

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion regarding the peer review of the pesticide risk assessment of the active substance aluminium phosphide

Issued on 29 September 2008

SUMMARY

Aluminium phosphide is one of the 84 substances of the third stage Part B of the review programme covered by Commission Regulation (EC) No 1490/2002¹. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State and to provide within six months a conclusion on the risk assessment to the EU-Commission.

Germany being the designated rapporteur Member State submitted the DAR on aluminium phosphide in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 19 June 2007. The peer review was initiated on 29 October 2007 by dispatching the DAR for consultation of the Member States and the applicants Casa Bernardo, Detia Freyberg GmbH and United Phosphorus Ltd. Subsequently, the comments received on the DAR were examined and responded by the rapporteur Member State in the reporting table. This table was evaluated by EFSA to identify the remaining issues. The identified issues as well as further information made available by the applicant upon request were evaluated in a series of scientific meetings with Member State experts in June - July 2008.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in September 2008 leading to the conclusions as laid down in this report.

This conclusion was reached on the basis of the evaluation of the representative uses as an insecticide, rodenticide, talpicide and leporicide as proposed by the notifier. Full details of the GAP can be found in the attached list of endpoints.

¹ OJ No L 224, 21.08.2002, p. 25, as amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19)

The representative formulated products for the evaluation were “Phostoxin Tabletten”, “Quickphos tablet/pellets/bags 56 GE”, and “Gastoxin” gas generating products (GE). The gas phosphine that is produced is the true active ingredient.

Pooling all the available data from all aluminium phosphide applicants a method of analysis for phosphine in products of plant origin is available; however ILV and a confirmatory method have been identified as a data gap. A method for products of animal origin is not required as MRLs have not been set. Methods for phosphine in soil are not required as the DT₉₀ in soil is < 3 days for phosphine. A method is available for phosphine in water but a confirmatory method has been identified as a data gap. It should be noted however, that there is a confirmatory method in the magnesium phosphide DAR. The method of analysis for air did not have a low enough LOQ and a data gap was identified. Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection products are possible. The meeting of experts considered the specification and impurities on the basis that the spent pellets were contained and removed from the treated material. Therefore, given the toxicity of phosphine, possible relevant impurities were ignored. The case where the spent material is not removed has not been considered in the peer review process. The batch data and the specification for the Casa Bernardo sources were not accepted. Some data gaps for physchem data for the individual formulations were identified.

The mammalian toxicology of aluminium phosphide was assessed in a series of tests. When coming into contact with moisture aluminium phosphide decomposes to aluminium hydroxide and phosphine, which is the toxicologically active ingredient and the relevant component for the assessment of mammalian toxicology of aluminium phosphide. Aluminium phosphide is classified as **R29 “Contact with water liberates toxic gas”** and **R32 “Contact with acids liberates very toxic gas”**. Phosphine is rapidly absorbed from the gastrointestinal tract and the lungs. It is widely and evenly distributed in the body and has no potential for accumulation. Phosphine is excreted as such via expired air or with the urine in form of hypophosphite or phosphite. Aluminium phosphide is very toxic by the oral and inhalation route and harmful by the dermal route. It is neither a skin nor an eye irritant nor a skin sensitizer. Based on data on acute toxicity a classification as **T+; R28 “Very toxic if swallowed”, Xn; R21 “Harmful in contact with skin”** and **T+; R26 “Very toxic by inhalation”** is proposed. A short term NOAEL of 1.1 mg/kg bw/d (the highest dose tested, no adverse effects observed) was derived for phosphine from a rat 90-day inhalation study. Aluminium phosphide is not genotoxic. In a 2-year inhalation study with rats a NOAEL of 1.1 mg/kg bw/d was established for phosphine which was the highest dose level tested since no adverse effects were observed. A mouse carcinogenicity study was not carried out and not considered necessary based on the toxicity profile of the substance (lethality anticipated at low doses). In an inhalation developmental study with rats (a rabbit study was not provided) no specific developmental effects were observed and an overall

NOAEL for phosphine of 1.9 mg/kg bw/d was set based on mortality occurring in dams. Effects on reproduction have not been assessed but are, based on the toxicity profile of the substance, not anticipated. The acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) have been set at 0.019 mg/kg bw/d. The acute reference dose (ARfD) was fixed at 0.032 mg/kg bw. The corresponding values for phosphine are 0.011 mg/kg bw/d (ADI and AOEL) and 0.019 mg/kg bw (ARfD). When applying aluminium phosphide containing formulations in rodent burrows without the use of respiratory protective equipment (RPE) maximum exposure levels amounted to 93% of the AOEL for operators, workers and bystanders, however more realistic exposure levels for workers and bystanders presented in the DAR accounted for 63% and 33% of the AOEL respectively. Application of aluminium phosphide in storage rooms when respiratory protective equipment is used amounted to 71% for operators and to 33% (or alternatively to 25%) for workers of the systemic AOEL. For unprotected bystanders a maximum value for exposure of 33% of the AOEL was derived.

Two main uses of aluminium phosphide were evaluated, 1) as rodenticide, talpicide, leporicide to control rodent and non-rodent vertebrates by fumigation of underground tunnels and burrows in cropland and non-cropland situations, 2) as fumigant to control insects in various harvested plant products and in empty warehouses or transportation facilities. Due to its physico-chemical properties, no specific studies to evaluate metabolism and distribution of aluminium phosphide in treated commodities were submitted. In contact with soil or atmospheric moisture, aluminium phosphide is rapidly hydrolysed to produce phosphine (PH_3) and aluminium hydroxide $\text{Al}(\text{OH})_3$. After treatment the major part of phosphine is volatilised and diluted in air or oxidised to phosphorous oxyacids of no significant concern for human health. Considering stored fumigated commodities may contain residual gaseous phosphine and residual metal phosphide, the residue definition for monitoring and risk assessment was set as “phosphine and phosphine generators (relevant phosphide salts) determined and expressed as phosphine”.

No residue trials were submitted to support the uses of aluminium phosphide as a rodenticide, considering that the direct application of the active substance into underground tunnels of rodent or non-rodent animals excludes the direct contact with plants and therefore, the possible residues in plants. For post harvest applications, in addition to the aeration period, the RMS proposed for each commodity or group of commodities a withholding period. Thus, during the meeting, the MRL proposals were not discussed on the basis of the residue levels observed at the end of the aeration period as stated in the GAP, but at the end of these additional withholding periods of 7 to 35 days, depending on the commodities. Consequently and after the meeting, EFSA was of the opinion that the fumigation practices have not been sufficiently defined to allow MRL setting, and considers the fact that the withholding periods were not clearly described in the intended GAP as a data gap.

No storage stability study was provided considering that the inherent properties of phosphine lead to a low stability in stored products. No processing studies and no livestock metabolism and feeding studies were provided since no significant residues of aluminium phosphide and phosphine are

expected in post harvested plant commodities. No rotational crop studies were submitted since no residues in soil are expected from the outdoor uses on rodent and non-rodent vertebrates. No chronic or acute risks to consumers are expected after fumigation of stored commodities with aluminium phosphide if a withholding period is taken into account in the GAP, and considering that the proposed MRL values do not reflect the critical GAPs as initially defined by the applicants.

When placed in animal burrows (i.e. the soil environment) aluminium phosphide will rapidly hydrolyse producing phosphine gas and aluminium salts. The phosphine gas produced, which was shown to exhibit very low persistence, will volatilise to the atmosphere or adsorb to soil and be converted to phosphate anions. Any phosphine gas that reaches the upper atmosphere will be subject to indirect photooxidation to phosphonic acid and phosphoric acid that would be removed from the atmosphere by wet deposition. The rate of indirect photooxidation of phosphine measured was rapid enough to indicate that phosphine will not be subject to long range atmospheric transport. The potential for groundwater exposure of aluminium phosphide and its breakdown products above the relevant parametric drinking water limits set out in the relevant EU legislation² was assessed as low from the applied for intended uses. There is a potential for surface water exposure by phosphine gas when treated target organism burrows are adjacent to surface water (via movement in the gas phase). A data gap was identified to better characterise this exposure potential.

Due to the representative uses (applied outdoor directly into the burrow systems or indoor in food storage rooms), the exposure to non-target species was considered to be only local or negligible. On the basis of the potential exposure of surface water to phosphine where target organism burrows are adjacent to water bodies, the risk from the outdoor use to aquatic organisms needs to be addressed and therefore valid studies for invertebrates and algae should be provided.

The risk to birds, mammals, bees, non-target arthropods, earthworms, soil non target macro- and micro- organisms, non-target plants and biological methods of sewage treatment was expected to be low for the representative use evaluated.

Key words: aluminium phosphide, peer review, risk assessment, pesticide, insecticide, rodenticide, talpicide and leporicide

² Council Directive 98/83/EC on the quality of water intended for human consumption

TABLE OF CONTENTS

Summary.....	1
Table of Contents.....	5
Background.....	6
The Active Substance and the Formulated Product.....	7
Specific Conclusions of the Evaluation	7
1. Identity, physical/chemical/technical properties and methods of analysis.....	7
2. Mammalian toxicology	9
2.1. Absorption, Distribution, Excretion and Metabolism (Toxicokinetics).....	9
2.2. Acute toxicity	10
2.3. Short term toxicity	10
2.4. Genotoxicity	10
2.5. Long term toxicity.....	10
2.6. Reproductive toxicity.....	11
2.7. Neurotoxicity	11
2.8. Medical data.....	11
2.9. Acceptable daily intake (ADI), acceptable operator exposure level (AOEL) and acute reference dose (ARfD)	12
2.10. Dermal absorption.....	12
2.11. Exposure to operators, workers and bystanders	12
3. Residues	18
3.1. Nature and magnitude of residues in plant.....	18
3.2. Nature and magnitude of residues in livestock	20
3.3. Consumer risk assessment	20
3.4. Proposed MRLs.....	20
4. Environmental fate and behaviour.....	21
4.1. Fate and behaviour in soil.....	21
4.1.1. Route of degradation in soil.....	21
4.1.2. Persistence of the active substance and their metabolites, degradation or reaction products.....	22
4.1.3. Mobility in soil of the active substance and their metabolites, degradation or reaction	23
4.2. Fate and behaviour in water.....	23
4.2.1. Surface water and sediment	23
4.2.2. Potential for ground water contamination of the active substance their metabolites, degradation or reaction products.....	25
4.3. Fate and behaviour in air	25
5. Ecotoxicology	26
5.1. Risk to terrestrial vertebrates	26
5.2. Risk to aquatic organisms	27
5.3. Risk to bees	27
5.4. Risk to other arthropod species	27
5.5. Risk to earthworms	28
5.6. Risk to other soil non-target macro-organisms	28
5.7. Risk to soil non-target micro-organisms	28
5.8. Risk to other non-target-organisms (flora and fauna)	28
5.9. Risk to biological methods of sewage treatment.....	28
6. Residue definitions.....	28
List of studies to be generated, still ongoing or available but not peer reviewed.....	32
Conclusions and Recommendations	33
Critical areas of concern.....	36
Appendix 1 – List of endpoints for the active substance and the representative formulation.....	37
Appendix 2 – Abbreviations.....	73
Appendix 3 – used compound code(s)	78

BACKGROUND

Commission Regulation (EC) No 1490/2002 laying down the detailed rules for the implementation of the third stages of the work program referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000 as amended by Commission Regulation (EC) No 1095/2007, regulates for the European Food Safety Authority (EFSA) the procedure of evaluation of the draft assessment reports provided by the designated rapporteur Member State. Aluminium phosphide is one of the 84 substances of the third stage, part B, covered by the Regulation (EC) No 1490/2002 designating Germany as rapporteur Member State.

In accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, Germany submitted the report of its initial evaluation of the dossier on aluminium phosphide, hereafter referred to as the draft assessment report, received by EFSA on 19 June 2007. Following an administrative evaluation, the draft assessment report was distributed for consultation in accordance with Article 11(2) of the Regulation (EC) No 1095/2007 on 29 October 2008 to the Member States and the applicants Casa Bernardo, Detia Freyberg GmbH and United Phosphorus Ltd as identified by the rapporteur Member State.

The comments received on the draft assessment report were evaluated and addressed by the rapporteur Member State. Based on this evaluation, EFSA identified and agreed on lacking information to be addressed by the notifier as well as issues for further detailed discussion at expert level.

Taking into account the requested information received from the notifier, a scientific discussion took place in expert meetings in June – July 2008. The reports of these meetings have been made available to the Member States electronically.

A final discussion of the outcome of the consultation of experts took place during a written procedure with the Member States in September 2008 leading to the conclusions as laid down in this report.

During the peer review of the draft assessment report and the consultation of technical experts no critical issues were identified for consultation of the Scientific Panel on Plant Protection Products and their Residues (PPR).

In accordance with Article 11c(1) of the amended Regulation (EC) No 1490/2002, this conclusion summarises the results of the peer review on the active substance and the representative formulation evaluated as finalised at the end of the examination period provided for by the same Article. A list of the relevant end points for the active substance as well as the formulation is provided in appendix 1.

The documentation developed during the peer review was compiled as a **peer review report** comprising of the documents summarising and addressing the comments received on the initial evaluation provided in the rapporteur Member State's draft assessment report:

- the comments received,
- the resulting reporting table (rev 1-1 of 14 March 2008)

as well as the documents summarising the follow-up of the issues identified as finalised at the end of the commenting period:

- the reports of the scientific expert consultation,
- the evaluation table (rev 2-1 of 26 September 2008).

Given the importance of the draft assessment report including its addendum (compiled version of August 2008 containing all individually submitted addenda) and the peer review report with respect to the examination of the active substance, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

Aluminium phosphide is the (IUPAC) name for this compound. There is no ISO common name.

Aluminium phosphide is a phosphine generator. Other examples of phosphine (IUPAC name phosphane) generators are calcium and magnesium phosphide. The mode of action is by inhibition of cellular respiration.

The representative formulated products for the evaluation were "Phostoxin Tabletten", "Quickphos tablet/pellets/bags 56 GE", and "Gastoxin" gas generating products (GE).

The evaluated representative uses are as an insecticide, rodenticide, talpicide and leporicide. Full details of the GAP can be found in the attached list of end points.

SPECIFIC CONCLUSIONS OF THE EVALUATION

1. Identity, physical/chemical/technical properties and methods of analysis

The minimum purity of aluminium phosphide as manufactured should not be less than 830 g/kg. At the moment no FAO specification exists. The meeting of experts considered the specification and impurities on the basis that the spent pellets were contained and removed from the treated material. Therefore, given the toxicity of phosphine, possible relevant impurities were ignored. Therefore the

case where the spent material is not removed has not been considered in the peer review process. A data gap for a new specification where other components at less than 1 g/kg should be removed was set for all of the sources. With the exception of Casa Bernardo the specifications and supporting batch data were accepted by the meeting of experts. A data GAP should have been set for the Casa Bernardo source but this was over looked. So for completeness EFSA has set a data gap.

The content of aluminium phosphide in the representative formulation is between 56 - 57 % w/w (pure) depending on the formulation.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of aluminium phosphide or the respective formulation.

The main data regarding the identity of aluminium phosphide and its physical and chemical properties are given in appendix 1.

Sufficient test methods and data relating to physical, chemical and technical properties are available, although data gaps were identified for some of the individual formulations. Also adequate analytical methods are available for the determination of aluminium phosphide in the technical materials and in the representative formulations (except for the Casa Bernardo formulation) as well as for the determination of the respective impurities in the technical materials.

The meeting of experts noted that a lot of the physchem data were from published sources. It was considered if this was acceptable or if actual studies should be presented for this compound. The meeting could not come to a conclusion on this issue. However, it should be noted that in previous experts meetings it had been concluded that published data rarely contain sufficient information to conclude on its acceptability.

