

## II

*(Acts whose publication is not obligatory)*

## COMMISSION

## COMMISSION DECISION

of 21 December 1998

on the national provisions notified by the Kingdom of Sweden concerning the use of certain colours and sweeteners in foodstuffs

*(notified under document number C(1998) 4193)*

**(Only the Swedish text is authentic)**

**(Text with EEA relevance)**

(1999/5/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 100a(4) thereof,

Whereas:

of foodstuffs to which these additives may be added, the conditions under which they may be added, and, where appropriate, a limit on the technological purpose of their use.

- (2) Pursuant to the above provision, the Commission presented three proposals for specific Directives, the first on sweeteners, the second on colours and the third on various additives. These proposals were prepared in accordance with the requirements of Article 6 of Directive 89/107/EEC after consultation with the Scientific Committee for Food (SCF) which was asked by the Commission to evaluate the safety of additives. The opinions of the SCF which were used as a basis for the Commission's proposals for Directives were constantly taken into consideration throughout the discussions on these proposals for Directives in the European Parliament and the Council, right up to the adoption of the Directives themselves. On 30 June 1994 two <sup>(2)</sup> specific Directives (forming part of the comprehensive Directive pursuant to Article 3 of Directive 89/107/EEC) were adopted by the European Parliament and the Council in accordance with the procedure laid down in Article 100a, namely Directive 94/35/EC <sup>(3)</sup> on sweeteners for use in

## THE FACTS

## 1. Community legislation

- (1) Council Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption <sup>(1)</sup> was adopted on 21 December 1988. Article 3(2) of this Directive provides that the Council shall, acting on a proposal from the Commission under the procedure laid down in Article 100a of the EC Treaty, adopt a list of additives the use of which is authorised to the exclusion of all others and the list

<sup>(1)</sup> OJ L 40, 11. 2. 1989, p. 27; Directive as last amended by Directive 94/34/EC, (OJ L 237, 10. 9. 1994, p. 1).

<sup>(2)</sup> The third Directive, 95/2/EC, is not concerned by this Decision.

<sup>(3)</sup> OJ L 237, 10. 9. 1994, p. 3; Directive as last amended by Directive 96/83/EC, (OJ L 48, 19. 2. 1997, p. 16; corrigendum: OJ L 259, 7. 10. 1994, p. 33).

foodstuffs and Directive 94/36/EC on colours for use in foodstuffs<sup>(1)</sup>.

## 2. The national provisions

- (3) On 1 December 1995 the Swedish authorities adopted their national measures transposing Directives 94/35/EC and 94/36/EC<sup>(2)</sup>. Member States had been required to bring into force the laws, regulations and administrative provisions necessary to comply with these two Directives by 31 December 1995 at the latest. The Swedish measures were communicated to the Commission in a letter dated 30 April 1996. But in a previous letter, dated 5 December 1995, the Swedish authorities had informed the Commission of their decision not to transpose these two Directives in their entirety. In this letter of 5 December 1995 the Swedish Government notified the Commission, pursuant to Article 100a(4) of the EC Treaty, of its decision to continue to apply the national provisions concerning the use in foodstuffs of azo dyes (tartrazine E 102, orange yellow S, E 110, azorubine E 122, amaranth E 123, ponceau 4R, E 124, red 2G, E 128, allura red AC, E 129, black PN, E 151, brown FK, E 154, brown HT, E 155 and litholrubine BK, E 180) and cyclamate (cyclamic acid and its Na and Ca salts E 952)<sup>(3)</sup> by way of derogation from Directives 94/35/EC and 94/36/EC.
- (4) The Swedish provisions concerning additives appear in three separate texts: the Foodstuffs Act<sup>(4)</sup>, the Foodstuffs Decree<sup>(5)</sup> and the Foodstuffs Administrative Order<sup>(6)</sup>. This Order comprises the positive list of additives authorised in Sweden and the conditions for their use.

## 3. The case of azo dyes

- (5) Directive 94/36/EC on colours provides that only the substances listed in Annex I thereto may be used as colours in foodstuffs. The Directive has four other annexes. Annex II lists the foodstuffs which may not contain added colours, except where specifically provided for in Annex III, IV or V. Annex III lists the foodstuffs to which only certain permitted colours may be added. Annex IV covers colours permitted for certain uses only, and Annex V lists the colours permitted in foodstuffs other than those mentioned in Annexes II and III.

