CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment of the active substance zinc phosphide[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Zinc phosphide is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004[3], as amended by Commission Regulation (EC) No 1095/2007[4]. In accordance with the Regulation, Germany, being the designated rapporteur Member State (RMS) submitted an initial evaluation, i.e. the Draft Assessment Report (DAR) on zinc phosphide. The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 24e, to withdraw support for the inclusion of zinc phosphide in Annex I to Council Directive 91/414/EEC.

Following the Commission Decision of 8 December 2008 (2008/941/EC)[5] concerning the non-inclusion of zinc phosphide in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant, the Zinc Phosphide Pool made a resubmission application for the inclusion of zinc phosphide in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008[6]. The resubmission dossier included further data in response to the issues identified in the DAR.

In accordance with Article 18 of Commission Regulation (EC) No. 33/2008, Germany, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report. The Additional Report was received by the EFSA on 22 October 2009.

In accordance with Article 19 of Commission Regulation (EC) No. 33/2008, the EFSA distributed the Additional Report to Member States and the applicant for comments on 9 November 2009. The DAR was also distributed for comments. The EFSA collated and forwarded all comments received to the Commission on 4 January 2010.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission requested the EFSA to conduct a focused peer review in the area of mammalian toxicology and deliver its conclusions on zinc phosphide.

1 On request from the European Commission, Question No EFSA-Q-2010-00162, issued on 2 July 2010.
2 Correspondence: praper@efsa.europa.eu
3 OJ L 379, 24.12.2004, p.13
4 OJ L 246, 21.9.2007, p. 19
5 OJ L 335, 13.12.2008, p.91
6 OJ L 15, 18.01.2008, p.5

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The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of zinc phosphide as a rodenticide in forestry, as proposed by the applicant. Full details of the representative uses can be found in Appendix A to this report.

The representative formulated product for the evaluation was 'ARREX E Köder', a ready-for-use bait (RB) formulation.

Sufficient analytical methods and data relating to physical, chemical and technical properties are available to ensure that quality control measurements of the plant protection product are possible. Adequate methods are available to monitor zinc phosphide residues as phosphine in plant commodities with high water content, in animal products, in soil, and in surface and ground water.

The data available on mammalian toxicology are sufficient to carry out the human health assessments at EU level for the representative use.

No significant residues in plant or animal matrices are expected based on the product being applied in a targeted manner. Therefore consumer risk assessments are not required.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative use.

Based on the insignificant exposure expected from the intended mode of application, the risk to birds and non-target mammals was assessed as low. Based on the negligible exposure expected from the representative use of zinc phosphide, the risk to aquatic organisms, bees, non-target arthropods, earthworms, non-target soil macro- and micro-organisms, non-target plants, and the function of waste water treatment plants was assessed as low.

KEY WORDS

Zinc phosphide, peer review, risk assessment, pesticide, rodenticide

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BACKGROUND

Legislative framework

Commission Regulation (EC) No 2229/2004[7], as amended by Commission Regulation (EC) No 1095/2007[8], lays down the detailed rules for the implementation of the fourth stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC. This regulates for the European Food Safety Authority (EFSA) the procedure for organising, upon request of the Commission of the European Communities (hereafter referred to as 'the Commission'), a peer review of the initial evaluation, i.e. the Draft Assessment Report (DAR), provided by the designated rapporteur Member State.

Commission Regulation (EC) No 33/2008[9] lays down the detailed rules for the application of Council Directive 91/414/EEC for a regular and accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC but which were not included in Annex I. This regulates for the EFSA the procedure for organising the consultation of Member States and the applicant(s) for comments on the Additional Report provided by the designated RMS, and upon request of the Commission the organisation of a peer review and/or delivery of its conclusions on the active substance.

Peer review conducted in accordance with Commission Regulation (EC) No 2229/2004

Zinc phosphide is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004, as amended by Commission Regulation (EC) No 1095/2007. In accordance with the Regulation, the designated rapporteur Member State, Germany submitted an initial evaluation, i.e. the DAR on zinc phosphide, which was received by the EFSA on 3 December 2007 (Germany, 2007).

The peer review process was subsequently terminated following the applicant's decision, in accordance with Article 24e, to withdraw support for the inclusion of zinc phosphide in Annex I to Council Directive 91/414/EEC.

Peer review conducted in accordance with Commission Regulation (EC) No 33/2008

Following the Commission Decision of 8 December 2008 (2008/941/EC)[10] concerning the non-inclusion of zinc phosphide in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance, the applicant, the Zinc Phosphide Pool made a resubmission application for the inclusion of zinc phosphide in Annex I in accordance with the provisions laid down in Chapter III of Commission Regulation (EC) No. 33/2008. The resubmission dossier included further data in response to the issues identified in the DAR, as follows: further data on analytical methods for residue analysis, as well as updated classification for toxicological hazards according to GHS.

In accordance with Article 18, Germany, being the designated RMS, submitted an evaluation of the additional data in the format of an Additional Report (Germany, 2009b). The Additional Report was received by the EFSA on 22 October 2009.

In accordance with Article 19, the EFSA distributed the Additional Report to Member States and the applicant for comments on 9 November 2009. The DAR (Germany, 2009a) was also distributed to Member States and the applicant for comments in view of the fact that the original peer review had been terminated following the applicant's notification of withdrawal of support. In addition, the EFSA conducted a public consultation on the Additional Report and the DAR. The EFSA collated and

[7] OJ L 379, 24.12.2004, p.13
[8] OJ L 246, 21.9.2007, p.19
[9] OJ L 15, 18.01.2008, p.5
[10] OJ L 335, 13.12.2008, p.91

forwarded all comments received to the Commission on 4 January 2010. At the same time, the collated comments were forwarded to the RMS for compilation in the format of a Reporting Table. The applicant was invited to respond to the comments in column 3 of the Reporting Table. The comments and the applicant's response were evaluated by the RMS in column 3.

In accordance with Article 20, following consideration of the Additional Report, the comments received, and where necessary the DAR, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 3 March 2010, the Commission requested the EFSA to arrange a consultation with Member State experts as appropriate and deliver its conclusions on zinc phosphide within 6 months of the date of receipt of the request, subject to an extension of a maximum of 90 days where further information were required to be submitted by the applicant in accordance with Article 20(2).

