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

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Abstract
According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance phosmet. Although this active substance is no longer authorised within the European Union, MRLs were established by the Codex Alimentarius Commission (codex maximum residue limits; CXLs). Based on the available data, EFSA assessed the CXLs and a consumer risk assessment was carried out. The CXLs were found to be supported by inadequate data and a possible chronic and acute risk to consumers was identified for several commodities. Hence, further consideration by risk managers is needed.

Keywords: phosmet, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, organophosphorus, insecticide

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Summary

Phosmet was initially included in Annex I to Council Directive 91/414/EEC on 23 April 2007 by Commission Directive 2007/25/EC. As the active substance was approved before the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, 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(2) of the aforementioned regulation. In the meantime, an application to renew the approval of phosmet, expiring in July 2022, was submitted by Gowan Comércio Internacional e Serviços, Limitada in accordance with Regulation (EC) No 1107/2009. Subsequently, a peer review of the pesticide risk assessment on the rapporteur Member State (RMS) evaluation, with Spain designated as RMS, was conducted by EFSA and finalised in 2021. In 2022, a decision of non-renewal of phosmet was taken by Commission Implementing Regulation (EU) 2022/94.

As the basis for the MRL review, in order to verify whether import tolerances may still be in place in some Member States, on 17 January 2022 EFSA initiated the collection of data for this active substance. In a first step, Member States and the UK were invited to submit by 14 February 2022 Good Agricultural Practices (GAPs) reflecting import tolerances in the format of specific GAP forms, allowing the designated RMS Spain to identify the critical GAPs. However, no import tolerances were provided by Member States and the UK during the collection period. Although the use of phosmet is no longer authorised within the EU and uses authorised in third countries were not reported to EFSA, the codex maximum residue limit (CXLs) based on the use of phosmet which were previously evaluated by the Joint Meeting on Pesticide Residues (JMPR), are currently still in place.

Based on the information provided by the RMS and the EURs and taking into account the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009 and the MRLs established by the Codex Alimentarius Commission (CAC), EFSA prepared in May 2022 a draft reasoned opinion, which was circulated to Member States and the EURs for consultation via a written procedure. Comments received by 3 June 2022 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of phosmet in plant was investigated in primary crops, in the framework of the peer review for renewal. According to the results of the metabolism studies, the residue definition for enforcement is proposed as phosmet only, and as phosmet, phosmet-oxon and phthalic acid for risk assessment, pending additional data on the characterisation of metabolites and further toxicological assessment. A specific residue definition for rotational crops is not deemed necessary considering the very limited persistence of phosmet in the soil and that no uses were reported in Europe. A residue definition could not be derived for processed commodities. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all four plant matrices at the limit of quantification (LOQ) of 0.01 mg/kg. According to the EURs, the LOQ of 0.005 mg/kg is achievable in the four main matrix groups of plant origin by using the QuEChERS method in routine analyses.

As phosmet uses are no longer authorised in Europe and import tolerances were not reported for feed items, the assessment of livestock exposure is not relevant under this review.

Chronic and acute consumer exposure resulting from the internationally recommended CXLs established for phosmet were calculated using revision 3.1 of the EFSA PRIMO. These calculations are indicative only, considering the data gaps identified during the peer review for renewal which are still relevant under the current review. Exceedances of the acute reference dose (ARfD) were identified for several commodities: citrus fruits, wine and table grapes, blueberries, cranberries, kumquats, coconuts and potatoes, while no exceedances were observed for tree nuts, except coconuts, and cotton seeds. Lowering the CXLs of concern to the proposed LOQ of 0.01 mg/kg, except for potatoes and oranges for which the CXLs were lowered to the achievable LOQ of 0.005 mg/kg, the highest chronic exposure represented 6% of the acceptable daily intake (ADI) for 6 representative diets (DE child, GEMS/food G07, GEMS/food G11, IE adult, NL toddler and PT general) and the highest acute exposure represented 79% of the ARfD for grapefruits. It can be concluded that the proposed LOQ for potatoes and oranges might not provide a satisfactory level of protection for European consumers. Nonetheless, the LOQ of 0.005 mg/kg achievable according to the EURs would provide sufficient protection. According to the calculations performed following the internationally agreed methodology, some of the CXLs will not result in consumer intake exceeding the ARfD. However, EFSA noted a narrow safety margin. Hence, if residues of phosmet occur in pistachio at the proposed MRL value, the dietary exposure of certain consumers may exceed the ARfD under certain conditions. Risk managers should decide whether the safety margin of the exposure assessment based on the highest residue is
sufficient, considering that in reality residues in individual units/lot consumed may occur at the proposed MRL.

EFSA emphases that this assessment does not consider phosmet-oxon and phthalic acid, as no sufficient information is available on their toxicological profile and on the occurrence in the environment of phthalic acid from multiple sources.
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Background

Regulation (EC) No 396/2005\(^1\) (hereinafter referred to as ‘the Regulation’) establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(2) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide by 1 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Council Directive 91/414/EEC\(^2\) before 2 September 2008.

Phosmet was initially included in Annex I to Council Directive 91/414/EEC on 23 April 2007 by means of Commission Directive 2007/25/EC\(^3\). Therefore, EFSA initiated the review of all existing MRLs for that active substance. In the meantime, an application for the renewal of the approval of phosmet, expiring in July 2022, was submitted by Gowan Comercio Internacional e Servicos, Limitada in accordance with Regulation (EC) No 1107/2009\(^4\). Subsequently, phosmet was evaluated by Spain, designated as rapporteur Member State (RMS) and a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2021). Consequently, the approval of phosmet was not renewed by Commission Implementing Regulation (EU) 2022/945\(^5\).

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Council Directive 91/414/EEC repealed by Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, only a few representative uses are evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU) and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Regulation (EC) No 1107/2009 is therefore insufficient for the assessment of all existing MRLs for a given active substance.

As the basis for the MRL review, in order to verify whether import tolerances may still be in place in some Member States, on 17 January 2022 EFSA initiated the collection of data for this active substance. In a first step, Member States and the UK\(^6\) were invited to submit by 14 February 2022 Good Agricultural Practices (GAPs) reflecting import tolerances in the format of specific GAP forms, allowing the designated RMS Spain to identify the critical GAPs. However, no import tolerances were provided by Member States and the UK during the collection period. Although the use of phosmet is no longer authorised within the European Union (EU) and uses authorised in third countries were not reported to EFSA, the Codex Limits (CXLs) based on the use of phosmet which were previously evaluated by the Joint Meeting on Pesticide Residues (JMPR), are currently still in place.

Considering all the available information, and taking into account the MRLs established by the Codex Alimentarius Commission (CAC) (i.e. CXLs), EFSA prepared in May 2022 a draft reasoned opinion, which was circulated to Member States and the EURs for commenting via a written procedure. All comments received by 3 June 2022 were considered by EFSA during the finalisation of the reasoned opinion.

The EURs report on analytical methods (EURs, 2022) and the Member States consultation report (EFSA, 2022) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available. Furthermore, the exposure calculations for all crops considered in the framework of this review performed using the EFSA Pesticide Residues Intake Model are considered in the framework of this review performed using the EFSA Pesticide Residues Intake Model

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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 2007/25/EC of 23 April 2007 amending Council Directive 91/414/EEC to include dimethoate, dimethomorph, glufosinate, metribuzin, phosmet and propamocarb as active substances. OJ L 106, 24.4.2007, p. 34-42.