A data gap for the degassing rate of the “Phostoxin Tabletten” was identified by the meeting of experts, as it was presumed that the new study in the addendum 2 to Vol. 3 was not in the original dossier. In view of the restrictions concerning the acceptance of new (i.e. newly submitted) studies after the submission of the DAR to EFSA, as laid down in Commission Regulation (EC) No. 1095/2007, it was considered that these new studies could not be considered in the peer review. However, it has since come to light that this is not the case and that this study was in the original dossier. At this point in the procedure this oversight can not be corrected, and as this study was not correctly peer reviewed it remains as a data gap.

Enough data are available to ensure that quality control measurements of the plant protection products are possible.

Pooling all the available data from all the aluminium phosphide applicants a method of analysis for phosphine in products of plant origin is available, however ILV and a confirmatory method have been identified as a data gap. A method for products of animal origin is not required as MRLs have not been set. Methods for phosphine in soil are not required as the DT₉₀ in soil is < 3 days for phosphine. A method is available for phosphine in water but a confirmatory method has been identified as a data gap. It should be noted however, that there is a confirmatory method in the magnesium phosphide DAR. The method of analysis for air did not have a low enough LOQ and a data gap was identified. A method of analysis for body fluids and tissues is not necessary, since phosphine will be quickly exhaled or metabolised to phosphates, even though the active substance is classified as very toxic.

The method of analysis in products of plant origin is by GC-NPD with a LOQ of 0.01-0.0024 mg/kg depending on the commodity. The method of analysis for water is GC-NPD with an LOQ of 0.1 µg/L.

2. Mammalian toxicology

Aluminium phosphide was discussed at the meeting of experts in July 2008 (PRAPeR 54, round 11, subgroup 2).

Phosphides in contact with moisture readily decompose to hydroxides and phosphine. At the meeting of experts it was agreed that due to the decomposition by moisture other metal phosphides can be regarded as adequate model compounds for the evaluation of aluminium phosphide because phosphine is the toxicologically active component. Inhalation is the most relevant route of exposure based on the use of the substance as a fumigant. Classification of the substance as **R29 “Contact with water liberates toxic gas”** and **R32 “Contact with acids liberates very toxic gas”** has been confirmed by the experts (both are current ECB classifications). The experts agreed to propose additionally the safety phrase **SPo1 “After contact with skin first remove product with a dry cloth and then wash the skin with plenty of water”**.

2.1. ABSORPTION, DISTRIBUTION, EXCRETION AND METABOLISM (TOXICOKINETICS)

The experts agreed that, although formally the data requirements as laid down in Directive 91/414/EC were not fulfilled for this section, the information provided in the DAR was sufficient for an adequate evaluation of the active substance. Based on data obtained in experiments with zinc phosphide it is evident that phosphine is rapidly absorbed from the gastrointestinal tract and rapidly and quantitatively absorbed through the lungs. Phosphine is widely and evenly distributed in the body (temporarily higher levels have been detected in liver and medulla oblongata). It has no potential for

accumulation. Phosphine is either excreted as such via the expired air or, after metabolic oxidation, with the urine in form of hypophosphite or phosphite.

2.2. ACUTE TOXICITY

Aluminium phosphide is very toxic by the oral ($LD_{50} = 8.7$ mg/kg bw), harmful by the dermal ($460 < LD_{50} < 900$ mg/kg bw) and very toxic by the inhalation route ($LC_{50} = 0.048$ mg/L phosphine generated from aluminium phosphide). Aluminium phosphide was negative in adequate tests for skin and eye irritation. The experts agreed that, based on the negative results obtained in guinea pigs with zinc phosphide in a Magnusson & Kligman test, aluminium phosphide should be considered as not skin sensitising.

Based on the available data on acute effects classification of aluminium phosphide as **T+; R28 “Very toxic; Very toxic if swallowed”** (also current ECB classification), **Xn; R21 “Harmful; Harmful in contact with skin”** and **T+; R26 “Very toxic; Very toxic by inhalation”** is proposed.

2.3. SHORT TERM TOXICITY

Short term investigations with oral or dermal application of aluminium phosphide are not presented in the DAR. However, the experts agreed that, based on the mechanism of phosphine mediated toxicity (inhibition of mitochondrial respiration) no species specific toxicity was anticipated, and considering the fact that the relevant route of exposure was by inhalation, the available information (a short term inhalation study with phosphine in rats) was sufficient for the assessment of short term effects of the compound. The NOAEL obtained in the 90-day inhalation study was 1.1 mg/kg bw/d of phosphine which was the highest doses tested (no adverse effects have been observed).

2.4. GENOTOXICITY

The genotoxic effects of aluminium phosphide, zinc phosphide, magnesium phosphide and phosphine have been assessed in a series of standard genotoxicity assays (six *in vitro* and eight *in vivo* tests are presented in the DAR). They gave consistently negative results. However, in section B.6.9 of the DAR (Medical Data and Information) increased rates of chromosomal aberrations have been reported after exposure to phosphine in humans. The experts agreed, though the human evidence presented was contradictory and inconclusive, and concluded that the overall weight of evidence suggested clearly that aluminium phosphide had no genotoxic potential.

2.5. LONG TERM TOXICITY

A 2-year combined chronic/carcinogenicity study with inhalation exposure (whole body) of rats to phosphine was presented in this section. As no adverse effects (and also no tumours) were observed in this study the NOAEL (for phosphine) was set at a dose of 1.1 mg/kg bw/d (the highest dose tested). A carcinogenicity study with mice was not presented in the DAR. Considering the lack of genotoxic potential, the known mechanism of phosphine mediated toxicity (no species specific

toxicity anticipated) and the very steep dose response curve (lethality expected to be the main endpoint) the experts agreed that a carcinogenicity study with mice was not necessary for the evaluation of the compound.

2.6. REPRODUCTIVE TOXICITY

In this section a developmental study with inhalation exposure (whole body) of rats to phosphine is presented. A NOAEL for maternal and developmental effects of 5 ppm or 1.9 mg/kg bw/d of phosphine was set based on mortalities of the dams observed at the next higher (=highest) dose of 10 ppm. No effects indicative of developmental toxicity were observed in this study.

Neither a two-generation study nor a developmental study with rabbits is reported in the DAR. Based on the assumptions that lethality would be the main endpoint, that maternal toxicity would dominate any specific effects, and that no species specific differences were anticipated, the experts agreed that neither a two-generation study nor a developmental study with rabbits was necessary for a satisfactory evaluation of the active substance.

2.7. NEUROTOXICITY

An acute and a repeated dose neurotoxicity study with rats using phosphine are reported in this section of the DAR.

From the acute study a NOAEL of 40 ppm phosphine was set based on anatomic pathology, behavioural and neurological changes while a lower NOAEL of 21 ppm of phosphine was derived from observations of changes in motor activity.

The NOAEL for neurotoxicity in the 90-day study set at the highest dose tested of 3 ppm or 1.1 mg/kg bw/d phosphine. At that dose, effects on palpebral closure and body temperature occurred which were dismissed by the experts as not clearly substance related since they were within the range of the normal fluctuations.

2.8. MEDICAL DATA

Several studies on cytogenetic effects in humans by exposure to phosphine are reported in this part of the DAR. These studies have been evaluated by the experts (see section 2.4. Genotoxicity). Furthermore a series of epidemiological studies and reports of clinical cases and poisoning incidents with phosphine, aluminium phosphide and zinc phosphide are described in this section of the DAR, overall, confirming the steep dose response curve of phosphine. Exposure of a human being for up to one hour to a concentration of up to 0.26 mg phosphine/L air could still result in no serious health effects while a concentration of 2.8 mg phosphine/L air is immediately fatal.

2.9. ACCEPTABLE DAILY INTAKE (ADI), ACCEPTABLE OPERATOR EXPOSURE LEVEL (AOEL) AND ACUTE REFERENCE DOSE (ARFD)

Values have been transferred from phosphine to aluminium phosphide assuming a maximum liberation of gas of 0.59 g phosphine per g aluminium phosphide.

The ADI for aluminium phosphide was set at 0.019 mg/kg bw/d based on the NOAEL of 1.1 mg/kg bw/d for phosphine obtained in the two year rat inhalation study with phosphine applying a safety factor of 100.

The corresponding ADI for phosphine is 0.011 mg/kg bw/d.

The AOEL for aluminium phosphide was set at 0.019 mg/kg bw/d based on the NOAEL of 1.1 mg/kg bw/d obtained in the 90-day rat inhalation study with phosphine applying a safety factor of 100.

The corresponding AOEL for phosphine is 0.011 mg/kg bw/d.

The ARfD for aluminium phosphide was set at 0.032 mg/kg bw based on the NOAEL of 1.9 mg/kg bw/d obtained in the rat developmental inhalation study with phosphine applying a safety factor of 100.

The corresponding ARfD for phosphine is 0.019 mg/kg bw.

2.10. DERMAL ABSORPTION

No measured data for dermal absorption of aluminium phosphide are available. The experts agreed, considering the evaluations of dermal absorption of phosphine and metal phosphides by the WHO³ and the dermal absorption value already set for aluminium phosphide under the scope of Directive 98/8/EC (biocides directive), to set an overall dermal absorption value of 10% for aluminium phosphide (phosphine).

2.11. EXPOSURE TO OPERATORS, WORKERS AND BYSTANDERS

Aluminium phosphide is used for the control of rodents and other non-rodent vertebrates in burrows by placing the products, either mechanically or by hand (tablets, pellets or sachets), into the burrow and then closing the entrance with earth. It is also used for the control of insect pests in storage rooms where the product is directly placed in the storage buildings for fumigation.

Three different applicants are seeking approval for their aluminium phosphide containing formulations. These formulations are Gastoxin, Phostoxin Tabletten and Quickphos tablets/pellets/bags 56 GE. Although these formulations have a similar content of aluminium

³Phosphine and Selected Metal Phosphides, Environmental Health Criteria 73, International Programme on Chemical Safety, World Health Organization, Geneva, 1988.

phosphide and their uses are essentially the same, individual and independent exposure assessments for each of the three formulations have been provided in the DAR.

The experts agreed that a lower breathing rate (in the calculations in the original DAR a breathing rate of 3.6 m³/h was used) and an inhalation absorption value of 100% should be used (in the original DAR an inhalation absorption value of 3% was employed) for the assessment of exposure. The revised assessments using a breathing rate of 1.75 m³/h and a value for inhalation absorption of 100% have been provided with an addendum to the DAR (Addendum 5, 1st August 2008).

EFSA Note: In several of the new calculations provided in the addendum 5 to the DAR also the work rate was altered (i.e. from 8 hrs to 2 hrs or 30 min). This was not discussed/agreed upon at the meeting of experts.

EFSA Note: In the Addendum 5 to the DAR further information on the use of the substance was presented by the rapporteur. Fumigation of storage rooms is restricted to well trained authorised personnel only, possessing a certificate of competence and fumigation licence. Appropriate personal protective equipment has to be used. Regular measurements of phosphine concentration outside the building under fumigation are carried out. If limit values are exceeded fumigation is interrupted. A safety zone restricted to authorised fumigation personnel is established. Following the fumigation, ventilation and phosphine concentration measurements are carried out. Final release of the area is given and re-entry for workers is only permitted when phosphine levels are below the limit of detection. Buildings under fumigation are not entered until residual phosphine is removed.

EFSA Note: No agreed models exist for the assessment of gaseous exposures. However, no in depth explanations on how the input parameters have been chosen for the calculations are provided. In addition, no in depth explanations on which considerations the formulas used for the exposure calculations have been based are provided either.

Exposure assessment Gastoxin

The formulation Gastoxin is used in form of 0.6 g pellets, 3 g tablets, 34 g sachets or chains of 34 g sachets containing 570 g/kg aluminium phosphide. Gastoxin is either placed directly in rodent burrows at a maximum amount of 2 tablets or 10 pellets or is directly added in storage facilities either empty or for the post-harvest fumigation of wheat, sorghum, maize, rice and barley grain, soy bran, wheat flower, beans, coffee beans, cotton seed and tobacco where it is applied once up to a maximum concentration of 3 g a.s./m³ (corresponding to 15 pellets, 3 tablets or 27 sachets). Gastoxin is usually applied once in rodent burrows. The product can be applied a second time if necessary.

Operator exposure

Application of Gastoxin in rodent burrows

The calculated operator exposure when Gastoxin is applied in rodent burrows and no PPE is used assuming a maximum concentration of 0.1 ppm of phosphine in the air (value based on highest measured value in a field study), an inhalation absorption of 100%, a density of phosphine of 1390 g/m³, a breathing rate of 1.75 m³/h, a body weight of 70 kg and a reduced work rate of 2 hrs (in the initial DAR 8 hrs were used) amounts to 63% of the systemic AOEL (0.03 ppm phosphine). In addition measurements in a monitoring study show that total daily exposure of operators to phosphine was below the AOEL and often effectively zero. Nevertheless, since temporary exposure concentrations exceeding the AOEL cannot be excluded, PPE/RPE should be recommended (exposure when using RPE was calculated to amount to 5.1% of the AOEL assuming a work rate of 2 hrs and a protection factor of 0.08).

Application of Gastoxin in storage rooms

The calculated operator exposure when Gastoxin is used for fumigation and respiratory protective equipment is used assuming a (worst case) concentration of 22 ppm of phosphine (a worst case concentration an order of magnitude higher than the average values reported in a monitoring study), an inhalation absorption of 100%, a density of phosphine of 1390 g/m³, a breathing rate of 1.75 m³/h, a body weight of 70 kg, a protection factor due to RPE of 0.02 and a reduced work rate of 30 min (in the initial DAR 8 hrs were used) amounts to 71% of the AOEL. In addition an assessment based on measured data has shown that phosphine levels (full shift time weighted average) are within acceptable levels. In effect they do not exceed 80% of the AOEL of 0.03 ppm (phosphine) when adequate personal protective equipment is used.

Worker exposure

Application of Gastoxin in rodent burrows

No individual calculations were carried out but it is assumed that unprotected re-entry workers when present in the vicinity of the burrow both during and after treatment will be at a considerably greater distance from the burrow than the operator. In addition to that, phosphine is rapidly degraded in the ambient air (5-28 hours half life). Thus exposure will be lower than that of operators (i.e. 63% of the AOEL).

Application of Gastoxin in storage rooms

The calculated exposure of a re-entry worker wearing RPE and assuming a concentration of 0.01 ppm of phosphine (a value that is considered to be a level below the limit of detection which is a prerequisite for a release of the fumigated area for re-entry workers), an inhalation absorption of

100%, a density of phosphine of 1390 g/m³, a breathing rate of 1.75 m³/h, a body weight of 70 kg and a work rate of 8 hrs amounts to 25% of the AOEL.

Bystander exposure

Application of Gastoxin in rodent burrows

No individual calculations were carried out but it is assumed that bystanders when present in the vicinity of the burrow both during and after treatment (considering a treatment duration of two hours) will be at a greater distance from the burrow than the operator and their presence will be shorter. In addition, phosphine is rapidly degraded in the ambient air. Thus exposure of bystanders is anticipated to be lower than that of operators (i.e. 63% of the AOEL).

Application of Gastoxin in storage rooms

Based on the assumption that outside the safety zone that has to be established maximum concentrations of 0.01 ppm of phosphine are not exceeded, and that inside the safety zone only authorised fumigation personnel are admitted, bystanders are not expected to be exposed to phosphine concentrations exceeding 33% of the systemic AOEL of 0.03 ppm of phosphine.

