Review of the existing maximum residue levels for 2-phenylphenol according to Article 12 of Regulation (EC) No 396/2005

European Food Safety Authority (EFSA)

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 2-phenylphenol. To assess the occurrence of 2-phenylphenol 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 the Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and all MRL proposals derived by EFSA still require further consideration by risk managers.

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Keywords: 2-phenylphenol, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, fungicide

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Summary

2-phenylphenol was included in Annex I to Directive 91/414/EEC on 1 January 2010 by Commission Directive 2009/160/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Directive 2010/81/EU and Commission Implementing Regulation (EU) No 541/2011. As 2-phenylphenol 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 Spain, 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 24 June 2016 and finalised on 24 August 2016. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 26 September 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 November 2016 a draft reasoned opinion, which was circulated to the Member States for consultation via a written procedure. Comments received by 13 December 2016 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of 2-phenylphenol in primary crops was evaluated in oranges and pears treated after harvest by dipping. According to the results of the available, metabolism studies and considering the lack of information on the toxicological potential of 2-phenylhydroquinone, the residue definition for enforcement and risk assessment in fruit crops following post-harvest treatment is tentatively proposed as the sum of 2-phenylphenol and 2-phenylhydroquinone and their conjugates, expressed as 2-phenylphenol. Since 2-phenylphenol showed to be stable following standard processing conditions, the same residue definition applies also to processed commodities. Analytical method for the enforcement of the proposed residue definition in acidic commodities at the combined limit of quantification (LOQ) of 0.3 mg/kg, is available. Considering that 2-phenylphenol is only authorised for post-harvest uses, there was no need to derive a residue definition for rotational crops.

Regarding the magnitude of the residues in primary crops, the available residue data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. Nevertheless, it is noted that, pending on the toxicological assessment of the metabolite 2-phenylhydroquinone, the derived MRL proposals should be considered tentative only. Available residue data also allow deriving robust peeling factors for citrus fruits.

2-Phenylphenol is authorised for use on citrus fruits and citrus fruits dry pulp might be fed to livestock. The dietary burdens calculated for cattle and swine were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in these livestock commodities.

The metabolism in ruminants was investigated in lactating goats dosed with phenol-labelled 2-phenylphenol. According to the results of the metabolism study, no residues are expected in animal commodities at the calculated dietary burden. Consequently, in the framework of this review, the residue definition was proposed as the parent compound only by default. Since no metabolites could be identified in the metabolism study on ruminants due to the low residue levels found in milk and tissues, it was not possible to conclude whether the metabolism in rats and ruminants is similar. Consequently, the proposed residue definition for ruminants was extrapolated to pigs on a tentative basis only. Considering that an analytical method for enforcement of 2-phenylphenol in animal tissues and in milk is not available, the default LOQ of 0.01 mg/kg is tentatively proposed.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA Pesticide Residues Intake Model (PRiMo). The highest chronic consumer exposure was calculated for Dutch children diet, representing 0.4% of the acceptable daily intake (ADI). Acute exposure calculations were not carried out because an acute reference dose (ARID) was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended Codex maximum residue limits (CXLs) have also been established for 2-phenylphenol. It is noted that a
different residue definition not including 2-phenylhydroquinone has been established by the Joint Meeting on Pesticide residues (JMPR) for plants. Nevertheless, considering that metabolite 2-phenylhydroquinone was found to be always below the LOQ in the residue trials used to derive the CXLs for citrus fruits, this difference is not considered to be of relevance for these CXLs and they could be included in the calculation. On the other hand, in the residue trials used to derive the CXL for pears, residues were analysed for 2-phenylphenol only. Therefore, the current CXL for pears can be underestimated and a risk assessment including this CXL could not be performed. According to this second scenario, the highest chronic exposure was calculated for German children diet, representing 4.5% of the ADI.
Table of contents

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 ................................................................................................... 9
       1.1.5. Stability of residues in plants .................................................................................................... 9
       1.1.6. Proposed residue definitions ................................................................................................... 9
   1.2. Magnitude of residues in plants ............................................................................................... 10
       1.2.1. Magnitude of residues in primary crops .................................................................................... 10
       1.2.2. Magnitude of residues in rotational crops .............................................................................. 10
       1.2.3. Magnitude of residues in processed commodities ..................................................................... 10
       1.2.4. Proposed MRLs .................................................................................................................... 10
2. Residues in livestock ....................................................................................................................... 10
   2.1. Nature of residues and methods of analysis in livestock ............................................................ 11
3. Consumer risk assessment .............................................................................................................. 11
   3.1. Consumer risk assessment without consideration of the existing CXLs ....................................... 11
   3.2. Consumer risk assessment with consideration of the existing CXLs ........................................... 11
Conclusions ............................................................................................................................................. 12
Recommendations .................................................................................................................................... 13
References ............................................................................................................................................... 14
Abbreviations ........................................................................................................................................... 15
Appendix A – Summary of authorised uses considered for the review of MRLs .................................... 16
Appendix B – List of end points ............................................................................................................ 18
Appendix C – Input values for the exposure calculations ....................................................................... 25
Appendix D – Decision tree for deriving MRL recommendations ........................................................ 27
Appendix E – Used compound codes .................................................................................................. 29
Review of the existing MRLs for 2-phenylphenol

Background

Regulation (EC) No 396/2005 (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 a reasoned opinion on the review of the existing MRLs for that active substance. As 2-phenylphenol was included in Annex I to Council Directive 91/414/EEC on 1 January 2010 by means of Commission Directive 2009/160/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011 as amended by Commission Implementing Regulation (EU) No 541/2011 and Commission Directive 2010/81/EU, EFSA initiated the review of all existing MRLs for that active substance.

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

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

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

Spain, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for 2-phenylphenol and to prepare a supporting evaluation report (Spain, 2014). The PROFile and the supporting evaluation report were submitted to EFSA on 21 March 2014 and made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 24 June 2016 and finalised on 24 August 2016. Additional evaluation reports were submitted by the Member States (Spain, 2016; Portugal, 2016) and the EU Reference Laboratories for Residues of Pesticides (EURL, 2016) and, after having considered all the information provided by the RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 26 September 2016. No further clarifications were sought from Member States.

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 November 2016 a draft reasoned opinion, which was submitted to the Member States for commenting via a written procedure. All comments received by 13 December 2016 were considered by EFSA during the finalisation of the reasoned opinion.

