

EUROPEAN PARLIAMENT

# Working Documents

1979 - 1980

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18 March 1980

DOCUMENT 1-834/79

## Report

drawn up on behalf of the Committee on the Environment, Public Health and Consumer Protection

**on the proposal from the Commission of the European Communities to the Council (Doc. 1-273/79) for a directive amending for the seventh time the Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorized for use in foodstuffs intended for human consumption**

**Rapporteur: Mrs J. MAIJ-WEGGEN**

By letter of 9 August 1979 the President of the Council of the European Communities requested the European Parliament to deliver an opinion on the proposal from the Commission of the European Communities to the Council for a Directive amending for the seventh time the Directive of 23 October 1962 on the approximation of the rules of the Member States concerning colouring matters authorized for use in foodstuffs intended for human consumption (Doc. 1-273/79).

The President of the European Parliament referred this proposal to the Committee on the Environment, Public Health and Consumer Protection on 24 September 1979.

On 25 September 1979 the Committee on the Environment, Public Health and Consumer Protection appointed Mrs Maij-Weggen rapporteur.

It considered this proposal at its meetings of 23 November 1979, 25 January 1980 and 28 February 1980 and at the last of these meetings adopted the motion for a resolution and attached explanatory statement unanimously but for two votes against.

Present: Mr Collins, chairman; Mr Johnson, vice-chairman; Mrs Weber, vice-chairman; Mrs Maij-Weggen, rapporteur; Mr Ceravolo (deputizing for Mr Segre), Mr Ghergo, Miss Hooper, Mr Mertens, Mr Muntingh, Mr Newton Dunn, Mrs Schleicher, Mrs Seibel-Emmerling, Mrs Squarcialupi.

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The Committee on the Environment, Public Health and Consumer Protection hereby submits to the European Parliament, the following motion for a resolution, together with explanatory statement:

MOTION FOR A RESOLUTION

embodying the opinion of the European Parliament on the proposal from the Commission of the European Communities to the Council for a Directive amending for the seventh time the Directive of 23 October 1962 on the approximation of the rules of the Member States concerning colouring matters authorized for use in foodstuffs intended for human consumption.

The European Parliament,

- having regard to the proposal from the Commission of the European Communities to the Council<sup>1</sup>,
  - having been consulted by the Council pursuant to Article 100 of the EEC Treaty (Doc. 1-273/79),
  - having regard to the report by its Committee on the Environment, Public Health and Consumer Protection (Doc.1-834/79),
1. Welcomes the Commission's proposal to tighten up further the rules governing authorized colouring matters in foodstuffs intended for human consumption;
  2. Takes the view that the use of chemical colouring matters and diluents for colouring matters in foodstuffs should be restricted rather than encouraged, and stresses that these substances should only be authorized when their use is necessary for technical and economic reasons, and if they have been scientifically shown to be safe;
  3. Approves the temporary use of carrageenan (E 407) and gum arabic (E 414) as diluents for carotenoid colouring matters (E 160 and E 161), since these substances already feature on the Community list of permitted emulsifiers, stabilizers, thickeners and jelling agents;
  4. Urges, however, that before the use of gum arabic is definitively approved, further research should be conducted, since this substance is believed to possess allergenic properties;<sup>2</sup>
  5. Hopes that the proposed prohibition of Yellow 2G, about which reservations were expressed at an earlier date, will come into force as quickly as possible;

<sup>1</sup> OJ No. C 201, 10.8.1979, p. 13

<sup>2</sup> WHO list of foodstuff additives No 5, 1976, pp. 331 ff.

6. Takes the view that the use of Brilliant Blue in foodstuffs, although toxicologically acceptable, is of doubtful validity, because the substance cannot be stated to be completely safe, and because the technical and economic need to use it has been insufficiently demonstrated;
7. Is prepared to allow the use of this substance in limited quantities if the economic and technical need can be specifically demonstrated, and asks the Commission to submit more detailed proposals to Parliament in this connection;
8. Requests the Commission, when submitting directives and amendments to directives of this kind in future, not to confine itself to toxicological factors but to take allergenic properties and technical and economic arguments into account as well;
9. Requests the Commission to determine to what extent it is possible for product labels to specify what colouring matters have been used;
10. Considers that in view of the large number of changes to the original directive of 1962, an overall view of the present situation is urgently required and requests the Commission to provide Parliament and the committee responsible with such an overall view when it next submits proposals for the amendment of this directive;
11. Approves the proposal, subject to the following amendments pursuant to Article 149(2) of the EEC Treaty.