Exposure Assessment Phostoxin

The formulation **Phostoxin** is used in form of tablets and pellets containing 560 g/kg aluminium phosphide. It is either placed in rodent burrows (applied once if required to a maximum amount of 2 tablets) or in storage facilities either for gassing of empty rooms or for the post-harvest fumigation of grain, oilseed, tapioca, dried fruit, vegetables, spices, tea, coffee, cocoa beans, pulses, rice, nuts and tobacco. It is applied once a year at a maximum amount of 15 tablets per ton or m³ respectively.

Operator exposure

Application of Phostoxin in rodent burrows

Based on an assumed average airborne concentration of phosphine of 0.05 mg/m³ (default assumption based on OECD Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides During Agricultural Application OECD/GD (97) 148) it was calculated that phosphine levels (8 h time weighted average) when using Phostoxin in rodent burrows when no PPE is used make up 93% for “high use” of Phostoxin (treatment of rodents along railway embankment, exposure duration 6.25 hours) and 55% for “typical use” (treatment by a farmer, exposure duration 3.75 hours) of the systemic AOEL of 0.03 ppm or 0.011 mg/kg bw/d phosphine.

Application of Phostoxin in storage rooms

Calculations based on input parameters from a monitoring study resulted in potential phosphine levels (8 h time weighted average) in storage rooms that make up 30% of the AOEL when only 1

fumigation procedure is applied and without the use of respiratory protective equipment. The respective values amount to 120% and 10% of the AOEL when 4 fumigation procedures are carried out without and with the use of respiratory protective equipment respectively.

EFSA Note: Taking into account the results from a series of exposure calculations and field studies with similar products and similar uses (i.e. Gastoxin and Quickphos) where exposures below the AOEL could only be achieved with the use of full respiratory protective equipment, and taking also into account the uncertainties remaining regarding the way the exposures have been calculated in this particular case, EFSA disagrees with the operator exposure assessment for the use of Phostoxin in storage rooms.

Worker exposure

Application of Phostoxin in rodent burrows

No specific calculations have been carried out but based on the assumption that the levels detected for operators will be diluted further with unlimited potential since the operation is performed in the open air, and phosphine is rapidly degraded in ambient air (half life of phosphine is 5-28 hrs) it is assumed that the worker exposure will not exceed the value of 93% of the AOEL calculated for the exposure of operators.

Application of Phostoxin in storage rooms

No specific calculations have been carried out but based on the calculated worker exposure to phosphine when using Gastoxin namely 25% of the AOEL when RPE is used (see Application of Gastoxin in storage rooms) it can be reasonably assumed that when Phostoxin is used in the same manner the AOEL will not be exceeded.

Bystander exposure

Application of Phostoxin in rodent burrows

No specific calculations have been presented but measurements of operator exposure resulted in an exposure of maximally 93% of the AOEL. Based on the assumptions that bystanders will be at a greater distance from the burrow, and that the phosphine concentration will be further diluted with unlimited potential since the operation is performed in the open air, it can be expected that exposure of bystanders will be considerably lower than that of the operator.

Application of Phostoxin in storage rooms

Based on the assumption that outside the safety zone that has to be established maximum concentrations of 0.01 ppm of phosphine are not exceeded and that inside the safety zone only

authorised fumigation personnel are admitted bystanders are not expected to be exposed to phosphine concentrations exceeding 33% of the systemic AOEL of 0.03 ppm of phosphine.

Exposure Assessment Quickphos

The formulation **Quickphos** is used in form of tablets, pellets and 34 g bags containing 570 g/kg aluminium phosphide. It is directly added in storage facilities either for fumigation of empty rooms or for the fumigation of grain, tobacco, processed food and animal feed. It is not used outdoors (rodent burrows). It is applied once if required at a maximum amount of 5 tablets or 25 pellets per ton or 2 bags per 10 m³ (corresponding to 2 g/m³ of aluminium phosphide).

Operator exposure

Estimated exposures when applying Quickphos pellets and tablets for fumigation purposes in storage rooms using respiratory protective equipment (a self contained breathing apparatus is necessary since protection with full face gas mask with hydrogen phosphide canister is insufficient) assuming a maximum concentration of 3 g/m³ of phosphine and a protection by the self-contained breathing apparatus of 99.99% amount to 60% of the systemic AOEL of 0.03 ppm of phosphine assuming an 8 hrs work rate and to 15% of the AOEL when an alternative work rate of 2 hrs is assumed. When Quickphos bags are used the corresponding exposure values are 33% and 8% of the AOEL respectively.

Worker exposure

No specific calculations have been carried out but based on the calculated worker exposure to phosphine when using Gastoxin namely 25% of the AOEL when RPE is used (see *Application of Gastoxin in storage rooms*) it can be reasonably assumed that when Quickphos is used in the same manner the AOEL will not be exceeded.

Bystander exposure

Based on the assumption that outside the safety zone that has to be established maximum concentrations of 0.01 ppm of phosphine are not exceeded and that inside the safety zone only authorised fumigation personnel are admitted bystanders are not expected to be exposed to phosphine concentrations exceeding 33% of the systemic AOEL of 0.03 ppm of phosphine.

3. Residues

Aluminium phosphide was discussed at the PRAPeR experts' meeting for residues (PRAPeR 55, round 11) in July 2008.

Three applicants, Detia Freyberg GmbH, United Phosphorus Limited and Casa Bernardo have submitted data in order to support two main uses of aluminium phosphide:

1 - As rodenticide, talpicide, leporicide to control rodent and non-rodent vertebrates (rat, voles, rabbits, moles, ...) by fumigation of underground tunnels and burrows in cropland and non-cropland situations.

2 - As fumigant to control insects in various harvested plant products (cereals, tree nuts, spices, ...), processed food commodities (cereal flour, ...) in storage premises (mill, silo, ...) and to control insects in empty warehouses or transportation facilities. The fumigation practices on stored commodities were defined as a treatment at a rate of 1 to 6 g PH_3/m^3 (tonne) with a length of fumigation of 2 to 9 days depending on the temperature. Following fumigation, an aeration period was recommended in order to reach a concentration of phosphine in air that makes the handling of the treated commodities safe for the workers. A minimum aeration period of 2 days was specified by the Casa Bernardo Company only but no time limits were proposed by the two others applicants. During the meeting, the MRL proposals were not discussed on the basis of the residue levels observed at the end of the aeration period as stated in the GAP, but at the end of an additional withholding period that was proposed by the RMS for each commodity or group of commodities. Consequently and after the meeting, EFSA was of the opinion that the fumigation practices have not been sufficiently defined in the GAP to allow the MRL setting, and considers the fact that the withholding periods were not clearly described in the intended GAP as a data gap. Finally, applicants were also asked to clarify the list of commodities intended to be fumigated and especially if the use of aluminium phosphide is restricted to dry stored products only (cereals, tree nuts, spices, ...) or if uses are also envisaged on some fresh products (fresh fruits or fresh vegetables).

3.1. NATURE AND MAGNITUDE OF RESIDUES IN PLANT

Due to its physico-chemical properties no specific studies to evaluate metabolism and distribution of aluminium phosphide in treated commodities have been submitted but some information from public literature was reported to support the fate of the active substance after application. In contact with soil or atmospheric moisture, aluminium phosphide is rapidly hydrolysed to phosphine (PH_3) and aluminium hydroxide $\text{Al}(\text{OH})_3$, this decomposition depending mainly on temperature and soil/air humidity. After treatment the major part of phosphine is volatilised and diluted in air or oxidised to phosphorous oxyacids (hypophosphite, phosphite, phosphate...), these oxidation products being widespread in nature and thus considered of no significant concern for human health. Considering stored fumigated commodities may contain residual gaseous phosphine (adsorbed and interstitial) and residual metal phosphine when reaction with atmospheric moisture is incomplete, the residue

definition for monitoring and risk assessment was proposed as “phosphine and phosphine generators (relevant phosphide salts) determined and expressed as phosphine”.

No residue trials were submitted to support the uses of aluminium phosphide as a rodenticide, considering that the direct application of the active substance into underground tunnels of rodent or non-rodent animals excludes the direct contact with plant and therefore, the possible residues in plants. This statement was supported by information from public literature⁴. Three days after soil application of calcium or aluminium phosphide to control voles, residues of phosphine were below 0.01 mg/kg in carrots and radish roots collected in the treated plots.

For post harvest applications on stored commodities, the MRL proposals were based on data provided by Detia Freyberg GmbH company only. The data from the company Casa Bernardo were not taken into account as the experimental designs were considered to be insufficiently described and some analyses were performed using a too high LOQ (0.10 mg/kg). However some of these results were considered to confirm the proposed MRLs. No residue trials were provided by United Phosphorus Limited. Detia trials were performed using aluminium phosphide or magnesium phosphide at dose rates of 4.5 to 10 g/m³ and during a fumigation period of 5 to 14 days. The commodities were fumigated in gastight containers where relative humidity and temperature were recorded. All information concerning the experimental designs was detailed in the addendum of June 2008 provided by the RMS. After fumigation the containers were aerated for approximately 1 or 2 days until the phosphine concentration in air reached a value below 0.01 ppm. Samples were then collected at day zero and at predetermined intervals of 7 to 56 days after the end of aeration. Samples were shipped to the laboratory and analysed for residues on the day of sampling using a LOQ of 0.005 or 0.010 mg/kg. When analyses could not take place on the same day, samples were stored in liquid nitrogen and analysed at least within two days. However, the applicant was asked to precisely describe the way the samples were handled between sampling and analyse in the study RIP2002-148, since this information was missing in the report.

In addition to the aeration period following the completion of the fumigation, a specific withholding period was proposed by the RMS for each commodity or group of commodities, this withholding period being an additional storage period after fumigation and aeration necessary to reach phosphine residue levels below or at the MRL value. Thus, the MRLs proposed for cereals grains, cereal processed products, tree nuts, cocoa beans, coffee beans and pulses were not calculated taking into account the residue levels observed just after the aeration period (day 0), but after a withholding period of 7 to 35 days, depending on the commodities. Therefore, EFSA was of the opinion that MRLs were not defined following practices as stated in the critical GAPs where only an aeration period is

⁴ Martens-Menzel, R. et al, 1994 ; Rückstandsverhalten von Phosphorwasserstoff in Rettichen und Möhren nach Begasung zur Bekämpfung der Wühlmaus. Translation: Residue behaviour of phosphor-hydrogen in radish and carrot following gassing in vole control. Mitt. a. d. Biol. Bundesanst., 1994, 197

recommended. Moreover, the meeting asked the RMS for clarification regarding the setting of these withholding periods since some of them were set for a long period (up to 35 days) and to reconsider, as an alternative, if higher MRLs with a shorter withholding period could be proposed.

No storage stability study was provided considering that the inherent properties of phosphine (melting point -133.5°C , boiling point -87.4°C , oxidation to phosphorous compound) lead to a low stability in stored products. Information from public literature confirmed that at -18°C phosphine residues in soya beans and wheat grain were stable up to 33 days only. However, the fumigation conditions may also act upon stability and at equal storage temperature residues are more persistent in crops that have been fumigated for a longer period than equal residues in crops that have been fumigated for a shorter period. In addition a study performed with tea, meal and shell fruits stored under deep frozen condition in liquid nitrogen showed that phosphine residues were stable for at least two days. Based on this information, the results of fumigation trials used to derive the MRL values were considered as reliable, since samples were analysed immediately or stored in liquid nitrogen and analysed within two days. No processing studies were provided, considering that no significant residues are expected in plant commodities when aluminium phosphide is used as a fumigant on post harvest plant commodities following the GAP and the proposed withholding periods. No rotational crop studies were submitted since no residues in soil are expected from the outdoor uses on rodent and non-rodent species.

3.2. NATURE AND MAGNITUDE OF RESIDUES IN LIVESTOCK

Since no significant residues resulting from the use of aluminium phosphide as post harvest fumigant are expected in livestock feed, no metabolism and feeding studies were provided and no MRLs were proposed for products of animal origin.

3.3. CONSUMER RISK ASSESSMENT

Chronic and acute consumer risk assessments were performed using the EFSA and the German models and the MRL values listed below, taking into account that EFSA considers that these values do not reflect the GAP as initially defined by the applicants. The calculated Theoretical Maximum Daily Intake was in the range of $<0.1\%$ to 12% of the ADI (ADI = $0.011\text{ mg phosphine/kg bw/d}$) with the EFSA model and approximately 5% of the ADI using the German consumption data. The acute consumer risk assessments show a maximum NESTI/ESTI in a range of 3% to 8% of the ARfD ($0.019\text{ mg phosphine/kg bw}$) for stored goods. Therefore, no chronic or acute concerns are expected after fumigation of stored commodities with aluminium phosphide **if a withholding period is taken into account in the GAP as given in the point 3.4 below.**

3.4. PROPOSED MRLS

As mentioned previously, EFSA is of the opinion that MRLs could not be defined with regard to the proposed GAPs where only an aeration period was considered.

Nevertheless, and considering the GAPs proposed by the RMS, and including provisional withholding periods in addition to the aeration period, the following provisional MRLs were proposed for phosphine:

0.10 mg/kg	unprocessed grains of cereals	(withholding period: 7 days)
0.10 mg/kg	tree nuts	(withholding period: 21 days)
0.10 mg/kg	pistachio	(withholding period: 35 days)
0.10 mg/kg	coffee beans	(withholding period: 7 days)
0.05 mg/kg	cacao beans	(withholding period: 7 days)
0.05 mg/kg	spices, roots of medicinal plants	(withholding period: 7 days)
0.02 mg/kg	processed cereal products	(withholding period: 14 days)
0.01* mg/kg	dried vegetables, fruits and mushrooms	(withholding period: 7 days)
0.01* mg/kg	pulses	(withholding period: 7 days)
0.01* mg/kg	other products of plant origin	

No MRLs were proposed for products of animal origin.

4. Environmental fate and behaviour

Aluminium phosphide was discussed at the PRAPeR experts' meeting for environmental fate and behaviour PRAPeR 52 in June/July 2008.

4.1. FATE AND BEHAVIOUR IN SOIL

4.1.1. ROUTE OF DEGRADATION IN SOIL

In moist soil under field conditions aluminium phosphide will undergo relatively rapid chemical hydrolysis producing phosphine gas (the efficacious rodenticide substance, note phosphine is denser than air) and aluminium salts (for example aluminium hydroxide). The proportion of phosphine produced that readsorbs to soil will oxidise to form phosphate anions. A closed system laboratory experiment demonstrating that these processes regarding oxidation of phosphine to phosphate anions occur in soils was available where zinc phosphide was used as the test substance that generated the phosphine gas.

The Member State experts discussed whether the aluminium hydroxide produced from the applied for requested use of aluminium phosphide outdoors might be expected to significantly increase the environmental concentration of aluminium hydroxide or of freely available Aluminium³⁺ ions. The experts noted that the natural levels of aluminium in soil are very variable (over several orders of magnitude) so it is not possible to make conclusions regarding the impact of the use of aluminium phosphide in every situation. However aluminium is the most commonly occurring metallic element

in soil. Therefore the experts agreed that the additional inputs of aluminium as a result of the use of aluminium phosphide are unlikely to significantly increase the levels of exchangeable aluminium in soil (acidification would not be expected). The experts considered that the use of aluminium phosphide as proposed would not be expected to cause concern in relation to these issues.

The applicants and Member State experts compared the quantity of phosphate anions that may originate from the use of aluminium phosphide as a rodenticide with agricultural land phosphate fertiliser recommendations (see addendum 3 to the DAR dated May 2008). Phosphorous levels from the rodenticide use gave a maximum estimate of 0.35 kg/ha (calculated in the meeting of experts using the RMS assumptions regarding an application rate per unit area that was higher than those assumed by the applicants), fertiliser recommendations are ca. 40 kg phosphorous /ha. The Member State experts considered that the contribution from aluminium phosphide as a rodenticide was low compared to the phosphate fertiliser anthropogenic source of phosphate to agricultural soils.

