 2016. 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, 2016. 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 prochloraz, July 2016. Available online: www.efsa.europa.eu

United Kingdom, 2016. 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 prochloraz, July 2016. Available online: www.efsa.europa.eu

Abbreviations

a.i. active ingredient
a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAC Codex Alimentarius Commission
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
DT 50 period required for 50% dissipation (define method of estimation)
DT 90 period required for 90% dissipation (define method of estimation)
EC emulsifiable concentrate
EMS evaluating Member State
eq residue expressed as a.s. equivalent
EW emulsion, oil in water
EURLs EU Reference Laboratories (former CRLs)
FAO Food and Agriculture Organization of the United Nations
FS flowable concentrate for seed treatment
GAP Good Agricultural Practice
HPLC–MS/MS high-performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
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
MRL  maximum residue level
MW  molecular weight
NEU  northern European Union
OECD  Organisation for Economic Co-operation and Development
PBI  plant-back interval
PF  processing factor
PHI  pre-harvest interval
PRIMo  (EFSA) Pesticide Residues Intake Model
PROFile  (EFSA) Pesticide Residues Overview File
RA  risk assessment
RAC  raw agricultural commodity
RD  residue definition
RMS  rapporteur Member State
SANCO  Directorate-General for Health and Consumers
SC  suspension concentrate
SEU  southern European Union
SMILES  simplified molecular-input line-entry system
STMR  supervised trials median residue
TRR  total radioactive residue
WHO  World Health Organization
WP  wettable powder
### Appendix A – Summary of authorised uses considered for the review of MRLs

#### A.1. Northern outdoor GAPs

| Crop and/or situation | MS or country | FG or X | Pests or group of pests controlled | Preparation | Conc. a.s. | Method kind | Range of growth stages and season | Number min-max | Interval between application | g a.s./hl/min-max | Water L/ha/min-max | kg a.s./ha/min-max | PHI (days) | Remarks |
|-----------------------|--------------|---------|-------------------------------------|-------------|-----------|------------|-------------------------------|----------------|-----------------------------|----------------|----------------|----------------|-----------|---------|
| Strawberries          | BE           | F       | Alternaria                          | WP          | 46% (w/w)| Foliar treatment – spraying | 45-55           | –                           | –               | 0.32                        | n.a.                 | –                   | Application ‘after planting’ (autumn) |
| Linseeds              | UK           | F       | Powdery mildew, Rhynchosporium; Pseudocercosporella herpotrichoides | EW          | 400 g/L | Foliar treatment – spraying | 69              | 2                           | –               | 0.44                        | 56                   | –                   |
| Poppy seeds           | CZ           | F       | Alternaria, Helminthosporium, Sclerotinia | EC          | 400 g/L | Foliar treatment – spraying | 51-58           | 1                           | –               | 0.4                         | n.a.                 | –                   |
| Sunflower seeds       | HU, CZ       | F       | Sclerotinia scl., Botrytis cinerea, Alternaria spp., Phomopsis helianthi | EW          | 267 g/L | Foliar treatment – spraying | 20-65           | 2                           | 21              | 0.4                         | 56                   | –                   |
| Rapeseeds             | UK           | F       | Alternaria, Botrytis, Cylindrosporium, Phoma | EC          | 400 g/L | Foliar treatment – spraying | 20-69           | 2                           | 21              | 0.44                        | 56                   | –                   | A different GAP authorised in DE (1 single application at 0.68 kg as/ha) is also authorised and was shown to produce equivalent residue levels (see Germany, 2016) |
| Crop and/or situation | MS or country | FG or T(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|------------|------------------------------------|-------------|------------|-------------------------------|---------------|---------|
|                       |               |            |                                    | Type(b)     | Conc. a.s. | Method kind                   | g a.s./hL min-max | Water L/ha min-max | kg a.s./ha min-max |               |
| Barley                | DE, HU        | F          | Rhynchosporium secalis             | EW          | 450 g/L    | Foliar treatment – spraying   | 30 - 61        | 2                   | 14             | –           | 0.45          | 35    | – |
| Oat                   | FR, HU, LT, LV, EE | F           | Pseudocercosporella herpotrichoides, Septoria tritici | EC          | 450 g/L    | Foliar treatment – spraying   | 30 - 59        | 2                   | 14             | –           | 0.45          | 35    | – A similar GAP is authorised in HU, LT, LV and EE with application rate of 0.40 kg as/ha (BBCH 65) |
| Rye                   | UK            | F          | Blumeria graminis, Septoria spp, Puccinia spp, Fusarium spp, Helminthosporium | EW          | 450 g/L    | Foliar treatment – spraying   | 30 - 65        | 2                   | 14             | –           | 0.45          | n.a.  | Similar GAPs authorised in HU, DE and FR with application rate of 0.4-0.45 kg ai/ha (BBCH 59-69) |
| Wheat                 | UK            | F          | Blumeria graminis, Septoria spp, Puccinia spp, Fusarium spp, Helminthosporium | EW          | 450 g/L    | Foliar treatment – spraying   | 30 - 65        | 2                   | 14             | –           | 0.45          | n.a.  | Similar GAPs authorised in HU, DE and FR with application rate of 0.4-0.45 kg ai/ha (BBCH 59-69) |
| Sugar beets           | DE, BE, SK, CZ | F          | Erysiphe betae, Uromyces betae, Cercospora beticola | EC          | 400 g/L    | Foliar treatment – spraying   | 16 - 49        | 2                   | 28             | –           | 0.44          | 28    | BBCH 16-39 for 1st application |
| Fodder beets          | CZ, BE        | F          | Cercospora beticola                | EC          | 400 g/L    | Foliar treatment – spraying   | 16 - 49        | 2                   | 14             | –           | 0.4           | 28    | BBCH 16-39 for 1st application |
### A.2. Southern outdoor GAPs

| Crop and/or situation | MS or country | FG or I<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|---------------|------------------------|-----------------------------------|-------------|----------------|-------------------------------|-----------------|---------|
| Almonds               | EL            | F                      | Monilia spp.                      | WP          | 50% (w/w)     | Foliar treatment – spraying   | 69              | 3       | 0.44 n.a. Application authorised until end of flowering (i.e. petal fall) |

**MRL:** maximum residue level; GAP: Good Agricultural Practice; a.s.: active substance; WP: wettable powder; EW: emulsion, oil in water; EC: emulsifiable concentrate; MS: Member State.

<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 pre-harvest interval.
| Crop and/or situation | MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|--------------|-------------|-----------------------------------|-------------|------------|--------------------------------|---------------|---------|
| Apricots              | EL           | F           | Monilia spp.                      | WP 50% (w/w) | Foliar treatment - spraying | 69 3               | – – 0.44 n.a. | Application authorised until end of flowering (i.e. petal fall) |
| Cherries              | EL           | F           | Monilia spp.                      | WP 50% (w/w) | Foliar treatment - spraying | 69 3               | – – 0.44 n.a. | Application authorised until end of flowering (i.e. petal fall) |
| Peaches               | EL           | F           | Monilia spp.                      | WP 50% (w/w) | Foliar treatment - spraying | 69 3               | – – 0.44 n.a. | Application authorised until end of flowering (i.e. petal fall) |
| Plums                 | EL           | F           | Monilia spp.                      | WP 50% (w/w) | Foliar treatment - spraying | 69 3               | – – 0.44 n.a. | Application authorised until end of flowering (i.e. petal fall) |
| Barley                | FR, IT       | F           | Fungi: rouilles, helminthosporiose et ramulariose, rhynchosporiose | EC 225 g/L | Foliar treatment - spraying | 31-49 1-2 14 | – – 0.45 n.a. | In Italy, a PHI of 40 days is reported but timing of application is similar (until BBCH 51) and application rate is the same |
| Crop and/or situation | MS or country | F or G (a) | Pest(s) or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|---------------|------------|-------------------------------------|-------------|------------|--------------------------------|----------------|---------|
| Oat | FR | F | Fungi: *oidiums, rouille couronnée* | EC | Foliar treatment – spraying | 30-59 | 2 | 14 | – | – | 0.45 | 35 | Other GAPs are authorised in FR, with earlier timing of application (BBCH 49) and same application rate |
| Rye | IT | F | *Rhynchosporium*, brown rust | EW | Foliar treatment – spraying | 30-49 | 2 | 14 | – | – | 0.32 | 28 | Other GAPs are authorised with PHI 35 and similar application rate |
| Wheat | IT | F | Septoria, powdery mildew, *Fusarium*, brown rust, yellow rust | EW | Foliar treatment – spraying | 30-69 | 2 | 14 | – | – | 0.45 | 28 | Also authorised in FR for same application rate at BBCH 59, PHI 35 days |
| Rape (for forage) | BG | F | *Alternaria, Botrytis, Cylindrosporium, Phoma* | EW | Foliar treatment – spraying | 65-69 | 2 | 14 | – | – | 0.4 | 28 | PHI 28 represents the 28 days withholding period before harvest of feed stuff |

MRL: maximum residue level; GAP: Good Agricultural Practice; a.s.: active substance; WP: wettable powder; EW: emulsion, oil in water; EC: emulsifiable concentrate; MS: Member State.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
### A.3. Indoor GAPs and post-harvest treatments

| Crop and/or situation | MS or country | FG or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|-------------|-------------|-------------------------------|-------------|---------|
|                       |               |             |                                   | Type(b)     | Conc. a.s.  | Method kind                   | Range of growth stages and season(c) | Number min-max | Interval between application (min) | g a.s./hL min-max | Water L/ha min-max | Rate and unit | PHIs |                         |
| Grapefruits           | EL            | I           | Penicillium digitatum, Penicillium italicum | EC          | 450 g/L     | Post-harvest – spraying       | n.a.                    | 1                       | – – | 0.95 kg a.i./hL           | n.a. | Spraying or dipping of fruits during packaging |
| Oranges               | EL            | I           | Penicillium digitatum, Penicillium italicum | EC          | 450 g/L     | Post-harvest – spraying       | n.a.                    | 1                       | – – | 0.95 kg a.i./hL           | n.a. | See grapefruits           |
| Lemons                | EL            | I           | Penicillium digitatum, Penicillium italicum | EC          | 450 g/L     | Post-harvest – spraying       | n.a.                    | 1                       | – – | 0.95 kg a.i./hL           | n.a. | See grapefruits           |
| Limes                 | EL            | I           | Penicillium digitatum, Penicillium italicum | EC          | 450 g/L     | Post-harvest – spraying       | n.a.                    | 1                       | – – | 0.95 kg a.i./hL           | n.a. | See grapefruits           |
| Mandarins             | EL            | I           | Penicillium digitatum, Penicillium italicum | EC          | 450 g/L     | Post-harvest – spraying       | n.a.                    | 1                       | – – | 0.95 kg a.i./hL           | n.a. | See grapefruits           |
| Strawberries          | BE            | I           | Alternaria                         | WP          | 46% (w/w)   | Foliar treatment – spraying   | 45 -55                  | – –                     | – – | 0.32 kg a.i./ha          | n.a. | Application ‘after planting’ (autumn) |
| Cultivated fungi      | PL, EL, BE    | I           | Verticillium fungicola             | WP          | 46.1% (w/w) | Soil treatment – spraying     | 0 to 0                  | 1                       | – – | 13.83 kg a.i./ha         | 10   | Other existing GAP in EU: EC formulation with 4.50 kg a.i./ha; (PHI 10 days) |

MRL: maximum residue level; GAP: Good Agricultural Practice; a.s.: active substance; a.i.: active ingredient; WP: wettable powder; EC: emulsifiable concentrate; MS: Member State.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

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

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.
## A.4. Fall-back GAPs identified

| Crop and/or situation | MS or country | FG or I\(^{(a)}\) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)\(^{(d)}\) | Remarks |
|-----------------------|---------------|-------------------|-----------------------------------|-------------|----------------|--------------------------------|----------------|---------|
| Barley grain          | BE            | F                 | Fusarium                          | FS          | 60 g/L        | Seed treatment – general       | 0 to 0         | 1       | –      | –      | 12     | n.a.   | Fall-back GAP reported by BE (Belgium, 2016) |
| Oat grain             | BE            | F                 | Fusarium                          | FS          | 60 g/L        | Seed treatment – general       | 0 to 0         | 1       | –      | –      | 12     | n.a.   | Fall-back GAP reported by BE (Belgium, 2016) |

GAP: Good Agricultural Practice; a.s.: active substance; FS: flowable concentrate for seed treatment; MS: Member State.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

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

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum pre-harvest interval.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) |
|-----------------------------------|-------------|---------|----------------|----------------|
| Fruit crops                       | Apple       | Local application: 1 × 120 g a.s./L | 0, 16, 24, 33, 48, 63 |
| Cereals/ grass crops              | Wheat       | Foliar: 2 × 450 g a.s./ha (BBCH 31 & 59) | Forage: 0; hay: 24 Straw, chaff, grain: 53 |
|                                  |             | Seed treatment: 20 g a.s./100 kg seeds (eq to 1 × 36 g a.s./ha) | Forage: 66; hay: 90 Straw, chaff, grain: 118 |
|                                  |             | Foliar: 1 × 800-900 g a.s. (BBCH 16) Microsyringe: 1 × 0.4 mg a.s./plant (eq 1 kg a.s./ha) at BBCH 16 | Roots, shoots, leaves: 59 (BBCH 16) Grain: 92 |
|                                  |             | Foliar: 1 × 405 g a.s./ha (BBCH 39) | 20 DAT and at maturity |
|                                  | Barley      | Foliar: 2 × 540 g a.s./ha (BBCH 51/55 and 55/59) | 41 |
| Pulses/ oilseeds                 | Rapeseed    | Foliar: 2 × 600 g a.s./ha (BBCH 30 & 40) | 1, 37, 86 (eq maturity) |
|                                  |             | Foliar: 2 × 3,000 g a.s./ha (BBCH 30 & 40) | 1, 37, 86 (eq maturity) |
|                                  |             | Spray solution droplets on leaves: 1 × 663 g a.s./ha | 0, 18/19, 83–90 (eq maturity) |
|                                  |             | Spray solution droplets on leaves: 1 × 6,130 g a.s./ha | 0, 18/19, 83–90 (eq maturity) |
| Miscellaneous                    | Mushroom    | Surface of compost bed (post emergence): 1 × 3 g a.s./m² | 8, 16, 23, 30, 37 |

- Apple: $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2007); applied on the fruit surface.
- Wheat (1st and 2nd studies): $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2010).
- Wheat (3rd study): $^{14}$C-prochloraz radiolabelled in phenyl and imidazole rings (Ireland, 2010).
- Wheat (4th study): $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2007).
- Barley: $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2010).
- Rapeseed: $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2007, 2010).
- Mushroom: $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2007).

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) |
|--------------------------------------|-------------|---------|----------------|------------|
| Root/tuber crops                     | Radish      | a) Bare soil: 1 × 1.11 kg as/ha | a) 30, 120, 365 b) 29 |
|                                      |             | b) Bare soil: 1 × 1.08 kg as/ha | |
|                                      | Potato      | Foliar, Wheat (BBCH 47): 1 × 0.94 kg as/ha | 276 |
| Leafy crops                          | Lettuce     | a) Bare soil: 1 × 1.11 kg as/ha | a) 30, 120, 365 b) 29 |
|                                      |             | b) Bare soil: 1 × 1.08 kg as/ha | |
|                                      | Cabbage     | Bare soil: 1 × 1.08 kg as/ha | 29 |
| Cereal (small grain)                 | Wheat       | Bare soil: 1 × 1.11 kg as/ha | 30, 120, 365 |
|                                      | Barley      | Bare soil: 1 × 1.08 kg as/ha | 29 |

- Radish, lettuce, wheat, potato: $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2007).
- Radish, lettuce, cabbage, barley: $^{14}$C-prochloraz radiolabelled in phenyl ring (Ireland, 2010).
| Processed commodities (hydrolysis study) | Conditions | Investigated? |
|-----------------------------------------|------------|--------------|
| | Pasteurisation (20 min, 90°C, pH 4) | Yes |
| | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes |
| | Sterilisation (20 min, 120°C, pH 6) | Yes |
| | $^{14}$C-prochloraz radiolabelled labelled in phenyl ring (Ireland, 2007) | |

- Can a general residue definition be proposed for primary crops? Yes
- 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): Sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz
- Plant residue definition for risk assessment (RD-RA): Sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz
- Conversion factor (monitoring to risk assessment): See Appendix B.1.2.1
- Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs): HPLC-MS/MS (Ireland, 2010, 2015; EURLs, 2016):
  - Fully validated in all plant matrices;
  - Fully validated for analysis of prochloraz, metabolite BTS 44595 and metabolite BTS 44596;
  - LOQ = 0.01 mg for each compound;
  - Combined LOQ of 0.03 mg/kg proposed for the sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz.

