CHEMI S.P.A - PHOSPHOLIPASE D

DOCUMENT 3

PUBLIC SUMMARY

Application for the Authorisation of the food enzyme

Phospholipase D
derived from
Streptomyces netropsis

submitted pursuant to

Regulation (EC) No 1332/2008 of the European Parliament
and of the Council of 16 December 2008
on food enzymes

prepared by: RDA Scientific Consultants GmbH
Dachauer Straße 4
80335 München
Germany

on behalf of: Chemi S.p.A.
Via Vadisi 5
03010 Patrica (Fr)
Italy

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Chemi S.p.A., producer inter alia of ingredients for food supplements and functional foods, applies for authorization of a food enzyme under EU-law. According to Food Enzyme Regulation (EC) No. 1332/2008, an approval is necessary for putting food enzymes on the market as such and using them in foods. The European Commission will set up a Union list including all authorized enzymes. Currently, applications for food enzymes are collected and assessed for safety by the European Food Safety Authority (in brief: EFSA).

The present application refers to the food enzyme Phospholipase D (PLD) derived from *Streptomyces netropsi*s. A certain class of substances, namely modified phospholipids such as phosphatidylserine, is or will be produced by an enzymatic process exploiting the catalytic activity of this enzyme. The applicant does not commercialize the food enzyme but produces a respective preparation in collaboration with a contract manufacturer for its own in-house use.

The enzyme is a so-called processing aid that is used in the production of the food ingredient but is thoroughly removed once the reaction has been stopped. However, technically unavoidable residues may remain in the final foodstuff requiring a risk assessment.

In the present application, all necessary data has been compiled that shall enable EFSA to perform its risk assessment. The enzyme preparation has been subjected to various analyses to describe its composition, the amount of possible contaminants and impurities resulting from the production process. Special emphasis has been laid on the verification that the enzyme has been successfully removed. In the end, if any, only negligible traces could be found.

Under certain production conditions, representatives of the species of the production organism may build undesired antimicrobials. This is not the case for the enzyme production process chosen by the applicant. The absence of antimicrobial activity has been shown for the intermediate fermentation broth as well as for the final enzyme preparation.

Chemi S.p.A. exploits the high specificity of the Phospholipase D to transform natural phospholipids into distinct modified phospholipids of high purity, e.g. the well-known ingredient phosphatidylserine may be produced from soy or egg lecithin.

The toxicological assessment addresses the fact that the food enzyme, formulation ingredients and possible impurities are removed in a multi-stage purification process. This procedure is not possible in conventional food processing but in the production of a distinct food ingredient. Taking into account the circumstances of the manufacturing and purification processes, the analysis results and the restricted exposure of consumers to this kind of ingredients, the omission of the toxicological dataset generally required for this kind of food enzymes is justified.

In conclusion, neither the source of the food enzyme nor its composition nor use represent a risk for the consumer. Expected amounts of residual substances have been shown to be negligible in this particular case of enzyme use. Additionally, phosphatidyserine that was produced by Chemi with the proprietary enzyme preparation applied for, already has been used within the European Union (marketed under the brand name SerinAid®) in food supplements for many years without reported adverse effects. This assessment could have been reached without the required toxicological studies. We therefore conclude that Chemi´s Phospholipase D derived from *Streptomyces netropsis* is a safe food enzyme according to article 6(a) of Regulation (EU) No. 1332/2008.