

Outcome of the consultation with Member States and EFSA on the basic substance application for diammonium phosphate for use in plant protection as a non-lethal food attractant for fruit flies

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context, EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for diammonium phosphate are presented. The context of the evaluation was that required by the European Commission in accordance with Article 23 of Regulation (EC) No 1107/2009 following the submission of an application for approval of diammonium phosphate as a basic substance for use in plant protection as a non-lethal food attractant for fruit flies. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

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Key words: diammonium phosphate, basic substance, application, consultation, plant protection, pesticide

Requestor: European Commission

Question number: EFSA-Q-2015-00457

Correspondence: pesticides.peerreview@efsa.europa.eu

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Summary

Diammonium phosphate is an active substance for which, in accordance with Article 23(3) of Regulation (EC) No 1107/2009, the European Commission received an application from the Institut Technique de l'Agriculture Biologique (ITAB) for approval as a 'basic substance'. Regulation (EC) No 1107/2009 introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest in applying for approval may be limited. Article 23 of Regulation (EC) No 1107/2009 lays down specific provisions for consideration of applications for approval of basic substances.

In March 2013, the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission in July 2015, EFSA was asked to organise a consultation on the basic substance application for diammonium phosphate, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table within three months of acceptance of the specific request.

A consultation on the basic substance application for diammonium phosphate, organised by EFSA, was conducted with Member States via a written procedure in April – June 2015. Subsequently, EFSA also provided comments and the applicant was invited to address all the comments received in the format of a reporting table and to provide an application update as appropriate, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by EFSA on the basic substance application for diammonium phosphate and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

The basic substance should be defined as oenological grade diammonium phosphate complying with Commission Regulation (EC) No 606/2009.

The use for this substance is in orchards as a non-lethal food attractant for fruit flies (*Ceratitis capitata*, *Rhagoletis cerasi* and *Bactrocera oleae*) placed in physical traps.

Diammonium phosphate is considered a processing aid in oenology; as such it is not consumed or used as food additive. Therefore its toxicological properties should be assessed. No toxicological data have been provided that would clarify the acute toxicity, including irritant and sensitising properties of diammonium phosphate, short-term, reproduction/developmental toxicity, or genotoxicity. This information would be needed for the setting of reference value (AOEL) as well as exposure estimates to perform an operator and worker exposure risk assessment to diammonium phosphate/ammonia in a vapour-releasing product. The operator and worker exposure risk assessment has not been addressed. There is no need to set dietary reference values for the compound as no residues are expected to occur on food commodities.

Since diammonium phosphate is used as an attractant for mass trapping in physical traps and not sprayed on plants, residues are not expected to occur on food commodities and therefore, a quantitative consumer risk assessment has not been provided and is not required.

For the representative use of diammonium phosphate as a dispenser trap, the risk to non-target organisms is considered to be addressed due to low exposure in relation to the use of diammonium phosphate as an agricultural fertiliser.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1107/2009¹ (hereinafter referred to as 'the Regulation') introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of the Regulation lays down specific provisions to identify a substance as a basic substance with a view to ensure that such active substances that do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment can be approved as 'basic' and used for plant protection purposes.

Diammonium phosphate is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from the Institut Technique de l'Agriculture Biologique (ITAB) for approval as a 'basic substance' for use in plant protection as a non-lethal food attractant for fruit flies.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for diammonium phosphate, which was conducted via a written procedure in April – June 2015. The comments received, including EFSA's comments, were consolidated by EFSA in the format of a reporting table. Subsequently, the applicant was invited to address the comments in column 4 of the reporting table and to provide an application update as appropriate. The comments received and the response of the applicant thereon, together with the application update submitted by the applicant, were considered by EFSA in column 5 of the reporting table.

The current report aims to summarise the outcome of the consultation process organised by EFSA on the basic substance application for diammonium phosphate and to present EFSA's scientific views on the individual comments received in the format of a reporting table.

The application and, where relevant, any update thereof submitted by the applicant for approval of diammonium phosphate as a 'basic substance' in the context of Article 23 of the Regulation, is a key supporting documentation, therefore it is considered as a background documentation to this report and will also be made publicly available, excluding its appendices (ITAB, 2015).

