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REASONED OPINION

Evaluation of confirmatory data following the Article 12 MRL review and modification of the existing maximum residue levels for aluminium phosphide and magnesium phosphide

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Abstract

The applicant Detia Freyberg GmbH submitted to the competent national authority in Germany two requests to evaluate the confirmatory data that were identified for tree nuts, oilseeds, cereals and commodities of animal origin in the framework of the maximum residue level (MRL) review under Article 12 of Regulation (EC) No 396/2005 as not available and two requests in accordance with Article 6 of Regulation (EC) No 396/2005 to increase the existing MRL for the active substance aluminium phosphide in peanuts, barley, oat, rye, rice and wheat, roots of herbal infusions, cocoa beans and seed spices and for the active substance magnesium phosphide in oilseeds (except peanuts) and pistachios. The four applications were combined by EFSA under the current assessment. To address the data gaps, validation data for the method of analysis for enforcement of phosphide in high-oil content commodities and new residue trials were submitted. The data gaps on additional residue trials supporting authorisations on oilseeds and cereal grains, on clarifications regarding the discrepancies observed in the residue trial results for pistachios, and on data confirming the negligible occurrence of phosphane and its oxidation products in livestock products were considered addressed. The data gap on independent laboratory validation (ILV) and a confirmatory method for monitoring of phosphide in high-oil content commodities was considered not fully addressed. The information provided justified a lowering of the current tentative MRLs for the whole group of cereals (except rice and 'others'), an increase of the current tentative MRLs for pistachios, the whole group of oilseeds, rice and 'other' cereals, herbal infusions from roots, cocoa beans and seed spices, and a revision of the risk assessment performed for phosphane and its phosphide salts. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of AlP and Mg_3P_2 according to the reported agricultural practices is unlikely to present a risk to consumer health. Further risk management considerations are required.

KEYWORDS

aluminium phosphide, confirmatory data, magnesium phosphide, MRL review, pesticide, risk assessment

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SUMMARY

In 2015, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for active substance according to Article 12 of Regulation (EC) No 396/2005, EFSA identified data gaps and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1. an ILV and a confirmatory method for monitoring of phosphide in high-oil content commodities;
2. clarifications regarding the discrepancies observed in the residue trial results for pistachios;
3. additional residue trials supporting authorisations on oilseeds and cereal grains;
4. data confirming that occurrence of phosphane and its oxidation products (phosphonic acid in particular) is negligible in livestock products (data gap mainly relevant for large grain cereals which are the main contributors to the livestock dietary burden).

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 2016/1785, including footnotes related to data gaps above indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 8 October 2018.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, Detia Freyberg GmbH submitted two applications to the competent national authority in Germany (evaluating Member State, EMS), in order to address the above confirmatory data requests. The EMS assessed the new information in two separate evaluation reports (one for aluminium phosphide and one for magnesium phosphide, respectively), which were submitted to the European Commission and forwarded to EFSA on 11 September 2020. In addition, the applicant Detia Freyberg GmbH submitted two applications in accordance with Article 6 of Regulation (EC) No 396/2005 to the competent national authority in Germany to modify the existing MRLs for the active substances aluminium phosphide and magnesium phosphide in oilseeds, peanuts, cereals, pistachios, herbal infusions (roots), cocoa beans and seed spices accordingly. Those applications were submitted to the European Commission and forwarded to EFSA on 5 May 2022. Subsequently, the EMS updated the previously mentioned evaluation reports on art.12 Confirmatory data including the new information on intended uses and provided the Authority with two comprehensive evaluation reports for aluminium and magnesium phosphide respectively.

To accommodate for the new intended uses of aluminium phosphide and magnesium phosphide, the EMS proposed to raise the existing MRLs for oilseeds (except peanuts) from 0.05 to 0.4 mg/kg, for peanuts from 0.05 to 1.5 mg/kg, for rice and 'other' cereals from 0.05 to 0.15 mg/kg, for pistachios from 0.1 to 0.2 mg/kg, for herbal infusions (dried roots) from 0.02 to 0.03 mg/kg, for cocoa beans from 0.02 to 0.15 mg/kg, for seed spices from 0.02 to 0.03 mg/kg.

EFSA assessed the applications and the evaluation reports as required by Articles 9 and 10 of the MRL regulation and in accordance with the agreed procedure set out in the working document SANTE/ 10235/2016 for the MRL confirmatory data. For reasons of efficiency, all four applications were assessed in one EFSA output. When assessing the combined evaluation reports, EFSA identified data gaps which needed further clarifications and requested the EMS to address them. On 6 March 2023, the EMS submitted the revised evaluation reports which replaced the previously submitted evaluation reports. Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated in the framework of the art. 12 MRL review, and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

Following the assessment of the confirmatory data, EFSA concluded that data gap number 2, 3 and 4 were sufficiently addressed, whereas data gap number 1 was not addressed.

For the new intended uses of aluminium phosphide on soyabeans, peanuts, sunflower seeds, cotton seeds, rice and 'other' cereals, herbal infusions (dried roots), cocoa beans and seed spices and for the new intended uses of magnesium phosphide on oilseeds and pistachios, EFSA concluded that the submitted residue data are sufficient to derive new MRL proposals, which are higher than the existing tentative MRLs.

Additional residues trials on dried flowers and dried leaves and herbs for herbal infusions, fruit and root and rhizome spices, coffee beans, pulses and tea were submitted by the applicant; however, these additional data were not further assessed as for these commodities neither Article 12 confirmatory data gaps were set, nor MRL application for raising existing MRLs was submitted by the applicant.

Metabolism studies are not available and are not required because relevant residues other than phosphane or its salts are not expected in plant commodities. Thus, for the new intended uses no further data were required, the nature of residues in plants was considered addressed and the risk assessment and enforcement residue definitions derived as 'phosphane and phosphide salts (sum of phosphane and phosphane generators (relevant phosphide salts), determined and expressed as phosphane)' was considered applicable.

As the proposed uses of aluminium phosphide and magnesium phosphide are for post-harvest application, investigations of residues in rotational crops are not required.

For the new uses on oilseeds and rice under consideration, EFSA calculated the livestock dietary burdens according to OECD guidelines (OECD, 2013). The data on cereals supporting existing or adjusted uses and on oilseeds supporting new uses were considered. The calculated dietary burden exceeded the trigger value of 0.1 mg/kg DM and the main contributing commodity was peanut meal. The results of the investigation of residues in animal matrices are affected by uncertainties related to the lack of metabolism and feeding studies with phosphane. However, there are indications from a rat metabolism study that phosphane in mammals is metabolised to phosphonates and phosphines and therefore the MRL

review concluded that livestock metabolism studies are not required. For an indicative estimate of residues of phosphorous compounds in animal matrices, EFSA considered the livestock feeding studies with phosphonic acid and concluded that, at the calculated dietary burdens for phosphane and phosphide salts, residues requiring the modification of the existing MRLs for phosphonic acid in animal commodities are unlikely to occur.

EFSA performed the consumer risk assessment using the revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo) and considering the crops for which the authorised, adjusted and new GAPs were submitted in the current application. EFSA concluded that the proposed use of aluminium phosphide and magnesium phosphide on oilseeds, cereal grains, pistachios, herbal infusions from dried roots, cocoa beans and seed spices will not result in a consumer exposure exceeding the currently established toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EU) No 396/2005.

Code[a]	Commodity	Existing MRL[b]	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/recommendation
Enforcement residue definition both for aluminium phosphide and magnesium phosphide: Phosphane and phosphide salts (sum of phosphane and phosphane generators (relevant phosphide salts), determined and expressed as phosphane)					
0120000 (except 0120100 and 0120990)	Tree nuts (except pistachios and others)	0.09 (ft 1, ft 3)	Footnote related to data gap No 1 [an ILV and a confirmatory method for monitoring of phosphide]	0.01* or 0.09 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide residues was not fully addressed. A risk management decision is required New trials supporting the authorised GAP for AlP and an adjusted GAP for Mg_3P_2 on tree nuts were submitted to address the uncertainties identified by the MRL review related to varying residue levels in tree nuts. The new submitted trials indicate that a higher MRL of 0.2 mg/kg would be required for the whole group of tree nuts, based on the critical data set on Mg_3P_2. However, in the context of the present assessment, raising of the current MRL was not requested for the uses of AlP and Mg_3P_2 on tree nuts (except pistachios) and is therefore not proposed. No risk for consumers identified
0120100	Pistachios	0.1 (ft 2)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 2 [clarifications regarding the discrepancies observed in the residue trial results for pistachios]	0.01* or 0.2 (further risk management decision required)	The data gaps identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning clarifications regarding the discrepancies observed in the residue trial results for pistachios (data gap No 2) can be considered addressed New trials supporting the new GAP for Mg_3P_2 on pistachios indicate that a higher EU MRL is required for which no risk for consumers identified
0401010	Linseeds	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the adjusted GAP for AlP and the new GAP for Mg_3P_2 on linseeds are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on Mg_3P_2. No risk for consumers identified

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Code[a]	Commodity	Existing MRL[b]	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/recommendation
0401020	Peanuts/ groundnuts	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 1.5 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of AlP and Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the new GAPs for AlP and Mg_3P_2 on peanuts are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified
0401030 0401040	Poppy seeds Sesame seeds	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the authorised GAP for AlP and the new GAP for Mg_3P_2 are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified
0401050	Sunflower seeds	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of AlP and Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the new GAPs for AlP and Mg_3P_2 in sunflower seeds are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified
0401060	Rapeseeds/ canola seeds	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of Mg_3P_2. A risk management decision is required. The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed. A sufficient number of trials supporting the authorised GAP for AlP and the new GAP for Mg_3P_2 are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified

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Code[a]	Commodity	Existing MRL[b]	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/recommendation
0401070	Soyabeans	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of AlP and Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the new GAPs for AlP and Mg_3P_2 on soyabeans are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on Mg_3P_2. No risk for consumers identified
0401080	Mustard seeds	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the authorised GAP for AlP and the new GAP for Mg_3P_2 are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified
0401090	Cotton seeds	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of AlP and Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the new GAPs for AlP and Mg_3P_2 in cotton seeds are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified

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Code[a]	Commodity	Existing MRL[b]	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/recommendation
0401100 0401110 0401120 0401130 0401140 0401150	Pumpkin seeds Safflower seeds Borage seeds Gold of pleasure seeds Hemp seeds Castor beans	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of Mg_3P_2. A risk management decision is required. The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed. A sufficient number of trials supporting the authorised GAP for AIP and the new GAP for Mg_3P_2 available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AIP. No risk for consumers identified
0401990	Other oilseeds	0.05		0.01* or 0.3 (further risk management decision required)	MRL proposal based on the critical data set on AIP on minor oilseeds. No risk for consumers identified ILV of the analytical method for enforcement in high-oil content commodities is not available. A risk management decision is required
0500010	Barley	0.05 (ft 5)	Footnote related to data gap No 3. [residue trials supporting authorisations on oilseeds and cereal grains]	0.02	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AIP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on Mg_3P_2. No risk for consumers identified
0500020	Buckwheat and other pseudo-cereals	0.7 (ft 5)	Footnote related to data gap No 3. [residue trials supporting authorisations on oilseeds and cereal grains]	0.15	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AIP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AIP. No risk for consumers identified
0500030	Maize/corn	0.7 (ft 5)	Footnote related to data gap No 3. [residue trials supporting authorisations on oilseeds and cereal grains]	0.2	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AIP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AIP. No risk for consumers identified
0500040	Common millet/proso millet	0.7 (ft 5)	Footnote related to data gap No 3. [residue trials supporting authorisations on oilseeds and cereal grains]	0.15	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AIP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AIP. No risk for consumers identified

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Code[a]	Commodity	Existing MRL[b]	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/recommendation
0500050	Oat	0.05 (ft 5)	Footnote related to data gap No 3. [residue trials supporting authorisations on oilseeds and cereal grains]	0.02	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AlP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on Mg_3P_2. No risk for consumers identified
0500060	Rice	0.05 (ft 5)	Footnote related to data gap No 3. [residue trials supporting authorisations on oilseeds and cereal grains]	0.15	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the new GAP for AlP and the adjusted GAP for Mg_3P_2 in rice are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified
0500070	Rye	0.05 (ft 5)	Footnote related to data gap No 3. [residue trials supporting authorisations on oilseeds and cereal grains]	0.02	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AlP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on Mg_3P_2. No risk for consumers identified
0500080	Sorghum	0.7 (ft 5)	Footnote related to data gap No 3. [residue trials supporting authorisations on oilseeds and cereal grains]	0.15	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AlP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified
0500090	Wheat	0.05 (ft 5)	Footnote related to data gap No 3. [residue trials supporting authorisations on oilseeds and cereal grains]	0.02	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AlP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on Mg_3P_2. No risk for consumers identified
0500990	Other cereals	0.01*		0.15	MRL proposal based on the critical data set on AlP in support of the new GAP on rice and other cereal grains. No risk for consumers identified
0633000	Herbal infusions (dried roots)	0.02		0.03	The submitted data are sufficient to derive an MRL proposal for the post-harvest use. Risk for consumers unlikely
0640000	Cocoa beans	0.02		0.15	The submitted data are sufficient to derive an MRL proposal for the post-harvest use. Risk for consumers unlikely
0810000	Spices (seeds)	0.02		0.03	The submitted data are sufficient to derive an MRL proposal for the post-harvest use. Risk for consumers unlikely

Code[a]	Commodity	Existing MRL[b]	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/recommendation
1000000	Products of animal origin - terrestrial animals	0.01 (ft 6)	Footnote related to data gap No 4. [data confirming that occurrence of phosphane and its oxidation products is negligible in livestock products]	0.01*	The data gap identified by EFSA concerning the occurrence of phosphane and its oxidation products in commodities of animal origin is considered addressed

Abbreviations: GAP, Good Agricultural Practice; ILV, independent laboratory validation; MRL, maximum residue level.

*Indicates that the MRL is set at the limit of analytical quantification (LOQ).

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]Existing EU MRL and corresponding footnote on confirmatory data.

[ft 1]The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1).

[ft 2]The European Food Safety Authority identified some information on analytical methods and clarifications regarding residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gaps No 1 and 2).

[ft 3]The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1).

[ft 4]The European Food Safety Authority identified some information on analytical methods and residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1 and 3).

[ft 5]The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 3).

[ft 6]The European Food Safety Authority identified some information on the occurrence of phosphane and its oxidation products in commodities of animal origin as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 4).

ASSESSMENT

The European Food Safety Authority (EFSA) received four applications to evaluate the confirmatory data that were identified for phosphane and phosphide salts in the framework of the maximum residue level (MRL) review under Article 12 of Regulation (EC) No 396/2005 as not available, and to raise the existing MRLs for the active substances aluminium phosphide and magnesium phosphide in oilseeds, cereals, pistachios, herbal infusions from dried roots, cocoa beans and seed spices.

The detailed description of the intended uses of aluminium phosphide (AlP) and magnesium phosphide (Mg_3P_2) and the uses assessed in the framework of the MRL review that were not fully supported by data and for which confirmatory data were requested is listed in Appendix A.

There are no ISO common names for the active substances under assessment because they were all named in accordance with the IUPAC nomenclature. It is noted however that phosphane was previously referred to as phosphine (former IUPAC name). The chemical structure of the active substance and its main metabolites are reported in Appendix E.

Aluminium phosphide and magnesium phosphide were evaluated in the framework of Directive 91/414/EEC[1] with Germany designated as (rapporteur Member State, RMS) for the representative uses as rodenticide, talpicide and leporicide to control rodent and non-rodent vertebrates by fumigation of underground tunnels and burrows in cropland and non-cropland situations, and as a fumigant to control insects in various harvested plant products and in empty warehouses or transportation facilities. The draft assessment reports (DARs) prepared by the RMS have been peer reviewed by EFSA (EFSA, 2008a, 2008c). Following the peer review, a decision on inclusion of the two active substances in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2008/125/EC,[2] which entered into force on 1 September 2009. According to Regulation (EU) No 540/2011,[3] the two substances are also deemed to have been approved under Regulation (EC) No 1107/2009.[4] These approvals are restricted to ready-to-use products as insecticide, rodenticide (only outdoor use), talpicide (only outdoor use) and leporicide (only outdoor use). In addition, authorisations should be limited to professional users.

The EU MRLs for phosphines and phosphides were set in Part A of Annex III to Regulation (EC) No 396/2005.[5] The review of existing MRLs for aluminium phosphide and magnesium phosphide according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2015). EFSA identified some data gaps and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified. The following data gaps were identified by EFSA:

1. an ILV and a confirmatory method for monitoring of phosphide in high-oil content commodities;
2. clarifications regarding the discrepancies observed in the residue trial results for pistachios;
3. additional residue trials supporting authorisations on oilseeds and cereal grains;
4. data confirming that occurrence of phosphane and its oxidation products (phosphonic acid in particular) is negligible in livestock products (data gap mainly relevant for large grain cereals which are the main contributors to the livestock dietary burden).

The MRL modifications proposed following the MRL review have been implemented in the MRL legislation by Commission Regulation (EU) No 2016/1785,[6] including footnotes implementing the data gaps identified by EFSA (1), (2), (3) and (4) as confirmatory data requirements. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 8 October 2018.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016 (European Commission, 2020a), Detia Freyberg GmbH submitted two applications to the competent national authority in Germany (evaluating Member State, EMS), in order to address the above confirmatory data requests. The EMS assessed the new information in two separate evaluation reports (one for aluminium phosphide and one for magnesium phosphide respectively), which were submitted to the European Commission and forwarded to EFSA on 11 September 2020. In addition, the applicant Detia Freyberg GmbH submitted two applications in accordance with Article 6 of Regulation (EC) No 396/2005 to the competent national authority in Germany to modify the existing MRLs for the active substances aluminium phosphide and magnesium phosphide in oilseeds, peanuts, cereals, pistachios, herbal infusions (roots), cocoa beans and seed spices accordingly. Those applications were submitted to the European Commission and forwarded to EFSA on 5 May 2022. Subsequently, the EMS updated the previously mentioned evaluation reports on art.12 Confirmatory data including the

[1]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.

[2]Commission Directive 2008/125/EC of 19 December 2008 amending Council Directive 91/414/EEC to include aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole and triadimenol as active substances. OJ L 344, 20.12.2008, p. 78–88.

[3]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.

[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]Regulation (EC) No 396/2005 of the 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.

[6]Commission Regulation (EU) 2016/1785 of 7 October 2016 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 cymoxanil, phosphane and phosphide salts and sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate in or on certain products.

new information on intended uses and provided the Authority with two comprehensive evaluation reports for aluminium and magnesium phosphide respectively (Germany, 2020a, 2020b).

To accommodate for the intended uses of aluminium phosphides and magnesium phosphides, the EMS proposed to raise the existing MRLs for oilseeds (except peanuts) from 0.05 to 0.4 mg/kg, for peanuts from 0.05 to 1.5 mg/kg, for rice from 0.05 to 0.15 mg/kg, for pistachios from 0.1 to 0.2 mg/kg, for herbal infusions (dried roots) from 0.02 to 0.03 mg/kg, for cocoa beans from 0.02 to 0.15 mg/kg, for seed spices from 0.02 to 0.03 mg/kg. Additional residues trials on dried flowers and dried leaves and herbs for herbal infusions, fruit and root and rhizome spices, coffee beans, pulses and tea were also submitted by the applicant; however, these additional data were not further assessed as for these commodities neither Article 12 confirmatory data gaps were set, nor MRL application for raising existing MRLs was submitted by the applicant.

EFSA assessed applications and the evaluation reports as required by Articles 9 and 10 of the MRL regulation and in accordance with the agreed procedure set out in the working document SANTE/ 10235/2016 for the MRL confirmatory data. For reasons of efficiency, all four applications were assessed in one EFSA output. When assessing the combined evaluation reports, EFSA identified data gaps which needed further clarifications and requested the EMS to address them. On 6 March 2023, the EMS submitted the revised evaluation reports which replaced the previously submitted evaluation reports.

EFSA based its assessment on the evaluation reports submitted by the EMS Germany (2020a, 2020b[7]), DAR (and its addenda) (Germany, 2007a, 2007b, 2008a, 2008b) prepared under Council Directive 91/414/EEC, the Commission review reports on aluminium and magnesium phosphides (European Commission, 2008), EFSA conclusions on the peer review of the pesticide risk assessment of the active substance aluminium and magnesium phosphides (EFSA, 2008a, 2008c), as well as the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2015).

For these applications, the data requirements established in Regulation (EU) No 544/2011[8] and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 2016/1785 are applicable (European Commission, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.[9]

A detailed description of the good agricultural practices (GAPs) for the uses of aluminium phosphide and magnesium phosphide, which are relevant for the current confirmatory data evaluation, is reported in Appendix A.

An updated list of end points, including the end points of relevant studies assessed previously and the confirmatory data evaluated in this application, is presented in Appendix A.