\(^4\) 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) 2022/94 of 24 January 2022 concerning the non-renewal of the approval of the active substance phosmet, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 16, 25.1.2022, p. 33-35.

\(^6\) The United Kingdom withdrew from EU on 1 January 2020. In accordance with the Agreement on the Withdrawal of the United Kingdom from the EU, and in particular with the Protocol on IE/NI, the EU requirements on data reporting are also applicable to NI.
PRIMo are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheets of the PRIMo is presented in Appendix C.

Terms of reference

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

The active substance and its use pattern

Phosmet is the ISO common name for O,O-dimethyl S-phthalimidomethyl phosphorodithioate or N-[(dimethoxyphosphinothiol)thiol)methyl]phthalimide (IUPAC). The chemical structure of the active substance and its main metabolites are reported in Appendix F.

The EU MRLs for phosmet are established in Annexes IIIA of Regulation (EC) No 396/2005. CXLs for phosmet were also established by the CAC (Codex Alimentarius Commission), however not taken over in the EU legislation yet. According to non-renewal under Regulation (EC) No 1107/2009, plant protection products containing phosmet are no longer authorised within EU Member States. For the purpose of this MRL review, Member States did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment

Although the use of phosmet is no longer authorised within the EU and uses authorised in third countries were not reported to EFSA, the uses of phosmet were previously evaluated by the JMPR and CXLs were established (FAO, 1998, 2002, 2008a, 2014). The CXLs resulting from this assessment by the JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. EFSA bases its assessment on the renewal assessment report (RAR) and its revised document prepared under Regulation (EU) No 1107/2009 (Spain, 2017, 2020) and the recent conclusion on the peer review of the pesticide risk assessment of the active substance phosmet (EFSA, 2021). To facilitate consideration of the existing CXLs by risk managers, EFSA assessed the available data with particular attention to the analytical methods and the nature of residues in plants and livestock. 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.

The metabolism of phosmet was investigated after foliar treatment in fruits (apple and cherry), roots (potato) and cereals (maize) and assessed in the framework of the peer review for renewal (Spain, 2020; EFSA, 2021), as well as by the JMPR (FAO, 1998). According to these studies performed with phosmet radiolabelled in the carbonyl position of the molecule, parent phosmet was the major compound identified in apples (63% of the total radioactive residues (TRRs)) and in maize fodder, forage and cobs (24–53% TRR), while it was present in smaller amount in cherry fruits (<10% TRR) and not detected at all in potato and maize grain. Phthalic acid was a major metabolite in cherry, potato and maize grain and cob (16–61% TRR), detected also in apple but in very low proportions. Phthalamic acid was predominant in potato (48% TRR). Several other metabolites were characterised but in very low amounts. Nevertheless, during the peer review for renewal, several data gaps were identified regarding the metabolism studies, that are still relevant under the current review. Metabolite phosmet-oxon was recovered in low amounts in the studies on cherry, potato and maize; however, limited storage stability data were provided, and sample storage periods were missing, therefore the findings cannot be quantitatively relied on. In addition, metabolism studies with a second radiolabel were not conducted, leading to uncertainties regarding the relevance of some potential metabolites for the consumer (EFSA, 2021).

Rotational crops studies are not triggered since phosmet is no longer authorised in Europe. In addition, these studies were also not required during the peer review since phosmet degrades rapidly in soil (DT90 < 100 days) and does not form persistent soil metabolites (EFSA, 2021).
Two different studies investigating the nature of residues in processed commodities were assessed (Spain, 2020; EFSA, 2021). These experiments simulating representative hydrolytic conditions for pasteurisation, boiling/brewing/baking and sterilisation showed that phosmet was stable to hydrolysis under standard conditions of pasteurisation (up to 84% TRR recovered), while during baking/brewing/boiling and sterilisation significant degradation in multiple compounds was observed. However, the two studies presented different results regarding the identity and magnitude of some degradation products, and it was concluded that a scientific justification or confirmatory investigation would be required to clarify this discrepancy (EFSA, 2021).

It was concluded that the metabolism of phosmet was similar in all primary crops assessed. As the parent compound was found to be a sufficient marker in fruits, roots and cereals, the residue definition for enforcement is proposed as phosmet only. The same residue definition was set by the JMPR. A hyphenated analytical method based on high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) is validated for the enforcement of the proposed residue definition with a limit of quantification (LOQ) of 0.01 mg/kg in the four main plant matrices (EFSA, 2021). According to the EURs, the LOQ of 0.005 mg/kg is achievable for phosmet by using the QuEChERS method in routine analyses in the four main matrix groups of plant origin (EURs, 2022).

Considering the metabolism studies and the toxicological data available, during the peer review, the residue definition for risk assessment was proposed as phosmet, phosmet-oxon and phthalic acid. This residue definition is provisional pending further information on residue occurrence and a toxicological evaluation of phthalic acid and phosmet-oxon, for which a conclusion on the toxicological relevance could not be drawn (EFSA, 2021). It differs from the residue definition set by the JMPR, as phosmet only (FAO, 1998). No residue definition is required for rotational crops in the framework of this review.

Regarding processing commodities, it could not be concluded whether a separate residue definition was required, pending further clarity on the possible occurrence of residues expected in commodities after food processing (EFSA, 2021).

As phosmet uses are no longer authorised in Europe and import tolerances were not reported for feed items, further investigation on livestock exposure is not required. It is noted that CXLs for cattle meat and milks were initially established and are still reported erroneously in the Codex Alimentarius pesticides database. As it was not possible to estimate any maximum residue levels for animal feeds or animal products in the absence of animal transfer studies, the JMPR recommended the withdrawal of the existing CXLs for these livestock commodities (FAO, 1998) and the Codex Committee on Pesticide Residues (CCPR) recommended revocation of these CXLs (FAO, 2001). It is therefore not relevant to assess phosmet residues in livestock under the current review.

Although no uses nor import tolerances were reported for phosmet under this review, CXLs are still in place. To facilitate consideration of these CXLs by risk managers, an indicative consumer exposure was calculated. All data relevant to the consumer exposure assessment have been collected from JMPR evaluations. Considering the European reservation expressed for apples, pears, apricots and nectarines due to short-term intake concerns (FAO, 2008b), the existing CXLs for pome fruits, apricots and peaches were, thus, not considered in the current assessment. For all commodities, supervised trial median residue (STMR) and highest residue (HR), applying a peeling factor for citrus fruits, were used as input values to calculate the chronic and acute exposure. An overview of the input values used for this exposure calculation is provided in Appendix D.

Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA PRIMO (EFSA, 2018, 2019). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. The exposure values calculated were compared with the toxicological reference values for phosmet derived by EFSA (European Commission, 2021). The highest chronic exposure was calculated for PT general diet, representing 880% of the acceptable daily intake (ADI), noting that the ADI is exceeded for 25 diets. An exceedance of the acute reference dose (ARfD), from 130% (coconuts) to 67083% (table grapes), was identified for several crops: all citrus fruits, table and wine grapes, coconuts, blueberries, cranberries, kumquats and potatoes. Acute risk was also identified for several processed commodities (up to 13314% ARfD for wine grapes juice). The CXLs for tree nuts, except coconuts did not exceed the ARfD, with the highest exposure contributing up to 52% of the ARfD for pistachio. In addition, it should be noted that phosmet-oxon was analysed for in all residue trials on tree nuts and residue levels were always below the LOQ of 0.05 mg/kg (FAO, 2008a). Acute consumption data are not available for cotton seeds. However, considering the low relevance of this commodity in the European diets and that a no-residue situation is expected (FAO, 1998), an unacceptable risk for European consumers is unlikely to occur.
A second exposure calculation was performed lowering the CXLs of concern to the proposed LOQ of 0.01 mg/kg, except for potatoes and oranges for which a lower LOQ of 0.005 mg/kg, achievable according to the EURLs, was used as input value. Indeed, when considering the proposed LOQ of 0.01 mg/kg for these two commodities, exceedances were still identified. In this second scenario, the highest chronic exposure declined to 6% of the ADI (DE child, GEMS/food G07, GEMS/food G11, IE adult, NL toddler and PT general) and the highest acute exposure was calculated for grapefruits, representing 79% of the ARfD.

Based on these indicative calculations, a potential risk to consumers was identified for the CXLs of phosmet in all citrus fruits, wine and table grapes, coconuts, blueberries, cranberries, kumquats and potatoes, and even the proposed LOQ of 0.01 mg/kg for potatoes and oranges would not provide a satisfactory level of protection for consumers. Nonetheless, the LOQ of 0.005 mg/kg achievable according to the EURLs would provide sufficient protection. For the remaining CXLs (tree nuts, except coconuts, and cotton seeds), although uncertainties remain due to the data gaps identified, the exposure calculation did not indicate a risk to consumers. EFSA notes that for pistachio, although no acute consumer intake concerns were identified according to the internationally agreed methodology for acute risk assessment which is based on the highest residue found in the supervised field trials, the safety margin for acute exposure is narrow. If this commodity contains residues at the proposed MRL, an exceedance of the ARfD cannot be excluded (acute exposure accounts for 116% of the ARfD).

EFSA emphasizes that this assessment does not consider phosmet-oxon and phthalic acid, as sufficient information is not available on their toxicological profile and on the occurrence in the environment of phthalic acid from multiple sources. To conclude on the relevance of phthalic acid in primary crops and on the contribution of phosmet residues to consumer dietary exposure to phthalic acid, background levels should be considered (EFSA, 2021).

Conclusions

Although the use of phosmet is no longer authorised within the EU and no uses in third countries were reported, CXLs previously assessed by the JMPR are still in place and should be considered. The current reasoned opinion relies on the data recently assessed during the peer review for renewal.

The metabolism of phosmet in plant was investigated in primary crops. According to the results of the metabolism studies, the residue definition for enforcement is proposed as phosmet only, and as phosmet, phosmet-oxon and phthalic acid for risk assessment, pending additional data on the characterisation of metabolites and further toxicological assessment. A specific residue definition for rotational crops is not deemed necessary considering the very limited persistence of phosmet in the soil and that no uses were reported in Europe. A residue definition could not be derived for processed commodities. Fully validated analytical methods are available for the enforcement of the proposed residue definition in all four plant matrices at the LOQ of 0.01 mg/kg. According to the EURLs the LOQ of 0.005 mg/kg is achievable in the four main matrix groups of plant origin by using the QuEChERS method in routine analyses.

As phosmet uses are no longer authorised in Europe and import tolerances were not reported for feed items, the assessment of livestock exposure is not relevant under this review.

Chronic and acute consumer exposure resulting from the internationally recommended CXLs established for phosmet was calculated using revision 3.1 of the EFSA PRIMO. These calculations are indicative only, considering the data gaps identified during the peer review for renewal which are still relevant under the current review. Exceedances of the ARfD were identified for several commodities: citrus fruits, wine and table grapes, blueberries, cranberries, kumquats, coconuts and potatoes, while no exceedances were observed for tree nuts, except coconuts, and cotton seeds. Lowering the CXLs of concern to the proposed LOQ of 0.01 mg/kg, except for potatoes and oranges for which the CXLs were lowered to the achievable LOQ of 0.005 mg/kg, the highest chronic exposure represented 6% of the ADI (DE child, GEMS/food G07, GEMS/food G11, IE adult, NL toddler and PT general) and the highest acute exposure represented 79% of the ARfD (grapefruits). It can be concluded that the proposed LOQ for potatoes and oranges might not provide a satisfactory level of protection for European consumers. Nonetheless, the LOQ of 0.005 mg/kg achievable according to the EURLs, would provide sufficient protection. According to the calculations performed following the internationally agreed methodology, some of the CXLs will not result in consumer intake exceeding the ARfD. However, EFSA noted a narrow safety margin. Hence, if residues of phosmet occur in pistachio at the proposed MRL value, the dietary exposure of certain consumers may exceed the ARfD under certain conditions. Risk managers should decide whether the safety margin of the exposure assessment based
on the highest residue is sufficient, considering that in reality residues in individual units/lot consumed may occur at the proposed MRL.

EFSA emphases that this assessment does not consider phosmet-oxon and phthalic acid, as no sufficient information is available on their toxicological profile and on the occurrence in the environment of phthalic acid from multiple sources.

**Recommendations**

All MRL values, resulting from CXLs, listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see Table 1 footnotes for details). In particular, all tentative MRLs need to be confirmed by the following data (data gaps already identified during the peer review and still relevant under the current review):

1) additional information regarding sample storage time and conditions for the metabolism studies in cherry, potato and maize;
2) information to address the relevance for consumers of potential metabolites that could be formed from the phosphorodithioate side chain in plant commodities;
3) scientific justification on the discrepancy between the two standard hydrolysis studies or confirmatory investigations regarding the occurrence of relevant metabolites under processing;
4) additional information on the genotoxicity of phosmet-oxon and general toxicity assessment of phosmet-oxon and phthalic acid.

It is highlighted that, also in view of the very low toxicological reference values, for commodities for which no uses are authorised, the default value of 0.01 mg/kg could not be sufficient to protect European consumers. This should be considered by risk managers when setting the LOQ or default MRL for these commodities.

EFSA emphases that due to the data gaps identified, phthalic acid and phosmet-oxon could not be considered in this consumer risk assessment. In addition, since the occurrence of phthalic acid in the environment has multiple sources, background levels should be investigated and compared with residue levels in crops resulting from phosmet treatments. This would allow to assess the contribution of phosmet uses to consumer dietary exposure to phthalic acid.

