EUROPEAN ECONOMIC COMMUNITY

EUROPEAN ATOMIC ENERGY COMMUNITY

ECONOMIC AND SOCIAL COMMITTEE

/DOSSIER : ENVI/73/

Brussels, 17 January 1980

R E P O R T
of the Section for Protection of the Environment,
Public Health and Consumer Affairs
on the
Proposal for a Council Directive
Amending for the Seventh Time 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
(COM(79) 413 final)

Rapporteur : Mr DE GRAVE

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I. INTRODUCTION

In a letter dated 13 August 1979, the Council of the European Communities asked the Economic and Social Committee for an Opinion on the

> Proposal for a Council Directive Amending for the Seventh Time 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 (COM(79) 413 final).

On 4 September 1979 the Committee's Chairman, acting in pursuance of Article 22 of the Rules of Procedure, instructed the Section for Protection of the Environment, Public Health and Consumer Affairs to draw up an Opinion and Report on the matter.

At its meeting on 2 October 1979 the abovementioned Section appointed Mr DE GRAVE as Rapporteur.

The Section issued its Opinion on ...

II. GIST OF THE DRAFT DIRECTIVE

The Draft Directive amends the Annex to the basic Directive of 1962 in respect of Yellow 2G, which will no longer be authorized from 1 July 1980. Food products containing this substance may not be marketed from 1 July 1981.

The Draft Directive also includes Brilliant Blue FCF in the Community's approved list.

Finally, the Draft Directive authorizes, on a temporary basis, the use of Carrageenan and Gum Arabic, subject to certain conditions, as these substances are already included in the list of emulsifiers and the Commission is in the course of considering the specific issue of substances used as diluents.

III. COMMENTS BY THE SECTION

The rules governing food additives in the Community and in the individual Member States are based on approved lists.

The criteria used in determining whether colouring matters, or indeed any other additives, are to be authorized as follows :

- harmlessness;

- technical usefulness.

Authorization to use colouring matters in foods is also subject to verification that the colouring matter cannot be used to deceive the consumer (see the end of 1.1.5.4.) (at least this is the practice to a certain extent and in some Member States). The use of this third criteria is a matter for national decisions, even in the case of some products which are covered by vertical Directives (jam) (1). The horizontal Directives, however, only take into account the first two criteria mentioned above.

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(1) Directive 79/693 of 24 July 1979, Article 15(1)(a)(iii) 2nd indent, OJ No. L 205 of 13 August 1979.

There is a need to adopt Community methods of identification and quantity determination. The Section calls upon the Commission to prepare a Directive on this subject. Such a Directive was provided for in Article 11 of the 1962 basic Directive.

1. Harmlessness

This criterion must be considered from three points of view :

a) The toxic properties of the additive must be sufficiently well known (immediate and long-term toxic properties). The Scientific Committee for Food normally lays down an acceptable daily intake (ADI) in the light of the available toxicological information and taking account of the need for a safety margin. Synergistic effects are not considered.

A temporary ADI has been laid down for some additives. (Additives whose toxicological properties are regarded by the Scientific Committee for Food as partially but inadequately known).

b) Measures must be taken to ensure that consumers do not exceed the ADI. This is an obvious consequence of the provision in (a) above since toxicity depends mainly on the intake. If that were not the case there would be no point in laying down an ADI. An additive whose properties are known but which has an extremely low ADI can therefore not be used or can only be used in a very limited way.

c) Toxic effects vary from individual to individual. The ADI of a given substance has been laid down in respect of an average consumer; it includes a safety margin but it does not apply to persons who are allergic to the substance. Some additives are known to be extremely allergenic.

1.1 Setting of ADIs and classification of additives by the Scientific Committee for Food; action taken by the Commission and the Council

The tables below outline the action taken :

1.1.1. Opinions issued by the Scientific Committee on 27 June and 14 November 1975

Colouring Matter	Opinion of the Scientific Committee	Action taken by the Commission and the Council (up to 8 January 1980)
E 103 E 105 E 111 E 121 E 125 E 126 E 130 E 152 E 181	Unacceptable	Banned with effect from 1 January 1978
E 180	Temporary authorization up to 1980 (1)	Nil
E 120	Temporarily authorized up to the end of 1980 in some alcoholic beverages (1)	Nil (The use of this additive has not been banned in food and non-alcoholic beverages)
E 160 b (2) E 104 E 122 E 123 (3) E 124 E 131 E 142 E 150 (ammonia caramel) E 151	Temporary authorization up to the end of 1978. Some research has to be carried out in the intervening period In its Opinion issued on 23 March 1979 the Scientific Committee announced that it would reconsider these substances once the current research had been completed	Continuation of authorization for an indefinite period. (Scheduled for review in 1981/82; after this review the authorization will be made permanent or the use of the products will be banned, the ban taking effect three years after the review) Permanent authorization proposed for E 160 b
Brown FK Chocolate brown HT	ditto	Extension of the authorization (4) to all Member States for an indefinite period
Yellow 2 G	Temporarily authorized up to the end of 1978. In its Opinion of 23 March 1979 the Scientific Committee cancelled the temporary ADI as no research had been carried out into this substance	Extension of authorization (4) to all the Member States in 1978 and in the following year. A total ban is proposed with effect from 1 January 1981.
Red 2 G	Authorized	Extension of authorization (4)
Tartrazine caramel (E 150) etc.	ditto	Continuation of authorization

