



EUROPEAN COMMISSION
DIRECTORATE-GENERAL XXIV
CONSUMER POLICY AND CONSUMER HEALTH PROTECTION
Directorate B - Scientific opinions on health matters
Unit B3 - Management of scientific committees II

SCIENTIFIC COMMITTEE ON FOOD

SCF/CS/NF/PHOS/3 Final
17 June 1999

Opinion
on the safety assessment of phospholipds
obtained from egg yolk as food produced using a new process

(adopted on 17/6/99)

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OPINION

ON THE SAFETY ASSESSMENT OF PHOSPHOLIPIDS OBTAINED FROM EGG YOLK AS FOOD PRODUCED USING A NEW PROCESS

(expressed on 17 June 1999)

Terms of reference

With reference to the initial assessment carried out by the Belgian authorities and pursuant to Article 11 of Regulation (EC) 258/97, The Committee is asked to assess the safety, from the point of view of consumer health, of phospholipids obtained from egg yolk as a food/food ingredient produced using a new process.

Background

Within the framework of Regulation (EC) N° 258/97 on novel foods and novel food ingredients a request for authorisation has been received by the Belgian authorities for phospholipids obtained from egg yolk as a food/food ingredient using a new process, including 8 steps of purification and conversion from the raw material egg yolk. The proposed decision in the initial assessment report was to give a favourable opinion on the production process for purification of the phospholipids for 100 % including step 6. Some reservations about the separation and enzymatic conversion at step 7 and 8 as a final phase in the process were expressed, as there has probably been little experience with the proposed enzyme. This step also produces a fundamental change in the structure. A number of member states has reacted to this initial assessment and made a number of remarks and questions.

Introduction

Egg yolk contains a variety of different phospholipids (PL) in an amount proportional to the weight of the yolk. Phosphatidyl choline (PC) (true lecithin from the chemical point of view) is the most abundant PL (around 73 %). Other constituents of egg yolk are phosphatidyl ethanolamine (PE); 15 %, lysophosphatidyl choline (LPC); 6 %, sphingomyelin (SH) 2,5 %, lysophosphatidyl ethanolamine (LPE); 2 %, Plasmalogen (PM); 1 % and phosphatidyl inositol (PI); 0.5 %. The different PLs contain various fatty acids similar to those encountered in the phospholipids of most animal tissues depending

on characteristics of the animal feed. PLs are essential for human metabolism especially for neural development and membrane function. PLs derived from egg yolk have been used for some years in the EC as lecithin (E 322) in infant formulae and follow up formulae. The SCF expressed a positive opinion in 1983 concerning the use of lecithin as an emulsifier in infant formulae foods at a maximum concentration of 5 g/l.

The commercially available PL as a food ingredient for infant formulae is obtained from egg yolk powder by the traditional extraction procedure in organic solvents that ends up with a product of 30 % enriched egg yolk lecithin (PL-30). This phospholipid product can be considered as the traditional reference point for the product obtained by the new process.

Description of the new process

The new selective extraction process includes 8 steps of treatment of egg yolk:

- Step 1 Mechanical separation of egg yolk from fresh eggs
- Step 2 Extraction of the granules by dilution and electrophoresis
- Step 3 Extraction of PL using resin in a polar medium
- Step 4 Concentration of PL using reversed osmosis
- Step 5 Lyophilisation

This procedure produces an intermediate product (PL-85) containing 85 % PL, 10 % triglycerides and 5 % cholesterol as well as traces of minerals and simple sugars.

Further purification includes:

- Step 6 Immersion in polar solvent and selective adsorption.

This leads to a 100 % pure PL fraction (PL-100).

The final two steps in the process are the separation and enzymatic conversion:

- Step 7 Immersion in polar solvent and chromatographic fractionation.
- Step 8 Enzymatic conversion of phosphatidyl choline into synthetic equivalents of certain naturally occurring PL in man, but absent in egg yolk such as phosphatidyl serine (PS), phosphatidyl glycerol (PG) and phosphatidic acid (PA).

Evaluation according to the Novel Food regulatory protocols

These food ingredients are produced using a new process. Therefore the novel food classification is in category: 6 with information requirements accordingly for protocol I, II, III, IX, X, XI, XII and XIII.

Protocol I Specification of the Novel Food

The dossier contains detailed information about the composition of the PL-85 and PL-100 mixtures. The composition of the PL fraction is comparable with the traditionally produced egg yolk PL. Also information about the fatty acid composition of the PL-100 product is given. Contaminants such as heavy metals (Cr; Ni; Pb; Hg; Cd; Cu and Zn) and extraction solvent residues (methanol, ethanol, 2-propanol, hexane and methylethylacetone) are far below authorised maximum levels and not essentially different or better than the lecithin obtained with the traditional method. Microbial contamination is in the first place possible by transfer of bacteria present on the shell during the mechanical extraction of the yolk. This step is not different from the traditional procedure. Analytical data do not reveal any results that do not fulfil the European norms in force.

