EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C2 - Management of scientific committees; scientific co-operation and networks

OPINION OF THE SCIENTIFIC COMMITTEE ON ANIMAL NUTRITION ON THE SAFETY OF PRODUCT EMULBESTO 3000®

(Adopted on 18 October 2002)

1. BACKGROUND

The product Emulbesto 3000®, acetylated hydrolyzed lecithin, is intended for the use as feed additive. It is composed of lyso-form of N-acetyl-phosphatidylethanolamine and is intended for use for veal calves. The Commission received a request for provisional Community authorisation of this product.

The company producing Emulbesto 3000® prepared a dossier that has been submitted through the national rapporteur (France) to the Commission. The dossier was checked by the Member States for its compliance with the requirements of Council Directive 87/153/EEC fixing guidelines for the assessment of additives in animal nutrition. The Member States concluded in the Standing Committee of Animal Nutrition on 27 April 2001 that the dossier fulfilled these requirements.

The authorisation procedure laid down in article 4 of Council Directive 70/524/EEC as last amended by Council Directive 96/51/EC includes a period of 320 days for the evaluation of the dossier submitted to the Commission. The Standing Committee of Animal Nutrition started the evaluation of the product on 27 April 2001.

2. TERMS OF REFERENCE

The Scientific Committee for Animal Nutrition (SCAN) is requested to advise the Commission on the safety of the use of acetylated hydrolyzed lecithin for the target animal, the user, the consumer and for the environment.

3. PRODUCT

Lecithins are mixtures of phospholipids, glycolipids, triglycerides and related compounds obtained by physical procedures from animal or vegetable foodstuffs. Lecithin also comprises hydrolysed products (lyso-forms of phosphatides) through the use of appropriate enzymes.

Emulbesto 3000® is the trade name for acetylated hydrolysed lecithin and is prepared by a succession of chemical treatments of food grade soybean lecithin E 322.

The average composition is 36 % phospholipids, 30 % triglycerides, 15 % glycolipids, 5 % carbohydrates, 2 % diglycerides and 12 % free fatty acids. Water is max. 1.2 %. Toluene insoluble matter (impurities) is given with <0.65 %.

Informations are also given on acid value, viscosity, and heavy metals (arsenic ≤ 3 mg/kg, lead ≤ 5 mg/kg, mercury ≤ 1 mg/kg and total heavy metals expressed as Pb ≤ 10mg/kg.

Emulbesto 3000® is liquid, dispersible in water and soluble in fat and oil.

Data on the fatty acid pattern (product and free fatty acids) are not presented.

4. MANUFACTURING PROCESS

Phosphatidylethanolamine (PE) is one of the major constituents of lecithine. It has a free amino group which is to about 2 to 7% coupled with a fatty acid by an amide bound. These naturally occurring phosphatidylethanolamines (PE) are called N-acyl-PE (APE). By the technical process, the fatty acid in the amide bound is replaced by a definite short chain fatty acid (acetate) and the degree of PE with an amide bound is increased. By acetylation, the amount of APE (as N-acetyl-PE) in lecithins increases to 60 % of PE. Like food grade lecithins, Emulbesto 3000® is enzymatically hydrolyzed (mainly in the C2-position of glycerol) forming the lyso-form of APE and other phospholipids and increasing the hydrophilic properties of the emulsifier.

The process consists of the following steps:

- Addition of food grade acetic acid anhydride to produce N-acetyl phosphatidyl ethanolamine (APE) for hydrolysis.
- Neutralisation with potassium hydroxide,
- Adding calcium chloride plus enzyme for hydrolysis,
- Disinfection with H_2O_2 (0.1%),
- Drying to 1.2 % H_2O and keeping under liquid form.

Table 1 informs on the shift of PE to APE and its lyso-form (LPE) due to the manufacturing process.