(1) Confirmed in the Scientific Committee's Opinion issued on 23 March 1979.
(2) A permanent ADI was laid down in the Opinion issued on 23 March 1979.
(3) Position confirmed on 27 February 1976.
(4) The Consumers' Consultative Committee, the ESC, the European Parliament and the Commission (in its latest proposal) were against this extension (December 1977)

1.1.2. Opinion issued on 16 September 1977 (marking colour)

Colouring Matter	Opinion of the Scientific Committee	Action taken by the Commission up to 8 January 1980
Methyl Violet	Unacceptable	Nil

1.1.3. Opinion of 27 March 1979

Colouring Matter	Opinion of the Scientific Committee	Action taken by the Commission up to 8 January 1980
Brilliant Blue FCF	A permanent ADI was laid down	As was the case with the other colours, the Member States would be obliged to authorize the use of this colour in at least one food-stuff (not necessarily the same one in each Member State) At the present time Member States may authorize the use of this substance.

The Scientific Committee considers that the approach of the current studies on amaranth and azorubine seems to be "satisfactory" whilst that of the studies on other colouring matters is "acceptable".

The Section wonders what exactly is meant by these terms and whether the approach of the research should not be defined more closely in the interests of both consumers and industry.

1.1.4. The Commission has given the following reasons for not imposing immediately the bans recommended by the Scientific Committee (1).

1. Lithol-rubine BK (E 180)

> "The results of any research carried out in Lithol-rubine BK, and made known to the Commission will be presented to the Scientific Committee for Food for its evaluation before expiry of the period suggested by the Committee".

The Commission also states that it has been informed that

> "Toxicological research is being carried out, or has been completed on all colouring matters mentioned by the Honourable Member except Yellow 2G and Lithol-rubine BK".

The situation as regards this colouring matter is thus the same as that for Yellow 2G, which the Commission proposes should be banned, but when the Scientific Committee was drawing up its Opinion it was still thought by some people that this substance could be researched.

Furthermore, if the use of this colour is only authorized until 1980 there will be a need to draw up a Directive in 1979, bearing in mind the time needed to incorporate the Directive into national law and the six of twelve months needed to dispose of stocks. It already seems that it will not be possible to keep to the date of 1980 set by the Scientific Committee.

2. Cochineal (E 120)

> "The Commission believes that it is premature to propose Community measures on the use of cochineal in foodstuffs until the results of the research now being carried out have been assessed by the Scientific Committee for Food".

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(1) See the Commission's reply given on 3 May 1979 to Written Question No. 17/79 asked by Mr SCHYNS (OJ No. C 139 of 5 June 1979, p. 11.).

It was, however, after it had considered the results of this research that the Scientific Committee called, in 1975, for a ban on the use of this substance; this view was reiterated in an Opinion issued on 27 March 1979, in which it is stated that the use of this colour is temporarily acceptable in certain alcoholic beverages.

3. Colouring matters authorized for use until 31 December 1978

> "The Scientific Committee has noted that the presently anticipated completion dates for the ongoing studies fall broadly into two groups one at the end of 1980, the other at the end of 1981, and has recommended that it should review the results as soon as practicable after each of these periods. The Commission accepts this recommendation".

As things stand, the Section does not call for changes in the provisions governing the use of these colouring matters, particularly since on page 9 of its Opinion the Scientific Committee points out that the interim reports have not indicated any unfavourable aspects. The Section would, however, draw attention to the fact that the use of approved lists presupposes that, on the basis of current knowledge, there is no doubt as to the harmlessness of the substances concerned. If there are any grounds for doubt the interests of the consumer should take precedence.

In the Explanatory Memorandum of the Draft Directive it is stated that :

> "Yellow 2G and Brilliant Blue FCF are colouring matters the temporary use until 31 December 1977 of which was provided for in the Treaty of Accession of Denmark, Ireland and the United Kingdom to allow a complete scientific review of their utility and safety-in-use.
>
> The Council, acting on a proposal from the Commission, and knowing the opinion of the Scientific Committee for Food, extended the original temporary approval to January 1981 of Yellow 2G, Brilliant Blue FCF and certain other colouring matters to allow sufficient time for any studies on their safety-in-use to be completed".

The Committee approved the temporary derogations granted to Member States until permanent arrangements in respect of these additives were laid down.

In the Committee's view, however, the Commission has not made out a satisfactory case. The scientific review of the utility of these substances and research on their safety-in-use will not be facilitated by their authorization.

Authorization of the use of these substances is not necessary to "allow" a review to be made nor to "allow sufficient time" for research bodies to carry out their studies as these bodies investigate products irrespective of the legal position as regards the products.