Accordingly it follows from Directive 94/36/EC that azo dyes may be used in specific maximum quantities in certain foodstuffs, namely non-alcoholic flavoured drinks, confectionery, pastries, ice cream, desserts, sauces, mustard, soups and certain fish products, but also in alcoholic drinks, cocktail cherries and lumpfish roe caviar.

- (6) Order No 33 of 1993 permits azo dyes to be used only under the following conditions:
- tartrazine E 102: cocktail cherries (maximum 200 mg/kg), alcoholic drinks and extracts for the manufacture of similar drinks and of mixtures of drinks (maximum 500 mg/l),
  - orange yellow S, E 110: lumpfish roe caviar (maximum 200 mg/kg), alcoholic drinks and extracts for the manufacture of similar drinks and of mixtures of drinks (maximum 500 mg/l),
  - amaranth E 123: alcoholic drinks and extracts for the manufacture of similar drinks and of mixtures of drinks (maximum 100 mg/l),
  - ponceau 4R, cochineal red A, E 124: alcoholic drinks and extracts for the manufacture of similar drinks and of mixtures of drinks (maximum 100 mg/l),
  - brilliant black BN, black PN, E 151: lumpfish roe caviar (maximum 300 mg/kg),
  - use of the colours azorubine E 122, red 2G, E 128, allura red AC, E 129, brown FK, E 154, brown HT E 155 and litholrubine BK, E 180 is prohibited.

## 4. The case of cyclamate

- (7) Directive 94/35/EC on sweeteners provides that only sweeteners listed in the annex thereto may be placed on the market with a view to sale to the ultimate consumer or use in the manufacture of foodstuffs. Sweeteners listed in the annex to the Directive placed on the market with a view to the manufacture of foodstuffs may only be used in the manufacture of the foodstuffs listed in the annex under the conditions specified therein. Accordingly it follows from Directive 94/35/EC that cyclamate may be marketed as such and used in specific maximum doses in certain reduced-energy foodstuffs or foodstuffs without added sugar, namely water-based flavoured drinks, desserts, confectionery, edible ices, jams, and formulae for weight control.

<sup>(1)</sup> OJ L 237, 10. 9. 1994, p. 13.

<sup>(2)</sup> SLV FS 1995: 31.

<sup>(3)</sup> SLV FS 1993: 33.

<sup>(4)</sup> 1971: 511.

<sup>(5)</sup> 1971: 807.

<sup>(6)</sup> SLV FS 1993: 33 and SLV FS 1995: 31.

(8) Foodstuffs Administration Order No 33 of 1993 provides that foodstuffs containing cyclamate may be placed on the market only if the Foodstuffs Administration gives its authorisation. No such authorisation has been given. The Order provides only that table-top sweeteners with saccharine or cyclamate or a mixture of these products as their sole sweetening agents may be placed on the market, under certain labelling conditions.

#### THE PROCEDURE

(9) On 26 July 1994, some weeks after the adoption of Directives 94/35/EC and 94/36/EC, the Swedish delegation to the European Communities submitted a first request for derogation from these directives to the General Secretariat of the Council, invoking Article 151(2) of the Act of Accession. The dossier was passed to the Commission departments, which then examined it. It was the subject of in-depth discussions between the representatives of the Swedish authorities and the Commission departments. The Commission departments informed the Swedish authorities that a derogation could not be authorised on the basis of the scientific grounds with which they had justified their request. In a further letter sent to the General Secretariat of the Council on 23 December 1994 the Swedish authorities noted the unfavourable opinion of the Commission departments, accepted that the Article 151 procedure had to be terminated and affirmed that if Sweden had been able to take part in the vote when the two Directives were adopted it would have voted against their adoption.

(10) In a letter dated 5 December 1995 the Swedish Government made a new request for derogation from these two Directives, invoking Article 100a(4) of the EC Treaty. In this request the Swedish authorities gave a detailed account of the reasons why they had decided to keep their national legislation in force. The notification was forwarded to the other Member States for their opinions. The Commission received opinions from Germany, Greece, Spain, France, Portugal, Finland and the United Kingdom. None of these Member States is in favour of Sweden's request.

