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Opinion of the Scientific Committee on Food on impurities of ethylene oxide in food additives

(expressed on 17 April 2002)

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Terms of reference

The Committee is asked to re-evaluate the safety in use of the selection of food additives as listed below in view of the potential presence of ethylene oxide, 1,4-dioxane and mono- and diethylene glycol as impurities.

In the light of the Committee's evaluation, the Commission will consider taking any necessary legal steps for the amendment of the Community legislation on food additives.

E No	Name	Established purity criteria (Commission Directive 98/86/EC)		
		Ethylene oxide	1,4-dioxane	Ethylene glycols (mono- and di-)
E 431	Polyoxyethylene (40) stearate	≤ 1 mg/kg	≤ 5 mg/kg	≤ 0.25%
E 432	Polyoxyethylene sorbitan monolaurate (polysorbate 20)	≤ 1 mg/kg	≤ 5 mg/kg	≤ 0.25%
E 433	Polyoxyethylene sorbitan monooleate (polysorbate 80)	≤ 1 mg/kg	≤ 5 mg/kg	≤ 0.25%
E 434	Polyoxyethylene sorbitan monopalmitate (polysorbate 40)	≤ 1 mg/kg	≤ 5 mg/kg	≤ 0.25%
E 435	Polyoxyethylene sorbitan monostearate (polysorbate 60)	≤ 1 mg/kg	≤ 5 mg/kg	≤ 0.25%
E 436	Polyoxyethylene sorbitan tristearate (polysorbate 65)	≤ 1 mg/kg	≤ 5 mg/kg	≤ 0.25%
-	Polyethylene glycol 6000	≤ 1 mg/kg	Ns	ns

ns = not specified

The Committee is also asked to reconsider the safety in use of ethyl hydroxyethyl cellulose as a food additive previously evaluated by the Committee on 24 March 1999 (SCF, 1999), in the

light of additional information, in particular regarding the potential presence of impurities such as ethylene oxide, 1,4-dioxane, ethylene chlorohydrin and mono- and diethylene glycol.

Background

Ethylene oxide is used in the production of several authorised food additives and may be present as an impurity in low amounts in the final product, as shown in the table above.

The modified cellulose, ethyl hydroxyethyl cellulose (EHEC), when previously evaluated by the Committee was included in the Acceptable Daily Intake (ADI) "not specified" already allocated for five other modified celluloses (SCF, 1999). Its proposed authorisation was subsequently questioned by the European Parliament (2000) because of the possible presence of impurities such as ethylene oxide and 1,4-dioxane, which have been classified as 'carcinogenic to humans (Category 1)' and 'possibly carcinogenic to humans (Category 2B)', respectively, by the International Agency for Research on Cancer (IARC, 1994, 1999). Accordingly, it is not yet authorised for use in the EU pending re-evaluation by the SCF. The five other modified celluloses already approved by the SCF and authorised for use in the EU are made from different starting materials and do not contain these impurities.

Purity criteria for ethylene oxide in food additives

Ethylene oxide purity criteria have been set for polyoxyethylene stearate, polyoxyethylene sorbitan esters (Commission Directive 98/86/EC) and polyethylene glycol (Commission Directive 2000/63/EC), as shown in the table above. There is no proposed EU specification for EHEC, but the most recent specification from the Joint FAO/WHO Expert Committee on Food Additives sets a maximum residue limit for ethylene oxide of not more than 0.5 mg/kg of EHEC (JECFA, 1997). These limits in the EU and JECFA specifications were based on the then applicable limits of detection for ethylene oxide.

The Committee has now been informed that the currently achievable detection limit for ethylene oxide is well below the specified purity criteria of 0.5 and 1.0 mg/kg. For example, the used and reported detection limit for ethylene oxide in EHEC is, according to the petitioner, 0.2 mg ethylene oxide per kg cellulose (OFCA, 1996). The same limit has been used in the screening of spices for their ethylene oxide content (Fowles et al., 2001).

Uses of ethylene oxide-containing food additives

Polyoxyethylene stearate (E 431) is permitted only in wine that has been imported from certain countries where it is used to inhibit foam formation during fermentation; it is not permitted in wine made within the EU. The polysorbates (E 432-436) are permitted in various foods from 1-5 g/kg, as surfactants, often in combination with other emulsifiers (European

Parliament and Council Directive 95/2/EC). Polyethylene glycol 6000 is permitted only as a carrier for sweeteners (Council Directive 98/72/EC). EHEC has been used as an additive in the past in Sweden and was restricted to gluten free bread at a use level of 0.5 % (5 g/kg) in dry bread mixture, corresponding to about 3 g/kg bread (OFCA, 1996).