### Table 1: Summary table

| Code number | Commodity  | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|------------|------------------------|---------------------|----------------------|---------|
| 110010      | Grapefruit | 0.5                    | 3                   | Further consideration needed<sup>(a)</sup> | Data gap #1, 2, 3, 4 |
| 110020      | Oranges    | 0.5                    | 3                   | Further consideration needed<sup>(a)</sup> | Data gap #1, 2, 3, 4 |
| 110030      | Lemons     | 0.5                    | 3                   | Further consideration needed<sup>(a)</sup> | Data gap #1, 2, 3, 4 |
| 110040      | Limes      | 0.5                    | 3                   | Further consideration needed<sup>(a)</sup> | Data gap #1, 2, 3, 4 |
| 110050      | Mandarins  | 0.5                    | 3                   | Further consideration needed<sup>(a)</sup> | Data gap #1, 2, 3, 4 |
| 120010      | Almonds    | 2                      | 0.2                 | Further consideration needed<sup>(b)</sup> | Data gap #1, 2, 3, 4 |
| 120020      | Brazil nuts| 0.05*                  | 0.2                 | Further consideration needed<sup>(b)</sup> | Data gap #1, 2, 3, 4 |
| 120030      | Cashew nuts| 0.05*                  | 0.2                 | Further consideration needed<sup>(b)</sup> | Data gap #1, 2, 3, 4 |
| Code number | Commodity       | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Outcome of the review                                      |
|-------------|-----------------|-------------------------|----------------------|-------------|------------------------------------------------------------|
| 120040      | Chestnuts       | 2                       | 0.2                  | 0.2         | Further consideration needed<sup>(b)</sup> Data gap #1, 2, 3, 4 |
| 120050      | Coconuts        | 0.05*                   | 0.2                  | –           | Further consideration needed<sup>(b)</sup> Data gap #1, 2, 3, 4 |
| 120060      | Hazelnuts       | 0.1                     | 0.2                  | 0.2         | Further consideration needed<sup>(b)</sup> Data gap #1, 2, 3, 4 |
| 120070      | Macadamia       | 0.05*                   | 0.2                  | 0.2         | Further consideration needed<sup>(b)</sup> Data gap #1, 2, 3, 4 |
| 120080      | Pecans          | 0.05*                   | 0.2                  | 0.2         | Further consideration needed<sup>(b)</sup> Data gap #1, 2, 3, 4 |
| 120090      | Pine nuts       | 0.05*                   | 0.2                  | 0.2         | Further consideration needed<sup>(b)</sup> Data gap #1, 2, 3, 4 |
| 120100      | Pistachios      | 2                       | 0.2                  | 0.2         | Further consideration needed<sup>(b)</sup> Data gap #1, 2, 3, 4 |
| 120110      | Walnuts         | 2                       | 0.2                  | 0.2         | Further consideration needed<sup>(b)</sup> Data gap #1, 2, 3, 4 |
| 130010      | Apples          | 0.5                     | 3                    | –           | Further consideration needed<sup>(c)</sup> Data gap #1, 2, 3, 4 |
| 130020      | Pears           | 0.5                     | 3                    | –           | Further consideration needed<sup>(c)</sup> Data gap #1, 2, 3, 4 |
| 130030      | Quinces         | 0.5                     | 3                    | –           | Further consideration needed<sup>(c)</sup> Data gap #1, 2, 3, 4 |
| 130040      | Medlar          | 0.5                     | 3                    | –           | Further consideration needed<sup>(c)</sup> Data gap #1, 2, 3, 4 |
| 130050      | Loquat          | 0.5                     | 3                    | –           | Further consideration needed<sup>(c)</sup> Data gap #1, 2, 3, 4 |
| 140010      | Apricots        | 0.05*                   | 10                   | –           | Further consideration needed<sup>(c)</sup> Data gap #1, 2, 3, 4 |
| 140030      | Peaches         | 1                       | 10                   | –           | Further consideration needed<sup>(c)</sup> Data gap #1, 2, 3, 4 |
| 151010      | Table grapes    | 0.05*                   | 10                   | –           | Further consideration needed<sup>(c)</sup> Data gap #1, 2, 3, 4 |
| 151020      | Wine grapes     | 0.05*                   | 10                   | –           | Further consideration needed<sup>(c)</sup> Data gap #1, 2, 3, 4 |
| 154010      | Blueberries     | 10                      | 10                   | –           | Further consideration needed<sup>(c)</sup> Data gap #1, 2, 3, 4 |
| 154020      | Cranberries     | 10                      | 3                    | –           | Further consideration needed<sup>(c)</sup> Data gap #1, 2, 3, 4 |
| 161040      | Kumquats        | 2                       | 3                    | –           | Further consideration needed<sup>(c)</sup> Data gap #1, 2, 3, 4 |
| 211000      | Potatoes        | 0.05*                   | 0.05*                | –           | Further consideration needed<sup>(c)</sup> Data gap #1, 2, 3, 4 |
| 401090      | Cotton seeds    | 0.05*                   | 0.05*                | 0.05        | Further consideration needed<sup>(c)</sup> Data gap #1, 2, 3, 4 |
| –           | Other commodities of plant and/or animal origin | See Reg. (EU) No 737/2014 | – | – | Further consideration needed<sup>(d)</sup> |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(a): There are no relevant authorisations or import tolerances reported at EU level; CXL is not sufficiently supported by data and a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-IV in Appendix E).
(b): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the existing residue definition); there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).
(c): There are no relevant authorisations or import tolerances reported at EU level. European reservation expressed for existing CXL due to short-term intake concerns. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
(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 E).
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Abbreviations

a.s. active substance
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAC Codex Alimentarius Commission
CCPR Codex Committee on Pesticide Residues
CXL codex maximum residue limit
DALT days after last treatment
DAR draft assessment report
DAT days after treatment
DT$_{90}$ period required for 90% dissipation (define method of estimation)
EMS evaluating Member State
EURLs European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
HPLC–MS/MS high-performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
IELSI international estimated short-term intake
ILV independent laboratory validation
InChIKey International Chemical Identifier Key
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
MS Member States
MW molecular weight
NEDI national estimated daily intake
NESTI national estimated short-term intake
NTMDI national theoretical maximum daily intake
OECD Organisation for Economic Co-operation and Development
PBI plant back interval
PF processing factor
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RD residue definition
RMS rapporteur Member State
SMILES simplified molecular-input line-entry system
STMR supervised trials median residue
TMDOI theoretical maximum daily intake
TRR total radioactive residue
WHO World Health Organization
Appendix A – Summary of authorised uses considered for the review of MRLs

Phosmet is no longer approved in the EU and no import tolerances were reported. Therefore, the current review focuses on the existing CXLs only.
### Appendix B – List of end points

#### B.1. Residues in plants

| Crop groups (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|---------------------------------|-------------|---------|----------------|----------------|----------------|
| **Primary crops**               | Fruit crops | Apple   | Foliar, 2 × 0.84 kg a.s./ha BBCH 75–76 and BBCH 78 | 0, 14, 28 DALT | \[^14C\]-carbonyl labelled phosmet (Spain, 2020) |
|                                 |             | Cherry  | Foliar, 1 × 0.42 kg a.s./hl | 0, 7, 14 | \[^14C\]-carbonyl labelled phosmet (Spain, 2020) |
| **Root crops**                  | Potato      | Foliar, 4 × 1.7 to 2 kg a.s./ha Applications on day 0, 40, 60 and 88 | Immature: 40 DAT1 and 20 DAT2 Mature: 7 DAT3 and 7 DALT | \[^14C\]-carbonyl labelled phosmet (Spain, 2020) |
| **Cereals/grass**               | Maize       | Foliar, 2 × 1.12 kg a.s./ha At silk stage and 14 days before final harvest | Forage: 28 DAT1 Fodder, grain, cob: 76 DAT1 and 14 DAT2 | \[^14C\]-carbonyl labelled phosmet (Spain, 2020) |

| Crop groups (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|---------------------------------|-------------|---------|----------------|-----------|----------------|
| **Rotational crops**            |             | –       | –              | –         | No study required (EFSA, 2021) |

| **Processed commodities** (hydrolysis study) | Conditions | Stable? | Comment/Source |
|-----------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)            | Yes        |         | Spain (2020), EFSA (2021) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | No         | Two studies were provided, showing discrepancies in the identification and occurrence of degradation products (Spain, 2020; EFSA, 2021) |
| Sterilisation (20 min, 120°C, pH 6)            | No         |         | |

