European Food Safety Authority

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TECHNICAL REPORT

Outcome of the consultation with Member States and EFSA on the basic substance application for lecithins for use in plant protection as a fungicide on vineyards, fruit trees, vegetables and ornamentals[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

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 lecithins 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 lecithins as a basic substance. Lecithins is intended to be used as a fungicide on vineyards, fruit trees, vegetables and ornamentals. The current report summarises the outcome of the consultation process organised by the EFSA and presents EFSA's scientific views on the individual comments received.

KEY WORDS

lecithins, basic substance, application, consultation, plant protection, pesticide, fungicide

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SUMMARY

Lecithins 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 of 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 on February 2014, EFSA was asked to organize a commenting on the basic substance application for lecithins, 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 3 months of acceptance of the specific request.

A consultation on the basic substance application for lecithins, organised by the EFSA, was conducted with Member States and EFSA via a written procedure in February 2014-April 2014. Subsequently the applicant was invited to address the comments received in the format of a Reporting Table, within a period of 30 days.

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

Lecithins are mixtures or fractions of phosphatides obtained by physical procedures from animal or vegetable foodstuff; they also include hydrolysed products obtained through the use of harmless and appropriate enzymes. The final product must not show any signs of residual enzyme activity.

Lecithins are predominantly used in the pharmaceutical industry, in animal feed, in the paint industry and also in textile, rubber and other industries. The intended use as a basic substance is as a fungicide on vineyards, fruit trees, vegetables and ornamentals.

Lecithins, as proposed in the submission, fulfill the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002. Lecithins (E322) is an approved food additive and its specifications have been established under Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.

Concerning mammalian toxicology no further information is needed as lecithins can be considered as a foodstuff according to the current legislation.

Since lecithins fulfill the criteria of a foodstuff under Regulation (EC) No 178/2002, no residues of concern are expected to be present in food and feed commodities at harvest.

The information provided is insufficient to address fate and behaviour in the environment and characterise environmental exposure.

A specific assessment, including the exposure characterisation, on the impact to non-target organisms following the representative uses of lecithins as a fungicide, was not provided. However, considering the nature of the active substance, no further information is necessary.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1107/2009[3] (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.

Lecithins is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Institut Technique de l'Agriculture Biologique for approval as a "basic substance".

The European Food Safety Authority (EFSA) organised a consultation with Member States and EFSA on the basic substance application for lecithins as a fungicide on vineyards, fruit trees, vegetables and ornamentals, which was conducted via a written procedure in February 2014-April 2014. The comments received were collated by EFSA in the format of a Reporting Table. Subsequently, the applicant was invited to address the comments in column 3 of the Reporting Table. The comments received and the response of the applicant thereon, together with the application submitted by the applicant, were considered by EFSA in column 4 of the Reporting Table.

The current report aims to summarise the outcome of the consultation process organised by the EFSA on the basic substance application for lecithins 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 lecithins 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 (Institut Technique de l'Agriculture Biologique (ITAB); 2014a, 2014b).

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

On 6 March 2013 the European Commission requested the 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 February 2014, EFSA was asked to organise a commenting on the basic substance application for lecithins, 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 prepared by EFSA. The agreed deadline for providing the finalised report is 12 September 2014.

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.

[3] 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.

EVALUATION

The comments received on the basic substance application for lecithins and the conclusions drawn by the EFSA are presented in the format of a Reporting Table.

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

The finalised Reporting Table is provided in the Appendix of this report.

DOCUMENTATION PROVIDED TO EFSA

1. ITAB (Institut Technique de l'Agriculture Biologique), 2014a. Lecithins. Basic substance application submitted in the context of Article 23 of Regulation (EC) No 1107/2009. February 2014. Submitted by ITAB (Institut Technique de l'Agriculture Biologique). Documentation made available to EFSA by the European Commission.

2. ITAB (Institut Technique de l'Agriculture Biologique), 2014b. Soybean Lecithins. Basic substance application update submitted in the context of Article 23 of Regulation (EC) No 1107/2009. June 2014. Submitted by Institut Technique de l'Agriculture Biologique. Documentation made available to EFSA by the applicant.

