Hydrolysed proteins

DOCUMENT A

STATEMENT OF THE CONTEXT

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A 1. Introduction (BIO)

This dossier is presented for the renewal of approval of the active substance "Hydrolysed proteins", which was included on Annex I of Directive 91/414/EEC on 1 December 2009 under Inclusion Directive 2009/153/EC.

The active substance Hydrolysed proteins is one of the 295 substances of the fourth stage of the review programme covered by Commission Regulation (EC) No 2229/2004, as amended by Commission Regulation (EC) No 1095/2007, belonging to the Group 2 – low-risk substances. Substances included in Group 2 are presumed to be low-risk substances. They have been identified based on input from the EU low-risk expert group.

For its authorisation, in accordance with the provisions of Article 4 in Regulation (EC) No 1112/2002, three applicants notified to the Commission of their wish to secure the inclusion of the active substance Hydrolysed proteins in Annex I to the Directive 91/414/EEC.

The three applicants for the active substance under the general category term "Hydrolysed proteins", were:

A) BIOIBERICA, S.A. (Ref. Code:BIO)

B) "PHYTOPHYL"-N.G.STAVRAKIS (Ref. Code:PHY)

C) SICIT 2000 S.p.A. (Ref. Code:SIC)

Each applicant notified for the active substance under the general category term "Hydrolysed proteins" but presented the term for his active substance indicating the origin of his active substance and the source of starting material, each term is:

A. Animal tissue Hydrolysate (Ref. Code:BIO)

B. Beet molasses-Urea Hydrolysate (Ref. Code:PHY)

C. Collagen Protein Hydrolysate (Ref. Code:SIC)

The representative plant protection products are three:

a. BIOCEBO of BIOIBERICA S.A.

b. ENTOMELA 50SL of "PHYTOPHYL"- N.G.STAVRAKIS and

c. NUTREL of SICIT 2000 S.p.A.

In Annex I to Regulation (EC) No 2229/2004 the Commission designated Greece as rapporteur Member State to carry out the assessment of hydrolysed proteins on the basis of the dossiers submitted by the notifiers. In Article 12 of Regulation (EC) No 2229/2004 the Commission specified furthermore that the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required, as well as for other parties with regard to further technical and scientific information was 30 June 2005.

Bioiberica SA, Phytophyl N.G. Stavrakis and SICIT 2000 submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses.

In accordance with the provisions of Article 21(1) of Regulation (EC) No 2229/2004, Greece submitted in April 2008 to the EFSA the draft assessment report (DAR), including, as required, a recommendation concerning the possible inclusion of hydrolysed proteins in Annex I to the Directive.

The overall conclusion from DAR, the recommendations by the rapporteur Member State and the result of the examination in accordance with the provisions of Article 24a of Regulation 2229/2004 is that there are clear indications that it may be expected that hydrolysed proteins does not have any harmful effects on human or animal health or on groundwater or any unacceptable influence on the environment, as set out in Annex VI of regulation (EC) 2229/2004 as last amended by Regulation (EC) 1095/2007.

Finally, Hydrolysed proteins were included on Annex I of Directive 91/414/EEC on 1 December 2009 under Inclusion Directive 2009/153/EC, having data protection for 10 years starting Nov 30th, 2009.

In compliance with the provisions of Article 25a of Regulation (EC) No 2229/2004, EFSA delivered its conclusions on hydrolysed proteins on 16 December 2011. The Commission referred on 01 June 2012 an updated review report to the Standing Committee on the Food Chain and Animal Health SANCO/2615/08 rev 4 – 1/6/2012.

As stated in the EFSA conclusions, hydrolysed proteins per se are likely to be of low toxicological concern provided hydrolysed proteins of animal origin are pathogen-free and hydrolysed proteins from plant origin do not have sensitisation potential.

These indications were however subject to compliance with the particular requirements, the most important endpoints were identified during the re-evaluation process and some data gaps were notified. These endpoints are listed in the EFSA Conclusions:

(a) the specifications of the technical material, as commercially manufactured, supported by appropriate analytical data;

(b) the risk to aquatic organisms.