4.1.2. PERSISTENCE OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

In a laboratory soil incubation test carried out at 22°C in two different sand soils phosphine gas (which was applied directly as the test substance mixed with nitrogen) was shown to have a DT₅₀ of 5.4 to 5.7 hours. In further laboratory soil incubations (again the test substance applied was phosphine gas mixed with nitrogen) carried out on 7 different soils at 25°C DT₅₀ estimates were reported to be 8 to 60 minutes.

In a field study formulated pellets of aluminium phosphide (2 or 4 pellets) were placed in a constructed artificial burrow (15m long 0.3m below the soil surface). Phosphine concentrations were measured in this burrow at various distances (3, 6, 9, 12 and 15m) from the pellets over a 24 hour period. The gas was shown to move along the burrow away from the pellets and decrease in concentration over 24 hours. In a second field study using formulated pellets of aluminium phosphide as the generator of phosphine gas it was demonstrated that vertical spreading of phosphine in soil was low but horizontal spreading was relatively fast with maximum concentrations being measured at 30-90cm from buried pellets 4 hours after burying pellets. Phosphine was not detected after 28 to 48 hours when 1 pellet was buried, but it took 168 hours for phosphine not to be detected when 2 pellets were buried.

The Member State experts agreed the soil PEC in appendix 1 for phosphine as appropriate for the applied for intended use outdoors that used a biocides emission scenario⁵. They also agreed that soil exposure from phosphine from the applied for intended uses indoors in the vicinity of treated

⁵ Supplement to the methodology for risk assessment of biocides; Emission scenario document for biocides used as rodenticides; May 2003; Danish EPA; J. Larsen; CA-Jun03-Doc.8.2-PT14

structures might be expected to be negligible based on the arguments that the applicants put forward as evaluated by the RMS in addendum 3 to the DAR dated May 2008 regarding the low potential for wet deposition consequent to the low air concentrations expected (<0.11ppm monitored at distances greater than 5m in one trial) that must be achieved with respect to worker safety when treated structures are vented in accordance with good practice.

4.1.3. MOBILITY IN SOIL OF THE ACTIVE SUBSTANCE AND THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

Due to the expected rapid transformation of both aluminium phosphide and phosphine gas, leaching in soil for these two compounds can be precluded as a concern for the applied for intended uses outdoors. The transformation products that will be produced, namely aluminium salts and phosphate anions needed to have their potential mobility considered further.

As discussed in section 4.1.1 above the Member State experts considered that the contribution of phosphate from aluminium phosphide as a rodenticide was low compared to the phosphate fertiliser anthropogenic source of phosphate to agricultural soils. There is also the legal issue that there is no parametric drinking water limit set for phosphates in the EU drinking water directive⁶ so there is no legal limit set in the pertinent EU legislation against which to assess potential groundwater contamination of phosphate.

In addendum 3 to the DAR dated May 2008 simple calculations of possible levels of aluminium in annual average groundwater recharge (using FOCUS scenario water recharge volumes) from the applied for intended use outdoors were presented. These confirmed that even if all the aluminium applied according to recommendations were leached to groundwater, concentrations would be significantly lower than the indicator parametric level of 200 µg/L for aluminium in the EU drinking water directive (The RMS worst case calculation resulted in a concentration of 27 µg Al³⁺ /L). These calculations are of course overestimates based on worst case assumptions. In reality all the aluminium applied could not leach, as aluminium salts (the most prevalent of which would be expected to be aluminium hydroxide) are nearly insoluble. The majority of the aluminium that is applied would be immobile in soil of pH used for agricultural production.

4.2. FATE AND BEHAVIOUR IN WATER

4.2.1. SURFACE WATER AND SEDIMENT

The rate of aqueous hydrolytic transformation of aluminium phosphide was investigated at pH 4, 7 and 9 at 20, and 50°C. At the first sampling time phosphine had reached its theoretical maximum concentration (115 mg/L), indicating that the hydrolytic degradation rate of aluminium phosphide to phosphine gas was too rapid to estimate. The estimated half life of phosphine at 20°C was estimated

⁶ Council Directive 98/83/EC on the quality of water intended for human consumption

to be 39, 36 and 23 hours at pH 4, 7 and 9 respectively. In a second study where the rate of aqueous hydrolytic transformation of phosphine gas was investigated at pH 5, 7 and 9 at 22 °C at a significantly higher concentration (1090 mg/L) a half life of approximately 2 days could be estimated, being roughly the same at all pH. A study on the sterile aqueous photolysis of phosphine gas indicated the same rate of decline under light as in dark controls indicating light does not enhance transformation rates in aqueous systems.

The Member State experts considered that the potential for surface water exposure by phosphate anions that would be formed in soil was expected to be low compared to levels that would occur from phosphate fertiliser uses (as already discussed at sections 4.1.1 and 4.1.3).

The Member State experts considered that the potential for additional surface water exposure by aluminium salts moving from soil was expected to be negligible, compared to that which already occurs naturally. This conclusion is consequent to the conclusions of the member state experts outlined at section 4.1.1 above, that acidification and significant increase in exchangeable aluminium in soil is not expected, and outlined at section 4.1.3 above that aluminium salts are nearly insoluble and the majority of the aluminium that is applied would be immobile in soil of pH used for agricultural production.

The Member State experts had an extensive discussion regarding the potential for surface water exposure resulting from phosphine consequent to the applied for intended use outdoors. The applicants had been asked to address this. The arguments and calculations the applicants put forward regarding the low potential for phosphine to be transported by drainage water, i.e. in solute flow several days after tablets were placed in burrows that included a period for degradation in soil / soil water to occur, were accepted by the experts and it was agreed that surface water exposure via this process (drainage / solute flow) was likely to be negligible. However there was the potential concern that where treated burrows were immediately adjacent to surface water that phosphine in the gas phase in the burrow, may exit the burrow entrance, then being denser than air reach surface water and potentially partition between the air and water. (This potential concern was the comment made by a Member State that had resulted in the applicants being asked to address the potential for surface water exposure by phosphine). The experts at the meeting carried out a very worst case calculation that took a measured burrow air concentration of 0.331 mg/L (from a field study described in section 4.1.2 above, measurement taken 6 hours after 4 pellets were placed in the burrow at 3 m distance from the 4 pellets) and the Henry's law constant for phosphine of 33269 Pa m³/mol. The phosphine concentration calculated was 25 µg/L. This is a low concentration but cannot be considered negligible as phosphine is very hazardous to aquatic organisms and with this concentration a risk cannot be excluded using 1st tier annex VI criteria (The uniform principles for decision making under directive 91/414/EEC). The experts noted that this calculation assumes equilibrium and does not include any dilution in air 3 metres away from pellets in the burrow, dilution in air outside the

burrow, resistance to transfer across the air/water interface, any dilution in the water body (mixing with water that is not adjacent to a treated burrow) and has no temporal element (break down processes in water). With further information it would probably be possible to demonstrate that concentrations would respect tier 1 annex VI criteria, but the applicants had not provided any additional calculations that enabled the experts to confirm that this was the case. The experts agreed that it was necessary to identify a data gap as the exposure of surface water by phosphine from the requested outdoor applications of aluminium phosphide needs to be addressed. It was suggested that if filling this data gap in the future, the applicants should provide consideration of the impact of one or more of the following processes on phosphine surface water concentrations: dilution in air in the burrow, dilution in air outside the burrow, resistance to transfer across the air water interface and any dilution in the water body. In addition, temporal elements could be included (e.g. break down processes in water). The opinion of the member state experts was that the information provided to fill this data gap could be assessed nationally when assessing applications for product authorisations.

The Member State experts considered that the potential for surface water exposure by phosphine would be expected to be negligible from the applied for intended uses indoors as vented concentrations in the vicinity of the treated structures would be expected to be low, so wet deposition to surface water would also be low (following the same considerations already discussed above relating to soil exposure from the indoor uses at section 4.1.2).

4.2.2. POTENTIAL FOR GROUND WATER CONTAMINATION OF THE ACTIVE SUBSTANCE THEIR METABOLITES, DEGRADATION OR REACTION PRODUCTS

See section 4.1.3

4.3. FATE AND BEHAVIOUR IN AIR

Aluminium phosphide itself has a low vapour pressure (1×10^{-8} Pa calculated for 25°C) so is not volatile. However the phosphine produced by hydrolysis is a dense gas (vapour pressure 3.44×10^6 Pa at 20°C) which will enter the atmosphere. The experimentally derived reaction rate constant for indirect photooxidation in the atmosphere through reaction with hydroxyl radicals for phosphine (1.6×10^{-11} cm³/mol.sec) resulted in an atmospheric half life estimated at 24 hours (assuming an atmospheric hydroxyl radical concentration of 5×10^5 radicals cm⁻³) indicating that phosphine would be unlikely to be subject to long range atmospheric transport when it reaches the upper atmosphere. The atmospheric reaction products expected where oxygen is present are phosphonic acid and phosphoric acid that would be removed from the atmosphere by wet deposition.

5. Ecotoxicology

Aluminium phosphide was discussed at the PRAPeR experts' meeting for ecotoxicology (PRAPeR 53 – sub-group 2) in July 2008 on the basis of the Draft Assessment Report (DAR) and the Addendum 3 (May 2008).

The relevant supported uses evaluated were: a) control of rodents, rabbit, moles and other terrestrial vertebrates (outdoor); b) control of insects in plant product storage rooms (indoor). The representative formulated products were “Phostoxin Tabletten”, “Quickphos tablet/pellets/bags 56 GE”, and “Gastoxin” (gas generating products), which were formulated as pellets, tablets or sachets, with a maximum concentration of the active substance of 57%.

Aluminium phosphide containing products for outdoor use are applied directly into the burrow systems. Therefore, the exposure of non target species was considered as only local for the field use or considered as negligible for the indoor use. No standard risk assessment was conducted.

5.1. RISK TO TERRESTRIAL VERTEBRATES

Two acute oral toxicity studies were provided for Japanese quail (*Coturnix japonica*) and pigeon (*Columba livia*) with LD₅₀ values of 49 mg/kg bw/day and between 45 and 90 mg/kg bw/day, respectively. No short term or reproductive studies were presented.

On the basis of the mammalian toxicity data, the acute oral LD₅₀ (rat) was 8.7 mg aluminium phosphide/kg bw/day and the acute inhalation LD₅₀ was 179 ppm in air (PH₃). No data on the long term reproduction effects were available, while a NOAEL of 1.1 mg PH₃/kg bw/day (=3 ppm in air equivalent to 0.0042 mg/L) was observed in a long term 90-day inhalation study and a NOE(A)L of 5 ppm in air (PH₃) was observed in an embryo toxicity and teratogenicity inhalation study.

The member state experts discussed the possibility of secondary poisoning via bioaccumulation in the food chain. A clarification on the need to address the risk to predatory birds and mammals had been asked to the applicant and this was presented by the RMS in addendum 3 (May 2008).

The argumentations were related to the mode of action of phosphide and the metabolism of inhaled phosphine. The main route of phosphide exposure is by inhalation. Studies concerning absorption, distribution, metabolism and excretion of ingested zinc phosphide in rats indicated that the evolved phosphine was rapidly and completely excreted by exhalation or via urine after oxidation to hypophosphite or phosphate. These phosphine metabolites were less toxic than phosphine itself. The log P_{OW} of phosphine is 1.05. Moreover, intoxicated target animals do not escape from the treated burrows. The Member State experts agreed that it was reasonable to assume that no bioaccumulation in the food chain was expected.

The experts discussed the need to address the potential risk to non-target organisms due to the degradation product Al(OH)₃. The applicant had been asked to provide a clarification and it was presented by the RMS in addendum 3 (May 2008). The meeting agreed with the argumentation that as the major degradation product Al(OH)₃ is known to be ubiquitous in the environment, under the

intended use of aluminium phosphide the background concentration of aluminium does not increase considerably.

Overall, the experts concluded that for the indoor application the exposure of vertebrates to aluminium phosphide and evolving phosphine gas could be excluded. For the outdoor use no relevant exposure was expected. Therefore, further testing of the effects on terrestrial vertebrates was unnecessary and a low risk was expected.

However, it was recommended to include on the label a sentence to make sure for outdoor use that burrows are closed and that no pellets remain on the surface.

5.2. RISK TO AQUATIC ORGANISMS

Acute toxicity studies were conducted with aluminium phosphide to rainbow trout (*Oncorhynchus mykiss*, static test, 96-h LC_{50} = 9.65 µg Aluminium Phosphide/L, equivalent to 4.68 µg PH_3 /L) and zebrafish (*Brachydanio rerio*, semi-static test, 96-h LC_{50} = 48 µg Aluminium Phosphide/L). Studies conducted on invertebrates (acute) and algae were considered not valid by the member state experts because no analytical measurements were performed. No chronic studies were provided. Classification based on the available data was R50 “Very toxic to aquatic organisms”, N “Dangerous for the environment”.

The fate experts agreed that the potential exposure of surface water to phosphine from the outdoor use should be further addressed. In a very worst case calculation a phosphine concentration of 25 µg/L was estimated by the fate experts (see point 4.2.1) for the situation where an entrance to a treated target organism burrow is adjacent to surface water (via movement in the gas phase). Due to the potential high toxicity of the compound a risk to aquatic organisms could not be excluded on the basis of the available data. Therefore, a data gap was identified to further address the risk and consequently to provide valid studies on aquatic organisms (invertebrates and algae).

For the indoor use, the potential atmospheric deposition of aluminium phosphide on surface water that might occur when enclosed spaces were aerated after fumigation, was considered negligible by the fate meeting. No risk was expected.

5.3. RISK TO BEES

Acute oral toxicity study was conducted with aluminium phosphide technical showing a high toxicity to bees (48h- LD_{50} 0.24 µg a.s./bee). However, as exposure is not expected, HQ values were not calculated. No risk was expected for bees from the proposed uses.

5.4. RISK TO OTHER ARTHROPOD SPECIES

No studies on non target organisms were performed with aluminium phosphide. According to the recommended uses, exposure was not expected, therefore no data were required.

5.5. RISK TO EARTHWORMS

The acute toxicity to earthworms (*Eisenia foetida*) was tested with aluminium phosphide and the formulated products (Quickphos pellet and Quickphos tablet). A 14 day-LC₅₀ of 663.5 mg Aluminium Phosphide/kg soil was observed in the active substance study; while 14 day-LC₅₀ values of 185.01 and 187.74 mg product/kg soil (equivalent to 107.3 and 108.6 mg a.s./kg soil) were observed for the pellet and tablet formulations, respectively. No relevant exposure to earthworms was expected for both the indoor and outdoor use. To take into account the potential risk due to the exposure in the burrows a TER value was calculated for the phosphine metabolite. The calculation was based on the lowest acute toxicity end point (14 day-LC₅₀ of 107.3 mg a.s./kg soil, equivalent to 62.9 mg PH₃/kg soil) and the estimated PEC in the burrows of 3.379 mg PH₃/kg soil (as agreed by the fate meeting, see point 4.1.2 and appendix 1). The resulting TER of 18.6 was well above the annex VI trigger of 10, indicating a low risk for earthworms.

5.6. RISK TO OTHER SOIL NON-TARGET MACRO-ORGANISMS

No acceptable studies with aluminium phosphide on other soil non-target macro-organisms were provided. Under the recommended uses, exposure was not expected; therefore no further data were required.