[^14C]: Carbon-14 labelled
Can a general residue definition be proposed for primary crops? | Yes | Similar metabolism in three crop groups, however, storage stability data are missing and studies with a second radio-label are not available (data gaps)
---|---|---
Rotational crop and primary crop metabolism similar? | Not applicable | No study required
Residue pattern in processed commodities similar to residue pattern in raw commodities? | Inconclusive | Available studies do not allow to conclude (data gap)
Plant residue definition for monitoring (RD-Mo) | Phosmet (EFSA, 2021)
Plant residue definition for risk assessment (RD-RA) | Phosmet, phosmet-oxon and phthalic acid (tentative)
Residue definition is provisional pending further toxicological data on phosmet-oxon and phthalic acid (EFSA, 2021)
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs) | Matrices with high water content, high oil content, high acid content and dry matrices: HPLC–MS/MS, LOQ 0.01 mg/kg | ILV available (Spain, 2020; EFSA, 2021) | QuEChERS for enforcement in routine analysis, LOQ 0.005 mg/kg achievable (EURLs, 2022)

**B.2. Residues in livestock**

As the use of phosmet is no longer authorised in Europe and no import tolerances on feed items were reported in the framework of this review, further investigation on livestock exposure is not required.
B.3. Consumer risk assessment considering the existing CXLs

| ARfD                  | Phosmet: 0.001 mg/kg bw (European Commission, 2021) Phosmet-oxon and phthalic acid: open |
|-----------------------|------------------------------------------------------------------------------------------|
| Highest IESTI, according to EFSA PRiMo (rev.3.1) |                                                                                           |
| **Scenario 1** (phosmet only):                      |                                                                                           |
| Table grapes: 67083% of ARfD                         |                                                                                           |
| Wine grapes: 8536% of ARfD                           |                                                                                           |
| Blueberries: 5902% of ARfD                           |                                                                                           |
| Exceedances observed for other 9 commodities (from 130% to 4536% ARfD): coconuts, kumquats, cranberries, potatoes, citrus fruits. |                                                                                           |
| Exceedances also observed for processed commodities (from 194% ARfD, lemon jam, to 13314% of ARfD, wine grapes juice) |                                                                                           |
| **Scenario 2** lowering the CXLs leading to acute risk (phosmet only): |                                                                                           |
| Grapefruits: 79% of ARfD                             |                                                                                           |
| Potatoes: 77% of ARfD                                |                                                                                           |
| Table grapes: 73% of ARfD                            |                                                                                           |
| Oranges: 66% of ARfD                                 |                                                                                           |
| Phosmet-oxon and phthalic acid: not assessed.         |                                                                                           |

| NESTI (% ARfD) | Not assessed in this review. |
|----------------|-------------------------------|
| **Assumptions made for the calculations** |                                                                                           |
| **Scenario 1:** |                                                                                           |
| The calculation is based on the highest residue (HR) levels expected in raw agricultural commodities (median residue level, STMR, for cotton seeds), to which a peeling factor was applied for citrus fruits (PeF = 0.19). |                                                                                           |
| **Scenario 2:** |                                                                                           |
| The calculation is based on the HR levels expected in raw agricultural commodities, except for cotton seeds for which the STMR was considered. For all commodities for which an exceedance of the ARfD was noted in scenario 1, the proposed LOQ of 0.01 mg/kg was used as input value, except for potatoes and oranges. For potatoes and oranges, as the proposed LOQ of 0.01 mg/kg was still leading to exceedances, the LOQ of 0.005 mg/kg achievable according to the EURLs was considered. |                                                                                           |
| It is noted that in both scenarios only parent phosmet is covered by the calculation, as data are missing regarding metabolites phosmet-oxon and phthalic acid. |                                                                                           |

| ARfD: acute reference dose; bw: body weight; NESTI: national estimated short-term intake; PRiMo: (EFSA) Pesticide Residues Intake Model; IESTI: international estimated short-term intake. |

| ADI | Phosmet: 0.001 mg/kg bw (European Commission, 2021) Phosmet-oxon and phthalic acid: open |
|-----|------------------------------------------------------------------------------------------|
| TMDI according to EFSA PRiMo | Not assessed in this review. |
| NTMDI, according to (to be specified) | Not assessed in this review. |
Highest IEDI, according to EFSA PRIMO (rev.3.1)

| **Scenario 1** (phosmet only): |
| --- |
| 880% ADI (PT general) |
| The ADI is exceeded for 25 diets. |

| **Scenario 2** lowering the CXLs leading to acute risk (phosmet only): |
| --- |
| 6% ADI for 6 representative diets (DE child, GEMS/food G07, GEMS/food G11, IE adult, NL toddler and PT general) |
| Phosmet-oxon and phthalic acid: not assessed. |

NEDI (% ADI)

Assumptions made for the calculations

**Scenario 1:**
The calculation is based on the median residue levels (STMR) derived for raw agricultural commodities to which a peeling factor was applied for citrus fruits (PeF = 0.19).

**Scenario 2:**
The calculation is based on the STMR levels expected in raw agricultural commodities. For all commodities for which an exceedance of the ARfD was noted in scenario 1, the proposed LOQ of 0.01 mg/kg was used as input value, except for potatoes and oranges. For potatoes and oranges, as the proposed LOQ of 0.01 mg/kg was still leading to exceedances, the LOQ of 0.005 mg/kg achievable according to the EURLs was considered.

In both scenarios, the contribution of commodities for which no CXLs are established, or an EU reservation was expressed, were not included in the calculation.

It is noted that only parent phosmet is covered by the calculation, as data are missing regarding metabolites phosmet-oxon and phthalic acid.