The scope of the peer review and the necessity for additional information, not concerning new studies, to be submitted by the applicant in accordance with Article 20(2), was considered in a telephone conference between the EFSA, the RMS, and the Commission on 1 February 2010; the applicant was also invited to give its view on the need for additional information. On the basis of the comments received, the applicant's response to the comments, and the RMS' subsequent evaluation thereof, it was concluded that the EFSA should organise a consultation with Member State experts in the area of mammalian toxicology, and that no further information should be requested from the applicant.

The outcome of the telephone conference, together with EFSA's further consideration of the comments is reflected in the conclusions set out in column 4 of the Reporting Table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in consultation with Member State experts, were compiled by the EFSA in the format of an Evaluation Table.

The conclusions arising from the consideration by the EFSA, and as appropriate by the RMS, of the points identified in the Evaluation Table, together with the outcome of the expert discussions where these took place, were reported in the final column of the Evaluation Table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in April-May 2010.

This conclusion report summarises the outcome of the peer review of the risk assessment on the active substance and the representative formulation evaluated on the basis of the representative uses as a rodenticide in forestry, as proposed by the applicant. A list of the relevant end points for the active substance as well as the formulation is provided in Appendix A. In addition, a key supporting document to this conclusion is the Peer Review Report (EFSA, 2010), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The Peer Review Report comprises the following documents:

- the comments received,
- the Reporting Table (revision 1-1; 1 February 2010),
- the Evaluation Table (21 June 2010),
- the report(s) of the scientific consultation with Member State experts (where relevant).

Given the importance of the DAR and the Additional Report including its addendum (compiled version of April 2010 containing all individually submitted addenda) (Germany, 2010) and the Peer Review Report, both documents are considered respectively as background documents A and B to this conclusion.

THE ACTIVE SUBSTANCE AND THE FORMULATED PRODUCT

There is no ISO common name for trizinc diphosphide (IUPAC). Zinc phosphide is the common name for this compound.

The representative formulated product for the evaluation was 'ARREX E Köder', a ready-for-use bait (RB) formulation, containing 30 g/kg zinc phosphide.

The evaluated representative use is as a rodenticide in forestry. Full details of the representative use can be found in Appendix A to this report.

CONCLUSIONS OF THE EVALUATION

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

The minimum purity of zinc phosphide as manufactured should not be less than 800 g/kg. There are no relevant impurities. No FAO specification exists.

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 zinc phosphide or the respective formulation. The main data regarding the identity of zinc phosphide and its physical and chemical properties are given in Appendix A.

Adequate analytical methods are available for the determination of zinc phosphide in the technical material and in the representative formulation, as well as for the determination of the respective impurities in the technical material.

The residue definition for zinc phosphide in soil and ground water is zinc phosphide and phosphine, the analytical method used determines this residue as phosphine. Adequate analytical methods are available to monitor zinc phosphide residues as phosphine in the environmental matrices (GC-NPD, GC-FPD). An analytical method for air is not required as there is no exposure scenario. GC-NPD methods are also available for products of plant and animal origin, but they are not required as there is no residue definition proposed. An analytical method for body fluids and tissues is not required, since phosphine, the toxicologically active compound, will be quickly exhaled or metabolised to phosphates, which would not be found in analysis.

2. Mammalian toxicity

When coming into contact with the acidic environment of the stomach, zinc phosphide decomposes to zinc hydroxide and phosphine, with phosphine being the toxicologically active compound and the relevant component for the assessment of the mammalian toxicology of zinc phosphide. A classification as R32 "Contact with acids liberates very toxic gas" is proposed.

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. Zinc phosphide is very toxic by the oral 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 (zinc phosphide), a classification as T+; R28 "Very toxic if swallowed" and Xn; R21 "Harmful in contact with skin" is proposed. A short-term NOAEL of 1.1 mg/kg bw/day (the highest dose tested) was derived for phosphine from a 90-day rat inhalation study. There is no evidence of a genotoxic potential at realistic exposure levels. In a 2-year inhalation study with rats a NOAEL of 1.1 mg/kg bw/day 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 was not considered necessary based on the toxicity profile of the substance (mortality 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/day was set based on mortality occurring in dams. The effects on reproduction have not

been assessed, however, based on the toxicity profile of the substance, such effects are not anticipated. For zinc phosphide, the acceptable daily intake (ADI) and the acceptable operator exposure level (AOEL) have been set at 0.042 mg/kg bw/day. The acute reference dose (ARfD) was established at 0.073 mg/kg bw. The corresponding values for phosphine are 0.011 mg/kg bw/day (ADI and AOEL), and 0.019 mg/kg bw (ARfD). When applying 'ARREX E Köder' in bait stations, considering bait material enclosed in foil bags, the maximum exposure levels were below the AOEL for operators without the use of personal protective equipment. The worker and bystander exposure estimates were considered to be negligible.

3. Residues

The submission of metabolism and residues data to support the representative use of zinc phosphide was not considered necessary. The product is applied in a targeted manner, exclusively as a bait against rodents, and therefore no significant residues in plant or animal matrices are expected. No residue definitions have therefore been set for plant or animal products, and no consumer risk assessments are required.

4. Environmental fate and behaviour

When placed in animal burrows (i.e. the soil environment) as a formulated bait, zinc phosphide will remain stable. After being ingested by target vertebrates, the acid conditions in their stomachs will produce phosphine gas and zinc salts within the animal. The potential for the production of phosphine and zinc salts in the soil (in the absence of ingestion and exposure to stomach acid) will be limited, and any limited amount of phosphine gas that would be produced has been shown to exhibit very low to moderate persistence, and will volatilise to the atmosphere or adsorb to soil, and be converted to phosphate anions. Any limited amount of phosphine gas that reaches the upper atmosphere will be subject to indirect photo-oxidation to phosphonic acid and phosphoric acid that would be removed from the atmosphere by wet deposition. The rate of indirect photo-oxidation 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 zinc phosphide from the representative use is considered negligible (due to its formulation as a bait), and its transformation products do not have parametric drinking water limits set in the relevant EU legislation[11]. It was concluded that there is negligible potential for surface water exposure by zinc phosphide or any of its potential breakdown products from the representative use, and that any exposure would not significantly add to that which can occur from crop fertiliser applications of phosphate and zinc.