The evaluation reports submitted by the EMS (Germany, 2020a, 2020b) are considered the supporting documents to this reasoned opinion and, thus, are made publicly available as the background documents to this reasoned opinion.[10]

1 | RESIDUES IN PLANTS

1.1 | Nature of residues and methods of analysis in plants

1.1.1 | Nature of residues in primary crops

Not relevant for the assessment of Article 12 confirmatory data.

Metabolism studies are not available and are not required because relevant residues other than phosphane or its salts are not expected in plant commodities (EFSA, 2015). Thus, for the new intended uses no further data are required and the nature of residues is considered addressed.

1.1.2 | Nature of residues in rotational crops

Not relevant for the assessment of Article 12 confirmatory data.

Metabolism studies in rotational crops are not available and are not required for the new intended post-harvest uses.

[7]It is noted that the evaluation reports submitted in support of the application covered not only the confirmatory data but also contained the assessment of data submitted in support of the requests for modification of MRLs for aluminium and magnesium phosphides in various crops (EFSA-Q-2022-00302 and EFSA-Q-2022-00303); these MRL applications are assessed in the present reasoned opinion.

[8]Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

[9]Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

[10]Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following links:
https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00302
https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00303
https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00607
https://open.efsa.europa.eu/study-inventory/EFSA-Q-2022-00608

1.1.3 | Nature of residues in processed commodities

Not relevant for the assessment of Article 12 confirmatory data.

Studies investigating nature of residues in processed commodities are not available and are not required because relevant residues other than phosphane or its salts are not expected in processed commodities (EFSA, 2015). Thus, for the new intended uses no further data are required and the nature of residues in processed commodities is considered addressed.

1.1.4 | Methods of analysis in plants

In the Article 12 MRL review the analytical method using gas chromatography with nitrogen/phosphorous detector (GC–NPD), was evaluated and validated for the determination of phosphane in high-oil content commodities (shell fruit) with a limit of quantification (LOQ) of 0.01 mg/kg (EFSA, 2015), but an independent laboratory validation (ILV) and a confirmatory method were not reported for this crop group. Consequently, as an outcome of the MRL review, a **data gap number 1**[11] was implemented in the MRL legislation for MRLs in oilseeds and tree nuts.

In order to address data gap number 1, the applicant provided validation data for a method that has not been previously assessed at the EU level and where residues of phosphane were determined using gas chromatography with flame photometric detector (GC–FPD) in butter biscuits, potato chips, tobacco, powdered egg, dry cured ham and fat (Germany, 2020a, 2020b). The method was sufficiently validated for the determination of phosphane residues in all these matrices at the LOQ of 0.005 mg/kg. For this method, the ILV was also provided where residues of phosphane were determined in butter biscuits, dried tobacco, dried cured ham and fat. The determination was performed with GC–NPD, the validated LOQ was 0.005 mg/kg. The EMS concluded that the Article 12 confirmatory data gap for ILV and confirmatory method in high-oil content plant matrices is addressed.

EFSA, however, is of the opinion that the data gap number 1 is **not fully addressed** with regard to the requirement for the ILV, because the ILV has not been performed for plant matrices of high-oil content. The processed commodities analysed, except tobacco, are of animal origin, considering the origin of fat. Despite the fact that successful validation was achieved in complex matrices, the ILV does not fulfil the requirements of the Guidance document SANCO/2020/12830, rev.1 on pesticide analytical methods for risk assessment and post-approval control and monitoring purposes (European Commission, 2021) regarding matrix groups.

Regarding the confirmatory method, EFSA considers the data gap addressed as the method provided under the present assessment uses alternative detector (GC–FPD) than the detector used in the method assessed by the MRL review (GC–NPD) for the determination of phosphane residues in high-oil content plant matrices. The method validation data provided for potato chips can be considered as representative in this case for high-oil content plant matrices.

EFSA concludes that data gap number 1 identified in the framework of the MRL review is **not fully addressed**. EFSA notes that for the new intended uses of magnesium phosphide on oilseeds and pistachios and the new intended uses of aluminium phosphide in soyabeans, peanuts, sunflower seeds and cotton seeds, the data gap on the lack of ILV and confirmatory methods remains valid.

Information on the extraction efficiency of the analytical methods applied for the enforcement of residues in the commodities under assessment[12] is not available and was not required. It is indeed noted that the extraction efficiency of the analytical methods cannot be investigated according to the EU Technical Guideline (European Commission, 2017), considering that metabolism studies on primary crops are not available.

1.1.5 | Stability of residues in plants

Studies investigating the freezer storage stability of phosphane and/or its salts are not available. Provided that treated samples are analysed within 48 hours of sampling or stored under liquid nitrogen for a few days, the storage stability studies are not required (EFSA, 2015). Since this is the case for the studies submitted for the present assessment, further data on freezer storage stability are not required.

1.1.6 | Proposed residue definitions

The previously derived residue definitions are still applicable. Residue definition for risk assessment and enforcement is established as 'sum of phosphane and phosphane generators (relevant phosphide salts), determined and expressed as phosphane' (EFSA, 2015). The same residue definition has been enforced in Regulation (EC) 396/2005.

[11]The data gap refers to the submission of an ILV and a confirmatory method for monitoring of phosphane in high-oil content commodities.

[12]Relevant only for the commodities for which the raising of the existing EU MRL is requested.

1.2 | Magnitude of residues in plants

In the framework of the MRL review (EFSA, 2015), lack of clarifications regarding residue trials on pistachios (**data gap number 2**[13]) and lack of trials on oilseeds and cereals (**data gap number 3**[14]) were identified. Therefore, for these commodities, a tentative MRL was set with the footnotes specifying 'clarifications regarding residue trials as unavailable' (for pistachios) and 'residue trials as unavailable' (for oilseeds and cereals).

In the context of the present application, the applicant provided new residue trials performed on pistachios, sunflower seeds, peanuts, soyabeans, wheat, maize and rice, in support of new and adjusted GAPs. New trials on hazelnuts and walnuts were also provided in support of the authorised GAP for AlP and an adjusted GAP for Mg_3P_2 on tree nuts except pistachios to further investigate the varying residue levels of phosphane among treated tree nuts. In addition, new trials on liquorice, cocoa beans and coriander were submitted to support the new intended GAPs for herbal infusions (dried roots), cocoa beans and seed spices.

Despite a request to modify the MRL on herbal infusions (dried flowers and dried leaves), pulses, tea, coffee beans and spices (fruits, root and rhizome) was not included in the application form, residue data were submitted for these commodities. The data confirm the existing MRLs for herbal infusions (dried flowers and dried leaves), pulses, tea and coffee beans. As regards to spices (fruits, roots and rhizomes), residue data on coriander and liquorice provide indication that a higher MRL may be needed for these groups of commodities. As the proposal of an MRL modification in spices (fruits, root and rhizome) was not in the scope of the current assessment, no MRL modification was proposed by EFSA. Should the applicant wish to request an MRL modification for these commodities, a new application should be submitted.

Fumigation experiments were conducted in tightly closed and gastight containers. All trials are considered independent. The samples of the residue trials were analysed on the day of sampling (tree nuts, oilseeds, cereals) or stored under liquid nitrogen for maximum 48 h before being analysed (cereals).

The methods used in the analysis of samples in the context of the residue trials are based on GC-FPD and GC-NPD. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Germany, 2020a, 2020b). However, the methods were only validated for dried tobacco, butter biscuits, dry cured ham, cattle fat (GC-FPD and GC-NPD), potato chips and powdered eggs (GC-FPD), not representing all plant matrices under consideration. Validation data for dried tobacco is considered sufficiently representative for difficult to analyse matrices under consideration: cocoa beans, roots of herbal infusions and seed spices. For remaining matrices of high-oil content (tree nuts and oilseeds) and dry commodities (cereals), according to EFSA, these methods cannot be considered to fulfil requirements of the EU Guidance document SANTE/2020/12830 (European Commission, 2021). However, considering that EMS recognised these methods to be fully validated and noting that these methods were validated in a wide range of complex matrices demonstrating a good performance, EFSA did not disregard the submitted residue trials and accepted them as valid to assess the magnitude of phosphane residues in the commodities under consideration.

Information on extraction efficiency of the analytical methods used for data generation for crops for which the raising of the MRL is proposed is not available. It is indeed noted that extraction efficiency of the analytical methods cannot be investigated according to the EU Technical Guideline (European Commission, 2017), considering that metabolism studies on primary crops are not available.

The residue data from the supervised residue trials in primary crops are summarised in **Appendix B.1.2**.

Pistachios

For pistachios the applicant reported new intended use of magnesium phosphide as well as provided data to address the data gap identified in the MRL review (data gap number 2) related to clarifications regarding discrepancies observed for pistachios in the residue trials (i.e. trials on pistachios performed at lower application rates resulting in higher residue levels after treatment). The existing tentative MRL of 0.1 mg/kg has been derived from underdosed residue trials supporting the authorised GAP of magnesium phosphide.

In order to address the **data gap number 2**, the applicant submitted the following information:

- for aluminium phosphide: adjusted GAP on pistachios, two new trials on pistachios (treated with half-opened shell);
- for magnesium phosphide: new GAP on pistachios, four new trials on pistachios (treated with half-opened shell).

The MRL proposal was separately derived based on the critical data set on Mg_3P_2 or AlP.

Aluminium phosphide

MRL review GAP (post-harvest, indoor): 1 × 3–11 g/m^3, 35 days WHP, 5–14 days treatment, ventilation until concentration PH_3 < 0.01 ppm

Adjusted GAP (post-harvest, indoor): 1 × 10 g/m^3, 21 days WHP

[13]The data gap number 2 refers to the submission of 'clarifications regarding residue trials'.

[14]The data gap number 3 refers to the submission of 'additional residue trials supporting authorisations on oilseeds and cereal grains'.

The applicant provided the same residue trials on pistachios (four) which were assessed in the MRL review. The trials are compliant with the adjusted GAP. The trials consisted of one post-harvest treatment at an application rate of 10 g PH_3/m^3 during a 14-day fumigation period and a 2-h ventilation period. Pistachios were treated with half-opened shell and residues were measured in the commodity after removal of shell. Residues were measured 0, 3, 7, 14 and 21 days after the treatment, corresponding to the withholding period (WHP). Residues were not measured at longer WHPs; however, considering that decline of residues was observed across all sampling points, the lack of measurement at longer WHPs than in the adjusted GAP is considered only a minor deviation.

Two additional trials were submitted in the current application; these were performed with a shorter WHP of 14 days. Residues were measured below the LOQ of 0.05 mg/kg, however, as no information on residue levels at shorter or longer WHP is available (i.e. residues were only measured at 0 and 14 days after treatment (DAT)), no indication of residue decline was available to justify the lack of measurement performed at the intended WHP. These trials were therefore disregarded by EFSA.

Residues of phosphane in pistachio nuts from GAP-compliant trials ranged between < 0.005 (LOQ) and 0.006 mg/kg. The submitted data are sufficient to derive an MRL of 0.015 mg/kg for phosphane and phosphide salts in pistachios, according to the adjusted GAP of aluminium phosphide in pistachios. The MRL proposal derived by EFSA differs from the MRL derived by the EMS (i.e. 0.01 mg/kg), the latter being derived based on the pistachios data set including the two non-GAP-compliant trials.

Magnesium phosphide

MRL review GAP (post-harvest, indoor): 1 × 3–11 g/m^3, 35 days WHP, 5–14 days treatment, ventilation until concentration PH_3 < 0.01 ppm

New GAP (post-harvest, indoor): 1 × 5.5 g/m^3, 21 days WHP

The applicant provided the same residue trials on pistachios (4) which were assessed in the MRL review to derive a tentative MRL of 0.1 mg/kg (underdosed trials). The trials are now compliant with the new GAP in terms of application rate and withholding period. The trials consisted of one post-harvest treatment at an application rate of 5.5 g PH_3/m^3 during a 2.5-day fumigation period and a 24-h ventilation period. Pistachios were treated without shell. The trials were designed as decline trials. Residues were measured before the treatment, 0, 7, 21 (corresponding to withholding period (WHP)), 28, 35, 42, 49 and, in some trials, 56, 63 and 70 days after the treatment. Decline of residues after the WHP of 21 days was observed. At the WHP of 21 days, residues ranged between 0.038 and 0.099 mg PH_3/kg.

Four additional trials compliant with the new GAP were submitted in the current application. The trials consisted of one post-harvest treatment at an application rate of 5.5 g PH_3/m^3 during a 5-day fumigation period, and a 30-min ventilation period. Pistachios were treated with half-opened shell and residues were measured in the commodity after removal of shell. Residues were measured 0, 3, 7, 14 and 21 (corresponding to WHP) days after the treatment. Residues were not measured at longer WHPs; however, as decline of residues was observed across all sampling points, the lack of residue measurement after the intended WHP was only considered a minor deficiency. In all trials, residues were measured below the LOQ of 0.005 mg PH_3/kg.

During the assessment EFSA noted that there is a difference in the treatment patterns in trials reported for the MRL review and in the trials submitted under present assessment related to the duration of treatment (2.5 days vs. 5 days, respectively) and the state of the commodity (without shell vs. half-opened shell). Since the MRL review considered the only discrepancy with the authorised GAP being the application rate and the WHP, EFSA did not question the effect of shorter treatment period on the magnitude of phosphane residues.

In the context of the current application, the applicant and the EMS confirmed that the trials resulting in higher residue levels after treatment were performed on pistachios without shell. This is in contrast with the consideration of the MRL review that residues in nuts without shell are expected to be lower than residue levels in nuts with shell. The EMS suggested that the observed divergencies in the residue data populations for pistachios may be due to the different designs used for the trials (differences in duration of the treatment, ventilation period, packaging type). However, considering that the trials resulting in the highest residue levels at WHP of 21 days were performed on pistachios without shell in closed paper boxes (same packaging type as for other trials on pistachios treated with half-opened shell performed with magnesium phosphide and aluminium phosphide), at an application rate of 5.5 g PH_3/kg (same application rate as for the trials on pistachios treated with half-opened shell performed with magnesium phosphide and lower application compared to 10 g/m^3 of the trials on pistachios treated with half-opened shell performed with aluminium phosphide), during a lower treatment period of 2.5 days (compared to 5- and 14-day fumigation period of the other trials performed with magnesium phosphide and aluminium phosphide, respectively), and with a higher ventilation period of 24 h (compared to 30 min and 2 h of the other trials performed with magnesium phosphide and aluminium phosphide, respectively), EFSA does not consider the reasoning provided by the EMS sufficient to justify the discrepancies observed in the trials. The residue trials submitted for the MRL review and under the present assessment on magnesium phosphide are considered similar regarding treatment patterns and provide indication that in case of pistachios the main parameter affecting the magnitude of residues seems to be the state of the crop undergoing the treatment, i.e. nut without shell or nut with half-opened shell.

Based on the consideration above, EFSA concluded that the data **gap number 2** identified in the framework of the MRL review **is addressed**.

Considering that the MRL estimated from residue data on pistachios treated without shell and pistachios treated with half-opened shell belong to two distinctive MRL classes (0.01* and 0.2 mg/kg), the data were not merged to derive an overall MRL for pistachios. Based on the critical data set on pistachios treated with half-opened shell, an MRL of 0.2 mg/kg was derived for phosphane and phosphide salts in pistachios, following the new intended uses of magnesium phosphide.

Overall, the MRL of 0.2 mg/kg is proposed for phosphane and phosphide salts in pistachios, based on the critical data set on magnesium phosphide. This MRL proposal is higher than the current tentative MRL of 0.1 mg/kg and supports the proposal of the applicant.

Tree nuts, except pistachios

For tree nuts other than pistachios, the applicant has not reported new intended GAPs. In the MRL review the only data gap identified for the tentative MRL of 0.09 mg/kg was related to some information on analytical methods as unavailable (see section 1.1.4).

In the context of the current application, the applicant submitted the following information, intended to provide further clarifications on varying residue levels of phosphane observed in tree nuts treated in various forms:

- for aluminium phosphide: four new trials on hazelnuts (treated with shell), four new trials on walnuts (treated with shell), two new trials on pistachios (treated with half-opened shell; same trials as reported for the GAP on pistachios, see above);
- for magnesium phosphide: adjusted GAPs on the whole group of tree nuts except pistachios, eight new trials on hazelnuts (four treated with shell and four treated without shell), four new trials on walnuts (treated with shell), four new trials on pistachios (treated with half-opened shell; same trials as reported for the GAP on pistachios, see above).

Tree nuts were treated either in their form with shell or after removal of this protective layer (i.e. nutmeat is directly treated). Fumigation experiments were run on all forms, i.e. on nuts with shell, removed shell, and in-between (semi-)open shell, simulating the full pattern of real-life conditions.

Aluminium phosphide

MRL review GAP (post-harvest, indoor) (still relevant): 1 × 3–11 g PH_3/m^3, 21 days WHP, 5–14 days treatment, ventilation until concentration PH_3 < 0.01 ppm

The applicant provided the same residue trials on hazelnuts (four; treated as nutmeat) and pistachios (four, treated when shell half-open) as submitted for the MRL review. Additionally, 10 new trials on hazelnuts (four), walnuts (four) and pistachios (two) were submitted. As described in the section above, the two new trials on pistachios were performed with a shorter WHP of 14 days and were therefore not considered further by EFSA. The four new trials on hazelnuts and the four new trials on walnuts are GAP-compliant; these consisted of one post-harvest treatment at an application rate of 10 g PH_3/m^3 during a 14-day fumigation period, and around 3-hour ventilation period. Hazelnuts and walnuts were treated with shell and residues were measured in the commodities after removal of shell. Residues were measured 0, 3, 7, 14 and 21 (corresponding to WHP) days after the treatment. Residues were not measured at longer WHPs. However, decline of residues across the sampling points was observed in all trials on walnuts (with residue levels reaching < 0.005 mg/kg at WHP 21 days) and in half of the trials on hazelnuts (with residue levels reaching 0.005 to 0.006 mg PH_3/kg at WHP 21 days). In the two remaining trials on hazelnuts, an increase of residue levels at WHP 21 days compared to the previous sampling points was observed, but a consistent trend of residue increase was not observed (i.e. F1 container 2: < 0.005 [day −0], 0.024 [day 0], 0.026 [day 3], 0.022 [day 7], 0.015 [day 14], 0.033 [day 21]; F1 container 4: < 0.005 [day −0], 0.083 [day 0], 0.028 [day 3], 0.017 [day 7], 0.006 [day 14], 0.014 [day 21]).

The residue data indicate that when hazelnuts were treated with shell, the residues in nutmeat ranged from < 0.005 to 0.033 mg/kg, whereas in walnut kernels, when nut was treated with shell, the residues in all four samples were below the LOQ of 0.005 mg/kg. In the trials submitted for the MRL review where hazelnut were treated without shell residues ranged from 0.013 to 0.019 mg/kg. This could be explained by a different penetration of residues in the kernel (structure of shell, size, etc.).

The EMS proposed to:

1. derive a common MRL of 0.05 mg/kg for the whole group of tree nuts (including pistachios), based on the combined data set on hazelnuts and walnuts treated with shell. Such an extrapolation is not acceptable according to the EU Technical Guidelines (European Commission, 2020a).
2. alternatively, to merge residue trials on hazelnuts (treated without shell) and pistachios (treated with half-opened shell) and to derive an overall MRL of 0.04 mg/kg for tree nuts. This extrapolation is also not in line with the requirement in the EU Technical Guidelines SANTE 2019/12752 (European Commission, 2020a) to only use data on hazelnuts and/or pistachios without shell to derive MRLs for the whole group of tree nuts.
3. set a separate MRL in hazelnuts, considering higher levels of residues measured in this commodity. Separate MRL proposals of 0.05 and 0.07 mg/kg were derived based on the available trials on hazelnuts treated without shell and hazelnuts treated with shell, respectively.

EFSA notes that, in principle, additional trials on pistachios, brazil nuts or cashew nuts treated without shell would be required to supplement the available residue data set on hazelnuts (treated without shell) to sufficiently support extrapolation of residue data to the whole group of tree nuts. In the absence of such data and considering wide differences in measured residue levels among various nuts treated at various states (shelled, unshelled, semi-open shelled), EFSA considered the EMS proposal to use the data on half-open pistachios together with data on hazelnuts (treated without shell) to accommodate for the intended use pattern on tree nuts. Based on the combined data set on hazelnuts treated without shell and pistachios treated with half-opened shell, an MRL of 0.04 mg/kg for phosphane and phosphide salts would be sufficient for the whole group of tree nuts (lower than the existing tentative EU MRL), except pistachios and hazelnuts. For hazelnuts an MRL proposal of 0.05 mg/kg is estimated based on the combined data sets on hazelnuts treated with and without shell, which belong to the same statistical population. It is noted that for pistachios a higher MRL of 0.2 mg/kg is proposed on the basis of new GAP notified for magnesium phosphide.