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; NEDI: national estimated daily intake; PRIMO: (EFSA) Pesticide Residues Intake Model; TMDI: theoretical maximum daily intake; NTMDI: national theoretical maximum daily intake.
### 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): phosmet (phosmet and phosmet-oxon, expressed as phosmet) |
| Enforcement residue definition (proposed): phosmet |
| 110010      | Grapefruit          | 0.5                     | 3                    | –                     | Further consideration needed(a) Data gap #1, 2, 3, 4 |
| 110020      | Oranges             | 0.5                     | 3                    | –                     | Further consideration needed(a) Data gap #1, 2, 3, 4 |
| 110030      | Lemons              | 0.5                     | 3                    | –                     | Further consideration needed(a) Data gap #1, 2, 3, 4 |
| 110040      | Limes               | 0.5                     | 3                    | –                     | Further consideration needed(a) Data gap #1, 2, 3, 4 |
| 110050      | Mandarins           | 0.5                     | 3                    | –                     | Further consideration needed(a) Data gap #1, 2, 3, 4 |
| 120010      | Almonds             | 2                       | 0.2                  | 0.2                   | Further consideration needed(b) Data gap #1, 2, 3, 4 |
| 120020      | Brazil nuts         | 0.05*                   | 0.2                  | 0.2                   | Further consideration needed(b) Data gap #1, 2, 3, 4 |
| 120030      | Cashew nuts         | 0.05*                   | 0.2                  | 0.2                   | Further consideration needed(b) Data gap #1, 2, 3, 4 |
| 120040      | Chestnuts           | 2                       | 0.2                  | 0.2                   | Further consideration needed(b) Data gap #1, 2, 3, 4 |
| 120050      | Coconuts            | 0.05*                   | 0.2                  | –                     | Further consideration needed(b) Data gap #1, 2, 3, 4 |
| 120060      | Hazelnuts           | 0.1                     | 0.2                  | 0.2                   | Further consideration needed(b) Data gap #1, 2, 3, 4 |
| 120070      | Macadamia           | 0.05*                   | 0.2                  | 0.2                   | Further consideration needed(b) Data gap #1, 2, 3, 4 |
| 120080      | Pecans              | 0.05*                   | 0.2                  | 0.2                   | Further consideration needed(b) Data gap #1, 2, 3, 4 |
| 120090      | Pine nuts           | 0.05*                   | 0.2                  | 0.2                   | Further consideration needed(b) Data gap #1, 2, 3, 4 |
| 120100      | Pistachios          | 2                       | 0.2                  | 0.2                   | Further consideration needed(b) Data gap #1, 2, 3, 4 |
| 120110      | Walnuts             | 2                       | 0.2                  | 0.2                   | Further consideration needed(b) Data gap #1, 2, 3, 4 |
| 130010      | Apples              | 0.5                     | 3                    | –                     | Further consideration needed(c) |
| 130020      | Pears               | 0.5                     | 3                    | –                     | Further consideration needed(c) |
| 130030      | Quinces             | 0.5                     | 3                    | –                     | Further consideration needed(c) |
| 130040      | Medlar              | 0.5                     | 3                    | –                     | Further consideration needed(c) |
| 130050      | Loquat              | 0.5                     | 3                    | –                     | Further consideration needed(c) |
| 140010      | Apricots            | 0.05*                   | 10                   | –                     | Further consideration needed(c) |
| 140030      | Peaches             | 1                       | 10                   | –                     | Further consideration needed(c) |
| 151010      | Table grapes        | 0.05*                   | 10                   | –                     | Further consideration needed(c) Data gap #1, 2, 3, 4 |
| 151020      | Wine grapes         | 0.05*                   | 10                   | –                     | Further consideration needed(c) Data gap #1, 2, 3, 4 |
| 154010      | Blueberries         | 10                      | 10                   | –                     | Further consideration needed(c) Data gap #1, 2, 3, 4 |
| 154020      | Cranberries         | 10                      | 3                    | –                     | Further consideration needed(c) Data gap #1, 2, 3, 4 |

Review of the existing MRLs for phosmet

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| Code number | Commodity                  | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | MRL (mg/kg) | Outcome of the review                                      | Comment                                      |
|------------|----------------------------|-------------------------|----------------------|-------------|----------------------------------------------------------|----------------------------------------------|
| 161040     | Kumquats                   | 2                       | 3                    | –           | Further consideration needed<sup>a</sup>                | Data gap #1, 2, 3, 4                        |
| 211000     | Potatoes                   | 0.05<sup>*</sup>         | 0.05<sup>*</sup>      | –           | Further consideration needed<sup>a</sup>                | Data gap #1, 2, 3, 4                        |
| 401090     | Cotton seeds               | 0.05<sup>*</sup>         | 0.05<sup>*</sup>      | 0.05        | Further consideration needed<sup>b</sup>                | Data gap #1, 2, 3, 4                        |
|            | Other commodities of plant | See Reg. (EU) No 737/2014| –                    | –           | Further consideration needed<sup>d</sup>                |                                              |

MRL: maximum residue level; CXL: codex maximum residue limit.  
*: Indicates that the MRL is set at the limit of quantification.  
(a): There are no relevant authorisations or import tolerances reported at EU level; CXL is not sufficiently supported by data and a risk to consumers cannot be excluded. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-IV in Appendix E).  
(b): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified (assuming the existing residue definition); there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix E).  
(c): There are no relevant authorisations or import tolerances reported at EU level. European reservation expressed for existing CXL due to short-term intake concerns. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered.  
(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 E).
| Commodity/group of commodities | % of ADI | % of ADI | % of ADI | % of ADI | % of ADI | % of ADI |
|--------------------------------|----------|----------|----------|----------|----------|----------|
| Table grapes                   | 880%     | 8.80     | 759%     | 85%      | 27%      | Potatoes |
| Oranges                        | 755%     | 7.55     | 708%     | 35%      | 7%       | Oranges  |
| Potatoes                       | 603%     | 6.03     | 452%     | 101%     | 19%      | Potatoes |
| Potatoes                       | 592%     | 5.92     | 512%     | 56%      | 19%      | Potatoes |
| Potatoes                       | 543%     | 5.43     | 472%     | 27%      | 21%      | Potatoes |
| Oranges                        | 502%     | 5.02     | 418%     | 49%      | 13%      | Potatoes |
| Potatoes                       | 500%     | 5.00     | 311%     | 128%     | 20%      | Potatoes |
| Potatoes                       | 460%     | 4.60     | 317%     | 101%     | 20%      | Potatoes |
| Oranges                        | 443%     | 4.43     | 307%     | 102%     | 19%      | Oranges  |
| Oranges                        | 421%     | 4.21     | 301%     | 102%     | 18%      | Oranges  |
| Oranges                        | 386%     | 3.86     | 255%     | 92%      | 23%      | Oranges  |
| Oranges                        | 375%     | 3.75     | 253%     | 78%      | 19%      | Oranges  |
| Oranges                        | 370%     | 3.70     | 248%     | 76%      | 12%      | Oranges  |
| Oranges                        | 361%     | 3.61     | 243%     | 75%      | 11%      | Oranges  |
| Oranges                        | 353%     | 3.53     | 241%     | 74%      | 10%      | Oranges  |
| Oranges                        | 322%     | 3.22     | 237%     | 73%      | 9%       | Oranges  |
| Oranges                        | 301%     | 3.01     | 232%     | 72%      | 8%       | Oranges  |
| Oranges                        | 248%     | 2.48     | 227%     | 71%      | 7%       | Oranges  |
| Oranges                        | 217%     | 2.17     | 222%     | 70%      | 6%       | Oranges  |
| Oranges                        | 211%     | 2.11     | 219%     | 69%      | 5%       | Oranges  |
| Oranges                        | 204%     | 2.04     | 216%     | 68%      | 4%       | Oranges  |
| Oranges                        | 197%     | 1.97     | 213%     | 67%      | 3%       | Oranges  |
| Oranges                        | 190%     | 1.90     | 210%     | 66%      | 2%       | Oranges  |
| Oranges                        | 183%     | 1.83     | 207%     | 65%      | 1%       | Oranges  |
| Oranges                        | 176%     | 1.76     | 203%     | 64%      | 0%       | Oranges  |
| Oranges                        | 169%     | 1.69     | 199%     | 63%      | 1%       | Oranges  |
| Oranges                        | 162%     | 1.62     | 195%     | 62%      | 0%       | Oranges  |
| Oranges                        | 155%     | 1.55     | 190%     | 61%      | 1%       | Oranges  |
| Oranges                        | 148%     | 1.48     | 185%     | 60%      | 0%       | Oranges  |
| Oranges                        | 141%     | 1.41     | 180%     | 59%      | 1%       | Oranges  |
| Oranges                        | 134%     | 1.34     | 175%     | 58%      | 0%       | Oranges  |
| Oranges                        | 127%     | 1.27     | 170%     | 57%      | 0%       | Oranges  |
| Oranges                        | 120%     | 1.20     | 165%     | 56%      | 0%       | Oranges  |
| Oranges                        | 113%     | 1.13     | 160%     | 55%      | 0%       | Oranges  |
| Oranges                        | 106%     | 1.06     | 155%     | 54%      | 0%       | Oranges  |
| Oranges                        | 99%      | 0.99     | 150%     | 53%      | 0%       | Oranges  |
| Oranges                        | 92%      | 0.92     | 145%     | 52%      | 0%       | Oranges  |
| Oranges                        | 85%      | 0.85     | 140%     | 51%      | 0%       | Oranges  |
| Oranges                        | 78%      | 0.78     | 135%     | 50%      | 0%       | Oranges  |
| Oranges                        | 71%      | 0.71     | 130%     | 49%      | 0%       | Oranges  |
| Oranges                        | 64%      | 0.64     | 125%     | 48%      | 0%       | Oranges  |
| Oranges                        | 57%      | 0.57     | 120%     | 47%      | 0%       | Oranges  |
| Oranges                        | 50%      | 0.50     | 115%     | 46%      | 0%       | Oranges  |
| Oranges                        | 43%      | 0.43     | 110%     | 45%      | 0%       | Oranges  |
| Oranges                        | 36%      | 0.36     | 105%     | 44%      | 0%       | Oranges  |
| Oranges                        | 29%      | 0.29     | 100%     | 43%      | 0%       | Oranges  |
| Oranges                        | 22%      | 0.22     | 95%      | 42%      | 0%       | Oranges  |
| Oranges                        | 15%      | 0.15     | 90%      | 41%      | 0%       | Oranges  |
| Oranges                        | 8%       | 0.08     | 85%      | 40%      | 0%       | Oranges  |
| Oranges                        | 1%       | 0.01     | 80%      | 39%      | 0%       | Oranges  |