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; HPLC-MS/MS: high-performance 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 | Lettuce       | –18    | 19                |
|                                    | High acid content  | Oranges       | –18    | 12                |
|                                    | High oil content   | Rapeseed      | –18    | 6                 |
|                                    | Dry/high starch    | Wheat grain   | –18    | 6                 |
|                                    | Specific matrices  | Cereal straw  | –18    | 6                 |

**High water content:** A new study reported in the framework of the MRL review demonstrates storage stability of prochloraz, metabolite BTS 44595 and metabolite BTS 44596 separately for up to 19 months (France, 2016). It is noted that total residues (2,4,6-trichlorophenol moiety) was demonstrated stable for 24 months (EFSA, 2011).

**High acid content:** A new study reported in the framework of the MRL review demonstrates storage stability of prochloraz, metabolite BTS 44595 and metabolite BTS 44596 separately for up to 12 months (France, 2016).

**High oil content:** Storage stability was separately demonstrated for prochloraz (8 months), metabolite BTS 44595 (8 months) and metabolite BTS 44596 (6 months) (EFSA, 2011; Ireland, 2015). A new study reported in the framework of the MRL review demonstrates storage stability of prochloraz and metabolite BTS 44595 for up to 25 months but confirmed the very limited stability for metabolite BTS 44596 (France, 2016). It is noted that total residues (2,4,6-trichlorophenol moiety) was demonstrated stable for 36 months (EFSA, 2011).

**Dry/high starch:** Storage stability was separately demonstrated for prochloraz (8 months), metabolite BTS 44595 (8 months) and metabolite BTS 44596 (6 months) (EFSA, 2011; Ireland, 2015). A new study reported in the framework of the MRL review demonstrates storage stability of prochloraz and metabolite BTS 44595 for up to 25 months but confirmed very limited stability for metabolite BTS 44596 (France, 2016). It is noted that total residues (2,4,6-trichlorophenol moiety) was demonstrated stable for 24 months (EFSA, 2011).

**Cereal straw:** There is no specific study available. However, as storage stability was demonstrated in the four main plant matrices, the most limiting storage stability conditions are assumed to be applicable to cereal straw: prochloraz (8 months), metabolite BTS 44595 (8 months) and metabolite BTS 44596 (6 months). Total residues analysed as 2,4,6-trichlorophenol moiety: 12 months at –20°C.

**MRL:** maximum residue level.
### B.1.2. Magnitude of residues in plants

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

| Crop                  | Region/indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations)                      | MRL proposals (mg/kg) | HR_{Mo} (mg/kg)(b) | STMR_{Mo} (mg/kg)(c) | CF(d) |
|-----------------------|------------------|-----------------------------------------------------------------------------------------------|-------------------------------------------------------------------|-----------------------|-------------------|---------------------|------|
| Citrus fruits         | EU               | No trials available                                                                         |                                                                   |                       |                   |                     |      |
| Almonds               | SEU              | Trials were reported by Greece (2016) but available summaries do not allow assessing if compliant with GAP |                                                                   |                       |                   |                     |      |
| Stone fruits          | SEU              | Trials were reported by Greece (2016) but available summaries do not allow assessing if compliant with GAP |                                                                   |                       |                   |                     |      |
| Strawberries          | NEU              | No trials available                                                                         |                                                                   |                       |                   |                     |      |
| EU                    |                  | Belgium proposed a waiver based on the rational that no residues are expected if application is performed just after planting (Belgium, 2016). However, this waiver is not deemed sufficient without residue trials |                                                                   |                       |                   |                     |      |
| Cultivated fungi      | EU               | **Mo:** < 0.01; 0.05; 0.13; 0.58; 0.21; 0.25; 0.48; 0.71; 0.74; 1.3; 1.4 **RA:** < 0.01; 0.05; 0.13; 0.58; 0.21; 0.25; 0.48; 0.71; 0.74; 1.3; 1.4 | Trials compliant with GAP analysing for total residues as 2,4,6-TCP moiety or for enforcement RD (0.05; 0.13 mg/kg) (Ireland, 2015; JMPR, in FAO 2004, 2009a,b); acceptable since residues in mushrooms are mainly composed of parent compound (EFSA, 2011) MRL_{OECD} = 2.44 | 3                 | 1.4              | 0.48                | 1    |
### Crop Residue Levels and Recommendations

| Crop | Region/indoor | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR\textsubscript{MO} (mg/kg) | STMR\textsubscript{MO} (mg/kg) | CF (d) |
|------|---------------|-----------------------------------------------------------------|---------------------------------------------|-----------------------|-----------------|-----------------|--------|
| Rapeseed, Linseed, Poppy seed, Sunflower seed | NEU | Mo: 0.03; 0.03; 0.15; 0.11; 0.03; 0.18; 0.063; 0.07; 0.05; 0.12 RA: < 0.05; < 0.05; < 0.05; 0.12; < 0.05; 0.10; 0.08; < 0.05; 0.05; 0.12 | Trials on rapeseeds compliant with GAP for rapeseeds (Ireland, 2015). Extrapolation to sunflower seed, linseed and poppy seed is acceptable as timing of application and/or PHI are in the same range \text{MRL}_{\text{OECD}} = 0.30 | 0.3 | 0.18 | 0.07 | 1 |
| Barley grain | NEU | Mo: < 0.03; < 0.03; 0.03; 0.03; 0.04; 0.05; 0.05; 0.06; 0.06; 0.09; 0.27; 0.08; 0.27; 0.07; 0.26; 0.33; 0.15; \ldots; \ldots; 0.04; 0.09; 0.05; 0.1; 0.04; 0.06 | Trials on barley grain compliant with GAP, considering BBCH 59-65 at last application to be the relevant parameter (EFSA, 2011; Ireland, 2015) \text{MRL}_{\text{OECD}} = 0.46 | 0.5 | 0.33 | 0.06 | 1.70 (e) |
| Oat grain | SEU | Mo: \ldots; RA: 0.10; 0.23 | Trials on barley compliant with GAP, considering BBCH 49 at last application to be the relevant parameter (France, 2016). Not sufficient to derive MRL. All other available trials support a more critical GAP with application between BBCH 59-65 | -- | -- | -- | -- |

### Notes
- \text{MRL}_{\text{OECD}} = 0.30
- \text{MRL}_{\text{OECD}} = 0.46
- \text{MRL}_{\text{OECD}} = 0.46
- \text{MRL}_{\text{OECD}} = 0.46
- \text{MRL}_{\text{OECD}} = 0.46

\text{OECD} = \text{Organisation for Economic Co-operation and Development}

\text{HR} = \text{Highest residue}

\text{STMR} = \text{Safety threshold multiplier ratio}

\text{CF} = \text{Correction factor}

\text{NEU} = \text{North Euro-Mediterranean Unit}

\text{RA} = \text{Reasonable assurance}

\text{SEU} = \text{South Euro-Mediterranean Unit}

\text{BBCH} = \text{Biological Integrated Control}

\text{storage period to be verified}

\text{similar GAP authorised}
| Crop          | Region/ indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR<sub>Mo</sub>(b) | STMR<sub>Mo</sub>(c) | CF(d) |
|--------------|-------------------|-----------------------------------------------------------------------------------------------|---------------------------------------------|-----------------------|---------------------|---------------------|-------|
| SEU          |                   | M<sub>o</sub>: < 0.03; < 0.03; < 0.03; < 0.03; < 0.03; 0.03; 0.03; 0.04; 0.04; 0.1; 0.03; 0.18; 0.06; 0.06; 0.04; 0.06; 0.12; 0.072; 0.25; 0.16; 0.05; 0.29; 0.76; 0.07; 0.12; -; -; -; 0.11; 0.07; 0.25; 0.26 RA: < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; 0.06; 0.06; 0.11; 0.14; < 0.05; 0.17; < 0.05; < 0.05; 0.06; 0.05; 0.12; 0.15; 0.36; 0.30; 0.07; 0.35; 0.99; 0.28; 0.23; < 0.04; < 0.04; < 0.04; 0.2; 0.13; 0.17; 0.12                               | Trials on barley compliant with GAP on oat, considering BBCH 59-65 at last application to be the relevant parameter (EFSA, 2011; Ireland, 2015) [In italic: storage period to be verified] M<sub>RL</sub><sub>OECD</sub> = 0.76                                                                 | 0.8  | 0.76  | 0.06  | 1.70(e) |
| Barley straw | NEU                | M<sub>o</sub>: 0.5; 0.52; 0.6; 0.63; 0.89; 0.93; 1.12; 1.32; 1.76; 1.88; 2.06; 6.60; 2.40; 6.0; 1.50; 29.0; 13.0; 1.70; -; -; -; -; 3.2; 2.1; 2.50; 1.10; 2.40; 1.20 RA: 0.78; 1.6; 1.97; 1.9; 2.4; 2.7; 2.10; 2.7; 3.6; 5.4; 3.3; 8.70; 3.40; 4.70; 1.80; 16.90; 13.70; 2.98; 0.10; 0.22; 0.23; 0.47; 1.72; 5.2; 4.4; 3.80; 3.80; 2.90; 2.80 | Trials on barley compliant with GAP, considering BBCH 59-65 at last application to be the relevant parameter (EFSA, 2011; Ireland, 2015) [In italic: storage period to be verified] M<sub>RL</sub><sub>OECD</sub> = 29                                                                 | 30 (tentative)(f) | 29    | 1.73  | 1.80(e) |
| SEU          |                   | M<sub>o</sub>: – RA: 7.71; 20.6                                                                 | Trials on barley compliant with GAP with application at BBCH 49 (France, 2016). Not sufficient to derive MRL All other available trials support a more critical GAP with application between BBCH 59-65 (Ireland, 2015) | –       | –      | –      | –     |
| Crop                   | Region/indoor<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>Mo</sub> (mg/kg)<sup>(b)</sup> | STMR<sub>Mo</sub> (mg/kg)<sup>(c)</sup> | CF<sup>(d)</sup> |
|------------------------|-----------------------------|---------------------------------------------------------------------------------|---------------------------------------------|----------------------|-------------------------------|---------------------------------|-------------|
| Oat straw              | NEU                         | Mo: 0.5; 0.52; 0.6; 0.63; 0.89; 0.93; 1.12; 1.32; 1.76; 1.88; 2.06; 6.60; 2.40; 6.0; 1.50; 29.0; 1.30; 1.70; 3.2; 2.1; 2.50; 1.10; 2.40; 1.20 RA: 0.78; 1.6; 1.9; 2.4; 2.7; 2.10; 2.7; 3.6; 5.4; 3.3; 8.70; 3.40; 4.70; 1.80; 16.90; 13.70; 2.98; 0.10; 0.22; 0.23; 0.47; 1.72; 4.4; 3.80; 3.80; 2.90; 2.80 | Direct extrapolation from Barley straw (similar GAP authorised) [In italic: storage period to be verified] MRL<sub>OECD</sub> = 29 RA: 0.78; 1.6; 1.97; 1.9; 2.4; 2.7; 2.10; 2.7; 3.6; 5.4; 3.3; 8.70; 3.40; 4.70; 1.80; 16.90; 13.70; 2.98; 0.10; 0.22; 0.23; 0.47; 1.72; 4.4; 3.80; 3.80; 2.90; 2.80 | 30 (tentative)<sup>(f)</sup> | 29                                    | 1.73                             | 1.80<sup>(e)</sup> |
|                        | SEU                         | Mo: 0.28; 0.46; 0.68; 1.08; 1.09; 1.11; 1.17; 1.24; 1.33; 1.90; 2.40; 5.40; 2.50; 7.90; 1.2; 2.6; 5.7; 19.0; 2.10; 9.0; 1.20; 6.50; 14.0; 1.30; 2.60; 3.9; 7.5; 4.30; 11.0 RA: 0.73; 1.2; 1.73; 2.2; 2.5; 2.7; 2.9; 3.8; 1.5; 5.7; 3.0; 8.0; 4.0; 6.2; 2.10; 4.40; 9.20; 23.0; 2.19; 14.16; 1.90; 8.88; 14.80; 2.31; 6.04; 0.17; 0.46; 0.97; 7.0; 12.0; 4.30; 9.90 | Trials on barley compliant with GAP, considering BBCH 59-65 at last application to be the relevant parameter (EFSA, 2011; Ireland, 2015) [In italic: storage period to be verified] MRL<sub>OECD</sub> = 22.1 RA: 0.73; 1.2; 1.73; 2.2; 2.5; 2.7; 2.9; 3.8; 1.5; 5.7; 3.0; 8.0; 4.0; 6.2; 2.10; 4.40; 9.20; 23.0; 2.19; 14.16; 1.90; 8.88; 14.80; 2.31; 6.04; 0.17; 0.46; 0.97; 7.0; 12.0; 4.30; 9.90 | 30 (tentative)<sup>(f)</sup> | 19                                    | 2.4                              | 1.80<sup>(e)</sup> |
| Wheat and rye grain    | NEU                         | Mo: 10 × < 0.03; 0.04; < 0.03; 0.05; < 0.03; < 0.03; 0.02; 0.19; 0.10; 0.18; 0.1; 0.1; 0.1; 0.1; 0.3; 0.03; 0.03; 0.05; 0.03; < 0.03; 0.03; 0.03 RA: 10 × < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; 0.14; 0.1; 0.14; 4 < 0.04; 7 < 0.05; 0.05; 2 < 0.05; < 0.05; 0.05; < 0.05; < 0.05; < 0.05 < 0.05; < 0.05; < 0.05; < 0.05; 0.05 | Trials on wheat compliant with GAP, considering BBCH 65-69 at last application to be the relevant parameter (EFSA, 2011; Ireland, 2015) [In italic: storage period to be verified] MRL<sub>OECD</sub> = 0.3 RA: 10 × < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; 0.14; 0.1; 0.14; 4 < 0.04; 7 < 0.05; 0.05; 2 < 0.05; < 0.05; 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05; 0.05 | 0.3                                    | 0.19                             | 0.03                              | 1.70                |
|                        | SEU                         | Mo: 9 × < 0.03; 2 × < 0.03; 0.04; ; 0.03; 0.03; 0.03; 0.16; 4 × 0.03 RA: 9 × < 0.05; 2 × < 0.05; 0.05; < 0.04; < 0.05; < 0.05; < 0.05; 0.06; 0.07; 0.137; < 0.05; 0.07; 0.05; 0.12; 4 × < 0.05 | Trials on wheat compliant with GAP for wheat and rye, considering BBCH 65-69 at last application to be the relevant parameter (EFSA, 2011; Ireland, 2015) [In italic: storage period to be verified] MRL<sub>OECD</sub> = 0.2 RA: 9 × < 0.05; 2 × < 0.05; 0.05; < 0.04; < 0.05; < 0.05; < 0.05; 0.06; 0.07; 0.137; < 0.05; 0.07; 0.05; 0.12; 4 × < 0.05 | 0.2                                    | 0.16                             | 0.03                              | 1.70                |
| Crop                  | Region/indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations)                                                                 | MRL proposals (mg/kg) | HR_{Mo}^{(b)} (mg/kg) | STMR_{Mo}^{(c)} (mg/kg) | CF(d) |
|----------------------|------------------|-----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|----------------------|-----------------------|------------------------|-------|
| N/S-EU               | Combination of NEU/SEU data showing similar results.                                            | Overall MRL derived from N/S-EU data MRL_{OECD} = 0.19                                                                 |                                                                     | 0.2                  | 0.19                  | 0.03                   | 1.70(f) |
| Wheat and rye straw  | NEU              | Mo: 0.39; 0.52; 0.57; 0.69; 0.97; 0.99; 0.99; 1.11; 1.13; 1.2; 1.67; 1.10; 3.40; 1.30; 1.40; 2.50; 12.0; 13.0; 11.0; 1.3; 2.10; 2.8; 2.10; 2.20; 0.84 RA: 0.76; 0.66; 1.50; 1.70; 1.70; 3.50; 1.70; 2.40; 1.30; 4.0; 2.3; 1.80; 4.40; 3.1; 1.30; 4.80; 9.20; 14.0; 10.0; < 0.04; 0.13; 0.14; 0.20; 0.30; 1.8; 3.6; 4.4; 5.3; 5.9; 9.2; 1.7; 4.1; 3.50; 3.60; 2.20; 3.60; 1.70; 0.99 RA: 1.0; 1.9; 2.0; 2.4; 1.8; 1.9; 4.0; 2.3; 4.8; 1.20; 2.10; 7.50; 0.3; 4.1; 4.6; 5.9; 6.1; 6.6; 8.5; 8.9; 8.9; 2.40; 5.20; 3.7; 4.10; 3.80; 11.0 Trials on wheat compliant with GAP for wheat and rye, considering BBCH 65-69 at last application to be the relevant parameter (EFSA, 2011; Ireland, 2015) [In italic: storage period to be verified] | 20 (tentative) | 13                   | 1.3                    | 1.70 |
| SEU                  | Mo: 0.59; 0.74; 1.02; 1.18; 1.39; 1.6; 2.28; 2.42; 3.28; 0.59; 1.10; 7.70; 2.1; 7.2; 1.60; 5.50; 4.10; 3.60; 4.10; 9.20 RA: 1.0; 1.9; 2.0; 2.4; 1.8; 1.9; 4.0; 2.3; 4.8; 1.20; 2.10; 7.50; 0.3; 4.1; 4.6; 5.9; 6.1; 6.6; 8.5; 8.9; 8.9; 2.40; 5.20; 3.7; 4.10; 3.80; 11.0 Trials on wheat compliant with GAP for wheat, considering BBCH 65-69 at last application to be the relevant parameter (EFSA, 2011; Ireland, 2015) [In italic: storage period to be verified] | 15 (tentative) | 9.2                  | 2.2                    | 1.40 |
| N/S-EU               | Combination of NEU/SEU data showing similar results.                                            | Overall MRL derived from N/S-EU data MRL_{OECD} = 15.2                                                                 |                                                                     | 15 (tentative) | 13                   | 1.6                    | 1.50(f) |
| Barley and oat grain | NEU (fall-back GAP with seed treatment)                                                         | Mo: < 0.03; < 0.03; < 0.03; < 0.03; < 0.05; < 0.05; < 0.05; < 0.05; < 0.05 Trials performed on wheat and barley at the overdosed rate of 0.21 g/100 kg, deemed acceptable as residues levels are found < LOQ. Two trials performed with analysis of both RD for monitoring and risk assessment (Ireland, 2010), noting that four other trials performed in SEU showed similar results. Three trials with only analysis for RD for risk assessment (Ireland, 2007). | 0.03*               | < 0.03               | < 0.03                 | 1.70(f) |
| Crop                        | Region/indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | MRL proposals (mg/kg) | HR\(_{\text{Mo}}\) (mg/kg)(b) | STMR\(_{\text{Mo}}\) (mg/kg)(c) | CF(d) |
|-----------------------------|------------------|------------------------------------------------------------------------------------------------|------------------------------------------------|-----------------------|-----------------------------|-----------------------------|-------|
| Barley and oat straw        | NEU (fall-back GAP with seed treatment) | **Mo**: < 0.03; < 0.03; < 0.03; < 0.1; < 0.1<br>**RA**: < 0.05; < 0.05; < 0.1; < 0.1 | Trials performed on wheat and barley at the overdosed rate of 0.21 g/100 kg, deemed acceptable as residues levels are found < LOQ. Two trials performed with analysis of both RD for monitoring and risk assessment (Ireland, 2010), noting that four other trials performed in SEU showed similar results. Three trials with only analysis for RD for risk assessment (Ireland, 2007). | 0.03* | < 0.03 | < 0.03 | 1.80(e) |
| Sugar and fodder beet root  | NEU              | **Mo**: 0.06; 0.06; 0.04; 0.04; 0.07; 0.06; 0.03; 0.03; 0.03; 0.03; < 0.03; 0.03<br>**RA**: 0.14; 0.11; 0.08; 0.05; 0.12; 0.11; 0.06; 0.06; 0.05; 0.05; 0.05; 0.11 | Trials on sugar beets compliant with GAP for sugar and fodder beets (Ireland, 2015). Residue data also assessed in a previous EFSA opinion on MRL (2018a)<br>MRL\(_{\text{OECD}}\) = 0.12 | 0.15 | 0.07 | 0.03 | 2 |
| Sugar and fodder beet tops  | NEU              | **Mo**: 0.71; 0.43; 0.64; 0.53; 1.00; 0.20; 0.42; 0.22; 0.44; 0.29; 0.39; 0.56; 1.6<br>**RA**: 2.00; 0.9; 1.40; 2.20; 2.10; 0.40; 1.20; 1.20; 1.60; 0.59; 2.4; 2.90; 2.70 | Trials on sugar beets compliant with GAP for sugar and fodder beets (Ireland, 2015). Residue data also assessed in a previous EFSA opinion on MRL (2018a)<br>MRL\(_{\text{OECD}}\) = 2.08 | 2(tentative)(f) | 1.60 | 0.44 | 2.8 |
| Rape/canola forage         | NEU              | **Mo**: 0.27; 0.45; 0.17; 0.17; 0.2<br>**RA**: 0.54; 0.99; 0.62; 1.8; 1.1 | Trials on rapeseeds compliant with GAP for rape for forage (Ireland, 2015)<br>MRL\(_{\text{OECD}}\) = 0.76 | 0.8(tentative)(f) | 0.45 | 0.2 | 4 |
|                            | SEU              | **Mo**: 0.13; 0.7; 0.18<br>**RA**: 0.74; 2.3; 0.73 | Trials on rapeseeds compliant with GAP for rape for forage (Ireland, 2015)<br>MRL\(_{\text{OECD}}\) = 1.6 | 2(tentative)(f) | 0.7 | 0.18 | 4 |
Review of the existing MRLs for prochloraz