Magnesium phosphide

MRL review GAP (post-harvest, indoor): 1 × 3–11 g PH_3/m^3, 21 days WHP, 5–14 days treatment, ventilation until concentration PH_3 < 0.01 ppm

Adjusted GAP (post-harvest, indoor): 1 × 5.5 g PH_3/m^3, 21 days WHP

The applicant provided the same residue trials on pistachios (treated without shell [four]) as submitted for the MRL review. Residue levels measured at the WHP of 21 days were selected. These trials are described in the relevant section on pistachios (above).

Sixteen new GAP-compliant trials on hazelnuts (treated with shell (four) and treated without shell (four)), pistachios (treated with half-opened shell (four)) and walnuts (treated with shell (four)) were submitted in the current application.

The new trials on pistachios (treated with half-opened shell) are described in the relevant section on pistachios (above).

The trials on hazelnuts treated with shell consisted of one post-harvest treatment at an application rate of 5.5 g PH_3/m^3 during a 2.5-day fumigation period, and a 24-h ventilation period. The residues were measured in the commodities after removal of shell. Residues were designed as decline trials, with residues measured 0, 7, 21 (corresponding to WHP), 28, 35 and, in some cases, 42, 49, 56 days after the treatment. Decline of residues was observed in all trials. The residues in hazelnuts treated with shell ranged from 0.011 to 0.045 mg/kg.

The trials on hazelnuts treated without shell consisted of one post-harvest treatment at an application rate of 5.5 g PH_3/m^3 during a 5-day fumigation period, and a 30-min ventilation period. Residues were not designed as decline trials. Residues were measured 0, 3, 7, 14 and 21 (corresponding to WHP) days after the treatment. Decline of residues was observed in all trials except one, where a minor fluctuation was observed (i.e. F1 container 3: 0.75 (day 0), 0.13 (day 3), 0.18 (day 7), 0.007 (day 14), 0.010 (day 21)). However this was only considered a minor deviation. The residues in hazelnuts treated without shell ranged from < 0.005 (LOQ) to 0.010 mg/kg. Overall, the presence of the shell in hazelnuts seems to play a significant role in the residues detected, even if not all conditions in these trials were comparable.

The trials on walnuts consisted of one post-harvest treatment at an application rate of 5.5 g PH_3/m^3 during a 5-day fumigation period, and a 3.5-h ventilation period. Walnuts were treated with shell and residues were measured in the commodities after removal of shell. Residues were not designed as decline trials. Residues were measured before the treatment, 0, 3, 7, 14 and 21 (corresponding to WHP) days after the treatment. Decline of residues was observed in all trials except one, where a minor fluctuation was observed (i.e. container 4: 0.51 (day 0), 0.009 (day 3), 0.005 (day 7), 0.006 (day 14), 0.008 (day 21)). However this was only considered a minor deviation. The residues in walnuts ranged between < 0.005 (LOQ) and 0.008 mg/kg.

It is noted that diverging residue data are available for hazelnuts treated with or without shell. This may be explained by a slow migration of phosphane through the shell during the treatment. After treatment this trapped residue will also require more time to be again released in the atmosphere.

Based on the more critical dataset on hazelnuts (i.e. hazelnuts treated with shell), an MRL of 0.09 mg/kg is derived for this commodity, which confirms the existing tentative EU MRL in hazelnuts.

The EMS derived an MRL of 0.09 mg/kg for the whole group of tree nuts (except pistachios), via extrapolation from the hazelnuts treated with shell data set. Such an extrapolation is not acceptable according to the EU Technical Guidelines SANTE/2019/12752 (European Commission, 2020a) which states that trials on hazelnuts should be combined with trials on brazil nuts, cashew nuts and/or pistachios to allow extrapolation to the whole group of tree nuts, provided that only data on the commodity treated without shell are selected for the extrapolation (footnote 4 of SANTE/2019/12752). A combined residue data set on pistachios (treated without shell) and hazelnuts (treated without shell) is available, indicating that an MRL of 0.2 mg/kg would be required for the whole group of tree nuts to accommodate the reported adjusted GAP on magnesium phosphide. The derived MRL is higher than the existing EU MRL for tree nuts. It is noted that new residue data on nuts supporting the adjusted GAP of magnesium phosphide were submitted with a remit to address uncertainties identified by the MRL review related to varying residue levels in tree nuts and not to propose raising of the existing MRL in tree nuts (except pistachios). In the context of the present assessment new MRL is therefore not proposed for the reported use of magnesium phosphide on tree nuts (except pistachios). Should the applicant wish to raise the existing EU MRL in the whole group of tree nuts (except pistachios), a new MRL application shall be submitted in accordance with Article 6 of Regulation (EC) No 396/2005.

Oilseeds

In order to raise the existing EU MRL in all oilseeds and to address the **data gap number 3**[15] (*eight residue trials performed on oilseeds with shell and compliant with the GAP*), the applicant submitted the following information:

- for aluminium phosphide: adjusted GAP on linseeds, new GAPs on soyabeans, peanuts, sunflower seeds and cotton seeds, the same GAP as authorised for rapeseeds and the minor oilseeds poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds and castor beans, new GAP-compliant trials on sunflower seeds (four), soya beans (four) and peanuts (four).
- for magnesium phosphide: new GAPs on the whole group of oilseeds, new GAP-compliant trials on peanuts (four) and sunflower seeds (four).

The existing tentative MRL in the whole group of oilseeds is set at 0.05 mg/kg. New MRL proposals were separately derived based on the critical data set on Mg_3P_2 or AlP.

Aluminium phosphide

Linseeds

MRL review GAP (post-harvest, indoor): 1 × 3–11 g PH_3/m^3, 7 days WHP, 5–14 days treatment, ventilation until concentration PH_3 < 0.01 ppm

Adjusted GAP (post-harvest, indoor): 1 × 10 g PH_3/m^3, 0 days WHP

The applicant provided the same residue trials on linseeds (eight) as submitted in the MRL review. The trials are compliant with the adjusted GAP. The trials consisted of one post-harvest treatment at an application rate of 10 g PH_3/m^3 during a 14-day fumigation period and a 2-h ventilation period. Residues were measured 0 (corresponding to WHP), 3 and 7 days after the treatment. Residues were found between < 0.005 mg/kg (LOQ) to 0.011 mg/kg at 0 DAT and declined to < 0.005 mg/kg LOQ at 3 and 7 DAT.

The available data are sufficient to derive an MRL of 0.015 mg/kg for phosphane and phosphide salts in linseeds, following the intended adjusted GAP on aluminium phosphide. This is lower than the current tentative EU MRL, which is set at 0.05 mg/kg.

Soyabeans

MRL review GAP (post-harvest, indoor): 1 × 3–11 g PH_3/m^3, 7 days WHP, 5–14 days treatment, ventilation until concentration PH_3 < 0.01 ppm.

New GAP (post-harvest, indoor): 1 × 10 g PH_3/m^3, 3 days WHP

The applicant provided four new residue trials on soya beans compliant with the new GAP. The trials consisted of one post-harvest treatment at an application rate of 10 g PH_3/m^3 during a 14-day fumigation period and a 3-hour ventilation period. Soyabeans were treated without pods. Residue trials were designed as decline trials. Residues were measured 0, 3 (corresponding to withholding period (WHP)) and 7 days after the treatment. In a single trial a higher residue level was measured at the later WHP of 7 days. Overall, residues ranged between < 0.005 mg/kg (LOQ) to 0.034 mg/kg.

The submitted data are sufficient to derive an MRL of 0.07 mg/kg for phosphane and phosphide salts in soyabeans, following the new intended GAP on aluminium phosphide. The MRL proposal is higher than the current tentative EU MRL of 0.05 mg/kg.

Peanuts, sunflower seeds, cotton seeds, rapeseeds, poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds, castor beans

MRL review GAP (post-harvest, indoor) (still relevant for rapeseeds, poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds, castor beans): 1 × 3–11 g PH_3/m^3, 7 days WHP, 5–14 days treatment, ventilation until concentration PH_3 < 0.01 ppm

New GAP (post-harvest, indoor) (peanuts, sunflower seeds, cotton seeds): 1 × 10 g PH_3/m^3, 7 days WHP

The applicant provided eight new residue trials on peanuts (four) and sunflower seeds (four) compliant with the new GAP for peanuts, sunflower seeds and cotton seeds and the authorised GAP on oilseed rape, poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds, castor beans. The trials

[15]The data gap number 3 refers to the submission of 'additional residue trials supporting authorisations on oilseeds and cereal grains'.

consisted of one post-harvest treatment at an application rate of 10 g PH_3/m^3 during a 14-day fumigation period and a 2-h (peanuts) and 3-h (sunflower seeds) ventilation period. Peanuts and sunflower seeds were treated with shell; residues were then measured in peanut kernels without shell and sunflower kernels with shell, in line with Commission Regulation (EU) 2018/62[16] replacing Annex I to Regulation (EC) 396/2005. Residue trials were designed as decline trials. Residues were measured 0, 3, 7 (corresponding to WHP), 14, 21 and, in sunflower seeds, 28 days after the treatment. Residues ranged between 0.33 to 0.68 mg/kg in peanut kernels and between 0.051 to 0.16 mg/kg in sunflower seeds.

The EMS proposes to extrapolate residue data from sunflower seeds to rapeseeds and such an extrapolation is acceptable for post-harvest treatments according to EU Technical guidelines (European Commission, 2020a). Extrapolation to cotton seeds is also possible. The data allow to derive an MRL of 0.3 mg/kg for phosphane and phosphide salts in sunflower seeds, cotton seeds and rapeseed. For peanuts, an MRL of 1.5 mg/kg is derived, as proposed by the applicant.

For the remaining oilseeds (minor oilseeds) – poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds, castor beans – the EMS proposed to derive a group tolerance for minor oilseeds having same application regime (i.e. all minor oilseeds, except linseeds) based on the combined data set on sunflower seeds and soyabeans (residue levels selected at 7 days WHP). The trials on soyabeans are described in the relevant section above. Such an extrapolation is acceptable according to the EU Technical guidelines (European Commission, 2020a). Based on the combined data set, an MRL of 0.3 mg/kg is derived for all minor oilseeds except linseeds.

The submitted data are sufficient to derive MRLs of 1.5 mg/kg for phosphane and phosphide salts in peanuts, as proposed by the applicant, and 0.3 mg/kg for phosphane and phosphide salts in sunflower seeds, cotton seeds, rapeseeds, poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds and castor beans, the latter one being different than the MRL of 0.4 mg/kg proposed by the applicant for the whole group of oilseeds (except peanuts). The MRLs derived are higher than the current tentative EU MRL of 0.05 mg/kg for the whole group of oilseeds.

Magnesium phosphide

Whole group of oilseeds: linseeds, peanuts, poppy seeds, sesame seeds, sunflower seeds, rapeseeds, soyabeans, mustard seeds, cotton seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds, castor beans

MRL review GAP (post-harvest, indoor): 1 × 3–11 g PH_3/m^3, 7 days WHP, 5–14 days treatment, ventilation until concentration $PH_3 < 0.01$ ppm

New GAP (post-harvest, indoor): 1 × 5.5 g PH_3/m^3, 14 days WHP

The applicant provided the same residue trials on sunflower seeds (four) and linseeds (four) as submitted for the MRL review. The trials on sunflower seeds are compliant with the new GAP. The trials on sunflower seeds were conducted as decline trials (i.e. residues were measured before the treatment and at 0, 3, 7, 14 (corresponding to WHP), 21 and, in some trials, 10 and 24 days after the treatment). As regards to linseed, residues were measured up to a WHP of 7 days (lower than the intended 14 days WHP). Since all residues were uniformly measured below the LOQ at the earlier WHP of 0, 3 and 7 days, these trials were not disregarded.

In addition, the applicant submitted eight new GAP-compliant trials on peanuts treated with shell (four) and sunflower seeds treated with shell (four). The trials consisted of one post-harvest treatment at an application rate of 5.5 g PH_3/m^3 during a 5-day fumigation period and a 3.5-h (peanuts) and 4.5-h (sunflower seeds) ventilation period. Peanuts and sunflower seeds were treated with shell; residues were then measured in peanut kernels without shell and sunflower kernels with shell, in line with Commission Regulation (EU) 2018/62 replacing Annex I to Regulation (EC) 396/2005. Residue trials were designed as decline trials. Residues were measured before treatment, 0, 3, 7, 14 (corresponding to WHP), 21 and, in peanut kernels, 31, 42 and 51 days after the treatment. Residues ranged between 0.091 to 0.15 mg/kg in peanut kernels and between 0.009 to 0.012 mg/kg in sunflower seeds. In addition, four trials on soyabean seeds treated without pods were also submitted. These were disregarded by the EMS as residue data at the new intended WHP of 14 days were not available and residues above the LOQ of 0.005 mg/kg (i.e. 0.007 and 0.008 mg/kg) were measured at the earlier WHP of 7 days in half of the trials.

It is noted that the EMS proposed to derive an MRL of 0.4 mg/kg to the whole group of oilseeds based on the trials on soyabean seeds and peanut kernels. However, considering that trials on soyabean seeds were appropriately disregarded for MRL purposes by the EMS, EFSA did not support such extrapolation. On the other hand, the combined residue data set on sunflower seeds (replacing trials on soyabean seeds) and peanuts was considered acceptable for extrapolation to the whole group of oilseeds, as agreed by various Member State experts and EFSA for the assessment of phosphide uses in the preparation for the renewal of the approval process.

Based on the available trials, MRLs of 0.4 and 0.3 mg/kg were derived for phosphane and phosphide salts in peanuts and the whole group of oilseeds (except peanuts), respectively, following the new intended uses of magnesium phosphide.

[16]Commission Regulation (EU) 2018/62 of 17 January 2018 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council. C/2018/0138. OJ L 18, 23.1.2018, p. 1–73.

Overall, there are 8 trials with oilseeds treated with shell available to address the Article 12 confirmatory data gap. EFSA concludes that **data gap number 3** is sufficiently **addressed in the whole group of oilseeds**. Overall, based on the data assessed for AlP and Mg_3P_2, the following MRL modification are required:

- an increasing of the existing tentative MRLs of 0.05 mg/kg to 0.3 mg/kg in linseeds and soyabeans based on the critical data set on magnesium phosphide (via extrapolation from the combined data set on sunflower seeds and peanuts);
- an increasing of the existing tentative MRLs of 0.05 mg/kg to 0.3 mg/kg in sunflower seeds, cotton seeds, rapeseeds based on the critical data set on aluminium phosphide (via extrapolation from sunflower seeds);
- an increasing of the existing tentative MRLs of 0.05 mg/kg to 0.3 mg/kg in poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds and castor beans based on the critical data set on aluminium phosphide (via extrapolation from the combined data set on sunflower seeds and soyabeans);
- an increasing of the existing tentative MRLs of 0.05 mg/kg to 1.5 mg/kg in peanuts, based on the critical data set on aluminium phosphide.

Cereals

In order to address the **data gap number 3**[17] (*eight residue trials on a small grain cereal (barley, oat, rye, rice and wheat) and eight residue trials on a large grain cereal (maize, millet, sorghum, buckwheat) for aluminium phosphide; four additional trials on a small grain cereal and four additional trials on large grain cereal for magnesium phosphide*) the applicant submitted the following information:

- for aluminium phosphide: adjusted GAPs on whole group of cereals (except rice), new GAP on rice, new GAP-compliant residue trials on maize grains (8), wheat (10 compliant with GAP on small size grains; 8 compliant with GAP on large size grains) and rice (4);
- for magnesium phosphide: adjusted GAPs on cereals, new GAP-compliant trials on maize grains (9), wheat (11 compliant with GAP on large size grains; 10 compliant with GAP on small size grains) and rice (4). In addition, the same trials that were assessed during the MRL review were considered in support of the adjusted GAPs on small and large cereals as relevant.

The applicant proposes to raise the existing tentative EU MRL of 0.05 mg/kg in barley, oat, rye, rice and wheat and the existing EU MRL of 0.01* mg/kg in 'other' cereals (0500990) to 0.15 mg/kg and to lower the existing tentative EU MRL of 0.7 mg/kg in buckwheat, maize/corn, millet, sorghum to 0.15 mg/kg on the basis of the use of aluminium phosphide. MRL proposals were separately derived based on the critical data set on Mg_3P_2 or AlP.

Aluminium phosphide

Barley, oat, rye, wheat (small size cereals)

MRL review GAP (post-harvest, indoor): 1 × 22.4 g PH_3/m^3, 14-day fumigation period, 0 days WHP

Adjusted GAP (post-harvest, indoor): 1 × 10 g PH_3/m^3, 3 days WHP

The applicant provided 10 new GAP-compliant residue trials on wheat. The trials consisted of one post-harvest treatment at an application rate of 10 g PH_3/m^3 during a 14-day fumigation period and a 0–2-h ventilation period. More than half of the residue trials (8) were designed as decline trials. Residues were measured 0, 3 (corresponding to WHP) and 7 days after the treatment. Residues were all measured < 0.005 mg/kg (LOQ).

Based on the available trials, the EMS derived MRLs of 0.01* mg/kg for phosphane and phosphide salts in wheat and barley, oat, rye (via extrapolation from wheat), following the intended use of aluminium phosphide. These MRLs are lower than the current tentative MRL of 0.05 mg/kg in wheat, barley, oat and rye.

It is noted that six residue trials on maize measuring residues at WHP of 3 days are also available. According to the EU Technical guidelines SANTE/2019/12752 (European Commission, 2020a), these could in principle be combined with residue trials on wheat to derive a group tolerance for all cereals. The MRL derived based on this combined data set would be 0.2 mg/kg. However, given that considerably higher residues are observed in maize (i.e. residues ranging from 0.017 to 0.093 mg/kg), EFSA agrees with the proposal of the EMS to derive individual MRLs in barley, oat, rye and wheat at the LOQ level of 0.01 mg/kg, based on the wheat data set.

Buckwheat, maize, millet, sorghum, others (large size grains) and rice (small size cereal)

MRL review GAP (post-harvest, indoor): 1 × 22.4 g PH_3/m^3, 14-day fumigation period, 0 days WHP

[17]The data gap refers to the submission of 'additional residue trials supporting authorisations on oilseeds and cereal grains'.

Adjusted GAP (post-harvest, indoor) (buckwheat, maize, millet and sorghum): 1 × 10 g PH_3/m^3, WHP 7 days

New GAP (post-harvest, indoor) (rice, others): 1 × 10 g PH_3/m^3, WHP 7 days

The applicant provided eight new residue trials on maize and four new residue trials on rice, compliant with the adjusted GAP on buckwheat, maize, millet, sorghum and the new GAP on rice. The trials consisted of one post-harvest treatment at an application rate of 10 g PH_3/m^3 during a 5-day (maize) and 14-day (maize and rice) fumigation period and a 3-h (maize and rice) to 27.5-h (maize) ventilation period. More than half of the residue trials on maize (7) were designed as decline trials; residues were measured 0, 3 (in some trials), 7 (corresponding to WHP) and 14 or 24 days after the treatment. As regard to rice, residues levels were not measured after the intended WHP of 7 days. However, as residue decline was observed across the sampling points, the lack of decline trials on rice was considered only a minor deficiency. Residues ranged between 0.007 and 0.091 mg/kg in maize and between 0.006 and 0.018 mg/kg in rice.

In addition, eight residue trials on wheat were provided. These are described above; residue levels measured at WHP of 7 days were selected.

The available residue data on maize and rice are sufficient to derive MRLs of 0.2 and 0.04 mg/kg for phosphane and phosphide salts in maize and rice, respectively. The EMS proposed to combine residue data on wheat and maize and to extrapolate these residue data to the whole group of cereals treated according to the same GAP. Such an extrapolation is acceptable according to the EU Technical Guideline SANTE/2019/12752 (European Commission, 2020a). Based on the combined residue data set on wheat and maize available for a 7-day WHP, a common MRL of 0.15 mg/kg was derived for cereals having same post-harvest application regime, except maize (i.e. buckwheat, maize, millet, rice and sorghum). For maize, considering the higher residue levels measured in this commodity, a separate MRL of 0.2 mg/kg was derived for phosphane and phosphide salts.

The MRLs derived are lower than the current tentative MRL of 0.7 mg/kg in buckwheat, maize, millet and sorghum. As regard to rice and 'others' (0500990), the MRLs derived are higher than the current tentative MRL of 0.05 mg/kg for rice and the existing MRL of 0.01* mg/kg for 'others'.

<u>*Magnesium phosphide*</u>

Large size grains (corn/maize, millet, sorghum, buckwheat, others)

MRL review GAP (post-harvest, indoor): 1 × 5.5 g PH_3/m^3, 2.5-day fumigation period, 0 days WHP

Adjusted GAP: 1 × 5.5 g PH_3/m^3, 7 days WHP

A total of 26 GAP-compliant trials on maize (13) and wheat (13) are available in support of the adjusted GAP on large size grains. Among these, six (four trials on maize and two trials on wheat) were already submitted and assessed during the MRL review; residue levels measured at the adjusted WHP of 7 days were selected. The trials consisted of one post-harvest treatment at an application rate between 4.5 and 5.5 g PH_3/m^3 during a 2.5, 5 and 14-day fumigation periods and a 45-min to 24-h ventilation period (or ventilation until PH_3 concentrations were measured < 0.005 mg/kg).