Proposal for a Council Directive

amending for the seventh time the Directive of  
23 October 1962 on the approximation of the rules  
of the Member States concerning the colouring  
matters authorized for use in foodstuffs intended  
for human consumption

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission, Unchanged

Having regard to the opinion of the European Parliament, Unchanged

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

Whereas Annex II to the Council Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorized for use in foodstuffs intended for human consumption, as last amended by Directive 78/144/EEC, lays down a list of colouring matters which may temporarily be authorized by the Member States; Unchanged

Whereas in the light of present-day requirements regarding the safety in use of colouring matters, Yellow 2G should no longer be permitted for use in foodstuffs; Unchanged

Whereas the prohibition so required should be given effect under conditions which ensure the protection of public health, while avoiding as far as possible all disruption of a technological and economic nature; Unchanged

Whereas having regard to the most recent scientific and toxicological information on Brilliant Blue FCF it is possible to authorize this colouring matter within the Community; Deleted

Whereas the use of the carotenoid colouring matters E 160 and E 161 is facilitated by their dilution with carrageenan (E 407) and gum arabic (E414); Unchanged

Whereas the Commission is reviewing the use of all substances used for diluting and dissolving colouring matters and it is therefore not possible to take a final decision on whether these two substances should be authorized within the Community, Unchanged

<sup>1</sup> For full text see OJ No. C 201, 10.8.1979, p. 13

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Directive of 23 October 1962 is hereby amended as follows:

1. The indent in Annex II referring to Brilliant Blue FCF is transferred to Annex I and inserted between E 132 and E 140 under the number E 133
2. The following substances are added to part (B) of Annex II under the conditions specified:  
Carrageenan (exclusively for the colouring matters listed under numbers E 160 and E 161 in Annex I)  
Gum Arabic (exclusively for the colouring matters listed under numbers E 160 and E 161 in Annex I)
3. The colouring matter Yellow 2G is deleted from part (A) of Annex II from 1 July 1980.

Article 1

Unchanged

Deleted

Unchanged

Unchanged

Articles 2, 3 and 4 unchanged

EXPLANATORY STATEMENTI. INTRODUCTION

1. The aim of this proposed amendment is to subject to further regulation the use of colouring matters in foodstuffs on the basis of recent scientific findings. The following specific proposals are made:

- a. to permit the use of carrageenan and gum arabic as diluents only temporarily for carotenoid colouring matters,
- b. to delete (=ban) colouring matter Yellow 2G from Annex II of the basic directive, the ban to take effect only as from 1 July 1980,
- c. to authorize definitively, for use in the Community by inclusion in Annex I, Brilliant Blue FCF, one of the substances already permitted temporarily and thus figuring in Annex II of the basic directive,

2. Annex I of the basic directive of 23.10.62 lists those colouring matters authorized definitively for use in foodstuffs in the Community whilst Annex II lists those colouring matters which are authorized only temporarily by virtue of certain national statutory provisions.

3. The Commission's proposed amendments are based on the opinions of the Scientific Committee for Food published on 23 March 1979. These opinions were published in the 8th Series of Reports sent to Members on 11 October.

II. SPECIAL OBSERVATIONS

4. The committee takes the view that the use of chemical substances (colouring and flavouring agents, etc.,) in foodstuffs for human consumption must be approached with the greatest possible care, since the evidence is increasing that these substances can have adverse effects on health. In determining whether chemical or other substances should be authorized for use in foodstuffs, several factors such as toxicity, allergic reactions, technical and economic requirements play an important role.



5. The diluents carrageenan and gum arabic are natural vegetable substances which already appear on the Community list of permitted emulsifiers, stabilizers, thickeners and jelling agents for use in foodstuffs. These diluents appear to be technically necessary when certain carotenoid colouring matters are used in some soft drinks. Since the Commission is engaged in a thorough reappraisal of all diluents used in colouring matters in foodstuffs, all that is being asked for is temporary authorization for the inclusion of these substances in Annex II under certain conditions.
6. The committee can agree with this proposal, but also wishes to point out that gum arabic, according to a joint FAO/WHO committee of experts, can cause allergic reactions (WHO list of foodstuff additives No 5, 1976, pp.331 ff). The committee therefore considers that it would be both appropriate and necessary, before the substance is definitively approved, for the Scientific Committee for Food to deliver an opinion on the allergenic properties of this substance.
7. The colouring matter Yellow G2 was authorized until 1 January 1981, under the basic directive of 1962, pending the outcome of investigations by the Scientific Committee for food. However, the substance is widely considered to be suspect, and is already banned under national legislation in various Member States. The permissible daily dosage (p.d.d.) is very low at only 1/100mg per kg of body weight per day.
8. When this directive was amended for the sixth time, the Committee on the Environment, Public Health and Consumer Protection expressed disappointment that there was still no ban on the use of this colouring matter (Doc. 455/77, p.5, para 4). Today the position is still unchanged. There has been no further research, owing to the lack of interest in the substance (see the report of the Scientific Committee for Food, eighth series, 1979, p.12). The committee poses the question as to whether guidelines for consumer protection policy should be based on the doubts and warnings of the Committee on the Environment, Public Health and Consumer Protection, or the interests of industry. In this case the supposed interests of industry seemed to have carried more weight than the interests of the consumer.