The three applicants provided the requested information, which was reported in the Regulation (EU) No 571/2012 as regards the conditions of approval of the active substances aluminium silicate, hydrolysed proteins and 1,4-diaminobutane (putrescine).

Directive 91/414/EEC was repealed by the Regulation (EC) No 1107/2009, and the active substance Hydrolysed proteins also complied with the Regulation (EU) No 540/2011, implementing Regulation (EC) No 1107/2009 regarding the list of approved active substances, which was amended by the Regulation (EU) No 571/2012 as regards the conditions of approval of the active substances aluminium silicate, hydrolysed proteins and 1,4-diaminobutane (putrescine).

This dossier is presented for the renewal of approval of the active substance Hydrolysed proteins. All the data provided since the authorisation of the active substance has been included, comprehending the active substance itself but also the three PPPs presented.

To do so, the following regulations and guidance documents have been followed:

- Greece 2008. Draft Assessment Report (DAR) on the active substance hydrolysed proteins. Prepared by the rapporteur Member State Greece in the framework of Directive 91/414/EEC, April 2008.

- Greece, 2011. Final Addendum to Draft Assessment Report on hydrolysed proteins, compiled by EFSA, June 2011.

- EFSA (European Food Safety Authority), 2011. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance hydrolysed proteins.

- European Commission, 2012. Review Report for the active substance hydrolysed proteins finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 28 October 2008 in view of the inclusion of hydrolysed proteins. in Annex I of Directive 91/414/EEC. SANCO/2615/08 – rev 04, 1 June 2012

- 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

- Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

- European Commission, 2014. Guidance Document on the renewal or approval or active substances to be assessed in compliance with Regulation (EU) Nº 844/2012 (the Renewal Regulation). SANCO/2012/11521 – rev 04, 12 December 2014

- European Commission, 2014. Guidance document for applicants on preparing dossiers for the approval of a chemical new active substance and for the renewal of approval of a chemical active substance according to Regulation (EU) no 283/2013 and Regulation (EU) no 284/2013. SANCO/10181/2013– rev. 3, 12 December 2014

The Inclusion Directive for Hydrolysed proteins (Directive 2009/153/EC) authorised the Hydrolysed proteins as attractant. The Hydrolysed proteins of animal origin, as is the case, comply with the requirements of Regulation (CE) 1069/2009 on animal by-products not fit for human consumption as stated in the Standing Committee on the Food Chain and Animal Health on 03/10/2009 (SANCO/2615/08 rev 4) report.

The Annex I Inclusion Directive for Hydrolysed proteins (2009/153/EC) provides specific provisions under Part B which were considered by the applicant in the preparation of their submission for the final Plant Protection Products to the Member States.

For the implementation of the Uniform Principles of Annex VI, the conclusions of the review report on the Hydrolysed proteins, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 03/10/2009 (SANCO/2615/08 - rev 3) were taken into account.

The dossier was performed following the indications and template documents of the guidance document SANCO/10181/2013-rev.3:

1) Document A – Statement on the context (cd-filename: DOCUMENT A Hydrolysed proteins.doc).

2) Document B - Documentation relating to the joint submission of dossiers.

3) Document C – Existing labels (cd-filename: DOCUMENT C Hydrolysed proteins.doc).

4) Document D – Registered and intended uses information (cd-filename: DOCUMENT D Hydrolysed proteins.doc)

5) Document F – Notification submitted to the Commission (cd-filename: DOCUMENT F Hydrolysed proteins.doc)

6) Document H – Safety data sheets for the formulants (cd-filename: DOCUMENT H Hydrolysed proteins.doc)

7) Document J – Confidential data and information (cd-filename: DOCUMENT J Hydrolysed proteins.doc). Three document J for each applicant's confidential data submitted. These documents will be separately submitted by each applicant.

