

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(78) 488 final.

Brussels, 29 September 1978

Proposal for a
COUNCIL DIRECTIVE
amending for the 14th time Directive 64/54/EEC on the approximation of
the laws of the Member States concerning the preservatives
authorized for use in foodstuffs intended for
human consumption

(submitted to the Council by the Commission)

COM(78) 488 final.



EXPLANATORY NOTE

1. The annex of Council Directive 64/54/EEC of 5 November 1963 on the approximation of the laws of the Member States concerning the preservatives authorized for use in foodstuffs intended for human consumption¹ as modified by the Council Directive 76/629/EEC of 20 July 1976² authorises the presence of thiabendazole at up to a maximum residual amount of 6 mg/kg for citrus fruit and 3 mg/kg for bananas. This authorisation has been given on a temporary basis by the Directive of 20 July 1976 up to 1 January 1979 to permit the necessary examination to take place on the efficacy of the additive, and in particular the level to be retained definitively.

2. As far as questions of safety in use were concerned, the Commission's proposal was based on the advice of the Scientific Committee for Food of 2 April 1976. The Commission has reconsulted the Committee on the basis of toxicological and technological data submitted to it since that date. On 23 June 1978 the Scientific Committee for Food advised the Commission that after considering all the relevant toxicological data the Committee could establish an ADI of 0.3 mg/kg body weight for thiabendazole which it understands to be the same as that established by the Joint FAO/WHO Committees on pesticide residues. The Committee has been provided with a good deal of information concerning residues of thiabendazole in raw agricultural products and in food commodities, and some data on the total human intake from all sources, including the intake resulting from the use of thiabendazole as a pesticide and in veterinary medicine.

In the absence of convincing evidence of technological justification for an increase in the levels already stipulated in the Directive on Preservatives, the Committee recommends that the provisions in the Directive be maintained and that the permitted residue levels for citrus fruits and bananas should not be raised.

¹OJ No 12 of 27.1.1964, p. 161/164

²OJ No L 223 of 16.8.1976, p. 23

The present proposal implements this advice by the deletion of the time period in the Directive relating to thiabendazole.

3. Following consultations with the Advisory Committee for Food the Commission also proposes the reintroduction of the mandatory labelling provision for citrus fruit sold by retail. This provision was temporarily suspended until a definitive decision was taken on the inclusion of Thiabendazole in the text.

4. The Commission has been informed that there is technological justification in having several permitted treatment agents for the protection of fruits (in this case citrus fruit and bananas) against deterioration by microorganisms because the spectrum of activity is not the same for each substance. The Commission continues to examine the possibility of proposing a comprehensive Directive on such fruit treatment agents but has not yet completed the necessary consultations. In the meantime the Commission sees no reason to suggest other amendments to the Directive on preservatives in respect of the use of biphenyl (E 230), orthophenylphenol (E 231) and sodium orthophenylphenate (E 232).

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THE COUNCIL OF THE EUROPEAN COMMUNITIES

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas Council Directive 64/54/EEC of 5 November 1963 on the approximation of the laws of the Member States concerning the preservatives authorized for use in foodstuffs intended for human consumption¹, as last amended by Directive 78/145/EEC², and in particular by Directive 76/629/EEC³, provides for the temporary use of thiabendazole until 1 January 1979 at a maximum residue level of 6 mg/kg in the case of citrus fruit and 3 mg/kg in the case of bananas;

Whereas, on a toxicological basis, the use of thiabendazole on the surface of these fruits in quantities leading to such residues in the whole fruit is acceptable;

Whereas experience in the use of thiabendazole has shown that the maintenance of these levels is technologically justified;

Whereas, therefore, it is now possible to take a final decision to authorize the use of thiabendazole without prejudice to its possible inclusion in a subsequent Community system on the treatment of fruits and vegetables;

Whereas, therefore, the mandatory labelling provision for citrus fruit sold by retail can be reintroduced,

¹OJ No 12 of 27.1.1964, p. 161/ 64

²OJ No L 44 of 15.2.1978, p. 23

³OJ No L 223 of 16.8.1976, p. 3

HAS ADOPTED THIS DIRECTIVE:

Article 1

In No E 233 of Section I of the Annex to Directive 64/54/EEC, the column "Conditions of use" is amended as follows:

1. The text of subparagraph (b)(ii), second indent, shall be replaced by the following:

"- in the retail trade, a visible indication shall be given ensuring beyond doubt that the consumer is made aware that the fruit has been treated."

2. Subparagraph (c) is deleted.

Article 2

Member States shall bring into force not later than 31 December 1978 the laws, regulations or administrative provisions necessary to comply with this Directive and shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.