1.2. Interpretation of the Terms of Reference

On 6 March 2013 the European Commission requested EFSA to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received by EFSA on 30 July 2015, EFSA was asked to organise a consultation on the basic substance application for diammonium phosphate, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table.

To this end, a technical report containing the finalised reporting table is being prepared by EFSA. The agreed deadline for providing the finalised report is 30 October 2015.

On the basis of the reporting table, the European Commission may decide to further consult EFSA to conduct a full or focussed peer review and to provide its conclusions on certain specific points.

¹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

2. Assessment

The comments received on the basic substance application for diammonium phosphate and the conclusions drawn by EFSA are presented in the format of a reporting table.

The comments received are summarised in columns 2 and 3 of the reporting table. The applicant's considerations of the comments, where available, are provided in column 4, while EFSA's scientific views and conclusions are outlined in column 5 of the table.

The finalised reporting table is provided in Appendix A of this report. In addition, an overview table on the identity and biological properties of the substance and the list of intended uses in plant protection (GAP table) are provided in Appendix C and D, respectively.

Documentation provided to EFSA

1. ITAB, 2014. Basic substance application on diammonium phosphate submitted in the context of Article 23 of Regulation (EC) No 1107/2009. September 2014. Documentation made available to EFSA by the European Commission.
2. ITAB, 2015. Basic substance application update on diammonium phosphate submitted in the context of Article 23 of Regulation (EC) No 1107/2009. August 2015. Documentation made available to EFSA by the applicant.

References

None

Abbreviations

a.s.	active substance
AOEL	acceptable operator exposure level
DAP	diammonium phosphate
DAR	draft assessment report
FAO	Food and Agricultural Organisation
GAP	good agricultural practice
EFSA	European Food Safety Authority
EU	European Union
LC ₅₀	lethal concentration, median
LD ₅₀	lethal dose, median; dosis letalis media
MTDI	maximum tolerable daily intake
RMS	rapporteur Member State
VP	vapour releasing product
WHO	World Health Organization

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for diammonium phosphate and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

General					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(1)	2.1.5.1. Food and Oenological GRADE specification	EFSA: Please confirm which grade of material you are applying for.	A clear statement is needed on what grade of material and what the full specification of the basic substance is. See also comments in Section 2 below.	Oenological GRADE specifications are retained	Addressed: The basic substance should be defined as oenological grade diammonium phosphate complying with Commission Regulation (EC) No 606/2009 ² .

2. Identity of the substance/product as available on the market and predominant use

2.1. Identity and Physical and chemical properties of the substance and product to be used					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	General	DE: Different chemical denominations can be assigned to DAP. However, it would be preferable to conclude on one for the complete application template.	See 1(1)	Diammonium phosphate (DAP) is retained as denomination, as the title of the dossier.	See comment 1(1) above

² Commission Regulation (EC) No 606/2009 of 10 July 2009 laying down certain detailed rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions. OJ L 193, 24.7.2009, p. 1–59.

2.1. Identity and Physical and chemical properties of the substance and product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(2)	2.1.5/2.1.5.1. Specification	<p>DE: The specification for the basic substance should be clarified and clearly stated.</p> <p>According to the basic substance application template specifications of diammonium phosphate (DAP) are different in uses as fertiliser or in oenology. The specification provided in 2.1.5.1 seems to be not in compliance with the International oenological codex 2000.</p>	See 1(1)	Oenological GRADE specifications are retained.	See comment 1(1) above
2(3)	General substance name	<p>NL: Is diammonium phosphate the appropriate name to use for this substance or should this be diammonium hydrogen phosphate?</p> <p>Does the substance as manufactured contain water (is it a hydrate)?</p>	EFSA: The correct name for this basic substance should be clarified in a statement. Also see 1(1)	<p>Diammonium phosphate (DAP) is retained, title of the Dossier. Molecular formula is clearly described in 2.1.3: $(\text{NH}_4)_2\text{HPO}_4$</p> <p>No water molecule.</p>	Addressed: The identity of the material has been clarified.