Table 1: Main Phospholipids in Lecithin E 322, the acetylated product and the acetylated and hydrolyzed product (Emulbesto 3000) [Mol-%]

	E 322	Acetylated	Emulbesto 3000®
Phosphatidylcholine (PC)	34.62	33.24	13.65
Phosphaditylinositol (PI)	17.60	16.74	9.15
Lyso-Phosphaditylinositol (LPI)	3.10	2.78	7.06
Phosphatidylethanolamine (PE)	24.83	8.04	3.70
Lyso-Phosphatidylethanolamine (LPE)	1.74	0.65	4.11
N-acyl-Phosphatidylethanolamine (APE)	3.42	20.52	10.30

Emulsifiers are often classified according to the hydrophilic-lipophilic balance (HLB) system, the scale reaching from 1 (highest lipophilic property) to 20 (highest hydrophilic property). The turning point between lipophilic and hydrophilic

emulsifiers lies at a HLB value of 10. Standard lecithin has an HLB of 3, Emulbesto 3000® shows an HLB value of 9.

5. PHOSPHOLIPID COMPOSITION

NMR spectroscopy recognized 9 phospholipids (limit of detection: 0.1 %): phosphatidylcholine¸13.65 mol-%; 1-lyso-phosphatidylcholine 2.15 mol-%; 2-lyso-phosphatidylcholine 14.34 mol-%; glycerophosphatidylcholine 17.04 mol-%; phosphaditylinositol 9.15 mol-%; lyso-phosphaditylinositol 7.06 mol-%; phosphatidylethanolamine 3.70 mol-%; lyso-phosphatidylethanolamine 4.11 mol-%; N-acyl-phosphatidylethanolamine 10.30 mol-%.

6. ANIMAL SAFETY

The minimum and maximum content of Emulbesto 3000® in milk replacer is given by the company with "quantum satis". This reflects the fact that any recommendation on the quantitative use of an emulsifier depends on the level and kind of dietary lipids as well as the technique applied to incorporate the lipids into the milk replacer and is in practice related to the dietary lipid level (and not the complete feed). Having this in mind SCAN recommends the company to establish minimum and maximum contents.

For further considerations it is assumed that a lecithin-based emulsifier may amount to a maximum 10 % of dietary lipids and that these lipids do not exceed 30 %. This very conservative estimate results in a maximum content of 3 % Emulbesto 3000® in a milk replacer. A comparable lecithin level would also be reached at about 30 % soy oil in a complete feed.

No tolerance data were supplied.

According to two letters in the dossier, indications from trials involving several thousands milk calves seemed to show no differences in the weight gain of calves being fed with milk replacers containing either Emulbesto 3000® or a commercial emulsifier. However, no data are presented.

7. CONSUMERS SAFETY

The only difference between N-acetyl-PE and the naturally occurring N-acyl-PE is the shorter chain length of the N-acyl fatty acid. Therefore, according to the company, N-acetyl-PE and its lyso–form are not to be regarded as unnatural compounds.

SCAN presumes that the N-acetyl-PEs of Emulbesto 3000® are metabolised in the same way as the other N-acyl-PEs of lecithins by the animal and therefore the fate of Emulbesto 3000® is similar to that of natural lecithins. Assuming that this is the case, no residues are to be expected in the products of animals fed feed treated with Emulbesto 3000®.

Based on the above assumptions, it appears unlikely that product Emulbesto 3000® would be of concern for consumers of animal products. However SCAN recommends that these assumptions be supported by experimental data.

8. USER SAFETY

No information has been provided by the company.

9. SAFETY FOR THE ENVIRONMENT

Although no data on environmental safety are supplied by the company, the SCAN assumes that Emulbesto 3000® behaves in the same way as naturally occurring food grade lecithins, being extensively metabolised. Therefore, no risk for the environment is expected and an environmental risk assessment is not considered necessary.

10. CONCLUSION

In general, arguments used in the present dossier are only based on the fact that the product is derived from the chemical treatment of a naturally-occurring material with "GRAS" (generally regarded as safe) status in the United States of America.

No experimental data on the safety of the product for the target animals (veal calves), those handling the product, a modified lecithin, or the human consumers have been provided.

SCAN recognises that lecithin occurs in foods and that isolated lecithin is widely used in human and animal nutrition. However SCAN is reluctant to conclude on the safety of the product without data demonstrating:

- that the metabolic fate of the N-acetylated phospholipids is the same as the naturally occurring acylated counterparts, and
- to what extent animals are able to tolerate an overdose of the product