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1 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
2 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.
3 Commission Directive 2009/160/EU of 17 December 2009 amending Council Directive 91/414/EEC to include 2-phenylphenol as active substance. OJ L 338, 19.12.2009, p. 83–86.
4 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
5 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.
6 Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.
7 Commission Directive 2010/81/EU of 25 November 2010 amending Council Directive 91/414/EEC as regards an extension of the use of the active substance 2-phenylphenol. OJ L 310, 26.11.2010, p. 11–13.
The evaluation report submitted by the RMS (Spain, 2014), and the additional evaluation reports submitted by the Member States (EURL, 2016; Portugal, 2016; Spain, 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, 2016a) and the Member States consultation report (EFSA, 2016b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also, the chronic exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) and the PROFile are key supporting documents and 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**

2-Phenylphenol is the common name for biphenyl-2-ol (IUPAC). This substance is considered by the International Organization for Standardization (ISO) not to require a common name.

2-Phenylphenol acts as a general disinfectant disrupting cell walls and cell membranes and it is applied as a post-harvest fungicide on citrus fruits. It acts as a residual contact substance with a broad spectrum of activity against moulds and rots (e.g. Penicillium spp. and Rhizopus spp.). The inhibition of fungal growth and sporulation is achieved by infecting in the cell wall the cytoplasmic membrane and the cytoplasm. A translocation in plants cannot be observed.

The chemical structure of 2-phenylphenol and its main metabolites are reported in Appendix E.

2-Phenylphenol was evaluated in the framework of Directive 91/414/EEC with Spain designated as rapporteur Member State (RMS). The representative uses supported for the peer review process were as a post-harvest fungicide on citrus and pear (indoor use, closed drench chamber). Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2009/160/EU, which entered into force on 1 January 2010. The approval Directive was amended by Commission Directive 2010/81/EU of 25 November 2010 as regards the extension of use of the active substance 2-phenylphenol. According to Regulation (EU) No 540/2011, 2-phenylphenol is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to indoor uses as a post-harvest fungicide. Following the approval, an MRL of 5 mg/kg was provisionally set on citrus fruits by means of Commission Regulation (EC) No 304/2010, pending the confirmation that the analytical method applied in the residue trials correctly quantifies the residues according to the proposed residue definition, and the submission of a valid storage stability study and two additional residue trials on citrus fruit. In 2012, confirmatory data were submitted to the European Commission and evaluated by Spain but not peer reviewed by EFSA (European Commission, 2013). In order to provide the necessary time for EFSA to evaluate the new data submitted, the validity of the MRL for citrus fruits was extended by means of Commission Regulations (EU) No 34/2013 and No 737/2014 until the entry into force of the Regulation reviewing the existing MRLs for 2-phenylphenol.

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8 Commission Regulation (EU) No 304/2010 of 9 April 2010 amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-phenylphenol in or on certain products. OJ L 94, 15.4.2010, p. 1–14.
9 Commission Regulation (EU) No 34/2013 of 16 January 2016 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-phenylphenol, ametocardin, Aureobasidium pullulans strains DSM 14940 and DSM 14941, cyproconazole, difenoconazole, dithiocarbamates, folpet, propamocarb, spinosad, spirodilofen, tebufenpyrad and tetaconazole in or on certain products. OJ L 25, 26.1.2013, p. 1–48.
10 Commission Regulation (EU) No 737/2014 of 24 June 2014 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-phenylphenol, chloromequat, cyflufenamid, cyfluthrin, dicamba, fluopicolide, flutriafol, fosetyl, isoprothiolane, mandipropamid, metaldehyde, metconazole, phosmet, picothram, propyzamide, pyriproxyfen, saflufenacil, spinosad and trifloxystrobin in or on certain products. OJ L 202, 10.7.2014, p. 1–63.
The EU MRLs for 2-phenylphenol are established in Annex II of Regulation (EC) No 396/2005 and CXLs for 2-phenylphenol were also established by the Codex Alimentarius Commission (CAC).

For the purpose of this MRL review, the critical uses of 2-phenylphenol currently authorised within the EU have been collected by the RMS and reported in the PROFile. The additional Good Agricultural Practices (GAPs) reported during the completeness check were also considered. Details of the authorised GAPs for 2-phenylphenol 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 which includes also the confirmatory data relevant for the existing uses (Spain, 2014), the additional evaluation reports submitted by the Member States (Portugal, 2016; Spain, 2016) and the EURL (EURL, 2016), the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Spain, 2007, 2008), the conclusion on the peer review of the pesticide risk assessment of the active substance 2-phenylphenol (EFSA, 2009), and the Joint Meeting on Pesticide residues (JMPR) Evaluation reports (FAO, 1999, 2002). 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, 2011 and OECD, 2011, 2013).

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

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of 2-phenylphenol after post-harvest treatments on oranges and pears was evaluated during the peer review (Spain, 2007, 2008).

In these studies, 2-phenylphenol was applied by dipping oranges and pears in solutions containing phenol-labelled sodium salt of 2-phenylphenol at concentrations of 0.1% and 0.5% (oranges, corresponding to approximately 2 and 10 times the dose rate) and 4% (pears, corresponding to approximately 60 times the dose rate).

In oranges, the amount of total radioactive residues (TRRs) found in the whole fruits after the low dose application remained relatively constant throughout the study at approximately 10 mg/kg. According to the results, 2-phenylphenol showed moderate metabolism in oranges: after 12 weeks, 86% of TRR were identified as 2-phenylphenol and its conjugates, 7% as 2-phenylhydroquinone and its conjugates and 0.3% as 2-methoxybiphenyl.

The amount of TRRs found in the whole pear was 22 mg/kg 2 h after the treatment, increased to 57 mg/kg by day two, and afterwards remained relatively constant throughout the study at approximately 40 mg/kg. In pears, analysed 28 weeks after treatment, the main residues found in extracts of the different fractions of the fruits were 2-phenylphenol (6% of TRR) and its conjugates (74% of TRR). Rinse and peel contained also the unidentified metabolite C (1.3% of TRR) and further polar and non-polar unidentified compounds. Post-extraction solids of peel and pulp were further characterised by hydrolysis steps which released conjugates of 2-phenylphenol.

Unidentified metabolite C is expected at very low concentrations after application of 2-phenylphenol at the authorised dose rate and therefore further efforts to identify the residues were not required during the peer review. Nevertheless, a concern was raised regarding the toxicological potential of the metabolite 2-phenylhydroquinone and the applicant was asked to address the toxicological potential of this metabolite.

Metabolism study on oranges also showed that residues penetrate from the surface of the fruits into the peel (TRR in the peel increased to 95% within 12 weeks), while further penetration into the...
orange pulp was low with only approximately 0.2% of TRR found in juice and pulp throughout the storage period. In pears, the penetration of the residues from the surface of the fruits was not limited to the peel but was observed also in the pulp (TRR in the peel and the pulp increased to approximately 70% and 30%, respectively, within 28 weeks of storage).