GAP: Good Agricultural Practice; MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development; Mo: monitoring; RA: risk assessment; 2,4,6-TCP: 2,4,6-trichlorophenol; PHI: preharvest interval; BBCH: growth stages of mono- and dicotyledonous plants.

*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue according to the residue definition for monitoring.
(c): Supervised trials median residue according to the residue definition for monitoring.
(d): Conversion factor for risk assessment; median of the individual conversion factors at the supported PHI for each residues trial.
(e): For cereals, harmonised conversion factors are proposed for grain (1.7), barley/oat straw (1.8) and wheat/rye straw (1.5) on the basis of the overall data.
(f): Tentative MRLs are derived for feed items in view of the future need to set MRLs on these commodities.
B.1.2.2. Residues in succeeding crops

| Confinned rotational crop study (quantitative aspect) | Considering the residue definition for risk assessment, significant residues in rotational crops can be expected in cereal straw and root crops tops (up to PBI 365 days) and in roots (at PBI 30 days). Confinned rotational crops studies allow proposing indicative mitigation measures: it was tentatively concluded that a minimum PBI of 365 days would allow limiting the residues uptake in cereal straw (0.42 mg/kg), root crop tops (0.05 mg/kg) and roots (0.03 mg/kg).
| | - For wheat, rye, barley and oats straw and sugar/fodder beet (root and tops), this limited uptake is not significant compared to the residues arising from primary crops;
| | - For all cereal straw and root crops for which no GAPs are currently authorised, the possible uptake expected at PBI 365 days was considered in the livestock dietary burden. Considering the residue definition for enforcement, potential residue uptakes from rotational crops is covered by the MRLs derived on the basis of the primary crops data for all food commodities.

| Field rotational crop study | No studies available. Further studies should be required to propose robust mitigation measures (see above) and/or to assess further refined scenarios considering residues in rotational crops.

PBI: plant-back interval; GAP: Good Agricultural Practice.

B.1.2.3. Processing factors

| Processed commodity | Number of studies(a) | Processing factor (PF) | CFp(b) |
|---------------------|----------------------|------------------------|--------|
|                     | Individual values    | Median PF              |        |
| Indicative processing factors (limited data set)(c) |                     |                       |        |
| Barley, brewing malt | 3                    | 0.31; 0.57; 0.62       | 0.57   | 1.7   |
| Barley, beer         | 4                    | 0.03(d); 0.08(d); 0.10(d) | 0.08   | 1.7   |
| Barley, dry milled by-products (incl. bran) | 1                    | 0.62                   | 0.62   | 1.7   |
| Wheat, dry milled by-products (incl. bran) (→ extrapolation to rye) | 3                    | 0.75; 4.3(d); 7.0      | 4.3    | 1.7   |
| Wheat, white flour (→ extrapolation to rye) | 3                    | 0.53; 0.6(d); < 0.75(e) | 0.6    | 1.7   |
| Wheat, white bread (→ extrapolation to rye) | 1                    | < 0.75(e)              | < 0.75 | 1.7   |
| Wheat, whole-meal flour (→ extrapolation to rye) | 1                    | 1.4                    | 1.4    | 1.7   |
| Wheat, whole-meal bread (→ extrapolation to rye) | 2                    | 0.53; 1.3(d)           | 0.92   | 1.7   |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factors for risk assessment in the processed commodity should normally be calculated. However, since separate analysis for enforcement and risk assessment residue definitions were not performed in processed commodities, CFs could not be derived. Assuming that processing does not affect the nature of residues, the CFs derived for raw plant commodities can tentatively be used for processed commodities.
(c): Specific analysis for parent and metabolites BTS 44595 (M201-04) and BTS 44596 (M201-03) was not carried out in the available studies. Indicative processing factors are derived considering total residues determined as 2,4,6-trichlorophenol moiety.
(d): Data from peer review (Ireland, 2007); all other data were compiled by RMS in the framework of the present review (Ireland, 2015).
(e): Processing factors reported as < 0.75 because residues in processed commodity was below LOQ.
### B.2. Residues in livestock

| Relevant groups | Dietary burden expressed in | Most critical diet\(^{(a)}\) | Most critical commodity\(^{(a)}\) | Trigger exceeded \((Y/N)\) |
|----------------|-----------------------------|-----------------------------|---------------------------------|---------------------------|
|                | mg/kg bw per day | mg/kg DM | Med. | Max. | Med. | Max. |
| **Scenario EU1:** Considering all critical GAPs authorised in EU and possible uptake in rotational crops (PBI 365 days) | | | | | | |
| Cattle (all diets) | 0.0990 | 0.6965 | 2.82 | 18.1 | Cattle (dairy) | Barley, straw | Y |
| Cattle (dairy only) | 0.0990 | 0.6965 | 2.57 | 18.1 | Cattle (dairy) | Barley, straw | Y |
| Sheep (all diets) | 0.1101 | 1.5165 | 2.59 | 35.7 | Sheep (lamb) | Barley, straw | Y |
| Sheep (ewe only) | 0.0863 | 1.1894 | 2.59 | 35.7 | Sheep (ram/ewe) | Barley, straw | Y |
| Swine (all diets) | 0.0358 | 0.1108 | 1.55 | 4.80 | Swine (breeding) | Beet, mangel, tops | Y |
| Poultry (all diets) | 0.0276 | 0.2100 | 0.40 | 3.07 | Poultry (layer) | Barley, straw | Y |
| Poultry (layer only) | 0.0276 | 0.2100 | 0.40 | 3.07 | Poultry (layer) | Barley, straw | Y |
| **Scenario EU2:** Excluding GAPs on citrus fruits, sugar and fodder beet, considering fall-back GAPs on barley and oat (seed treatment) and considering the possible uptake in rotational crops (PBI 365 days) | | | | | | |
| Cattle (all diets) | 0.025 | 0.174 | 0.65 | 4.54 | Cattle (dairy) | Rye, straw | Y |
| Cattle (dairy only) | 0.025 | 0.174 | 0.64 | 4.53 | Cattle (dairy) | Rye, straw | Y |
| Sheep (all diets) | 0.052 | 0.382 | 1.22 | 8.99 | Sheep (lamb) | Rye, straw | Y |
| Sheep (ewe only) | 0.040 | 0.299 | 1.20 | 8.97 | Sheep (raw/ewe) | Rye, straw | Y |
| Swine (all diets) | 0.016 | 0.046 | 0.68 | 2.01 | Swine (breeding) | Rape, forage | Y |
| Poultry (all diets) | 0.025 | 0.158 | 0.36 | 2.31 | Poultry, layer | Wheat, straw | Y |
| Poultry (layer only) | 0.025 | 0.158 | 0.36 | 2.31 | Poultry, layer | Wheat, straw | Y |

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 | Animal | Dose (mg/kg bw per day) | Duration (days) | N rate/comment |
|-----------|--------|--------------------------|-----------------|----------------|
| Lactating cow | 1.5 | 3 | 1–2.2N compared to sheep and cattle (all diets) under scenario EU1 |
| Lactating goat | 0.29 | 10 | Dose rate recalculated assuming body weight of 70 kg and food intake of 2 kg per day < 0.5 N rate compared to sheep and cattle (all diets) under scenario EU1 |
| Laying hen | 0.34 | 14 | Nominal dose rate of 5 and 10 mg/kg diet recalculated assuming body weight of 1.9 kg and feed intake of 0.13 kg per day 1.6 and 3.2N rate compared to poultry (all diets) |

bw: body weight.
### Time needed to reach a plateau concentration in milk and eggs (days)

|          | Milk: 4 | Eggs: 8 |
|----------|---------|---------|

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

|          | Yes |
|----------|-----|

### Animal residue definition for monitoring (RD-Mo)

|          | Sum of prochloraz, BTS 44595 (M201-04) and BTS 44596 (M201-03), expressed as prochloraz |
|----------|-------------------------------------------------------------------------------------|

### Animal residue definition for risk assessment (RD-RA)

|          | Sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz |
|----------|----------------------------------------------------------------------------------------------------------|

### Conversion factor (monitoring to risk assessment)

|          | Ruminant muscle, fat, liver and kidney: 2 (based on cow and goat metabolism studies; EFSA, 2011)  
Milk: 4 (based on cow metabolism study)  
Poultry: muscle (9), fat (6), liver (6) and eggs (2) (based on laying hens metabolism study) |
|----------|----------------------------------------------------------------------------------------------------------|

### Fat soluble residues (Yes/No)

|          | Yes |
|----------|-----|

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

|          | HPLC-MS/MS (Ireland, 2015; EURLs, 2016):  
- Fully validated in muscle, fat, liver, kidney, milk and eggs;  
- Fully validated for analysis of prochloraz, metabolite BTS 44595 and metabolite BTS 44596;  
- LOQ = 0.01 mg for each compound;  
- Combined LOQ of 0.03 mg/kg proposed for the sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz. |
|----------|----------------------------------------------------------------------------------------------------------|

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

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

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability (months) |
|-------------------------------------|--------|-----------|--------|--------------------|
|                                     | Bovine | Muscle    | −18    | 3                  |
|                                     | Bovine | Fat       | −18    | 3                  |
|                                     | Bovine | Liver     | −18    | 3                  |
|                                     | Bovine | Kidney    | −18    | 3                  |
|                                     | Bovine | Milk      | −18    | 3                  |
|                                     | Hens   | Egg       | −18    | 3                  |

**Muscle, fat, liver, kidney, milk:** Storage stability was separately demonstrated for prochloraz, metabolite 44595 and metabolite 44596 for up to 3 months (Ireland, 2015). A new study reported in the framework of the MRL review confirmed this finding (France, 2016). It is noted that total residues (2,4,6-trichlorophenol moiety) was demonstrated stable for 12 months (EFSA, 2011).