REFERENCES

Fiume Z. 2001. Final Report on the Safety Assessment of lecithins and Hydrogenated lecithins International Journal of Toxicology, 20(Suppl. 1):21-45

APPENDIX

COLLATION OF COMMENTS FROM MEMBER STATES AND EFSA ON THE BASIC SUBSTANCE APPLICATION FOR LECITHINS 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(1)		ES: No comments	-	Noted

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

2.1. Predominant Use				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	2.2.3 and 2.2.7.3	DE: The molecular formulas of lecithins do not correspond to the molecular masses presented in the identity section. Based on presented formulas the mass range would be 758 – 815 g/mol, while the indicated numbers were 677.9-789 g/mol. In addition, the identity presented in 2.2.3 is not in line with the identity described in 2.2.7 (which also includes phosphatidyl ethanolamines, serines and inositols). Clarification is needed.	Corrected Soybean lecithins was selected, therefore, composition is known	In the updated submission there is still discrepancy between the molecular formula and the structural formula and molar mass of phosphatidyl choline.
2(2)		ES: No comments		Noted

2.2. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	General comment 2.2.5. Description and specification of purity of the active substance and product	ES: Is the lecithins composition similar when it comes from animal and plant tissues? Are the rates among the major components constant?	Soybean lecithins is from vegetal origin Corrected	Addressed: See comment 2(2)
2(2)	$2; Wendel, A.; Kirk-Othmer Encyclopedia of Chemical Technology.	NL: Different kind of categories are stated here as commercially available lecithins. Regarding establishing the identity, this seems to be somewhat too general description.	Corrected, restricted to Soybean lecithins from vegetal origin The main phospholipids in lecithins from soya and sunflower are phosphatidyl choline,	Addressed: The updated application was submitted for soybean lecithins only, still claiming that it

2.2. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		Like the various lengths of the fatty acid chains, the various kind of phospholipid groups, and so on. It would be preferred if the identity of lecithins would be narrowed down to a selection of phospholipids and also regarding the length of the possible fatty acid chains, ….	phosphatidyl inositol, phosphatidyl ethanolamine, and phosphatidic acid. They often are abbreviated to PC, PI, PE, and PA, respectively. Soybean-derived Lecithins are composed of 19-21% Phosphatidylcholine (PC), 8-20% Phosphatidylethanolamine, 20-21% Inositol phosphatides (PI), 33-35% Soybean oil, 2-5% Sterols, 5% Carbohydrates/free, 1% Moisture, and 5-11% Other phosphatides.	is complying with Commission Regulation (EU) No 231/2012[4] of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. Lecithins (E322) approved as food additive is not limited only to soybean origin. Regulation (EU) No 231/2012 defines lecithins as being mixtures or fractions of phosphatides obtained by physical procedures from animal or vegetable foodstuffs; they also include hydrolysed products obtained through the use of harmless and appropriate enzymes. The final product must not show any signs of residual enzyme activity The lecithins may be slightly bleached in aqueous medium by means of hydrogen peroxide. This oxidation must not chemically modify the lecithins phosphatides. The limitation of the basic substance submission to soybean lecithins is not necessary.
2(3)	$2; Wendel, A.; Kirk-Othmer Encyclopedia of Chemical Technology,	NL: 6 commercial grades seem to be available for lecithins, see table 6. composition. The composition of the various lecithins can vary	Corrected, restricted to Soybean lecithins from vegetal origin "food grade"	Addressed: See comment 2(2)

4 Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 103).

2.2. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	4. commercial grades	significantly, hence indicate a different behaviour at water solubility/ solubility in organic solvents, hence might have an effect.		
2(4)	$2; Wendel, A.; Kirk-Othmer Encyclopedia of Chemical Technology, 9. purity	NL: Heavy metals seem to be present at 4o ppm. Shouldn't these heavy metals be more specified than just gathered under one general name heavy metals?	The limits for Copper, Lead, and Arsenic should fall within any overall limits for heavy metals specified for all foods by the Codex Committee on Food Additives. The limits proposed are put forward as technologically unaviodable	Addressed: The specifications must meet the criteria described in Reg. 231/2012
2(5)	$2 MacLean H., 1912	NL: This refrence on the purification of phospatides dates from 1912, is over hundred years old. Could it be considered as the latest view on purification on phosphatides? It seems somewhat outdated and it should be considered whether it is relevant here or could be deleted.	Corrected, restricted to Soybean lecithins from vegetal origin. The main phospholipids in lecithins from soya and sunflower are phosphatidyl choline, phosphatidyl inositol, phosphatidyl ethanolamine, and phosphatidic acid. They often are abbreviated to PC, PI, PE, and PA, respectively. Soybean-derived Lecithins are composed of 19-21% Phosphatidylcholine (PC), 8-20% Phosphatidylethanolamine, 20-21% Inositol phosphatides (PI), 33-35% Soybean oil, 2-5% Sterols, 5% Carbohydrates/free, 1% Moisture, and 5-11% Other phosphatides. Finally, "Old science" dug the groove to synthetic substances and going back to nature formally permit us to "re-discover" old usages of natural compounds.	Addressed: See comment 2(2)
2(6)	2.2.1 Common name, p.7	EFSA: there is no ISO common name for this 'substance' Based on the CAS number 8002-43-5, and on COMMISSION DECISION of 9 February 2006 amending Decision 96/335/EC	Corrected	Addressed.

