

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(88) 132 final - SYN 43

Brussels, 6 April 1988

Amended Proposal for a
COUNCIL DIRECTIVE

amending for the eighth time the Directive of 23 October 1962 of
the approximation of the rules of the Member States concerning
the colouring matters that are authorized for use in foodstuffs
intended for human consumption (COM(85) 474 final)

(submitted to the Council by the Commission pursuant to the third
paragraph of Article 149 of the EEC Treaty)

EXPLANATORY NOTE

In September 1985 the Commission proposed that the Directive concerning colouring matters in food should be updated in three ways to reflect the situation in the enlarged Community. These were as follows:

1. modifying the list of permitted substances
2. updating the purity criteria for the permitted substances
3. consequential editorial modifications

The Council has still not been able to agree on a common position for submission to the Parliament for its second reading, despite the clear statement in the initial proposal that the modifications should be quickly adopted (see paragraphs 3.3 to 3.5 of the explanatory note to the initial proposal).

In the intervening period new data have become available on the safety of a number of colouring matters which, in the opinion of the Commission, require it to modify its initial proposed amendment.

The purpose of the present proposal is to address the new situation and is without prejudice to other action which the Commission believes should be taken in the context of its aims to introduce an internal market by 1992, in particular in the fixing of limits for the conditions of use for colouring matters in general. This is especially important where the safety margin between the level of consumption accepted by the Scientific Committee for Food as without effect (i.e based on the Acceptable Daily Intake set by the committee on the basis of the safety data on the substance) and the actual intake based on information on current usage patterns in food of the colouring matter concerned is small.

The Commission regrets that its proposals for simplifying the procedure by which technical changes to Directives on food additives (including colouring matters) may be adopted has still not been agreed by the Council (COM (86) 87 final and COM (87) 243 final).

As soon as the new simplified procedure is agreed, the Commission intends to make further proposals for introducing Community rules on conditions of use for other colouring matters not covered by the present proposal. In the meantime the Commission believes it should exceptionally use the more cumbersome procedure in Article 100A to modify the Directive in respect of canthaxanthin, erythrosine and caustic sulphite caramel, given the implications to public health of the recently agreed opinion of the Scientific Committee for Food.

The latest report of the Scientific Committee for Food, which was agreed on 10 December 1987, includes the following recommendations on the three above-mentioned colouring matters:

Canthaxanthin

The committee noted reports that the use of the substance as an orally-administered skin pigmenting agent had led to crystalline deposits in the human retina, with possible other related effects on vision. The committee has requested additional data to clarify the situation, and assess the implications of the food use of the substance. These data have been requested for 1989.

The Committee concluded that in the meantime, on the basis of current knowledge, the Acceptable Daily Intake (ADI) should be substantially reduced to a temporary value of 0-0.05 mg/kg bw.

Severe limitations on use must be introduced to ensure that the ADI is not exceeded. It has been put to the Commission by industry that canthaxanthin has a limited use in a wide range of foods, but that the overall average consumption based on sales is well within the ADI set by the committee. The limited information available to the Commission on the actual food consumption of individual consumers made it impossible to confirm that consumers with diets which might not be equivalent to the average are also protected. Therefore the Commission has proposed restrictions on use which err on the side of caution to ensure that the consumer has a high level of protection, bearing in mind that canthaxanthin is already permitted in animal feedingstuffs for certain uses by other Community rules.

Clearly, when more detailed information on actual eating habits, or on the safety of the substance is provided, the Commission will re-assess the situation and make appropriate proposals.

Erythrosine

Erythrosine has now been shown to cause adverse effects on experimental animals in particular to the thyroid of rats fed at higher doses than would be expected to occur from its food use. Other effects suggesting that the substance may be carcinogenic to animals were also noted.

Clinical studies have shown that the substance has minimal effect in humans at a dose of 200mg daily over 14 days, while a dose of 60mg daily is without effect.