**Eggs:** A new study reported in the framework of the MRL review demonstrates storage stability of prochloraz, metabolite 44595 and metabolite 44596 separately for up to 3 months (France, 2016). It is noted that total residues (2,4,6-trichlorophenol moiety) was demonstrated stable for 12 months (EFSA, 2011).
### B.2.2. Magnitude of residues in livestock

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

**Scenario EU1**: considering all authorised GAPs and possible uptake in rotational crops (PBI 365 days)

| Animal commodity     | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) | CF<sup>(c)</sup> |
|----------------------|-----------------------------------------------|-----------------------|---------------------|-------------------|
|                      | Mean                                          | Highest               | STMR<sup>(a)</sup> (mg/kg) | HR<sup>(b)</sup> (mg/kg) |                  |
| **Cattle (all diets)**<sup>(e)</sup> – Closest feeding level (0.92 mg/kg bw; 1.3N rate)<sup>(e)</sup> | | | | | |
| Muscle               | Mo: 0.11                                       | Mo: 0.050             | Mo: 0.108 0.15<sup>(e)(f)</sup> (0.15)<sup>(g)</sup> | 2                  |
| Fat                  | Mo: 0.38                                       | Mo: 0.041             | Mo: 0.417 0.2<sup>(e)(f)</sup> (0.5)<sup>(g)</sup> | 2                  |
| Liver                | Mo: 5.8                                        | Mo: 0.911             | Mo: 6.901 3<sup>(e)(f)</sup> (7)<sup>(g)</sup> | 2                  |
| Kidney               | Mo: 1.3                                        | Mo: 0.168             | Mo: 1.354 0.7<sup>(e)(f)</sup> (1.5)<sup>(g)</sup> | 2                  |
| **Cattle (dairy only)** – Closest feeding level (0.92 mg/kg bw; 1.3N rate)<sup>(e)</sup> | | | | | |
| Milk                 | < 0.005                                       | n.a.                  | < 0.03 0.03* (tentative)(i) 6 | 0.03* 4           |
| **Sheep (all diets)**<sup>(d)</sup> – Closest feeding level (3.1 mg/kg bw; 2N rate)<sup>(e)</sup> | | | | | |
| Muscle               | Mo: 0.37                                       | Mo: 0.49              | Mo: 0.240 0.15<sup>(e)(f)</sup> (0.3)<sup>(g)</sup> | 2                  |
| Fat                  | Mo: 1.1                                        | Mo: 0.045             | Mo: 0.823 0.5<sup>(e)(f)</sup> (0.9)<sup>(g)</sup> | 2                  |
| Liver                | Mo: 23                                         | Mo: 1.01              | Mo: 13.1 7<sup>(e)(f)</sup> (15)<sup>(g)</sup> | 2                  |
| Kidney               | Mo: 3.2                                        | Mo: 0.187             | Mo: 2.241 1.5<sup>(e)(f)</sup> (3)<sup>(g)</sup> | 2                  |
| **Sheep (dairy only)**<sup>(d)</sup> – Closest feeding level (0.92 mg/kg bw; 0.8N rate)<sup>(e)</sup> | | | | | |
| Milk                 | < 0.005                                       | n.a.                  | < 0.03 0.03* (tentative)(f) 2 | 0.03* 4           |
| **Swine**<sup>(e)</sup> – Closest feeding level (0.31 mg/kg bw; 3N rate)<sup>(e)</sup> | | | | | |
| Muscle               | Mo: 0.05                                       | Mo: 0.03             | Mo: 0.03* (tentative)(f) (0.03)<sup>(g)</sup> | 2                  |
| Fat                  | Mo: 0.13                                       | Mo: 0.024             | Mo: 0.086 0.05<sup>(e)(f)</sup> (0.09)<sup>(g)</sup> | 2                  |
| Liver                | Mo: 2.8                                        | Mo: 0.330             | Mo: 1.187 0.6<sup>(e)(f)</sup> (1.5)<sup>(g)</sup> | 2                  |
| Kidney               | Mo: 0.52                                       | Mo: 0.061             | Mo: 0.212 0.15<sup>(e)(f)</sup> (0.3)<sup>(g)</sup> | 2                  |
| **Poultry (all diets)** – Metabolism study as surrogate of feeding study<sup>(f)</sup> (0.68 mg/kg bw; 3N rate)<sup>(e)</sup> | | | | | |
| Muscle               | n.r.                                           | < 0.03               | < 0.03 0.03* (tentative)<sup>(f)</sup> 9 | 0.03* 6           |
| Fat                  | n.r.                                           | < 0.03               | < 0.03 0.03* (tentative)<sup>(f)</sup> 6 | 0.03* 6           |
| Liver                | n.r.                                           | < 0.03               | 0.043 0.05 (tentative)<sup>(f)</sup> 6 | 0.05 (tentative)<sup>(f)</sup> 6 |
| **Poultry (layer only)** – Metabolism study as surrogate of feeding study<sup>(f)</sup> (0.68 mg/kg bw; 3N rate)<sup>(e)</sup> | | | | | |
| Egg                  | n.r.                                           | 0.040               | 0.125 0.15 (tentative)<sup>(f)</sup> 2 | 2                  |

GAP: Good Agricultural Practice; PBI: plant-back interval; STMR: supervised trials median residue; HR: highest residue; Mo: monitoring; RA: risk assessment; bw: body weight; n.a.: not applicable; n.r.: not reported.

* Indicates that the MRL is proposed at the limit of quantification.

(a): The mean residue levels in milk and the highest residue levels in 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): Tentative conversion factors from enforcement to risk assessment are derived from the metabolism studies.
Review of the existing MRLs for prochloraz

(d): Livestock feeding study performed on dairy cow only provide results in accordance with the residue definition for risk assessment in tissues. These data can be used to derive risk assessment values directly in accordance with residue definition for risk assessment for cattle, sheep and swine tissues.

(e): Closest feeding level and N dose rate related to the maximum dietary burden.

(f): Tentative MRLs are derived for cattle, sheep and swine tissues based on the HR expressed according with the residue definition for risk assessment divided by the conversion factor of 2.

(g): Indicative MRL which would be derived according with the residue definition for risk assessment (based on the 2,4,6-trichlorophenol moiety) is reported between brackets for cattle, sheep and swine tissues.

(h): In the absence of feeding study performed with laying hens, results of the metabolism study were used to assess residue levels according to the residue definition for enforcement (only considering relevant metabolites) and for risk assessment (considering TRR levels) in hens tissues and eggs; for eggs results of both yolk and white were taken into account considering a weight ratio yolk/white of 40/60.

(i): Tentative MRLs are derived for poultry tissues and eggs based on results of the metabolism study.

Scenario EU2: excluding GAPs on citrus fruits, sugar and fodder beets, considering fall-back GAPs on barley and oat (seed treatment) and considering the possible uptake in rotational crops (PBI 365 days)

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) | CF(c) |
|------------------|-----------------------------------------------|-----------------------|----------------------|------|
|                  | Mean | Highest       | STMR(a) | HR(b) | (mg/kg) |
| Cattle (all diets)(d) – Closest feeding level (0.31 mg/kg bw; 1.8 N rate)(e) |      |              |         |       |         |
| Muscle           | Mo:  | Mo: < 0.05    | Mo:     | Mo:   | 0.03* (tentative)(f) |
| Fat              | Mo:  | Mo: < 0.05    | Mo:     | Mo:   | 0.07 (tentative)(f) |
| Liver            | Mo:  | Mo: 0.24      | Mo:     | Mo:   | 1 (tentative)(f) |
| Kidney           | Mo:  | Mo: 0.042     | Mo:     | Mo:   | 0.2 (tentative)(f) |
| Cattle (dairy only) – Closest feeding level (0.92 mg/kg bw; 5 N rate)(e) |      |              |         |       |         |
| Milk             | < 0.005 | n.a.            | < 0.03 | < 0.03 | 0.03* |
| Sheep (all diets)(d) – Closest feeding level (0.92 mg/kg bw; 2.4 N rate)(e) |      |              |         |       |         |
| Muscle           | Mo:  | Mo: 0.14      | Mo:     | Mo:   | 0.03* (tentative)(f) |
| Fat              | Mo:  | Mo: 0.51      | Mo:     | Mo:   | 0.15 (tentative)(f) |
| Liver            | Mo:  | Mo: 0.477     | Mo:     | Mo:   | 3 (tentative)(f) |
| Kidney           | Mo:  | Mo: 0.088     | Mo:     | Mo:   | 0.5 (tentative)(f) |
| Sheep (dairy only)(d) – Closest feeding level (0.92 mg/kg bw; 3 N rate)(e) |      |              |         |       |         |
| Milk             | < 0.005 | n.a.            | < 0.03 | < 0.03 | 0.03* |
| Swine(e) – Closest feeding level (0.31 mg/kg bw; 7 N rate)(e) |      |              |         |       |         |
| Muscle           | Mo:  | Mo: < 0.05    | Mo:     | Mo:   | 0.03* (tentative)(f) |
| Fat              | Mo:  | Mo: 0.24      | Mo:     | Mo:   | 0.03* (tentative)(f) |
| Liver            | Mo:  | Mo: 0.143     | Mo:     | Mo:   | 0.3 (tentative)(f) |
| Kidney           | Mo:  | Mo: 0.026     | Mo:     | Mo:   | 0.05 (tentative)(f) |
| Poultry (all diets) – Metabolism study as surrogate of feeding study(f) (0.68 mg/kg bw; 4 N rate)(e) |      |              |         |       |         |
| Muscle           | n.r. | 0.008         | < 0.03 | < 0.03 | 0.03* |
| Fat              | n.r. | 0.014         | < 0.03 | < 0.03 | 0.03* |
| Liver            | n.r. | 0.139         | < 0.03 | 0.032  | 0.04 (tentative)(f) |

www.efsa.europa.eu/efsajournal 49  EFSA Journal 2018;16(8):5401
### Animal commodity

| Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) | CF(c) |
|---------------------------------------------|-----------------------|----------------------|-------|
| Mean                                        | Highest               | STMR(a) (mg/kg)      | HR(b) (mg/kg) |
|                                             |                       |                      |       |
| Poultry (layer only) – Metabolism study as surrogate of feeding study\(5)\ (0.68 mg/kg bw; 4N rate)\(5\) |                       |                      |       |
| Egg                                         | n.r.                  | < 0.03               | 0.094 | 0.1 (tentative)\(7\) | 2    |

GAP: Good Agricultural Practice; PBI: plant-back interval; STMR: supervised trials median residue; HR: highest residue; Mo: monitoring; RA: risk assessment; bw: body weight; n.a.: not applicable; n.r.: not reported.

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

(a): The mean residue levels in milk and the highest residue levels in 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): Tentative conversion factors from enforcement to risk assessment are derived from the metabolism studies.

(d): Livestock feeding study performed on dairy cow only provide results in accordance with the residue definition for risk assessment in tissues. These data can be used to derive risk assessment values directly in accordance with residue definition for risk assessment for cattle, sheep and swine tissues.

(e): Closest feeding level and N dose rate related to the maximum dietary burden.

(f): Tentative MRLs are derived for cattle, sheep and swine tissues based on the HR expressed according with the residue definition for risk assessment divided by the conversion factor of 2.

(g): Indicative MRL which would be derived according with the residue definition for risk assessment (based on the 2,4,6-trichlorophenol moiety) is reported between brackets for cattle, sheep and swine tissues.

(h): In the absence of feeding study performed with laying hens, results of the metabolism study were used to asses residue levels according to the residue definition for enforcement (only considering relevant metabolites) and for risk assessment (considering TRR levels) in hens tissues and eggs; for eggs results of both yolk and white were taken into account considering a weight ratio yolk/white of 40/60.

(i): Tentative MRLs are derived for poultry tissues and eggs based on results of the metabolism study.

### B.3. Consumer risk assessment

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

| ADI | 0.01 mg/kg bw per day (EFSA, 2011) |
|-----|----------------------------------|
| Highest IED, according to EFSA PRImo |
| Scenario EU1: 483.8% ADI (DE, child) |
| Scenario EU2: 52.7% ADI (FR, toddler) |

| Assumptions made for the calculations |
|-------------------------------------|
| Scenario EU1: The calculation is based on the median residue levels in the raw agricultural commodities. For plant commodities, for poultry commodities and for milk, the conversion factor from enforcement to risk assessment (CF) derived under this review were considered. For ruminant commodities, the median values directly calculated according to the residue definition for risk assessment was considered. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation, noting that the existing EU MRLs are already expressed according to the residue definition for risk assessment The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation, assuming that a mitigation measure (minimum PBI of 365 days for rotational crops) is applied and sufficient to avoid residue uptakes in non-treated food commodities |
| Scenario EU2: The critical GAPs for citrus fruits, barley, oats, and sugar and fodder beets were disregarded. Fall-back GAPs were considered for barley and oats (seed treatment) For citrus fruits, the current MRLs assessed under scenario EU1 were disregarded as leading to acute concerns For sugar and fodder beets, no fall-back GAPs were identified as all other GAPs also induce high livestock dietary burden, leading to exceedances of the ARFD for bovine liver. Residue levels in livestock commodities were recalculated accordingly. All other input values remain unchanged |

www.efsa.europa.eu/efsajournal 50 EFSA Journal 2018;16(8):5401
| ARfD | 0.025 mg/kg bw (EFSA, 2011) |
|---|---|
| **Highest IESTI, according to EFSA PRIMo** | **Scenario EU1:**  
5,305% ARfD (oranges)  
3,568% ARfD (grapefruits)  
2,226% ARfD (mandarins)  
1,378% ARfD (lemons)  
805.2% ARfD (limes)  
222.7% ARfD (bovine liver)  
| **Scenario EU2:**  
60.3% ARfD (bovine liver) |

**Assumptions made for the calculations**

**Scenario EU1:**

The calculation is based on the highest residue levels in the raw agricultural commodities. For plant commodities, for poultry commodities and for milk, the conversion factor from enforcement to risk assessment (CF) derived under this review were considered. For ruminant commodities, the median values directly calculated according to the residue definition for risk assessment was considered.

For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation, noting that the existing EU MRLs are already expressed according to the residue definition for risk assessment.

The contributions of commodities where no GAP was reported in the framework of this review were not included in the calculation, assuming that a mitigation measure (minimum PBI of 365 days for rotational crops) is applied and sufficient to avoid residue uptakes in non-treated food commodities.

**Scenario EU2:**

The critical GAPs for citrus fruits, barley, oats, and sugar and fodder beets were disregarded. Fall-back GAPs were considered for barley and oats (seed treatment).

For citrus fruits, the current MRLs assessed under scenario EU1 were disregarded as these led to acute concerns.

For sugar and fodder beets, no fall-back GAPs were identified as all other GAPs also induce high livestock dietary burden, leading to exceedances of the ARfD for bovine liver. Residue levels in livestock commodities were recalculated accordingly. All other input values remain unchanged.

---

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

| ADI | 0.01 mg/kg bw per day (EFSA, 2011) |
|---|---|
| **Highest IEDI, according to EFSA PRIMo** | **Indicative results considering CXLs only:**  
18.8% ADI (WHO Cluster diet B) |
| **Assumptions made for the calculations** | CXLs have been established for prochloraz (as sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety expressed as prochloraz). However, this residue definition for enforcement is not compatible with the residue for enforcement proposed by EFSA. Therefore, a consumer risk assessment including CXLs values together with EU MRLs could not be performed.  
An indicative risk assessment with the existing CXLs only was performed. As CXLs were derived according to residue definition for risk assessment, the available values could directly be considered for an indicative risk assessment. For citrus fruits as well as for the subgroup of tropical and sub-tropical fruits with inedible peel, the highest residue values measured in pulp were considered in the calculations. |
ARfD 0.025 mg/kg bw (EFSA, 2011)

Indicative results considering CXLs only:
- 488% ARfD (oranges)
- 328% ARfD (grapefruits)
- 283% ARfD (pineapples)
- 234% ARfD (bananas)
- 220% ARfD (mangoes)
- 205% ARfD (mandarins)
- 200% ARfD (bovine liver)
- 127% ARfD (lemons)
- 113% ARfD (kiwi)

Assumptions made for the calculations:
CXLs have been established for prochloraz (as sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety expressed as prochloraz). This residue definition for enforcement is not compatible with the residue for enforcement proposed by EFSA. Therefore, a consumer risk assessment including CXL values together with EU MRLs could not be performed. An indicative risk assessment with the existing CXLs only was performed. As CXLs were derived according to residue definition for risk assessment, the available values could directly be considered for an indicative risk assessment. For citrus fruits as well as for the subgroup of tropical and subtropical fruits with inedible peel, the highest residue values measured in pulp were considered in the calculations.