2.2. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		establishing an inventory and a common nomenclature of ingredients employed in cosmetic products (2006/257/EC) the proposal is to define the 'substance' lecithins as The complex combination of diglycerides of fatty acids linked to the choline ester of phosphoric acid		
2(7)	2.2.2 IUPAC name, p.8	EFSA: there are some small inconsistencies between the chemical names CAS numbers and structural formulas. The IUPAC name given corresponds to $C_{46}H_{89}NO_8P$, whose structure is not drawn, the structure of 8002-43-5 is drawn, but the name not given **(**(2*S*)-2-[(9*Z*,12*Z*)-octadeca-9,12-dienoyloxy]-3-(palmitoyloxy)propyl 2-(trimethylammonio)ethyl phosphate**)** The structure of $C_{42}H_{82}NO_8P$ is drawn, but not mentioned.	Corrected	The small inconsistencies between the chemical names and structural formulas remained also in the updated submission. See also comment 2(1)
2(8)	2.2.2 IUPAC name, p.8	EFSA: as the name of the proposed basic substance is "lecithins", in plural, this suggests also that this basic substance is a complex mixture of chemicals and the composition depends on the origin of the lecithins.(lecithins is amixture of glycerophospholipids obtained from animal, vegetable, or microbial sources, containing a variety of substances, such as sphingosylphospholipids, triglycerides, fatty acids, and glycolipids, as submitted in Wendel A.)	Corrected, restricted to Soybean lecithins from vegetal origin	Addressed: See comment 2(2)

2.3. Current Former and in case proposed trade names				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)		ES: No comments	-	Noted.

2.4. Manufacturer of the substance/products				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)		ES: No comments	-	Noted.

2.5. Type of preparation				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)		ES: No comments	-	Noted.

2.6. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)		ES: No comments	-	Noted.

2.7. Function on plant protection				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)		ES: No comments	-	Noted.

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		ES: In the field of use, "ornamentals" should be included, which appears in the GAP table.	Corrected in 3.1	The field of use was updated according to the GAP table, including also ornamentals.

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		ES: No comments	-	Noted.
3(2)		DE: The literature cited and submitted does not provide the prediction of sufficient efficacy in the intended uses. The cited literature speculates on the mode of action. It remains unclear whether the active substance has fungicidal, plant strengthening or fertilization effects. Overall, only limited effect in some uses described should be expected.	German Company XXX sell it as fungicide even for Organic Farming (OF), as it is listed in Annex II of regulation CE No 889/2008.	The intended use is as a fungicide.

3.3. Summary of intended uses				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)	General comment	ES: Is the efficacy of the treatment affected by the lecithins composition if this is different according to the origin (see above comment to the issue "2.2. Identity and Physical and chemical properties of the substance and product to be used")? Has it also considered this fact in the application rate?	Most commonly effective described lecithins is soybean lecithins. Corrected, restricted to Soybean lecithins from vegetal origin	Addressed: See comment 2(2)
3(2)	3.3	ES: All the application rates per treatment should be revised. The water (l/ha) values do not correspond with the amounts specified. Also the g a.i./ha in the second group should be revised. There are some errors. In the cases of Lettuce, Mash, Tomato and Endive, the number min and max of application is different (4 to 6) to the other uses, and because of that, the total rate should be changed. In the summary of intended uses (GAP table) some units should be corrected. In "total rate" columns it should say "g a.i./ha min max (g/ha)"	Corrected All cases align on lecithins density Total rate in kg/ha	The heading of the GAP table of the updated submission for 'Total rate' is still misleading as it is containing two units: kg a.s./ha and g/ha. The correct unit should be kg a.s./ha
3(3)		DE: No specific data were provided which allow the detailed description of GAPs.	Neben der Wahl resistenter Sorten kann bei ersten Befallssymptomen Lecithins oder Netzschwefel eingesetzt werden. Aufgrund des späten Erscheinens ist die Bekämpfung des Echten Mehltaus im Freiland in der Regel nicht notwendig(1). (Siehe auch: Zugelassene Pflanzenschutzmittel - Auswahl für den ökologischen Landbau) *[Marlies Schnabel]*	Addressed: A GAP table is available.