The Scientific Committee for Food concluded that the ADI for erythrosine could be fixed at 0-0.1mg/kg bw.

The Commission has been informed by industry that in many cases other colouring matters, e.g. Allura Red, can be used. However, for some purposes, erythrosine is said to be irreplaceable. Similar problems to those described for canthaxanthin were encountered when the Commission was drawing up the restricted list of uses it is now proposing. The Commission has made its decision on the principle that the consumer requires a high level of protection. Uses, ranging from sugar confectionery to cured meats, are currently common, but the Commission believes that the short list of uses it is proposing is a more appropriate choice given the ADI for the substance and the nature of the effects found in the animals tested.

Caustic sulphite caramels

The Scientific Committee for Food wishes to see further information confirming its assumptions that materials on the market are reasonably homogeneous and are chemically similar to other classes of caramels. In the meantime the committee has accepted the temporary use of the material in alcoholic beverages. The Commission believes that it would be appropriate to introduce this restriction on use as part of the present proposal.

The present proposal to allow the substance in alcoholic beverages is without prejudice to Community rules which prohibit the use of colouring matters in certain categories of alcoholic beverages.

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The Commission has also been asked to reintroduce the substance **lycopene** into the Community list. The Commission is making no proposal at this time as it has been informed that no lycopene obtained from foods (notably tomatoes) is available on the market and that the alternative, synthetically manufactured material cannot be economically produced. The Scientific Committee for Food has advised that while it would see no objection to the continued use of a material prepared from foods (it has made specific suggestions on the procedure to be followed in such cases), if a synthetic substance were to become available the committee would expect to evaluate it in terms of a modern toxicological data base appropriate to the substance and its intended use. The Commission would take this opinion into account in formulating any new proposals.

The following new amendments are made to Annex 1:

1. The references to E127, E150b and E161g are deleted from Part 1.
2. The following references are added to Part 3:

Column 1	Column 2	Column 3
E127	Erythrosine	45430 (Food Red 14)
	-cocktail cherries -	
	cherries 350 mg/kg	
	-glacé cherries -	
	cherries 150 mg/kg	
	-canned mixed	
	fruit -	
	cherries 150 mg/kg	
	canned cherries -	
	cherries 150 mg/kg	
E150b	Caustic sulphite caramel	Caramel prepared by the
	-alcoholic beverages only	controlled heat treat-
		ment of carbohydrates
		with sulphite
		containing compounds
E160g	Canthaxanthin	40850 (Food Orange 8)
	-Strasbourg sausages	
	30 mg/kg	
	-cake decorations	
	60 mg/kg	
	-candied fruit	
	150 mg/kg	
	-chewing gum	
	100 mg/kg	
	-sugar-coated	
	dragees	
	50 mg/kg	

COMPETITIVENESS AND EMPLOYMENT IMPACT STATEMENT

- I. What is the main reason for introducing the measure?
Evidence of adverse effects on animals (including man) from the use of these materials.
- III. Features on the businesses in question. In particular:
- (a) Are there many SMEs? Yes, food manufacturers.
- (b) Are they concentrated in regions which are:
- (i) eligible for regional aid in the Member States? No.
- (ii) eligible under the ERDF? No.
- Please note that the colour manufacturers concerned are not SMEs.
- III. What direct obligations does this measure impose on businesses?
They may only use the colours in a restricted list of foods specified at Community level. Without the proposal all Member States would act similarly but not necessarily identically. Therefore the impact of the proposal will not add appreciably to these national measures.
- IV. What indirect obligations are local authorities likely to impose on businesses?
None.
- V. Are there any special measures in respect of SMEs? Please specify.
No.
- VI. What is the likely effect on:
- (a) the competitiveness of business? None
- (b) employment? None
- VII. Have both sides of industry been consulted? Yes.
Please indicate their opinions.
Generally favourable to restrictions on use of these colourings.
Some differences of opinion on the actual list of food to be specified.