More than half of the residue trials on maize (10) were designed as decline trials; residues were measured before the treatment, 0, 7 (corresponding to WHP), 14 and, in some trials 3 and 10 days after the treatment. A decline of residues over time was observed in all decline trials except in one trial on maize where a slightly higher residue level was measured at the longer WHP of 14 days (WHP 0 days: 0.042 mg/kg; WHP 3 days: 0.008; WHP 7 days: 0.007; WHP 14 days: 0.008 mg/kg).

Overall, residues ranged between < 0.005 to 0.08 mg PH_3/kg in maize at the intended WHP of 7 days. As regard to wheat, residues levels after the intended WHP of 7 days were measured in one trial only, where residues at the longer WHP of 14 days were also measured. However, as residue decline was observed across the sampling points (0, 3, 7 and when available, 14 days after the treatment), with residues ranging from < 0.005 to 0.04 mg PH_3/kg, the lack of decline trials on wheat was considered only a minor deficiency.

The EMS proposed to combine residue data on wheat and maize and to extrapolate these residue data to the whole group of cereals having the same post-harvest application regime. Such an extrapolation is acceptable according to EU Technical Guideline (European Commission, 2020a). Based on the available trials on maize and wheat, EFSA derived an MRL of 0.09 mg/kg for phosphane and phosphide salts in the whole group of large size grains, except maize. For maize, considering the higher residue levels measured in this commodity, a separate MRL of 0.15 mg/kg was derived for phosphane and phosphide salts. It is noted that the EMS proposed an MRL of 0.1 mg/kg in the whole group of large size grains except maize, however this is probably due to rounding errors. The MRLs derived are lower than the current tentative MRLs of 0.7 mg/kg in corn/maize, millet, sorghum, buckwheat and the existing MRL of 0.01* mg/kg (LOQ) in other cereals.

Small size grains (rice, wheat, barley, oat, rye)

MRL review GAP (post-harvest, indoor): 1 × 5.5 g PH_3/m^3, 0 days WHP

Adjusted GAP: 1 × 5.5 g PH_3/m^3, 3 days WHP

A total of 16 GAP-compliant trials on wheat (12) and rice (4) are available in support of the adjusted GAP on small size grains. Among these, two trials on wheat were already submitted and assessed during the MRL review; residue levels measured at the adjusted WHP of 3 days were selected. The trials consisted of one post-harvest treatment at an application rate between 4.5 to 5.5 g PH_3/m^3 during a 2.5 (wheat), 5 (wheat and rice) and 14-day (wheat) fumigation periods and a 45-min to 15-h ventilation period (or ventilation until PH_3 concentrations were measured < 0.005 mg/kg).

All the trials except one on wheat were designed as decline trials (i.e. residues were measured at 0, 3 (corresponding to WHP) and 7 days after the treatment, and, in some trials, before the treatment). A decline of residues over time was observed in all decline trials. Residues ranged between < 0.005 and 0.012 mg/kg in wheat and between < 0.005 to 0.007 mg/kg in rice.

The EMS proposed to combine residue data on wheat and rice [WHP 3 days] and to extrapolate to barley, rye and oat, deriving a common MRL of 0.02 mg/kg. Such an extrapolation is not acceptable according to the EU Technical Guidelines (European Commission, 2020a). On the other hand, extrapolation from data on wheat to barley, rye and oat is possible. Based on the data set available on wheat the same MRL of 0.02 mg/kg as derived by the EMS was derived by EFSA for barley, rye and oat.

It is noted that nine residue trials on maize measuring residues at WHP of 3 days are also available. According to the EU Technical guidelines SANTE/2019/12752 (European Commission, 2020a), these could in principle be combined with residue trials on wheat to derive a group tolerance for all cereals having the same regime of use. The MRL derived based on this combined data set would be 0.08 mg/kg. However, given that higher residues were observed in maize (i.e. residues ranging from 0.008 to 0.057 mg/kg), EFSA agrees with the proposal of the EMS to derive individual MRLs of 0.02 mg/kg in barley, oat, rye and wheat.

Based on the available trials, EFSA derived MRLs of 0.02 mg/kg for phosphane and phosphide salts in wheat, barley, oat and rye (via extrapolation from wheat) and 0.015 mg/kg for phosphane and phosphide salts in rice (based on trials on rice). The MRLs derived are lower than the existing MRLs of 0.05 mg/kg in rice, wheat, barley, oat and rye.

Overall, a sufficient number of trials was submitted to address the Article 12 confirmatory data gap. EFSA concludes that **data gap number 3** is sufficiently **addressed in the whole group of cereals**. Overall, based on the data assessed for AlP and Mg_3P_2, the following MRL modification are required:

- a lowering of the existing tentative MRLs of 0.05 mg/kg to 0.02 mg/kg in barley, oat, rye and wheat, based on the critical data set on magnesium phosphide;
- a lowering of the existing tentative MRLs of 0.7 mg/kg to 0.15 mg/kg in buckwheat, millet and sorghum, based on the critical data set on aluminium phosphide;
- an increase of the existing tentative MRL of 0.05 mg/kg to 0.15 mg/kg in rice, based on the critical data set on aluminium phosphide;
- an increase of the existing MRL of 0.01* mg/kg in other cereals (00500990) to 0.15 mg/kg, based on the critical data set on aluminium phosphide;
- a lowering of the existing tentative MRL of 0.7 mg/kg to 0.2 mg/kg in maize, based on the critical data set on aluminium phosphide.

Herbal infusions (dried roots)

Aluminium phosphide

MRL review GAP (post-harvest, indoor): 1 × 3–11 g PH_3/m^3, 7 days WHP, 5–14 days treatment, ventilation until concentration PH_3 < 0.01 ppm

New GAP (post-harvest, indoor): 1 × 10 g PH_3/m^3, 7 days WHP

In support of the new GAP on aluminium phosphide, the applicant provided the same residue trials on liquorice (4) as submitted for the MRL review. The trials are compliant with the new GAP. These consisted of one post-harvest treatment at an application rate of 10 g PH_3/m^3 during a 14-day fumigation period and about 3-h ventilation period. The trials were not designed as decline trials. Residues were measured 0, 3 and 7 (corresponding to WHP) days after the treatment. Decline of residues was observed in three out of four trials at WHP of 7 and 3 days compared to WHP of 0 days. In one trial, residues remained stable (i.e. WHP 0 days: 0.012 mg/kg; WHP 3 days: 0.01 mg/kg; WHP 7 days: 0.012 mg/kg). Residues were measured between 0.008 and 0.012 mg/kg. Due to the lack of measurement taken after the intended WHP, higher residue levels at longer WHP cannot be excluded.

The available residue data are sufficient to derive MRLs of 0.03 mg/kg for phosphane and phosphide salts in the whole group of herbal infusions from dried roots (0633000) via extrapolation from liquorice, in accordance to the EU Technical Guidelines SANTE/2019/12752 (European Commission, 2020a). The MRL derived is higher than the current MRL of 0.02 mg/kg.

As an alternative, the EMS also proposed to additionally consider four GAP-compliant residue trials on dried carrots and to derive an MRL for the whole group of herbal infusions based on the combined residue data set on liquorice and dried carrots. Based on this approach, the EMS derived a slightly lower MRL of 0.02 mg/kg. EFSA considered that such extrapolation from the combined data set is not appropriate, in line with the EU Technical Guidelines SANTE/2019/12752 (European

Commission, 2020a), which recommends extrapolation based on the data sets considered separately. Therefore, these trials were not further considered for MRL calculations.

Magnesium phosphide

MRL review GAP (post-harvest, indoor): 1 × 3–11 g PH_3/m^3, 7 days WHP, 5–14 days treatment, ventilation until concentration PH_3 < 0.01 ppm

Adjusted GAP (post-harvest, indoor): 1 × 5.5 g PH_3/m^3, 7 days WHP

In support of the adjusted GAP on magnesium phosphide, the applicant submitted four new residue trials on liquorice. The trials are compliant with the adjusted GAP. These consisted of one post-harvest treatment at an application rate of 5.5 g PH_3/m^3 during a 5-day fumigation period and a 30-min ventilation period. Residues were measured 0, 3 and 7 (corresponding to WHP) days after the treatment. Decline of residues was observed across the sampling points in all trials. Residue levels ranged from < 0.005 to 0.005 mg/kg (LOQ).

The available residue data are sufficient to derive MRLs of 0.01 mg/kg for phosphane and phosphide salts in the whole group of herbal infusions from dried roots (0633000) via extrapolation from liquorice, in accordance to the EU Technical Guidelines SANTE/2019/12752 (European Commission, 2020a). The MRL derived is covered by the current MRL of 0.02 mg/kg.

In addition, the EMS also proposed to consider four GAP-compliant residue trials on dried carrots and to derive an MRL for the whole group of herbal infusions based on the combined residue data set on liquorice and dried carrots. Based on this approach, the EMS derived the same MRL of 0.01 mg/kg. EFSA considered that such extrapolation from the combined data set is not appropriate, in line with the EU Technical Guidelines SANTE/2019/12752 (European Commission, 2020a), which recommends extrapolation based on the data sets considered separately. Therefore, these trials were not further considered for MRL calculations.

Overall, an MRL of 0.03 mg/kg is proposed for phosphane and its phosphide salts in herbal infusions from dried roots, based on the critical data set on AlP. The MRL derived is higher than the existing MRL, which is set to 0.02 mg/kg. An MRL modification is therefore required.

Cocoa beans

Aluminium phosphide

MRL review GAP (post-harvest, indoor): 1 × 17.10 g PH_3/m^3, 21 days WHP, 5 days treatment, ventilation until concentration PH_3 < 0.01 ppm

New GAP (post-harvest, indoor): 1 × 10 g PH_3/m^3, 7 days WHP.

In support of the new GAP on aluminium phosphide, the applicant provided five new residue trials on cocoa beans. The trials are compliant with the new GAP. These consisted of one post-harvest treatment at an application rate of 10 g PH_3/m^3 during a 5-day (one trial) or 14-day (four trials) fumigation period and about 2-h (four trials) or 27.5-h (one trial) ventilation period. Only one trial was designed as decline trial. Residues were measured 0, 3 and 7 (corresponding to WHP) and, in one trial, 21 days after the treatment. Decline of residues was observed in all trials, therefore the lack of residue measurement at longer WHPs is only considered a minor deficiency. Residue ranged between < 0.005 (LOQ) to 0.03 mg/kg.

Additionally, eight trials incompliant with the GAP were submitted but not further assessed by the EMS.

The available residue data on cocoa beans are sufficient to derive an MRL of 0.06 mg/kg for phosphane and phosphide salts in cocoa beans.

In addition, in order to have a more robust data set, the EMS also proposed to consider 6 GAP-compliant residue trials on coffee beans and to derive an MRL based on the combined residue data set on cocoa beans and coffee beans. These trials were already submitted and assessed in the context of the MRL review (EFSA, 2015) and are compliant with the new GAP on cocoa beans. Based on this approach, the EMS derived an MRL of 0.15 mg/kg for phosphane and its phosphide salts in cocoa beans. The same MRL of 0.15 mg/kg was derived for cocoa beans by EFSA via extrapolation from the data set on coffee beans considered separately. The MRL derived is higher than the existing MRL of 0.02 mg/kg.

Magnesium phosphide

MRL review GAP (post-harvest, indoor) (still relevant): 1 × 5.5 g PH_3/m^3, 7 days WHP, 2.5 days treatment, ventilation until concentration PH_3 < 0.01 ppm

In support of the authorised GAP on magnesium phosphide, the applicant provided the same residue trials on cocoa beans (four) as submitted for the MRL review. The trials are compliant with the GAP. These consisted of one post-harvest treatment at an application rate of 5.5 g PH_3/m^3 during a 2.5-day fumigation period and 24 to 26-h ventilation period. Only one trial was designed as decline trial. Residues were measured 0, 3 and 7 (corresponding to WHP) and, in one trial, 21 days

after the treatment. Decline of residues was observed in all trials, therefore the lack of residue measurement at longer WHPs is only considered a minor deficiency. Residue ranged between < 0.005 (LOQ) to 0.011 mg/kg.

In addition, the applicant submitted 4 new GAP-compliant trials on cocoa beans. These consisted of one post-harvest treatment at an application rate of 5.5 g PH_3/m^3 during a 5-day fumigation period and 15-hour ventilation period. Residues were measured 0, 3 and 7 (corresponding to WHP) days after the treatment. Residues < 0.005 mg/kg (LOQ) were measured in all trials.

The available residue data are sufficient to derive an MRL of 0.015 mg/kg for phosphane and phosphide salts in cocoa beans. The MRL derived is covered by the current MRL of 0.02 mg/kg.

Overall, an MRL of 0.15 mg/kg is proposed for phosphane and its phosphide salts in cocoa beans, based on the critical data set on AlP. The MRL derived is higher than the existing MRL, which is set to 0.02 mg/kg. An MRL modification is therefore required.

Spices (seed)

Aluminium phosphide

MRL review GAP (post-harvest, indoor): 1 × 3–11 g PH_3/m^3, 7 days WHP, 5 days treatment, ventilation until concentration PH_3 < 0.01 ppm

New GAP (post-harvest, indoor): 1 × 10 g PH_3/m^3, 7 days WHP

In support of the new GAP on aluminium phosphide for seed spices, the applicant provided the same residue trials on coriander (four) as submitted for the MRL review. The trials are compliant with the new GAP. These consisted of one post-harvest treatment at an application rate of 10 g PH_3/m^3 during a 14-day fumigation period and a 2-h ventilation period. The trials were not designed as decline trials. Residues were measured 0, 3 and 7 (corresponding to WHP) days after the treatment. Decline of residues was observed in all trials across the sampling points. Residues were measured between 0.006 and 0.008 mg/kg. Due to the lack of measurement taken after the intended WHP, higher residue levels at longer WHP cannot be excluded.

In addition, the applicant provided two new GAP-compliant residue trials on pepper (fruit spice).

The EMS proposed to derive an MRL of 0.03 mg/kg for phosphane and its phosphide salts in seed spices based on the combined data set on coriander (four) and pepper (two). A sufficient number of residue trials on coriander is available in support of the new post-harvest GAP on the whole group of seed spices. Based on the data set available on coriander (seed spice), the same MRL of 0.03 mg/kg as derived by the EMS was derived by EFSA.

Magnesium phosphide

MRL review GAP (post-harvest, indoor): 1 × 3–11 g PH_3/m^3, 7 days WHP, 5 days treatment, ventilation until concentration PH_3 < 0.01 ppm

Adjusted GAP (post-harvest, indoor): 1 × 5.5 g PH_3/m^3, 7 days WHP

In support of the new GAP on aluminium phosphide for seed spices, the applicant provided four new trials on coriander. The trials are compliant with the new GAP. These consisted of one post-harvest treatment at an application rate of 5.5 g PH_3/m^3 during a 5-day fumigation period and a 30-min ventilation period. The trials were not designed as decline trials. Residues were measured 0, 3 and 7 (corresponding to WHP) days after the treatment. Residue at WHP of 7 days were all < 0.005 mg/kg (LOQ).

The available residue data are sufficient to derive MRLs of 0.01 mg/kg for phosphane and phosphide salts in the whole groups of seed spices.

Overall, based on the critical data sets on AlP, an MRL of 0.03 mg/kg for phosphane and phosphide salts in the whole groups of seed spices was derived. The MRL derived is higher than the existing MRL of 0.02 mg/kg for seed spices. An MRL modification is therefore required.

2 | RESIDUES IN LIVESTOCK

Aluminium and magnesium phosphides are authorised for uses on several crops under consideration in this assessment that may be fed to livestock. Specific data to assess the nature of residues in livestock are not available, but available rat metabolism studies demonstrated that phosphane is mainly oxidised to phosphonate and phosphinate in mammals and accumulation of residues in tissues was not observed (EFSA, 2015). The MRL review concluded that further studies investigating the nature of residues in livestock are not necessary (EFSA, 2015).

Livestock dietary burdens (DB) calculated by the MRL review using (EFSA) Pesticide Residues Overview File PROFile version 2.3 exceeded the trigger value of 0.1 mg/kg dry matter (DM) in all livestock species and the main contributing

commodity was always maize grain if residue data for the uses supporting a withholding period of 0 days are used. Under the assumption that WHP is extended to 3 days, the livestock DB was no longer triggered (EFSA, 2015). Overall, the MRL review could not conclude on the magnitude of phosphane and phosphide residues in animal matrices from the authorised uses and set the data gap for data confirming that the occurrence of phosphane and its oxidation products (phosphonic acid in particular) is negligible in livestock products (data gap mainly relevant for large grain cereals which are the main contributors to the livestock dietary burden) (data gap number 4). Since now the WHP for the uses of aluminium and magnesium phosphide on large grain cereals (maize, millet, sorghum, buckwheat) is extended from 0 to 7 days and the proposed MRLs in these crops are lower than the existing tentative MRLs (resulting in lower risk assessment values), EFSA considers this data gap no longer relevant. The livestock dietary burden was nevertheless recalculated with the PROFile version 2.3 using the new residue data on cereals and the same input values for other feed items, which were considered by the MRL review: dry peas, beans, lupins, rape seed meal, cotton seed/seed meal, linseeds meal, sunflower seed meal, soyabean seed/meal and peanuts meal. The calculated dietary burden did not exceed the trigger value of 0.1 mg/kg DM confirming that the Article 12 confirmatory data gap **is sufficiently addressed**.[18]

For the new uses on oilseeds under consideration, EFSA calculated the livestock dietary burdens according to OECD guidelines (OECD, 2013). The data on cereals supporting existing, adjusted and new uses and on oilseeds supporting new uses were considered. The calculated dietary burdens exceeded the trigger value of 0.1 mg/kg DM and the main contributing commodity was peanut meal. The maximum dietary burdens accounted for 0.24 mg/kg DM for cattle (0.006 mg/kg body weight [bw] per day), 0.20 mg/kg DM for sheep (0.009 mg/kg bw per day), 0.23 mg/kg DM for swine (0.007 mg/kg bw per day) and 0.15 mg/kg DM four poultry (0.011 mg/kg bw per day).

Regarding the magnitude of residues, phosphane was shown to be extensively metabolised in the rat to phosphonate and phosphinate. There are no feeding studies with aluminium or magnesium phosphides available, but the MRL review referred to feeding studies with phosphonic acid (assessed for the review of MRLs of fosetyl) (EFSA, 2012b).

In the feeding studies with phosphonic acid, assessed by the MRL review for potassium phosphonates, the lactating cows were dosed for 28 days at levels corresponding to 11, 22 and 66 mg phosphonic acid equivalents/kg bw per day. Residues of phosphonic acid were quantified in milk, fat, liver and kidney at all dosing levels. The MRL review proposed raising of MRLs for phosphonic acid in animal commodities on the basis of the dietary burdens calculated for the use of potassium phosphonates. The laying hens were dosed for 28 consecutive days with phosphonic acid at dosing levels of 0.95, 3.703 and 11.387 mg/kg bw per day. Residues of phosphonic acid were found to be below the LOQ of 0.5 mg/kg in eggs, muscle, liver and fat at all dose levels. Since the estimated maximum DB for phosphane and phosphide residues in livestock and poultry are significantly lower than the levels investigated in feeding studies with phosphonic acid, EFSA concludes that residues in livestock commodities from the use of magnesium and aluminium phosphides are expected to be low and the setting of MRLs in commodities of animal origin is not required. It is noted, however, that this assumption is based on the feeding studies with phosphonic acid. EFSA proposes that the magnitude of phosphane and phosphide salts in livestock from the uses of magnesium and aluminium phosphides on plant commodities is further assessed in the framework of the renewal of the approval of these active substances.

3 | CONSUMER RISK ASSESSMENT

EFSA updated the previous risk assessment, taking into account the new data submitted under this application and the revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2018, 2019), which contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for phosphane used in the risk assessment (i.e. ADI and ARfD values) were derived by EFSA (2008a, 2008b, 2008c, 2010, 2012a) under Directive 91/414/EEC.

The calculation is based on the supervised trials median residue (STMR) values and highest residue levels (HR values) derived for raw agricultural commodities according to the residue definition for risk assessment. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.

The input values used to perform the exposure assessment are reported in Appendix D.2. The outcome of the calculations is reported in Appendix B.3.