2.2. Current Former and in case proposed trade names

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

2.3. Manufacturer of the substance/products

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

2.4. Type of preparation

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

2.5. Description of the recipe for the product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

3. Uses of the substance and its product

3.1. Field of use

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

3.2. Effects on harmful organisms or on plants

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

4. Classification and labelling of the substance

Classification and labelling of the substance

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
4(1)	4. Classification and labelling of the substance	EFSA: it is acknowledged that no harmonised classification is yet in place for DAP, however notified classifications refer to harmful effects in contact with skin and if inhaled (acute Tox. 4, H312/H335), skin and eye irritation 2 (H315/H319) and STOT SE 3 (may cause respiratory irritation).	This information might be retrieved from the studies referred by DE under section 5.2 below.	Applicant has no access to REACH Dossier. Although harmful effects are described in REACH classification, DAP is used as fertilizer up to 150 kg per hectare.	No information has been provided allowing to clarify the potential hazard properties of DAP. See also 5(1)

5. Impact on Human and Animal Health

5.1. Toxicokinetics and metabolism in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

5.2. Acute toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	5.2. Acute toxicity	DE: It is stated, that there is no report for DAP on acute toxicity. However, e.g. in the ECHA registration dossier data of animal studies (or supporting data) with DAP on acute oral, inhalative, dermal toxicity as well as on skin/eye irritating potential and on sensitisation were reported. Furthermore, data on acute oral toxicity have already been published on several occasions.	DE: The basic substance application template should be amended by available information on toxicity studies and/or supporting data of DAP (please refer to the working document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No1107/2009, Point 5 Impact on human and animal health).	Applicant has no access to REACH Dossier. ECHA classification may occur in large scale uses as fertilizer (up to 150 kg / ha). Di Ammonium Phosphate described here is oenological grade, accepted as food additive by FAO/WHO at rate of 30 g/L for traps containing ½L to 1L.	Toxicological properties of DAP (acute toxicity, irritation and sensitisation potential) have not been addressed that may be relevant to labelling of the product. See also 4(1)

5.3. Short-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(2)	5.3. Short-term toxicity	DE: It is stated, that there is no report for DAP on short term toxicity. However, in the ECHA registration dossier a combined repeated dose and reproduction/developmental screening according to OECD TG 422 was reported.	DE: Please refer to DE comment under section 5.2 above.	Applicant has no access to REACH Dossier. If DAP used in large scale as fertilizer (up to 150 kg / ha) is toxic in any circumstances, do not hesitate to remove it from DE market as it is sale and used in fields by tons.	The short-term toxicity has not been addressed.

5.4. Genotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(3)	5.4. Genotoxicity	DE: It is stated, that there is no report for DAP on genotoxicity. However, in the ECHA registration dossier <i>in vitro</i> tests on the genotoxic potential of DAP were presented.	DE: Please refer to DE comment under section 5.2 above.	Again, if DAP, is genotoxic, do not hesitate to remove it from DE market as it is sale by tons and used in fields in large scale as fertilizer, up to 150 kg / ha. DAP described here is oenological grade, accepted as food additive by FAO/WHO and used at rate of 30 g/L in water for traps containing ½L to 1L.	Genotoxicity testing has not been provided.

5.5. Long-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

5.6. Reproductive toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(4)	5.6. Reproductive	DE: Please refer to DE comment		Identical answer.	Reproduction/developmental

5.6. Reproductive toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	toxicity	under section 5.3 above.			toxicity have not been addressed.

5.7. Neurotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

5.8. Toxicity studies on metabolites

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

5.9. Medical Data: adverse effects reported in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(5)	5.9. Medical data: adverse effects	EFSA: A published paper (Effect of ammonia, urea and	EFSA: protective measures may be considered to ensure	DAP is cited in Bhat 1993 and conclusions are: " <i>In conclusion,</i>	See comments under 5(6) and 5(7) for the setting of

5.9. Medical Data: adverse effects reported in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	reported in humans	diammonium phosphate (DAP) on lung functions in fertilizer plant workers, Bhat, Ramaswamy, 1993) refers that DAP may affect the lung function of workers after prolonged exposure (> 10 years of exposure). This might be linked to the possible respiratory irritative properties of the substance (please refer to point 4 on classification above)	operators/workers safety	<i>it is evident that fertilizer chemicals affect the pulmonary larger airway function first, followed by bronchospasm thus predominantly causing obstructive type of lung disorders. They also affect the pulmonary alveoli only after longer exposure to cause restrictive type of lung disorders. "</i> This study is about fertilizer workers exposed to large quantities of DAP over 10 years. Di Ammonium Phosphate described here in this Dossier is oenological grade, accepted as food and wine additive by FAO/WHO and use at rate of 30 g/L in water for traps containing ½L to 1L.	reference values and/or exposure estimates relevant to operator and worker exposure.