5.7. RISK TO SOIL NON-TARGET MICRO-ORGANISMS

A study on the effects of Phostoxin on the activity of the soil microflora was provided. The study was accepted by the RMS. The nitrification activity was inhibited for a fortnight and the dehydrogenase activity was reduced by approx 29% in one of the tested soils. Both effects were reversible. Overall, it was concluded that no risk was expected for non target micro-organisms.

5.8. RISK TO OTHER NON-TARGET-ORGANISMS (FLORA AND FAUNA)

No relevant exposure of non-target organisms (flora and fauna), including those organisms that co-inhabit the tunnel systems, was expected from the proposed uses.

5.9. RISK TO BIOLOGICAL METHODS OF SEWAGE TREATMENT

No relevant exposure of biological waste water treatment organisms was expected from the proposed use.

6. Residue definitions

Soil

Definition for risk assessment:	phosphine
Definition for monitoring:	none

Water

Ground water

Definition for exposure assessment: phosphine and aluminium salts

Definition for monitoring: none

Surface water

Definition for risk assessment: phosphine

Definition for monitoring: phosphine

Air

Definition for risk assessment: phosphine

Definitions for monitoring: phosphine

Food of plant origin

Definition for risk assessment: phosphine and phosphine generators (relevant phosphide salts) determined and expressed as phosphine

Definition for monitoring: phosphine and phosphine generators (relevant phosphide salts) determined and expressed as phosphine

Food of animal origin

Definition for risk assessment: no residue definition proposed

Definition for monitoring: no residue definition proposed

Overview of the risk assessment of compounds listed in residue definitions for the environmental compartments

Soil

Compound (name and/or code)	Persistence	Ecotoxicology
phosphine	Very low persistence DT ₅₀ 8 minutes to 6 hours at 22-25°C	The risk was assessed as low

Ground water

Compound (name and/or code)	Mobility in soil	> 0.1 µg / L 1m depth for phosphine or >200µg/L for aluminium and its salts for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
phosphine		No	Yes	Yes	Yes
aluminium salts	Low solubility in water expected to be immobile at relevant pH	No	Data not available assessment not triggered	Data not available assessment not triggered	Data not available assessment not triggered

Surface water and sediment

Compound (name and/or code)	Ecotoxicology
phosphine	Data gap (in case that target organism burrows are adjacent to surface water)

Air

Compound (name and/or code)	Toxicology
phosphine	Very high inhalation toxicity ($LC_{50} = 0.048$ mg phosphine /L air) Aluminium phosphide is currently classified (ECB) as T+; R28 “Very toxic; Very toxic if swallowed”

LIST OF STUDIES TO BE GENERATED, STILL ONGOING OR AVAILABLE BUT NOT PEER REVIEWED

- A specification with supporting batch data and analytical methods (relevant for Casa Bernardo, data gap identified by EFSA August 2008, proposed submission date unknown, refer to chapter 1).
- Flammability of the active substance in accordance with method EEC A12 (UPL) (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1).
- Flammability of the active substance in accordance with method EEC A10, A12 (CAS) (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1).
- Degassing rate of the formulation before and after storage (UPL), (CAS) (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1).
- Degassing rate of the formulation before and after storage (Detia) (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, data available in addendum 2 to Vol. 3 but not peer reviewed, refer to chapter 1).
- 2 year shelf life study (CAS) (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1).
- Components present at < 0.1 % must be deleted from the specifications (all applicants) (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1).
- Analytical method for the active substance in the formulated product (CAS) (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1).
- For the products of plant origin: ILV and a confirmatory method (Detia) (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1).
- Method of analysis for products of plant origin including ILV (CAS), (UPL) (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1).
- Confirmatory method of analysis for water (all applicants) (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1).
- Method of analysis for air with an appropriate LOQ (all applicants) (relevant for all uses evaluated, data gap identified by meeting of experts June 2008, proposed submission date unknown, refer to chapter 1).

- Detia and UPL, to precisely describe in the GAP the length of the minimum aeration period needed after fumigation to make the handling of the commodities safe for workers (relevant for all representative uses evaluated, proposed submission date unknown; refer to point 3)
- Detia, to precisely describe the way the samples were handled between sampling and analyses in the study RIP2002-148 (relevant for all representative uses evaluated, proposed submission date unknown; refer to point 3.1).
- UPL and CAS, to submit post harvest residue studies to support GAP (relevant for all intended post-harvest uses evaluated, proposed submission date unknown; refer to point 3.1).
- All applicants, to clearly define GAPs that include a withholding period in addition to the minimum aeration period (relevant for all representative uses evaluated, proposed submission date unknown; refer to point 3.1)
- The potential for exposure of surface water to phosphine moving in the gas phase from the requested outdoor applications of aluminium phosphide has yet to be adequately addressed (relevant for the outdoor representative uses evaluated where target organism burrows are adjacent to surface water; submission date proposed by the notifier: unknown; refer to point 4.2.1)
- Studies for aquatic invertebrates and algae with phosphine as test substance (relevant for the outdoor representative uses evaluated where target organism burrows are adjacent to surface water; data gap confirmed by EFSA after the PRAPeR 53 meeting in July 2008; refer to point 5.2).
- Risk assessment on aquatic organisms from exposure to phosphine (relevant for the outdoor representative uses evaluated where target organism burrows are adjacent to surface water; data gap confirmed by EFSA after the PRAPeR 53 meeting in July 2008; refer to point 5.2).

CONCLUSIONS AND RECOMMENDATIONS

Overall conclusions

This conclusion was reached on the basis of the evaluation of the representative uses as an insecticide, rodenticide, talpicide and leporicide. Full details of the GAP can be found in the attached list of endpoints.

The representative formulated products for the evaluation were “Phostoxin Tabletten”, “Quickphos tablet/pellets/bags 56 GE“, and “Gastoxin“ gas generating products (GE). The gas phosphine that is produced is the true active substance.

Pooling all the available data from all aluminium phosphide applicants a method of analysis for phosphine in products of plant origin is available however ILV and a confirmatory method have been identified as a data gap. A method for products of animal origin is not required as MRLs have not been set. Methods for phosphine in soil are not required as the DT₉₀ in soil is < 3 days for phosphine.

A method is available for phosphine in water but a confirmatory method has been identified as a data gap. It should be noted however, that there is a confirmatory method in the magnesium phosphide DAR. The method of analysis for air did not have a low enough LOQ and a data gap was identified. Sufficient analytical methods as well as methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection products are possible. The meeting of experts considered the specification and impurities on the basis that the spent pellets were contained and removed from the treated material. Therefore, given the toxicity of phosphine, possible relevant impurities were ignored. The case where the spent material is not removed has not been considered in the peer review process. The batch data and the specification for the Casa Bernardo sources were not accepted. Some data gaps for physchem data for the individual formulations were identified.

When coming into contact with moisture aluminium phosphide decomposes to aluminium hydroxide and phosphine which is the toxicologically active ingredient and the relevant component for the assessment of mammalian toxicology of aluminium phosphide. Aluminium phosphide is classified as **R29 “Contact with water liberates toxic gas”** and **R32 “Contact with acids liberates very toxic gas”**. Phosphine is rapidly absorbed from the gastrointestinal tract and the lungs. It is widely and evenly distributed in the body and has no potential for accumulation. Phosphine is excreted as such via expired air or with the urine in the form of hypophosphite or phosphite. Aluminium phosphide is very toxic by the oral and inhalation route and harmful by the dermal route. It is neither a skin nor an eye irritant nor a skin sensitizer. Based on data on acute toxicity a classification as **T+; R28 “Very toxic if swallowed”, Xn; R21 “Harmful in contact with skin”** and **T+; R26 “Very toxic by inhalation”** is proposed. A short term NOAEL of 1.1 mg/kg bw/d (the highest dose tested, no adverse effects observed) was derived for phosphine from a rat 90-day inhalation study. Aluminium phosphide is not genotoxic. In a 2-year inhalation study with rats a NOAEL of 1.1 mg/kg bw/d was established for phosphine which was the highest dose level tested since no adverse effects were observed. A mouse carcinogenicity study was not carried out and not considered necessary based on the toxicity profile of the substance (lethality anticipated at low doses). In an inhalation developmental study with rats (a rabbit study was not provided) no specific developmental effects were observed and an overall NOAEL for phosphine of 1.9 mg/kg bw/d was set based on mortality occurring in dams. Effects on reproduction have not been assessed but are, based on the toxicity profile of the substance, not anticipated. The acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) have been set at 0.019 mg/kg bw/d. The acute reference dose (ARfD) was fixed at 0.032 mg/kg bw. The corresponding values for phosphine are 0.011 mg/kg bw/d (ADI and AOEL) and 0.019 mg/kg bw (ARfD). When applying aluminium phosphide containing formulations in rodent burrows without the use of respiratory protective equipment (RPE) maximum exposure levels amounted to 93% of the AOEL for operators, workers and bystanders, however more realistic exposure levels for workers and bystanders presented in the DAR accounted for 63% and 33% of the AOEL respectively. Application

of aluminium phosphide in storage rooms when respiratory protective equipment is used amounted to 71% for operators and to 33% (or alternatively 25%) for workers of the systemic AOEL. For unprotected bystanders a maximum value for exposure of 33% of the AOEL was derived.

Two main uses of aluminium phosphide were evaluated, 1) as a rodenticide, talpicide, leporicide to control rodent and non-rodent vertebrates by fumigation of underground tunnels and burrows in cropland and non-cropland situations, 2) as a fumigant to control insects in various harvested plant products and in empty warehouses or transportation facilities. Due to its physico-chemical properties, no specific studies to evaluate metabolism and distribution of aluminium phosphide in treated commodities were submitted. In contact with soil or atmospheric moisture, aluminium phosphide is rapidly hydrolysed to produce phosphine (PH_3) and aluminium hydroxide $\text{Al}(\text{OH})_3$. After treatment the major part of phosphine is volatilised and diluted in air or oxidised to phosphorous oxyacids of no significant concern for human health. Considering stored fumigated commodities may contain residual gaseous phosphine and residual metal phosphide, the residue definition for monitoring and risk assessment was set as “phosphine and phosphine generators (relevant phosphide salts) determined and expressed as phosphine”.

No residue trials were submitted to support the uses of aluminium phosphide as a rodenticide, considering that the direct application of the active substance into underground tunnels of rodent or non-rodent animals excludes the direct contact with plants and therefore, the possible residues in plants. For post harvest applications, in addition to the aeration period, the RMS proposed for each commodity or group of commodities a withholding period. Thus, during the meeting, the MRL proposals were not discussed on the basis of the residue levels observed at the end of the aeration period as stated in the GAP, but at the end of these additional withholding periods of 7 to 35 days, depending on the commodities. Consequently and after the meeting, EFSA was of the opinion that the fumigation practices have not been sufficiently defined to allow the MRL setting, and considers the fact that the withholding periods were not clearly described in the intended GAP as a data gap.

No storage stability study was provided considering that the inherent properties of phosphine lead to a low stability in stored products. No processing studies and no livestock metabolism and feeding studies were provided since no significant residues of aluminium phosphide and phosphine are expected in post harvested plant commodities. No rotational crop studies were submitted since no residues in soil are expected from the outdoor uses on rodent and non-rodent vertebrates. No chronic or acute risks to consumers are expected after fumigation of stored commodities with aluminium phosphide if a withholding period is taken into account in the GAP, and considering that the proposed MRL values do not reflect the critical GAPs as initially defined by the applicants.

The Member State experts concluded that in relation to the applied for intended uses, the information available on the fate and behaviour of aluminium phosphide, phosphine gas, phosphate and aluminium salts in the environment was sufficient to complete an adequate environmental exposure

characterisation with one exception. This exception was that for the use outdoors in animal burrows, where these burrows had openings directly adjacent to surface water, further data were necessary to enable a more realistic exposure estimate for potential concentrations of phosphine gas in surface water and if necessary, demonstrate the effectiveness of potential exposure mitigation measures that might need to be proposed. The potential for groundwater exposure of aluminium phosphide and its breakdown products above the relevant parametric drinking water limits set out in the relevant EU legislation⁷ was assessed as low from the applied for intended uses.

Due to the representative uses (applied outdoor directly into the burrow systems or indoor in food storage rooms), the exposure to non-target species was considered to be only local or negligible. On the basis of the potential exposure of surface water to phosphine (data gap from the fate meeting) where target organism burrows are adjacent to water bodies, the risk from the outdoor use to aquatic organisms needs be addressed (data gap) and therefore valid studies for invertebrates and algae should be provided (data gap).

The risk to birds, mammals, bees, non-target arthropods, earthworms, soil non target macro- and micro- organisms, non-target plants and biological methods of sewage treatment was expected to be low for the representative use evaluated.

Particular conditions proposed to be taken into account to manage the risk(s) identified

- For operators and workers respiratory protective equipment is necessary.
- To protect birds and mammals, include on the label a phrase to make sure that burrows are closed and no granules remain on the surface.

Critical areas of concern

- EFSA disagrees with the outcome of the operator exposure assessment for fumigation of storage rooms with Phostoxin.
- The peer review has only considered the situation where the spent pellets are removed from the food commodity. The situation where the material remains in the food after the release of phosphine has not been considered in the peer review. If this situation is to be covered then a different technical specification would be required and a risk assessment for the material remaining in the food commodity would have to be conducted.
- Consumer risk assessment for intended uses could not be finalised.