9. The committee therefore absolutely agrees with a ban on Yellow G2 and urges that it be implemented as quickly as possible.
10. As regards colouring matter Brilliant Blue FCF it is proposed that its use can be permitted within the Community until 1981 where already permitted by national legislation. Its use is not permitted in most Member States. It may only be used in the United Kingdom, Ireland and Denmark in limited quantities.
11. There are also varying opinions on the toxicity of this substance, as is clear from, for instance, the great differences in the provisions banning the substance both in EEC and non-EEC countries. In 1975 the Scientific Committee fixed the p.d.d. of the substance provisionally at 0 to 2.5mg per kg of body weight per day. According to recent research (see eighth series of reports of the Scientific Committee, 1979 p.11) human tolerance levels are higher, and it is accepted that the p.d.d. can be fixed at 0 to 12.5mg per kg of body weight per day. The responsible departments of WHO and FAO came to comparable conclusions.
12. The Committee on the Environment, Public Health and Consumer Protection wishes to make the following marginal comments:
  - (a) Brilliant Blue has been clearly shown to cause cancer, when injected subcutaneously into experimental animals, at the point of injection. This research was carried out in the early 60's and is described in a recent report by the International Agency for Cancer Research (Monographs on the evaluation of carcinogenic risk of chemicals to man, part 16, p.180, 1978).
  - (b) Among scientists it is generally believed however that a substance which is carcinogenic when injected subcutaneously is not necessarily unacceptable for oral consumption provided that metabolic tests have clearly shown that it is not absorbed, or is absorbed in insignificant amounts by the alimentary canal and has no harmful effects on it.
  - (c) The Scientific Committee on Food recently investigated this point and concluded in its eighth report in 1979 that tests on three species of animals showed that Brilliant Blue was not absorbed by the intestines, and that the same could be expected to apply to humans.

- (d) The committee is, however, of the opinion that the fact that this substance is carcinogenic when injected subcutaneously makes it impossible to rule out carcinogenic reactions if absorption by the intestines takes place when the substance is taken orally.
- (e) The metabolic tests described by the Scientific Committee were carried out on healthy animals. The rate of intestinal absorption can, however, take place under different circumstances in humans; people may be suffering from infections or irritations of the intestinal lining, or be taking certain medicines (e.g. laxatives) or foodstuffs (purgatives).
- (f) In view of these considerations the committee takes the view that brilliant blue FCF can in fact be described as toxicologically acceptable but should not therefore be designated 'completely safe'.
- (g) There is therefore good reason to ask what pressing economic and technical reasons exist for the use of this substance, and the committee regrets that the Commission's proposal is silent on this aspect.
- (h) The Committee considers that since the substance is not entirely free of risk, the economic and technical need must be proved overwhelmingly, and requests the committee to clarify this aspect of the matter.
- (i) The Committee on the Environment, Public Health and Consumer Protection is prepared to give a favourable opinion on restricted and carefully specified use of this substance if the need for it is positively demonstrated.

13. In connection with the above considerations the committee urges the Commission, when submitting proposals for directives and proposals for the amendment of directives of this kind, not to confine itself to toxicological factors but to take account of allergy factors but and technical and economic arguments as well, since each of these factors can play an important if not a decisive role in reaching a political decision, especially in dubious cases.

14. The committee considers it important for the consumer to be treated as a mature adult and again urges that colouring and diluting agents used should be listed on foodstuff package labels in the consumer's own language. The committee also considers harmonization of foodstuff labelling to be a matter of some urgency so that the consumer will be taken as seriously in one country as he is in another, and to safeguard fair competition.
  
15. Finally the committee notes that since 1962 various amendments have been made to the original directive so that an overall view of the situation as regards colouring matters which are not permitted for use in foodstuffs has become somewhat distorted. It therefore considers it a matter of some importance for the committee to give such an overall view when it next submits proposals for amendments, possibly in the form of an annex to the proposal.