1.1.2. Nature of residues in rotational crops

The active substance is only authorised for post-harvest uses. Therefore, no additional investigation on the nature and the magnitude of the residues in rotational crops is needed.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of the residues of 2-phenylphenol was investigated in hydrolysis studies simulating pasteurisation, baking, brewing, and boiling and sterilisation (Spain, 2007). 2-Phenylphenol was shown to be stable under conditions simulating pasteurisation and boiling, but a loss of approximately 15% was found in the experiment simulating sterilisation. However, since no metabolites were detected, it was concluded that no breakdown of 2-phenylphenol was observed and that the compound could be regarded as stable under the conditions studied (EFSA, 2009).

1.1.4. Methods of analysis in plants

An analytical method using gas chromatography with mass spectrometry (GC–MS) was evaluated in the framework of this review and considered suitable for the determination of free and conjugated 2-phenylphenol, and free and conjugated 2-phenylhydroquinone in acidic commodities at the limit of quantifications (LOQs) of 0.1 and 0.2 mg/kg, respectively (Spain, 2014). The proposed analytical method also includes a sufficiently validated hydrolysis step.

According to the information received by the EURLs, 2-phenylphenol can be enforced during routine analyses by using the Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) method with a LOQ of 0.01 mg/kg (gas chromatography with tandem mass spectrometry (GC–MS/MS)) in high water content, high acidic and high oil content commodities, and with a LOQ of 0.02 mg/kg (GC–MS/MS) in dry commodities (EURL, 2016). No information on the availability of an analytical method for the enforcement of 2-phenylhydroquinone was provided by the EURLs.

1.1.5. Stability of residues in plants

The storage stability of 2-phenylphenol and 2-phenylhydroquinone in acidic commodities (orange whole fruits, orange peel and orange pulp) was investigated in the framework of this review (Spain, 2014). According to the results of this study, 2-phenylphenol is stable for at least 6 months in all products analysed when stored at −22°C. At the same storage temperature, 2-phenylhydroquinone was stable for up to 6 months in whole fruits and pulp but was not stable in peel (only 29% of the initial amount of 2-phenylhydroquinone was detected after 1 month, declining to <LOQ after 6 months of storage). Considering that residues in peel are not relevant for MRL setting and risk assessment (processing factors are calculated considering the residues in whole fruits and pulp only), the observed degradation in peel is not expected to have an impact on the present assessment.

1.1.6. Proposed residue definitions

According to the results of the available metabolism studies, the residue definition for enforcement and risk assessment in fruit crops following post-harvest treatment with 2-phenylphenol is tentatively proposed as the sum of 2-phenylphenol and 2-phenylhydroquinone and their conjugates, expressed as 2-phenylphenol. The residue definition is based on the assumption that the same toxicological reference value as derived for 2-phenylphenol can be applied also to 2-phenylhydroquinone, and should be re-addressed when information on the toxicological potential of this metabolite is available. The same residue definition is also proposed to processed commodities. An analytical method for the enforcement of the proposed residue definition in acidic commodities at the combined LOQ of 0.3 mg/kg is available. Considering that 2-phenylphenol is only authorised for post-harvest uses, there is no need to derive a residue definition for rotational crops.
1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of 2-phenylphenol residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Spain, 2014), including residue trials evaluated in the framework of the peer review (Spain, 2007) and additional data submitted during the completeness check (Portugal, 2016; Spain, 2016). All residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2011).

For all crops under evaluation, available residue trials are sufficient to derive MRL and risk assessment values.

It is noted that during the peer review the applicant was asked to demonstrate that the analytical methods used in the residue trials correctly quantify the residues of 2-phenylphenol, 2-phenylhydroquinone and their conjugates according to the proposed residue definition. Based on the confirmatory information received after the approval of the substance and evaluated in this review (Spain, 2014), it can be concluded that the methods used in the residue trials were adequate to measure all compounds included in the residue definition.

1.2.2. Magnitude of residues in rotational crops

Since the existing uses are limited to post-harvest treatments, studies on the residues in rotational and succeeding crops are not required. Therefore no additional investigation on the nature and the magnitude of the residues in rotational crops is needed.

1.2.3. Magnitude of residues in processed commodities

Studies on the level of residues in processed orange commodities (juice and dry pomace) were evaluated during the peer review (Spain, 2007). In line with the data gap identified for the residue trials during the peer review, the applicant was asked to demonstrate that the analytical methods used in the processing studies correctly quantify the residues of 2-phenylphenol and 2-phenylhydroquinone and their conjugates. Additional information on the validation of the hydrolysis step and residue trials on oranges and mandarins allowing the calculation of peeling factors for citrus fruits were submitted in the framework of this review (Spain, 2014; Portugal, 2016). Robust processing factors could be derived only for peeled citrus fruits. No robust processing factors could be derived for orange juice and dry pomace as they were not sufficiently supported by studies (a minimum of 3 processing studies is normally required).

Considering that the indicative processing factor for dry pomace has been taken into account for the calculation of the livestock dietary burden, additional processing studies allowing the calculation of a more robust processing factor would in principle be required. Nevertheless, considering that the chronic exposure does not exceed 10% of the acceptable daily intake (ADI) (see Section 3), such studies are only desirable.

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. Nevertheless, it is noted that, pending on the toxicological assessment of the metabolite 2-phenylhydroquinone, the proposed MRLs should be considered tentative only.

2. Residues in livestock

2-Phenylphenol is authorised for use on citrus fruits and citrus fruits dry pulp might be fed to cattle and swine. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013) that has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix C. The dietary burden values calculated for cattle and swine were found to exceed the trigger value of 0.1 mg/kg dry matter (DM). Behaviour of residues was therefore assessed in these livestock commodities.
2.1. Nature of residues and methods of analysis in livestock

A metabolism study on lactating goats dosed for 5 days with phenol-labelled 2-phenylphenol at 0.31 and 0.91 mg/kg body weight (bw) per day (corresponding to 5–15 N compared to the maximum dietary burden) was evaluated during the peer review (Spain, 2007). Transfer of radioactivity into milk and tissues was low. The duration of the study was not long enough to reach a residue plateau in milk. For the low-dose group, TRR in milk amounted for a maximum of 0.008 mg/kg. In tissues, the highest residue levels were found in the kidney and liver (approximately 0.005 mg/kg). Radioactive residues in milk, kidney and liver were further analysed by extraction and high-performance liquid chromatography (HPLC) analysis. Radioactive compounds could not be identified and therefore no metabolic pathway could be established.

According to the results of the metabolism study, no residues are expected in animal commodities at the calculated dietary burden. Consequently, in the framework of this review, the residue definition can be proposed as the parent compound only by default. Since no metabolites could be identified in the metabolism study on ruminants due to the low residue levels found in milk and tissues, it was not possible to conclude whether the metabolism in rats and ruminants is similar. Consequently, the proposed residue definition for ruminants was extrapolated to pigs on a tentative basis only. An analytical method for the enforcement of the proposed residue definition in animal commodities is not available.