5. Ecotoxicology

Zinc phosphide is highly toxic to vertebrates, and even the consumption of one sunflower kernel results in a TER of 0.1 for birds. The representative use of zinc phosphide intends to eliminate the exposure to birds and non-target mammals by application as a ready-for-use bait formulation in foil bags in bait stations or in animal burrows. However, in addition, appropriate mitigation measures should be considered to avoid the spread of sunflower kernels from the foil bags where only part of the content has been consumed. Secondary poisoning of birds and non-target mammals was considered unlikely due to: 1) the rapid dissipation of phosphine in carcasses of zinc phosphide poisoned target rodents; 2) predators tend not to take up the gastro-intestinal tract of pray, which contains the highest amount of residues; and 3) poisoned target organisms usually die in their holes. Based on the insignificant exposure expected from the representative use, the risk to birds and non-target mammals was assessed as low. In case other modes of application of zinc phosphide are considered, appropriate risk mitigation measures should be considered at Member State level for the protection of birds and non-target mammals.

[11] Council Directive 98/83/EC on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p. 32–54). Note: parametric values are not specified in this legislation for inorganic pesticides, phosphate, zinc or its salts.

Zinc phosphide is very toxic to aquatic organisms. However, given that there is only negligible potential for exposure of surface waters with zinc phosphide, the existing information on toxicity to aquatic organisms was considered sufficient. The risk to aquatic organisms from the representative use of zinc phosphide was assessed as low.

Based on the negligible exposure expected from the representative use of zinc phosphide, the risk to bees, non-target arthropods, earthworms, non-target soil macro- and micro-organisms, non-target plants, and the function of waste water treatment plants was assessed as low. Effects data were provided for earthworms, non-target micro-organisms, and activated sludge, however these do not change the outcome of the assessment.

6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments

6.1. Soil

Compound (name and/or code)	Persistence	Ecotoxicology
zinc phosphide	Stable (in the bait product as formulated)	Risk to soil-dwelling organisms was assessed as low for the representative use, based on negligible exposure and lack of effects in the studies available.
phosphine	Very low to moderate persistence, DT_{50} 3 hours to 14 days at 20ºC (in investigations where phosphine was generated from calcium phosphide).	Risk not assessed, based on the negligible exposure expected from the representative use.

6.2. Ground water

Compound (name and/or code)	Mobility in soil	>0.1 µg/L 1m depth for the representative uses (at least one FOCUS scenario or relevant lysimeter)	Pesticidal activity	Toxicological relevance	Ecotoxicological activity
zinc phosphide	-	Formulation as a ready-to-use bait and the method of application will preclude groundwater exposure for the representative use assessed.	No	Yes	Yes
phosphine		No	Yes	Yes	Yes

6.3. Surface water and sediment

Compound (name and/or code)	Ecotoxicology
None, exposure of zinc phosphide and its degradation products expected to be negligible.	Very toxic to aquatic organisms. Risk assessed as low, based on expected negligible exposure.

6.4. Air

Compound (name and/or code)	Toxicology
phosphine	Very high inhalation toxicity (LC_{50}>0.016 mg phosphine/L air). The representative use of zinc phosphide does not entail occupational exposure to phosphine.

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

None.

PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- The representative use for zinc phosphide intends to eliminate the exposure to birds and non-target mammals by application as a ready-for-use bait formulation in foil bags in bait stations or in animal burrows. However, in addition, appropriate mitigation measures should be considered to avoid the spread of sunflower kernels from the foil bags where only part of the content has been consumed.
  In case other modes of application of zinc phosphide are considered, appropriate risk mitigation measures should be considered at Member State level for the protection of birds and non-target mammals (see section 5).

ISSUES THAT COULD NOT BE FINALISED

None.

CRITICAL AREAS OF CONCERN

None.

REFERENCES

ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

Germany, 2007. Draft Assessment Report (DAR) on the active substance zinc phosphide prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, November 2007.

Germany, 2009a. Revised Draft Assessment Report (DAR) on the active substance zinc phosphide prepared by the rapporteur Member State Germany in the framework of Directive 91/414/EEC, October 2009.

Germany, 2009b. Additional Report to the Draft Assessment Report on the active substance zinc phosphide prepared by the rapporteur Member State Germany in the framework of Commission Regulation (EC) No 33/2008, October 2009.

Germany, 2010. Final Addendum to Draft Assessment Report and Additional Report on zinc phosphide, compiled by EFSA, April 2010.

EFSA (European Food Safety Authority), 2010. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance zinc phosphide.

APPENDICES

APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

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

Active substance (ISO Common Name) ‡	zinc phosphide (there is no ISO common name for this compound)
Function (*e.g.* fungicide)	rodenticide
Rapporteur Member State	Federal Republic of Germany
Co-rapporteur Member State	none

Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡	trizinc diphosphide
Chemical name (CA) ‡	zinc phosphide
CIPAC No ‡	69
CAS No ‡	1314-84-7
EC No (EINECS or ELINCS) ‡	215-244-5
FAO Specification (including year of publication) ‡	none
Minimum purity of the active substance as manufactured ‡	800 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	none
Molecular formula ‡	Zn_3P_2
Molecular mass ‡	258.1 u
Structural formula ‡	Zn_3P_2

Physical and chemical properties (Annex IIA, point 2)

Melting point (state purity) ‡	> 500 °C (purity: 82 %)
Boiling point (state purity) ‡	> 500 °C (purity: 82 %)
Temperature of decomposition (state purity)	No decomposition until 500 °C
Appearance (state purity) ‡	grey-black solid powder, garlic-like odour (purity: 82 %)
Vapour pressure (state temperature, state purity) ‡	6.5×10^{-9} Pa at 20 °C (purity: 82%)
Henry's law constant ‡	Not applicable
Solubility in water (state temperature, state purity and pH) ‡	< 1.4 µg/L (20 °C) (purity: 82%)
Solubility in organic solvents ‡ (state temperature, state purity)	Solubility at 20 °C: (purity: 82%) *n*-heptane: < 0.5 g/L *p*-xylene: < 0.5 g/L 1,2-dichloroethane: < 0.5 g/L methanol: < 0.5 g/L acetone: < 0.5 g/L ethyl acetate: < 0.5 g/L
Surface tension ‡ (state concentration and temperature, state purity)	72.8 mN/m at 20.1 °C
Partition co-efficient ‡ (state temperature, pH and purity)	Not applicable
Dissociation constant (state purity) ‡	Not applicable
UV/VIS absorption (max.) incl. ε ‡ (state purity, pH)	Not applicable
Flammability ‡ (state purity)	The submitted test shows that zinc phosphide is not highly flammable under the test conditions (EEC A12). However, the ECB has classified zinc phosphide as F (highly flammable).
Explosive properties ‡ (state purity)	no explosive properties (purity: 82%)
Oxidising properties ‡ (state purity)	no oxidising properties (statement)