— Germany considers that the arguments put forward by the Swedish authorities cannot call into question the opinions of the SCF on the basis of which the Directives were adopted,

— Greece thinks the demands of the internal market make it necessary to find a solution to the problem at Community level. A system for monitoring trends in the consumption of additives has already been set up to this end,

— Spain considers that no toxicological or epidemiological study justifies the taking of measures more restrictive than Community legislation,

— France thinks the Swedish restrictions do not seem justified since the Swedish authorities have not supplied case-by-case proof of the public health risk,

— Portugal considers that Sweden has not proved that the additives in question present health risks or that the danger is greater for Swedish consumers,

— Finland considers that the grounds given by Sweden do not take account of scientific bases which would make it possible to decide that the situation of the Swedish population is exceptional compared with the other Member States,

— The United Kingdom considers that the Swedish request does not appear to be based on factors which would concern only the Swedish population.

#### LEGAL ASSESSMENT

##### 1. Consideration of admissibility

(11) Directives 94/35/EC and 94/36/EC were adopted on 31 June 1994. At that time Sweden was not a member of the European Community but had observer status. Sweden had therefore been unable to take part in the voting on these two Directives but it had pointed out that had it been able to participate it would have voted against adoption of the text. Sweden had therefore declared its intention to request a derogation from these Directives. Sweden could not obtain a derogation from these Directives in the framework of the accession negotiations which had been concluded six months previously, on 31 December 1993. It could not, therefore, set in motion the machinery provided for in Article 151(2) of the Act of Accession. This provides for the possibility for a Member State to enjoy a temporary derogation from acts of the institutions adopted between 1 January and 24 June 1994, the date of signature of the Accession Treaty. But the Directives in question were adopted after that date, on 30 June 1994. On 7 December 1995 the Commission received a notification from Sweden pursuant to Article 100a(4) of the EC Treaty, the admissibility of which has to be examined in the light of that Article.

- (12) In this respect it should be pointed out first of all that the Commission received Sweden's notification pursuant to Article 100a(4) before 31 December 1995, the time limit for the transposition of Directives 94/35/EC and 94/36/EC.
- (13) The first indent of Article 100a(4) reads as follows: 'If, after the adoption of a harmonisation measure by the Council acting by a qualified majority, a Member State deems it necessary to apply national provisions on grounds of (...) it shall notify the Commission of these provisions'. The Commission considers this to mean that the State in question is a Member State at the time when it notifies the Commission of its national provisions. The provision has, moreover, to be interpreted in the light of what it seeks to achieve, which is to allow a Member State to obtain the right to derogate from a harmonisation measure which it has not agreed to, since such a measure may be adopted by a qualified majority and no longer unanimously as was the case before the entry into force of the Single European Act which introduced Article 100a(4).
- (14) In the case in point the Commission therefore considers the Kingdom of Sweden to be entitled to notify the Commission of a request for derogation from Directives 94/35/EC and 94/36/EC under Article 100a(4) of the EC Treaty, since it was not in a position to agree to the adoption of the Directives in question and made its notification as a Member State before the time limit for transposition of the Directives in question.

## 2. Assessment of the merits

- (15) In accordance with the substance provisions of Article 100a(4) of the EC Treaty the Commission has to make sure that the national provisions notified pursuant to that Article are justified on grounds of major needs referred to in Article 36, or relating to protection of the environment or the working environment. In their notification letter the Swedish authorities give as their objective the protection of public health. The Commission therefore has to verify whether these measures are necessary and in proportion to the objective. Once the Commission has concluded that the national provisions notified were justified, it must also verify whether these measures do not constitute a means of arbitrary discrimination or a disguised restriction of trade between Member States.
- (a) *Justification with regard to the major need to protect public health*
- (i) The case of azo dyes
- (16) In the 1970s the Swedish authorities decided to limit the use of azo dyes in Sweden. These restrictions were justified by the risks of allergies caused by azo dyes. Azo dyes may cause allergic reactions in certain individuals, or hypersensitivity reaction such as urticaria and asthma. The Swedish authorities mention in their notification letter a number of epidemiological studies of the Swedish population which they claim indicate the presence of allergic complaints<sup>(1)</sup>. They also refer to several studies of children in another Member State, which show an increase over time in the number of children suffering from allergies for reasons connected with the azo dyes which are permitted there<sup>(2)</sup>. The Swedish authorities have sent the Commission copies of these different studies.
- (17) The Commission is not calling into question either the methods used or the results obtained in these studies. It considers that they tally with those carried out by the SCF on the same issues. These SCF evaluations, on the basis of which Directive 94/36/EC on colours was adopted, also highlighted cases of certain individuals' intolerance to azo dyes. The SCF's latest evaluations on these matters are contained in its 'Report on adverse reactions to foodstuffs and their ingredients', published on 22 September 1995. In this report the SCF states that 'although azo dyes and non-azo colours were involved in a number of anecdotal hypersensitivity reactions, it was concluded that their involvement was rare'. It must therefore be recognised that the