8) MCA Section 1 – Identity of the active substance (cd-filename: DOCUMENT M-CA, Section 1.doc)

9) MCA Section 2 – Physical and chemical properties of the active substance (cd-filename: DOCUMENT M-CA, Section 2.doc)

10) MCA Section 3 – Further information on the active substance (cd-filename: DOCUMENT M-CA, Section 3.doc)

11) MCA Section 4 – Analytical methods (cd-filename: DOCUMENT M-CA, Section 4.doc)

12) MCA Section 5 – Toxicological and metabolism studies on the active substance (cd-filename: DOCUMENT M-CA, Section 5.doc)

13) MCA Section 6 – Residues in or treated products, food and feed and plant metabolism (cd-filename: DOCUMENT M-CA, Section 6.doc)

14) MCA Section 7 – Fate and behaviour in the environment (cd-filename: DOCUMENT M-CA, Section 7.doc)

15) MCA Section 8 – Ecotoxicological studies on the active substance (cd-filename: DOCUMENT M-CA, Section 8.doc)

16) MCA Section 9 – Literature data (cd-filename: DOCUMENT M-CA, Section 9.doc)

17) MCA Section 10 – Classification and labelling of the active substance (cd-filename: DOCUMENT M-CA, Section 10.doc)

18) MCP Section 1 – Identity of the plant protection product (cd-filename: DOCUMENT M-CP, Section 1.doc)

19) MCP Section 2 – Physical and chemical properties of the plant protection product (cd-filename: DOCUMENT M-CP, Section 2.doc)

20) MCP Section 3 – Data on application (cd-filename: DOCUMENT M-CP, Section 3.doc)

21) MCP Section 4 – Further information on the plant protection product (cd-filename: DOCUMENT M-CP, Section 4.doc)

22) MCP Section 5 – Analytical methods (cd-filename: DOCUMENT M-CP, Section 5.doc)

23) MCP Section 7 – Toxicological studies on the plant protection product (cd-filename: DOCUMENT M-CP, Section 7.doc)

24) MCP Section 8 – Residues in or on treated products, food or feed (cd-filename: DOCUMENT M-CP, Section 8.doc)

25) MCP Section 9 – Fate and behaviour in the environment (cd-filename: DOCUMENT M-CP, Section 9.doc)

26) MCP Section 10 – Ecotoxicological studies in the environment (cd-filename: DOCUMENT M-CP, Section 10.doc)

27) MCP Section 11 – Literature data (cd-filename: DOCUMENT M-CP, Section 11.doc)

28) MCP Section 12 – Classification and labelling of the plant protection product (cd-filename: DOCUMENT M-CP, Section 12.doc)

29) LC-A Sections 1-10 (References lists)

30) LC-P Sections 1-12 (References lists)

31) OC-A documents

32) OC-P documents

33) N2 documents (Endpoints)

A 2. Statement of context

A.1.1 STATEMENT OF THE CONTEXT BY BIOIBERICA (BIO)

BIOIBERICA, S.A., as manufacturer of hydrolysed proteins used in plant protection products in Spain, notified to the Biologische Bundesanstalt für Land und Forstwirtschaft (RENDER 4) its interest in securing the inclusion of hydrolysed proteins in Annex I of Directive 91/414/EEC and its undertaking to submit all the required information for a proper evaluation of this active substance.

The list of uses supported in the appendix II of the Standing Committee on the Food Chain and Animal Health SANCO/2615/08 rev 4 comprehends the following crops and pests: Fruit trees, Citrus and olive trees to control the pests of Diptera insects; such as *Ceratitis capitata*, *Rhagoletis cerasi* and *Bactrocera olea*, among others.

Hydrolysed proteins were included on Annex I of Directive 91/414/EEC on 1 December 2009, from then three Plant Protection Products have been authorised in Spain containing the active substance Hydrolysed proteins: BIOCEBO (num. 22270), FLYRAL (num. 24630) and CERA TRAP (num. 24937) according to Uniform Principles of Annex VI to Directive 91/414/EEC. The conclusions of the review report on the Hydrolysed Proteins, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 03/10/2009 (SANCO/2615/08 - rev 3) were taken into account.