⁷ Council Directive 98/83/EC on the quality of water intended for human consumption

Appendix 1 – list of endpoints

APPENDIX 1 – LIST OF ENDPOINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡	Aluminium phosphide (there is no ISO common name for this compound)
Function (<i>e.g.</i> fungicide)	Insecticide, rodenticide, talpicide and leporicide
Rapporteur Member State	Federal Republic of Germany

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	Aluminium phosphide
Chemical name (CA) ‡	Aluminium phosphide
CIPAC No ‡	227
CAS No ‡	20859-73-8
EEC No (EINECS or ELINCS) ‡	244-088-0
FAO Specification (including year of publication)‡	none
Minimum purity of the active substance as manufactured‡	830 g/kg
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured	none
Molecular formula ‡	AlP
Molecular mass ‡	57.96 g/mol
Structural formula ‡	Al-P-lattice (ionic structure)

Appendix 1 – list of endpoints

Physical-chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	DET: > 500 °C (86.5 %) UPL: > 1000 °C CAB: > 2550 °C [PH ₃ : -133 °C]
Boiling point (state purity) ‡	DET: > 500 °C (86.5 %) UPL: not applicable CAB: not applicable [PH ₃ : -88 °C]
Temperature of decomposition (state purity)	DET: > 500 °C UPL: not applicable CAB: not applicable [PH ₃ : > 550 °C]
Appearance (state purity) ‡	DET: grey solid (86.5 %) UPL: greenish yellow powder with garlic-like odour (86.17 %) CAB: green or yellow cubic crystals with garlic odour [PH ₃ : colourless gas of garlic/decaying fish like odour]
Vapour pressure (state temperature, state purity) ‡	DET: 1 x 10 ⁻⁸ Pa (calculated for 25 °C) UPL: 0 Pa (open point) CAB: low at 1000 °C [PH ₃ : 3.44 x 10 ⁻⁶ Pa (20 °C); 3.90 x 10 ⁻⁶ Pa (25 °C)]
Henry's law constant‡	rapid hydrolysis, not applicable [PH ₃ : 33269 Pa x m ³ x mol]
Solubility in water (state temperature, state purity and pH) ‡	rapid hydrolysis, not applicable [PH ₃ : 260 mL/L (20 °C)]
Solubility in organic solvents (state temperature, state purity and pH) ‡	not soluble, due to ionic structure (not determined) [PH ₃ : good soluble (> 500 mL/L) in organic solvents]
Surface tension‡ (state concentration and temperature, state purity)	rapid hydrolysis, not applicable [PH ₃ : –]
Partition co-efficient (log P _{OW}) (state temperature, pH and purity) ‡	rapid hydrolysis, not applicable [PH ₃ : 1.05]

Appendix 1 – list of endpoints

Dissociation constant (state purity)‡	rapid hydrolysis, not applicable [PH ₃ : pkb 7.4 at 20 ° C]
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	not applicable [PH ₃ : ε = 3400 l * mol ⁻¹ at 191 nm]
Flammability ‡ (state purity)	The submitted test shows that aluminium phosphide is not highly flammable under the test conditions (EEC A10), but will evolve extremely flammable phosphine at contact with water (EEC A 12). However, the ECB has classified aluminium phosphide as F (highly flammable), [PH ₃ : F+, extremely flammable]
Explosive properties ‡ (state purity)	no explosive properties (according to structure) [PH ₃ : may explode at conc. > 1.8 % (v/v)]
Oxidising properties ‡ (state purity)	No oxidising properties (experimental data)

DET: Detia Freiberg GmbH; UPL: United Phosphorus Ltd; CAB: Casa Bernardo

Appendix 1 – list of endpoints

Summary of representative uses evaluated (aluminium phosphide, Detia Freyberg GmbH)*

Crop and/or situation (a)	MS or Country	Product name	F/G /I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI	Remarks
					Type (d-f)	Conc. of as (i)	Method kind (f-h)	Growth stage & season (j)	Number min & max (k)	Interval between applications (min)	kg as/hl min & max	Water L/ha min & max	kg as/ha min & max	Days (l)	
Out-door control of rodent and non-rodent species in underground burrows, e.g. in fields and meadows, orchards, forests:	Europe	Phostoxin Tabletten*	F	Moles Rabbits Rodents	GE	56 %	gassing	n.a.	1	n.a.	n.a.	n.a.	1 tablet (or 5 pellets) / 3-5 meters burrow length (light soil)/ or 1 tablet (or 5 pellets) / 8-10 meters burrow length (all other soils) 1-2 tablets / hole or mole hill	n.a.	[1]

*) same formulation as Phostoxin, Phostoxin Fumigation Tablets, Phostoxin P, Phostoxin RT, Phostoxin WM

[1] The environmental exposure and risk assessment presented in the DAR it's addenda and this conclusion does not cover the use of 2 tablets. Only the use of up to 5 pellets or 1 tablet was assessed.

Appendix 1 – list of endpoints

Crop and/or situation (a)	MS or Country	Product name	F/ G /I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI	Remarks
					Type	Conc. of as	Method kind	Growth stage & season	Number min & max	Interval between applications (min)	kg as/hl min & max	Water L/ha min & max	kg as/ha min & max	Days	
					(d-f)	(i)	(f-h)	(j)	(k)					(l)	(m)
In-door control of insects mainly in food storage practice:															
grain in silos and on barges, expeller, flour, oilseed, tapioca, hides; quarantine treatment against insect pests	Europe	Phostoxin Tabletten*	I	Storage pests	GE	56 %	gassing	n.a.	1	n.a.	n.a.	n.a.	2-15 tablets / t		[1], [2]
dried fruits and vegetables spices, tea, coffee and cocoa beans, oilseed, pulses, rice, nuts, tobacco	Europe	Phostoxin Tabletten*	I	Storage pests	GE	56 %	gassing	n.a.	1	n.a.	n.a.	n.a.	1-15 tablets / m ³		[1], [2]
empty rooms and buildings	Europe	Phostoxin Tabletten*	I	Storage pests	GE	56 %	gassing	n.a.	1	n.a.	n.a.	n.a.	1 – 3 tablets / m ³		[1], [2]

*) same formulation as Phostoxin, Phostoxin Fumigation Tablets, Phostoxin P, Phostoxin RT, Phostoxin WM

- 1) EFSA disagrees with the outcome of the operator exposure assessment for fumigation of storage rooms with Phostoxin.
- 2) Solid residues from the formulation have to be removed from the food commodities

Appendix 1 – list of endpoints

Remarks:	(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (<i>e.g.</i> fumigation of a structure)	(i)	g/kg or g/L
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(j)	Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	(c)	<i>e.g.</i> biting and suckling insects, soil born insects, foliar fungi, weeds	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(d)	<i>e.g.</i> wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(l)	PHI - minimum pre-harvest interval
	(e)	GCPF Codes – GIFAP Technical Monograph No 2, 1989	(m)	Remarks may include: Extent of use/economic importance/restrictions
	(f)	All abbreviations used must be explained		
	(g)	Method, <i>e.g.</i> high volume spraying, low volume spraying, spreading, dusting, drench		
	(h)	Kind, <i>e.g.</i> overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated		

Summary of representative uses evaluated (aluminium phosphide, United Phosphorus Limited)*

Crop and/or situation	MS or Country	Product name	F/G/I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI days	Remarks
					Type	Conc. of as	method kind	growth stage & season	number min & max	interval between applications (min)	kg as/hL min & max	water L/ha min & max	kg as/ha min & max		
(a)			(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)					(l)	(m)
Bulk grain loosely piled in silo bins	Europe	Quickphos Tablets*	I	Storage pest	GE	57 %	fumigation	n.a.	1	n.a.	n.a.	n.a.	2 - 5 tablets per tonne	n.a.	Professional use [1]
Bagged grain	Europe	Quickphos Pellets**	I	Storage pest	GE	57 %	fumigation	n.a.	1	n.a.	n.a.	n.a.	10 - 25 pellets per tonne	n.a.	Professional use [1]
Tobacco in bales Packed, Processed food and animal feed Space fumigation: Empty warehouses, mills etc	Europe	Quickphos Bags 56 GE***	I	Storage pest	GE	57 %	fumigation	n.a.	1	n.a.	n.a.	n.a.	1 - 2 bags (34 g) per 10 m ³	n.a.	Professional use [1]

* same formulation as Quickphos Comprimes Tablets, Quickphos TB, Quickphos Tableta, Quickphos Tablets 56 GE, Quickphos Tablete Fumigante, Quickphos-T,

** same formulation as Delicia Gastoxin, Trinol Fosforbrinte, Quickphos Comprime, Quickphos Pellets 56 GE

*** same formulation as Fumitoxin R, Quickphos Belts 56 GE, Quickphos Blankets 56 GE,

1) Solid residues from the formulation have to be removed from the food commodities

Appendix 1 – list of endpoints

- | | | |
|----------|--|---|
| Remarks: | <ul style="list-style-type: none"> (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure) (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I) (c) e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) GCPF Codes - GIFAP Technical Monograph No. 2, 1989 (f) All abbreviations must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench | <ul style="list-style-type: none"> (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated (i) g/kg or g/L (j) Growth stage at last treatment (BBCH Monograph, growth stages of plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant information on season at time of application (k) The minimum and maximum number of applications possible under practical conditions of use must be provided (l) Duration of exposure / re-entry period (m) Withholding period after exposure before commodity may be released for further processing or consumption (n) Remarks may include: Extent of use/ economic importance/restrictions |
|----------|--|---|

Appendix 1 – list of endpoints

Summary of representative uses evaluated (aluminium phosphide, Casa Bernardo)*

Crop and/or situation (a)	Member State or Country	Product Name	F, G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment	Exposure period (days) (l)	Ventilation period (days) (m)	Remarks (n)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g as/100 m ³ min max			
Soy bran Wheat flour Barley grain Cocoa beans Wheat grain Sorghum grain	Europe	Gastoxin	I	Insects	GE	570 g/kg in 0.6 g pellets or 3 g tablets or 34 g sachets or chains of 34 g sachets	Direct addition of pellets, tablets or sachets	Post-harvest	1	n/a	100 - 310 500 – 1500 pellets 100 – 300 tablets 9 – 27 sachets	5 – 10 °C – at least 16 days 12 – 15 °C – at least 14 days 16 – 20 °C – at least 10 days above 20 °C – at least 7 days	Minimum 2 days aeration	Do not fumigate at temperatures < 5 °C [1], [3]
Maize grain Beans Coffee beans Rice grain Peanuts Cotton seed Tobacco	Europe	Gastoxin	I	Insects	GE	570 g/kg in 0.6 g pellets or 3 g tablets or 34 g sachets or chains of 34 g sachets	Direct addition of pellets, tablets or sachets	Post-harvest	1	n/a	100 - 310 500 – 1500 pellets 100 – 300 tablets 9 – 27 sachets	5 – 10 °C – at least 16 days 12 – 15 °C – at least 14 days 16 – 20 °C – at least 10 days above 20 °C – at least 7 days	Minimum 2 days aeration	Do not fumigate at temperatures < 5 °C [1], [3]

Appendix 1 – list of endpoints

Crop and/or situation (a)	Member State or Country	Product Name	F, G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment	Exposure period (days) (l)	Ventilation period (days) (m)	Remarks (n)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g as/100 m ³ min max			
Empty storage facilities	Europe	Gastoxin	I	Insects	GE	570 g/kg in 34 g sachets or chains of 34 g sachets	Direct placement of sachets	n/a	1	n/a	100 - 300 500 – 1500 pellets 100 – 300 tablets 9 – 27 sachets	5 – 10 °C – at least 16 days 12 – 15 °C – at least 14 days 16 – 20 °C – at least 10 days above 20 °C – at least 7 days	n/a	Do not fumigate at temperatures < 5 °C [1]
Rodent control in cropland and non-cropland situations	Europe	Gastoxin	F	Rodents, rabbits, moles, voles	GE	570 g/kg in 0.6 g pellets or 3 g tablets	Direct placement of product in burrows	As required	1 – 2	2 days	1 – 2 tablets (5 – 10 pellets) per burrow	n/a	n/a	[1] [2]

[1] The specification was not accepted

[2] The environmental exposure and risk assessment presented in the DAR it's addenda and this conclusion does not cover the use of 2 tablets or 10 pellets. Only the use of up to 5 pellets or 1 tablet was assessed.

[3] Solid residues from the formulation have to be removed from the food commodities

- Remarks:
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Codes - GIFAP Technical Monograph No. 2, 1989
 - (f) All abbreviations must be explained
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/L
 - (j) Growth stage at last treatment (BBCH Monograph, growth stages of plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant information on season at time of application
 - (k) The minimum and maximum number of applications possible under practical conditions of use must be provided
 - (l) Duration of exposure
 - (m) period
 - (n) Remarks may include: Extent of use/ economic importance/restrictions

Appendix 1 – list of endpoints

Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	Detia Freyberg GmbH titration after acid hydrolysis and reaction with mercury chloride	United Phosphorus Ltd GC-FPD and titration	Casa Bernardo open
Impurities in technical as (principle of method)	titration, ICP-AES, FIAS-AAS, calculation	AAS, titration, ICP-MS	ICP-AES
Plant protection product (principle of method)	titration after acid hydrolysis and reaction with mercury chloride	GC-FPD and titration	open

Residue definitions for monitoring purposes

Food of plant origin	Phosphine and phosphine generators (relevant phosphide salts) determined and expressed as phosphine
Food of animal origin	Not relevant, no MRL, no residue definition for monitoring
Soil	Not relevant, $DT_{90} < 3$ days
Water surface	Phosphine
drinking/ground	None
Air	Phosphine

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Primary method: GC-NPD 0.01 mg/kg (meal, shell fruit, tea)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Not relevant, no MRL proposed by the RMS, no residue definition for monitoring

Appendix 1 – list of endpoints

Soil (principle of method and LOQ)	Not relevant, $DT_{90} < 3$ days
Water (principle of method and LOQ)	GC-NPD 0.1 µg/L (drinking and surface water) Open confirmatory method.
Air (principle of method and LOQ)	No method is available for the determination of the limit of 3.3 µg/m ³ (LOQ calculated on basis of the AOEL)
Body fluids and tissues (principle of method and LOQ)	not necessary, since phosphine will be quickly exhaled or metabolised to phosphates, even though the active substance is classified as very toxic

Classification and proposed labelling (Annex IIA, point 10)

	RMS/peer review process
Active substance	F

Appendix 1 – list of endpoints

Impact on human and animal health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption ‡	Ready absorption of phosphine through the lungs and after oral exposure to zinc phosphide
Distribution ‡	Widely distributed
Potential for accumulation ‡	No potential for accumulation
Rate and extent of excretion ‡	Rapid excretion with urine as hypophosphite and phosphite and via lungs as phosphine
Metabolism in animals ‡	Hydrolysis to phosphine, oxidation to hypophosphite and phosphite
Toxicologically relevant compounds ‡ (animals and plants)	Phosphine
Toxicologically relevant compounds ‡ (environment)	Phosphine

Acute toxicity (Annex IIA, point 5.2)

Rat LD ₅₀ oral ‡	8.7 mg/kg bw (aluminium phosphide)	T+; R 28
Rat LD ₅₀ dermal ‡	Approx. 460 - 900 mg/kg bw (aluminium phosphide)	Xn; R 21
Rat LC ₅₀ inhalation ‡	11 ppm (> 0.016 mg PH ₃ /L air or > 2.8 mg/kg bw) – 51 ppm (0.072 mg PH ₃ /L air) (4 h exposure, whole body) LC ₅₀ =0.048 mg/L (phosphine levels from aluminium phosphide dust)	
Skin irritation ‡	Not irritant (aluminium phosphide)	
Eye irritation ‡	Not irritant (aluminium phosphide)	
Skin sensitisation ‡	No indication of skin sensitisation (Buehler-test, 3 inductions using a product containing 56 % w/w aluminium phosphide and M&K-test using zinc phosphide)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect ‡	Mortality
Relevant oral NOAEL ‡	No reliable data, no study required
Relevant dermal NOAEL ‡	No data, no study required

Appendix 1 – list of endpoints

Relevant inhalation NOAEL ‡	NOAEL 3 ppm phosphine (equivalent to 1.1 mg/kg bw/d), rat 90-d, the highest dose tested	
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Genotoxicity ‡ (Annex IIA, point 5.4)

No genotoxic potential at realistic exposure levels	
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Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect ‡	None	
Relevant NOAEL ‡	3 ppm phosphine equivalent to 1.1 mg/kg bw/d (rat 2-yr inhalation)	
Carcinogenicity ‡	Not carcinogenic in the rat Data on mice not required, not necessary	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect ‡	Not required, not necessary	
Relevant parental NOAEL ‡	Not required, not necessary	
Relevant reproductive NOAEL ‡	Not required, not necessary	
Relevant offspring NOAEL ‡	Not required, not necessary	

Developmental toxicity

Developmental target / critical effect ‡	Rat: Mortality of dams	
Relevant maternal NOAEL ‡	Rat, developmental study, inhalation: 4.9 ppm phosphine (equivalent to 1.9 mg/kg bw/d) Data on rabbits not required, not necessary.	
Relevant developmental NOAEL ‡	Rat, developmental study, inhalation: 4.9 ppm (equivalent to 1.9 mg/kg bw/d) Data on rabbits not required, not necessary.	

Appendix 1 – list of endpoints

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity ‡	NOAEL (acute study, inhalation): 40 ppm PH ₃ (analytical conc. 38 ppm) (with regard to anatomic pathology, behavioural and neurological status); < 21 ppm PH ₃ (with regard to changes in motor activity)	
Repeated neurotoxicity ‡	NOAEL (subchronic study 90 days): 3 ppm phosphine equivalent to 1.1 mg/kg bw/d	
Delayed neurotoxicity ‡	No study required.	