2.2. Magnitude of residues in livestock

At the calculated dietary intake and considering the results from the metabolism studies, residues above the LOQ are not expected in animal commodities. Consequently, no livestock feeding studies are required. Considering that an analytical method for enforcement is not available, the default LOQ of 0.01 mg/kg is tentatively proposed for swine and cattle tissues and for milk.

3. Consumer risk assessment

In the framework of this review, only the uses of 2-phenylphenol reported by the RMS in Appendix A were considered; however, the use of 2-phenylphenol was previously also assessed by the JMPR (FAO, 1999, 2002). 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. To facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs.

3.1. Consumer risk assessment without consideration of the existing CXLs

Chronic 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 D. Hence, for those commodities where a tentative MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). For all citrus fruits, the derived peeling factor was taken into account to refine the risk assessment. All input values included in the exposure calculations are summarised in Appendix C. Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

The exposures calculated were compared with the toxicological reference value for 2-phenylphenol derived by EFSA (2009) under Directive 91/414/EEC. The highest chronic exposure was calculated for Dutch children diet, representing 0.4% of the ADI. Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers.

3.2. Consumer risk assessment with consideration of the existing CXLs

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix D and all data relevant to the consumer exposure assessment have been collected from JMPR evaluations. It is noted that a different residue definition not including 2-phenylhydroquinone has been established by the JMPR for plants. Nevertheless, considering that metabolite 2-phenylhydroquinone was found to be always below the LOQ in the
residue trials used to derive the CXLs for citrus fruits, this difference is not considered to be of relevance for these CXLs and they could be included in the calculation. On the other hand, in the residue trials used to derive the CXL for pears, residues were analysed for 2-phenylphenol only. Therefore, the current CXL for pears can be underestimated and a risk assessment including this CXL could not be performed. It is noted that the same data gaps identified during the assessment of the EU MRLs are also applicable to the current CXLs for citrus fruits. An overview of the input values used for this exposure calculation is also provided in Appendix C.

Chronic exposure calculation was also performed using revision 2 of the EFSA PRIMo and the exposure calculated was compared with the toxicological reference value derived for 2 phenylphenol. The highest chronic exposure was calculated for German children diet, representing 4.5% of the ADI. Although uncertainties remain due to the data gaps identified for these CXLs, this indicative exposure calculation did not indicate a risk to consumers.

Conclusions

The metabolism of 2-phenylphenol in primary crops was evaluated in oranges and pears treated after harvest by dipping. According to the results of the available metabolism studies and considering the lack of information on the toxicological potential of 2-phenylhydroquinone, the residue definition for enforcement and risk assessment in fruit crops following post-harvest treatment is tentatively proposed as the sum of 2-phenylphenol and 2-phenylhydroquinone and their conjugates, expressed as 2-phenylphenol. Since 2-phenylphenol showed to be stable following standard processing conditions, the same residue definition applies also to processed commodities. Analytical method for the enforcement of the proposed residue definition in acidic commodities at the combined LOQ of 0.3 mg/kg, is available. Considering that 2-phenylphenol is only authorised for post-harvest uses, there was no need to derive a residue definition for rotational crops.

Regarding the magnitude of the residues in primary crops, the available residue data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. Nevertheless, it is noted that, pending on the toxicological assessment of the metabolite 2-phenylhydroquinone, the derived MRL proposals should be considered tentative only. Available residue data also allow deriving robust peeling factors for citrus fruits.

2-Phenylphenol is authorised for use on citrus fruits and citrus fruits dry pulp might be fed to livestock. The dietary burdens calculated for cattle and swine were found to exceed the trigger value of 0.1 mg/kg DM. Behaviour of residues was therefore assessed in these livestock commodities.

The metabolism in ruminants was investigated in lactating goats dosed with phenol-labelled 2-phenylphenol. According to the results of the metabolism study, no residues are expected in animal commodities at the calculated dietary burden. Consequently, in the framework of this review, the residue definition was proposed as the parent compound only by default. Since no metabolites could be identified in the metabolism study on ruminants due to the low residue levels found in milk and tissues, it was not possible to conclude whether the metabolism in rats and ruminants is similar. Consequently, the proposed residue definition for ruminants was extrapolated to pigs on a tentative basis only. Considering that an analytical method for enforcement of 2-phenylphenol in animal tissues and in milk is not available, the default LOQ of 0.01 mg/kg is tentatively proposed.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic consumer exposure was calculated for Dutch children diet, representing 0.4% of the ADI. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for 2-phenylphenol. It is noted that a different residue definition not including 2-phenylhydroquinone has been established by the JMPR for plants. Nevertheless, considering that metabolite 2-phenylhydroquinone was found to be always below the LOQ in the residue trials used to derive the CXLs for citrus fruits, this difference is not considered to be of relevance for these CXLs and they could be included in the calculation. On the other hand, in the residue trials used to derive the CXL for pears, residues were analysed for 2-phenylphenol only. Therefore, the current CXL for pears can be underestimated and a risk assessment including this CXL could not be performed. According to this second scenario, the highest chronic exposure was calculated for German children diet, representing 4.5% of the ADI.
Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see Table 1 below). None of the MRL values listed in the table are recommended for inclusion in Annex II to the Regulation as they are not sufficiently supported by data and they require further considerations by risk managers (see summary table footnotes for details). In particular, all tentative MRLs need to be confirmed by the following data:

- Toxicological assessment of the metabolite 2-phenylhydroxyquinone;
- A fully validated analytical method for the determination of 2-phenylphenol in livestock tissues and in milk.

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

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 data are therefore considered desirable but not essential:

- Additional processing studies allowing the calculation of a robust processing factor for citrus, dry pomace.

Table 1: Summary table

| Code number(a) | Commodity                     | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment                                               |
|---------------|-------------------------------|-------------------------|----------------------|-----------------------|-------------------------------------------------------|
|               | Enforcement residue definition (existing): 2-phenylphenol |                         |                      |                       |                                                       |
|               | Enforcement residue definition (proposed): sum of 2-phenylphenol and 2-phenylhydroquinone and their conjugates, expressed as 2-phenylphenol |                         |                      |                       |                                                       |
| 110000        | Citrus fruits                 | 5                       | 10                   | 10                    | Further consideration needed(b)                       |
| 130020        | Pears                         | 0.05*                   | 20                   | –                     | Further consideration needed(c)                       |
| –             | Other commodities of plant origin | See Reg. (EC) No 839/2008 | –                    | –                     | Further consideration needed(d)                       |