B.4. Proposed MRLs

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment |
|-------------|-----------|------------------------|---------------------|-------------|---------|
| 110010      | Grapefruit| 10                     | 10                  | 10          | Further consideration needed (g) |
| 110020      | Oranges   | 10                     | 10                  | 10          | Further consideration needed (g) |
| 110030      | Lemons    | 10                     | 10                  | 10          | Further consideration needed (g) |
| 110040      | Limes     | 10                     | 10                  | 10          | Further consideration needed (g) |
| 110050      | Mandarins | 10                     | 10                  | 10          | Further consideration needed (g) |
| 120010      | Almonds   | 0.1*                   | –                   | 0.1         | Further consideration needed (c) |
| 140010      | Apricots  | 0.05*                  | –                   | 0.05        | Further consideration needed (c) |
| 140020      | Cherries (sweet) | 0.05* | – | 0.05 | Further consideration needed (c) |
| 140030      | Peaches   | 0.05*                  | –                   | 0.05        | Further consideration needed (c) |
| 140040      | Plums     | 0.05*                  | –                   | 0.05        | Further consideration needed (c) |
| 152000      | Strawberries | 0.05* | – | 0.05 | Further consideration needed (c) |
| 161040      | Kumquats  | 0.05*                  | 10                  | 0.05        | Further consideration needed (c) |
| 162010      | Kiwi      | 0.05*                  | 7                   | –           | Further consideration needed (c) |
| 162020      | Lychee (Litchi) | 0.05* | 7 | – | Further consideration needed (c) |
| 162030      | Passion fruit | 0.05* | 7 | – | Further consideration needed (c) |
| 162040      | Prickly pear (cactus fruit) | 0.05* | 7 | – | Further consideration needed (c) |
| 162050      | Star apple | 0.05* | 7 | – | Further consideration needed (c) |
| 162060      | American persimmon (Virginia kaki) | 0.05* | 7 | – | Further consideration needed (c) |
| 163010      | Avocados  | 5                      | 7                   | 7           | Further consideration needed (h) |

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; EFSA PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; CXL: codex maximum residue limit; MRL: maximum residue level; GAP: Good Agricultural Practice; PBI: plant-back interval; ARfD: acute reference dose; IESTI: international estimated short-term intake.
| Code number | Commodity             | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Comment                          |
|------------|-----------------------|-------------------------|----------------------|-------------|----------------------------------|
| 163020     | Bananas               | 0.05*                   | 7                    |             | Further consideration needed(h)  |
| 163030     | Mangoes               | 5                       | 7                    |             | Further consideration needed(h)  |
| 163040     | Papaya                | 5                       | 7                    |             | Further consideration needed(h)  |
| 163050     | Pomegranate           | 0.05*                   | 7                    |             | Further consideration needed(h)  |
| 163060     | Cherimoya             | 0.05*                   | 7                    |             | Further consideration needed(h)  |
| 163070     | Guava                 | 0.05*                   | 7                    |             | Further consideration needed(h)  |
| 163080     | Pineapples            | 5                       | 7                    |             | Further consideration needed(h)  |
| 163090     | Bread fruit           | 0.05*                   | 7                    |             | Further consideration needed(h)  |
| 163100     | Durian                | 0.05*                   | 7                    |             | Further consideration needed(h)  |
| 163110     | Soursop (guanabana)   | 0.05*                   | 7                    |             | Further consideration needed(h)  |
| 280010     | Cultivated fungi      | 3                       | 3                    | 3           | Recommended(d)                   |
| 401010     | Linseeds              | 0.5                     | 0.05*                | 0.3         | Recommended(d)                   |
| 401030     | Poppy seeds           | 0.1*                    | –                    | 0.3         | Recommended(d)                   |
| 401050     | Sunflower seeds       | 0.5                     | 0.5                  | 0.3         | Recommended(d)                   |
| 401060     | Rapeseeds/canola seeds| 0.5                     | 0.7                  | 0.3         | Recommended(d)                   |
| 500010     | Barley grains         | 1                       | 2                    | 0.03*       | Recommended(d)                   |
| 500020     | Buckwheat grain       | 0.05*                   | 2                    |             | Further consideration needed(h)  |
| 500030     | Maize grain           | 0.05*                   | 2                    |             | Further consideration needed(h)  |
| 500040     | Millet grain          | 0.05*                   | 2                    |             | Further consideration needed(h)  |
| 500050     | Oat grains            | 1                       | 2                    | 0.03*       | Recommended(d)                   |
| 500060     | Rice grain            | 1                       | 2                    |             | Further consideration needed(h)  |
| 500070     | Rye grains            | 0.5                     | 2                    | 0.2         | Recommended(d)                   |
| 500080     | Sorghum grain         | 0.05*                   | 2                    |             | Further consideration needed(h)  |
| 500090     | Wheat grains          | 0.5                     | 2                    | 0.2         | Recommended(d)                   |
| 820000     | Spices (fruits and berries) | 0.2                 | 10                   |             | Further consideration needed(h)  |
| 900010     | Sugar beet roots      | 0.1                     | –                    |             | Further consideration needed(h)  |
| 1011010    | Swine muscle          | 0.1*                    | 0.5                  | 0.03*       | Further consideration needed(f)  |
| 1011020    | Swine fat tissue      | 0.1*                    | 0.5                  | 0.03*       | Further consideration needed(f)  |
| 1011030    | Swine liver           | 0.1*                    | 10                   | 0.3         | Further consideration needed(f)  |
| 1011040    | Swine kidney          | 0.1*                    | 10                   | 0.05        | Further consideration needed(f)  |
| 1012010    | Bovine muscle         | 0.1*                    | 0.5                  | 0.03*       | Further consideration needed(f)  |
| 1012020    | Bovine fat tissue     | 0.2                     | 0.5                  | 0.07        | Further consideration needed(f)  |
| 1012030    | Bovine liver          | 2                       | 10                   | 1           | Further consideration needed(f)  |
| 1012040    | Bovine kidney         | 0.5                     | 10                   | 0.2         | Further consideration needed(f)  |
| 1013010    | Sheep muscle          | 0.1*                    | 0.5                  | 0.03*       | Further consideration needed(f)  |
| 1013020    | Sheep fat tissue      | 0.1*                    | 0.5                  | 0.15        | Further consideration needed(f)  |
| 1013030    | Sheep liver           | 0.1*                    | 10                   | 3           | Further consideration needed(f)  |
| 1013040    | Sheep kidney          | 0.1*                    | 10                   | 0.5         | Further consideration needed(f)  |
| 1014010    | Goat muscle           | 0.1*                    | 0.5                  | 0.03*       | Further consideration needed(f)  |
| 1014020    | Goat fat tissue       | 0.1*                    | 0.5                  | 0.15        | Further consideration needed(f)  |
| 1014030    | Goat liver            | 0.1*                    | 10                   | 3           | Further consideration needed(f)  |
| 1014040    | Goat kidney           | 0.1*                    | 10                   | 0.5         | Further consideration needed(f)  |
| 1015010    | Equine muscle         | 0.1*                    | 0.5                  | 0.03*       | Further consideration needed(f)  |
| 1015020    | Equine fat tissue     | 0.1*                    | 0.5                  | 0.07        | Further consideration needed(f)  |
| 1015030    | Equine liver          | 0.1*                    | 10                   | 1           | Further consideration needed(f)  |
| 1015040    | Equine kidney         | 0.1*                    | 10                   | 0.2         | Further consideration needed(f)  |
| 1016010    | Poultry muscle        | 0.1*                    | 0.05*                | 0.03*       | Further consideration needed(f)  |
| Code number | Commodity            | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|----------------------|------------------------|---------------------|----------------------|---------|
| 1016020     | Poultry fat tissue   | 0.1*                   | 0.05*               | 0.03*                | Further consideration needed\(^{(f)}\) |
| 1016030     | Poultry liver        | 0.1*                   | 0.2                 | 0.04                 | Further consideration needed\(^{(f)}\) |
| 1020010     | Cattle milk          | 0.02*                  | 0.05*               | 0.03*                | Further consideration needed\(^{(f)}\) |
| 1020020     | Sheep milk           | 0.02*                  | 0.05*               | 0.03*                | Further consideration needed\(^{(f)}\) |
| 1020030     | Goat milk            | 0.02*                  | 0.05*               | 0.03*                | Further consideration needed\(^{(f)}\) |
| 1020040     | Horse milk           | 0.02*                  | 0.05*               | 0.03*                | Further consideration needed\(^{(f)}\) |
| 1030000     | Birds eggs           | 0.1*                   | 0.1                 | 0.1                  | Further consideration needed\(^{(f)}\) |
| –           | Other commodities of plant and animal origin | See Reg. 520/2011 | –                   | –                    | Further consideration needed\(^{(e)}\) |

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

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

(F): The proposed residue definition is fat soluble.

(a): 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; no CXL is available (combination G-I in Appendix E).

(b): GAP evaluated at EU level is fully supported by data but a risk to consumers cannot be excluded; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination F-I in Appendix E).

(c): 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).

(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; CXL is not compatible with EU residue definitions (combination G-II in Appendix E).

(e): 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).

(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; CXL is not compatible with EU residue definitions (combination E-II in Appendix E).

(g): GAP evaluated at EU level is not supported by data and a risk to consumers cannot be excluded for the existing EU MRL; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination B-II in Appendix E).

(h): There are no relevant authorisations or import tolerances reported at EU level; CXL is not compatible with EU residue definitions. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-II in Appendix E).
# Appendix C – Pesticide Residue Intake Model (PRIMo)

## PRIMo(EU)

### Prochloraz

| Toxicological end points | Code no. | LOQ (mg/kg bw): | Proposed LOQ: | ADI (mg/kg bw per day): | ARfD (mg/kg bw): | Source of ADI: | Year of evaluation: | Source of ARfD: | Year of evaluation: |
|--------------------------|----------|----------------|---------------|--------------------------|----------------|----------------|-------------------|----------------|-------------------|
|                          |          |                |               |                          |                | EFSA          | 2011              | EFSA            | 2011              |

### Status of the active substance:

- Included

### Chronic risk assessment – refined calculations

#### No of diets exceeding ADI: 15

| Commodity/group of commodities | TMDI (range) in % of ADI | MS Diet |
|-------------------------------|--------------------------|---------|
| Oranges                       | 49.3 – 484%              | 15      |
| Mandarins                     | 40.9 – 466%              | 15      |
| Grapefruit                    | 21.7 – 244%              | 15      |
| Milk and cream                | 35.2 – 36%               | 15      |
| Mandarins                     | 24.8 – 25%               | 15      |
| Milk and cream                | 24.8 – 25%               | 15      |
| Mandarins                     | 23.4 – 24%               | 15      |
| Milk and cream                | 19.6 – 20%               | 15      |
| Mandarins                     | 18.0 – 19%               | 15      |
| Milk and cream                | 18.0 – 19%               | 15      |
| Mandarins                     | 16.4 – 17%               | 15      |
| Milk and cream                | 16.4 – 17%               | 15      |
| Mandarins                     | 14.8 – 16%               | 15      |
| Milk and cream                | 14.8 – 16%               | 15      |
| Mandarins                     | 13.2 – 14%               | 15      |
| Milk and cream                | 13.2 – 14%               | 15      |
| Mandarins                     | 11.6 – 12%               | 15      |
| Milk and cream                | 11.6 – 12%               | 15      |
| Mandarins                     | 10.0 – 11%               | 15      |
| Milk and cream                | 10.0 – 11%               | 15      |
| Mandarins                     | 8.4 – 9%                 | 15      |
| Milk and cream                | 8.4 – 9%                 | 15      |
| Mandarins                     | 6.8 – 7%                 | 15      |
| Milk and cream                | 6.8 – 7%                 | 15      |
| Mandarins                     | 5.2 – 6%                 | 15      |
| Milk and cream                | 5.2 – 6%                 | 15      |
| Mandarins                     | 3.6 – 4%                 | 15      |
| Milk and cream                | 3.6 – 4%                 | 15      |
| Mandarins                     | 2.0 – 2%                 | 15      |
| Milk and cream                | 2.0 – 2%                 | 15      |
| Mandarins                     | 0.4 – 1%                 | 15      |

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 13.6 – 446% of the ADI. For 15 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

---

**Review of the existing MRLs for prochloraz**

[www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal) 55 EFSA Journal 2018;16(8):5401
### 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.

For processed commodities, the ARfD/ADI was exceeded in one or several cases.

The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**pTMRL:** provisional temporary MRL.

**pTMRL for unprocessed commodity.**

The estimated short-term intake (ESTI 1) exceeded the ARfD/ADI for 6 commodities.

Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 6 commodities.

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

**Conclusion:**

For prochloraz, 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.

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

For processed commodities, the ARfD/ADI was exceeded in one or several cases.

---

| Commodity     | pTMRL/threshold MRL (mg/kg) | pTMRL/threshold MRL (mg/kg) | pTMRL/threshold MRL (mg/kg) | pTMRL/threshold MRL (mg/kg) |
|---------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| 530.8 Oranges | 10/0.18                     | 10/0.28                     | 10/0.28                     | 10/0.28                     |
| 3568.0 Grapefruit | 10/0.28                 | 10/0.28                     | 10/0.28                     | 10/0.28                     |
| 2225.9 Mandarins | 10/0.44                  | 10/0.44                     | 10/0.44                     | 10/0.44                     |
| 1377.8 Lemons | 10/0.72                     | 10/0.72                     | 10/0.72                     | 10/0.72                     |
| 655.2 Limes  | 10/1.24                     | 10/1.24                     | 10/1.24                     | 10/1.24                     |
| 222.7 Bovine: Liver | 6.90/3.09               | 6.90/3.09                   | 6.90/3.09                   | 6.90/3.09                   |
| 1981.4 Orange juice | 10/0.6                  | 10/0.6                      | 10/0.6                      | 10/0.6                      |
| 15.3 Wheat flour | 0.32/-                   | 0.32/-                      | 0.32/-                      | 0.32/-                      |
| 3.6 Peach juice | 0.05/-                    | 0.05/-                      | 0.05/-                      | 0.05/-                      |
| 2.8 Plums juice | 0.05/-                    | 0.05/-                      | 0.05/-                      | 0.05/-                      |
| 597.5 Grapefruit | 10/1.24                  | 10/1.24                     | 10/1.24                     | 10/1.24                     |
| 417.5 Mandarins | 10/1.86                   | 10/1.86                     | 10/1.86                     | 10/1.86                     |
| 201.4 Lemons  | 10/4.56                    | 10/4.56                     | 10/4.56                     | 10/4.56                     |
| 188.4 Limes   | 10/5.3                     | 10/5.3                      | 10/5.3                      | 10/5.3                      |

---

**The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.**

**pTMRL:** provisional temporary MRL.

**pTMRL for unprocessed commodity.**
### Prochloraz

| Toxicological end points |
|--------------------------|
| ADI (mg/kg bw per day): | Proposed LOQ: |
| 0.01 | 0.025 |

| Source of ADI: | Source of ARfD: |
|---------------|-----------------|
| EFSA          | EFSA            |

| Year of evaluation: | Year of evaluation: |
|---------------------|---------------------|
| 2011                | 2011                |

| No of diets exceeding ADI: |
|-----------------------------|
| TMDI (range) in % of ADI     |
| minimum – maximum           |
| 1                           | 53                  |

### Chronic risk assessment – refined calculations

| Commodity/ group of commodities | MS Diet | 2nd contributor to MS diet | 3rd contributor to MS diet | pTMLRs at LOQ (in % of ADI) |
|---------------------------------|---------|---------------------------|---------------------------|-----------------------------|
| Milk and cream                  |         |                          |                           |                             |
| Poultry: Meat                   |         |                          |                           |                             |
| 47.5                             | 2.2     | 1.3                       | 0.8                       | Birds' eggs                 |
| 46.5                             | 1.3     | 1.8                       | 0.4                       | Poultry: Meat               |
| 30.9                             | 2.0     | 1.6                       | 0.5                       | Birds' eggs                 |
| 17.1                             | 2.1     | 2.3                       | 1.6                       | Poultry: Meat               |
| 15.0                             | 3.4     | 2.3                       | 2.3                       | Wheat                       |
| 15.2                             | 2.8     | 2.3                       | 2.3                       | Rye                         |
| 14.9                             | 1.6     | 0.5                       | 0.5                       | Birds' eggs                 |
| 5.8                              | 2.3     | 1.5                       | 1.5                       | Wheat                       |
| 6.1                              | 3.3     | 1.0                       | 1.0                       | Poultry: Meat               |
| 7.9                              | 1.1     | 0.9                       | 0.9                       | Poultry: Meat               |
| 3.6                              | 2.6     | 2.0                       | 2.0                       | Wheat                       |
| 5.9                              | 1.7     | 1.2                       | 1.2                       | Wheat                       |
| 3.3                              | 1.2     | 1.1                       | 1.1                       | Cultivated fungi            |
| 4.8                              | 1.8     | 1.2                       | 1.2                       | Poultry: Meat               |
| 6.4                              | 1.0     | 0.3                       | 0.3                       | Rye                         |
| 6.8                              | 0.5     | 0.3                       | 0.3                       | Rye                         |
| 4.8                              | 0.8     | 0.5                       | 0.5                       | Rye                         |
| 3.2                              | 1.7     | 1.6                       | 1.6                       | Poultry: Meat               |
| 3.9                              | 1.0     | 0.6                       | 0.6                       | Cultivated fungi            |
| 3.6                              | 0.9     | 0.3                       | 0.3                       | Cultivated fungi            |
| 3.4                              | 0.2     | 0.2                       | 0.2                       | Cultivated fungi            |
| 2.1                              | 0.2     | 0.2                       | 0.2                       | Poultry: Meat               |
| 2.0                              | 0.2     | 0.2                       | 0.2                       | Peaches                      |
| 0.8                              | 0.1     | 0.0                       | 0.0                       | Cherries                    |

### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMLRs were below the ADI. A long-term intake of residues of prochloraz 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 calculations, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce, a variability factor of 5 was used.