4. Methyl violet

"The Commission is currently studying this matter".

5. It is really astounding to note the delays and the prevarications of the Commission about banning additives which have been condemned by the toxicologists consulted by the Commission. These delays are symbolized by :

- the fact that this substance has been under review for more than two years;
- the results of the research have been awaited but it has recently been stated that such research has not in fact been carried out;
- the fact that a ban recommended in 1975 is regarded as being premature in 1979.
- etc.

The above attitude is tantamount to authorizing, without hesitation, a new colouring matter on which the Scientific Committee has not yet issued its opinion even though there is no urgent reason for such an authorization.

The haste with which the Commission has acted would be more readily understood if it were a matter of safeguarding the health of consumers and if the Commission finally came round to proposing bans on colouring matters which were described as "unacceptable" four and a half years ago.

Be that as it may, the difference in the attitudes adopted by the Commission is both clear and incomprehensible. Any bans are still "under consideration" as the officials concerned are giving priority to new authorizations (Blue) and the extension of earlier authorizations, these extensions being granted in such haste that sometimes it proves to be necessary to propose a ban on substances immediately after an extension of their possible uses has been granted (Yellow 2G).

1.1.5. Views expressed by the Economic and Social Committee in earlier Opinions

1.1.5.1. Cochineal

In the Opinion which it issued on 14 December 1977, the Committee drew attention to the conclusion reached by the Scientific Committee that cochineal should be banned (Points 1.2. and 1.3. of the Opinion (*)). It stated that :

> "1.2. The Committee notes that the present proposal intends to extend the list of colourants permitted in food. Such a move is contrary to consumers' wishes and market trends. In most of the Community the amount of artificial colouring in food is being reduced.

(*) Opinion of the Economic and Social Committee on the Sixth Amendment to the Directive of 23 October 1962 Published in OJ No. C 59 of 8 March 1978.

1.3. The proposal does not even incorporate all the Scientific Committee's recommendations on reducing colourant use. The Scientific Committee proposed that one colourant be banned (although its use in alcoholic drinks could be permitted until 1980). But so far no action has been taken on this recommendation, despite the backing it has received from the Economic and Social Committee.

The Committee asks the Commission to take this into consideration when the Directive is next amended, bearing in mind any advance in toxocoligical knowledge in the meantime".

1.1.5.2. Lithol Rubine BK

The Committee did not give its views on this colour in 1977. The Scientific Committee proposes that it be banned from the end of 1980.

1.1.5.3. Methyl Violet

The Opinion of the Scientific Committee of 16 September 1977 had not been communicated to the ESC at the time that it drew up its Opinion on 14 December 1977.

In the meantime the Committee has urged, in its Opinion of 24 October 1979 (on the amendments to Directives 72/461/EEC and 77/99/EEC) that the authorization of this colouring matter be reconsidered, as advocated by the Scientific Committee.

1.1.5.4. Extension to all Member States of the authorization to use five colours

a) Yellow 2G (The Commission proposes that this colour be banned)(*) :

"2.2.1. The opinion of the Scientific Committee on this colourant expresses some reservations (see the Section's report). But the Scientific Committee considers that it may be authorized temporarily until 31 December 1978, provided that it is used in fairly small doses and that it undergoes a series of toxicity tests before being included on the Community list of authorized colourants.

(*) See the ESC Opinion on the sixth amendment to the Directive of 23 October 1962 (OJ No. C 59 of 8 March 1978)

2.2.2. To the Committee's knowledge these tests will not be carried out because the Community industry in question has not asked for this colourant to be included (confirmed by representatives of the industry at a meeting).

2.2.3. The Committee therefore asks that the Member States be allowed to continue to authorize Yellow 2G until 31 December 1980, in line with the Scientific Committee's recommendation. This would enable stocks to be used up.

The provisional ADI for Yellow 2G is particularly small, being only one-hundredth of a milligram per kilogram of body weight".

The Commission supported the stand taken by the ESC (and the European Parliament) but only after first obtaining an inexplicable extension of the authorization. No new facts had emerged between the time at which the proposal was made to ban this substance and the extension of the authorization. It was confirmed that the industry in the Community would not carry out investigations into this colouring matter. The ESC already knew this, however, when it drew up its Opinion; this was pointed out in the Opinion.

b) Red 2G (see Point 3 below) (*)

"2.3.5. The Committee understands the Commission is trying to put an end to national laws which theoretically are incompatible with a common market. But the present waiver is a minor matter when compared with the other derogation schemes at present in operation. Moreover, allowing Red 2G to be used in all nine Member States would not make it any easier to set up a common market unless measures were taken to ensure that this colourant, if used, could only be added to the same foodstuff or foodstuffs in each country.

(*) Ibid.

c) Brilliant Blue FCF - Brown FK - Chocolate Brown HT (*)

"2.4.1. On 27 June 1975 the Scientific Committee on Food carried out a provisional toxicological assessment of these three colourants.

The provisional ADI for Brown FK is particularly low (one-twentieth of a milligram per kilogram of body weight), but for the other two colourants the figure is higher (2.5 milligrams per kilogram of body weight).