These three PPPs have been used extensively in our country to control these pests. BIOCEBO and FLYRAL are mixed with an insecticide, where the attractant power over the plague increases the efficacy of the insecticide itself, while CERA TRAP is placed inside a trap, the formulation attracts by its characteristic odour the flies, which get inside the trap and cannot escape. They die by drowning in the liquid. The traps hang on the branches of the fruit trees. Because of this, there is no contact between the liquid attractant inside the trap and the plant or their fruits.

Either both kind of formulations, based on Hydrolysed Proteins, are devoid of toxicity. For the authorisation of these PPPs, BIOIBERICA S.A. performed several acute toxicity tests. The results of toxicity studies provide confidence in that these formulations are safe and pose no risk of toxicity, dermal or ocular irritation, or inhalation and that they would not produce harmful effects on humans, other living organisms (flora and fauna) and the environment.

For the initial dossier of active substance approval, BIOIBERICA presented the results of one PPP; BIOCEBO. For the present dossier of active substance renewal we therefore provide data related only to this PPP.

BIOCEBO was re-evaluated recently by Spanish Authorities for the implementation of the Uniform Principles of Annex VI. Due to this, new data of BIOCEBO has been provided in this dossier, which also fulfils the data gaps reported for BIOCEBO in EFSA Peer Review Report.

BIOIBERICA, S.A. changed its official and registered corporate name due to the assumption of a sole shareholder company status. From January 2017, BIOBERICA S.A. has been named BIOIBERICA S.A.U.

A 1.2 STATEMENT OF THE CONTEXT BY PHYTOPHYL (PHY)

Phytophyl as manufacturer of Hydrolysed protein of plant origin (beet molasses) is seeking with this dossier the renewal of approval of the active substance Hydrolysed Protein, which was included on Annex I of Directive 91/414/EEC on 1 December 2009 under Inclusion Directive 2009/153/EC.

Hydrolysed protein and in our case beet molasses - urea hydrolysates are used for more than 30 years in Greece as attractants for the control of Bactrocera oleae.

Phytophyl notified hydrolysed proteins and urea for inclusion in Annex I of Directive 91/414/EEC, in accordance with the provisions of Article 4 in Regulation (EC) No 1112/2002.

Both were included on Annex I of Directive 91/414/EEC on 1 December 2009 under Inclusion Directive 2009/153/EC and having data protection for 10 years starting Nov 30th, 2009.

During last four years two PPPs “ENTOMELA 50SL” and “ENTOMELA 75SL” are registered in Greece, Spain, Cyprus and Portugal as insect attractants for B. Oleae according to Regulation (EC) No 1107/2009.

In this dossier we are presenting:

1) All the data submited during the first inclusion of hydrolysed protein inclusion in Annex I of Directive 91/414/EEC.

2) The confirmatory data given for the specifications of the technical material of hydrolysed protein according to EC regulation 571/2012.

3) The confirmatory data given for the risk to aquatics from hydrolysed proteins according to EC regulation 571/2012.

4) All the data submitted for the last authorization in Greece for ENTOMELA 50SL which will be the representative PPP product in this dossier.

5) An open literature review for Hydrolysed protein in accordance with the EFSA guidance document “Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009“.

6) All new data we have in our knowledge to support this renewal of Beet Molasses urea Hydrolysate under the generic term of Hydrolysed protein.

A 1.3. STATEMENT OF THE CONTEXT BY SICIT

The hydrolysed protein manufactured by SICIt 2000 is obtained from "hides and skins", i.e. materials classified as category 3 animal by-products (ABP) not intended for human consumption, in accordance with art. 10 of the Regulation (EC) 1069/2009 of 21st October 2009 and therefore it's exempt from any risk of BSE/TSE contamination and transmission. In fact, this material comes from countries with negligible or controlled BSE risk, listed in the EU Commission Implementing Decision of 20th October 2014, amending the Decision 2007/453 / EC and Reg. (EC) 999/2001). In any case, the use of material coming from animals dead for disease and in any case of all the category 1 materials (high disease risk materials) is strictly forbidden.

The cat. 3 ABP is treated in SICIT 2000 manufacturing plant located in Via del Lavoro 114 – 36071 Arzignano (VI) Italy, officially authorized by the Giunta Regionale del Veneto (Veneto Regional Council) according to the Reg. CE 1069/2009 and registered in the national list with the identification number ABP 333 PROCP3 (Category 3 processing plant for hydrolysed protein), decree no. 066 dated July 23rd, 2014.