| Enforcement residue definition: 2-phenylphenol |
|------------------------------------------------|
| 1011010 | Swine meat | 0.05* | – | 0.01* | Further consideration needed(e) |
| 1011020 | Swine fat  | 0.05* | – | 0.01* | Further consideration needed(e) |
| 1011030 | Swine liver | 0.05* | – | 0.01* | Further consideration needed(e) |
| 1011040 | Swine kidney | 0.05* | – | 0.01* | Further consideration needed(e) |
| 1012010 | Bovine meat | 0.05* | – | 0.01* | Further consideration needed(e) |
| 1012020 | Bovine fat  | 0.05* | – | 0.01* | Further consideration needed(e) |
| 1012030 | Bovine liver | 0.05* | – | 0.01* | Further consideration needed(e) |
| 1012040 | Bovine kidney | 0.05* | – | 0.01* | Further consideration needed(e) |
| 1015010 | Equine meat | 0.05* | – | 0.01* | Further consideration needed(e) |
| 1015020 | Equine fat  | 0.05* | – | 0.01* | Further consideration needed(e) |
| 1015030 | Equine liver | 0.05* | – | 0.01* | Further consideration needed(e) |
| 1015040 | Equine kidney | 0.05* | – | 0.01* | Further consideration needed(e) |
| 1020010 | Cattle milk   | 0.05* | – | 0.01* | Further consideration needed(e) |
| 1020040 | Horse milk    | 0.05* | – | 0.01* | Further consideration needed(e) |
| –             | Other commodities of animal origin | See Reg. (EC) No 839/2008 | – | – | Further consideration needed(d)                       |

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

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

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.

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

(c): There are no relevant authorisations or import tolerances reported at the 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 D).

(d): There are no relevant authorisations or import tolerances reported at the 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 D).

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

| Abbreviation | Definition |
|--------------|------------|
| a.i.         | active ingredient |
| a.s.         | active substance |
| ADI          | acceptable daily intake |
| ARfD         | acute reference dose |
| BBCH         | growth stages of mono- and dicotyledonous plants |
| bw           | body weight |
| CAC          | Codex Alimentarius Commission |
| CXL          | codex maximum residue limit |
| DAR          | draft assessment report |
| DAT          | days after treatment |
| DM           | dry matter |
| EU Reference Laboratories (former CRLs) |
| FAO          | Food and Agriculture Organization of the United Nations |
| GAP          | Good Agricultural Practice |
| GC – MS      | gas chromatography with mass spectrometry |
| GC – MS/MS   | gas chromatography with tandem mass spectrometry |
| HPLC         | high-performance liquid chromatography |
| 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) |
| LOQ          | limit of quantification |
| MRL          | maximum residue level |
| NEU          | northern European Union |
| OECD         | Organisation for Economic Co-operation and Development |
| PBI          | plant back interval |
| PF           | processing factor |
| PHI          | preharvest interval |
| PRIMo (EFSA) | Pesticide Residues Intake Model |
| PROFile (EFSA) | Pesticide Residues Overview File |
| QuEChERS     | Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RA           | risk assessment |
| RAC          | raw agricultural commodity |
| RD           | residue definition |
| RD-Mo        | plant residue definition for monitoring |
| RD-RA        | plant residue definition for risk assessment |
| RMS          | rapporteur Member State |
| SANCO        | Directorate-General for Health and Consumers |
| SEU          | southern European Union |
| SMILES       | simplified molecular-input line-entry system |
| STMR         | supervised trials median residue |
| TRR          | total radioactive residue |
| WHO          | World Health Organization |
### Appendix A – Summary of authorised uses considered for the review of MRLs

#### Critical indoor GAPs for northern and southern Europe (including post-harvest treatments)

| Crop | Scientific name | Region | Member state or country | Pest controlled | Formulation Type | Content | PHI or waiting period (days) | Comments |
|------|-----------------|--------|--------------------------|-----------------|------------------|---------|-----------------------------|----------|
|      |                 |        |                          |                 |                  | Conc. Unit |                         |          |
| Grapefruits | *Citrus paradisi* | NEU/SEU Indoor ES | Fruit rotting fungi | EC | 100.0 | g/L | 85–89 | 1 | 60.00 g a.i./hL | Application in a closed drenching chamber. Covers also wax and foam curtain applications |
| Oranges | *Citrus sinensis* | NEU/SEU Indoor ES, PT | Fruit rotting fungi | EC | 100.0 | g/L | 85–89 | 1 | 60.00 g a.i./hL | Application in a closed drenching chamber. Covers also wax and foam curtain applications |
| Lemons | *Citrus limon* | NEU/SEU Indoor ES | Fruit rotting fungi | EC | 100.0 | g/L | 85–89 | 1 | 60.00 g a.i./hL | Application in a closed drenching chamber. Covers also wax and foam curtain applications |
| Limes | *Citrus aurantifolia* | NEU/SEU Indoor ES | Fruit rotting fungi | EC | 100.0 | g/L | 85–89 | 1 | 60.00 g a.i./hL | Application in a closed drenching chamber. Covers also wax and foam curtain applications |
| Crop Common name | Scientific name | Region | Member state or country | Pest controlled | Formulation Type | Content Concentration | Application Method | Growth stage From BBCH | Number | Interval (days) | Rate | PHI or waiting period (days) | Comments |
|------------------|-----------------|--------|-------------------------|-----------------|------------------|----------------------|---------------------|-----------------------|--------|----------------|------|-----------------------------|----------|
| Mandarins        | Citrus reticulata, syn: Citrus deliciosa | NEU/SEU Indoor ES, PT | Fruit rotting fungi | EC | 100.0 g/L | Post-harvest treatment – drenching | 85 – 89 | 1 | 60.00 g a.i./hL | n.a. | Application in a closed drenching chamber. Covers also wax and foam curtain applications |

MRL: maximum residue level; GAP: Good Agricultural Practice; BBCH: growth stages of mono- and dicotyledonous plants; NEU: northern European Union; SEU: southern European Union; a.i.: active ingredient.
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 | Application | Sampling |
|----------------------------------|-------------|------|-------------|----------|
| Fruit crops                      | Oranges     | Post-harvest dipping, solutions 0.1% and 0.5% | 2 h, 2 days and 1, 2, 4, 6, 8, 12 weeks after application |
|                                  | Pears       | Post-harvest dipping, solution at 4% | 2 h, 2 days and 1, 2, 4, 6, 8, 12, 16, 20, 24, 28 weeks after application |
| Source: Spain, 2007              |             |      |             |          |

| Rotational crops (available studies) | Crop groups | Crop | Application | PBI (DAT) |
|--------------------------------------|-------------|------|-------------|-----------|
| 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 |
| Source: Spain, 2007                   |             |      |             |          |

PBI: plant back interval; DAT: days after treatment.