3.3. Summary of intended uses				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			Rupp, J.; Marx, P.; Gärber, U., 2011: Anbauleitfaden "Gurken im Ökologischen Landbau", 2011, 22. S.	
3(4)	3.3 Summary of intended uses, p. 13	EFSA: in the 'Total rate' column of the GAP table there are two units kg/ha and g/ha. Which one is the correct unit? The apllication might be more than 6 tons/ha?	Corrected Total rate in kg/ha nothing above 9 kg/ha/year	Addressed: See also comment 3(2)
3(5)	3.3 Summary of intended uses, p. 12	EFSA: in Misato et al. the effectiveness was shown at a concentration of 2000 µg/ml, in the proposed GAP the maximum concentration is 365 µg/ml. Was the efficiency at this concentration also proved?	Corrected Value of 200 g/hl conserved for the corresponding uses.	Addressed: The GAP table was updated to 200 g/hl

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 Follow up response from applicant	Column 4 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	DE: The substance with the CAS number 8002-43-5 should be named "Lecithins" instead of "soja lecithins" according to the ECHA website.	Opposite comment to above demand (chapter §2) to reduce "lecithins" to a specific more define category. At the admissibility check opposite demand was formulated by DGSanco: no specific lecithins. Original Title was "GMO free food grade mechanically extracted lecithins" Don't know what to choose in this case !	See comment 2(2)

5. Impact on Human and Animal Health

5.1. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	Fiume 2001, abstract	NL: on page 15 it is stated "with concentrations up **1050**% were reported for two moisturizing products". Since this is impossible this should probably be up **to 50**%.	We agreed Corrected "up TO 50%"	Addressed
5(2)	General comment	EFSA: no comment. It is agreed Lecithins is a basic substance.	Absolutely no comment	Lecithins fulfil the criteria for definition as a foodstuff.
5(3)	5. Impact on human and animal health	DE: The authorisation of the use of lecithins as additive in Food Additives should be reported more detailed to demonstrate that the exposure due to the intended use as a basic substance for plant protection purposes does not lead to higher exposures than already resulting from the uses regulated. More details of lecithins as food additive are given in the EU database on Food Additives (*https://webgate.ec.europa.eu/sanco_foods/main/index.cfm).*	Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes 11 and HI to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. Refer to pure lecithins; product use in the application is a dilution.	Addressed
5(4)	5. Impact on human and animal health	DE: Toxicological data should be reported covering every endpoint. An evaluation of the toxicity in the regulatory view of uses as food additive should be included. Evaluations performed by the Joint FAO/WHO Expert Committee on Food Additives should also be considered (*http://www.inchem.org/documents/jecfa/jecmono/v05je42.htm*).	Included	Addressed
5(5)	5.1 and 5.5 Impact on human and animal health	DE: The citation of a complete abstract is not useful such as done under 5.1 and 5.5. The		Addressed

5.1. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		content of publications should be reported referring to the topics of the application template. For instance the quote of the reported abstract of Fiume Z. 2001 (5.1) "*In an oral carcinogenicity study, brain neoplasms were found in mice exposed to Lecithins.*" should be discussed in view of the specific criteria laid down in Article 3(4) of Regulation 1107/2009 ("substance of concern").	Added in 5.4 Genotoxicity	

5.2. Toxicokinetics and metabolism in humans				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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

5.3. Acute toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)		NL: it is stated that no information on the LD50 of lecithins has been found in literature. This seems incorrect. In the paper Fiume 2001 (referenced under 5.1) several acute oral toxicity studies are reported showing LD50s in the range of 4.75 g/kg to >16 g/kg.	Corrected Fiume 2001 added	Addressed