<sup>(1)</sup> Settipane G. A., Chafee F. H., Postman I. M., Levine M. I., Saker J. H., Barrik R. H., Nicholas S. S., Schwartz H. J., Honsinger R. W., Klein D. E., Significance of tartrazine sensitivity in chronic urticaria of unknown etiology. *J. Allergy Clin. Immunol* 1976; 57; 541-6.

Åberg N., Hässelmar B., Åberg B., Eriksson B., 1995. Increase of asthma, allergic rhinitis and eczema in Swedish school-children between 1979 and 1991. *Clin. and Exp. Allergy*, Vol. 25, 815-819.

Slorach S. A. 1981. The problem with intolerance to food additives and Nordic strategies for dealing with it. *Toxicology Forum Meeting*, Genève, 6 to 9 April.

<sup>(2)</sup> Fuglsang G., Madsen C., Saval P., Osterballe O., 1993. Prevalence of intolerance to food additives among Danish school children. *Pediatric and Allergy Immunology*, 4: 123-129.

restrictive measures applied in Sweden with regard to azo dyes are in fact based on public health considerations. But it has to be verified whether these measures are necessary and in proportion to the objective of protecting public health.

- (18) The Swedish authorities point out in their request that their objective is to protect public health and that in order to achieve this objective the use of additives likely to damage the health of consumers must be reduced as far as possible. The Commission recognises this principle and recalls that it is the basis of the Directives on additives. Annex II to the framework Directive 89/107/EEC on additives sets the general criteria for the use of food additives. Accordingly, food additives can be approved only if (i) there can be shown to be a sufficient technological need and the objective pursued cannot be achieved by other economically and technologically feasible methods, (ii) if they present no danger to the health of the consumer, in so far as the scientific data available allow this to be judged, and (iii) if their use does not mislead the consumer. The use of a food additive can be envisaged only if it is proved that the proposed use of the additive brings demonstrable benefits for the consumer. To determine the possible harmful effects of a food additive or its derivatives, the additive has to be subjected to appropriate toxicological testing and evaluation. This evaluation has to take into account, for example, any cumulative, synergistic or potentiating effect depending on its use, as well as any intolerance of the foreign substances by the human body. Directive 94/36/EC was adopted on the basis of the opinions delivered by the SCF on colours. Due account has been taken in that Directive of the opinions of the SCF stating that azo dyes cause allergies in certain individuals. Directive 94/36/EC defines the conditions for use of azo dyes in a restrictive way by setting limits as to the foodstuffs in which these additives can be used and by specifying maximum quantities for their use. But the Swedish authorities want to go further. They think the use of these additives should be restricted even more since their use is not technically indispensable. Since azo dyes have a technological function, which consists in colouring food which does not have a colour of its own so that it will have a more attractive appearance, the Swedish authorities take the view that this simple need for colouring could be satisfied with other colours which would not present allergy risks.

- (19) The Commission does not share this view. It has no knowledge of any non-azo colours which can be

substituted for each of the azo dyes to give equivalent colouring of foodstuffs. The colouring of a foodstuff meets a technological need. In most cases, a specific colouring chosen for commercial purposes to give a food an attractive appearance can be obtained only by using a specific colour. In a number of cases this specific colour has to be used in a particular food to the exclusion of other substances for technological reasons to do with its effectiveness (uniform colouring) and stability (durable colouring) in the finished product. Thus it may become necessary for both commercial and technological reasons to use azo dyes in order to obtain precise colouring of certain foods such as confectionery or drinks.