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed only for the commodities assessed in this application in accordance with the internationally agreed methodology (FAO, 2016). The short-term exposure did not exceed the acute reference dose (ArfD) for any of the crops assessed in this application. The highest acute consumer exposure was calculated for

[18]EFSA acknowledges that, according to Commission working document SANTE/10235/2016 rev. 4, the livestock dietary burden for the present assessment, including both Article 12 confirmatory data and Article 10 MRL applications, has to be performed using the OECD livestock dietary burden calculator (case 2). However, considering that the OECD livestock dietary burden calculator includes a wide range of feed items not considered in the Article 12 MRL review (processing by-products as maize hominy meal, gluten feed, gluten meal, etc.) and excludes some feed commodities contributing to the dietary burden calculated in the Article 12 MRL review (cereal bran), EFSA considered the use of PROFile 2.3, applicable at the time of the Article 12 assessment, as more fit for purpose to evaluate data submitted with respect to the data gap number 4.

peanuts (5.21% of the ArfD). No specific data for the short-term consumption of cotton seeds, gold of pleasure seeds, castor beans and commodities belonging to a subgroup of 'other' oilseeds (0401990), 'other' cereals (0500990), 'other' herbal infusions from dried roots (0633990) and 'other' seed spices (0810990) are available. However, the exposure calculations performed with the whole commodity groups of respective crops (oilseeds, cereals, herbal infusions from dried roots and seed spices) indicate low acute exposure thus confirming that no acute intake concerns will be associated with the consumption of cotton seeds, gold of pleasure seeds, castor beans, 'other' oilseeds (0401990), 'other' cereals (0500990), 'other' herbal infusions from dried roots (0633990) and 'other' seed spices (0810990).

Long-term (chronic) dietary risk assessment

The highest estimated long-term dietary intake accounted for 4% of the acceptable daily intake (ADI) (NL toddler diet). The contributions of the commodities assessed in the present MRL application to the overall long-term exposure ranged from < 0.01% of the ADI to 2.37% of the ADI (maize in NL toddler diet). No specific data for the long-term consumption of gold of pleasure seeds and herbal infusions from dried roots are available. However, the low chronic exposure calculated for the intake of the whole group of oilseeds and herbal infusions (dried flowers and dried leaves) suggests that, the contribution of residues in the gold of pleasure seeds and dried roots of herbal infusions to the overall dietary exposure is of minor relevance (see Appendix B.3).

EFSA concluded that the long-term intake of residues of phosphane and its phosphide salts resulting from the existing and the intended uses is unlikely to present a risk to consumer health. Overall, it is concluded that the calculated consumer exposure to phosphane and its phosphide salts is unlikely to pose a concern for public health. For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4 | CONCLUSION AND RECOMMENDATIONS

To address data gaps identified in the framework of the MRL review (EFSA, 2015) and implemented as footnotes in the Commission Regulation (EU) 2016/1785, the applicant submitted:

- validation data for an analytical method that has not been previously assessed at EU level and where residues of phosphane were determined using GC-FPD in butter biscuits, potato chips, tobacco, powdered egg, dry cured ham and fat.
- new residue field trials supporting the authorised or adjusted indoor post-harvest GAPs for AlP on pistachios, rapeseeds, linseeds, poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds, castor beans, the whole group of cereals except rice and 'others', and for Mg_3P_2 on the whole group of cereals, herbal infusions from dried roots, cocoa beans and seed spices.
- new indoor post-harvest GAPs and their supporting residue trials for AlP on soyabeans, peanuts, sunflower seeds, cotton seeds, rice and 'other' cereals (0500990), herbal infusions from dried roots, cocoa beans, seed spices and for Mg_3P_2 on the whole group of oilseeds and pistachios.

In addition, new residue trials on hazelnuts and walnuts were provided in support of the confirmatory data gap on pistachios.

EFSA assessed the new data and concluded that the data gaps number 2,[19] 3,[20] 4[21] were sufficiently addressed. Data gap number 1[22] was not addressed.

For the new uses of magnesium phosphide on pistachios and oilseeds, and the new uses of aluminium phosphide on soyabeans, peanuts, sunflower seeds, cotton seeds, rice and 'other' cereals (0500990), dried roots from herbal infusions, cocoa beans and seed spices EFSA concludes the following:

1. sufficient number of residue trials have been submitted to support the raising of the existing tentative EU MRL of 0.1 to 0.2 mg/kg in pistachios, the existing tentative EU MRL of 0.05 to 0.3 mg/kg in all oilseeds, except peanuts and to 1.5 mg/kg in peanuts, the existing tentative EU MRL of 0.05 to 0.15 mg/kg in rice, the existing EU MRL of 0.01* to 0.15 mg/kg in 'other' cereals (0500990) and the existing EU MRLs of 0.02 to 0.03 mg/kg in dried roots of herbal infusions, to 0.15 mg/kg in cocoa beans and to 0.03 mg/kg in seed spices.
2. there is no need to modify the existing EU MRLs for phosphane and phosphide salts in animal commodities
3. the ILV and confirmatory data for the existing enforcement method is not available.

[19]The data gap number 2 refers to the submission of 'clarifications regarding residue trials'.

[20]The data gap number 3 refers to the submission of 'additional residue trials supporting authorisations on oilseeds and cereal grains'.

[21]The data gap refers to the submission of 'information on the occurrence of phosphane and its oxidation products in commodities of animal origin'. Data gap mainly relevant for large grain cereals at WHP 0 days.

[22]The data gap number 1 refers to the submission of an ILV and a confirmatory method for monitoring of phosphide in high-oil content commodities.

The adjusted GAPs on cereals, except rice and others (0500990), indicate that lower MRLs are sufficient to support the adjusted uses of aluminium phosphide and magnesium phosphide on barley, oat, rye and wheat (MRLs of 0.02 mg/kg), buckwheat, millet and sorghum (MRLs of 0.15 mg/kg) and maize (MRL of 0.2 mg/kg).

Updated consumer exposure indicates no consumer intake concerns for the intended and existing EU uses of aluminium and magnesium phosphides.

The overview of the assessment of confirmatory data and the recommended MRL modifications are summarised in Appendix B.4.

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ArfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
Bw	body weight
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement to risk assessment residue definition
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90% dissipation (define method of estimation)
Dw	dry weight
EDI	estimated daily intake
EMS	evaluating Member State
Eq	residue expressed as a.s. equivalent
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GC–FPD	gas chromatography with flame photometric detector
GC–NPD	gas chromatography with nitrogen/phosphorous detector
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
IPCS	International Programme of Chemical Safety
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K_{oc}	organic carbon adsorption coefficient
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MW	molecular weight
OECD	Organisation for Economic Co-operation and Development
PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
P_{ow}	partition coefficient between n-octanol and water
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
STMR	supervised trials median residue
WHO	World Health Organization

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBERS

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APPENDIX A

Summary of GAPs assessed in the evaluation of confirmatory data and intended GAPs triggering the amendment of existing MRL

Aluminium phosphide

Code	Crop name	Region	Outdoor/ Indoor	Pests controlled	Active substance (a.s.)	Type[a]	a.s. concentration in formulation	Unit (concentration of a.s. in formulation)	Method	Max. number	Max. application rate (expressed as a.s.)	Unit for application rate	PHI or WHP (days)[b]	Comments (max.250 characters)
Authorised GAPs (MRL review, EFSA, 2015)														
0120010 0120020 0120030 0120040 0120050 0120060 0120070 0120080 0120090 0120110	Almonds Brazil nuts Cashew nuts Chestnuts Coconuts Hazelnuts Macadamia Pecans Pine nuts Walnuts	EU	Indoor	Insects	Aluminium phosphide	GE	570	g/kg	Post-harvest treatment - gassing	1	3–11	g/m^3	21	Duration of treatment UK: 14 days. Duration of treatment FR: 5 days Duration of ventilation: until concentration PH3 < 0.01 ppm
0120100	Pistachios	EU	Indoor	Insects	Aluminium phosphide	GE	570	g/kg	Post-harvest treatment - gassing	1	3–11	g/m^3	35	
Same GAP as authorised (Germany, 2020a)														
0120010 0120020 0120030 0120040 0120050 0120060 0120070 0120080 0120090 0120110	Almonds Brazil nuts Cashew nuts Chestnuts Coconuts Hazelnuts Macadamia Pecans Pine nuts Walnuts	EU	Indoor	Indoor control of insects in food storageall developmental stages	Aluminium phosphide	GE	560.0	g/kg	Post-harvest treatment - gassing	1	10.00	g/m^3	21	Product/m^3: 50 pellets
Adjusted GAPs (Germany, 2020a)														
0120100	Pistachios	EU	Indoor	Indoor control of insects in food storageall developmental stages	Aluminium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	**10.00**	g/m^3	**21**	Product/m^3: 50 pellets

(Continues)

(Continued)

Code	Crop name	Region	Outdoor/ Indoor	Pests controlled	Active substance (a.s.)	Type[a]	a.s. concentration in formulation	Unit (concentration of a.s. in formulation)	Method	Max. number	Max. application rate (expressed as a.s.)	Unit for application rate	PHI or WHP (days)[b]	Comments (max.250 characters)
Authorised GAPs (MRL review, EFSA, 2015)														
0401010 0401020 0401030 0401040 0401050 0401060 0401070 0401080 0401090 0401100 0401110 0401120 0401130 0401140 0401150	Linseeds Peanuts Poppy seeds Sesame seeds Sunflower seeds Rapeseeds Soyabeans Mustard seeds Cotton seeds Pumpkin seeds Safflower seeds Borage seeds Gold of pleasure Hemp seeds Castor beans	EU	Indoor	Insects	Aluminium phosphide	GE	570	g/kg	Post-harvest treatment - gassing	1	3–11	g/m^3	7	Duration of treatment UK: 14 days. Duration of treatment FR: 5 days Duration of ventilation: until concentration PH3 < 0.01 ppm
Adjusted GAPs (Germany, 2020a)														
0401010	Linseeds	EU	Indoor	Indoor control of insects in food storage all developmental stages	Aluminium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	**10**	g PH_3/m^3	**0**	Product/m^3: 10 pellets
New GAPs (Germany, 2020a)														
0401070	Soyabeans	EU	Indoor	Indoor control of insects in food storage all developmental stages	Aluminium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	**10**	g PH_3/m^3	**3**	Product/m^3: 10 pellets
0401020 0401050 0401090	Peanuts Sunflower seeds Cotton seeds	EU	Indoor	Indoor control of insects in food storage all developmental stages	Aluminium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	**10**	g PH_3/m^3	7	Product/m^3: 50 pellets

(Continued)

Code	Crop name	Region	Outdoor/ Indoor	Pests controlled	Active substance (a.s.)	Type[a]	a.s. concentration in formulation	Unit (concentration of a.s. in formulation)	Method	Max. number	Max. application rate (expressed as a.s.)	Unit for application rate	PHI or WHP (days)[b]	Comments (max.250 characters)
Same GAP as authorised (Germany, 2020a)														
0401030 0401040 0401060 0401080 0401100 0401110 0401120 0401130 0401140 0401150	Poppy seeds Sesame seeds Rapeseeds Mustard seeds Pumpkin seeds Safflower seeds Borage seeds Gold of pleasure Hemp seeds Castor beans	EU	Indoor	Insects	Aluminium phosphide	GE	570	g/kg	Post-harvest treatment – gassing	1	3–11	g PH_3/m^3	7	Duration of treatment UK: 14 days. Duration of treatment FR: 5 days Duration of ventilation: until concentration $PH_3 < 0.01$ ppm
Authorised GAPs (MRL review, EFSA, 2015)														
0500010 0500020 0500030 0500040 0500050 0500060 0500070 0500080 0500090	Barley Buckwheat Maize/corn Millet Oat Rice Rye Sorghum Wheat	EU	Indoor	Insects	Aluminium phosphide	GE	570	g/kg	Post-harvest treatment – gassing	1	22.4	g PH_3/m^3	0	Duration of treatment: 14 days Duration of ventilation: until concentration $PH_3 < 0.01$ ppm
Adjusted GAPs (Germany, 2020a)														
0500010 0500050 0500070 0500090	Barley Wheat Rye Oat	EU	Indoor	Indoor control of insects in food storage all developmental stages	Aluminium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	**10**	g PH_3/m^3	**3**	Product/m^3: 50 pellets or 0.9 bags or 10 tablets
0500020 0500030 0500040 0500080	Buckwheat Maize/corn Millet Sorghum	EU	Indoor	Indoor control of insects in food storage all developmental stages	Aluminium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	**10**	g PH_3/m^3	**7**	Product/m^3: 50 pellets or 0.9 bags or 10 tablets
New GAP (Germany, 2020a)														
0500060 0500990	Rice Others	EU	Indoor	Indoor control of insects in food storage all developmental stages	Aluminium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	**10**	g PH_3/m^3	**7**	Product/m^3: 50 pellets or 0.9 bags or 10 tablets

(Continues)

(Continued)

Code	Crop name	Region	Outdoor/ Indoor	Pests controlled	Active substance (a.s.)	Type[a]	a.s. concentration in formulation	Unit (concentration of a.s. in formulation)	Method	Max. number	Max. application rate (expressed as a.s.)	Unit for application rate	PHI or WHP (days)[b]	Comments (max.250 characters)
Authorised GAPs (MRL review, EFSA, 2015)														
0633000	Herbal infusions (dried roots)	EU	Indoor	Insects	Aluminium phosphide	GE	570.0	g/kg	Post-harvest treatment – gassing	1	3–11	g/m^3	7	Duration of treatment UK: 14 days. Duration of treatment FR: 5 days. Duration of ventilation: until concentration PH3 < 0.01 ppm
New GAPs (Germany, 2020a)														
0633000	Herbal infusions (dried roots)	EU	Indoor	Indoor control of insects in food storage all developmental stages	Aluminium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	**10.00**	g/m^3	7	
Authorised GAPs (MRL review, EFSA, 2015)														
640000	Cocoa beans	EU	Indoor	Indoor control of insects in food storage all developmental stages	Aluminium phosphide	GE	570.0	g/kg	Post-harvest treatment – gassing	1	17.10	g/m^3	21	Duration of treatment: 5 days Duration of ventilation: until concentration PH_3 < 0.01 ppm
New GAPs (Germany, 2020a)														
640000	Cocoa beans	EU	Indoor	Indoor control of insects in food storage all developmental stages	Aluminium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	**10.00**	g/m^3	**7**	Product/m^3: 50 pellets or 0.9 bags
Authorised GAPs (MRL review, EFSA, 2015)														
0810000	Seed spices	EU	Indoor	Insects	Aluminium phosphide	GE	570.0	g/kg	Post-harvest treatment – gassing	1	3–11	g/m^3	7	Duration of treatment FR: 5 days. Duration of ventilation: until concentration PH3 < 0.01 ppm
New GAPs (Germany, 2020a)														
0810000	Seed spices	EU	Indoor	Indoor control of insects in food storage all developmental stages	Aluminium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	**10.00**	g/m^3	7	Product/m^3: 50 pellets or 0.9 bags

Abbreviations: GAP, Good Agricultural Practice; GE, gas generating product; MRL, maximum residue level.

[a]CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

[b]PHI – minimum pre-harvest interval; WHP – withholding period

Magnesium Phosphide

Code	Crop name	Region	Outdoor / Indoor	Pests controlled	Active substance (a.s.)	Type[a]	a.s.concentration in formulation	Unit (concentration of a.s. in formulation)	Method	Max. number	Max. application rate (expressed as a.s.)	Unit for application rate	PHI or waiting period (days)[b]	Comments (max. 250 characters)
Authorised GAPs (MRL review, EFSA, 2015)														
0120010 0120020 0120030 0120040 0120050 0120060 0120070 0120080 0120090 0120110	Almonds Brazil nuts Cashew nuts Chestnuts Coconuts Hazelnuts Macadamia Pecans Pine nuts Walnuts	EU	Indoor	Insects	Magnesium phosphide	GE	570	g/kg	Post-harvest treatment - gassing	1	3–11	g PH_3/m^3	21	Duration of treatment UK: 14 days. Duration of treatment FR: 5 days. Duration of ventilation: until concentration PH3 < 0.01 ppm
0120100	Pistachios	EU	Indoor	Insects	Magnesium phosphide	GE	570	g/kg	Post-harvest treatment - gassing	1	3–11	g PH_3/m^3	35	
Adjusted GAP (Germany, 2020b)														
0120010 0120020 0120030 0120040 0120050 0120060 0120070 0120080 0120090 0120110	Almonds Brazil nuts Cashew nuts Chestnuts Coconuts Hazelnuts Macadamia Pecans Pine nuts Walnuts	EU	Indoor	Indoor control of insects in food storage all developmental stages	Magnesium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	**5.5**	g PH_3/m^3	21	Product/m^3: 1 plate/6 m^3
New GAP (Germany, 2020b)														
0120100	Pistachios	EU	Indoor	Indoor control of insects in food storage all developmental stages	Magnesium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	**5.5**	g PH_3/m^3	**21**	Product/m^3: 1 plate/6 m^3

(Continues)

(Continued)

Code	Crop name	Region	Outdoor / Indoor	Pests controlled	Active substance (a.s.)	Type[a]	a.s.concentration in formulation	Unit (concentration of a.s. in formulation)	Method	Max. number	Max. application rate (expressed as a.s.)	Unit for application rate	PHI or waiting period (days)[b]	Comments (max. 250 characters)
Authorised GAPs (MRL review, EFSA, 2015)														
0401010 0401020 0401030 0401040 0401050 0401060 0401070 0401080 0401090 0401100 0401110 0401120 0401130 0401140 0401150	Linseeds Peanuts Poppy seed Sesame seeds Sunflower seeds Rapeseeds Soyabeans Mustard seeds Cotton seeds Pumpkin seeds Safflower seeds Borage seeds Gold of pleasure Hemp seeds Castor beans	EU	Indoor	Insects	Magnesium phosphide	GE	570	g/kg	Post-harvest treatment – gassing	1	3–11	g PH_3/m^3	7	Duration of treatment UK: 14 days. Duration of treatment FR: 5 days Duration of ventilation: until concentration PH3 < 0.01 ppm
New GAPs (Germany, 2020b)														
0401000	Oilseeds	EU	Indoor	Indoor control of insects in food storage all developmental stages	Magnesium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	**5.5**	g PH_3/m^3	**14**	Product/m^3: 1 plate/6 m^3
Authorised GAPs (MRL review, EFSA, 2015)														
0500010 0500020 0500030 0500040 0500050 0500060 0500070 0500080 0500090	Barley Buckwheat Maize/corn Millet Oat Rice Rye Sorghum Wheat	EU	Indoor	Insects	Magnesium phosphide	GE	560	g/kg	Post-harvest treatment – gassing	1	5.5	g PH_3/m^3	0	Duration of treatment: 2.5 days Duration of ventilation: until concentration PH3 < 0.01 ppm
Adjusted GAPs (Germany, 2020b)														
0500010 0500050 0500060 0500070 0500090	Barley Oat Rice Rye Wheat	EU	Indoor	Indoor control of insects in food storage all developmental stages	Magnesium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	5.5	g PH_3/m^3	**3**	1 plate/6 m^3 or 5 tablets/m^3
0500020 0500030 0500040 0500080 0500990	Buckwheat Maize/corn Millet Sorghum Others	EU	Indoor	Indoor control of insects in food storage all developmental stages	Magnesium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	5.5	g PH_3/m^3	**7**	1 plate/6 m^3 or 5 tablets/m^3

(Continued)

Code	Crop name	Region	Outdoor / Indoor	Pests controlled	Active substance (a.s.)	Type[a]	a.s.concentration in formulation	Unit (concentration of a.s. in formulation)	Method	Max. number	Max. application rate (expressed as a.s.)	Unit for application rate	PHI or waiting period (days)[b]	Comments (max. 250 characters)
Authorised GAPs (MRL review, EFSA, 2015)														
0633000	Herbal infusions (dried roots)	EU	Indoor	Insects	Magnesium phosphide	GE	570.0	g/kg	Post-harvest treatment – gassing	1	3–11	g PH_3/m^3	7	Duration of treatment UK: 14 days. Duration of treatment FR: 5 days. Duration of ventilation: until concentration PH3 < 0.01 ppm
Adjusted GAPs (Germany, 2020b)														
0633000	Herbal infusions (dried roots)	EU	Indoor	Indoor control of insects in food storage all developmental stages	Magnesium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	**5.5**	g PH_3/m^3	7	
Authorised GAPs (MRL review, EFSA, 2015)														
0640000	Cocoa beans	EU	Indoor	Insects	Magnesium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	5.5	g PH_3/m^3	7	Duration of treatment: 2.5 days. Duration of ventilation: until concentration PH3 < 0.01 ppm
Same GAP as authorised (Germany, 2020b)														
0640000	Cocoa beans	EU	Indoor	Indoor control of insects in food storage all developmental stages	Magnesium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	5.5	g PH_3/m^3	7	
Authorised GAPs (MRL review, EFSA, 2015)														
0810000	Seed spices	EU	Indoor	Insects	Magnesium phosphide	GE	570.0	g/kg	Post-harvest treatment – gassing	1	3–11	g PH_3/m^3	7	Duration of treatment: 5 days. Duration of ventilation: until concentration PH3 < 0.01 ppm

(Continues)

(Continued)

Code	Crop name	Region	Outdoor / Indoor	Pests controlled	Active substance (a.s.)	Type[a]	a.s.concentration in formulation	Unit (concentration of a.s. in formulation)	Method	Max. number	Max. application rate (expressed as a.s.)	Unit for application rate	PHI or waiting period (days)[b]	Comments (max. 250 characters)
Adjusted GAPs (Germany, 2020b)														
0810000	Seed spices	EU	Indoor	Indoor control of insects in food storage all developmental stages	Magnesium phosphide	GE	560.0	g/kg	Post-harvest treatment – gassing	1	**5.5**	g PH_3/m^3	7	

Abbreviations: GAP, Good Agricultural Practice; GE, gas generating product; MRL, maximum residue level.