2.4.2. Toxicity tests are at present being conducted to determine if, and to what extent, these colourants can be definitively accepted. The Committee therefore does not think that a Directive should allow them to be used until 31 December 1978, as Article 4 does, because they may well be banned after this date.

If this happened, as well it might (1) the Council and Commission would not be shown in a very good light.

The Committee therefore proposes that these colourants continue to be allowed only in those Member States where they are allowed at present; they should not be authorized throughout the Community. A final solution should be worked out as soon as possible, when there is sufficient data available.

2.4.5. If the tests at present being carried out indicate that these colourants may be included on the Community's 'authorized' list, two things should be done :

- account should be taken of the ADI (see below);

(*) Ibid.
(1) This has in fact happened in the case of Yellow 2G.

- steps should be taken to prevent the colouring of a foodstuff by one of these colourants being such as to mislead consumers as to the nature and quantity of the ingredients used".

1.1.5.5. Ammonia caramel (*)

"2.5.1. The Committee notes that in one of the proposed Directives which was recently the subject of an Opinion, the Commission proposed drawing a distinction between pectins and amide pectins because the toxicological assessments of the two types differed considerably.

2.5.2. The Committee calls upon the Commission and the Council to make a similar distinction between natural and ammonia caramel, for the same reasons. It has only been possible to fix a provisional ADI for the latter because of the presence of impurities after manufacture. The proposed Directive would therefore read :

- E 150a caramel (except for ammonia caramel),

- E 150b ammonia caramel".

No action has been taken on the proposals made by the ESC.

1.1.5.6. Tartrazine

After it had discussed the Proposal for a Council Directive 78/25/EEC on the Approximation of the Laws of the Member States relating to the Colouring Matters which may be added to Medicinal Products (COM(79) 500 fin) the ESC's Section for Protection of the Environment, Public Health and Consumer Affairs issued an Opinion on 8 January 1980. The Opinion based its findings on the information set out in point 1.3.1. of this Report and it included the following passage :

(*) Ibid.

"... publications claiming that tartrazine (E 102) caused illness in certain patients (serious illness sometimes requiring hospitalization) lead the Section to ask for a reconsideration of the authorization of this colouring matter."

This Opinion is to be submitted to the ESC at its next Plenary Session.

1.1.6. Views of the Section on the proposed permanent inclusion of Brilliant Blue FCF on the list of approved colouring matters

The Section recognizes that Brilliant Blue FCF is carcinogenic when administered in the form of hypodermic injections.

As regards the toxicity of this substance when taken orally, the Commission has based its proposal on the fact that research carried out on animals has demonstrated that there is no intestinal absorption. The Section assumes, however, that the research into intestinal absorption was carried out on healthy animals which were receiving a normal diet. Intestinal absorption may be considerably increased when subjects are suffering from intestinal irritations (e.g. chronic colitis) or are receiving certain medicinal products (e.g. laxatives of a detergent nature) or consuming certain foods. Ever increasing amounts of surface-active agents (emulsifiers) capable of modifying the rates of intestinal absorption are being added to food. Though it is likely that, under normal circumstances, the absence of absorption noted in animals used for scientific research would also apply in the case of human beings, there is no evidence to prove that some people may not absorb this carcinogenic colouring matter.

Furthermore, even if the colour is not absorbed, this does not alter the fact that it comes into direct contact with the intestinal cells. There would also seem to be a contradiction between the establishment of an ADI and the fact that no intestinal absorption takes place.

As regards the carcinogenic properties of Brilliant Blue FCF when taken orally, the Section would draw attention, in particular, to the experiments carried out by Rowland in 1977. It was found that there were 7 cases of cancer of the kidney in a group of 30 male mice which received 0.15% of this colouring matter in their food. There was only one case of cancer in the control group of 44 mice. These finding are quoted in "IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Man", published recently by the International Agency for Research on Cancer (IARC), World Health Organization Section (Vol. 16, 1978, p. 171).

It is therefore perfectly possible that Brilliant Blue FCF is carcinogenic when taken orally by human beings.

The Section is therefore against the inclusion of this substance on the Community's list of approved colouring matters and would like to see it banned very soon in those Member States where its use is authorized.

Some members, on the other hand, hold the view that there is no major objection, on toxicological grounds, to the inclusion of Brilliant Blue FCF on the Community list of approved additives. They consider that the sole arbiter on this matter is the Scientific Committee. The IARC monograph contains a number of errors. The experiments carried out by Rowland which are referred to in the monograph

- were not in fact carried out in 1977 but some years earlier;

- have not been printed and were not intended for publication;

- contain a sentence which seem to suggest that Brilliant Blue FCF causes additional cases of cancer in mice whereas in fact it merely affects the distribution of the different types of cancer in these animals;

- were known to the Scientific Committee despite the fact that this is not stated explicitly in the Committee's Opinions;

- do not, in the view of the Scientific Committee, draw attention to any risks whatsoever to human health or require additional investigation.