- (20) The Commission also finds that the Swedish measures notified are inconsistent with the declared objective of protecting public health. The restrictive measures apply to azo dyes only. But azo dyes are not the only additives which present allergy risks. Thus one might, on the basis of the SCF's report of 22 September 1995 referred to above, mention the example of certain non-azo dyes, sulphites and benzoates. One might also take as a basis a study, mentioned by the Swedish authorities themselves in their notification letter, entitled 'The problem of intolerance to food additives and the Nordic countries' strategies for dealing with it', citing cases of allergies to benzoates. The Commission observes that in Sweden these different sources of allergies have not been subject to the same sort of restrictions as those applicable to azo dyes.

- (21) Furthermore, the Commission considers that Community legislation provides an appropriate response to the problem of food allergies in general. As mentioned in the previous point, it is recognised that a number of additives can set off allergic reactions in certain individuals. The Community legislator accepts that it is perfectly legitimate to avoid, as far as possible, exposing these individuals to risks of allergic reactions. But the Community legislator did not see fit to place a general ban on the use of these additives. The solution adopted by the Community is based on informing the consumer: individuals who are allergic to certain ingredients should be able to choose foodstuffs which do not contain them.

Directive 79/112/EEC on foodstuff labelling gives them this possibility by making it compulsory to indicate the ingredients on the labelling. In particular, under Article 6 of that Directive all additives which fulfil a technological function in the finished product (such as colours which have the function of giving the finished product a particular colouring) have to be mentioned on the labelling. Accordingly, azo dyes must always appear in the list of ingredients.

(22) In their letter of 5 December 1995 the Swedish authorities themselves recognise that these labelling measures are sufficient to allow consumers who are allergic to select foodstuffs they wish to consume. But the Swedish authorities state at the same time that this opportunity for consumers to make a choice is not available when they are offered the food without prepackaging, as for example in restaurants and school canteens. In such circumstances, where there is no labelling, the consumer cannot know the list of ingredients.

(23) The Commission considers that this does not in itself justify a total ban of the use of azo dyes in these non-prepackaged foodstuffs. The Commission would point out that measures other than prohibition can be carried out in conformity with existing Community legislation to settle this particular problem of foodstuffs offered for sale to the consumer without prepackaging. Article 12 of Directive 79/112/EEC provides that the Member States decide detailed rules for labelling these foodstuffs, such as the obligation to affix notices accompanying products sold in bulk and containing certain particulars on these products. Moreover, in order to inform all consumers fully about the content of certain foodstuffs Member States may require restaurants to include the list of ingredients on the menu. It is true that most of the time the consumers concerned are in fact children: the products in question are confectionery and non-alcoholic drinks which children tend to consume more often and in larger quantities than adults. Children cannot be considered to be 'consumers who are heedful of the composition of a product' within the meaning of the Court of Justice Decision of 26 October 1995 in Case C-51/94<sup>(1)</sup>. But the Commission thinks that the case of foodstuffs containing azo dyes and offered without prepackaging to children could also be resolved in

a positive way instead of via prohibition. From the Swedish authorities' notification letter the Commission notes that children eat such confectionery at school. In the Commission's view Swedish schools, like the parents, could take care not to make available to allergic children products which are likely to give them allergic reactions. In school canteens, for instance, posting up the list of ingredients in food offered to children would allow an adult to check whether this list tallied with a list, drawn up by a doctor, of ingredients causing allergic reactions in the child concerned.

(24) The Commission has also checked whether azo dyes pose a particular health problem for the Swedish population compared with the populations of other Member States. The Swedish authorities mention several epidemiological studies in their notification letter. The Commission has taken note of these studies and examined them in detail to see whether they contain the proof that the Swedish population or a subgroup of the population, such as children, are a special case compared with the populations of the other Member States with regard to allergies to azo dyes.