5.4. Short–term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	5.4 Short-term toxicity	DE: A more detailed justification needs to be given why this point does not apply (see 5.2).	Soybean Lecithins (E322) is approved as food additive under Commission Regulation (EU) No 231/2012 of 9 March 2012 therefore is fully entitled to regulation (EC) No 178/2002. Basic substance status is therefore is fully validated. If any doubt is created by this application, please ask for removal from foodstuff regulation.	Addressed

5.5. Genotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)		NL: The paper by Fiume 2001 should also be referred to here as it describes several genotoxicity studies.	Fiume 2001 added in 5.4 Genotoxicity (revision 9 numbering)	Addressed

5.6. Long-term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	5.6. Long-term Toxicity	DE: A more detailed justification needs to be given why this point does not apply (see 5.2).	Soybean Lecithins (E322) is approved as food additive under Commission Regulation (EU) No 231/2012 of 9 March 2012 therefore is fully entitled to regulation (EC) No 178/2002. Basic substance status is therefore is fully validated. If any doubt is created by this application, please ask for removal lecithins from foodstuff regulation.	Addressed

5.6. Long-term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(2)		NL: The paper by Fiume 2001 should also be referred to here as it describes several long-term studies.	Fiume 2001 added in 5.5 Long term toxicity (revision 9 numbering)	Addressed

5.7. Reproductive toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	5.7 Reproductive toxicity	DE: A more detailed justification needs to be given why this point does not apply (see 5.2).	Soybean Lecithins (E322) is approved as food additive under Commission Regulation (EU) No 231/2012 of 9 March 2012 therefore is fully entitled to regulation (EC) No 178/2002. Basic substance status is therefore is fully validated. If any doubt is created by this application, please ask for removal lecithins from foodstuff regulation.	Addressed

5.8. Neurotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	5.8 Neurotoxicity	DE: A more detailed justification needs to be given why this point does not apply (see 5.2).	Soybean Lecithins (E322) is approved as food additive under Commission Regulation (EU) No 231/2012 of 9 March 2012 therefore is fully entitled to regulation (EC) No 178/2002. Basic substance status is therefore is fully validated. If any doubt is created by this application, please ask for removal lecithins from foodstuff	Addressed

5.8. Neurotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			regulation.	

5.9. Toxicity studies on metabolites				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	5.9 Toxicity studies on metabolites	DE: A more detailed justification needs to be given why this point does not apply (see 5.2).	idem	Addressed

5.10. Medical Data adverse effects reported in humans				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	Adverse effects reported in humans.	NL: According to the BSA document no reports of adverse effects are described. However, the study by Fuime et al. 2001 describes adverse effects (bronchoconstriction) in asthma patients using inhalers containing lecithins.	Fiume 2001 added in 5.9 Adverse effects (revision 9 numbering)	Addressed

5.11. 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 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

5.12. Additional information related to use as food				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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

5.13. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	5.13 Acceptable daily intake, acute reference dose, acceptable operator exposure level	DE: A more detailed justification needs to be given why this point does not apply (see 5.2).	FAO / WHO Estimation of acceptable daily intake for man I : Not limited.*	Addressed

5.14. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	5.14, p.19	DE: A statement on the risk for operators, workers, bystanders and residents during/after application of lecithins as a fungicide should be given.	Oral Exposure The Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Committee on Food Additives reported in 1972 that it estimated that the average diet provided about 1 to 5 g daily of Led thin (FASEB 1979). Fiume Z. 2001 final Report on the Safety Assessment of lecithins and Hydrogenated lecithins *International Iournal of Toxicology*, 20(Suppl. 1):21-45	Addressed
5(2)		NL: We disagree with the statement that an impact on human health is not applicable. We agree that lecithins seems to be of low	Corrected if possible. Safety of lecithins is proven with centuries of use and consummation, no ADI limit and is recognised as G.R.A.S. (Generally	Addressed Currently there is no harmonised classification by ECHA on lecithins.