Exposure estimates

Exposure to ethylene oxide occurs from food additives, other food sources, the environment, smoking and endogenous production by bacteria in the intestine. According to a US Food and Drug Administration communication from 1986 (cited by Fowles et al., 2001), the potential daily intake of ethylene oxide from all combined food sources, such as migration from food contact materials, food additives and spices was estimated to be 10 μg/person, with a worst-case exposure estimate of 19 μg/person. No separate estimate was given for food additives alone and it should be noted that ethylene oxide is no longer permitted in the EU as a sterilising agent for spices.

For the EU, an extreme estimate of worst-case exposure could be derived by assuming 1 kg of food is consumed daily, all of which contains polysorbates as surfactants at the highest permitted use level of 5 g/kg of food. This would equate to an intake of 5 μg of ethylene oxide per day, assuming the polysorbates all contained ethylene oxide at the maximum permitted level of 1 μg/g of additive. Not only is this likely to be an unrealistic worst-case scenario, but it should also be noted that there is likely to be significant loss of ethylene oxide from foods during cooking. This suggests that the potential intake of ethylene oxide from food additives in the EU would be unlikely to exceed around one microgramme per day and would probably be much lower than that.

For comparison, the endogenous production by bacteria in the intestine has been estimated to be about 15-20 μg ethylene oxide per day (Törnqvist, 1996).

Conclusion

The Committee notes that estimated current intakes of ethylene oxide from the few food additives containing it, conforming to present specifications, are very low. However, since ethylene oxide is both genotoxic and carcinogenic, intakes from food sources should be as low as possible. The Committee has been informed that the currently achievable limit of detection for ethylene oxide is well below the upper limits of 0.5 mg/kg proposed for EHEC or the 1.0 mg/kg currently specified for E431-436. The Committee therefore recommends that the specifications of additives manufactured using ethylene oxide should be revised to restrict ethylene oxide as an impurity to below its current limit of detection.

The Committee will comment on 1,4-dioxane, ethylene chlorohydrin and mono- and diethylene glycol as impurities in additives in subsequent opinions.

References

European Parliament and Council Directive No. 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners. Official Journal of the European Communities L 61/1-40. 18.3.95.

Commission Directive 98/86/EC of 11 November 1998 amending Commission Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners. Official Journal of the European Communities L 334/1-63. 9.12.98.

Directive 98/72/EC of the European Parliament and of the Council of 15 October 1998 amending Directive 95/2/EC on food additives other than colours and sweeteners. Official Journal of the European Communities L 295/18-30. 04.11.1998.

Commission Directive 2000/63/EC of 5 October 2000 amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners. Official Journal of the European Communities L 277/1-61, p4. 30.10.2000.

European Parliament (2000). Report on the proposal; for a European Parliament and Council directive amending Directive 95/2/EC on food additives other than colours and sweeteners (COM(1999) 329 - C5-0068/1999 - 1999/0158(COD)). Committee on the Environment, Public Health and Consumer Policy. European Parliament Session document, 24 March 2000. FINAL A5-0072/2000. PE 232.063/fin.EN.

Fowles J, Mitchell J, McGrath H (2001). Assessment of cancer risk from ethylene oxide residues in spices imported into New Zealand. Food and Chemical Toxicology 39:1055-1062.

IARC (1994). IARC Monographs on the Evaluation of Carcinogenic Risk to Humans. Volume 60. Some Industrial Chemicals, pp.73-159. International Agency for Research on Cancer, Lyon, France.

IARC (1999). IARC Monographs on the Evaluation of Carcinogenic Risk to Humans. Volume 71. Evaluation of Some Organic Chemicals, Hydrazine and Hydrogen Peroxide (Part Two) Chemicals, pp.589-602. International Agency for Research on Cancer, Lyon, France.

JECFA (1997). Joint FAO/WHO Expert Committee on Food Additives. Specifications for identity and purity of certain food additives. WHO Food Additives Series 52: 41-48. World Health Organisation, Geneva.

OFCA (1996). Application for using ethylhydroxyethyl cellulose in food products as a thickening, dispersing and emulsifying agent. SCF Dossier EC 157.01 (1996), submitted by OFCA, Netherlands.

SCF (1991). Opinion on ethylhydroxyethyl cellulose (Addendum to the "Opinion on re-evaluation of five modified celluloses" of 13 March 1992) expressed on 24 March 1999. CS/ADD/EMU/176 Final. Scientific Committee on Food. Directorate-General XXIV, Brussels.

Törnqvist M (1996). Ethylene oxide as a biological reactive intermediate of endogenous origin. In R. Snyder et.al eds., Biological Reactive Intermediates, pp. 275-283. Plenum Press, New York.