These members are in favour of the permanent authorization of Brilliant Blue FCF. They base their view on the following findings of the Scientific Committee :

> "The Committee has been provided with an adequate metabolic study in 3 species which shows virtual absence of intestinal absorption. It is very likely that the same would be true for man".

Some of these members would like Member States to be empowered to authorize the use of Brilliant Blue FCF but not obliged to do so, in view of the question marks hanging over this colouring matter as regards its technical usefulness and its toxicological properties. The fact that a colour is deemed to be harmless does not mean, ipso facto, that all Member States are obliged to authorize its use.

These members draw attention to the fact that, though the Scientific Committee set out an ADI for Brilliant Blue FCF it did not state that this colouring matter could be included in the Community's approved list, as indicated in point 1.3. of the Commission's Explanatory Memorandum. Furthermore, the Scientific Committee's role is limited to considering additives from the point of view of their harmlessness.

Other members would draw attention to the following points : Despite the fact that BIBRA has finally decided against publishing the findings of a study which it passed on to the IARC in 1977, stating that the study was being printed, and even if the administration of Brilliant Blue FCF does not lead to an overall increase in the incidence of cancer but rather has an effect on the distribution of the different types of cancer, this latter fact nonetheless proves that this colour has an effect on health, even though the experiment referred to earlier demonstrated that there was no intestinal absorption.

When large amounts of this colouring matter are administered there will surely be intestinal absorption. In such a case, however, it is quite likely that the toxic effects would be more serious than the carcinogenic effects.

In his Encyclopédie de l'Hygiène alimentaire (pp. 108 et seq.), J. Lederer, Professor at the University of Louvain, holds the view that colouring matters derived from triphenlmethane have shown themselves to be carcinogenic, this being the case in particular for

- ....

- Brilliant Blue FCF.

The first opinion issued by the Scientific Committee (27 June 1975) was based on the findings reached by the WHO/FAO Joint Committee of Experts in 1970. It is stated in this opinion that "The Committee considered additional long-term reproduction and teratogenicity studies". The Scientific Committee does not therefore claim to have considered research on carcinogenic effects carried out after 1970 (in particular the experiments referred to by the IARC which could have caused the Scientific Committee some anxiety and led it to call for a case history of this colouring matter and additional research). In its opinion of 1975 the Scientific Committee called only for metabolic studies to be carried out. This work was carried out, at the request of the industry in the same laboratory which carried out the research into the effects of Brilliant Blue FCF when taken orally. Other members have claimed that this latter research was not intended for publication.

In its opinion published on 27 March 1979, the Scientific Committee noted that the metabolic studies were satisfactory in that they indicated that there was no intestinal absorption. (The studies dealt only with this one aspect and the opinion of the Scientific Committee was also limited to this aspect). Nowhere is it explicitly stated, therefore, that the Scientific Committee has held meetings to consider the data on the carcinogenic effects of Brilliant Blue FCF made available since 1970.

Earlier work in this field (1962 and 1966) which was carried out on rats and which, it would seem, served to a certain extent as the basis for the opinion of the Scientific Committee, is regarded by the IARC as not having the necessary scientific basis (1). See page 179 of the IARC study referred to earlier).

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(1) - "Inadequate histological examination of tissues in this experiment" (1962);
- "Inadequacy of the experiment" (1966).

The EC Commission's Directorate for Health Protection, based in Luxembourg, has observer status at meetings of the IARC. On page 181 of the IARC monograph it is stated that intestinal absorption is less than 5%, and therefore not zero as stated in the BIBRA study referred to by the Scientific Committee.

There are other differences between the conclusions reached by the IARC, which is a branch of the WHO, in 1978 and those reached by the Scientific Committee in 1975. According to the IARC (page 181 of the abovementioned monograph) no adequate information is available on embryotoxicity, teratogenesis and mutagenesis caused by Brilliant Blue FCF.

In view of this situation, which is confused to say the least, these members wonder whether other research is not necessary before authorizing a colouring matter which has up to now proved to be far from indispensable. They also understand that research is in progress and it would be advisable to await the outcome of this work.

The Section does not feel that it is in a position to state with certainty that Brilliant Blue FCF presents absolutely no risk to human beings. As the interests of consumers should take precedence in cases of doubt, the Section comes out against authorizing the use of this colouring matter.

1.2. The compatibility of ADIs with food intakes

Many colours have a very low ADI, as demonstrated by the following examples (expressed in mg. per kilo of body weight) :

Colours permanently authorized

Red 2G	0.1 mg
E 110	2.5 mg
E 127	2.5 mg

Colours temporarily authorized

Yellow 2G	0.01 mg
Brown FK	0.05 mg
E 124	0.15 mg
E 104	0.75 mg
E 123	0.75 mg
E 151	0.75 mg
E 122	2.00 mg

The Scientific Committee takes the precaution to state that additives are acceptable within the limits of their ADIs. This fundamental qualification is totally absent from the Commission's proposals. If the ADI is to be applicable to people of all ages, the following figures may be of some significance :

Taking the example of E 124 - which is not the colouring matter with the lowest ADI - the acceptable daily intake for a child weighing 20 kg would be equivalent to :

- 20 grams of pink-coloured dessert (flan) or

- 3 centilitres of a beverage containing the colour or

- 25 grams of sweets containing the colour.