5.10. Additional Information related to therapeutic properties or health claims

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

5.11. Additional information related to use as food

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(6)	5.12	DE: In the application template the calculation of the MTDI has not been clearly presented. The proposed MTDI of 70 mg/kg bw phosphate seems to be a conditional acceptance level (as food additive), only when dietary calcium level is high. However, the proposed MTDI is a reference value for phosphate and polyphosphates, only. Therefore, it is considered necessary to set also a reference dose for DAP, which is suitable for risk assessment for operators and workers. Reference values should be based on appropriate toxicity	DE: The derivation of reference values for the risk assessment for operators and workers is proposed.	Exposure from uses as fertilizer are much higher than rates generated by 30 g/L for traps in water.	The derivation of reference value for operators and workers (AOEL) is not possible due to the lack of toxicological data. See also 5(5) and 5(7)

5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		studies with DAP.			
5(7)	5.12. reference values	EFSA: the hazardous component of diammonium phosphate is ammonia rather than phosphorus as a decomposition product of DAP in a vapour releasing product. The setting of an AOEL for DAP would be more relevant than dietary health based values considering the proposed use.	EFSA: it is proposed to set non-dietary health based reference values for DAP and ammonia (see also REACH Annex XV restriction report for inorganic ammonium salts), and demonstrate that the exposure level is not of concern.	Applicant Agrees. No further comment from applicant	Toxicological data and/or exposure estimates to DAP/ammonia in a vapour releasing product have not been provided to perform operator/worker exposure assessment. See also 5(5) and 5(6)

5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

6. Residues

Residues					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(1)	General	EFSA: Since diammonium phosphate is used as an attractant for mass trapping in physical traps and not sprayed on plants, residues are not expected to occur on food commodities.		Comment included in §6 No further comment from applicant	Addressed

7. Fate and Behaviour in the environment

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)	general	NL: in the environmental fate part reference is made to the use as fertiliser especially with regard to exposure. However, for some other aspects reference is made to authorisation in oenology and as food additive. Both already known use areas are used to demonstrate	No further data requested or needed for the use proposed.	No further comment from applicant	No further comment from EFSA

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>compliance with art 23. The environmental exposure as fertiliser is much higher than as food additive and therefore worst case compared to the applied for use as attractant. We agree on the assessment that DAP fulfils the criteria of a basic substance.</p>			
7(2)		<p>EFSA: Whereas no specific reference to a previous EU assessment that has addressed environmental exposure to diammonium phosphate is made in the application, the known authorized uses of diammonium phosphate as fertilizer represent a clear worst case in relation to the proposed use as attractant in physical mass traps.</p>	<p>No further data requested or needed for the use proposed.</p>	<p>No further comment from applicant</p>	<p>No further comment from EFSA</p>

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

8. Effects on non-target species

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	Risk to terrestrial vertebrates	EFSA: It is agreed that exposure and risk to terrestrial vertebrates for the proposed use is low.		No further comment from applicant	Addressed. For the representative use of diammonium phosphate in a dispenser, a low risk to terrestrial vertebrates can be concluded due to low exposure

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(2)	Effects on aquatic organisms	DE: DAP is toxic to aquatic organisms. The use of	DE: A remark for "conditions of use": It has to be paid	No further comment from applicant	Addressed.