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

| No of critical MRLs (ESTI 1) | --- | No of critical MRLs (ESTI 2) | --- |
|--------------------------------|----------------|--------------------------------|----------------|
| Highest % of ARfD/ADI | Commodities | pTMRL (mg/kg) | Commodity | pTMRL (mg/kg) | Commodity | pTMRL (mg/kg) | Commodity | pTMRL (mg/kg) |
| 60.3 | Bovine: Liver | 1.867/- | 60.3 | Bovine: Liver | 1.867/- | 20.1 | Bovine: Liver | 1.867/- |
| 59.6 | Milk and milk products | 0.12/- | 59.6 | Milk and milk | 0.12/- | 16.4 | Cultivated fungi | 1.4/- |
| 47.3 | Cultivated fungi | 1.4/- | 47.3 | Cultivated fungi | 1.4/- | 12.3 | Poultry: Meat | 0.261/- |
| 16.7 | Wheat | 0.323/- | 16.7 | Wheat | 0.323/- | 11.9 | Sheep: Liver | 4.363/- |
| 11.9 | Peaches | 0.05/- | 11.7 | Poultry: Meat | 0.261/- | 10.1 | Wheat | 0.323/- |

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

| No of commodities for which ARfD/ADI is exceeded: | --- |
|--------------------------------|----------------|
| Highest % of ARfD/ADI | Commodities | pTMRL (mg/kg) |
| 19.5 | Wheat flour | 0.331/- |
| 3.6 | Peach juice | 0.05/- |
| 2.8 | Plums juice | 0.05/- |

Conclusion:
For processed commodities, 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.
### Prochloraz

**Status of the active substance:** Included

| Code no. | LOQ (mg/kg bw): | Proposed LOQ: | ADI (mg/kg bw per day): | ARfD (mg/kg bw): |
|----------|-----------------|----------------|-------------------------|-----------------|
|          |                 |                | 0.01                    | 0.025           |

**Source of ADI:** EFSA

**Year of evaluation:** 2011

#### Toxicological end points

| ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
|------------------------|-----------------|
| 0.01                   | 0.025           |

**Source of ADI:** EFSA

**Year of evaluation:** 2011

#### No of diets exceeding ADI:

| Highest calculated | TMDI values in % of ADI | Highest contributor to MS diet | Commodity (in % of ADI) |
|--------------------|--------------------------|--------------------------------|-------------------------|
| 18.8               | WHO Cluster diet B       | 9.4                            | Wheat                   |
| 17.5               | IE adult                 | 9.2                            | Sheep Liver             |
| 16.1               | NL child                 | 9.0                            | Oranges                 |
| 15.1               | DE child                 | 9.0                            | Oranges                 |
| 14.9               | DK child                 | 8.9                            | Oranges                 |
| 11.5               | WHO cluster diet D       | 8.4                            | Oranges                 |
| 11.1               | WHO cluster diet E       | 8.4                            | Barley                  |
| 11.0               | ES child                 | 8.4                            | Spices (fruits and berries) |
| 10.9               | IT kids/toddler          | 8.4                            | Maize                   |
| 9.6                | WHO Cluster diet F       | 8.4                            | Oranges                 |
| 9.5                | UK Infant                | 8.4                            | Maize                   |
| 9.4                | UK Toddler               | 8.3                            | Oranges                 |
| 8.4                | SE general population 90th percentile | 8.2 | Bananas |
| 7.6                | FR toddler               | 7.9                            | Oranges                 |
| 7.3                | PT General population    | 7.9                            | Barley                  |
| 7.2                | WHO regional European diet | 7.8                          | Oranges                 |
| 6.9                | NL general               | 7.8                            | Oranges                 |
| 6.8                | ES adult                 | 7.8                            | Oranges                 |
| 6.8                | IT adult                 | 7.8                            | Oranges                 |
| 5.3                | FR all population        | 7.8                            | Oranges                 |
| 5.2                | UK vegetarian            | 7.8                            | Oranges                 |
| 5.0                | DK adult                 | 7.8                            | Oranges                 |
| 4.1                | UK Adult                 | 7.7                            | Oranges                 |
| 4.0                | LT adult                 | 7.7                            | Oranges                 |
| 3.6                | FI adult                 | 7.6                            | Oranges                 |
| 3.1                | FR infant                | 7.6                            | Oranges                 |
| 1.2                | PL general population    | 7.6                            | Oranges                 |

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.

A long-term intake of residues of prochloraz 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, 7 and 5 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 leads to an exposure equivalent to 100% of the ARfD.

#### Table: No of critical MRLs (IESTI 1) and (IESTI 2)

| Commodity   | IESTI 1 | IESTI 2 |
|-------------|---------|---------|
| Oranges     | 9       | 7       |
| Grapefruit  | 9       | 7       |
| Bananas     | 9       | 7       |
| Mangoes     | 9       | 7       |
| Pineapples  | 9       | 7       |
| Kiwi        | 9       | 7       |
| Avocados    | 9       | 7       |
| Bovine: Liver | 9 | 7 |
| Bovine: Kidney | 9 | 7 |

The estimated short-term intake (IESTI 1) exceeded the ARfD/ADI for 9 commodities.

Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 7 commodities.

### Conclusion:

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

The estimated short-term intake (IESTI 1) exceeded the ARfD/ADI for 9 commodities.

Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 7 commodities.

For processed commodities, the ARfD/ADI was exceeded in one or several cases.
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                |
| Barley, straw          | 3.11                  | STMR × CF (1.8)        | 52.2                  | HR × CF (1.8)          |
| Oat, straw             | 4.32                  | STMR × CF (1.8)        | 52.2                  | HR × CF (1.8)          |
| Wheat/triticale, straw | 2.40                  | STMR × CF (1.5)        | 19.5                  | HR × CF (1.5)          |
| Rye, straw             | 2.40                  | STMR × CF (1.5)        | 19.5                  | HR × CF (1.5)          |
| Beet, mangel, roots    | 0.06                  | STMR × CF (2)          | 0.14                  | HR × CF (2)            |
| Beet, mangel, tops     | 1.23                  | STMR × CF (2.8)        | 4.48                  | HR × CF (2.8)          |
| Beet, sugar, tops      | 1.23                  | STMR × CF (2.8)        | 4.48                  | HR × CF (2.8)          |
| Rape, forage           | 0.80                  | STMR × CF (4)          | 2.80                  | HR × CF (4)            |
| Barley, grain          | 0.10                  | STMR × CF (1.7)        | 0.10                  | STMR × CF (1.7)        |
| Oat, grain             | 0.10                  | STMR × CF (1.7)        | 0.10                  | STMR × CF (1.7)        |
| Rye, grain             | 0.05                  | STMR × CF (1.7)        | 0.05                  | STMR × CF (1.7)        |
| Wheat/triticale, grain | 0.05                  | STMR × CF (1.7)        | 0.05                  | STMR × CF (1.7)        |
| Beet, sugar, dried pulp| 1.08                  | STMR × 18(a) × CF (2)  | 1.08                  | STMR × 18(a) × CF (2)  |
| Beet, sugar, ensiled pulp| 0.18                | STMR × 3(a) × CF (2)   | 0.18                  | STMR × 3(a) × CF (2)   |
| Beet, sugar, molasses  | 1.68                  | STMR × 28(a) × CF (2)  | 1.68                  | STMR × 28(a) × CF (2)  |
| Brewer’s grain, dried  | 0.34                  | STMR × 3.3(a) × CF (1.7)| 0.34                  | STMR × 3.3(a) × CF (1.7)|
| Flaxseed/Linseed, meal| 0.13                  | STMR × 2(a) × CF (1)   | 0.13                  | STMR × 2(a) × CF (1)   |
| Rape seed/canola, meal | 0.13                  | STMR × 2(a) × CF (1)   | 0.13                  | STMR × 2(a) × CF (1)   |
| Sunflower, meal        | 0.13                  | STMR × 2(a) × CF (1)   | 0.13                  | STMR × 2(a) × CF (1)   |
| Wheat, distiller’s grain (dry) | 0.17 | STMR × 3.3(a) × CF (1.7) | 0.17 | STMR × 3.3(a) × CF (1.7) |
| Wheat gluten, meal     | 0.09                  | STMR × 1.8(a) × CF (1.7)| 0.09                  | STMR × 1.8(a) × CF (1.7)|
| Wheat, milled by-pdts  | 0.22                  | STMR × PF (4.3) × CF (1.7)| 0.22                  | STMR × PF (4.3) × CF (1.7)|
| Corn, field, stover (fodder) | 0.43 | Rotational crops (tentative) | 0.43 | Rotational crops (tentative) |
| Corn, pop, stover     | 0.43                  | Rotational crops (tentative) | 0.43 | Rotational crops (tentative) |
| Millet, straw (fodder, dry) | 0.43 | Rotational crops (tentative) | 0.43 | Rotational crops (tentative) |
| Rice, straw           | 0.43                  | Rotational crops (tentative) | 0.43 | Rotational crops (tentative) |
| Sorghum, grain, stover| 0.43                  | Rotational crops (tentative) | 0.43 | Rotational crops (tentative) |
| Turnip, tops (leaves)  | 0.05                  | Rotational crops (tentative) | 0.05 | Rotational crops (tentative) |

Risk assessment residue definition: sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz

Scenario EU1: considering all authorised GAPs and possible uptake in rotational crops (PBI 365 days)

| Feed commodity         | Median dietary burden | Maximum dietary burden |
|------------------------|-----------------------|------------------------|
| Barley, straw          | 3.11                  | STMR × CF (1.8)        | 52.2                  | HR × CF (1.8)          |
| Oat, straw             | 4.32                  | STMR × CF (1.8)        | 52.2                  | HR × CF (1.8)          |
| Wheat/triticale, straw | 2.40                  | STMR × CF (1.5)        | 19.5                  | HR × CF (1.5)          |
| Rye, straw             | 2.40                  | STMR × CF (1.5)        | 19.5                  | HR × CF (1.5)          |

Scenario EU2: excluding GAPs on citrus fruits, sugar and fodder beets, considering fall-back GAPs on barley and oat (seed treatment) and considering the possible uptake in rotational crops (PBI 365 days)
| Feed commodity                        | Median dietary burden | Maximum dietary burden |
|--------------------------------------|-----------------------|------------------------|
|                                      | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment                |
| Beet, mangel, roots                  | –                     | No residues expected   | –                     | No residues expected   |
| Beet, mangel, tops                   | 0.05                  | Rotational crops (tentative)^(b) | 0.05                  | Rotational crops (tentative)^(b) |
| Beet, sugar, tops                    | 0.05                  | Rotational crops (tentative)^(b) | 0.05                  | Rotational crops (tentative)^(b) |
| Rape, forage                         | 0.80                  | STMR × CF (4)          | 2.80                  | HR × CF (4)            |
| Barley, grain                        | 0.05                  | STMR × CF (1.7)        | 0.05                  | STMR × CF (1.7)        |
| Oat, grain                           | 0.05                  | STMR × CF (1.7)        | 0.05                  | STMR × CF (1.7)        |
| Rye, grain                           | 0.05                  | STMR × CF (1.7)        | 0.05                  | STMR × CF (1.7)        |
| Wheat/triticale, grain               | 0.05                  | STMR × CF (1.7)        | 0.05                  | STMR × CF (1.7)        |
| Beet, sugar, dried pulp              | –                     | No residues expected   | –                     | No residues expected   |
| Beet, sugar, ensiled pulp            | –                     | No residues expected   | –                     | No residues expected   |
| Beet, sugar, molasses                | –                     | No residues expected   | –                     | No residues expected   |
| Brewer’s grain, dried                | –                     | No residues expected   | –                     | No residues expected   |
| Flaxseed/Linseed, meal               | 0.13                  | STMR × 2^(a) × CF (1)  | 0.13                  | STMR × 2^(a) × CF (1)  |
| Rape seed/canola, meal               | 0.13                  | STMR × 2^(a) × CF (1)  | 0.13                  | STMR × 2^(a) × CF (1)  |
| Sunflower, meal                      | 0.13                  | STMR × 2^(a) × CF (1)  | 0.13                  | STMR × 2^(a) × CF (1)  |
| Wheat, distiller’s grain (dry)       | 0.17                  | STMR × 3^(a) × CF (1.7)| 0.17                  | STMR × 3^(a) × CF (1.7) |
| Wheat gluten, meal                   | 0.09                  | STMR × 1.8^(a) × CF (1.7) | 0.09                  | STMR × 1.8^(a) × CF (1.7) |
| Wheat, milled by-puds                | 0.22                  | STMR × PF (4.3) × CF (1.7) | 0.22                  | STMR × PF (4.3) × CF (1.7) |
| Corn, field, stover (fodder)         | 0.43                  | Rotational crops (tentative)^(b) | 0.43                  | Rotational crops (tentative)^(b) |
| Corn, pop, stover                    | 0.43                  | Rotational crops (tentative)^(b) | 0.43                  | Rotational crops (tentative)^(b) |
| Millet, straw (fodder, dry)          | 0.43                  | Rotational crops (tentative)^(b) | 0.43                  | Rotational crops (tentative)^(b) |
| Rice, straw                          | 0.43                  | Rotational crops (tentative)^(b) | 0.43                  | Rotational crops (tentative)^(b) |
| Sorghum, grain, stover               | 0.43                  | Rotational crops (tentative)^(b) | 0.43                  | Rotational crops (tentative)^(b) |
| Turnip, tops (leaves)                | 0.05                  | Rotational crops (tentative)^(b) | 0.05                  | Rotational crops (tentative)^(b) |

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, brewer’s grain, meals of oilseeds, distiller’s grain and wheat gluten meal, in the absence of processing factors supported by data, default processing factors were included in the calculation to consider the potential concentration of residues in these commodities.

(b): No GAP is authorised for these crops but possible intake from rotational crops cannot be avoided, even with a PBI of 365 days. To take this into account, total residues (TRR) from confined rotational crops measured at PBI 365 days were considered on a tentative basis. No CF is needed as residues are already expressed as TRR.