Summary of representative uses evaluated (*zinc phosphide*)*

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days)	Remarks
					Type (d-f)	Conc. of as (i)	Method kind (f-h)	Growth stage & season (j)	Number min/max	Interval between applications (min)	Kg as/HL min & max (i)	Water L/ha min - max	Kg as/ha min & max (l)	(m)	
Forestry (deciduous and coniferous trees)	Germany (Northern Europe)	ARREX E Köder *	F	*Microtus agrestis* *Clethrionomys glareolus*)	RB	30 g/kg zinc phosphide	placing in bait stations or at locations attractive for target voles	all stages autumn/ winter	1	in case of repetition after 3 - 4 weeks	not applicable	not applicable	3.2 - 10.5 g as/ha	not required	seeds of sunflower laid out in foil bags

a. for crops, the EU and Codex Classifications (both) should be used; where relevant, the use situation should be described

b. outdoor or field use (F), glasshouse application (G) or indoor application (I)
c. e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
d. e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (G)
e. GIFAP codes – GIFAP technical monograph no. 2, 1989
f. all abbreviations used 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 plants, 1997, Blackwell, ISBN 3-8263-3152-4, including relevant, information on season at time of application
k. the minimum and maximum number of application possible under practical conditions of used must be provided
l. PHI – minimum pre-harvest interval
m. remarks may include: extend of use/economic importance/restrictions

Note: The entries marked in grey in the previous version of this table (referring to Köder 1 – 4) have been removed by EFSA together with the addendum to the summary of representatives uses evaluated, as **Arrex E Köder** was chosen as representative formulation to support the inclusion of zinc phosphide in Annex I of Council Directive 91/414/EEC. (Köder 1 – 4 are intended uses of zinc phosphide containing rodenticide products currently registered in Germany (and were marked in grey due to non-submission of supporting studies)).

Methods of Analysis

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

Technical as (analytical technique)	titration
Impurities in technical as (analytical technique)	ICP-AAS, photometric
Plant protection product (analytical technique)	GC-NPD and titration (both fully validated)

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin		Not relevant
Food of animal origin		Not relevant
Soil		Zinc phosphide and phosphine which are determined as phosphine
Water	surface	Not relevant
	drinking/ground	Zinc phosphide and phosphine which are determined as phosphine
Air		Not relevant

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Zinc phoshide, determined as phosphine GC-NPD 0.05 mg/kg (commodities with high water content e.g. cantaloupe, grass, potato, raspberry, spinach, squash)
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Zinc phosphide, determined as phosphine GC-NPD 0.0025 mg/kg (milk, muscle, liver)
Soil (analytical technique and LOQ)	Zinc phosphide, determined as phosphine GC-NPD 0.0025 mg/kg (soil: 66.1% sand, 23.5% silt, 5.2% clay) GC-NPD (using two columns of different polarity) 0.0025 mg/kg (soil: 57.4 % sand, 29.8 % silt, 12.9 % clay
Water (analytical technique and LOQ)	GC-NPD 0.1 µg/L (surface water, also acceptable for drinking water) GC-FPD 0.1 µg/L (drinking and surface water; UPL)
Air (analytical technique and LOQ)	No method required, since any exposure of operators, workers and bystanders can be excluded.
Body fluids and tissues (analytical technique and LOQ)	Not relevant

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

	RMS/peer review proposal
Active substance	F (Annex I of Directive 67/548/EEC)

Impact on human and animal health

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

Rate and extent of oral absorption ‡	Following oral administration, rapid absorption of the evolving phosphine
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)	Zinc phosphide and phosphine

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral ‡	12 mg/kg bw (Zinc phosphide)	R28
Rat LD_{50} dermal ‡	approx. 1000 mg/kg bw (Zinc phosphide)	R21
Rat LC_{50} inhalation ‡	>11 ppm (>0.016 mg PH_3/L air or >2.8 mg/kg bw) (4 h exposure, whole body) (Phosphine)	
Skin irritation ‡	Not irritant (Zinc phosphide)	
Eye irritation ‡	Not irritant (Zinc phosphide)	
Skin sensitisation ‡	No indication of skin sensitisation, 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	
Relevant inhalation NOAEL ‡	NOAEL 3 ppm phosphine (equivalent to 1.1 mg/kg bw/d), rat 90-d, the highest dose tested	

Genotoxicity ‡ (Annex IIA, point 5.4)

No evidence of a genotoxic potential at realistic exposure levels	

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 rats. 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 phosphine (equivalent to 1.9 mg/kg bw/d) No data on rabbits, justification given Data on rabbits not required, not necessary	

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); < 20 ppm (analytical conc. < 21 ppm) (with regard to changes in motor activity)	
Repeated neurotoxicity ‡	NOAEL (rat. 90-d): 3 ppm phosphine equivalent to 1.1 mg/kg bw/d	
Delayed neurotoxicity ‡	No study required.	

Other toxicological studies (Annex IIA, point 5.8)

Study on Heinz body formation	Phosphine induced Heinz bodies in human erythrocytes.
Influence on respiration and oxidative phosphorylation	The respiration of liver mitochondria is diminished by phosphine. The oxidative phosphorylation remains at normal level.

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)

Zinc phosphide	Value	Study	Safety factor
ADI ‡	0.042 mg/kg bw*	2-yr inhalation, rat	100
AOEL ‡	0.042mg/kg bw/d*	90-d inhalation, rat	100
ARfD ‡	0.073 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 ‡	0.03 ppm or 0.042 µg/L air or 0.011 mg/kg bw/d	90-d inhalation, rat	100
ARfD	0.049 ppm or 0.069 µg/L air or 0.019 mg/kg bw	Developmental study (inhalation), rat	100

* Based on a maximum liberation of gas of 0.26 g PH_3/g zinc phosphide in acidic medium.