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>dispensers into traps should prevent a danger for aquatic organisms in this case, but the protection of the aquatic environment has to be considered.</p>	<p>attention to the protection of the aquatic environment.</p> <p>EFSA: For the proposed use of diammonium phosphate a quantitative aquatic risk assessment is not needed due to the lack of exposure. Risk mitigation measures are not considered necessary. Labelling considering the hazard of the active substance is covered by the Regulation (EC) No 1272/2008.</p>		<p>It is noted that diammonium phosphate is toxic to aquatic organisms and DE suggests that a risk assessment is required. However, EFSA considers that for the representative use of diammonium phosphate in a dispenser, a low risk to aquatic organisms can be concluded due to low exposure.</p>
8(3)	Effects on aquatic organisms	<p>NL: we note that more information is available on aquatic species than is presented in the report, including aquatic snail and worm.</p> <p>(1) Thurston, RV and Russo RC. (1983) Acute toxicity of ammonia to rainbow trout. Trans. Am. Fish. Soc. 112: 696-704.</p> <p>(2) Sarkar, SK. (1997) Toxicity of Simazine, Diammonium phosphate and rock phosphate to fish, snail and</p>	<p>EFSA: For the proposed use of diammonium phosphate a quantitative aquatic risk assessment is not needed due to the lack of exposure. Consequently, these studies are not necessary.</p>	No further comment from applicant	See response to 8(2).

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>worm at various water temperatures. Geobios 24(2-3): 142-145.</p> <p>(3) Palanichamy S, Arunachalam S and Balasubramanian MP (1985) Food consumption of <i>Sarotherodon mosambicus</i> (Trewaves) exposed to sublethal concentration of diammonium phosphate. Hydrobiologia 128(3): 233-237.</p> <p>(4) Yadav, HN, Akela BP and Kumari A. (1998) Effect of DAP toxicity on certain haematological parameters of <i>Heteropneustes fossilis</i> (Bloch) Environ. Ecol. 16(2): 431-434.</p> <p>These data indicate potential sublethal effects, but the LC50 values remain in the reported range, also for aquatic molluscs and worms.</p>			
8(4)		NL: We agree that the criteria for a basic substance have been met.		No further comment from applicant	No comment.
8(5)	Risk to aquatic organisms	EFSA: It is agreed that the risk to aquatic organisms for the		No further comment from applicant	See response to 8(2).

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		proposed use is low.			

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(6)	8.3.1 + 8.3.2, Braham, M. 2013	DE: "There were significant captures of non-target insects ... in all traps..." The applicant has to show that the substance has not an unacceptable effect on the environment. Significant captures of non-target arthropods are an effect on the environment, which has to be evaluated with regard to its acceptability. DAP may be a substance of no concern (sound data not available), but the application method in traps may be a risk for non-target arthropods. The submitted literature indicates that there might	DE: Conduct a sound risk assessment for non-target arthropods which can be concerned by the use of traps with DAP. Describe a safe method of trapping, e. g. cover the vessels with a mesh which will prevent e. g. bees to get access to the substance. EFSA: see comment 8(9).	Due to the small size of <i>Bactrocera olea</i> special traps are designed and sold (yellow traps) other traps are used with small 3 mm diameter holes in order to prevent bigger insects to enter the corresponding trap.	Addressed. The diameter of the holes in the trap (3 mm) will prevent larger non-target arthropods entering the trap. This was not the case in the traps investigated in Braham, M., 2013, where a bucket, container and ball (mimicking fruit) traps were used. Furthermore, exposure to non-target arthropods from the representative use of diammonium phosphate in a mass trap dispenser is likely to lead to less exposure than the use of diammonium phosphate as a fertiliser which is applied on

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		be a risk for bees and beneficials (i. e. that they are attracted by the substance).			agricultural fields. Therefore, overall the risk to non-target arthropods is considered addressed.
8(7)	Effects on bees and other arthropod species	<p>NL: Published data are available for mediterranean flour moth:</p> <p>(1) Boczek JH, Wolska K and Davis R. (1987) Effects of mineral salts in the diet of the Mediterranean flour moth, <i>Anagasta kuehniella</i> (zeller) J Entomol Sci 22(1): 61-69.</p> <p>Dietary exposure seemed to indicate delayed development at 1% w/w (in diet).</p>	EFSA: The study could be used as part of the risk assessment for non-target arthropods (see 8(9)).	Due to the small size of <i>Bactrocera olea</i> special traps are designed and sold (yellow traps) other traps are used with small 3 mm diameter holes in order to prevent bigger insects to enter the corresponding trap.	See response to 8(6).
8(8)		NL: We agree that the criteria for a basic substance have been met.		No further comment from applicant	No comment.
8(9)	Risk to bees and other arthropod species	EFSA: Exposure to bees and non-target arthropods cannot be excluded for the proposed use of diammonium phosphate. A risk assessment, taking account of the likely exposure, is therefore needed.	To address the risk to bees and non-target arthropods a quantitative risk assessment could be performed to account for the toxicity and likely exposure. Alternatively, an argumentation could be presented by reference to another EU risk assessment (with equivalent or a higher	Large scale uses as fertilizer (up to 150 kg / ha) is common all over the world compare the rate of 30 g/L in water for traps containing ½L to 1L.	See response to 8(6).