Protocol II Effects of the production process followed on the NF

This new process which has not been used in the past does not change the composition or structure of the PL until the enzymatic conversion (step 8). Steps 1 - 7 are an improvement on the purification of the PL based on physical principles. This is not the case for the enzymatic conversion where new unique types of PLs are produced such as phosphatidyl serine (PS). This PL is not present in egg yolk.

Protocol III Background information about the organism used for the NF

The egg yolk as raw material is the same as the traditional reference product.

Protocol IX Expected frequency of use of the NF.

It is expected that the use of the preparations PL-85 and PL-100 as a source of PL and long chain fatty acids in formulae food supplements and in enteral and parenteral foods is not different from the traditionally prepared preparations. The products are more purified as PL supplements. The aim is not to replace other food but other ingredients.

Protocol X Information on the basis of previous exposure of human beings to the NF or its source.

The types of PL obtained are present in existing food from animal and plant origin. Taking the EC regulations into consideration concerning the use of lecithin in foods, such as infant formulae, the newly produced food ingredients are considered to be as acceptable as the traditionally produced lecithin. In addition in the dossier information is included about the possibility of traces of egg white which may be important in the case of problems of allergy. Contact hypersensitivity tests did not reveal any form of allergenicity.

Protocol XI Information about the food value of the NF

From the available information including NMR spectra and fatty acid distribution it can be concluded that both the PL-85 and PL-100 have a similar nutritional value per Mol PL compared with the traditionally produced PLs from egg yolk.

The dossier is incomplete regarding information on the structural similarity of the newly produced phospholipids with the naturally available identical PLs in the diet.

Protocol XII Microbiological information about the NF

From the dossier it can be concluded that based on the type of treatment in the new process as well as the microbiological analytical results, the new products are comparable with the traditional obtained reference product and therefore acceptable for human use.

Protocol XIII Toxicological information about the NF

In order to evaluate possible biological risks as a result of the new process, the production steps can be characterised as

- Step 1 Mechanical process;
- Step 2 Dilution and electrophoresis are physical processes
- Step 3 Extraction with a resin from alginate/carragenate esterified in acid medium using isopropanol is a physical process;
- Step 4 Hyperfiltration is a physical process;
- Step 5 Lyophilisation is a physical process;
- Step 6 For the removal of triglycerides and other minor components a silica gel/hexane or aluminium oxide/ethanol system is used. The solvents are removed by lyophilisation;
- Step 7 For chromatography methanol/isopropanol as solvents are used, followed by lyophilisation;
- Step 8 A phospholipase D of vegetable origin (cabbage) is used for the enzymatic conversion to obtain special PS. Other components must be added to this process such as for instance the amino acid serine for the production of PS. The dossier does not give adequate information. Therefore additional information is needed on step 8 of the new process with regard to the different components in the conversion process as well as information about the medium, residues of production components such as the enzymes or by products in order to evaluate the safety aspects.

Discussion

The information in the dossier is complete regarding the first six steps in the new process producing a more purified (85 % or 100 %) phospholipid (lecithin) mixture compared to the traditionally produced 30 % phospholipid mixture from egg yolk.

The different steps have been described properly and the additional required specifications and analysis are available. All steps are well known unit operations in food processing. Only the combination for this purification process is new.

From this part of the dossier it can be concluded that the phospholipids mixtures produced at a high purification level (85 % or 100 %) are comparable in safety to the traditionally obtained PL mixture (30%) from egg yolk.

In terms of novel food legislation it is questionable whether such improvements in the purification process should be considered as leading to a novel food or novel food ingredient. This is not the case for the final step in this new process using enzymatic conversion to produce new types of PL such as PS and PG.

Those PSs claimed to be synthesised in step 8 are naturally present in man, animals and plants. For instance phosphatidyl serine is the most abundant PL in the human brain and has been positively linked to cognitive performance in patients with memory impairment using bovine-PS supplements (Crook et al 1991). However these types of phospholipid are not available in egg yolk. Therefore the produced PLs as a result of step 8 enzymatic conversion can be considered as Novel Food ingredients.

The dossier is incomplete, particular as regards a precise description of the production process, purification, structural similarities of the newly produced PL with existing equivalents from animal/plant and human sources and unwanted residues from the production process or by-products.

Conclusion

It is concluded from the present dossier that the PL-85 and PL-100 obtained from egg yolk using steps 1 – 6 of the new process provide a food ingredient which, compared with that made using the traditional purification process does not lead to safety problems from the point of view of consumer health. For the newly produced types of phospholipids (PS, PG, and PA) which are not present in egg yolk and synthesised by enzymatic conversion (step 8) additional information is needed before a final assessment of their safety as a food ingredient can be given.

References

EU Commission (1997) Regulation 258/97/EC, Official Journal No L 43, 14.2.1997, p1-7.

Crook T., et al. Effects of phosphatidylserine in age-associated memory impairment. *Neurology* 1991, 41: 644- 649.

Initial assessment report prepared by the Belgian Competent Authority, submitted on 24.9.1998.