Other toxicological studies (Annex IIA, point 5.8)

Studies performed on metabolites or impurities ‡	No additional studies required. The relevant metabolite phosphine was generated in the submitted studies.
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Medical data ‡ (Annex IIA, point 5.9)

No compelling evidence of negative health effects from examinations of personnel with occupational exposure. Records of poisoning cases, mainly in connection with suicide and accidents (particularly with children) are available.

Summary (Annex IIA, point 5.10)

Aluminium phosphide	Value	Study	Safety factor
ADI ‡	0.019 mg/kg bw/d*	2-yr inhalation, rat	100
AOEL systemic ‡	0.019 mg/kg bw/d*	90-d inhalation, rat	100
ARfD ‡	0.032 mg/kg bw*	Developmental study (inhalation), rat	100
Phosphine			
ADI	0.03 ppm or 0.042 µg/L air or 0.011 mg/kg bw/d	2-yr inhalation, rat	100
AOEL systemic ‡	0.03 ppm or 0.042 µg/L air or 0.011 mg/kg bw/d	90-d inhalation, rat	100

Appendix 1 – list of endpoints

ARfD	0.049	ppm or	Developmental study (inhalation), rat	100
	0.069	µg/L air or		
	0.019	mg/kg bw		

* Based on a maximum liberation of gas of 0.59 g PH₃/g aluminium phosphide

Dermal absorption ‡ (Annex IIIA, point 7.3)

Default value 10 % for aluminium phosphide and PH₃ (based on expert judgement)

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Use for the control of rodents in burrows: acceptable without the use of personal protective equipment (≤ 93 % of systemic AOEL). Nevertheless, since temporary exposure concentrations exceeding the AOEL cannot be excluded, PPE/RPE should be recommended. Use for the control of insect pests in storage buildings in accordance with respective regulations: acceptable if respiratory protective equipment (RPE) is used (≤ 71 % of systemic AOEL).
Workers	Use for the control of rodents in burrows: acceptable (≤ 93 % of systemic AOEL) Use for the control of insect pests in storage buildings in accordance with respective regulations: acceptable (≤ 25 % of systemic AOEL when RPE is used).
Bystanders	Use for the control of rodents in burrows: acceptable (≤ 93 % of systemic AOEL) Use for the control of insect pests in storage buildings in accordance with respective regulations: acceptable (≤ 33 % of systemic AOEL), a safety zone must be established around buildings to be fumigated and closed off.

Appendix 1 – list of endpoints

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

Aluminium phosphide

T+; R 15/29-28-32 (up to 29th ATP)
 Additionally proposed by PRAPeR: T+, R26 Xn, R21
 Add Safety phrase SPo1: After contact with skin first remove product with a dry cloth and then wash the skin with plenty of water

Phosphine

T+; R 26 - 34 (up to 29th ATP)

Appendix 1 – list of endpoints

Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	<u>Outdoor use</u> not required <u>Indoor use</u> Not required, since no relevant residues apart from phosphine and aluminium phosphide in plants and agricultural products derived thereof are expected.
Rotational crops	Not required – Phosphine and aluminium phosphide residues will not be bioavailable to rotational crops.
Metabolism in rotational crops similar to metabolism in primary crops?	not applicable
Processed commodities	Not required, since no relevant residues of phosphine and aluminium phosphide in plants and agricultural products derived thereof are expected.
Residue pattern in processed commodities similar to residue pattern in raw commodities?	not applicable
Plant residue definition for monitoring	<u>Outdoor use:</u> Not required <u>Indoor use:</u> Phosphine and phosphine generators (relevant phosphide salts) determined and expressed as phosphine
Plant residue definition for risk assessment	<u>Outdoor use:</u> Not required <u>Indoor use:</u> Phosphine and phosphine generators (relevant phosphide salts) determined and expressed as phosphine
Conversion factor (monitoring to risk assessment)	none

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Not applicable – feeding studies not triggered
Time needed to reach a plateau concentration in milk and eggs	Not required for reasons given above.
Animal residue definition for monitoring	Not required, since no residues of phosphine and aluminium phosphide in plants or feed of plant origin are expected.
Animal residue definition for risk assessment	Not required, since no residues of phosphine and aluminium phosphide in plants or feed of plant origin are expected.

Appendix 1 – list of endpoints

Conversion factor (monitoring to risk assessment)	none
Metabolism in rat and ruminant similar (yes/no)	not applicable
Fat soluble residue: (yes/no)	not applicable

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

Not required – Phosphine and aluminium phosphide residues will not be bioavailable to succeeding crops.

Stability of residues (Annex IIA, point 6 Introduction, Annex IIIA, point 8 Introduction)

Guideline studies of the stability of aluminium phosphide and phosphine during storage of samples are not available.

The active substance is volatile. Therefore, samples should be stored at approximately $\leq -20^{\circ}\text{C}$ and analysed as soon as possible (≤ 2 days).

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	no	no	no
Potential for accumulation (yes/no):	no	no	no
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	not required	not required	not required
Feeding studies (specify the feeding rate in cattle and poultry studies considered as relevant) - not applicable (feeding studies not triggered)			
Residue levels in matrices : Mean (max) mg/kg			

Appendix 1 – list of endpoints

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies - not applicable (feeding studies not triggered)		
Muscle	no	no	no
Liver	no	no	no
Kidney	no	no	no
Fat	no	no	no
Milk	no		
Eggs		no	

Appendix 1 – list of endpoints

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region, field or glasshouse and any other useful information	Trials results relevant to the representative uses (mg/kg) (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (mg/kg) (c)	STMR (mg/kg) (b)
No MRLs could be defined according the critical GAPs as defined by the applicants where only an aeration period is considered. However, MRL proposals were discussed during the meeting of experts taking into account the additional withholding periods proposed by the RMS (see conclusion report).						
Explanatory note:						

- (a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x < 0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
 (b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use
 (c) Highest residue

Appendix 1 – list of endpoints

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.011 phosphine mg/kg bw/d
TMDI (% ADI) according to WHO European diet	No MRLs could be defined according the critical GAPs
TMDI (% ADI) according to national (to be specified) diets	However, the MRL proposals discussed during the meeting and based on the residue levels observed after an additional withholding period, lead to TMDI calculations that are below the ADI (see conclusion report).
IEDI (WHO European Diet) (% ADI)	not required
NEDI (specify diet) (% ADI)	not required
Factors included in IEDI and NEDI	not required
ARfD	0.019 phosphine mg/kg bw
IESTI (% ARfD)	No MRLs could be defined according the critical GAPs
NESTI (% ARfD) according to national (to be specified) large portion consumption data	However, the MRL proposals discussed during the meeting and based on the residue levels observed after an additional withholding period, lead to IESTI calculations that are below the ARfD (see conclusion report).
Factors included in IESTI and NESTI	not required

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Crop/ process/ processed product	Number of studies	Processing factors		Amount transferred (%) (Optional)
		Transfer factor	Yield factor	
not applicable				

Residue levels of phosphine and aluminium phosphide were < 0.1 mg/kg in all commodities at the end of the withholding periods and the TMDI generally < 10 % of the ADI value. Therefore, no studies on the effects on residue levels due to processing are necessary.

Appendix 1 – list of endpoints

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

Outdoor use

Not required

Indoor use

No MRLs could be defined according to critical GAPs as defined by the applicants where only an aeration period is considered.

However, MRL proposals were discussed during the meeting of experts taking into account additional withholding periods proposed by the RMS (see conclusion report).

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

Appendix 1 – list of endpoints

Fate and behaviour in the environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralisation after 100 days ‡	Not relevant*
Non-extractable residues after 100 days ‡	Not relevant
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Not relevant

* Recent, "state-of-the-art" investigations according to current guidelines for the elucidation of the degradation pathway of aluminium phosphide in soil do not exist. Aluminium phosphide is an inorganic molecule. The relatively rapid rate of chemical hydrolysis in the environment, would be expected to be the predominant mechanism for loss of aluminium phosphide when placed in the soil environment. Hydrolysis leads to the evolution of phosphine and residual aluminium salts will prevail. Phosphine is expected to either partition to the atmosphere due to its volatility, or become re-adsorbed onto soil. In both cases, oxidative processes are effective in finally transforming phosphine to phosphate anions

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation ‡	<p>Outdoor use: Not required since product is applied in underground tunnel systems and in this open field environment anaerobic conditions are not expected to be relevant.</p> <p>Indoor use: Due to application in closed/sealed rooms (storage protection) contact with soil is excluded.</p>
Soil photolysis ‡	<p>Not required since product is applied in underground tunnel systems so light will be excluded.</p>

Appendix 1 – list of endpoints

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Laboratory studies ‡

Metabolite PH ₃	Aerobic conditions						
Soil type	X ⁸	pH	t. °C / % MWHC	DT ₅₀ /DT ₉₀ (d)	DT ₅₀ (d) 20 °C pF2/10kPa	St. (r ²)	Method of calculation
sand		6	22 °C / 40 %	0.22 / 0.66*	-	-	
sand		6	22 °C / 40 %	0.24 / 0.72*	-	-	
Geometric mean/median				0.23 / 0.23	-		

* estimated

Laboratory studies ‡

PH ₃	<p>Aerobic conditions</p> <p>Aluminium phosphide is degraded in soil to yield phosphine gas as an intermediate, and aluminium salts. Theoretically, any phosphine generated during hydrolysis will either be volatilised and subsequently subject to oxidative degradation by reaction with OH-radicals, or it will become re-adsorbed onto soil and subsequently be degraded.</p> <p>After 6 hours only 50 % of the PH₃ amount used is found. Therefore, a fast primary degradation of PH₃ can be concluded.</p>
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Field studies ‡

	Field studies were not performed as the laboratory DT ₅₀ of 0.23 d was extremely fast
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pH dependence ‡
(yes / no) (if yes type of dependence)

Not relevant

Soil accumulation and plateau concentration ‡

Not relevant.

Laboratory studies ‡

Parent	Anaerobic conditions
	Not relevant

Soil adsorption/desorption (Annex IIA, point 7.1.2)

The performance of "state-of-the-art" adsorption/desorption experiments with aluminium phosphide is not considered to be required for the following reasons: (i) All high-resolution analytical methods for aluminium phosphide are based on the principle of liberating phosphine gas, with subsequent head

⁸ X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

Appendix 1 – list of endpoints

space gas chromatography. Thus, a discrimination between the parent compound aluminium phosphide and any phosphine already present would not be possible in experimental settings. (ii) The preparation of a solution in water for the subsequent adsorption/desorption experiments is not possible. As a result, this renders the performance of such studies as technically and scientifically unfeasible.

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching ‡	For this type of application and this type of pesticide no guideline exists, that can be followed. A study has been performed showing that after 24 hours PH ₃ has almost disappeared. The study is plausible.
Lysimeter/ field leaching studies ‡	No lysimeter studies performed

PEC (soil) (Annex IIIA, point 9.1.3)

Parent	DT ₅₀ (d): 0.24 (= 5.7 h)
Method of calculation	Kinetics: SFO Field or Lab: from laboratory studies.
Application data	5 pellets à 0.6 g per 3 - 5 m burrow length (light soils) 5 pellets à 0.6 g per 8 - 10 m burrow length (all other soils)

PEC(soil) (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	not applicable*		not applicable	
Short term 24 h	not applicable	not applicable	not applicable	not applicable
2 d	not applicable	not applicable	not applicable	not applicable
4 d	not applicable	not applicable	not applicable	not applicable
Long term 7 d	not applicable	not applicable	not applicable	not applicable
28 d	not applicable	not applicable	not applicable	not applicable
50 d	not applicable	not applicable	not applicable	not applicable
100 d	not applicable	not applicable	not applicable	not applicable
Plateau concentration	Not applicable			

Appendix 1 – list of endpoints

* Unlike conventional crop protection products, which must be applied over relatively large crop areas, aluminium phosphide products are predominantly applied to discrete sites in form of pellets for fumigation. Therefore a standard estimation of predicted environmental concentrations in soil (PEC_{soil}) as for conventional plant protection products can not be calculated

Based on estimations using an emission scenario document for biocides used as rodenticides⁹ the following PH_3 -concentrations can be estimated for applications of 5 pellets à 0.6 g = 3 g

Burrow length (application: 3 g product)	Amount of product per treated area (= 2000 m length of exposed hole)	PH_3 PEC_{soil} (mg/kg)
3 m	2000 g	3.379
5 m	1200 g	2.028
8 m	750 g	1.267
10 m	600 g	1.014

An additional field experiment showed that the horizontal spreading of PH_3 in soil was relatively fast whereas vertical spreading rate of PH_3 in soil was low. The highest concentration was found near the buried pellet. In a distance of 40 cm (60 cm depth) to the buried pellet (1 m depth) only 3 – 15 % of the values detected at 10 cm (90 cm depth) to the buried pellet were measured. After 24 hours phosphine has almost disappeared.

Though the results are plausible the study can only be taken as supplemental information as no guideline currently exists for this special type of application.

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	Active substance: Too rapid to estimate. Metabolite PH_3 (gas): 1 - 1 ½ d (23 – 39 h at pH 4,7 and 9 20°C)
Photolytic degradation of active substance and metabolites above 10 % ‡	Not relevant
Quantum yield of direct phototransformation in water at $\lambda > 290$ nm	Not relevant
Readily biodegradable ‡ (yes/no)	Not relevant

Degradation in water / sediment:

Mineralisation and non extractable residues	Not relevant
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⁹ Supplement to the methodology for risk assessment of biocides; Emission scenario document for biocides used as rodenticides; May 2003; Danish EPA; J. Larsen; CA-Jun03-Doc.8.2-PT14

Appendix 1 – list of endpoints

PEC surface water and PEC sediment (Annex IIIA, point 9.2.3)

Outdoor use

The calculation of predicted environmental concentrations in surface waters (PEC_{sw}) for aluminium phosphide following the GAP use of the product is not considered to be required, since the use of the plant protection product involves laying out of ready-to-use aluminium phosphide-containing product in underground burrows. Thus, any contamination of surface waters by events related in general to pesticides, such as over-spray, drift, run-off, atmospheric deposition etc. is not to be expected. Contamination of surface waters is excluded by the specific conditions of use. Therefore, an estimation of predicted environmental concentrations in surface waters and consequently in sediments for aluminium phosphide is not required. For PH₃ (gas) surface water exposure from movement in the gas phase where burrow entrances are adjacent to surface water cannot be completely excluded. A data gap was identified to address this.

Indoor use

Negligible both for aluminium phosphide and PH₃ (gas).

PEC ground water (Annex IIIA, point 9.2.1)

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter)

It is concluded that for the applied for intended uses there is no risk of contamination of ground water by aluminium phosphide or PH₃ and that aluminium salts and phosphate would not contaminate groundwater to any relevant degree (for phosphate exposure levels would be lower than from the use of phosphate as fertiliser and that for aluminium and its salts concentrations would be considerably lower than the indicator parametric level of 200µg/L for aluminium in the EU drinking water directive).

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air ‡

Not relevant for the parent and for PH₃

Quantum yield of direct phototransformation

Not relevant

Photochemical oxidative degradation in air ‡

Not relevant for the parent

Volatilisation ‡

Not relevant (vapour pressure << 10⁻⁷ hPa)

Appendix 1 – list of endpoints

Metabolites

PH₃ (gas, vapour pressure 3.44x10⁶ Pa, 20 °C):
DT₅₀ of approximately 24 hours
(reaction rate constant, determined experimentally
= 1.6 x 10⁻¹¹ cm³/mol·sec, assumed an average OH
radical concentration of 5.0 x 10⁵ OH/cm³ for a 24
h-day)

PEC_{air}

PEC_(a)

Maximum concentration

Due to the high vapour pressure of PH₃ discharge
into the air caused by aeration after application is
possible. However, PH₃ degrades rapidly in the
upper atmosphere (DT₅₀ air 24 h) and
contamination of the environment is expected to be
negligible.