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			level of exposure) demonstrating a low risk (e.g. the risk assessment for use as a fertiliser). A further alternative could be to prevent exposure to bees and non-target arthropods (see comment from DE).		

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(10)	Effects on earthworms and other soil macroorganisms	NL: Published data are available for root-knot nematode: (1) Oka Y and Pivonia S. (2002) Use of ammonia-releasing compounds for control of the root-knot nematode <i>Meloidogyne javanica</i> . The results showed an effect on "abundance" at 300 mg/kg soil (48 day exposure to 2 nd stage juveniles).	EFSA: For the proposed use of diammonium phosphate a quantitative risk assessment for soil organisms is not needed due to the lack of exposure. Consequently, these studies are not necessary.	No further comment from applicant	Addressed. For the representative use of diammonium phosphate in a dispenser, a low risk to earthworms and other soil macroorganisms can be concluded due to low exposure.
8(11)		NL: these data do not indicate a particularly high toxicity of DAP, thus we agree that the		No further comment from applicant	No comment.

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		criteria for a basic substance are met.			
8(12)	Risk to soil organisms	EFSA: It is agreed that the risk to soil dwelling organisms for the proposed use is low.		No further comment from applicant	See response to 8(10).

8.5. Effects on soil microorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(13)	Risk to soil organisms	EFSA: It is agreed that the risk to soil dwelling organisms for the proposed use is low.		No further comment from applicant	Addressed. For the representative use of diammonium phosphate in a dispenser, a low risk to soil microorganisms can be concluded due to low exposure.

8.6. Effects on other non-target organisms (flora and fauna)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(14)	Effects on other non-target organisms (flora and fauna)	<p>NL: Data is available for tomato and sugarcane:</p> <p>(1) Oka Y and Pivonia S. (2002) Use of ammonia-releasing compounds for control of the root-knot nematode <i>Meloidogyne javanica</i>. Nematology 4(1): 65-72.</p> <p>(2) Clements HF and Akamine E (1940) Root stimulation in sugar cane (<i>Saccharum officinarum</i>) with special reference to the effects of ethyl alcohol. Am J Bot 27:482-487.</p> <p>The LOEL for tomato shoot weight was 300 mg/kg soil (4 week exposure to treated soil).</p>	<p>EFSA: For the proposed use of diammonium phosphate a quantitative risk assessment for non-target plants is not needed due to the lack of exposure. Consequently, these studies are not necessary.</p>	<p>No further comment from applicant</p>	<p>Addressed.</p> <p>For the representative use of diammonium phosphate in a dispenser, a low risk to non-target plants can be concluded due to low exposure.</p>
8(15)		<p>NL: Considering the data, no particular toxicity is indicated for plants (and the substance is used as a fertilizer). Thus, we agree the criteria for a basic substance are met.</p>		<p>No further comment from applicant</p>	<p>No comment.</p>
8(16)	Risk to non-target plants	<p>EFSA: It is agreed that the risk to non-target plants for the proposed use is low.</p>		<p>No further comment from applicant</p>	<p>See response to 8(14).</p>

8.7. Effects on biological methods of sewage treatment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(17)	Risk to biological methods of sewage treatment	EFSA: It is agreed that the risk to biological methods of sewage treatment for the proposed use is low.		No further comment from applicant	Addressed. For the representative use of diammonium phosphate in a dispenser, a low risk to biological methods of sewage treatment can be concluded due to low exposure.

9. Overall conclusions with respect of eligibility of the substance to be approved as basic substance

Overall conclusions with respect of eligibility of the substance to be approved as basic substance

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

No comments.