Can a general residue definition be proposed for primary crops?
No

Rotational crop and primary crop metabolism similar?
Not applicable

Residue pattern in processed commodities similar to residue pattern in raw commodities?
Yes

Plant residue definition for monitoring (RD-Mo)
Sum of 2-phenylphenol and 2-phenylhydroquinone and their conjugates, expressed as 2-phenylphenol (limited to post-harvest uses on fruits and fruiting vegetables only, tentative pending confirmation of the toxicological properties of metabolite 2-phenylhydroquinone)

Plant residue definition for risk assessment (RD-RA)
Sum of 2-phenylphenol and 2-phenylhydroquinone and their conjugates, expressed as 2-phenylphenol (limited to post-harvest uses on fruits and fruiting vegetables only, tentative pending confirmation of the toxicological properties of metabolite 2-phenylhydroquinone)

Conversion factor (monitoring to risk assessment)
Not applicable

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)
- GC-MS (high acid content commodities):
  - LOQ (2-phenylphenol): 0.1 mg/kg
  - LOQ (2-phenylhydroquinone): 0.2 mg/kg
  - LOQ (combined): 0.3 mg/kg
  - Source: Spain, 2014
- QuECHERS (GC-MS/MS) (high water content, high acid content and high oil content commodities):
  - LOQ (2-phenylphenol): 0.01 mg/kg
  - Source: EURL, 2016
- QuECHERS (GC QqQ-MS/MS) (dry commodities):
  - LOQ (2-phenylphenol): 0.02 mg/kg
  - Source: EURL, 2016

LOQ: limit of quantification; GC-MS: gas chromatography with mass spectrometry; GC-MS/MS: gas chromatography with tandem mass spectrometry; QuECHERS: Quick, Easy, Cheap, Effective, Rugged, and Safe.
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category          | Commodity | T (°C) | Stability (months/years) |
|-----------------------------------|-------------------|-----------|--------|--------------------------|
| High acid content                 | Oranges           | –22       |        | ≤ 6 months               |

2-phenylphenol was stable for up to 6 months in pulp and peel. 2-phenylhydroquinone was stable in pulp up to 6 months, but not stable in peel. 

Source: Spain, 2007

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www.efsa.europa.eu/efsajournal 19 EFSA Journal 2017;15(2):4696
### 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 (mg/kg)\(^{(b)}\) | STMR (mg/kg)\(^{(c)}\) |
|------------|--------------------------|---------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|-----------------------|----------------------|------------------------|
| Citrus fruits | Indoor                   | **Oranges:** 0.85; 0.87; 1.01; 1.38; 1.61 and **Mandarins:** 1.2; 1.3; 1.7; 1.89; 2.1; 2.1; 2.2 | Combined data set on oranges and mandarins compliant with GAP for citrus fruits. Cover also the use by wax and foam curtain applications (Spain, 2008, 2014; Portugal, 2016) | 5                     | 2.2                  | 1.5                    |

Enforcement and risk assessment residue definition: sum of 2-phenylphenol and 2-phenylhydroquinone and their conjugates expressed as 2-phenylphenol.

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.

*: 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.

\(^{(c)}\): Supervised trials median residue.
B.1.2.2. Residues in succeeding crops

Confined rotational crop study (quantitative aspect)
Field rotational crop study

Not applicable
Not applicable

B.1.2.3. Processing factors

| Processed commodity | Number of studies<sup>(a)</sup> | Processing factor (PF) | Individual values | Median PF |
|---------------------|-------------------------------|-----------------------|-------------------|-----------|
| Citrus fruits, peeled | 11                            | 3 x 0.14; 0.18; 0.19; 0.22; 0.23; 0.25; 0.30; 0.34; 0.35 | 0.22              |
| Citrus fruits, juice | 1                             | 0.04                  | 0.04              |
| Citrus fruits, wet pomace | 1                  | 4.5                   | 4.5               |

<sup>(a)</sup>: Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

B.2. Residues in livestock

Relevant groups

| Relevant groups | Dietary burden expressed in mg/kg bw per day | Most critical diet<sup>(a)</sup> | Most critical commodity<sup>(a)</sup> | Trigger exceeded (Y/N) |
|----------------|---------------------------------------------|---------------------------------|--------------------------------------|------------------------|
| Cattle (all diets) | 0.057 0.057 1.48 1.48 | Cattle (dairy) | Grapefruits, dried pulp | Y |
| Cattle (dairy only) | 0.057 0.057 1.48 1.48 | Cattle (dairy) | Grapefruits, dried pulp | Y |
| Sheep (all diets) | 0 0 0 0 | – | – | N |
| Sheep (ewe only) | 0 0 0 0 | – | – | N |
| Swine (all diets) | 0.026 0.026 1.11 1.11 | Swine (breeding) | Grapefruits, dried pulp | Y |
| Poultry (all diets) | 0 0 0 0 | – | – | N |
| Poultry (layer only) | 0 0 0 0 | – | – | N |

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

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

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

| Livestock (available studies) | Animal | Dose (mg/kg bw per day) | Duration (days) | N rate/comment |
|-------------------------------|--------|------------------------|----------------|----------------|
| Lactating goat                | 0.31–0.91<sup>(a)</sup> | 5 | 5–15/compared to beef and dairy cattle |

bw: body weight.
<sup>(a)</sup>: Nominal doses of 11–32 mg/kg DM; theoretical administered dose was converted in mg/kg bw per day assuming for lactating goat a feed intake of 2 kg DM/day and a standard body weight of 70 kg.
**B.2.1.2. Stability of residues in livestock**

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability (months/years) |
|------------------------------------|--------|-----------|--------|-------------------------|
|                                    | Not available and not required |                     |        |                         |

**B.2.2. Magnitude of residues in livestock**

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

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1 N | MRL proposal (mg/kg) |
|------------------|---------------------------------------------|------------------------|---------------------|
|                  | Mean | Highest | STMR (mg/kg) | HR (mg/kg) | Mean | Highest | STMR (mg/kg) | HR (mg/kg) |
| Cattle (all diets) | Not available and not required |                     |        |                         |
| Cattle (dairy only) | Not available and not required (based on the metabolism study no residues are expected in milk at the calculated dietary burden) |                     |        |                         |
| Sheep (all diets) | MRLs are not required since the trigger value is not exceeded |                     |        |                         |
| Sheep (dairy only) | MRLs are not required since the trigger value is not exceeded |                     |        |                         |
| Swine (a) | Not available and not required (based on the metabolism study no residues are expected in swine tissues at the calculated dietary burden) |                     |        |                         |
| Poultry (all diets) | MRLs are not required since the trigger value is not exceeded |                     |        |                         |
| Poultry (layer only) | MRLs are not required since the trigger value is not exceeded |                     |        |                         |

MRL: maximum residue level; STMR: supervised trials median residue; HR: highest residue.

(a): As extrapolation from cattle to swine was tentatively considered acceptable, results on ruminants were relied upon to conclude on the residue levels expected in swine.
B.3. Consumer risk assessment

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

| ADI | Highest IEDI, according to EFSA PRIMO | Assumptions made for the calculations |
|-----|--------------------------------|-------------------------------------|
|     | 0.4 mg/kg bw per day (EFSA, 2009) |                                     |
|     | 0.4% ADI (NL, child)             |                                     |

CXL: codex maximum residue limit; ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; EFSA PRIMO: EFSA Pesticide Residues Intake Model; GAP: Good Agricultural Practice.