Dermal absorption ‡ (Annex IIIA, point 7.3)

Default value 10 % for zinc phosphide and PH_3 (based on expert judgement)

Exposure scenarios (Annex IIIA, point 7.2)

Operator	Exposure assessments considering bait material enclosed in foil bags: EASE model (TGD): Below the AOEL (without PPE).
Workers	Considered to be negligible.
Bystanders	Considered to be negligible (accidental exposure has to be prevented e.g. by appropriate recommendations for use)

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

According to the criteria in Dir. 67/548/EEC	**Zinc phosphide** T+ - Very toxic R 28 - Very toxic if swallowed R 32 - Contact with acids liberates very toxic gas Xn - Harmful R 21 - Harmful in contact with skin **Phosphine** T+ - Very toxic R26 - Very toxic by inhalation R34 - Causes burns
According to the criteria in Reg. 1272/2008	**Zinc phosphide** Acute Tox., cat. 2 – H300 - Fatal if swallowed EUH032 - Contact with acids liberates very toxic gas Acute Tox., cat. 3 H311 - Toxic in contact with skin **Phosphine** Acute Tox., cat. 2 Skin Corr., 1B H330 - Fatal if inhaled H314 - Causes severe skin burns

Residues

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

Plant groups covered	not required
Rotational crops	not required
Metabolism in rotational crops similar to metabolism in primary crops?	not required
Processed commodities	not required
Residue pattern in processed commodities similar to residue pattern in raw commodities?	not required
Plant residue definition for monitoring	not required
Plant residue definition for risk assessment	not required
Conversion factor (monitoring to risk assessment)	not required

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

Animals covered	not required
Time needed to reach a plateau concentration in milk and eggs	not required
Animal residue definition for monitoring	not required
Animal residue definition for risk assessment	not required
Conversion factor (monitoring to risk assessment)	not required
Metabolism in rat and ruminant similar (yes/no)	not required
Fat soluble residue: (yes/no)	not required

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

not required

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

not required

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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
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

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
	Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) - not required Residue levels in matrices : Mean (max) mg/kg		
Muscle	no	no	no
Liver	no	no	no
Kidney	no	no	no
Fat	no	no	no
Milk	no		
Eggs		no	

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 (a)	Recommendation/comments	MRL estimated from trials according to the representative use	HR (c)	STMR (b)
not required						

(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

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

ADI	0.011 mg phosphine/kg bw/day
TMDI (% ADI) according to WHO European diet	not required
TMDI (% ADI) according to national (to be specified) diets	not required
IEDI (WHO European Diet) (% ADI)	not required
NEDI (specify diet) (% ADI)	not required
Factors included in IEDI and NEDI	not required
ARfD	0.019 mg phosphine/kg bw
IESTI (% ARfD)	not required
NESTI (% ARfD) according to national (to be specified) large portion consumption data	not required
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				

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

Proposed MRLs	not required

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

Environmental fate and behaviour

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

Mineralisation after 100 days ‡.	CO_2 not relevant* zinc cations, phosphate anions (83 - 110 % in 25 - 100 % saturated soils)
Non-extractable residues after 100 days ‡	Not relevant
Metabolites requiring further consideration ‡ - name and/or code, % of applied (range and maximum)	Phosphine

* Recent, ”state-of-the-art” investigations according to current guidelines for the elucidation of the degradation pathway of zinc phosphide in soil do not exist. Zinc phosphide is an inorganic molecule, and therefore evolution of carbon dioxide is not possible, but ultimate transformation to inorganic salts occurs. Hydrolysis leading to the evolution of phosphine and residual salts will prevail when soil matrix is present to mediate the reaction. The former 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 ‡

Mineralisation after 100 days	Not required, since products containing zinc phosphide are applied for rodent control on rodent pathways, holes etc., and in this open field environment are not expected to be subject to anaerobic conditions
Non-extractable residues after 100 days	---
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not required, since products containing zinc phosphide are applied for rodent control on rodent pathways, holes etc., and in this open field environment are not expected to be subject to anaerobic conditions

Soil photolysis ‡

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	Not required, since for the active substance zinc phosphide any quantitatively relevant absorption of light in this range of wavelengths is ruled out

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

Laboratory studies ‡

Parent	Aerobic conditions: In a study with soil of 100 % saturated soil DT_{50} for zinc phosphide was observed from 7.8 to 14.1 days.*

* DT_{50} values for zinc phosphide were calculated from 100 % saturated soils. The decomposition of zinc phosphide at normal conditions may take more time, because 100 percent saturated soil is not expected to occur frequently and the rate of zinc phosphide decomposition decreases with decreasing moisture.

Laboratory studies ‡

Phosphine (PH_3)	Aerobic conditions Zinc phosphide is degraded in soil to yield phosphine gas as an intermediate, and zinc 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. According to laboratory studies performed in 3 soils the DT_{50} of PH_3 in the gas phase was found to be 6.7 – 13.6 days in soils with low organic matter content, but more rapidly in soils with high organic matter (DT_{50} = 3 – 11 hours). Note: In these experiments PH_3 was generated in situ from calcium phosphide.
Phosphine (PH_3)	Anaerobic conditions According to laboratory studies performed in 2 soils the maximum DT_{50} of PH_3 in the gas phase was found to be 14.8 d.

Field studies ‡

Parent and Metabolite	Not required since maximum DT_{50} values for Zn_3P_2 and PH_3 were significantly below 60 days

pH dependence ‡ (yes / no) (if yes type of dependence)	not relevant
Soil accumulation and plateau concentration ‡	not relevant

Soil adsorption/desorption (Annex IIA, point 7.1.2)

The performance of ”state-of-the-art” adsorption/desorption experiments with zinc phosphide is not considered to be required for the following reasons: 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.
Aged residues leaching ‡	-
Lysimeter/ field leaching studies ‡	No lysimeter studies performed

PEC (soil) (Annex IIIA, point 9.1.3)

Parent Method of calculation	DT_{50} (d): 14.1 days (worst case, n = 3) Kinetics: SFO Lab: representative worst case from laboratory studies.
Application data	Crop: no crop, GAP use baits in vole passages Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 0 Number of applications: 1 Interval (d): not relevant Application rate: 60 g as/ha

PEC(s) (µg/kg) Parent	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	80.00		n.a.	
Short term 24 h	76.16	78.07	n.a.	n.a.
2 d	72.51	76.19	n.a.	n.a.
4 d	65.72	72.63	n.a.	n.a.
Long term 7 d	56.71	67.69	n.a.	n.a.
21 d	28.49	49.89	n.a.	n.a.
28 d	20.20	43.45	n.a.	n.a.
50 d	6.85	29.76	n.a.	n.a.
100 d	0.59	16.15	n.a.	n.a.
Plateau concentration		not necessary		

n.a.: not applicable

Parent Method of calculation	DT_{50} (d): 14.1 days (worst case, n = 3) Kinetics: SFO Lab: representative worst case from laboratory studies.
Application data	Crop: no crop, GAP use in foil bags Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 0 Number of applications: 1 Application rate: 10.5 g as/ha