This colour is also contained in ice cream, lemonade, tomato soup, flour confectionery, etc. (1).

In its Opinion of 28 January 1976 on the Fifth Amendment to the Directive on Colouring Matters, the Economic and Social Committee was unanimous in the view that measures had to be taken to prevent people from ingesting inadmissible large quantities of additives liable to damage their health.

The Section would reiterate this belief.

It is not an acceptable state of affairs that colouring matters should continue to be authorized despite virtual certainty that they are a health hazard. As the Scientific Committee finds such colours to be acceptable only within the limits of their respective ADIs, the Commission should take up this issue as a matter of priority.

1.3. Allergic reactions

Some experts maintain that allergy is an individual problem affecting sensitive persons, and does not require general measures.

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(1) These are the levels of contents authorized under Belgian regulations.

However, a number of scientists disagree :

"Since 15% of the population is atopic, we feel it wrong to say that sensitization is an 'individual hazard'" (1).

The Scientific Committee gave its views on this matter as follows in its Opinion of 27 June 1975 :

"Hypersensitivity reactions to food colours : Various allergic reactions have been reported in man following the ingestion of certain food colours by sensitized individuals ...

It would not be reasonable to accept the addition to food of any substance causing serious or widespread hypersensitivity reactions, but where the incidence of hypersensitivity reactions is low, acceptability might (sic) be considered (2). However, the Committee recommended that there should be appropriate and clear labelling".

To put it in other words, the seriousness of the allergic reactions is the main criterion for assessing such substances as far as the majority of the members of the Scientific Committee is concerned. Be that as it may, the labelling of those substances should provide a way of warning people who are sensitive to these substances.

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(1) D.A. Moneret-Vautrin, J.-P. Grilliat and G. Demange in Allergy and Intolerance to Tartrazine, a paper submitted on 31 January 1979 to a meeting on "substances deliberately added to food", held at the initiative of the Société des Experts chimistes de France and the Association Française pour le Droit de l'alimentation.

(2) "One member of the Committee could not accept the addition of any substance known to cause hypersensitivity reactions".

Labelling is only useful to people who know which substances they are allergic to and who are in a position to read the labels. This would not be the case, for example, with hand-made confectionery sold at fairs and food eaten in restaurants. This is the reason why the Scientific Committee uses the words "acceptability might be considered", rather than "the substance is to be authorized".

The problem of labelling has not been resolved, as the Commission confirms in its reply to Written Question No. 637/79 from Mr MICHEL on tartrazine :

> "The intolerance of such individuals to tartrazine has been known for a number of years, but it can be argued that although it would not be reasonable to accept the addition to food of any substance causing serious or widespread hypersensitivity reactions, where the incidence is low, acceptability might be considered, particularly when the permission is associated with appropriate labelling of the foodstuffs containing such additives.
>
> The Honourable Member will recall that Council Directive 79/112/EEC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs for sale to the ultimate consumer (1) made compulsory the declaration of the number or the name of any colouring matter present in foodstuffs.
>
> In order to reach an agreement the Council granted the possibility of derogation from this rule. The Commission remains convinced that the consumer has a right to be informed that particular additives are present in food and that this would, to a large extent, resolve the problems raised by the Honorary Member."

(1) 79/112/EEC, OJ No. L 33 of 8/2/79, page 1.

It could be added that the technical usefulness of an additive should also be taken into consideration. On this ground toxic nitrites would be acceptable despite their toxic properties as they represent a lesser problem than botulism which their use prevents. Toxic additives which only serve a commercial purpose, on the other hand, would not be acceptable.

In its Opinion of 23 March 1979 the Scientific Committee stated that it was reviewing the question of hypersensitivity reactions to food additives and would report its conclusions separately in due course.

There are two problem areas in the field of colouring matters, namely :

- colours with known allergenic potential (E102, E127 for example);

- thickening agents (E414, for example).

1.3.1. Colours with known allergenic potential

The most obvious example of such a colour is tartrazine (E 102).

A research paper has been published in the "Revue Médicine et Nutrition" (May-June 1979) setting out a whole series of published observations concerning intolerance or allergy to tartrazine (see Pages 205 and 221). All the observations concord as to the allergenic effects of this colour when used in food and medicines.

The author of the paper, F. BRYLINSKI of the Foch Research Centre concludes by stating that it seems desirable to ban the use of tartrazine as a food additive. It is not necesary either to the manufacturing process or for preservation and it is liable to cause problems or even clinical accidents amongst people who are sensitive to this substance or who have been sensitized. The question which then arises is whether a colouring matter should continue to be authorized because industry wants to be able to use it and because it can be tolerated by the vast majority of consumers or whether more importance should be attached to safeguarding the health of the admittedly small number of consumers who are sensitive to the substance by banning its use, bearing in mind that the substance does not add anything to the products concerned.