During the manufacturing process, the cat. 3 ABP is submitted to extreme conditions of pH, temperature and pressure (140°C, for 30 minutes and at more than 3,6 bar abs), as provided by the Reg. 142/2011/EC, Annex X, Chapter II, Section 5, Point D, which establishes the treatments for "animal feed".

Therefore:

a) The raw material is of natural origin and is free from any risk of BSE / TSE contamination, as clearly shown by studies carried out by Dr. Robert A. Somerville, Institute of Animal Health, University of Edinburgh (Report to SICIT 2000 S.p.A. on experiments performed at NPU to test the reduction of TSE infectivity during the processing of "fleshings", 2003) and by Dr. David M. Taylor PhD MBE, SEDECON 2000, Edinburgh (A BSE-related risk assessment carried out on behalf of SICIT 2000 S.p.A. regarding hydrolysed proteins that are manufactured from bovine hides, January 2004)
b) The manufacturing process of hydrolysed protein provides a treatment capable of sanitizing the product
c) The formulated product (NUTREL) obtained from hydrolyzed protein consists essentially of a mixture of amino acids and peptides and it does not contain particular impurities or contaminants
d) The formulated product (NUTREL) is suitable for use as feed for farm animals, including ruminants and also as special fertilizer (crop bio stimulant)

Therefore the hydrolyzed protein manufactured by SICIT is a toxicologically safe product, non-toxic, non-harmful, does not require a period of deficiency before harvesting agricultural products.

Concerning the REACH (Reg. (EC) N. 1907/2006), hydrolysed protein manufactured by SICIT 2000 can be defined as a natural polymer, meeting the criteria of the art. 3(5) of the REACH Regulation and therefore the provisions relative to the REACH Regulation contained in the titles

II (registration of substances) and VI (Evaluation) shall not be applied according to the art. 2(9) of the REACH Regulation.

Registration and hystory of the hydrolysed product (SICIT)

- Hydrolysed protein is fit for the use as “Attractant, only in authorized applications in combination with other appropriate products” in organic farming, according to the Reg. (CE) N. 889/2008, Annex II, Pesticides
- 29/10/2002 - Notification of an active substance according to art. 4 and art. 5(2)(a) of Commission Reg. (EC) N. 1112/2002
- 22/11/2002 – Registration in Italy of the phytosanitary product NUTREL, based on hydrolysed protein, (Registration N. 11502 of 22/11/2002)
- 28/10/2008 – Review report for the active substance “Hydrolysed proteins” finalized in the Standing Committee on the Food Chain and Animal Health, in view of the inclusion of hydrolysed proteins in Annex I of Dir. 91/414/EC
- 18/12/2008 - Inclusion of the active substance “hydrolysed protein” in the Commission Directive 2008/127/EC (Annex, active substance N. 240), amending Dir. 91/414/EC
- 2013 – Registration of the formulated product “Nutrel” in Italy
- 15/05/2017 – Re-registration in Italy of the phytosanitary product NUTREL, based on hydrolysed protein, based on the dossier SIC378SL (Annex III), according to the Reg. (EC) N. 546/2011

Nowadays, hydrolyzed proteins are utilized in various countries of the Mediterranean area :

- Italy: Registration under the trademark NUTREL, N. 11502 of 22/11/2002, renovated in 2017 (dossier SIC378SL, Annex III)
- Spain: registration under the trademark NUTREL, N. 24.484 of 2006, currently under renovation
- Algeria: registration under the trademark NUTREL, N. 16 56 036 of 23/11/2016
- Cyprus: registration under the trademark NUTREL, N. 2655 of 18/05/2007
- Egypt: registration under the trademark NUTREL, data not available

In this dossier all the data available on the plant protection product NUTREL containing the existing active substance hydrolysed proteins was presented to support the application for the renewal ofapproval of the active substance “Hydrolysed proteins”, included on Annex I of Directive 91/414/EEC.