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Opinion of the Scientific Committee on Food on Citric acid esters of mono- and diglyglycerides (E472c): request for additional uses in foods for special medical purposes for infants and young children

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B-1049 Bruxelles/ Brussel - Belgium
Telephone: direct line (+32-2) 298.46.98 exchange 299.11.11. Fax: (+32-2) 299.48.91
Telex: COMEU B 21877. Telegraphic address: COMEUR Brussels.
http://europa.eu.int/comm/food/fs/sc/scf/index_en.html

OPINION OF THE SCIENTIFIC COMMITTEE ON FOOD ON CITRIC ACID ESTERS OF MONO- AND DIGLYGLYCERIDES (E 472C): REQUEST FOR ADDITIONAL USES IN FOODS FOR SPECIAL MEDICAL PURPOSES FOR INFANTS AND YOUNG CHILDREN

Terms of reference

E 472c citric acid esters of mono- and diglycerides of fatty acids are currently permitted in infant formulae and follow-on formulae (part 1 and 2 of Annex VI, part 4 of the European Parliament and Council Directive 95/2/EC, as amended by Directive 98/72/EC) and in foods for infants and young children for special medical purposes (part 4 of Annex VI), but only if the product contains protein hydrolysates, peptides or amino acids.

The Committee is asked whether E 472c could be used as an emulsifier also in other types of foods for infants and young children for special medical purposes (contain whole protein or do not contain any protein).

Background

Citric acid esters of mono- and diglycerides (E 472c) have been considered by the Scientific Committee on Food (SCF) on several occasions. In 1978, the SCF endorsed the "ADI not specified" for citric acid esters of mono- and diglycerides allocated by the Joint FAO/WHO Expert Committee on Food Additives (WHO, 1974; SCF, 1978). Subsequently, the Committee considered the use of E 472c was acceptable in weaning foods in biscuits, cereal-based and baby foods (SCF, 1990).

In 1997, the SCF concluded that the use of E 472c was acceptable in products which contain partially hydrolysed proteins for infants and young children in good health and in foods for special medical purposes (FSMPs) containing extensively hydrolysed proteins or amino acids for infants and young children, at levels up to 7.5g/l in ready-to-feed products made from dry powder and up to 9g/l in ready-to-use UHT-liquid formulae (SCF, 1998). This advice was implemented in Directive 95/2/EC as amended by Directive 98/72/EC, which allows the restricted use of E 472c in infant formulae and FSMPs containing partially hydrolysed proteins, peptides or amino acids.

Following a request by a petitioner (IDACE, 2001), the SCF has been asked to consider extension of the use of E 472c as an emulsifier to all types of FSMPs for infants and young children, not just those containing hydrolysed proteins, peptides or amino acids.

Technological evaluation

The present request to extend the use of E 472c to all FSMPs for infants and young children has been made in the context of a technological justification. The following technological justification has been provided by the petitioner. There are a number of FSMPs not based on protein hydrolysates or amino acids as their protein source but which still require the use of emulsifiers with high emulsifying capacity to provide a stable and palatable product. Products for infants and young children include a large percentage of energy in the form of fat, and may have a number of other attributes that make them difficult to emulsify, such as high levels of medium chain triglycerides, or the

complete absence of protein in any form. The current restrictions on use of E 472c limit the stability that may be achieved in these products. Stability is important for products fed via nasogastric tube to prevent separation of components and consequent blocking of the tube, for products reconstituted from powder that need to remain stable in liquid form for 24h, and for products fed orally to ensure palatability and dietary compliance. E472c has a relatively high Hydrophilic Lipophilic Balance (HLB) value and is said to achieve effective stability, whereas the currently permitted emulsifers for such products (lecithin - E 322 and mono- and diglycerides of fatty acids - E 471) have low HLB values and only limited emulsifying capacity. The use of currently permitted stabilisers and thickeners is not considered a viable alternative as they are said to affect both the appearance and organoleptic properties of the final product and to impair passage of the food through narrow tubes.

Conclusion

The Committee is mindful of the principle set out in its earlier reports, that it is prudent to keep the number of additives used in foods for infants and young children to the minimum necessary (SCF, 1983, 1990, 1994, 1998). The Committee has stressed in the past that there should be strong evidence of need as well as safety before additives can be regarded as acceptable for use in foods for infants and young children. The Committee continues to endorse these principles, but is aware that the nature of FSMPs is such that they may require a wider range of additives than those already permitted for foods for infants and young children in good health and/or they may require a higher level of addition of an additive already permitted for foods for infants and young children in good health.

The Committee has considered the request and sees no reason to object on safety grounds to the extension of use of E472c to all FSMPs for infants and young children, provided that the current limits on use levels of up to 7.5g/l in ready-to-feed products made from dry powder and up to 9g/l in ready-to-use UHT-liquid formulae will apply.

References

Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners. Official Journal L 61, 18.3.1995, p1.

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