COMMISSION DIRECTIVE

of 23 July 1986

amending Council Directive 83/229/EEC on the approximation of the laws of the Member States relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs

(86/388/EEC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 76/893/EEC of 23 November 1976 on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs (1), and in particular Article 6 (3) thereof,

Whereas, under heading B.1 of the First Part of its Annex II, Council Directive 83/229/EEC (2) authorizes the use of bis (2-hydroxyethyl) ether [= diethyleneglycol] and ethanediol [= monoethyleneglycol] as softeners, provided that the total amount contained does not exceed 20 % and that the film in question is to be coated and used exclusively for packaging foodstuffs which are not moist, i.e. which do not contain water that is physically free at the surface ;

Whereas, on the basis of the safeguard clause in Article 6 of Directive 76/893/EEC, the Federal Republic of Germany has communicated to the Commission that it intends to prohibit the use of bis (2-hydroxethyl) ether and ethanediol as a preventive measure in the interests of public health, on the grounds that these substances have been observed to migrate extensively to certain foodstuffs ;

Whereas consultation of the Member States within the Standing Committee for Foodstuffs, in accordance with Article 6 (2) of Directive 76/893/EEC, and other inquiries have proved inconclusive as regards the migration phenomena in question ;

Whereas the rates of migration observed are very variable, ranging from a few milligrams to several hundred milligrams per kilogram of foodstuff ; whereas it has not yet been possible to identify the foodstuffs or ingredients most likely to be affected by this migration ; whereas, furthermore, it appears that sources other than regenerated cellulose packaging, which have not yet been identified with any certainty, contribute to the presence of these two softeners in foodstuffs ;

Whereas, in the light of these observations, the possibility of a risk to human health cannot be ruled out ;

Whereas, however, a total and immediate prohibition of the two substances as envisaged by the Federal Republic of Germany would be a measure disproportionate to the possible risk ; whereas, as a preventive measure, it is more appropriate to establish a maximum amount of such substances in foodstuffs in contact with regenerated cellulose film ;

Whereas this amount must be calculated on the basis of toxicological data and be consistent with the principle of the inertia of materials embodied in the second indent of Article 2 of Directive 76/893/EEC ;

Whereas this restriction should be regarded as a temporary measure until such time as the research on migration of these two substances to different types of foodstuffs has been completed ;

Whereas, in any case, it can be concluded that use of the two substances in regenerated cellulose film does not constitute any immediate danger to human health ; whereas, therefore, provision can be made for a deadline for implementation of the preventive measure contained in this Directive which will allow stocks of both packages and foodstuffs that have already been packaged to be run down ;

Whereas the Member States should be left to determine the deadline for implementation in the light of both the levels of contamination observed and the dietary habits of their consumers in relation to those levels ; whereas, however, a maximum deadline of 31 March 1987 is in any case adequate ;

Whereas the measures provided for in this Directive are in accordance with the opinion of the Standing Committee for Foodstuffs,

(1) OJ No L 340, 9. 12. 1976, p. 19.
(2) OJ No L 123, 11. 5. 1983, p. 31.