5.14. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		toxicity via oral exposure. However, soy lecithins are classified as respiratory irritant by ECHA. Respiratory effects have also been observed in humans (see comment on section 5(10)). In the paper by Fiume 2001 it is concluded that "*the safety of use could not be substantiated in cosmetic products likely to be inhaled*". Since the product is used as a spray application, inhalation exposure is a relevant exposure route which should be addressed. The working document SANCO/10363/2012 rev. 9 also indicates that "*additional risk assessment may be needed due to the specific use in plant protection*".	Recognized As Safe) and FONSI (Finding of No Significant Impact) by USA administration. Soybean Lecithins (E322) is approved as food additive under Commission Regulation (EU) No 231/2012 of 9 March 2012 therefore is fully entitled to regulation (EC) No 178/2002. Basic substance status is therefore is fully validated. If any doubt is created by this application, please ask for removal lecithins from foodstuff regulation.	

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6. Residues

Residues				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(1)		ES: No comments	-	Noted

7. Fate and Behaviour in the environment

Fate and Behaviour in the environment				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)		ES: No comments	-	-
7(2)		NL: the information included in the application coming from a memorandum that is submitted is too brief. It refers to an exemption for labelling as food allergen. In the text there is mentioned that an increase in soybean growing will not result in significant environmental impacts as acknowledged by FDA. There is no further information on levels in the environment.	Lecithins is contained in most, if not all, vegetables, plant.	The information provided is insufficient to address fate and behaviour in the environment and characterise environmental exposure.
7(3)		NL: a reference to 8.7 should be included for the readily biodegradability	Conclusion written	The information provided is insufficient to address fate and behaviour in the environment and characterise environmental exposure. EFSA scrutinised the Danhong et al reference in the dossier referred to in section 8.7. The information presented is inadequate in quality compared to that which is usually expected to support a regulatory assessment. The identity / specification of the lecithins tested is unclear. The paper is not published in a peer reviewed journal. The experimental procedures employed are not transparently described. It is acknowledged that the results presented (using a not well described methodology for test material of unknown specification) do appear to indicate that whatever was tested was biodegradable by sewage sludge

Fate and Behaviour in the environment				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
				organisms.
7(4)		NL: there is no assessment on the impact of the proposed use on the environment compared to uses from other sources. This may as well be very low but at the moment such evaluation/information is missing. The working document SANCO/10363/2012 rev. 9 also indicates that "*additional risk assessment may be needed due to the specific use in plant protection*". NL would like to see a kind of assessment included for the specific uses.	Lecithins is contained in most, if not all, vegetables, plant.	The information provided is insufficient to address fate and behaviour in the environment and characterise environmental exposure.
7(5)	7 Fate and behaviour in the environment, page 20	EFSA: Statements on health and safety data sheets are not usually considered sufficient evidence to support a regulatory assessment. At the very least reports of the experiments from which the cited ready biodegradability results originate would normally be made available. No information / assessment of the mobility of lecithins in soil is presented. Estimations of concentrations in soil or natural surface water systems consequent to the uses proposed are not presented.	Lecithins is contained in most, if not all, vegetables, plant.	The information provided is insufficient to address fate and behaviour in the environment and characterise environmental exposure. See also comment 7(3).

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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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		NL: no specific comments	-	Noted
8(2)		ES: No comments	-	Noted

8.2. Effects on aquatic organisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		ES: No comments	-	Noted
8(2)		NL: no comments	-	Noted
8(3)		DE: The conclusion that lecithins has rather a positive than a negative impact on aquatic organisms seems to be acceptable based on the available information. However, from our point of view the statement that lecithins is required for maximum performance should be deleted as this refers to strongly anthropogenic influenced aquacultures which are not the focus of the assessment.	Lecithins used in Organic Aquatic farming is NEEDDED from external input, at least for juveniles. Comment was lightened on lecithins effect.	Addressed

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		ES: No comments	-	Noted
8(2)		NL: no specific comments	-	Noted
8(3)		DE: No information has been provided by the	Arthropods are also parasites of soybean plant	Addressed

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		applicant with regard to effects on arthropods. It has not been reasoned that the substance is harmless for other arthropods. This has to be considered especially because of the potential insecticidal effect of lecithins.	containing lecithins.	No specific information was provided to address the risk to non-target arthropods. Only evidence was provided that lecithins is used as bee food product. Considering the nature of the active substance, no further information is necessary. The intended uses are as a fungicide.
8(4)		DE: No data were submitted for the assessment of the product with regard to risk for bees.	Lecithins is a bee food product United States Patent C) BEE FOOD COMPOSITION Edmond G. Feo, Van Nuys, Edward D. Feldman, Hollywood, and Harry M. Goetz, Los Angeles, Calif., assignors to Atlas Laboratories, Inc., Hollywood, Calif., a corporation of California No Drawing. Application February-28, 1957 Serial No.-642,958	Addressed
8(5)		DE: No experimental reports were submitted from which information about effects on beneficial organisms can be derived.	Lecithins is present everywhere in all plants.	Addressed See 8(3)