(25) The studies mentioned by the Swedish authorities<sup>(2)</sup> tend to describe the prevalence of allergic disorders in Sweden in a general way. They show that the frequency of allergies is higher in children than in adults and that it is appreciably higher in the northern regions than in the more southern regions of Sweden. Another study carried out in Sweden over several years shows a rise in the number of allergy cases. These studies underline the fact that the allergic disorders found have environmental causes, and in particular the individuals' quality of life at school or work. These studies do not highlight cases of allergies connected with the consumption of foodstuffs containing additives such as azo dyes. There cannot in fact be any study connected with the consumption of foodstuffs containing azo dyes in Sweden on account of the prohibitions and restrictions on the use of these additives laid down in the relevant national legislation. But with the study tending to indicate a predisposition of Swedish children to allergies, one might be inclined to think that if the children eat food likely to contain azo dyes (basically confectionery and fizzy drinks) many of them are going to suffer allergic reactions. In their notification letter the Swedish authorities have thus referred to a study of Danish schoolchildren which reveals allergic disorders connected with additives including certain azo dyes, putting at 1 to 2 % the prevalence of allergy to food additives in Danish children.

<sup>(1)</sup> European Commission v. Federal Republic of Germany, ECR 1995 p. I-3599.

<sup>(2)</sup> See paragraph 16.

- (26) The Commission has to check whether all of the information submitted by the Swedish authorities shows that there is a causal link between the possible consumption in Sweden of foodstuffs containing azo dyes and specific allergic risks in the Swedish population and particularly in children. This involves several stages.
- (27) First of all the Commission has to make sure that it has the necessary information, and then compare it with the available information such as that collected at European or international level. The Swedish authorities have provided statistical data on the prevalence of allergy in the Swedish population, but not on the prevalence of food allergy or allergy to additives, and have not therefore been in a position to evaluate the prevalence of allergy to azo dyes. It is not possible to estimate the prevalence of allergy to azo dyes by referring to existing data on the prevalence of allergy in general, since the mechanisms, like the symptoms, of allergies differ from one allergen to another, an individual subject to one type of allergy not necessarily being subject to another. The Commission therefore finds that since the Swedish authorities have not supplied it with statistical data on the prevalence of allergy to azo dyes in the Swedish population, it cannot make comparisons with average data for the European population or the world population, in order to determine whether the Swedish population is a special case as regards the prevalence of allergy to azo dyes.
- (28) The Commission has also endeavoured to study the situation in greater depth by taking as its basis the SCF's report of 22 September 1995 on adverse reactions to food and food ingredients. In this report the SCF points out that according to the available studies carried out throughout the world 'the prevalence of food allergy is substantially less than 1 % in the adult population and may be slightly higher in children'. The SCF mentions several studies showing that the prevalence in respect of food additives in particular is less than 0,1 % of the population. But the SCF adds an important rider in its report: genetic and environmental factors and food habits can increase the prevalence of food allergy. The SCF gives the example of regions where allergens are present in the environment. It also mentions the cases of regions where allergens are widely consumed. The SCF concludes that 'the prevalence of food allergy depends very much on the geographical region'. The Commission has thus checked whether the Swedish authorities really have proved (in the studies which they have communicated to the Commission) the existence and the importance of such factors, connected with genetics, environment or food habits. The Finnish authorities too, in the context of the consultation of the Member States on the Swedish derogation request, described a similar situation with regard to Finnish children. These facts and studies quoted by the Swedish authorities do not allow one to conclude that the Swedish population, or Swedish children in particular, are a special case compared with the populations of the other Member States, in particular Sweden's immediate neighbours, with regard to this matter of allergies associated with azo dyes.
- (29) It appears in fact that the measures taken by the Swedish authorities in the 1970s to restrict the use of azo dyes were part of a general prevention policy and not because a specific public health risk had been found. The preventive nature of these policy measures has been explicitly confirmed in the study communicated by the Swedish authorities entitled 'The problem of intolerance to food additives and the Nordic countries' strategies for dealing with it'. The position of the Swedish authorities contrasts, moreover, with that taken on the same problem by the Danish and Finnish authorities, which did not pursue the same strategy as the Swedish authorities aimed at restricting the conditions of use of azo dyes compared with those provided for in Directive 94/36/EC, but which judged the labelling measures to be sufficient.
- (30) In the light of these facts the Commission finds that the Swedish measures, though based on public health considerations, are still not justified by the need to protect public health.
- (ii) **The case of cyclamate**
- (31) In the 1970s the Swedish authorities decided to limit the use of cyclamate as a food additive. The conditions of use of cyclamate provided for in Directive 94/35/EC are less restrictive than those laid down in Sweden. In the view of the Swedish authorities there are good public health reasons for keeping their more restrictive national provisions. The Swedish authorities refer to studies which show that the conditions of use of cyclamate provided for in Directive 94/35/EC can in certain consumers lead to the permissible daily dose being exceeded.