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

No of data exceeding the ADI: 25

**Conclusion:**

IT adult: 24.2%

IT toddler: 7.4%

SE general: 15.4%

Oranges: 8.7%

Table grapes: 7.8%

Wine grapes: 7.8%

Phosmet

Toxicological reference values

ADI (mg/kg bw per day): 0.001

ARfD (mg/kg bw): 0.001

Source of ADI: European Commission

Source of ARfD: European Commission

Year of evaluation: 2021

Year of evaluation: 2021

No of diets exceeding the ADI: 25
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Results for children

| Commodity |
|-----------|
| Table grapes |
| Wine grapes |
| Oranges |
| Grapefruits |
| Mandarins |
| Lemons |
| Potatoes |
| Cranberries |
| Kumquats |
| Coconuts |
| Chestnuts |
| Pistachios |
| Walnuts |

### Results for adults

| Commodity |
|-----------|
| Wine grapes/ juice |
| Oranges/ juice |
| Potatoes/ fried |
| Potatoes/ dried (flakes) |
| Lemons/ jam |
| Coconuts/ drink |
| Limes/ juice |
| Potatoes/ chips |
| Coconuts/ drink |
| Pecans |

### Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

- **Children**: 12
- **Adults**: 10

### Conclusion:

The estimated short-term intake (IESTI) exceeded the toxicological reference value for 12 commodities. For processed commodities, the toxicological reference value was exceeded in one or several cases.
LOQs (mg/kg) range from 0.005 to 1.0. ADI (mg/kg bw per day) is 0.001. ARfD (mg/kg bw) is 0.001. Source of ADI: European Commission. Source of ARfD: European Commission. EFSA PRIMo revision 3.1; 2019/03/19. Year of evaluation: 2021.

| Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | Commodities not under assessment (in % of ADI) |
|--------------------------------|----------------------------------|-----------------------------------------------|
| Potatoes                       | 6%                               | 6%                                            |
| Cotton seeds                   | 5%                               | 6%                                            |
| Grapefruits                    | 6%                               | 6%                                            |
| Oranges                        | 5%                               | 6%                                            |
| Table grapes                   | 5%                               | 6%                                            |
| Table grapes                   | 5%                               | 6%                                            |
| Table grapes                   | 4%                               | 6%                                            |
| Table grapes                   | 3%                               | 6%                                            |
| Table grapes                   | 3%                               | 6%                                            |
| Table grapes                   | 2%                               | 6%                                            |
| Table grapes                   | 2%                               | 6%                                            |
| Table grapes                   | 2%                               | 6%                                            |
| Table grapes                   | 2%                               | 6%                                            |
| Table grapes                   | 2%                               | 6%                                            |
| Table grapes                   | 2%                               | 6%                                            |

Chronic risk assessment: JMPR methodology (IEDI/TMDI).

Table grapes, Potatoes, and Oranges are the highest contributors to the MRL calculation (in % of ADI).

Conclusion:
- LT adult
- DK child
- FR infant
- Mandarins
- Potatoes
- Wine grapes
- Table grapes

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Phosmet is unlikely to present a public health concern.

Comments:
- CXLs leading to exceedances are lowered to the LOQ.
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Acute Risk Assessment / Children

| Commodity     | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|---------------|---------------------------|---------------------|------------------------|-------------|--------------------------|---------------------|------------------------|
| Grapes        | 0.01/0.01                 | 0.79                | 79%                    | Potatoes    | 0.01/0.01               | 0.41                | 41%                    |
| Potatoes      | 0.01/0.01                 | 0.77                | 77%                    | Table grapes| 0.01/0.01               | 0.79                | 34%                    |
| Table grapes  | 0.01/0.01                 | 0.73                | 73%                    | Mandarins   | 0.01/0.01               | 0.59                | 21%                    |
| Mandarins     | 0.01/0.01                 | 0.59                | 59%                    | Oranges     | 0.01/0.01               | 0.52                | 20%                    |
| Oranges       | 0.01/0.01                 | 0.52                | 52%                    | Wine grapes | 0.01/0.01               | 0.24                | 12%                    |
| Wine grapes   | 0.01/0.01                 | 0.24                | 24%                    | Hazelnuts   | 0.01/0.01               | 0.20                | 10%                    |
| Hazelnuts     | 0.01/0.01                 | 0.20                | 20%                    | Limes       | 0.01/0.01               | 0.10                | 5%                     |
| Limes         | 0.01/0.01                 | 0.10                | 10%                    | Cranberries| 0.01/0.01               | 0.09                | 4%                     |
| Cranberries  | 0.01/0.01                 | 0.09                | 4%                     | Potatoes/chips | 0.01/0.01 | 0.04                | 2%                     |
| Potatoes/chips| 0.01/0.01                 | 0.04                | 2%                     | Lemons      | 0.01/0.01               | 0.03                | 1%                     |
| Lemons        | 0.01/0.01                 | 0.03                | 1%                     | Coconuts    | 0.01/0.01               | 0.01                | 0.3%                   |
| Coconuts      | 0.01/0.01                 | 0.01                | 0.3%                   | Total number of commodities exceeding the ARfD in children and adult diets (IESTI calculation) |