(c): The GAP considered for this crop (seed treatment) is expected to lead to lower residue levels compared to possible intake from rotational crops (with PBI of 365 days). Therefore, residue levels from rotational crops were taken into account, considering the total residues (TRR) from confined rotational crops measured at PBI 365 days (tentative basis). No CF is needed as residues are already expressed as TRR.
### D.2. Consumer risk assessment without consideration of the existing CXLs

#### D.2.1. Scenario EU1: considering all authorised GAPs

| Commodity          | Chronic risk assessment | Acute risk assessment |
|--------------------|-------------------------|-----------------------|
|                    | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| **Risk assessment residue definition:** sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz |
| Grapefruits        | 10                      | EU MRL\(^{(a)}\)      | 10                  | EU MRL\(^{(a)}\)      |
| Oranges            | 10                      | EU MRL\(^{(a)}\)      | 10                  | EU MRL\(^{(a)}\)      |
| Lemons             | 10                      | EU MRL\(^{(a)}\)      | 10                  | EU MRL\(^{(a)}\)      |
| Limes              | 10                      | EU MRL\(^{(a)}\)      | 10                  | EU MRL\(^{(a)}\)      |
| Mandarins          | 10                      | EU MRL\(^{(a)}\)      | 10                  | EU MRL\(^{(a)}\)      |
| Almonds            | 0.10                    | EU MRL\(^{(a)}\)      | 0.10                | EU MRL\(^{(a)}\)      |
| Apricots           | 0.05                    | EU MRL\(^{(a)}\)      | 0.05                | EU MRL\(^{(a)}\)      |
| Cherries (sweet)   | 0.05                    | EU MRL\(^{(a)}\)      | 0.05                | EU MRL\(^{(a)}\)      |
| Peaches            | 0.05                    | EU MRL\(^{(a)}\)      | 0.05                | EU MRL\(^{(a)}\)      |
| Plums              | 0.05                    | EU MRL\(^{(a)}\)      | 0.05                | EU MRL\(^{(a)}\)      |
| Strawberries       | 0.05                    | EU MRL\(^{(a)}\)      | 0.05                | EU MRL\(^{(a)}\)      |
| Cultivated fungi   | 0.48                    | STMR\(_{Mo}\) × CF \((1)\) | 1.40                | HR\(_{Mo}\) × CF \((1)\) |
| Linseeds           | 0.07                    | STMR\(_{Mo}\) × CF \((1)\) | 0.18                | HR\(_{Mo}\) × CF \((1)\) |
| Poppy seeds        | 0.07                    | STMR\(_{Mo}\) × CF \((1)\) | 0.18                | HR\(_{Mo}\) × CF \((1)\) |
| Sunflower seeds    | 0.07                    | STMR\(_{Mo}\) × CF \((1)\) | 0.18                | HR\(_{Mo}\) × CF \((1)\) |
| Rapeseeds/canola seeds | 0.07                   | STMR\(_{Mo}\) × CF \((1)\) | 0.18                | HR\(_{Mo}\) × CF \((1)\) |
| Barley grains      | 0.10                    | STMR\(_{Mo}\) × CF \((1.7)\) | 0.56                | HR\(_{Mo}\) × CF \((1.7)\) |
| Oat grains         | 0.10                    | STMR\(_{Mo}\) × CF \((1.7)\) | 1.29                | HR\(_{Mo}\) × CF \((1.7)\) |
| Rye grains         | 0.05                    | STMR\(_{Mo}\) × CF \((1.7)\) | 0.32                | HR\(_{Mo}\) × CF \((1.7)\) |
| Wheat grains       | 0.05                    | STMR\(_{Mo}\) × CF \((1.7)\) | 0.32                | HR\(_{Mo}\) × CF \((1.7)\) |
| Sugar beet roots   | 0.06                    | STMR\(_{Mo}\) × CF \((2)\) | 0.14                | HR\(_{Mo}\) × CF \((2)\) |
| Swine meat         | 0.03*                   | 0.8 × STMR\(_{RA}\) \_ muscle + 0.2 × STMR\(_{RA}\) \_ fat \(\text{(tentative)}\) | 0.041              | 0.8 × HR\(_{RA}\) \_ muscle + 0.2 × HR\(_{RA}\) \_ fat \(\text{(tentative)}\) |
| Swine fat tissue   | 0.03*                   | STMR\(_{RA}\) \(\text{(tentative)}\) | 0.086              | HR\(_{RA}\) \(\text{(tentative)}\) |
| Swine liver        | 0.330                   | STMR\(_{RA}\) \(\text{(tentative)}\) | 1.187              | HR\(_{RA}\) \(\text{(tentative)}\) |
| Swine kidney       | 0.061                   | STMR\(_{RA}\) \(\text{(tentative)}\) | 0.212              | HR\(_{RA}\) \(\text{(tentative)}\) |
| Bovine meat        | 0.048                   | 0.8 × STMR\(_{RA}\) \_ muscle + 0.2 × STMR\(_{RA}\) \_ fat \(\text{(tentative)}\) | 0.170              | 0.8 × HR\(_{RA}\) \_ muscle + 0.2 × HR\(_{RA}\) \_ fat \(\text{(tentative)}\) |
| Bovine fat tissue  | 0.041                   | STMR\(_{RA}\) \(\text{(tentative)}\) | 0.417              | HR\(_{RA}\) \(\text{(tentative)}\) |
| Bovine liver       | 0.911                   | STMR\(_{RA}\) \(\text{(tentative)}\) | 6.901              | HR\(_{RA}\) \(\text{(tentative)}\) |
| Bovine kidney      | 0.168                   | STMR\(_{RA}\) \(\text{(tentative)}\) | 1.354              | HR\(_{RA}\) \(\text{(tentative)}\) |
| Sheep meat         | 0.049                   | 0.8 × STMR\(_{RA}\) \_ muscle + 0.2 × STMR\(_{RA}\) \_ fat \(\text{(tentative)}\) | 0.357              | 0.8 × HR\(_{RA}\) \_ muscle + 0.2 × HR\(_{RA}\) \_ fat \(\text{(tentative)}\) |
| Sheep fat tissue   | 0.045                   | STMR\(_{RA}\) \(\text{(tentative)}\) | 0.823              | HR\(_{RA}\) \(\text{(tentative)}\) |
| Sheep liver        | 1.013                   | STMR\(_{RA}\) \(\text{(tentative)}\) | 13.1               | HR\(_{RA}\) \(\text{(tentative)}\) |
| Sheep kidney       | 0.187                   | STMR\(_{RA}\) \(\text{(tentative)}\) | 2.24               | HR\(_{RA}\) \(\text{(tentative)}\) |
| Goat meat          | 0.049                   | 0.8 × STMR\(_{RA}\) \_ muscle + 0.2 × STMR\(_{RA}\) \_ fat \(\text{(tentative)}\) | 0.357              | 0.8 × HR\(_{RA}\) \_ muscle + 0.2 × HR\(_{RA}\) \_ fat \(\text{(tentative)}\) |
### Commodity

| Commodity             | Chronic risk assessment | Acute risk assessment |
|-----------------------|-------------------------|-----------------------|
|                       | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Goat fat tissue       | 0.045                   | STMR<sub>RA</sub> (tentative) | 0.823               | HR<sub>RA</sub> (tentative) |
| Goat liver            | 1.013                   | STMR<sub>RA</sub> (tentative) | 13.1                | HR<sub>RA</sub> (tentative) |
| Goat kidney           | 0.187                   | STMR<sub>RA</sub> (tentative) | 2.24                | HR<sub>RA</sub> (tentative) |
| Equine meat           | 0.048                   | 0.8 × STMR<sub>RA</sub> muscle + 0.2 × STMR<sub>RA</sub> fat (tentative) | 0.170               | 0.8 × HR<sub>RA</sub> muscle + 0.2 × HR<sub>RA</sub> fat (tentative) |
| Equine fat tissue     | 0.041                   | STMR<sub>RA</sub> (tentative) | 0.417               | HR<sub>RA</sub> (tentative) |
| Equine liver          | 0.911                   | STMR<sub>RA</sub> (tentative) | 6.901               | HR<sub>RA</sub> (tentative) |
| Equine kidney         | 0.168                   | STMR<sub>RA</sub> (tentative) | 1.354               | HR<sub>RA</sub> (tentative) |
| Poultry meat          | 0.261                   | STMR<sub>Mo</sub> × CF(9) (tentative) | 0.261               | HR<sub>Mo</sub> × CF(9) (tentative) |
| Poultry fat tissue    | 0.180                   | 0.9 × STMR<sub>Mo</sub> muscle × CF(9) + 0.1 × STMR<sub>Mo</sub> fat × CF(6) (tentative) | 0.180               | 0.9 × HR<sub>Mo</sub> muscle × CF(9) + 0.1 × HR<sub>Mo</sub> fat × CF(6) (tentative) |
| Poultry liver         | 0.180                   | STMR<sub>Mo</sub> × CF(6) (tentative) | 0.258               | HR<sub>Mo</sub> × CF(6) (tentative) |
| Cattle milk           | 0.120                   | STMR<sub>Mo</sub> × CF(4) (tentative) | 0.120               | HR<sub>Mo</sub> × CF(4) (tentative) |
| Sheep milk            | 0.120                   | STMR<sub>Mo</sub> × CF(4) (tentative) | 0.120               | HR<sub>Mo</sub> × CF(4) (tentative) |
| Goat milk             | 0.120                   | STMR<sub>Mo</sub> × CF(4) (tentative) | 0.120               | HR<sub>Mo</sub> × CF(4) (tentative) |
| Horse milk            | 0.120                   | STMR<sub>Mo</sub> × CF(4) (tentative) | 0.120               | HR<sub>Mo</sub> × CF(4) (tentative) |
| Birds eggs            | 0.060                   | STMR<sub>Mo</sub> × CF(2) (tentative) | 0.250               | HR<sub>Mo</sub> × CF(2) (tentative) |

* MRL: maximum residue level; STMR/HR<sub>Mo</sub>: Median residue/Highest residue reexpressed according to the residue definition for enforcement; STMR/HR<sub>RA</sub>: Median residue/Highest residue expressed according to the residue definition for risk assessment; CF: Conversion factor for risk assessment.
* Indicates that the input value is proposed at the limit of quantification.
* GAP reported is not supported by data; the existing EU MRL is used for indicative exposure calculations, noting that existing residue definition is equivalent to the proposed residue definition for risk assessment.

### D.2.2. Scenario EU2: excluding GAPs on citrus fruits, sugar and fodder beets and considering fall-back GAPs on barley and oat (seed treatment)

| Commodity             | Chronic risk assessment | Acute risk assessment |
|-----------------------|-------------------------|-----------------------|
|                       | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Almonds               | 0.10                    | EU MRL<sup>(a)</sup> | 0.10                | EU MRL<sup>(a)</sup> |
| Apricots              | 0.05                    | EU MRL<sup>(a)</sup> | 0.05                | EU MRL<sup>(a)</sup> |
| Cherries (sweet)      | 0.05                    | EU MRL<sup>(a)</sup> | 0.05                | EU MRL<sup>(a)</sup> |
| Peaches               | 0.05                    | EU MRL<sup>(a)</sup> | 0.05                | EU MRL<sup>(a)</sup> |
| Plums                 | 0.05                    | EU MRL<sup>(a)</sup> | 0.05                | EU MRL<sup>(a)</sup> |
| Strawberries          | 0.05                    | EU MRL<sup>(a)</sup> | 0.05                | EU MRL<sup>(a)</sup> |
| Cultivated fungi      | 0.48                    | STMR<sub>Mo</sub> × CF(1) | 1.40                | HR<sub>Mo</sub> × CF(1) |
| Linseeds              | 0.07                    | STMR<sub>Mo</sub> × CF(1) | 0.18                | HR<sub>Mo</sub> × CF(1) |
| Poppy seeds           | 0.07                    | STMR<sub>Mo</sub> × CF(1) | 0.18                | HR<sub>Mo</sub> × CF(1) |
| Sunflower seeds       | 0.07                    | STMR<sub>Mo</sub> × CF(1) | 0.18                | HR<sub>Mo</sub> × CF(1) |
| Rapeseed/canola seeds | 0.07                    | STMR<sub>Mo</sub> × CF(1) | 0.18                | HR<sub>Mo</sub> × CF(1) |
| Barley grains         | 0.05                    | STMR<sub>Mo</sub> × CF(1.7) | 0.05                | HR<sub>Mo</sub> × CF(1.7) |
| Oat grains            | 0.05                    | STMR<sub>Mo</sub> × CF(1.7) | 0.05                | HR<sub>Mo</sub> × CF(1.7) |
| Rye grains            | 0.05                    | STMR<sub>Mo</sub> × CF(1.7) | 0.32                | HR<sub>Mo</sub> × CF(1.7) |
| Wheat grains          | 0.05                    | STMR<sub>Mo</sub> × CF(1.7) | 0.32                | HR<sub>Mo</sub> × CF(1.7) |

Risk assessment residue definition: sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz.
| Commodity         | Input value (mg/kg) | Comment                                                                 | Input value (mg/kg) | Comment                                                                 |
|-------------------|--------------------|-------------------------------------------------------------------------|--------------------|-------------------------------------------------------------------------|
| Swine meat        | 0.03*              | 0.8 \times \text{STMR}_{\text{RA}} \text{ muscle} + 0.2 \times \text{STMR}_{\text{RA}} \text{ fat} (tentative) | 0.031              | 0.8 \times \text{HR}_{\text{RA}} \text{ muscle} + 0.2 \times \text{HR}_{\text{RA}} \text{ fat} (tentative) |
| Swine fat tissue  | 0.03*              | \text{STMR}_{\text{RA}} (tentative)                                     | 0.036              | \text{HR}_{\text{RA}} (tentative)                                       |
| Swine liver       | 0.143              | \text{STMR}_{\text{RA}} (tentative)                                     | 0.497              | \text{HR}_{\text{RA}} (tentative)                                       |
| Swine kidney      | 0.026              | \text{STMR}_{\text{RA}} (tentative)                                     | 0.089              | \text{HR}_{\text{RA}} (tentative)                                       |
| Bovine meat       | 0.03*              | 0.8 \times \text{STMR}_{\text{RA}} \text{ muscle} + 0.2 \times \text{STMR}_{\text{RA}} \text{ fat} (tentative) | 0.051              | 0.8 \times \text{HR}_{\text{RA}} \text{ muscle} + 0.2 \times \text{HR}_{\text{RA}} \text{ fat} (tentative) |
| Bovine fat tissue | 0.03*              | \text{STMR}_{\text{RA}} (tentative)                                     | 0.136              | \text{HR}_{\text{RA}} (tentative)                                       |
| Bovine liver      | 0.228              | \text{STMR}_{\text{RA}} (tentative)                                     | 1.867              | \text{HR}_{\text{RA}} (tentative)                                       |
| Bovine kidney     | 0.042              | \text{STMR}_{\text{RA}} (tentative)                                     | 0.334              | \text{HR}_{\text{RA}} (tentative)                                       |
| Sheep meat        | 0.03*              | 0.8 \times \text{STMR}_{\text{RA}} \text{ muscle} + 0.2 \times \text{STMR}_{\text{RA}} \text{ fat} (tentative) | 0.103              | 0.8 \times \text{HR}_{\text{RA}} \text{ muscle} + 0.2 \times \text{HR}_{\text{RA}} \text{ fat} (tentative) |
| Sheep fat tissue  | 0.03*              | \text{STMR}_{\text{RA}} (tentative)                                     | 0.273              | \text{HR}_{\text{RA}} (tentative)                                       |
| Sheep liver       | 0.477              | \text{STMR}_{\text{RA}} (tentative)                                     | 4.363              | \text{HR}_{\text{RA}} (tentative)                                       |
| Sheep kidney      | 0.088              | \text{STMR}_{\text{RA}} (tentative)                                     | 0.936              | \text{HR}_{\text{RA}} (tentative)                                       |
| Goat meat         | 0.03*              | 0.8 \times \text{STMR}_{\text{RA}} \text{ muscle} + 0.2 \times \text{STMR}_{\text{RA}} \text{ fat} (tentative) | 0.103              | 0.8 \times \text{HR}_{\text{RA}} \text{ muscle} + 0.2 \times \text{HR}_{\text{RA}} \text{ fat} (tentative) |
| Goat fat tissue   | 0.03*              | \text{STMR}_{\text{RA}} (tentative)                                     | 0.273              | \text{HR}_{\text{RA}} (tentative)                                       |
| Goat liver        | 0.477              | \text{STMR}_{\text{RA}} (tentative)                                     | 4.363              | \text{HR}_{\text{RA}} (tentative)                                       |
| Goat kidney       | 0.088              | \text{STMR}_{\text{RA}} (tentative)                                     | 0.936              | \text{HR}_{\text{RA}} (tentative)                                       |
| Equine meat       | 0.03*              | 0.8 \times \text{STMR}_{\text{RA}} \text{ muscle} + 0.2 \times \text{STMR}_{\text{RA}} \text{ fat} (tentative) | 0.051              | 0.8 \times \text{HR}_{\text{RA}} \text{ muscle} + 0.2 \times \text{HR}_{\text{RA}} \text{ fat} (tentative) |
| Equine fat tissue | 0.03*              | \text{STMR}_{\text{RA}} (tentative)                                     | 0.136              | \text{HR}_{\text{RA}} (tentative)                                       |
| Equine liver      | 0.228              | \text{STMR}_{\text{RA}} (tentative)                                     | 1.867              | \text{HR}_{\text{RA}} (tentative)                                       |
| Equine kidney     | 0.042              | \text{STMR}_{\text{RA}} (tentative)                                     | 0.334              | \text{HR}_{\text{RA}} (tentative)                                       |
| Poultry meat      | 0.261              | \text{STMR}_{\text{Mo}} \times \text{CF}(9) (tentative)                | 0.261              | \text{HR}_{\text{Mo}} \times \text{CF}(9) (tentative)                  |
| Poultry fat tissue| 0.180              | 0.9 \times \text{STMR}_{\text{Mo}} \text{ muscle} \times \text{CF}(9) + 0.1 \times \text{STMR}_{\text{Mo}} \text{ fat} \times \text{CF}(6) (tentative) | 0.180              | 0.9 \times \text{HR}_{\text{Mo}} \text{ muscle} \times \text{CF}(9) + 0.1 \times \text{HR}_{\text{Mo}} \text{ fat} \times \text{CF}(6) (tentative) |
| Poultry liver     | 0.180              | \text{STMR}_{\text{Mo}} \times \text{CF}(6) (tentative)                | 0.192              | \text{HR}_{\text{Mo}} \times \text{CF}(6) (tentative)                  |
| Cattle milk       | 0.120              | \text{STMR}_{\text{Mo}} \times \text{CF}(4) (tentative)                | 0.120              | \text{HR}_{\text{Mo}} \times \text{CF}(4) (tentative)                  |
| Sheep milk        | 0.120              | \text{STMR}_{\text{Mo}} \times \text{CF}(4) (tentative)                | 0.120              | \text{HR}_{\text{Mo}} \times \text{CF}(4) (tentative)                  |
| Goat milk         | 0.120              | \text{STMR}_{\text{Mo}} \times \text{CF}(4) (tentative)                | 0.120              | \text{HR}_{\text{Mo}} \times \text{CF}(4) (tentative)                  |
| Horse milk        | 0.120              | \text{STMR}_{\text{Mo}} \times \text{CF}(4) (tentative)                | 0.120              | \text{HR}_{\text{Mo}} \times \text{CF}(4) (tentative)                  |
| Birds eggs        | 0.060              | \text{STMR}_{\text{Mo}} \times \text{CF}(2) (tentative)                | 0.188              | \text{HR}_{\text{Mo}} \times \text{CF}(2) (tentative)                  |