- (32) The specific Community Directives on additives were adopted on the basis of a thorough safety evaluation carried out on all additives by the SCF so that only additives considered safe to use in food appear in these specific Directives and can therefore be used in the Community. The evaluation of the safety of an additive may reveal the need to fix an acceptable daily intake (ADI) to protect public health. This ADI represents the quantity which can safely be ingested without risk on average each day throughout a lifetime. The ADI, which itself includes a safety factor from 100 to 500, is expressed in milligrams per kilogram of body weight (mg/kg bw). The approval of any food additive and determination of the conditions for using it therefore have to take into account the technological need for the additive in question (dose needed to achieve the desired effect) and the probable daily supply of the additive in all foodstuffs, so as to verify that the use authorised will not exceed the ADI established for the additive in question.
- (33) The Swedish authorities consider that ingesting cyclamate in the conditions set out in Directive 94/35/EC while keeping to the precise limits laid down in it might cause the ADI to be exceeded if the levels of consumption of the various products in which cyclamate can be used are taken into account. The Swedish authorities rely on estimates made by the Swedish Foodstuffs Administration showing that there is a risk that the ADI will be exceeded for those population sub-groups who are advised to use this type of sweetener, namely diabetics and people on a diet, especially children. The figures given by the Swedish authorities therefore reflect the high consumption levels that such people may have. As these figures are not directly available they have been obtained by extrapolation on the basis of data on household food consumption<sup>(1)</sup>, by applying a factor of three to these average consumption levels.
- (34) The Swedish authorities cite a number of examples of consumers of different ages and hence different weights belonging to these population sub-groups who are liable to consume sweetened foodstuffs in greater quantities than the average for the population as a whole. They mention in particular the
- case of a five year-old child who, it would seem, consumes each day reduced-energy foods or foods without added sugar, amounting to 600 ml of soft drinks containing cyclamate in a dose of 400 mg/l, 60 g of sweets containing cyclamate in a dose of 500 mg/kg and 90 g of ice cream containing cyclamate in a dose of 250 mg/kg. It would seem that this diet provides the child with some 292 mg of cyclamate a day, this being the sum total of the cyclamate from the drinks (600 ml × 400 mg/l = 240 mg) from the sweets (60 g × 500 mg/kg = 30 mg) and from the ice cream (90 g × 250 mg/kg = 22 mg). This figure of 292 mg should be compared with the admissible daily intake for this child who weighs 20 kg. The admissible daily intake is calculated by multiplying the weight of the consumer by the ADI. The ADI set by the SCF is 11 mg/kg cw (value confirmed in a SCF opinion issued on 14 December 1995), and the admissible daily intake for the child is 220 mg (20 kg × 11 mg/kg cw). This child's daily intake of cyclamate, apparently 292 mg, is therefore significantly greater than the admissible intake which is 220 mg.
- (35) The Commission has examined in detail all the information communicated by the Swedish authorities. This examination has led it to express reserves about the methodology chosen in order to estimate the high levels of consumption of foodstuffs likely to contain cyclamate. The Commission recognises the difficulties that the Member States have in monitoring consumption of food additives in order to estimate the high consumption levels that some population sub-groups may have. These difficulties have been analysed in detail in a report submitted to the Commission in January 1998<sup>(2)</sup>. This report indicates that in the case of an additive from a single source (one group of foodstuffs) high levels may be estimated by extrapolation on the basis of the average data available using the factor 3. However, according to this report the same method is inappropriate for calculating the intake of an additive from several combined sources (e.g. drinks, sweets and desserts). It is recognised that a consumer with a large consumption of foodstuff belonging to a particular group of foodstuffs cannot be considered statistically as consuming in the same way, i.e. substantially, foodstuffs belonging to

<sup>(1)</sup> 'Hushållens livsmedelsinköp och kostvanor' HULK 1989 (household food purchases and eating habits).