[a]CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

[b]PHI – minimum pre-harvest interval; WHP – withholding period.

APPENDIX B

List of end points

B.1 | RESIDUES IN PLANTS

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

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

Primary crops (available studies)	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comment/source
	Not available and not required because relevant residues other than phosphane or its salts are not expected in plant commodities.				
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Not available and not required. When fumigating underground tunnels and burrows (rodenticide use), residues may be re-adsorbed onto soil but significant uptake of phosphane by plants is not expected				
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Not investigated		Not available and not required because relevant residues other than phosphane or its salts are not expected in processed commodities
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Not investigated		
	Sterilisation (20 min, 120°C, pH 6)		Not investigated		

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2015)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2015)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2015)
Plant residue definition for monitoring (RD-Mo)	Phosphane and phosphide salts (sum of phosphane and phosphane generators (relevant phosphide salts), determined and expressed as phosphane) (EFSA, 2015)	
Plant residue definition for risk assessment (RD-RA)	Sum of phosphane and phosphane generators (relevant phosphide salts), determined and expressed as phosphane	
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)	<u>Acidic, dry, high water content and coffee beans:</u> GC-NPD, 0.01 mg/kg (EFSA, 2012a). ILV and confirmatory method available (EFSA, 2015). <u>High oil content:</u> GC-NPD, 0.01 mg/kg (EFSA, 2015. Confirmation by use of alternative detector (Germany, 2020a,b). ILV not available (EFSA, 2015).	

DAT: days after treatment; PBI: plant-back interval; LOQ: limit of quantification; GC-NPD: Gas Chromatography coupled with the Nitrogen Phosphorous Detector; ILV: independent laboratory validation.

B.1.1.2 | Storage stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/Source
				Value	Unit		
	Not available and not required, provided that samples are analysed within 48 h of sampling or stored under liquid nitrogen for few days						

B.1.2 | Magnitude of residues in plants

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

Commodity	Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CFR[d]
Residue definition for enforcement: Phosphane and phosphide salts (sum of phosphane and phosphane generators (relevant phosphide salts), determined and expressed as phosphane) **Residue definition for risk assessment:** Sum of phosphane and phosphane generators (relevant phosphide salts), determined and expressed as phosphane							
Pistachios	**Aluminium phosphide, magnesium phosphide** **Authorised** indoor GAP (EFSA, 2015): 1 × 3–11 g PH_3/m^3, 5–14-day fumigation period, WHP 35 days	**MRL review (EFSA, 2015)** **Aluminium phosphide** Pistachios (treated with half-opened shell)[e] [10 g/m^3, 14-day fumigation period, 2-h ventilation, WHP 21 days]: 2 × < 0.005; 0.005; 0.006 **Magnesium phosphide** Pistachios (treated without shell)[e] [5.5 g/m^3, 2.5-day fumigation period, 24-h ventilation, WHP 35 days]: 0.014; 0.038; 0.042; 0.050	Tentative MRL of 0.1 mg/kg derived from underdosed residue trials supporting the authorised GAP of magnesium phosphide (EFSA, 2015) Data gaps No 1 and 2	–	–	–	–
	Aluminium phosphide **Adjusted** indoor GAP (Germany 2020a, b): 1 × 10 g PH_3/m^3, fumigation period not reported, WHP 21 days	**MRL review (EFSA, 2015)** Pistachios (treated with half-opened shell)[e] [10 g/m^3, 14-day fumigation period, 2-h ventilation, WHP 21 days]: 2 × < 0.005; 0.005; 0.006	Trials on pistachios available for the MRL review were re-submitted in the present assessment. Trials compliant with the adjusted GAP Residue analysis were performed on the commodities after removal of shell	0.015	0.006	0.005	
	Magnesium phosphide **New** indoor GAP (Germany, 2020a, 2020b): 1 × 5.5 g PH_3/m^3, fumigation period not reported, WHP 21 days	**MRL review** (EFSA, 2015) Pistachios (treated without shell)[e] [5.5 g g/m^3, 2.5-day fumigation period, 24-h ventilation, WHP 21 days]: 0.038; 0.053; 0.058; 0.099 **New trials (Germany, 2020a, 2020b)** Pistachios (treated with half-opened shell)[e] [5.5 g/m^3, 5-day treatment, 30 min ventilation, WHP 21 days]: 4 × < 0.005	Trials on pistachios available for the MRL review were re-submitted in the present assessment providing information on residues in treated pistachios at the WHP of 21 day. Trials compliant with the new GAP. New trials on pistachios compliant with the new GAP. Residue analysis were performed on the commodities after removal of shell The critical data set on pistachios treated without shell was used to derive an MRL proposal supporting the new GAP	**0.2**	0.099	0.056	

(Continues)

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Commodity	Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CFR[d]
Tree nuts, except pistachios	**Aluminium phosphide** **Authorised** indoor GAP (EFSA, 2015) (still relevant): 1 × 3–11 g PH_3/m^3, 5–14-day fumigation period, WHP 21 days	**MRL review (EFSA, 2015)** Hazelnuts (treated without shell) [10 g/m^3, 14-day fumigation period, 2-h ventilation, WHP 21 days]: 0.013; 0.014; 0.018; 0.019 Pistachios (treated with half-opened shell)[e] [10 g/m^3, 14-day fumigation period, 2-h ventilation, WHP 21 days]: 2 × < 0.005; 0.005; 0.006 **New trials (Germany, 2020a, 2020b)** Hazelnuts (treated with shell)[e] [10 g/m^3, 14-day fumigation period, 3-h ventilation, WHP 21 days]: < 0.005; 0.006; 0.014; 0.033 Walnuts (treated with shell)[e] [10 g/m^3, 14-day fumigation period, 3-h ventilation, WHP 21 days]: 4 × < 0.005[e]	Trials on hazelnuts and pistachios available for the MRL review were re-submitted in the present assessment. Trials compliant with the authorised GAP New trials on hazelnuts and walnuts compliant with the authorised GAP Residue analysis were performed on the commodities after removal of shell Extrapolation to the whole group of tree nuts based on the combined dataset on hazelnuts (treated without shell) and pistachios (treated with half-opened shell) was considered to accommodate for the intended use pattern on tree nuts For hazelnuts a separate MRL is derived based on the combined data set on hazelnuts treated with and without shell	Hazelnuts: 0.05 Tree nuts (whole group, except pistachios and hazelnuts): 0.04	Hazelnuts: 0.033 Tree nuts (whole group, except pistachios and hazelnuts): 0.019	Hazelnuts: 0.014 Tree nuts (whole group except pistachios and hazelnuts): 0.010	
	Magnesium phosphide **Authorised** indoor GAP (EFSA, 2015): 1 × 3–11 g PH_3/m^3, 5–14-day fumigation period, WHP 21 days **Adjusted** indoor GAP (Germany, 2020a, 2020b) Whole group of tree nuts: 1 × 5.5 g PH_3/m^3, fumigation period not reported, WHP 21 days	**MRL review** (EFSA, 2015) Pistachios (treated without shell) [5.5 g g/m^3, 2.5-day fumigation period, 24-h ventilation, WHP 35 days]: 0.014; 0.038; 0.042; 0.050 (non-GAP-compliant WHP) Pistachios (treated without shell) [5.5 g g/m^3, 2.5-day fumigation period, 24-h ventilation, WHP 21 days]: 0.038; 0.053; 0.058; 0.099 **New trials** (Germany, 2020a, 2020b) Hazelnuts (treated with shell)[e] [5.5 g/m^3, 2.5-day fumigation period, 24 h ventilation, closed paper box][e]: 0.011; 0.013; 0.031; 0.045 Hazelnuts (treated without shell) [5.5 g/m^3, 5-day fumigation period, 30 m ventilation, WHP 21 days]: 3 × < 0.005; 0.010 Pistachios (treated with half-opened shell)[e] [5.5 g/m^3, 5-day fumigation period, 30 min ventilation, WHP 21 days]: 4 × < 0.005 Walnuts (treated with shell)[e] [5.5 g/m^3, 5-day fumigation period, 3 h 30 min ventilation, WHP 21 days]: 3 × < 0.005; 0.008	Trials on pistachios (treated without shell) available for the MRL review were re-submitted in the present assessment providing information on residues in treated pistachios at the WHP of 21 day. Trials compliant with the adjusted GAP New trials on hazelnuts (treated with and without shell), walnuts (treated with shell) and pistachios (treated with half-opened shell) compliant with GAP Residue analysis were performed on the commodities after removal of shell Extrapolation to the whole group of tree nuts is possible based on the combined dataset on hazelnuts (treated without shell) and pistachios (treated without shell)	Tree nuts (whole group): 0.2	Tree nuts (whole group): 0.099	Tree nuts (whole group, except pistachios): 0.024	

(Continued)

Commodity	Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CFR[d]
Oilseeds	**Aluminium phosphide, magnesium phosphide** **Authorised** indoor GAP (EFSA, 2015) Whole group of oilseeds: 1 × 3–11 g PH_3/m^3, 5-14-days fumigation period, WHP 7 days	**MRL review** (EFSA, 2015) **Aluminium phosphide** Linseeds [1 × 10 g PH_3/m^3, 14-day fumigation period, WHP 7 days]: 8 × < 0.005 **Magnesium phosphide** Sunflower seed (treated with shell) [5.5 g PH_3/m^3, 2.5-day fumigation period, WHP 7 days]: 0.018; 0.020; 0.025; 0.032	Tentative MRL of 0.05 mg/kg (EFSA, 2015). Data gap number 1 and 3.	–	–	–	–
	Aluminium phosphide **Adjusted GAP** (Germany, 2020a, 2020b): Linseeds: 1 × 10 g PH_3/m^3, 5-14-days fumigation period, WHP 0 days	**MRL review** (EFSA, 2015) Linseeds [1 × 10 g PH3/m3, 14-days fumigation period, WHP 0 days]: 6 × < 0.005; 0.007; 0.011	Trials on linseeds available for the MRL review were re-submitted in the present assessment providing information on residues in treated linseeds at the WHP of 0 days. Trials compliant with the adjusted GAP.	Linseeds: 0.015	Linseeds: 0.011	Linseeds: 0.005	–
	Aluminium phosphide **New GAP** (Germany, 2020a, 2020b): Soyabeans: 1 × 10 g PH_3/m^3, 5-14-days fumigation period, WHP 3 days	**New trials** (Germany, 2020a, 2020b) Soyabeans (beans treated without pods) [1 × 10 g PH_3/m^3, 14-days fumigation period, WHP 3 days]: < 0.005; 0.023; 0.026$^{(7d\ WHP)}$; 0.034	Residue trials on soaybeans compliant with the new intended GAP.	Soyabeans: 0.07	Soyabeans: 0.034	Soyabeans: 0.025	–
	Aluminium phosphide **New** GAP (Germany, 2020a, 2020b) Peanuts, sunflower seed, cotton seed: 1 × 10 g PH_3/m^3, 5-14-days fumigation period, WHP 7 days	**New trials** (Germany, 2020a, 2020b) Peanuts (treated with shell)[e] [1 × 10 g PH_3/m^3, 14-days fumigation period, WHP 7 days]: 2 × 0.33; 0.35; 0.68 Sunflower seed (treated with shell) [1 × 10 g PH_3/m^3, 14-days fumigation period, WHP 7 days]: 0.051$^{(14d\ WHP)}$; 0.058$^{(21d\ WHP)}$; 0.075; 0.16$^{(14d\ WHP)}$	Residue trials on peanuts and sunflower seeds compliant with the new GAP. Extrapolation from sunflower seeds to cotton seed is possible.	Peanuts: **1.5** Sunflower seeds, cotton seeds: **0.3**	Peanuts: 0.680 Sunflower seeds, cotton seeds: 0.160	Peanuts: 0.340 Sunflower seeds, cotton seeds: 0.067	–
	Aluminium phosphide **Same GAP** (as MRL review Germany, 2020a, 2020b) Rapeseeds, poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds, castor beans: 1 × 3–11 g PH_3/m^3, 5-14-days fumigation period, WHP 7 days	**New trials** (Germany, 2020a, 2020b) Sunflower seed (treated with shell) [1 × 10 g PH_3/m^3, 14-days fumigation period, WHP 7 days]: 0.051$^{(14\ days\ WHP)}$; 0.058$^{(21\ days\ WHP)}$; 0.075; 0.16$^{(14\ days\ WHP)}$ Soyabeans [1 × 10 g PH_3/m^3, 14-day fumigation period, WHP 7 days]: 2 × < 0.005; 0.006; 0.026	Residue trials on sunflower seeds and soyabeans compliant with the authorised GAP Extrapolation from sunflower seeds to rapeseed is possible The combined residue data sets on sunflower seeds and soyabeans can be extrapolated to poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds, castor beans, other oilseeds (minor oilseeds)	Rapeseeds: **0.3** Poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds, castor beans: **0.3**	Rapeseeds: 0.160 Poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds, castor beans: 0.160	Rapeseeds: 0.067 Poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds, borage seeds, gold of pleasure seeds, hemp seeds, castor beans: 0.039	–

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Commodity	Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CFR[d]
	Magnesium phosphide **New** indoor GAPs (Germany, 2020a, 2020b) Whole group of oilseeds: 1 × 5.5 g PH_3/m^3, WHP 14 days	**Magnesium phosphide** **MRL review (**EFSA, 2015**)** Sunflower seed (treated with shell) [5.5 g PH_3/m^3, 2.5 days treatment duration, WHP 14 days]: 2 × 0.017; 0.019; 0.028 Linseeds [5.5 g PH_3/m^3, 5 days treatment duration, WHP 7 days]: 4 × < 0.005[f] **New trials (Germany, 2020a, 2020b)** Peanuts (treated with shell)[e] [5.5 g PH_3/m^3, 5 days treatment duration, WHP 14 days]: 0.091$^{(21\ days\ WHP)}$; 0.13$^{(21\ days\ WHP)}$; 0.13$^{(31\ days\ WHP)}$; 0.15$^{(31\ days\ WHP)}$ Sunflower seed (treated with shell) [5.5 g PH_3/m^3, 5 days treatment duration, WHP 14 days]: 0.009; 0.011$^{(21\ days\ WHP)}$; 0.012; 0.012$^{(21\ days\ WHP)}$	Trials on sunflower seeds (treated with shell) and linseeds available for the MRL review were re-submitted in the present assessment, providing information on residue levels at the new WHP of 14 days for sunflower seeds. Trials on linseeds were performed with a lower WHP (7 days, instead of 14 days).[f] New trials on sunflower seeds (treated with shell) and peanuts (treated with shell) compliant with the new GAP. The proposed extrapolation from the combined residue data set on sunflower seeds (MRL review and new trials) and peanuts to the whole group of oilseeds is not in line with the EU Technical Guidelines (European Commission, 2020a), but was alternatively considered acceptable by various MS and EFSA in discussions related to the renewal of the approval procedure of phosphides in 2018. Thus, such an extrapolation was accepted by EFSA in the present assessment Extrapolation from sunflower seeds to rapeseeds and cotton seeds is possible, but the MRL derived is covered by the MRL derived for the whole group of oilseeds A higher MRL is separately derived for peanuts	Peanuts: 0.4 Whole group of oilseeds (except peanuts): 0.3	Peanuts: 0.15 Whole group of oilseeds (except peanuts): 0.150	Peanuts: 0.13 Whole group of oilseeds (except peanuts): 0.018	

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Commodity	Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CFR[d]
Cereals	**Aluminium phosphide** **Authorised** indoor GAP Whole group of cereals: 1 × 22.4 g PH_3/m^3, 14-days fumigation period, WHP 0 days	**MRL review** (EFSA, 2015) No valid trials submitted	–	–	–	–	–
	Aluminium phosphide **Adjusted** indoor GAP Barley, oat, rye, wheat: 1 × 10 g PH_3/m^3, fumigation period not reported, 3 days WHP	**New trials (Germany, 2020a, 2020b)** Wheat [1 × 10 g PH_3/m^3, 14-days fumigation period, 3 days WHP]: 10 × < 0.005	Residue trials on wheat compliant with the adjusted GAP. Extrapolation to barley, oat and rye is possible	Barley, oat, rye, wheat: 0.01*	Barley, oat, rye, wheat: 0.005	Barley, oat, rye, wheat: 0.005	
	Aluminium phosphide **Adjusted** indoor GAP Buckwheat, maize, millet, sorghum, others: 1 × 10 g PH_3/m3, fumigation period not reported, 7 days PHI **New** indoor GAP Rice: 1 × 10 g PH_3/m^3, fumigation period not reported, 7 days PHI	**New trials (Germany, 2020a, 2020b)** Maize [1 × 10 g PH_3/m^3, 14-days fumigation period, 7-days WHP]: 0.031; 0.042; 0.049; 0.091 Maize [1 × 10 g PH_3/m^3, 5-days fumigation period, 7-days WHP]: 0.007; 0.009; 0.030; 0.080 Rice [1 × 10 g PH_3/m^3, 14-days fumigation period, 7-days WHP]: 0.006; 2 × 0.007; 0.018 Wheat [1 × 10 g PH_3/m^3, 14-days fumigation period, 7-days WHP]: 8 × < 0.005	Residue trials on maize and wheat compliant with the adjusted GAP on buckwheat, maize, millet, sorghum and others and with the new GAP on rice Residue trials on maize and wheat [7 days WHP] can be combined and extrapolated to the whole group of cereals having same post-harvest application regime (i.e. buckwheat, millet, sorghum, rice, others)	Maize: **0.2** Buckwheat, millet, sorghum, rice, others: **0.15**	Maize: 0.091 Buckwheat, millet, sorghum, rice, others: 0.091	Maize: 0.037 Buckwheat, millet, sorghum, rice, others: 0.006	
	Magnesium phosphide **Authorised** indoor GAP Whole group of cereals: 1 × 5.5 g PH_3/m^3, 2.5-days fumigation period, WHP 0 days	**MRL review** (EFSA, 2015) Maize grain [5.5 g Ph_3/m^3, 2.5-days treatment, WHP: 0 days]: 0.15; 0.22; 0.27; 0.33 Wheat [5.5 g PH_3/m^3, 2.5-days treatment, WHP: 0 days]: 0.010; 0.016; 0.021; 0.023	Tentative MRLs of 0.7 mg/kg and 0.05 mg/kg for large size grains and small size grains, respectively (EFSA, 2015) Data gap No. 3	–	–	–	–
	Magnesium phosphide **Adjusted** indoor GAP (Germany, 2020a, 2020b): Large size grains (corn/maize, millet, sorghum, buckwheat, others): 1 × 5.5 g PH_3/m^3, fumigation period not reported, WHP 7 days	**MRL review** (EFSA, 2015) Maize grain [5.5 g Ph_3/m^3, 2.5-days treatment, WHP: 7 days]: 2 × 0.014; 0.021; 0.029 Wheat [5.5 g PH_3/m^3, 2.5-days treatment, WHP: 7 days]: 2 × < 0.005 **New trials (Germany, 2020a, 2020b)** Maize grain [5.5 g PH_3/m^3, 5-days treatment, WHP: 7 days]: < 0.005; 0.005; 2 × 0.008 Maize grain [4.5–4.6 g PH_3/m^3, 14-days treatment, WHP: 7 days]: < 0.005; 0.03; 0.04; 0.05; 0.08 Wheat [5–5.5 g PH_3/m^3, 5-days treatment, WHP: 7 days]: 8 × < 0.005 Wheat [4.5 g PH_3/m^3, 14-days treatment, WHP: 7 days]: < 0.01; 0.005; 0.04	Trials on maize and wheat available for the MRL review were re-submitted in the present assessment, providing information on residue levels at the adjusted WHP of 7 days. Trials compliant with adjusted GAP New trials on maize and wheat compliant with the adjusted GAP Residue trials on maize and wheat [7 days WHP] can be combined and extrapolated to the whole group of cereals having same post-harvest application regime (i.e. millet, sorghum, buckwheat, others) A separate MRL of 0.15 mg/kg is derived for maize	Maize: 0.15 Millet, sorghum, buckwheat, others: 0.09	Maize: 0.080 Millet, sorghum, buckwheat, others: 0.08	Maize: 0.014 Millet, sorghum, buckwheat, others: 0.005	