It would seem, therefore, that less importance is attached to safeguarding the health of consumers when only a small number of consumers is involved, despite the fact that considerable research is being carried out now on rare diseases even though only a small number of people stand to benefit.

On the subject of colouring matters used in medicines, the study refers to the illnesses which have occured in people who have takn medicines which contain, or which used to contain, the colour E102, namely :

- Lixaminol, Dexamethasone (Deronil), Brednisolone (Paracortol), Butazolidin, Ideclaxyl, Ibuprofen (Motrin), Choledyl, unspecified antibiotics, ampicillin, contraceptives, antihistamines.

The symptoms of these illnesses disappeared after the people took medicines containing the same active principle but no colouring matters.

It would seem, therefore, despite all the reasons put forward continuing to authorize tartrazine, health protection should prevail (see 1.1.5.6.).

1.3.2. Proposal to authorize the use of gum arabic (E414) as a thickening agent

The Section understands that a Member State has submitted a request designed to facilitate the dispersion of carotenoid colours in aqueous solutions, particularly orange colouring in lemonade.

Although up to now few colouring matters are known to be allergens, the use of gum arabic as a dispersant could make other colouring matters allergenic as the Joint FAO/WHO Experts Committee has stated that gum arabic is an allergen (1).

It is true that this Committee has not considered it necessary to set any limits as regard the use of this substance, which is included on the list of additives which are toxicologically acceptable for use in food. Gum arabic is also included on the Community's list of approved emulsifiers, stabilizers, thickening agents and gelling agents. The use of gum arabic as a diluting agent for carotenoid colours therefore poses no public health problems, except for its allergenic properties which have so far not been taken into consideration when laying down the ADI.

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(1) WHO series of publications on food additives No. 5, 1976, pp. 331 et seq.

Furthermore, dispersants do not have to be mentioned in the lists of ingredients on labels. No steps have been taken to introduce the labelling provisions recommended by the Scientific Committee as being necessary to provide minimum health protection (see Report, point 1.3.). The conditions laid down by the Scientific Committee have therefore not been met.

The Section would also point out that :

- a Preliminary Draft Directive on non-alcoholic refreshing drinks is under consideration and the advisability of including a given colour should be considered only in this context;

- even if it were demonstrated that gum arabic had superior technical properties to those of gelatine, which is used at present, studies should first be carried out on other substances, particularly other (non-allergenic) gums which can be used for the same purpose.

  It would be in the interests of both consumers and the industry concerned if comparative studies were carried out before the use of gum arabic was authorized. This substance has the drawbacks mentioned above, notably when used in lemonade which is sometimes drunk in large quantities by children;

- as the Scientific Committee is in the process of investigating the potential allergenic properties of additives one should not anticipate its conclusions.

For the three reasons outlined above, the Section would ask that further consideration be given to this matter.

The Section would also draw attention to the fact that there is a degree of contradiction between the inclusion (even the temporary inclusion) of gum arabic and the final recital, worded as follows :

> "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."

1.4. Synergistic effects

In addition to the question of toxicity mentioned so far, the Section would draw attention to synergistic effects.

Some members emphasize that this matter is not merely theoretical. A cobalt salt used as a foam stabilizer in beer gave Quebec beer-drinkers severe and, in some cases, fatal myocarditis. The slight toxicity of the cobalt salt was magnified by the alcohol in the beer and the protein-deficient diet of the victims. "Synergistic effects should be studied and definitely have some surprises in store" (1).

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(1) Mr TRUHAUT (Chairman of the Scientific Committee) at a conference held on 31 January 1979. Speech published in the Annales des Falsifications et de l'Expertise chimique, Paris, June-July 1979, page 381.

2. Technological usefulness

2.1. Brilliant Blue FCF

The Commission provides no justification for its proposal concerning this colouring matter. According to the fourth recital of the proposal, "it is possible to authorize" Brilliant Blue FCF, but no indication is given as to why this possibility should be transformed into an obligation on Member States which do not wish to authorize this colouring matter and whose industry has never shown the slightest interest in it.

The IARC monograph published in 1978 states that the Codex Alimentarius Commission - before publication of Rowland's findings - had limited the use of Brilliant Blue FCF in tinned green peas to 100mg/kg and in tinned apple sauce to 200mg/kg (Codex Alimentarius Commission, 1973). Current use of this colouring matter seems to be on a much larger scale. The Section asked the Commission whether the Codex Commission had altered its views since 1973 but no reply was forthcoming.

The Section has noted the information provided by some members indicating that brilliant blue FCF provides a high degree of brilliance and a better stability in contact with light and SO_2. Because it is only used to a small extent, the intake of this substance should remain well below the ADI.

If doubts as to the toxicological aspects were to be removed, some members would have no objection to the use of Brilliant Blue FCF in place of other blue colours if its use were to prove to be more appropriate. However, they draw attention to the Committee's desire to prevent an extension of the use of colouring matters in food.