Residues requiring further assessment

Environmental occurring metabolite requiring
further assessment by other disciplines
(toxicology and ecotoxicology) or for which a
groundwater exposure assessment is triggered.

Soil: PH₃
Surface Water: PH₃
Sediment: PH₃
Ground water: PH₃, aluminium salts (exposure
assessment only)
Air: PH₃

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)

Not available

Surface water (indicate location and type of
study)

Not available

Ground water (indicate location and type of
study)

Not available

Air (indicate location and type of study)

Not available

Points pertinent to the classification and proposed labelling with regard to fate and behaviour data

No labelling

Appendix 1 – list of endpoints

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	Endpoint (mg/kg bw/d)	Endpoint (mg/kg feed)
Birds ‡				
<i>Coturnix coturnix japonica</i> (Japanese quail)	Aluminium phosphide	Acute oral, 21-d	LD ₅₀ 49	
<i>Columba livia</i> (pigeon)	Aluminium phosphide	Acute oral, 21-d	LD ₅₀ 45 – 90	
Mammals ‡				
Rat	Aluminium phosphide	Acute oral	LD ₅₀ 8.7	Not relevant
Rat	Phosphine PH ₃	Acute inhalation, 1 h, female		179 ppm in air
Rat	Aluminium phosphide	Long-term, 2-generation reproduction study	No data submitted, justification accepted	
Rat	PH ₃	Long-term, 90-day inhalation	NOAEL 1.1 l	3 ppm in air = 0.0042 mg/L
Rat	PH ₃	Embryo toxicity and teratogenicity, inhalation, day 6 - 15 p.c.		NO(A)EL 5 ppm in air
Additional higher tier studies ‡				
Not required				

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Indoor: For storage protection aluminium phosphide is exclusively used in enclosed spaces

Outdoor: Aluminium phosphide containing tablets/pellets (Phostoxin and Gastoxin)

Indicator species/Category ²	Time scale	ETE	TER	Annex VI Trigger ³
Tier 1 (Birds)		not relevant, no exposure		
Higher tier refinement (Birds)		not relevant		
Tier 1 (Mammals)		not relevant, no exposure		
Higher tier refinement (Mammals)		not relevant		

Appendix 1 – list of endpoints

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	Endpoint	Toxicity1 (µg/L)
Laboratory tests ‡				
Fish				
<i>Oncorhynchus mykiss</i>	Aluminium phosphide (tested as PH ₃) PH ₃	96 hr acute (static)	Mortality, LC ₅₀	9.65 _{nom} 4.68 _{nom}
<i>Brachydanio rerio</i>	Aluminium phosphide	96 hr acute (semi-static)	Mortality, LC ₅₀	48 _{nom}
Fish	Aluminium phosphide	Chronic	No data submitted, justification accepted	
Aquatic invertebrate				
<i>Daphnia magna</i>	Aluminium phosphide	chronic	No data submitted, justification accepted	
Sediment dwelling organisms				
No data submitted – not relevant				
Algae				
Higher plant				
No data submitted - not relevant (no exposure expected)				
Microcosm or mesocosm tests				
Not performed, not relevant (no exposure expected)				

¹ Indicate whether based on nominal (_{nom} = analytically confirmed) or mean measured concentrations (mm). In the case of preparations indicate whether endpoints are presented as units of preparation or as. No indication means effects related to compound indicated in column "Test substance".

Appendix 1 – list of endpoints

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

FOCUS Step1

Indoor: For storage protection aluminium phosphide is exclusively used in enclosed spaces.

Outdoor: Aluminium phosphide containing tablets/pellets (Phostoxin and Gastoxin) are laid out in underground burrows.

Test substance	Organism	Toxicity endpoint (mg as/L)	Time scale	PEC _{swi} µg/L	PEC _{tw} a	TER	Annex VI Trigger ¹
	not relevant, no exposure						100

Bioconcentration			
	Active substance	Metabolite H ₃ P	Metabolite
logPow	Not applicable AIP decompose in water to H ₃ P + Al(OH) ₃	Not applicable, gas	
Bioconcentration factor (BCF) ¹ ‡	-		
Annex VI Trigger for the bioconcentration factor	100		
Clearance time (days) (CT ₅₀)	-		
(CT ₉₀)	-		
Level and nature of residues (%) in organisms after the 14 day depuration phase	-		

¹ only required if log Pow > 3.

* based on total [¹⁴C] or on specific compounds

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD ₅₀ µg/bee)	Acute contact toxicity (LD ₅₀ µg/bee)
as ‡	LD ₅₀ (48 h) 0.24 µg as/bee LD ₅₀ (96 h) 0.1 µg as/bee	-
Preparation ¹	-	-
Metabolite 1	-	-
Field or semi-field tests		
Not required		

¹ for preparations indicate whether end point is expressed in units of as or preparation

Appendix 1 – list of endpoints

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Crop and application rate

Test substance	Route	Hazard quotient	Annex VI Trigger
Aluminium phosphide	Contact	In a laboratory test aluminium phosphide was toxic to honey bees after oral exposure. However, bees will not be exposed when aluminium phosphide is used for indoor application and in tablets or pellets for outdoor control of rodent and non-rodent species in underground burrows.	50
Aluminium phosphide	oral		50
Preparation	Contact		50
Preparation	oral		50

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Laboratory tests with standard sensitive species

Species	Test Substance	Endpoint	Effect (LR ₅₀ g/ha ¹)
<i>Typhlodromus pyri</i> ‡	---	Mortality	No studies were performed: Outdoor application: fumigated area is very small compared to the whole field; diffusion rate into soil is small and half-life is very short. Indoor application: any effect on non-target terrestrial arthropods is precluded
<i>Aphidius rhopalosiphi</i> ‡	---	Mortality	

¹ for preparations indicate whether endpoint is expressed in units of as or preparation

Crop and application rate:

Indoor: For storage protection aluminium phosphide is exclusively used in enclosed spaces.

Outdoor: Aluminium phosphide containing tablets/pellets (Phostoxin and Gastoxin) are laid out in underground burrows.

Test substance	Species	Effect (LR ₅₀ g/ha)	HQ in-field	HQ off-field ¹	Trigger
-- see above		-- see above	Not relevant	Not relevant	2

¹ indicate distance assumed to calculate the drift rate

Appendix 1 – list of endpoints

Test substance	Species	Effect (LR ₅₀ g /ha)	TER off-field ¹	Trigger value
-- see above		-- see above	Not relevant	10

¹ TER approach used by the German Federal Environmental Agency (Schulte et al., 1999: UWSF 11(5) 261 - 266).

PEC off-crop = Single application rate × drift factor/VDF(5). Without VDF if product is sprayed on plants.

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha) ^{1,2}	Endpoint	% adverse effect ³	Trigger value
No laboratory studies were performed: Out-door application: fumigated area is very small compared to the whole field; diffusion rate into soil is small and half-life is very short. In-door application: any effect on non-target terrestrial arthropods is precluded.						50 %

¹ indicate whether initial or aged residues

² for preparations indicate whether dose is expressed in units of as or preparation

³ indicate when the effect is not adverse

Field or semi-field tests
No field or semi-field tests were performed: Outdoor application: Fumigated area is very small compared to the whole field; diffusion rate into soil is small and half-life is very short (PH ₃ : around 6 hours = DT ₅₀ for decomposition in soil). Indoor application: any effect on non-target terrestrial arthropods is precluded.

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA, points 8.4 and 8.5, Annex IIIA, points 10.6 and 10.7)

Test organism	Test substance	Time scale	Endpoint ¹
Earthworms			
<i>Eisenia foetida</i>	as ‡	Acute 14 days	LC ₅₀ = 663.5 mg as/kg d.w. soil
	as ‡	Chronic 8 weeks	Not required, no exposure
<i>Eisenia foetida</i>	Product "Quickphos" pellet	Acute 14 days	LC ₅₀ = 185.01 mg product/ kg d.w. soil (107.3 mg as/kg d.w. soil)
<i>Eisenia foetida</i>	Product "Quickphos" tablet	Acute 14 days	LC ₅₀ = 187.74 mg product/ kg d.w. soil (108.8 mg as/kg d.w. soil)

Appendix 1 – list of endpoints

Test organism	Test substance	Time scale	Endpoint ¹
Other soil macro-organisms			
	Not relevant		
Soil micro-organisms			
Nitrogen mineralisation	15.9 mg Phostoxin (56 % AIP) /kg soil) according to 3 g product per 8 m burrow length with 5 cm radial extension, (333 (= 220 mL) mg PH ₃ evolution per g pellet)	28 days	< 25 % deviation from control
Carbon mineralisation	15.9 mg Phostoxin (56 % AIP) /kg soil) according to 3 g product per 8 m burrow length with 5 cm radial extension, (333 (= 220 mL) mg PH ₃ evolution per g pellet)	28 days	< 25 % deviation from control
Field studies			
Not required			

¹ indicate where endpoint has been corrected due to log P_{o/w} > 2.0 (e.g. LC_{50corr})

² litter bag, field arthropod studies not included at 8.3.2/10.5 above and earthworm field studies

Toxicity/exposure ratios for soil organisms

Crop and application rate

Indoor: For storage protection aluminium phosphide is exclusively used in enclosed spaces.

Outdoor: Aluminium phosphide containing tablets/pellets (Phostoxin and Gastoxin) are laid out in underground burrows.

Test organism	Test substance	Time scale	Soil PEC ¹	TER	Trigger
Earthworms (acute, chronic) With respect to an acute toxicity of earthworms with a LD ₅₀ (24 d) of 107.3 mg as/kg soil (equivalent to 62.9 mg PH ₃ /kg soil) for <i>Eisenia foetida</i> and an estimated PEC _{soil} of 3.379 mg PH ₃ /kg in the burrows a corresponding TER value of 18.6 was estimated.					

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

No data submitted, justification accepted (no exposure expected)

Appendix 1 – list of endpoints

Laboratory dose response tests

Most sensitive species	Test substance	ER ₅₀ (g/ha) ² vegetative vigour	ER ₅₀ (g/ha) ² emergence	Exposure ¹ (g/ha) ²	TER	Trigger
	as ‡ and Preparation	Not relevant	Not relevant			

¹ Explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)

² For preparations indicate whether dose is expressed in units of as or preparation

Additional studies (e.g. semi-field or field studies)

Not relevant

Effects on biological methods for sewage treatment (Annex IIA, point 8.7)

Test type/organism	endpoint
No data submitted, justification accepted	(no exposure expected)

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	Phosphine PH ₃
water	Phosphine PH ₃
sediment	Phosphine PH ₃
air	Phosphine PH ₃
groundwater	Phosphine PH ₃

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

Active substance

N, R 50
Dangerous for the environment
Very toxic to aquatic organisms

Phosphine

N, R 50
Dangerous for the environment
Very toxic to aquatic organisms

Appendix 1 – list of endpoints

Preparation

RMS/peer review proposal
N, R 50 Dangerous for the environment Very toxic to aquatic organisms

Appendix 2 – abbreviations

APPENDIX 2 – ABBREVIATIONS

ADI	acceptable daily intake
AOEL	acceptable operator exposure level
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
BCF	bioconcentration factor
bp	boiling point
bw	body weight
c	centi- ($\times 10^{-2}$)
°C	degree Celsius (centigrade)
CA	Chemical Abstract
CAS	Chemical Abstract Service
CIPAC	Collaborative International Pesticide Analytical Council Limited
cm	centimetre
d	day
DAR	draft assessment report
DM	dry matter
DT ₅₀	period required for 50 percent dissipation (define method of estimation)
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
ε	decadic molar extinction coefficient
EC ₅₀	effective concentration
ECD	electron capture detector
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINKS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER50	emergence rate, median
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FIA	fluorescence immuno assay
FID	flame ionisation detector
FIR	food intake rate
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
fp	freezing point
FPD	flame photometric detector

Appendix 2 – abbreviations

f(twa)	time weighted average factor
g	gram
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GE	Gas generating product
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GS	growth stage
h	hour(s)
H	Henry's Law constant (calculated as a unitless value) (see also K)
ha	hectare
hL	hectolitre
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HQ	hazard quotient
ID	ionisation detector
IEDI	international estimated daily intake
ILV	inter laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
k	kilo
K	Kelvin or Henry's Law constant (in atmospheres per cubic meter per mole) (see also H) ¹³
K _{ads}	adsorption constant
K _{des}	apparent desorption coefficient
K _{oc}	organic carbon adsorption coefficient
K _{om}	organic matter adsorption coefficient
kg	kilogram
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry

Appendix 2 – abbreviations

LC-MS-MS	liquid chromatography with tandem mass spectrometry
LC ₅₀	lethal concentration, median
LD ₅₀	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
LOQ	limit of quantification (determination)
m	metre
M	molar
MAF	multiple application factor
µm	micrometer (micron)
MC	moisture content
µg	microgram
mg	milligram
MHC	moisture holding capacity
min	minute(s)
mL	millilitre
mm	millimetre
mN	milli-Newton
mo	month(s)
mol	Mol
MOS	margin of safety
mp	melting point
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
n	normal (defining isomeric configuration)
nd	not detected
NEDI	no effect daily intake (mg/kg body wt/day)
NESTI	national estimated short term intake
ng	nanogram
NIR	near-infrared-(spectroscopy)
nm	nanometer
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level

Appendix 2 – abbreviations

NPD	nitrogen-phosphorus detector or detection
OC	organic carbon content
OM	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration
PEC _A	predicted environmental concentration in air
PEC _S	predicted environmental concentration in soil
PEC _{SW}	predicted environmental concentration in surface water
PEC _{GW}	predicted environmental concentration in ground water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
pK _a	negative logarithm (to the base 10) of the dissociation constant
PNEC	predicted no effect concentration
P _{ow}	partition coefficient between n-octanol and water
ppb	parts per billion (10 ⁻⁹)
PPE	personal protective equipment
ppm	parts per million (10 ⁻⁶)
ppp	plant protection product
PT	proportion of diet obtained in the treated area
r ²	coefficient of determination
RfD	reference dose
RH	relative humidity
RPE	respiratory protective equipment
s	second
SF	safety factor
sp	species (only after a generic name)
STMR	supervised trials median residue
t	tonne (metric ton)
t _{1/2}	half-life (define method of estimation)
TC	technical material
TER	toxicity exposure ratio
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
UF	uncertainty factor (safety factor)
UV	ultraviolet

Appendix 2 – abbreviations

WHO	World Health Organisation
WG	water dispersible granule
wk	week
yr	year

Appendix 3 – used compound code(s)

APPENDIX 3 – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula
Phosphine	Phosphane	$\begin{array}{c} \text{H} & & \text{H} \\ & \diagdown & / \\ & \text{P} \\ & / \\ \text{H} \end{array}$
-	Aluminium hydroxide	$\text{Al}^{3+} \text{HO}^- \text{HO}^- \text{HO}^-$
-	Phosphoric acid	$\begin{array}{c} \text{OH} \\ \\ \text{O}=\text{P}-\text{OH} \\ \\ \text{OH} \end{array}$
-	Phosphonic acid	$\begin{array}{c} \text{OH} \\ \\ \text{HP}=\text{O} \\ \\ \text{OH} \end{array}$
-	Hypophosphite	$\begin{array}{c} \text{O}^- \\ \\ \text{H}_2\text{P}=\text{O} \end{array}$
-	Phosphite	$\begin{array}{c} \text{O}^- \\ \\ \text{O}^--\text{P} \\ \\ \text{O}^- \end{array}$