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Commodity	Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CFR[d]
	Magnesium phosphide **Adjusted** indoor GAP (Germany, 2020a, 2020b): Small size grains (rice, wheat, barley, oat, rye): 1 × 5.5 g PH_3/m^3, WHP 3 days	**MRL review** (EFSA, 2015) Wheat [5.5 g PH_3/m^3, 2.5-days treatment, WHP: 3 days]: 2 × 0.012 **New trials (Germany, 2020a, 2020b)** Wheat [5–5.5 g PH_3/m^3, 5-days treatment, WHP: 3 days]: 8 × < 0.005 Wheat [4.5 g PH_3/m^3, 14-days treatment, WHP: 3 days]: 0.005; 0.006 Rice [4.5–5.5 g PH_3/m^3, 5-day treatment, WHP: 3 days]: < 0.005; 0.005; 0.006; 0.007	Trials on wheat and rice compliant with the adjusted GAP For post-harvest uses, extrapolation from wheat to barley, oat, and rye is possible	Wheat, barley, oat, rye: **0.02** Rice: 0.015	Wheat, barley, oat, rye: 0.012 Rice: 0.007	Wheat, barley, oat, rye: 0.005 Rice: 0.006	
Herbal infusions (dried roots)	**Aluminium phosphide** **Authorised** indoor GAP: 1 × 3–11 g PH_3/m^3, 5–14 days treatment, WHP 7 days **New GAP**: 1 × 10 g PH_3/m^3, WHP 7 days	**MRL review** (EFSA, 2015) Liquorice [1 × 10 g PH_3/m^3, 14 days treatment, WHP 7 days]: 0.008; 0.008; 0.009, 0.012	Residue trials on liquorice available for the MRL review were re-submitted in the present assessment. Trials compliant with the new GAP. Extrapolation from liquorice to the whole group of herbal infusions from dried roots is possible	**0.03**	0.012	0.009	
	Magnesium phosphide **Authorised** indoor GAP: 1 × 3–11 g PH_3/m^3, 5–14 days treatment, WHP 7 days **Adjusted GAP**: 1 × 5.5 g PH_3/m^3, WHP 7 days	**New trials (Germany, 2020a, 2020b)** Liquorice [1 × 5.5 g PH_3/m^3, 5 days treatment, WHP 7 days]: 3 × < 0.005; 0.005	Residue trials on liquorice compliant with the adjusted GAP. Extrapolation from liquorice to the whole group of herbal infusions from dried roots is possible	0.01	0.005	0.005	
Cocoa beans	**Aluminium phosphide** **Authorised** indoor GAP: 1 × 17.10 g PH_3/m^3, 5-days treatment, WHP 21 days **New GAP**: 1 × 10 g PH_3/m^3, WHP 7 days	**MRL review** (EFSA, 2015) Coffee beans [1 × 10 g PH_3/m^3, 5–14 days treatment, WHP 7 days]: 0.012; 0.016; 0.02; 0.035; 0.036; 0.08 **New trials (Germany, 2020a, 2020b)** Cocoa beans [1 × 10 g PH_3/m^3, 5–14 days treatment, WHP 7 days]: 4 × < 0.005; 0.03	Residue trials on coffee beans and cocoa beans compliant with the new GAP Extrapolation from coffee beans to cocoa beans is possible	0.06 (based on trials on cocoa beans) **0.15** (via extrapolation from coffee beans)	0.03 (based on trials on cocoa beans) 0.08 (via extrapolation from coffee beans)	0.005 (based on trials on cocoa beans) 0.028 (via extrapolation from coffee beans)	
	Magnesium phosphide **Authorised** indoor GAP (still relevant): 1 × 5.5 g PH_3/m^3, 2.5-days treatment, WHP 7 days	**MRL review** (EFSA, 2015) Cocoa beans [1 × 5.5 g PH_3/m^3, 2.5 days treatment, WHP 7 days]: 3 × < 0.005; 0.011 **New trials (Germany, 2020a, 2020b)** Cocoa beans [1 × 5.5 g PH_3/m^3, 5 days treatment, WHP 7 days]: 4 × < 0.005	Residue trials on cocoa beans available for the MRL review were re-submitted in the present assessment. New trials on cocoa beans submitted All residue trials on cocoa beans compliant with the GAP	0.015	0.011	0.005	

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Commodity	Indoor[a]	Residue levels observed in the supervised residue trials (mg/kg)	Comments/Source	Calculated MRL (mg/kg)	HR[b] (mg/kg)	STMR[c] (mg/kg)	CFR[d]
Seed spices	**Aluminium phosphide** **Authorised** indoor GAP: 1 × 3–11 g PH_3/m^3, 5 days treatment, WHP 7 days **New GAP**: 1 × 10 g PH_3/m^3, WHP 7 days	**New trials (Germany, 2020a, 2020b)** Coriander [1 × 10 g PH_3/m^3, 14 days treatment, WHP 7 days]: 0.006; 0.007; 2 × 0.008	Residue trials compliant with the new GAP. Extrapolation to the whole group of seed spices is possible	**0.03**	0.008	0.008	
	Magnesium phosphide **Authorised** indoor GAP: 1 × 3–11 g PH_3/m^3, 5 days treatment, WHP 7 days **Adjusted GAP**: 1 × 5.5 g PH_3/m^3, WHP 7 days	**New trials (Germany, 2020a, 2020b)** Coriander [1 × 5.5 g PH_3/m^3, 5 days treatment, WHP 7 days]: 4 × < 0.005	Residue trials compliant with the new GAP. Extrapolation to the whole group of seed spices is possible	0.01	0.005	0.005	

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

[a]Indoor: indoor EU trials.

[b]Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

[c]Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

[d]Supervised trials median residue according to the residue definition for monitoring.

[e]The post-harvest treatment was performed on the commodity with shell; residues were measured on the commodity without shell, in accordance to Annex B.

[f]Residue levels measured at earlier WHP of 7 days, instead of 14 days. However, since all residues were uniformly measured below the LOQ at DAT 0, DAT 3 and DAT 7, the trials were not disregarded.

B.1.2.2 | Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	Not triggered	Not available and not required. When fumigating underground tunnels and burrows (rodenticide use), residues may be re-adsorbed onto soil but significant uptake of phosphane by plants is not expected.
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	Not available and not required.

B.1.2.3 | Processing factors

No processing studies were submitted in the framework of the present MRL application. Not required.

B.2 | RESIDUES IN LIVESTOCK

Calculations performed with PROFile rev. 2.3 considering the adjusted uses on cereals (Germany, 2020a, 2020b) and the existing uses on various other feed crops assessed by the MRL review (EFSA, 2015).

	Medium dietary burden (mg/kg bw per day)	Maximum dietary burden (mg/kg bw per day)	Highest contributing commodity[a]	Trigger exceeded
Dairy ruminants	0.000992	0.000992	Wheat bran	N
Meat ruminants	0.001169	0.001169	Wheat bran	N
Poultry	0.00217	0.00217	Maize grain	N
Pigs	0.00109	0.00109	Wheat bran	N

[a]Calculated for the maximum dietary burden.

Dietary burden calculation according to OECD, 2013, considering the new intended uses on oilseeds and adjusted/existing and new uses on cereals (Germany, 2020a, 2020b).

Relevant groups (subgroups)	Dietary burden expressed in				Most critical subgroup[a]	Most critical commodity[b]	Trigger exceeded (Y/N)
	mg/kg bw per day		mg/kg DM				
	Median	Maximum	Median	Maximum			
Cattle (all)	0.005	0.006	0.19	0.24	Beef cattle	Peanut meal	Y
Cattle (dairy only)	0.004	0.005	0.09	0.12	Dairy cattle	Peanut meal	Y
Sheep (all)	0.007	0.009	0.17	0.20	Lamb	Peanut meal	Y
Sheep (ewe only)	0.006	0.007	0.17	0.20	Ram/Ewe	Peanut meal	Y
Swine (all)	0.006	0.007	0.19	0.23	Swine (finishing)	Peanut meal	Y
Poultry (all)	0.008	0.011	0.11	0.15	Poultry broiler	Peanut meal	Y
Poultry (layer only)	0.007	0.011	0.11	0.15	Poultry layer	Peanut meal	Y
Fish	–	–	–	–	–	–	–

Abbreviations: bw, body weight; DM, dry matter.

[a]When one group of livestock includes several subgroups (e.g. poultry 'all' including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as 'mg/kg bw per day'.

[b]The most critical commodity is the major contributor identified from the maximum dietary burden expressed as 'mg/kg bw per day'.

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)	Comment/Source
	Not available (EFSA, 2015). Relevant residues are not expected in animal commodities following the new intended uses on oilseeds, considering the calculated dietary burdens when compared to the feeding studies with phosphonic acid			

B.2.2 | Magnitude of residues in livestock

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

No feeding studies available.

Based on the lower estimated maximum DB for phosphane and phosphide residues in livestock and poultry compared to the levels investigated in feeding studies with phosphonic acid, EFSA concludes that the residues in livestock commodities from the use of magnesium and aluminium phosphides are expected to be low and the setting of MRLs in commodities of animal origin is not required. It is however proposed that the magnitude of residues in livestock is further assessed in the framework of the renewal of the approval process of magnesium and aluminium phosphides.

B.3 | CONSUMER RISK ASSESSMENT

ARfD	0.019 mg/kg bw (EFSA, 2008a,b,c, 2010, 2012a)
Highest IESTI, according to EFSA PRIMo	5.21% of ARfD (peanuts/groundnuts) **Oilseeds:** Peanuts/groundnuts: 5.21% of ARfD Sunflower seeds: 1.12% of ARfD Safflower seeds: 0.63% of ARfD Soyabeans: 0.52% of ARfD Rapeseeds/canola seeds: 0.49% of ARfD Pumpkin seeds: 0.33% of ARfD Sesame seeds 0.30% of ARfD Mustard seeds: 0.21% of ARfD Linseeds: 0.10% of ARfD Poppy seeds: 0.14% of ARfD Borage seeds: 0.10% of ARfD Hemp seeds: 0.02% of ARfD Cotton seeds, gold of pleasure seeds, castor beans, other oilseeds: consumption data not available to perform acute risk assessment **Pistachios**: 3.02% of ARfD **Cereals:** Maize/corn: 1.31% of ARfD Rice: 0.40% of ARfD Wheat: 0.38% of ARfD Rye: 0.17% of ARfD Buckwheat and other pseudo-cereals: 0.16% of ARfD Barley: 0.15% of ARfD Sorghum: 0.10% of ARfD Common millet/proso millet: 0.04% of ARfD Oat: 0.03% of ARfD Other cereals: consumption data not available to perform acute risk assessment **Herbal infusions (dried roots):** Valerian root: 0.04% of ARfD Ginseng root: 0.04% of ARfD Other herbal infusions (dried roots): consumption data not available to perform acute risk assessment **Cocoa beans:** 1.36% of ARfD **Spices (seed):** Fennel seed: 0.03% of ARfD Anise/aniseed: <0.01% of ARfD Black caraway/black cumin: <0.01% of ARfD Celery seed: no acute risk assessment Coriander seed: <0.01% of ARfD Cumin seed: <0.01% of ARfD Dill seed: <0.01% of ARfD Fenugreek: <0.01% of ARfD Nutmeg: <0.01% of ARfD Other spices (seeds): consumption data not available to perform acute risk assessment

Assumptions made for the calculations	Calculations performed with PRIMo revision 3.1. The calculation is based on the highest residue levels (HR values) expected in the raw agricultural commodities under assessment. For the gold of pleasure seeds, castor beans and crops belonging to subgroups of "other" pulses, cereals, roots of herbal infusions and seed spices no specific consumption data are available to calculate acute exposure. However, the exposure calculations performed with the whole commodity groups of respective crops (oilseeds, cereals, herbal infusions from dried roots and seed spices) indicate low acute exposure thus confirming that no acute intake concerns will be associated with the consumption of these minor commodities.
ADI	0.011 mg/kg bw per day (EFSA, 2008a,b,c, 2010, 2012a)
Highest IEDI, according to EFSA PRIMo	4% ADI (NL toddler diet) Contribution of crops assessed: **Cereals:** Maize/corn: 2.37% of ADI (NL toddler diet) Wheat: 0.33% of ADI (GEMS/Food G06 diet) Rye: 0.25% of ADI (DK child diet) Rice: 0.08% of ADI (GEMS/Food G06 diet) Barley: 0.04% of ADI (GEMS/Food G08 diet) Oat: 0.03% of ADI (FI 3 year diet) Buckwheat and other pseudo-cereals: 0.02% of ADI (IE adult diet) Common millet/proso millet: <0.01% of ADI (NL toddler diet) Sorghum: <0.01% of ADI (GEMS/Food G06 diet) Other cereals: 0.08% of ADI (IT toddler diet) **Oilseeds:** Peanuts/groundnuts: 0.82% of ADI (NL child diet) Soyabeans: 0.61% of ADI (GEMS/Food G11 diet) Rapeseeds/canola seeds: 0.58% of ADI (NL toddler diet) Sunflower seeds: 0.41% of ADI (RO general diet) Cotton seeds: 0.19% of ADI (GEMS/Food G06 diet) Other oilseeds: 0.11% of ADI (FR child 3-15 year diet) Linseeds: 0.02% of ADI (IE adult diet) Sesame seeds: 0.02% of ADI (GEMS/Food G06 diet) Mustard seeds: 0.01% of ADI (GEMS/Food G11 diet) Poppy seeds: <0.01% of ADI (DE child diet) Pumpkin seeds: <0.01% of ADI (DE child diet) Safflower seeds: <0.01% of ADI (NL child diet) Borage seeds: <0.01% of ADI (DE general diet) Hemp seeds: <0.01% of ADI (FR toddler 2-3 yeas diet) Castor beans: <0.01% of ADI (GEMS/Food G06 diet) Gold of pleasure seeds: consumption data not available to perform chronic risk assessment **Pistachios:** 0.02% of ADI (IE adult diet) **Herbal infusions (dried roots):** Consumption data not available to perform chronic risk assessment **Cocoa beans:** 0.13% of ADI (ES child diet) **Spices (seed):** Anise/aniseed: <0.01% of ADI (DE child diet) Black caraway/black cumin: <0.01% of ADI (DE women 14-50 year diet)

	Celery seed: consumption data not available to perform chronic risk assessment Coriander seed: <0.01% of ADI (DE child diet) Cumin seed: <0.01% of ADI (DE child diet) Dill seed: consumption data not available to perform chronic risk assessment Fennel seed: <0.01% of ADI (DE child diet) Fenugreek: <0.01% of ADI (DE women 14-50 year diet) Nutmeg: <0.01% of ADI (DE child diet) Other spices (seeds): <0.01% of ADI (FR toddler 2-3 year diet)
Assumptions made for the calculations	Calculations performed with PRIMo revision 3.1. The calculation is based on the median residue levels derived for raw agricultural commodities under assessment. For the remaining commodities, the input values as derived in the MRL review (EFSA, 2015) were used. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation. For the gold of pleasure seeds, celery seed, dill seed no consumption data are available to estimate the chronic exposure. Noting low exposures calculated from the intake of other crops belonging to the commodity groups of oilseeds and seed spices, it is unlikely that intake of gold of pleasure seeds and celery and dill seeds, which are considered minor commodities, will significantly add to the overall chronic exposure. For herbal infusions (dried roots) due to the lack of specific consumption data, no chronic risk assessment could be performed. Considering the low exposure (<0.01 % ADI) calculated from the intake of dried leaves and dried flowers of herbal infusions, it is unlikely that the intake of dried roots for herbal infusions will contribute significantly to the overall chronic exposure, additionally noting that these are minor commodities (valerian root, ginseng root and other herbal infusions (dried roots)).

B.4 | RECOMMENDED MRLS

Code[a]	Commodity	Existing MRLh[b]	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/recommendation
Enforcement residue definition both for aluminium phosphide and magnesium phosphide: Phosphane and phosphide salts (sum of phosphane and phosphane generators (relevant phosphide salts), determined and expressed as phosphane)					
0120000 (except 0120100 and 0120990)	Tree nuts (except pistachios and others)	0.09 (ft 1, ft 3)	Footnote related to data gap No 1 [an ILV and a confirmatory method for monitoring of phosphide]	0.01* or 0.09 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide residues was not fully addressed. A risk management decision is required New trials supporting the authorised GAP for AlP and an adjusted GAP for Mg_3P_2 on tree nuts were submitted to address the uncertainties identified by the MRL review related to varying residue levels in tree nuts. The new submitted trials indicate that a higher MRL of 0.2 mg/kg would be required for the whole group of tree nuts, based on the critical data set on Mg_3P_2. However, in the context of the present assessment, raising of the current MRL was not requested for the uses of AlP and Mg_3P_2 on tree nuts (except pistachios) and is therefore not proposed. No risk for consumers identified
0120100	Pistachios	0.1 (ft 2)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 2 [clarifications regarding the discrepancies observed in the residue trial results for pistachios]	0.01* or 0.2 (further risk management decision required)	The data gaps identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning clarifications regarding the discrepancies observed in the residue trial results for pistachios (data gap No 2) can be considered addressed New trials supporting the new GAP for Mg_3P_2 on pistachios indicate that a higher EU MRL is required for which no risk for consumers identified
0401010	Linseeds	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the adjusted GAP for AlP and the new GAP for Mg_3P_2 on linseeds are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on Mg_3P_2. No risk for consumers identified
0401020	Peanuts/ groundnuts	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 1.5 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of AlP and Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the new GAPs for AlP and Mg_3P_2 on peanuts are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified

(Continued)

Code[a]	Commodity	Existing MRLh[b]	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/recommendation
0401030 0401040	Poppy seeds Sesame seeds	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the authorised GAP for AIP and the new GAP for Mg_3P_2 are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AIP. No risk for consumers identified
0401050	Sunflower seeds	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of AIP and Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the new GAPs for AIP and Mg_3P_2 in sunflower seeds are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AIP. No risk for consumers identified
0401060	Rapeseeds/ canola seeds	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the authorised GAP for AIP and the new GAP for Mg_3P_2 are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AIP. No risk for consumers identified.
0401070	Soyabeans	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of AIP and Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the new GAPs for AIP and Mg_3P_2 on soyabeans are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on Mg_3P_2. No risk for consumers identified

(Continues)

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Code[a]	Commodity	Existing MRLh[b]	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/recommendation
0401080	Mustard seeds	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the authorised GAP for AlP and the new GAP for Mg_3P_2 are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified
0401090	Cotton seeds	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of AlP and Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the new GAPs for AlP and Mg_3P_2 in cotton seeds are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified
0401100 0401110 0401120 0401130 0401140 0401150	Pumpkin seeds Safflower seeds Borage seeds Gold of pleasure seeds Hemp seeds Castor beans	0.05 (ft 4)	Footnote related to data gaps No 1 [an ILV and a confirmatory method for monitoring of phosphide] and 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.01* or 0.3 (further risk management decision required)	The data gap identified by EFSA concerning an ILV and a confirmatory method for monitoring of phosphide (data gap No 1) was not fully addressed and is relevant for the new intended uses of Mg_3P_2. A risk management decision is required The data gap identified by EFSA concerning residue trials supporting authorisations on oilseeds (data gap No 3) was addressed A sufficient number of trials supporting the authorised GAP for AlP and the new GAP for Mg_3P_2 available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified
0401990	Other oilseeds	0.05		0.01* or 0.3 (further risk management decision required)	MRL proposal based on the critical data set on AlP on minor oilseeds. No risk for consumers identified ILV of the analytical method for enforcement in high-oil content commodities is not available. A risk management decision is required
0500010	Barley	0.05 (ft 5)	Footnote related to data gap No 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.02	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AlP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on Mg_3P_2. No risk for consumers identified

(Continued)

Code[a]	Commodity	Existing MRLh[b]	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/recommendation
0500020	Buckwheat and other pseudo-cereals	0.7 (ft 5)	Footnote related to data gap No 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.15	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AlP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified
0500030	Maize/corn	0.7 (ft 5)	Footnote related to data gap No 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.2	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AlP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified
0500040	Common millet/ proso millet	0.7 (ft 5)	Footnote related to data gap No 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.15	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AlP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified
0500050	Oat	0.05 (ft 5)	Footnote related to data gap No 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.02	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AlP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on Mg_3P_2. No risk for consumers identified
0500060	Rice	0.05 (ft 5)	Footnote related to data gap No 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.15	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the new GAP for AlP and the adjusted GAP for Mg_3P_2 in rice are available. A higher MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified
0500070	Rye	0.05 (ft 5)	Footnote related to data gap No 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.02	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AlP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on Mg_3P_2. No risk for consumers identified
0500080	Sorghum	0.7 (ft 5)	Footnote related to data gap No 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.15	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AlP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on AlP. No risk for consumers identified

(Continues)

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Code[a]	Commodity	Existing MRLh[b]	Data gap(s) Art.12 Review	Proposed MRL	Conclusion/recommendation
0500090	Wheat	0.05 (ft 5)	Footnote related to data gap No 3 [residue trials supporting authorisations on oilseeds and cereal grains]	0.02	The data gap identified by EFSA concerning residue trials supporting authorisations on cereal grains was addressed. A sufficient number of trials supporting the adjusted GAPs for AlP and Mg_3P_2 are available. A lower MRL than the one tentatively derived during the MRL review was derived based on the critical data set on Mg_3P_2. No risk for consumers identified
0500990	Other cereals	0.01*		0.15	MRL proposal based on the critical data set on AlP in support of the new GAP on rice and other cereal grains. No risk for consumers identified
0633000	Herbal infusions (dried roots)	0.02		0.03	The submitted data are sufficient to derive an MRL proposal for the post-harvest use. Risk for consumers unlikely
0640000	Cocoa beans	0.02		0.15	The submitted data are sufficient to derive an MRL proposal for the post-harvest use. Risk for consumers unlikely
0810000	Spices (seeds)	0.02		0.03	The submitted data are sufficient to derive an MRL proposal for the post-harvest use. Risk for consumers unlikely
1000000	Products of animal origin - terrestrial animals	0.01 (ft 6)	Footnote related to data gap No 4 [data confirming that occurrence of phosphane and its oxidation products is negligible in livestock products]	0.01*	The data gap identified by EFSA concerning the occurrence of phosphane and its oxidation products in commodities of animal origin is considered addressed

Abbreviations: GAP, Good Agricultural Practice. ILV, independent laboratory validation; MRL, maximum residue level.