ARfD | Highest IESTI, according to EFSA PRIMO | Assumptions made for the calculations |
|-----|--------------------------------|-------------------------------------|
|     | Not necessary (EFSA, 2009)     |                                     |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; EFSA PRIMO: EFSA Pesticide Residues Intake Model.

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

| ADI | Highest IEDI, according to EFSA PRIMO | Assumptions made for the calculations |
|-----|--------------------------------|-------------------------------------|
|     | 0.4 mg/kg bw per day (EFSA, 2009) |                                     |
|     | 4.5% ADI (DE, child)              |                                     |

For those commodities having a CXL higher than the EU MRL proposal, median residue levels applied in the EU scenario were replaced by the median residue levels derived by JMPR

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; EFSA PRIMO: EFSA Pesticide Residues Intake Model.

B.4. Proposed MRLs

| Code number | Commodity                  | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment               |
|-------------|----------------------------|-------------------------|----------------------|-----------------------|-----------------------|

| Enforcement residue definition (existing): 2-phenylphenol |
| Enforcement residue definition (proposed): sum of 2-phenylphenol and 2-phenylhydroquinone and their conjugates expressed as 2-phenylphenol |

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment               |
|-------------|-----------|-------------------------|----------------------|-----------------------|-----------------------|
| 110000      | Citrus fruits | 5                      | 10                   | Further consideration needed(b) |                         |
| 130020      | Pears | 0.05*                  | 20                   | Further consideration needed(c) |                         |
|             | Other commodities of plant origin | See Reg. (EC) No 839/2008 | – | Further consideration needed(d) |                         |

| Enforcement residue definition: 2-phenylphenol |

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment               |
|-------------|-----------|-------------------------|----------------------|-----------------------|-----------------------|
| 1011010     | Swine meat | 0.05*                | –                    | 0.01*                 | Further consideration needed(e) |
| 1011020     | Swine fat | 0.05*                 | –                    | 0.01*                 | Further consideration needed(e) |
| 1011030     | Swine liver | 0.05*               | –                    | 0.01*                 | Further consideration needed(e) |
| 1011040     | Swine kidney | 0.05*             | –                    | 0.01*                 | Further consideration needed(e) |
| 1012010     | Bovine meat | 0.05*                | –                    | 0.01*                 | Further consideration needed(e) |
| 1012020     | Bovine fat | 0.05*                 | –                    | 0.01*                 | Further consideration needed(e) |
| 1012030     | Bovine liver | 0.05*                | –                    | 0.01*                 | Further consideration needed(e) |
| 1012040     | Bovine kidney | 0.05*               | –                    | 0.01*                 | Further consideration needed(e) |
| Code number(a) | Commodity            | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review MRL (mg/kg) | Comment                                      |
|---------------|----------------------|-------------------------|----------------------|----------------------------------|---------------------------------------------|
| 1015010       | Equine meat          | 0.05*                   | –                    | 0.01*                            | Further consideration needed(e)             |
| 1015020       | Equine fat           | 0.05*                   | –                    | 0.01*                            | Further consideration needed(e)             |
| 1015030       | Equine liver         | 0.05*                   | –                    | 0.01*                            | Further consideration needed(e)             |
| 1015040       | Equine kidney        | 0.05*                   | –                    | 0.01*                            | Further consideration needed(e)             |
| 1020010       | Cattle milk          | 0.05*                   | –                    | 0.01*                            | Further consideration needed(e)             |
| 1020040       | Horse milk           | 0.05*                   | –                    | 0.01*                            | Further consideration needed(e)             |
| –             | Other commodities of animal origin | See Reg. (EC) No 839/2008 | –                    | –                                | Further consideration needed(d)             |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set/proposed at the limit of quantification.
(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(b): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix D).
(c): 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 D).
(d): 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 D).
(e): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).
## Appendix C – Input values for the exposure calculations

### C.1. Livestock dietary burden calculations

**Feed commodity** | Median dietary burden | Maximum dietary burden |
|-----------------------|-----------------------|-----------------------|
|                       | Input value (mg/kg)   | Comment               | Input value (mg/kg) | Comment               |

**Risk assessment residue definition:** sum of 2-phenylphenol and 2-phenylhydroquinone and their conjugates, expressed as 2-phenylphenol

Citrus fruits, dry pulp | 6.75 | STMR × PF (tentative) | 6.75 | STMR × PF (tentative) |

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

### C.2. Consumer risk assessment without consideration of the existing CXLs

| Commodity | Chronic risk assessment |
|-----------|------------------------|
|           | Input value (mg/kg)    | Comment               |

**Risk assessment residue definition:** sum of 2-phenylphenol and 2-phenylhydroquinone and their conjugates, expressed as 2-phenylphenol

Citrus fruits | 0.33 | STMR × PF (tentative) |

CXL: codex maximum residue limit; STMR: supervised trials median residue; PF: processing factor.

### C.3. Consumer risk assessment with consideration of the existing CXLs

| Commodity | Chronic risk assessment |
|-----------|------------------------|
|           | Input value (mg/kg)    | Comment               |

**Risk assessment residue definition:** sum of 2-phenylphenol and 2-phenylhydroquinone and their conjugates, expressed as 2-phenylphenol

Citrus fruits | 3.9 | STMR (CXL tentative) |

CXL: codex maximum residue limit; STMR: supervised trials median residue; PF: processing factor.

*: Indicates that the input value is proposed at the limit of quantification.
| Commodity      | Chronic risk assessment | Input value (mg/kg) | Comment         |
|---------------|-------------------------|--------------------|-----------------|
| Bovine liver  |                         | 0.01*              | STMR (tentative)|
| Bovine kidney |                         | 0.01*              | STMR (tentative)|
| Equine meat   |                         | 0.01*              | STMR (tentative)|
| Equine fat    |                         | 0.01*              | STMR (tentative)|
| Equine liver  |                         | 0.01*              | STMR (tentative)|
| Equine kidney |                         | 0.01*              | STMR (tentative)|
| Cattle milk   |                         | 0.01*              | STMR (tentative)|
| Horse milk    |                         | 0.01*              | STMR (tentative)|

CXL: codex maximum residue limit; STMR: supervised trials median residue. *: Indicates that the input value is proposed at the limit of quantification.
Appendix D – Decision tree for deriving MRL recommendations