10. Other comments

Other comments

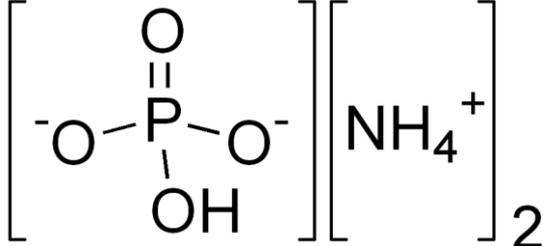
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

Appendix B – Used compound code(s)

Code/trivial name	Chemical name/SMILES notation	Structural formula
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Appendix C – Identity and biological properties

Common name (ISO)	Diammonium phosphate (diammonium hydrogen phosphate)
Chemical name (IUPAC)	diammonium hydrogen phosphate
Chemical name (CA)	Diammonium phosphate
Common names	DAP, ammonium phosphate dibasic
CAS No	7783-28-0
CIPAC No and EEC No	231-987-8
FAO specification	None
Minimum purity	Oenological grade
Relevant impurities	None
Molecular mass and structural formula	<p>Molecular formula: $(\text{NH}_4)_2\text{HPO}_4$ Structural formula:</p>  <p>Molecular mass: 132.07 [g/mol]</p>
Mode of Use	Used as an attractant for fruit flies
Preparation to be used	Aqueous solution
Function of plant protection	Attractant

Appendix D – List of uses

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application			Application rate per treatment			Total rate	PHI (days) (m)	Remarks		
					Type (d-f)	Conc of a.s. g/L (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	kg a.s./hl min max (kg/hl)	Water l/ha min max				kg a.s./ha min max (kg/ha) (l)	kg a.s./ha min max (kg/ha) (l)
Orchards Including cherry tree <i>Prunus spp</i>	FR For all Member States	-	F	Mediterranean Fruit fly <i>Ceratitis capitata</i> Cherry fly <i>Rhagoletis cerasi</i>	VP Vapour releasing product	40	Ground mass application by hand in different dispensers into traps		Mass trapping: 1 [£] Environ- monitoring (not PPP use): 1 to 3 / ha	Approx. 6 to 8 Weeks*	max 4		Mass trapping: max 100 [£] Environ- monitoring 1 to 3	Mass trapping: max 4 Environ- monitoring 0.04	Mass trapping: max 4 Environ- monitoring 0.04 to 0.12	Not relevant	
Olive trees <i>Olea europaea</i>				Olive fly <i>Bactrocera oleae</i>									Mass trapping: 1 [£] Environ- monitoring (not PPP use): 2 / ha	Mass trapping: max 100 [£] Environ- monitoring (not PPP use): 2	Mass trapping: max 4 Environ- monitoring (not PPP use): 0.04		Mass trapping: max 4 Environ- monitoring (not PPP use): 0.08
<i>Citrus spp</i>				Mediterranean Fruit fly <i>Ceratitis capitata</i>									Mass trapping: 1 [£] Environ- monitoring (not PPP use): 1 to 5 / ha	Mass trapping: max 100 [£] Environ- monitoring (not PPP use): 1 to 5	Mass trapping: max 4 Environ- monitoring (not PPP use): 0.04		Mass trapping: max 4 Environ- monitoring (not PPP use): 0.04 to 0.2
Other crops where <i>C. capitata</i> cause damage				Mediterranean Fruit fly <i>Ceratitis Capitata</i>									Mass trapping: 1 [£] Environ- monitoring (not PPP use): 1 to 2 / ha	Mass trapping: max 100 [£] Environ- monitoring (not PPP use): 1 to 2	Mass trapping: max 4 Environ- monitoring (not PPP use): 0.04		Mass trapping: max 4 Environ- monitoring (not PPP use): 0.04 to 0.08

* depending upon environmental factors such as climate and topography

£: Mass trapping: 1 by tree, up to 100 / ha

- (a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- (c) e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..
- (e) GCPF Codes – GIFAP Technical Monograph N° 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 plant – type of equipment used must be indicated
- (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)
- (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) Indicate the minimum and maximum number of application possible under practical conditions of use
- (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)
- (m) PHI - minimum pre-harvest interval