2.2. Gum arabic (see 1.3.2.)

3. Need to avoid technical barriers to trade

For the first time the Commission is proposing that a new colouring matter be authorized. In some members' view there is a need to stipulate the food or foods in which the colour may be used and the quantity which may be used in order to avoid creating new barriers to trade. The inclusion of Brilliant Blue FCF in Annex I means that Member States will be obliged to authorize its use in at least one food product.

In France amaranth may be used only in caviar. It may well be that a similar practice will also occur in the other Member States with one State authorizing the use of Brilliant Blue FCF in spirits, another authorizing its use in confectionary products and others authorizing its use in caviar or ice cream.

If the conditions of use of additives are not stipulated (bearing in mind their ADIs) new barriers to trade would inevitably arise. Would it not be a serious matter if a Directive based on Article 100 of the Treaty, i.e. the principle of free movement, not only failed to find solutions to difficulties in this field but even accentuated such difficulties?

Whilst it is true that it is exceptional for a Directive to specify the conditions of use of colouring matters, it must also be borne in mind that this is the first time the Commission has proposed that Member States be obliged to accept a new colouring matter.

The Section did not approve the inclusion of Brilliant Blue FCF on the Community list of approved additives and therefore did not have an opportunity of confirming its former views on this matter.

4. Conclusion

4.1. In the light of the continuing doubts on the toxicological level and for the reasons set out in 1.1.6., the Section is against the inclusion of this substance on the Community's list of approved colouring matters and would like to see it banned very soon in those Member States where its use is authorized.

The Section has noted that research is being carried out by the Martinique branch of the French National Institute for Agronomic Research (INRA) into the possibility of using colouring matters extracted from blue sea-weed.

4.2. In the Section's view all the opinions of the Scientific Committee on colouring matters should be acted upon, not just those selected by the Commission in the Explanatory Memorandum.

The possibility of authorizing the following colours should therefore be ruled out :

4.2.1. Yellow 2G. Authorization of the use of this substance was extended to all Member States in 1978 but the Scientific Committee considers that it should be banned (Opinion of 23 March 1979).

4.2.2. Cochineal (E120). In its Opinion isued on 27 June 1975, the Scientific Committee called for a ban on the use of this substance except for colouring alcoholic beverages (it subsequently confirmed this view in its Opinion of 23 March 1979).

4.2.3. Methyl violet : The Scientific Committee recommended that this substance be banned in its Opinion issued on 16 September 1979.

4.2.4. Lithol-rubine B.K. (E180) : This substance was given a temporary authorization, expiring in 1980. The Commission has, however, noted that the required toxicological research is not being carried out.

4.3. The Section notes that the Scientific Committee is in the course of reconsidering the question of additives liable to cause allergic reactions.

The Section observes (see 1.3.) that the labelling provisions which were laid down by the Scientific Committee in its Opinion of 27 June 1975 were not fully incorporated in the Directive on the labelling and presentation of food for the final consumer (1).

4.4. The Section urges that the question of authorizing the use of gum arabic as a dispersant should be reconsidered for the reasons given at the end of 1.3.2. above and that no decision be taken thereon for the time being.

As this issue is not related to colouring matters a solution could be found within the framework of the vertical Directive.

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(1) Directive No. 79/112/EEC published in OJ No. L 33 of 8 February 1979.

4.5. The Section deplores the fact that the Commission has still not acted on Article 11 of the 1962 Directive which made provision for the adoption of Community methods of identification and quantity determination. It therefore calls upon the Commission to prepare a Directive on this subject.

4.6. The Section would draw attention to the fact that the colouring matters and indeed all the substances included on the Community lists of approved additives are regarded by the Scientific Committee as being acceptable from a toxicological point of view only if the ADIs are not exceeded. The work which is being carried out with a view to preventing people from taking in higher quantities of additives than the amounts acceptable on health grounds should therefore be actively pursued (see 1.2.).

4.7. Even though ADIs may be determined for given colouring matters on the basis of the work carried out by the Scientific Committee and even if these ADIs incorporate a considerable safety margin to cover special cases, the fact remains that the synergistic effects arising from contacts between colouring matters and other additives, food or medicinal products are not known. Despite the complex nature of this matter it should be studied (see 1.4.).

4.8. The Section confirms the views which it expressed on ammonia caramel in its Opinion of 8 March 1978 (see Point 1.1.5.5. of this Report).

4.9. The Section wonders whether it would not be possible to define more closely the approach to be followed in the toxicological research to be carried out prior to the authorization of colouring matters (see this Report end of 1.1.3.).

1.10. The Section regrets that the Commission has not yet taken any action on the Opinion of the Scientific Committee of 16 September 1977 in which it recommended that Red 2G should not be used under conditions in which significant hydrolysis to Red 10B occurs.

The Chairman
of the
Section for Protection
of the Environment
Public Health and
Consumer Affairs

E. ROBERTS

The Rapporteur
of the
Section for Protection
of the Environment
Public Health and
Consumer Affairs

M. DE GRAVE

The Secretary-General
of the
Economic and Social Committee

R. LOUET