**Evaluation of the GAPs and available residues data at EU level**

- GAP is DB-1 or higher? (Yes/No)
  - Yes: MRL derived in Section 3?
    - Yes: MRL fully supported by data?
      - Yes: MRL is recommended.
    - No: Risk identified?
      - Yes: Median/highest values are included in the RA.
        - Fall-back MRLs available?
          - Yes: Tentative median/highest values are included in the RA.
          - No: Not considered for the RA.
        - No: Fall-back MRLs available?
          - Yes: Tentative median/highest values are included in the RA.
          - No: Not considered for the RA.
  - No: Specific LOQ or default MRL?
    - Yes: Maintain current EU MRL?
      - Yes: MRL is recommended.
      - No: Fall-back MRLs available?
        - Yes: Tentative median/highest values are included in the RA.
        - No: Not considered for the RA.
    - No: Specific LOQ or default MRL?
      - Yes: Maintain current EU MRL?
        - Yes: MRL is recommended.
        - No: Fall-back MRLs available?
          - Yes: Tentative median/highest values are included in the RA.
          - No: Not considered for the RA.
      - No: Specific LOQ or default MRL?
        - Yes: Maintain current EU MRL?
          - Yes: MRL is recommended.
          - No: Fall-back MRLs available?
            - Yes: Tentative median/highest values are included in the RA.
            - No: Not considered for the RA.
        - No: Specific LOQ or default MRL?
          - Yes: Maintain current EU MRL?
            - Yes: MRL is recommended.
            - No: Fall-back MRLs available?
              - Yes: Tentative median/highest values are included in the RA.
              - No: Not considered for the RA.
          - No: Specific LOQ or default MRL?
            - Yes: Maintain current EU MRL?
              - Yes: MRL is recommended.
              - No: Fall-back MRLs available?
                - Yes: Tentative median/highest values are included in the RA.
                - No: Not considered for the RA.
          - No: Specific LOQ or default MRL?
            - Yes: Maintain current EU MRL?
              - Yes: MRL is recommended.
              - No: Fall-back MRLs available?
                - Yes: Tentative median/highest values are included in the RA.
                - No: Not considered for the RA.
          - No: Specific LOQ or default MRL?
            - Yes: Maintain current EU MRL?
              - Yes: MRL is recommended.
              - No: Fall-back MRLs available?
                - Yes: Tentative median/highest values are included in the RA.
                - No: Not considered for the RA.
          - No: Specific LOQ or default MRL?
            - Yes: Maintain current EU MRL?
              - Yes: MRL is recommended.
              - No: Fall-back MRLs available?
                - Yes: Tentative median/highest values are included in the RA.
                - No: Not considered for the RA.
          - No: Specific LOQ or default MRL?
            - Yes: Maintain current EU MRL?
              - Yes: MRL is recommended.
              - No: Fall-back MRLs available?
                - Yes: Tentative median/highest values are included in the RA.
                - No: Not considered for the RA.
          - No: Specific LOQ or default MRL?
            - Yes: Maintain current EU MRL?
              - Yes: MRL is recommended.
              - No: Fall-back MRLs available?
                - Yes: Tentative median/highest values are included in the RA.
                - No: Not considered for the RA.
          - No: Specific LOQ or default MRL?
            - Yes: Maintain current EU MRL?
              - Yes: MRL is recommended.
              - No: Fall-back MRLs available?
                - Yes: Tentative median/highest values are included in the RA.
                - No: Not considered for the RA.
          - No: Specific LOQ or default MRL?
            - Yes: Maintain current EU MRL?
              - Yes: MRL is recommended.
              - No: Fall-back MRLs available?
                - Yes: Tentative median/highest values are included in the RA.
                - No: Not considered for the RA.
          - No: Specific LOQ or default MRL?
            - Yes: Maintain current EU MRL?
              - Yes: MRL is recommended.
              - No: Fall-back MRLs available?
                - Yes: Tentative median/highest values are included in the RA.
                - No: Not considered for the RA.
          - No: Specific LOQ or default MRL?
            - Yes: Maintain current EU MRL?
              - Yes: MRL is recommended.
              - No: Fall-back MRLs available?
                - Yes: Tentative median/highest values are included in the RA.
                - No: Not considered for the RA.
          - No: Specific LOQ or default MRL?
            - Yes: Maintain current EU MRL?
              - Yes: MRL is recommended.
              - No: Fall-back MRLs available?
                - Yes: Tentative median/highest values are included in the RA.
                - No: Not considered for the RA.
          - No: Specific LOQ or default MRL?
            - Yes: Maintain current EU MRL?
              - Yes: MRL is recommended.
              - No: Fall-back MRLs available?
                - Yes: Tentative median/highest values are included in the RA.
                - No: Not considered for the RA.
          - No: Specific LOQ or default MRL?
            - Yes: Maintain current EU MRL?
              - Yes: MRL is recommended.
              - No: Fall-back MRLs available?
                - Yes: Tentative median/highest values are included in the RA.
                - No: Not considered for the RA.
          - No: Specific LOQ or default MRL?
            - Yes: Maintain current EU MRL?
              - Yes: MRL is recommended.
              - No: Fall-back MRLs available?
                - Yes: Tentative median/highest values are included in the RA.
                - No: Not considered for the RA.
          - No: Specific LOQ or default MRL?
            - Yes: Maintain current EU MRL?
              - Yes: MRL is recommended.
              - No: Fall-back MRLs available?
                - Yes: Tentative median/highest values are included in the RA.
                - No: Not considered for the RA.
No

Yes

Maintain EU recommendation indicating that no CXL is available.

Maintain EU recommendation indicating CXL is not compatible.

Maintain EU recommendation indicating that CXL is not safe for consumer.

Maintain current CXL or EU recommendation.

Maintain current CXL or EU recommendation is covered as well.

Result EU assessment

Comparison of the EU recommendation with the existing CXL

CXL available?

Yes

RD comparable?

Yes

CXL higher?

Yes

Input values for the RA remain unchanged.

Input values for the RA remain unchanged.

CXL is included in the RA.

Yes

CXL is supported by data.

Yes

CXL higher?

Yes

CXL is included in the RA.

Yes

CXL is supported by data.

Yes

Codex residues highest residues are included in the RA.

Risk identified?

Yes

Yes

Yes

No

No

No

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Yes

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No
## Appendix E – Used compound codes

| Code/trivial name                        | Chemical name/SMILES notation               | Structural formula |
|-----------------------------------------|---------------------------------------------|--------------------|
| 2-Phenylphenol (OPP)                    | Biphenyl-2-ol Oc2ccccc2c1ccccc1              | ![Structural formula](image) |
| 2-Phenylhydroquinone (PHQ)              | Biphenyl-2,5-diol Oc2ccc(O)cc2c1ccccc1       | ![Structural formula](image) |
| 2-Methoxybiphenyl                       | 2-Methoxybiphenyl COc2ccccc2c1ccccc1         | ![Structural formula](image) |
| Sodium salt orthophenyl phenol (SOPP)   | Sodium biphenyl-2-olate [Na⁺].[O⁻]c2ccccc2c1ccccc1 | ![Structural formula](image) |

SMILES: simplified molecular-input line-entry system.