### Acute Risk Assessment / Adults

| Commodity     | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|---------------|---------------------------|---------------------|------------------------|-------------|--------------------------|---------------------|------------------------|
| Potatoes      | 0.01/0.01                 | 0.79                | 79%                    | Oranges     | 0.01/0.01               | 0.66                | 24%                    |
| Oranges       | 0.01/0.01                 | 0.66                | 66%                    | Mandarins   | 0.01/0.01               | 0.52                | 20%                    |
| Mandarins     | 0.01/0.01                 | 0.52                | 52%                    | Table grapes| 0.01/0.01               | 0.41                | 17%                    |
| Table grapes  | 0.01/0.01                 | 0.41                | 41%                    | Table grapes| 0.01/0.01               | 0.34                | 16%                    |
| Table grapes  | 0.01/0.01                 | 0.34                | 34%                    | Potatoes    | 0.01/0.01               | 0.24                | 12%                    |
| Potatoes      | 0.01/0.01                 | 0.24                | 24%                    | Limes       | 0.01/0.01               | 0.18                | 7%                     |
| Limes         | 0.01/0.01                 | 0.18                | 7%                     | Cashew nuts| 0.01/0.01               | 0.15                | 5%                     |
| Cashew nuts  | 0.01/0.01                 | 0.15                | 5%                     | Cranberries| 0.01/0.01               | 0.13                | 3%                     |
| Cranberries  | 0.01/0.01                 | 0.13                | 3%                     | Hazelnuts   | 0.01/0.01               | 0.11                | 1%                     |
| Hazelnuts     | 0.01/0.01                 | 0.11                | 1%                     | Total number of commodities exceeding the ARfD in children and adult diets (IESTI calculation) |

### Conclusion

No exceedance of the toxicological reference value was identified for any unprocessed commodity.

A short-term intake of residues of Phosmet is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD was identified.
**Appendix D – Input values for the exposure calculations**

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| **Risk assessment residue definition:** phosmet |                         |                       |                         |                       |
| Phosmet is part of a wider provisional residue definition derived during the peer review, including also phosmet-oxon and phthalic acid, for which no toxicological data are available. The risk assessment performed is indicative considering parent only. |                         |                       |                         |                       |
| Citrus fruits, except oranges | 0.12                   | Scenario 1: STMR (CXL) × PeF (0.19) (tentative) | 0.34                   | Scenario 1: HR (CXL) × PeF (0.19) (tentative) |
|                            | 0.01*                  | Scenario 2: LOQ       | 0.01*                  | Scenario 2: LOQ       |
| Oranges                    | 0.12                   | Scenario 1: STMR (CXL) × PeF (0.19) (tentative) | 0.34                   | Scenario 1: HR (CXL) × PeF (0.19) (tentative) |
|                            | 0.005*                 | Scenario 2: LOQ (EURLs) | 0.005*                 | Scenario 2: LOQ (EURLs) |
| Tree nuts, except coconuts | 0.05                   | STMR (CXL) (tentative) | 0.09                   | HR (CXL) (tentative)  |
|                            | 0.01*                  | Scenario 2: LOQ       | 0.01*                  | Scenario 2: LOQ       |
| Coconuts                   | 0.05                   | STMR (CXL) (tentative) | 0.09                   | HR (CXL) (tentative)  |
|                            | 0.01*                  | Scenario 2: LOQ       | 0.01*                  | Scenario 2: LOQ       |
| Table grapes               | 3.05                   | STMR (CXL) (tentative) | 9.2                    | HR (CXL) (tentative)  |
|                            | 0.01*                  | Scenario 2: LOQ       | 0.01*                  | Scenario 2: LOQ       |
| Wine grapes                | 3.05                   | STMR (CXL) (tentative) | 9.2                    | HR (CXL) (tentative)  |
|                            | 0.01*                  | Scenario 2: LOQ       | 0.01*                  | Scenario 2: LOQ       |
| Blueberries                | 4                      | STMR (CXL) (tentative) | 9.9                    | HR (CXL) (tentative)  |
|                            | 0.01*                  | Scenario 2: LOQ       | 0.01*                  | Scenario 2: LOQ       |
| Cranberries                | 0.85                   | STMR (CXL) (tentative) | 0.91                   | HR (CXL) (tentative)  |
|                            | 0.01*                  | Scenario 2: LOQ       | 0.01*                  | Scenario 2: LOQ       |
| Kumquats                   | 0.64                   | STMR (CXL) (tentative) | 1.8                    | HR (CXL) (tentative)  |
|                            | 0.01*                  | Scenario 2: LOQ       | 0.01*                  | Scenario 2: LOQ       |
| Potatoes                   | 0.05                   | STMR (CXL) (tentative) | 0.05                   | HR (CXL) (tentative)  |
|                            | 0.005*                 | Scenario 2: LOQ (EURLs) | 0.005*                 | Scenario 2: LOQ (EURLs) |
| Cotton seeds               | 0.05                   | STMR (CXL) (tentative) | 0.05                   | STMR (CXL) (tentative) |

**STMR:** supervised trial median residue; **PeF:** peeling factor; **HR:** highest residue; **CXL:** Codex maximum residue limit; **LOQ:** limit of quantification; **EURLs:** European Union Reference Laboratories for Pesticide Residues.

*: Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

- GAP or DB > 0.1 mg/kg, DM in EU?
  - Yes: Is RD-RA derived for this commodity?
    - No: MRL And RA derived in Section 3?
      - No: MRL fully supported by data?
        - Yes: Not considered for the RA
        - No: Risk identified?
          - Yes: Tentative median/highest values are included in the RA.
          - No: Median/highest values are included in the RA.
  - Yes: Consumer risk assessment for GAPs evaluated at EU level - EU scenarios

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

- Not considered for the RA
- 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: (A) Specific LOQ or default MRL?
    - No: (B) Specific LOQ or default MRL?
  - No: Fall back MRL available?
    - Yes: (C) Specific LOQ or default MRL?
    - No: (D) Specific LOQ or default MRL?

Recommendations resulting from EU authorisations and import tolerances

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

Comparison with CXLs
## Appendix F – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|----------------------|----------------------------------------|-----------------------|
| **Phosmet**          | $O,O$-dimethyl $S$-phthalimidomethyl phosphorodithioate or $N$-{$([\text{dimethoxyphosphinothioyl]}\text{thio}]\text{methyl})}\text{phthalimide}$ $S=P(OC)(SCN1C(C2 = CC=CC=C2C1 = O) = O)OC$ \text{LMNZTLDVJIUSHT-UHFFFAOYSA-N} | ![Phosmet structural formula](image1) |
| **Phosmet-oxon**     | $S-((1,3$-dioxoisooindolin-2-yl)\text{methyl}) \text{O},\text{O}$-dimethyl phosphorothioate $O=P(OC)(SCN1C(C2 = CC=CC=C2C1 = O) = O)OC$ \text{BEMXOWRVWRNPPL-UHFFFAOYSA-N} | ![Phosmet-oxon structural formula](image2) |
| **Phthalamic acid**  | 2-carbamoylbenzoic acid $OC(=O)c1ccccc1C(N) = O$ \text{CYMRPDYINXWJFU-UHFFFAOYSA-N} | ![Phthalamic acid structural formula](image3) |
| **Phthalic acid**    | phthalic acid $OC(=O)c1ccccc1C(=O)O$ \text{XNGIFLGASWRNHJ-UHFFFAOYSA-N} | ![Phthalic acid structural formula](image4) |

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

(a): The metabolite name in bold is the name used in the conclusion.

(b): ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).

(c): ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).