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		ES: No comments	-	Noted
8(2)		NL: no comments	-	Noted
8(3)	"No negative effects are determined"	DE: Based on references submitted to effects on the aquatic worm *Lumbriculus* variegates,		Data on *Lumbriculus variegates* cannot be considered relevant to address the risk for

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		the conclusion "no negative effects are determined" (i.e. on earthworms and other soil microorganisms) is very probable. But, robust experimental studies carried out with relevant soil macroorganisms (e.g. the standard test earthworm *Eisenia fetida*) were not submitted and would be helpful for the assessment of sustainability in the integrated pest management.		soil macro-organisms. However, considering the nature of the active substance, no further information is necessary.

8.5. Effects on soil microorganisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		ES: No comments	-	Noted
8(2)		NL: no comments	-	Noted
8(3)		DE: No information has been provided by the applicant with regard to effects of the described enhanced bacterial activity on the overall soil system.	Bacteria use lecithins as substrate. MENKINA, R. A. 1950 Bacteria which mineralize organic phosphorus compounds. Mikrobiologiya Vol. 19 pp. 308-316 Abstract A new strain, *B. megatherium phosphaticum* and a new variety, *Serratia* var. *phosphaticum* were isolated from soil cultures. They form inorganic P compounds from lecithins, nucleic acids, etc. Of two sporogenic forms, one was more specific to lecithins, the other to nucleic acids. A nonsporogenic form acted strongly on lecithins, feebly on nucleic acids. These organisms by	Addressed Evidence was provided to show that lecithins is used as a substrate to enhance bacterial activity.

8.5. Effects on soil microorganisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			liberating inorganic P from organic compounds, promote normal plant growth.	

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		ES: No comments	-	Noted
8(2)		NL: no specific comments	-	Noted

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		ES: No comments	-	Noted
8(2)		NL: no comments	-	Noted

8.8. Other comments				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		NL: there is no specific assessment on the impact of the proposed use on non target organisms compared to non pesticide uses from other sources. This may as well be very low but at the moment such evaluation/information is missing.	-	Noted A specific assessment, including exposure characterisation, on the impact to non-target organisms following the representative uses of lecithins as a

8.8. Other comments				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		The working document SANCO/10363/2012 rev. 9 also indicates that "*additional risk assessment may be needed due to the specific use in plant protection*". NL would like to see a kind of assessment/argumentation included for the specific uses as a plant protection product		fungicide, was not provided. However, considering the nature of the active substance, no further information is necessary.

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9(1)		ES: No comments	-	Noted.
9(2)	9. Overall conclusion, p. 22	EFSA agrees that the criteria described in Article 23 1. (a), (b), (c) and (d) of Regulation (EC) No. 1107/2009 are fulfilled.	-	The criteria described in Article 23 1. (a), (b), (c) and (d) of Regulation (EC) No. 1107/2009 are fulfilled for lecithins.
9(3)	9. Overall conclusion, p.22	EFSA agrees that lecithins as described in COMMISSION REGULATION (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (22.3.2012 Official Journal of the European Union L 83/1), as proposed in this submission fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002 and can be considered as a basic substance.	-	Lecithins as described in Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council, as proposed in this submission fulfils the criteria of a 'foodstuff' as defined in Article 2 of Regulation (EC) No 178/2002[5] and can be considered as a basic substance.

[5] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. (OJ L 31, 1.2.2002, p. 24).

10. Other comments

Other comments				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
10(1)		ES: No comments	-	Noted.

ABBREVIATIONS

µg	microgram
DG SANCO	European Commission Directorate General Health and Consumers
ECHA	European Chemical Agency
EFSA	European Food Safety Authority
EU	European Union
g	gram
GAP	good agricultural practice
GMO	genetically modified organism
ha	hectare
hL	hectolitre
kg	kilogram
L	litre
LD_{50}	lethal dose, median; dosis letalis media
mL	millilitre