*Indicates that the MRL is set at the limit of analytical quantification (LOQ).

[a]Commodity code number according to Annex I of Regulation (EC) No 396/2005.

[b]Existing EU MRL and corresponding footnote on confirmatory data.

[ft 1]The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1).

[ft 2]The European Food Safety Authority identified some information on analytical methods and clarifications regarding residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gaps No 1 and 2).

[ft 3]The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1).

[ft 4]The European Food Safety Authority identified some information on analytical methods and residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 1 and 3).

[ft 5]The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 3).

[ft 6]The European Food Safety Authority identified some information on the occurrence of phosphane and its oxidation products in commodities of animal origin as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 8 October 2018, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 4).

APPENDIX C

Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

phosphane and phosphide salts

LOQs (mg/kg) range from: 0.01 to: 0.05

Toxicological reference values

ADI (mg/kg bw per day):	0.011	ARfD (mg/kg bw):	0.019
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2008a,b,c, 2010, 2012a	Year of evaluation:	2008a,b,c, 2010, 2012a

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	4%	NL toddler	0.43	2%	Maize/corn	0.6%	Rapeseeds/canola seeds	0.4%	Peanuts/groundnuts		4%
	2%	GEMS/Food G11	0.20	0.7%	Peanuts/groundnuts	0.6%	Soyabeans	0.2%	Wheat		2%
	2%	GEMS/Food G10	0.20	0.5%	Soyabeans	0.3%	Peanuts/groundnuts	0.2%	Maize/corn		2%
	2%	NL child	0.20	0.8%	Peanuts/groundnuts	0.3%	Rapeseeds/canola seeds	0.2%	Sunflower seeds		2%
	2%	GEMS/Food G07	0.19	0.3%	Rapeseeds/canola seeds	0.3%	Peanuts/groundnuts	0.3%	Soyabeans		2%
	2%	GEMS/Food G06	0.18	0.4%	Maize/corn	0.3%	Wheat	0.2%	Soyabeans		2%
	2%	FI adult	0.17	1%	Coffee beans	0.0%	Rye	0.0%	Other oilseeds		2%
	2%	GEMS/Food G08	0.17	0.3%	Soyabeans	0.3%	Sunflower seeds	0.2%	Rapeseeds/canola seeds		2%
	1%	GEMS/Food G15	0.16	0.3%	Sunflower seeds	0.3%	Soyabeans	0.2%	Maize/corn		1%
	1%	RO general	0.13	0.4%	Sunflower seeds	0.3%	Maize/corn	0.2%	Wheat		1%
	0.9%	NL general	0.10	0.3%	Peanuts/groundnuts	0.2%	Rapeseeds/canola seeds	0.1%	Sunflower seeds		0.9%
	0.8%	FR child 3 15 yr	0.09	0.2%	Wheat	0.1%	Sunflower seeds	0.1%	Maize/corn		0.8%
	0.8%	IE adult	0.09	0.3%	Peanuts/groundnuts	0.1%	Sunflower seeds	0.1%	Wheat		0.8%
	0.7%	PT general	0.07	0.2%	Wheat	0.2%	Sunflower seeds	0.2%	Maize/corn		0.7%
	0.6%	DE child	0.06	0.2%	Wheat	0.1%	Cocoa beans	0.1%	Peanuts/groundnuts		0.6%
	0.6%	ES child	0.06	0.2%	Wheat	0.1%	Cocoa beans	0.1%	Maize/corn		0.6%
	0.6%	UK infant	0.06	0.3%	Maize/corn	0.1%	Wheat	0.0%	Peanuts/groundnuts		0.6%
	0.5%	FR toddler 2 3 yr	0.06	0.1%	Wheat	0.1%	Cocoa beans	0.1%	Sunflower seeds		0.5%
	0.5%	DK child	0.05	0.3%	Rye	0.2%	Wheat	0.0%	Oat		0.5%
	0.5%	DE general	0.05	0.1%	Coffee beans	0.1%	Wheat	0.1%	Peanuts/groundnuts		0.5%
	0.5%	IT toddler	0.05	0.3%	Wheat	0.1%	Other cereals	0.0%	Other oilseeds		0.5%
	0.5%	DE women 14-50 yr	0.05	0.1%	Coffee beans	0.1%	Wheat	0.1%	Peanuts/groundnuts		0.5%
	0.4%	FR adult	0.05	0.1%	Coffee beans	0.1%	Wheat	0.1%	Sunflower seeds		0.4%
	0.4%	UK toddler	0.04	0.2%	Wheat	0.1%	Peanuts/groundnuts	0.0%	Beans		0.4%
	0.3%	FI 3 yr	0.04	0.1%	Wheat	0.1%	Cocoa beans	0.0%	Rapeseeds/canola seeds		0.3%
	0.3%	FI 6 yr	0.03	0.1%	Cocoa beans	0.0%	Wheat	0.0%	Peanuts/groundnuts		0.3%
	0.3%	ES adult	0.03	0.1%	Wheat	0.1%	Sunflower seeds	0.0%	Cocoa beans		0.3%
	0.3%	IT adult	0.03	0.2%	Wheat	0.0%	Other cereals	0.0%	Peanuts/groundnuts		0.3%
	0.3%	UK vegetarian	0.03	0.1%	Peanuts/groundnuts	0.1%	Wheat	0.0%	Rice		0.3%
	0.2%	UK adult	0.02	0.1%	Wheat	0.1%	Peanuts/groundnuts	0.0%	Rice		0.2%
	0.2%	SE general	0.02	0.1%	Wheat	0.0%	Rice	0.0%	Rye		0.2%
	0.2%	LT adult	0.02	0.0%	Rye	0.0%	Wheat	0.0%	Sunflower seeds		0.2%
	0.1%	FR infant	0.01	0.0%	Wheat	0.0%	Other oilseeds	0.0%	Sunflower seeds		0.1%
	0.1%	DK adult	0.01	0.1%	Wheat	0.0%	Rye	0.0%	Rice		0.1%
	0.1%	IE child	0.01	0.1%	Wheat	0.0%	Rice	0.0%	Pistachios		0.1%
	0.0%	PL general	0.00	0.0%	Peanuts/groundnuts	0.0%	Sunflower seeds	0.0%	Walnuts		0.0%

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

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD.
The calculation is based on the large portion of the most critical consumer group.

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Peanuts/groundnuts	1.5/0.34	0.99
4%	Coconuts	0.09/0.05	0.72
3%	Pistachios	0.2/0.1	0.57
1%	Cocoa beans	0.15/0.08	0.26
1%	Maize/corn	0.2/0.04	0.25
1%	Sunflower seeds	0.3/0.07	0.21
1%	Chestnuts	0.09/0.05	0.21
0.9%	Walnuts	0.09/0.05	0.17
0.9%	Hazelnuts/cobnuts	0.09/0.05	0.16
0.8%	Almonds	0.09/0.05	0.14
0.7%	Pecans	0.09/0.05	0.14
0.7%	Cashew nuts	0.09/0.05	0.13
0.6%	Safflower seeds	0.3/0.04	0.12
0.5%	Rapeseeds/canola seeds	0.3/0.07	0.09
0.5%	Beans	0.01/0.01	0.09

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Peanuts/groundnuts	1.5/0.34	0.78
2%	Coconuts	0.09/0.05	0.43
1%	Pistachios	0.2/0.1	0.26
1%	Chestnuts	0.09/0.05	0.23
0.7%	Cocoa beans	0.15/0.08	0.13
0.6%	Pecans	0.09/0.05	0.11
0.6%	Walnuts	0.09/0.05	0.11
0.6%	Macadamia	0.09/0.05	0.11
0.5%	Soyabeans	0.3/0.02	0.10
0.4%	Cashew nuts	0.09/0.05	0.09
0.4%	Maize/corn	0.2/0.04	0.08
0.4%	Almonds	0.09/0.05	0.07
0.4%	Sunflower seeds	0.3/0.07	0.07
0.3%	Pumpkin seeds	0.3/0.04	0.06
0.3%	Hazelnuts/cobnuts	0.09/0.05	0.06

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

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Peanuts/peanut butter	1.5/0.34	1.2
5%	Maize/oil	0.2/0.93	0.86
0.8%	Sunflower seeds/oils	0.3/0.13	0.16
0.7%	Coconuts/drink	0.09/0.02	0.14
0.4%	Maize/processed (not specified)	0.2/0.04	0.08
0.4%	Soyabeans/soya drink	0.3/0.02	0.08
0.3%	Wheat/milling (flour)	0.02/0.01	0.06
0.3%	Coffee beans/extraction	0.15/0.01	0.05
0.2%	Lentils/boiled	0.01/0.01	0.04
0.2%	Rapeseeds/oils	0.3/0.13	0.04
0.2%	Rice/milling (polishing)	0.15/0	0.04
0.2%	Peas/canned	0.01/0	0.04
0.2%	Cocoa (fermented beans)/processed (not specified)	0.15/0	0.03
0.2%	Millet/boiled	0.15/0	0.03
0.2%	Buckwheat /bulgur and grits	0.15/0.01	0.03

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Maize/oil	0.2/0.93	0.47
0.7%	Coffee beans/extraction	0.15/0.01	0.13
0.3%	Coconuts/drink	0.09/0.02	0.06
0.2%	Barley/beer	0.02/0	0.04
0.2%	Beans/canned	0.01/0.01	0.04
0.1%	Rice/milling (polishing)	0.15/0	0.02
0.1%	Wheat/bread/pizza	0.02/0.01	0.02
0.1%	Cocoa (fermented beans)/processed (not specified)	0.15/0	0.02
0.1%	Wheat/pasta	0.02/0.01	0.02
0.09%	Wheat/bread (wholemeal)	0.02/0.01	0.02
0.07%	Millet/boiled	0.15/0	0.01
0.07%	Peas/canned	0.01/0	0.01
0.05%	Ginger/jam	0.02/0.01	0.01
0.04%	Oat/boiled	0.02/0.01	0.01
0.01%	Tea (dried leaves of Camellia sinensis)/infusion	0.02/0	0.00

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of phosphane and phosphide salts is unlikely to present a public health risk.

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

APPENDIX D

Input values for the exposure calculations

D.1 | LIVESTOCK DIETARY BURDEN CALCULATIONS

Calculations performed with PROFile rev.2.3 considering the adjusted uses on cereals (Germany, 2020a, 2020b) and the existing uses on various other feed crops assessed by the MRL review (EFSA, 2015).

	Median dietary burden		Maximum dietary burden	
Feed commodity	**Input value[a] (mg/kg)**	**Comment**	**Input value[a] (mg/kg)**	**Comment**
Risk assessment residue definition: Sum of phosphane and phosphane generators (relevant phosphide salts), determined and expressed as phosphane (EFSA, 2015)				
Wheat grain	0.01	STMR	0.01	HR
Barley grain	0.01	STMR	0.01	HR
Oat grain	0.01	STMR	0.01	HR
Maize grain	0.04	STMR	0.09	HR
Wheat, rye bran	0.08	STMR × PF (8)[b,c]	0.08	STMR × PF (8)[b,c]
Peas, beans, lupins (dry)	0.005*	STMR (EFSA, 2015)	0.01*	HR (EFSA, 2015)
Rape seed meal	0.01*	STMR × PF (2)[b,c] (EFSA, 2015)	0.01*	STMR × PF (2)[b,c] (EFSA, 2015)
Cotton seed	0.005*	STMR (EFSA, 2015)	0.03	HR (EFSA, 2015)
Cotton seed meal	0.007*	STMR × PF (1.3)[b,c] (EFSA, 2015)	0.007*	STMR × PF (1.3)[b,c] (EFSA, 2015)
Linseeds meal	0.01*	STMR × PF (2)[b,c] (EFSA, 2015)	0.01*	STMR × PF (2)[b,c] (EFSA, 2015)
Sunflower seed meal	0.01*	STMR × PF (2)[b,c] (EFSA, 2015)	0.01*	STMR × PF (2)[b,c] (EFSA, 2015)
Soyabean	0.005*	STMR (EFSA, 2015)	0.03	HR (EFSA, 2015)
Soyabean meal	0.007*	STMR × PF (1.3)[b,c] (EFSA, 2015)	0.007*	STMR × PF (1.3)[b,c] (EFSA, 2015)
Peanuts meal	0.01*	STMR × PF (2)[b,c] (EFSA, 2015)	0.01*	STMR × PF (2)[b,c] (EFSA, 2015)

Abbreviations: HR, highest residue; PF, processing factor; STMR, supervised trials median residue.

[a]Figures in the table are rounded to 2 digits, except for values at the LOQ, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

[b]In the absence of processing factors supported by data, default processing factors (in bracket) were respectively included in the calculation to consider the potential concentration of residues in these commodities.

[c]Default processing factors were applied as follows: 8 or wheat and rye bran, 2 for rapeseed, linseeds, sunflower and peanut meal, 1.3 for cotton seed and soyabean meal.

Calculations according to OECD 2013, considering the new intended uses on oilseeds and adjusted/existing and new uses on cereals (Germany, 2020a, 2020b).

	Median dietary burden		Maximum dietary burden	
Feed commodity	**Input value[a] (mg/kg)**	**Comment**	**Input value[a] (mg/kg)**	**Comment**
Risk assessment residue definition: Sum of phosphane and phosphane generators (relevant phosphide salts), determined and expressed as phosphane **(EFSA, 2015)**				
Barley grain	0.01	STMR	0.01	HR
Bean seed (dry)	0.01	STMR	0.01	HR
Corn, field (Maize) grain	0.04	STMR	0.09	HR
Corn, pop grain	0.04	STMR	0.09	HR
Cotton undelinted seed	0.07	STMR	0.16	HR
Cowpea seed	0.01	STMR	0.01	HR
Lupin seed	0.01	STMR	0.01	HR
Millet grain	0.01	STMR	0.09	HR
Oat grain	0.01	STMR	0.01	HR
Pea (Field pea) seed (dry)	0.01	STMR	0.01	HR
Rye grain	0.01	STMR	0.01	HR
Sorghum grain	0.01	STMR	0.09	HR
Soyabean seed	0.03	STMR	0.15	HR
Triticale grain	0.01	STMR	0.09	HR
Wheat grain	0.01	STMR	0.01	HR
Brewer's grain dried	0.02	STMR × default PF	–	–

(Continues)

(Continued)

	Median dietary burden		Maximum dietary burden	
Feed commodity	**Input value[a] (mg/kg)**	**Comment**	**Input value[a] (mg/kg)**	**Comment**
Coconut meal	0.01	STMR × default PF	–	–
Corn, field milled by-products	0.04	STMR × default PF	–	–
Corn, field hominy meal	0.22	STMR × default PF	–	–
Corn, field gluten feed	0.09	STMR × default PF	–	–
Corn, field gluten meal	0.04	STMR × default PF	–	–
Cotton meal	0.09	STMR × default PF	–	–
Distiller's grain dried	0.12	STMR × default PF	–	–
Flaxseed/Linseeds meal	0.04	STMR × default PF	–	–
Lupin seed meal	0.01	STMR × default PF	–	–
Peanut meal	0.68	STMR × default PF	–	–
Rice bran/pollard	0.06	STMR × default PF	–	–
Safflower meal	0.08	STMR × default PF	–	–
Soyabean meal	0.03	STMR × default PF	–	–
Soyabean hulls	0.33	STMR × default PF	–	–
Sunflower meal	0.13	STMR × default PF	–	–
Wheat gluten meal	0.01	STMR × default PF	–	–
Wheat milled by-products	0.04	STMR × default PF	–	–

Abbreviations: HR, highest residue; PF, processing factor; STMR, supervised trials median residue.

[a]Figures in the table are rounded to 2 digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

D.2 | CONSUMER RISK ASSESSMENT

			Chronic risk assessment		Acute risk assessment	
Commodity	**Existing/ Proposed MRL (mg/kg)**	**Source**	**Input value[a] (mg/kg)**	**Comment**	**Input value[a] (mg/kg)**	**Comment[b]**
Pistachios	0.2	MRL proposal	0.06	STMR-RAC	0.10	HR-RAC
Linseeds, Soyabeans	0.3	MRL proposal	0.02	STMR-RAC	0.02	STMR-RAC
Peanuts/groundnuts	1.5	MRL proposal	0.34	STMR-RAC	0.34	STMR-RAC
Poppy seeds, sesame seeds, mustard seeds, pumpkin seeds, safflower seeds borage seeds, gold of pleasure seeds, hemp seeds, castor beans, other oilseeds	0.3	MRL proposal	0.04	STMR-RAC	0.04	STMR-RAC
Sunflower seeds, Rapeseeds/canola seeds, Cotton seeds	0.3	MRL proposal	0.07	STMR-RAC	0.07	STMR-RAC
Barley, Oat, Rye, Wheat	0.02	MRL proposal	0.01	STMR-RAC	0.01	STMR-RAC
Buckwheat and other pseudo-cereals, Common millet/proso millet, Rice, Sorghum, Other cereals	0.15	MRL proposal	0.01	STMR-RAC	0.01	STMR-RAC
Maize/corn	0.2	MRL proposal	0.04	STMR-RAC	0.04	STMR-RAC
Herbal infusions (dried roots)	0.03	MRL proposal	0.01	STMR-RAC	0.01	HR-RAC
Cocoa beans	0.15	MRL proposal	0.03	STMR-RAC	0.08	HR-RAC
Spices (seed)	0.03	MRL proposal	0.01	STMR-RAC	0.01	HR-RAC
Tree nuts, except pistachios	0.09	EFSA (2015)	0.02	STMR-RAC	0.05	HR-RAC
Herbs and edible flowers	0.015	EFSA (2015)	0.01	STMR-RAC	0.01	HR-RAC
Pulses	0.01	EFSA (2015)	0.01	STMR-RAC	0.01	STMR-RAC
Tea (dried leaves of Camellia sinensis)	0.02	EFSA (2015)	0.01	STMR-RAC	0.01	STMR-RAC
Coffee beans	0.15	EFSA (2015)	0.03	STMR-RAC	0.03	STMR-RAC
Herbal infusions (dried flowers, dried leaves)	0.02	EFSA (2015)	0.01	STMR-RAC	0.01	HR-RAC

(Continued)

Commodity	Existing/ Proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Spices (fruit, bark, root and rhizome, buds, flower stigma, aril)	0.02	EFSA (2015)	0.01	STMR-RAC	0.01	HR-RAC

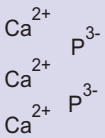
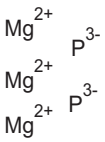
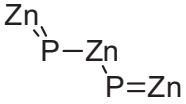
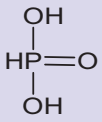
Abbreviations: HR-RAC, highest residue in raw agricultural commodity; PeF, Peeling factor; STMR-RAC, supervised trials median residue in raw agricultural commodity.

[a]Figures in the table are rounded to 2 digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce dietary burden calculations, the unrounded values need to be used.

[b]Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

APPENDIX E

Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
aluminium phosphide	Alumanylidynephosphane [Al]#P PPNXXZIBFHTHDM-UHFFFAOYSA-N	
calcium phosphide	calcium phosphide [P-3].[P-3].[Ca + 2].[Ca + 2].[Ca + 2] HMJZRBDFJAQGEY-UHFFFAOYSA-N	
magnesium phosphide	magnesium phosphide [Mg + 2].[Mg + 2].[Mg + 2].[P-3].[P-3] VUBDMGXNLNDGIY-UHFFFAOYSA-N	
phosphane (previously phosphine)	Phosphane P XYFCBTPGUUZFHI-UHFFFAOYSA-N	
zinc phosphide	zinc phosphide [Zn] = P[Zn]P = [Zn] NQDYSWQRWWTVJU-UHFFFAOYSA-N	
phosphonic acid (previously phosphorous acid)	phosphonic acid O=P(O)O ABLZXFCXXLZCGV-UHFFFAOYSA-N	

[a]The metabolite name in bold is the name used in the conclusion.

[b]ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 7 July 2021.

[c]ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021.