PEC(s) (µg/kg) Parent	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	14.00		n.a.	
Short term 24 h	13.33	13.66	n.a.	n.a.
2 d	12.69	13.33	n.a.	n.a.
4 d	11.50	12.71	n.a.	n.a.
Long term 7 d	9.92	11.85	n.a.	n.a.
21 d	4.99	8.73	n.a.	n.a.
28 d	3.53	7.60	n.a.	n.a.
50 d	1.20	5.21	n.a.	n.a.
100 d	0.10	2.83	n.a.	n.a.
Plateau concentration		not necessary		

n.a.: not applicable

Metabolite PH_3 Method of calculation	DT_{50} (d): 13.6 days (worst case, n = 3) Kinetics: SFO Lab: representative worst-case from laboratory studies.
Application data	Crop: no crop, GAP use baits in vole passages Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 0 Number of applications: 1 Application rate: 2.5 g /ha (32 % formation assumed) (Application rate (metabolite) = application rate (parent) * F_{met} * MW_{met}/MW_{par}[g/ha]; with F_{met} = fraction of the parent)

PEC(s) (µg/kg) PH_3	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	3.37		n.a.	
Short term 24 h	3.20	3.29	n.a.	n.a.
2 d	3.05	3.21	n.a.	n.a.
4 d	2.75	3.05	n.a.	n.a.
Long term 7 d	2.36	2.84	n.a.	n.a.
21 d	1.16	2.07	n.a.	n.a.
28 d	0.81	1.80	n.a.	n.a.
50 d	0.26	1.22	n.a.	n.a.
100 d	0.02	0.66	n.a.	n.a.
Plateau concentration		not necessary		

n.a.: not applicable

Metabolite PH_3 Method of calculation	DT_{50} (d): 13.6 days (worst case, n = 3) Kinetics: SFO Lab: representative worst-case from laboratory studies.
Application data	Crop: no crop, GAP use in foil bags Depth of soil layer: 5 cm Soil bulk density: 1.5 g/cm^3 % plant interception: 0 Number of applications: 1 Application rate: 0.44 g/ha (32 % formation assumed) (Application rate (metabolite) = application rate (parent) * F_{met} * MW_{met}/MW_{par}[g/ha]; with F_{met} = fraction of the parent)

PEC(s) (µg/kg) PH_3	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial	0.59		n.a.	
Short term 24 h	0.56	0.58	n.a.	n.a.
2 d	0.53	0.56	n.a.	n.a.
4 d	0.48	0.53	n.a.	n.a.
Long term 7 d	0.41	0.50	n.a.	n.a.
21 d	0.20	0.36	n.a.	n.a.
28 d	0.14	0.31	n.a.	n.a.
50 d	0.05	0.21	n.a.	n.a.
100 d	0.00	0.12	n.a.	n.a.
Plateau concentration		not necessary		

n.a.: not applicable

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

Hydrolytic degradation of the active substance and metabolites > 10 % ‡	Active substance: Hydrolytically stable at pH 5 to 9 and 20 °C pH 4 and 20 °C: DT_{50} = 38 d metabolite PH_3 (gas): Not required for the representative use applied for*.
Photolytic degradation of active substance and metabolites above 10 % ‡	not relevant
Quantum yield of direct phototransformation in water at λ > 290 nm	not relevant
Readily biodegradable ‡ (yes/no)	not relevant

* Note endpoints for this are available in the dossier/DAR for aluminium phosphide (EFSA Scientific Report (2008) 182, 1-78).

Degradation in water / sediment:	not relevant
Mineralisation and non extractable residues:	not relevant

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

	The calculation of predicted environmental concentrations in surface waters (PEC_{sw}) and consequently in sediments for zinc phosphide and the metabolite phosphine following the GAP use of ARREX E Köder is not considered to be required, since considering the mode of application of the rodenticide bait, any contamination of the compartment surface water by routes of exposure, such as run-off and drainage is not to be expected.

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 there is no risk of contamination of ground water to any relevant degree, therefore an estimation of a PEC_{gw} is not considered to be required.

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 PH_3
Quantum yield of direct phototransformation	Not applicable
Photochemical oxidative degradation in air ‡	Not applicable
Volatilisation ‡	Not relevant (vapour pressure << 10^{-7} hPa)
Metabolites	PH_3 (gas, vapour pressure 34600 hPa, 20 °C): DT_{50} of 24 hours. OH (24 h) concentration assumed = 5 x 10^5 OH/cm³ (rate constant 1.6 x 10^{-11} cm³/mol sec)

PEC (air)

Method of calculation	Not applicable.

$PEC_{(a)}$

Maximum concentration	Due to rapid degradation of the metabolite phosphine (DT_{50} air 24 h) any significant contamination of the atmosphere is unlikely.

Residues requiring further assessment

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).	Soil: zinc phosphide, phosphine (PH_3) Surface Water: no Sediment: no Ground water: zinc phosphide, phosphine (PH_3) Air: phosphine (PH_3)

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

* In a literature search on the occurrence of surface and groundwater contamination from pesticides most used in forest vegetation management in North America, no reports on zinc phosphide could be found.

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

Not relevant

Ecotoxicology

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

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Bobwhite quail	as	Acute	LD_{50}: 12.9	--
Bobwhite quail	Preparation	Acute	No data submitted, justification accepted	--
Bobwhite quail	as	Short-term	--	LC_{50}: 468.5
Mallard duck	as	Short-term	--	LC_{50}: 2885
Japanese quail	as	Long-term	NOEL: 1.2 for males, 0.99 females	NOEL: 5
Mammals ‡				
Rat	as	Acute	LD_{50}: 37*	--
Rat	as	90, d oral	LOEC: 3.5	--
Rat	as	Long-term	No data submitted, justification accepted	
Additional higher tier studies ‡				
In two acceptance tests, ARREX E Köder was not accepted by pheasants in the course of the 7-day feeding period. Additionally, in all trials, birds preferred to consume untreated food, and fed on zinc phosphide poisoned baits only as a ”second choice”. In conclusion, ARREX E Köder is of low attractiveness to birds. This is considered to be mainly caused by the foil bag, enhanced by a low attractiveness to birds of the zinc phosphide containing bait itself.				