\text{STMR/HR}_{\text{RA}}: \text{Median residue/Highest residue reexpressed according to the residue definition for enforcement; STMR/HR}_{\text{RA}}: \text{Median residue/Highest residue expressed according to the residue definition for risk assessment; CF: Conversion factor for risk assessment.}

\*: Indicates that the input value is proposed at the limit of quantification.

(a): GAP reported is not supported by data; the existing EU MRL is used for indicative exposure calculations, noting that existing residue definition is equivalent to the proposed residue definition for risk assessment.
### D.3. Indicative consumer risk assessment of the existing CXLs

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| **Risk assessment residue definition:** sum of prochloraz and its metabolites containing the 2,4,6-trichlorophenol moiety, expressed as prochloraz |
| Grapefruits                | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.92 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Oranges                    | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.92 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Lemons                     | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.92 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Limes                      | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.92 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Mandarins                  | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.92 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Kumquats                   | 3.40 | STMR<sub>RA</sub> (CXL) | 6.80 | HR<sub>RA</sub> (CXL) |
| Kiwi                       | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Lychee (Litchi)            | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Passion fruit              | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Prickly pear (cactus fruit)| 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Star apple                 | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| American persimmon (Virginia kaki) | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Avocados                   | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Bananas                    | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Mangoes                    | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Papaya                     | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Pomegranate                | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Cherimoya                  | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Guava                      | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Pineapples                 | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Bread fruit                | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Durian                     | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Soursop (guanabana)        | 0.10 | STMR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) | 0.70 | HR<sub>RA</sub> (CXL, pulp)\(^{(a)}\) |
| Cultivated fungi           | 0.71 | STMR<sub>RA</sub> (CXL) | 1.40 | HR<sub>RA</sub> (CXL) |
| Linseed                    | 0.05 | STMR<sub>RA</sub> (CXL) | 0.05 | HR<sub>RA</sub> (CXL) |
| Sunflower seed             | 0.10 | STMR<sub>RA</sub> (CXL) | 0.32 | HR<sub>RA</sub> (CXL) |
| Rape seed                  | 0.10 | STMR<sub>RA</sub> (CXL) | 0.48 | HR<sub>RA</sub> (CXL) |
| Barley grain               | 0.11 | STMR<sub>RA</sub> (CXL) | 1.20 | HR<sub>RA</sub> (CXL) |
| Buckwheat grain            | 0.11 | STMR<sub>RA</sub> (CXL) | 1.20 | HR<sub>RA</sub> (CXL) |
| Maize grain                | 0.11 | STMR<sub>RA</sub> (CXL) | 1.20 | HR<sub>RA</sub> (CXL) |
| Millet grain               | 0.11 | STMR<sub>RA</sub> (CXL) | 1.20 | HR<sub>RA</sub> (CXL) |
| Oats grain                 | 0.11 | STMR<sub>RA</sub> (CXL) | 1.20 | HR<sub>RA</sub> (CXL) |
| Rice grain                 | 0.11 | STMR<sub>RA</sub> (CXL) | 1.20 | HR<sub>RA</sub> (CXL) |
| Rye grain                  | 0.11 | STMR<sub>RA</sub> (CXL) | 1.20 | HR<sub>RA</sub> (CXL) |
| Sorghum grain              | 0.11 | STMR<sub>RA</sub> (CXL) | 1.20 | HR<sub>RA</sub> (CXL) |
| Wheat grain                | 0.11 | STMR<sub>RA</sub> (CXL) | 1.20 | HR<sub>RA</sub> (CXL) |
| Spices (fruits and berries)| 5.10 | STMR<sub>RA</sub> (CXL) | 5.10 | HR<sub>RA</sub> (CXL) |
| Swine muscle               | 0.02 | STMR<sub>RA</sub> (CXL) | 0.10 | HR<sub>RA</sub> (CXL) |
| Swine fat tissue           | 0.06 | STMR<sub>RA</sub> (CXL) | 0.38 | HR<sub>RA</sub> (CXL) |
| Swine liver                | 1.20 | STMR<sub>RA</sub> (CXL) | 6.20 | HR<sub>RA</sub> (CXL) |

---

**Review of the existing MRLs for prochloraz**

[www.efsa.europa.eu/efsajournal](http://www.efsa.europa.eu/efsajournal) 66 EFSA Journal 2018;16(8):5401
| Commodity          | Chronic risk assessment | Acute risk assessment |
|--------------------|-------------------------|-----------------------|
|                    | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Swine kidney       | 1.20                    | STMR<sub>RA</sub> (CXL)| 6.20               | HR<sub>RA</sub> (CXL) |
| Bovine muscle      | 0.02                    | STMR<sub>RA</sub> (CXL)| 0.10               | HR<sub>RA</sub> (CXL) |
| Bovine fat tissue  | 0.06                    | STMR<sub>RA</sub> (CXL)| 0.38               | HR<sub>RA</sub> (CXL) |
| Bovine liver       | 1.20                    | STMR<sub>RA</sub> (CXL)| 6.20               | HR<sub>RA</sub> (CXL) |
| Bovine kidney      | 1.20                    | STMR<sub>RA</sub> (CXL)| 6.20               | HR<sub>RA</sub> (CXL) |
| Sheep muscle       | 0.02                    | STMR<sub>RA</sub> (CXL)| 0.10               | HR<sub>RA</sub> (CXL) |
| Sheep fat tissue   | 0.06                    | STMR<sub>RA</sub> (CXL)| 0.38               | HR<sub>RA</sub> (CXL) |
| Sheep liver        | 1.20                    | STMR<sub>RA</sub> (CXL)| 6.20               | HR<sub>RA</sub> (CXL) |
| Sheep kidney       | 1.20                    | STMR<sub>RA</sub> (CXL)| 6.20               | HR<sub>RA</sub> (CXL) |
| Goat muscle        | 0.02                    | STMR<sub>RA</sub> (CXL)| 0.10               | HR<sub>RA</sub> (CXL) |
| Goat fat tissue    | 0.06                    | STMR<sub>RA</sub> (CXL)| 0.38               | HR<sub>RA</sub> (CXL) |
| Goat liver         | 1.20                    | STMR<sub>RA</sub> (CXL)| 6.20               | HR<sub>RA</sub> (CXL) |
| Goat kidney        | 1.20                    | STMR<sub>RA</sub> (CXL)| 6.20               | HR<sub>RA</sub> (CXL) |
| Equine muscle      | 0.02                    | STMR<sub>RA</sub> (CXL)| 0.10               | HR<sub>RA</sub> (CXL) |
| Equine fat tissue  | 0.06                    | STMR<sub>RA</sub> (CXL)| 0.38               | HR<sub>RA</sub> (CXL) |
| Equine liver       | 1.20                    | STMR<sub>RA</sub> (CXL)| 6.20               | HR<sub>RA</sub> (CXL) |
| Equine kidney      | 1.20                    | STMR<sub>RA</sub> (CXL)| 6.20               | HR<sub>RA</sub> (CXL) |
| Poultry muscle     | 0.001                   | STMR<sub>RA</sub> (CXL)| 0.005              | HR<sub>RA</sub> (CXL) |
| Poultry fat tissue | 0.001                   | STMR<sub>RA</sub> (CXL)| 0.007              | HR<sub>RA</sub> (CXL) |
| Poultry liver      | 0.015                   | STMR<sub>RA</sub> (CXL)| 0.100              | HR<sub>RA</sub> (CXL) |

STMR/HR<sub>RA</sub>: Median residue/Highest residue expressed according to the residue definition for risk assessment; CXL: codex maximum residue limit.

*: Indicates that the input value is proposed at the limit of quantification.

(a): Risk assessment values from analysis in pulp fractions were directly considered (FAO, 2004, 2009<sub>a,b</sub>).
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

- GAP or DB > 0.1 mg/kg DM in EU?
  - Yes
    - MRL derived in Section 3?
      - Yes
        - MRL fully supported by data?
          - Yes
            - MRL is recommended.
          - No
            - Fall-back MRL available?
              - Yes
                - MRL is recommended.
              - No
                - Not considered for the RA.
      - No
        - Risk identified?
          - Yes
            - Median/highest values are included in the RA.
          - No
            - Tentative median/highest values are included in the RA.
  - No
    - Fall-back MRL available?
      - Yes
        - MRL is recommended.
      - No
        - Not considered for the RA.

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

- Not considered for the RA.
- Current EU MRL is included in the RA.
- Tentative median/highest values are included in the RA.
- Median/highest values are included in the RA.

- Risk identified?
  - Yes
    - Fall-back MRL available?
      - Yes
        - MRL is recommended.
      - No
        - Not considered for the RA.
  - No
    - No
      - No

Recommendations resulting from EU authorisations and import tolerances

- (A) Specific LOQ or default MRL?
  - No
    - (B) Specific LOQ or default MRL?
      - No
        - (C) Maintain current EU MRL?
          - No
            - (D) Specific LOQ or default MRL?
              - No
                - (E) Establish tentative EU MRL?
                  - No
                    - (F) Specific LOQ or default MRL?
                      - No
                        - (G) MRL is recommended.
                      - Yes
                        - Recommendation resulting from EU authorisations and import tolerances.
                    - Yes
                      - Comparison with CXLs.
(I) Maintain EU recommendation indicating that no CXL is available.

(II) Maintain EU recommendation indicating CXL is not compatible.

(III) Maintain EU recommendation indicating CXL is covered.

(IV) Maintain current CXL or EU recommendation?

(V) Maintain current CXL or EU recommendation; higher CXL is not safe for consumer?

(VI) Maintain EU recommendation; higher CXL is not safe for consumer.

(VII) CXL is recommended; EU recommendation is covered as well.

CXL available?

Yes

No

RD comparable?

Yes

No

CXL higher?

Yes

No

CXL supported by data?

Yes

No

Risk identified?

Yes

No

Input values for the RA remain unchanged.

Input values for the RA remain unchanged.

Input values for the RA remain unchanged.

CXL is included in the RA.

Codex median/ highest residues are included in the RA.

Consumer risk assessment with consideration of the existing CXL

Comparison of the EU recommendation with the existing CXL

Result EU assessment

Input values for the RA remain unchanged.

Risk identified?

Yes

No

No

No

Yes

Yes

Yes

No

Yes

No

Yes

No

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No

Yes

No
## Appendix F – Used compound codes

| Code/trivial name | Chemical name/SMILES notation<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|-------------------|---------------------------------------------|----------------------------------|
| **Prochloraz**    | \(N\)-propyl-N-[2-(2,4,6-trichlorophenoxy)ethyl] imidazole-1-carboxamide<br>\(O=C(N(CCOc1c(Cl)cc(Cl)cccCl)(CC)NC)n2ccnc2\)<br>TVLSRXXILMWEO-UHFFFAOYSA-N | ![Structural formula](image1) |
| **BTS 44595 (M201-04)** | \(N\)-propyl-N-[2-(2,4,6-trichlorophenoxy)ethyl]urea<br>Cl1cc(C)cc(C)c1OCNC(C)(N)=O<br>MPNJTIZLDHBFX-UHFFFAOYSA-N | ![Structural formula](image2) |
| **BTS 44596 (M201-03)** | \(N\)\(_2\)propyl-[2-(2,4,6-trichlorophenoxy)ethyl] carbamoyl]formamide<br>Cl1cc(C)cc(C)c1OCNN(C)(N)C=O<br>RHDVQZCQBOXJU-UHFFFAOYSA-N | ![Structural formula](image3) |
| **2,4,6-TCP (BTS 45186, M201-15)** | 2,4,6-trichlorophenol<br>Cl1cc(C)cc(C)c1O<br>LINPIYWFGCPVE-UHFFFAOYSA-N | ![Structural formula](image4) |
| **BTS 9608**      | (2,4,6-trichlorophenoxy)acetic acid<br>Cl1cc(C)cc(C)c1OC(=O)O<br>KZDCLQBOHGBWOI-UHFFFAOYSA-N | ![Structural formula](image5) |
| **BTS 40348**     | \(N\)-[2-(2,4,6-trichlorophenoxy)ethyl]propan-1-amine<br>Cl1cc(C)cc(C)c1OCNC
CLFQSOIBYICELN-UHFFFAOYSA-N | ![Structural formula](image6) |
| **BTS 54906**     | 2,4,6-trichloro-3-(2-hydroxyethoxy)phenol<br>Cl1c(=O)c(C)cc(C)c1OCO<br>IXSVWXIPLCRURG-UHFFFAOYSA-N | ![Structural formula](image7) |
| **BTS 44770**     | \(N\)-[2-(2,4,6-trichlorophenoxy)ethyl]urea<br>Cl1cc(C)cc(C)c1OCN(N)=O<br>ZWFBODNCWIEJR-UHFFFAOYSA-N | ![Structural formula](image8) |
| **BTS 3037**      | 2-(2,4,6-trichlorophenoxy)ethanol<br>Cl1cc(C)cc(C)c1OCO<br>LZTSANFAWWCRW-UHFFFAOYSA-N | ![Structural formula](image9) |

**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).