* geometric mean value of five values (12, 43, 44, 54, 56 mg/kg bw)

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

Crop and application rate

Indicator species/Category	Time scale	ETE	TER	Annex VI Trigger
Tier 1 – uptake via diet (Birds): not relevant, no exposure Outdoor: Zinc phosphide containing bait products (ARREX E Köder) are placed in foil bags in bait stations or into the voles' holes, passages of the voles.				
	Acute	--	--	10
	Short-term	--	--	10
	Long-term	--	--	5
Tier 1– uptake via drinking water (Birds): not relevant, no exposure				
	Acute	--	--	10
Tier 1 – secondary poisoning (Birds): not relevant, no exposure				
Earthworm-eating bird	Long-term			5
Fish-eating bird	Long-term	--	--	5
Tier 1– uptake via diet (Mammals): not relevant, no exposure Outdoor: Zinc phosphide containing bait products (ARREX E Köder) are placed in foil bags in bait stations or into the voles' holes, passages of the voles.				
	Acute	--	--	10
	Long-term	--	--	5
Tier 1– uptake via drinking water (Mammals): not relevant, no exposure				
	Acute	--	--	10
Tier 1 – secondary poisoning (Mammals): not relevant, no exposure				
Earthworm-eating mammals	Long-term	--	--	5
Fish-eating mammals	Long-term	--	--	5

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)	End point	Toxicity[1] (mg/L)
Laboratory tests ‡				
Fish				
Golden Ite *(Leuciscus idus) (Teleostei, Cyprinidae)*	as	96 hr (semistatic)	Mortality, EC_{50}	> 21.7 $_{mm}$
Oncorhynchus mykiss	as	28 d (static)	Growth NOEC	--
Oncorhynchus mykiss	Preparation	96 hr (flow-through)	Mortality, EC_{50}	--
Oncorhynchus mykiss	Preparation	28 d (flow-through)	Growth NOEC	--
Aquatic invertebrate				
Daphnia magna	as	48 h (static)	Immobilization, EC_{50}	114 $_{mm}$
Daphnia magna	as	21 d (static)	Reproduction, NOEC	--
Daphnia magna	Preparation	48 h (static)	Mortality, EC_{50}	--
Daphnia magna	Preparation	21 d (static)	Reproduction, NOEC	--
Sediment dwelling organisms				
Chironomus riparius	as	28 d (static)	NOEC	--
Algae				
Desmodesmus subspicatus	as	72 h (static)	Biomass: E_bC_{50} NOE_bC Growth rate: E_rC_{50} NOE_rC	0.00821 $_{mm}$ 0.00323 $_{mm}$ 0.00375 $_{mm}$ 0.00140 $_{mm}$
Desmodesmus subspicatus	Preparation	72 h (static)	Biomass: E_bC_{50} Growth rate: E_rC_{50}	 --
Higher plant				
Lemna gibba	as	14 d (static)	Fronds, EC_{50}	--
Lemna gibba	Preparation	14 d (static)	Fronds, EC_{50}	--
Microcosm or mesocosm tests				
not required				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

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

No calculation was performed because no exposure of surface water due to mode of application is expected.

Outdoor: Zinc phosphide containing bait products (ARREX E Köder) are placed in foil bags in bait stations or into the voles' holes, passages of the voles.

Bioconcentration			
	Active substance	Metabolite PH_3	Metabolite
logPow	Not applicable Zn_3P_2 is hydrolytically stable at pH 5 to 9 and 20 °C.	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 ^{14}C or on specific compounds

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

Bees are not exposed when zinc phosphide is used for outdoor control of voles. Therefore no data are required.

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
as ‡	Not required	Not required
Preparation[1]	Not required	Not required
Metabolite 1	Not required	Not required
Field or semi-field tests		
Not required		

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

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

Test substance	Route	Hazard quotient	Annex VI Trigger
as	Contact	Not required	50
as	oral	Not required	50
Preparation	Contact	Not required	50
Preparation	oral	Not required	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	End point	Effect (LR_{50} g/ha[1])
Typhlodromus pyri ‡	--	Mortality	No data submitted. None required. Outdoor application: A direct exposure of non-target arthropods to zinc phosphide containing bait products (ARREX E Köder) is unlikely due to the type of application (placed in foil bags in bait stations or into the voles' holes, passages of the voles) of the product.
Aphidius rhopalosiphi ‡	--	Mortality	

[1] for preparations indicate whether end point is expressed in units of a.s. or preparation

Outdoor: Zinc phosphide containing bait products (ARREX E Köder) are placed in foil bags in bait stations or into the voles' holes, passages of the voles.

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
--	*Typhlodromus pyri*	--	Not relevant	Not relevant	2
--	*Aphidius rhopalosiphi*	--	Not relevant	Not relevant	2

[1] indicate distance assumed to calculate the drift rate

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)[1,2]	End point	% adverse effect[3]	Trigger value
--						50 %

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of active substace or preparation
[3] indicate when the effect is not adverse

Field or semi-field tests
--

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	End point[1]
Earthworms			
	as ‡	Acute 14 days	LC_{50} > 1000 mg a.s./kg d.w.soil
	as ‡	Chronic 8 weeks	No data submitted, not required
	Preparation "Mäusegiftweizen" grain kemels coated with zinc phosphide	Acute	LC_{50} > 500 grains/kg d.w. soil (~ 600 mg as/kg d.w.soil)[3]
	Preparation	Chronic	---
Other soil macro-organisms			
Soil mite	as ‡		No data submitted, not required
	Preparation		No data submitted, not required
Collembola			
	as ‡	Chronic	No data submitted, not required
	Preparation		No data submitted, not required
Soil micro-organisms			
Nitrogen mineralisation	as ‡	28 days	< 25 % effect at day 28 at 240 g/ha (0.32 mg/kg d.w.soil)
	Preparation ARREX M Köder klein (SAG 50600), 2.3 % Zinc phosphide	28 days	< 25 % effect at day 28 at 11.20 kg/ha (22.4 mg/kg d.w.soil)
Carbon mineralisation	as ‡	28 days	< 25 % effect at day 28 at 240 g/ha (0.32 mg/kg d.w.soil)
	Preparation ARREX M Köder klein (SAG 50600), 2.3 % Zinc phosphide	28 days	< 25 % effect at day 28 at 11.20 kg/ha (22.4 mg/kg d.w.soil)
Field studies[2]			
not required			

[1] indicate where end point has been corrected due to log Pow >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
[3] 500 grains: maximum test concentration; 5 grains = 250 mg test substance corresponding to 6 mg a.s.

Toxicity/exposure ratios for soil organisms

Due to the mode of application (placed in foil bags in bait stations or into the voles' holes, passages of the voles) any relevant exposure of earthworms or other soil macro-organisms to zinc phosphide containing bait products outside the place of application is not expected.

Test organism	Test substance	Time scale	Soil PEC[2]	TER	Trigger
Earthworms					
	as ‡	Acute	--	--	10
	as ‡	Chronic	--	--	5
	Preparation	Acute	--	--	10
	Preparation	Chronic	--	--	5
Other soil macro-organisms					
Soil mite	as ‡	--	--	--	--
	Preparation	--	--	--	--
Collembola	as ‡	--	--	--	--
	Preparation	--	--	--	--

[1] to be completed where first Tier triggers are breached
[2] indicate which PEC soil was used (e.g. plateau PEC)

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

Preliminary screening data

No data submitted, justification accepted (A direct exposure of non target plants to zinc phosphide containing bait products (ARREX E Köder) is unlikely due to the type of application (placed in foil bags in bait stations or into the voles' holes, passages of the voles)

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	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	end point
Activated sludge	EC_{20} = 14 µg/L (computed value) EC_{50} = 4150 µg/L;(computation not possible, real effect of highest test concentration) NOEC < 14.6µg/L
Pseudomonas sp	--

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

Compartment	
soil	Parent (Zinc phosphide), Phosphine (PH_3)
water	no
sediment	no
air	Phosphine (PH_3)
groundwater	Parent (Zinc phosphide), Phosphine (PH_3)

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

	RMS/peer review proposal
Zinc phosphide (according to the criteria in Dir. 67/548/EEC)	(according to the criteria in Dir. 67/548/EEC): N, R 50/R53* Dangerous for the environment Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. (according to the criteria in Reg. 1272/2008): Aquatic acute 1 Aquatic chronic 1 GHS09 Hazardous to the aquatic environment H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects

* according to Directive 2001/59/EC of 6 August 2001 adapting to technical progress for the 28th time Council Directive 67/548/EEC

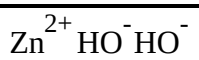
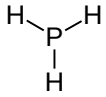
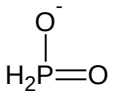
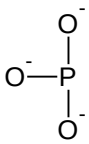
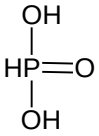
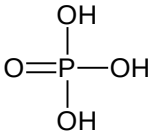
	RMS/peer review proposal
Phosphine (PH_3) (according to the criteria in Dir. 67/548/EEC)	(according to the criteria in Dir. 67/548/EEC): N, R50* Dangerous for the environment Very toxic to aquatic organisms (according to the criteria inReg. 1272/2008): Aquatic acute 1 GHS09 Hazardous to the aquatic environment H400: Very toxic to aquatic life

* according to Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the 29th time Council Directive 67/548/EEC, Corrigenda (Official Journal of the European Union L 216/3 of 16 June 2004)

	RMS/peer review proposal

Preparation (according to the criteria in Directive 1999/45/EC)	According to the classification of zinc phosphide in Annex I of Directive 67/548/EEC and the provisions of Annex III Part B Table 1b of Directive 1999/45/EC: Deduced from data for the active substance zinc phosphide (concentration 3.0 %; toxicity to algae E_bC_{50} = 0.00821 mg/L, E_rC_{50} = 0.00375 mg/L): Preparation ARREX E Köder: N, R 50/R53 Dangerous for the environment Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. (according to the criteria in Reg. 1272/2008): Aquatic acute 1 Aquatic chronic 1 GHS09 Hazardous to the aquatic environment H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name	Structural formula*
zinc hydroxide	zinc hydroxide	
phosphine	phosphane	
hypophosphite	hypophosphite (anion)	
phosphite	phosphite (anion)	
phosphonic acid	phosphonic acid	
phosphoric acid	phosphoric acid	

* ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).

ABBREVIATIONS

1/n	slope of Freundlich isotherm
ε	decadic molar extinction coefficient
°C	degree Celsius (centigrade)
µg	microgram
µm	micrometer (micron)
a.s.	active substance
ADE	actual dermal exposure
ADI	acceptable daily intake
AF	assessment factor
AOEL	acceptable operator exposure level
AP	alkaline phosphatase
AR	applied radioactivity
ARfD	acute reference dose
AST	aspartate aminotransferase (SGOT)
AV	avoidance factor
BCF	bioconcentration factor
BUN	blood urea nitrogen
bw	body weight
CAS	Chemical Abstract Service
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CIPAC	Collaborative International Pesticide Analytical Council Limited
CL	confidence limits
d	day
DAA	days after application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EASE	Estimation and Assessment of Substance Exposure
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
ECHA	European Chemical Agency
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMDI	estimated maximum daily intake
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
EUROPOEM	European Predictive Operator Exposure Model
f(twa)	time weighted average factor
FAO	Food and Agriculture Organisation of the United Nations
FIR	Food intake rate
FOB	functional observation battery
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GC	gas chromatography
GC-FPD	gas chromatography - flame photometric detector

GC-NPD	gas chromatography - nitrogen phosphorus detector
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GHS	Globally Harmonised System of Classification and Labelling of Chemicals
GM	geometric mean
GS	growth stage
h	hour(s)
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
ICP-AAS	inductively coupled plasma - atomic absorption spectrometry
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint Meeting on the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
K_{doc}	organic carbon linear adsorption coefficient
kg	kilogram
K_{Foc}	Freundlich organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC_{50}	lethal concentration, median
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
m	metre
M/L	mixing and loading
MAF	multiple application factor
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
mg	milligram
mL	millilitre
mm	millimetre
MRL	maximum residue limit or level
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MWHC	maximum water holding capacity
NESTI	national estimated short-term intake
ng	nanogram
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OM	organic matter content
Pa	Pascal

PD	proportion of different food types
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHED	pesticide handler's exposure data
PHI	pre-harvest interval
PIE	potential inhalation exposure
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
PPE	personal protective equipment
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
QSAR	quantitative structure-activity relationship
r^2	coefficient of determination
RB	ready-for-use bait
RMS	rapporteur Member State
RPE	respiratory protective equipment
RUD	residue per unit dose
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
STMR	supervised trials median residue
$t_{1/2}$	half-life (define method of estimation)
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TK	technical concentrate
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
TWA	time weighted average
UDS	unscheduled DNA synthesis
UV	ultraviolet
W/S	water/sediment
w/v	weight per volume
w/w	weight per weight
WHO	World Health Organisation
wk	week
yr	year