<sup>(2)</sup> Report dated 16 January 1998 submitted to the Commission by a number of Member States, including Sweden, entitled 'Development of methodologies for the monitoring of food additive intake across the European Union'. This report was drawn up in the context of a scientific cooperation programme provided for by Council Directive 93/5/EEC of 25 February 1993 on assistance to the Commission and cooperation by the Member States in the scientific examination of questions relating to food (OJ L 52, 4. 3. 1993, p. 18).



other groups. It is therefore recommended in this report that an alternative statistical method should be used which does not run the risk of overestimating actual consumption levels. The Commission finds that this method was not used by the Swedish authorities, with the result that it has reservations about the figures submitted to it. However, above and beyond these considerations about extrapolation methods, the Commission wonders whether the figures put forward by the Swedish authorities are realistic. The statistical method used shows that there would seem to be a significant exceeding of the ADI in the case of diabetics and in particular diabetic children. The Commission is not convinced that these results, arrived at on the basis of statistics, are realistic. They do not take account of the fact that diabetics are a population sub-group who, more than any other consumers, attach particular importance to their diet, which in order to be balanced is in most cases the subject of medical supervision. Be that as it may, and whatever method is used, the data supplied by the Swedish authorities do not, in the Commission's opinion, show that the Swedish population or population sub-groups are in a specific situation compared with the populations of the other Member States with regard to this question of exceeding the cyclamate ADI.

(36) The Commission has examined whether the restrictive measures in force in Sweden are proportionate. In other words, the aim of the Swedish provisions must not be achievable by means that are less restrictive of trade within the Community. The Commission would point out that the Directive authorises the use of cyclamate in a number of reduced-energy products or products without added sugars, namely certain soft drinks, certain fruit-based or milk-based drinks, desserts, sweets, ice cream, jam and dietary preparations. Foodstuffs Administrative Order No 33 of 1993 prohibits in principle the use of cyclamate in foodstuffs. Cyclamate is only authorised in Sweden as a table-top sweetener. In the Commission's view the Swedish measures seem to go further than is necessary to deal with the problem. They appear radical in that in practice they amount purely and simply to a ban on the use of cyclamate in foodstuffs. To the Commission, a less unreasonable way to avoid cases of exceeding the ADI for cyclamate would seem to be to tighten up the conditions for using cyclamate in food, for example, by limiting the foodstuffs in which cyclamate can be used. Above

all, however, these measures do not seem to take account of the fact that consumers are informed of the presence of cyclamate in food.

(37) The Commission considers that existing Community legislation gives consumers or, in the case of children, their parents or the persons responsible for them, for example, teachers, an assurance of sufficiently clear and full information as to whether or not foodstuffs contain cyclamate. As an additive, cyclamate has to be included in the list of ingredients, under Articles 3 and 6 of Directive 79/112/EEC. Also, products containing cyclamate must state 'with sweetener' on their labelling, pursuant to Council Directive 96/21/EC of 29 March 1996 amending Commission Directive 94/54/EC concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Directive 79/112/EEC<sup>(1)</sup>. These labelling rules are mandatory for products offered for sale to the consumer in prepackaged form. As regards products containing cyclamate which are not prepackaged, the Commission recalls to mind that under Article 12 of Directive 79/112/EEC the Member States decide the manner in which these foodstuffs are labelled, such as the obligation to affix notices accompanying products sold in bulk and containing certain particulars on these products. To sum up, the Commission finds that there are labelling measures in existence which are, moreover, considered sufficient by the authorities of the other Member States, which have not thought it necessary to tighten up the conditions of use of cyclamate compared with those provided for in Directive 94/35/EC.

(38) The Commission considers that the uses of cyclamate currently provided for in Directive 94/35/EC are sufficiently regulated and unlikely to lead to risks of exceeding the ADI expressed by the SCF. The Directive lays down conditions for use of cyclamate such that there should not be consumers or groups of consumers with a balanced diet who regularly exceed the ADI over a substantial period of time. Moreover, the Commission would point out that the Community provisions on cyclamate may be revised. The revision of Directive 94/35/EC could take place in three possible ways: (i) in the framework of Article 4 of Directive 89/107/EEC, which introduces a safeguard clause into the framework legislation on additives; (ii) at the Commission's initiative, which might be envisaged as a way of following up the opinion which the SCF should

<sup>(1)</sup> OJ L 88, 5. 4. 1996, p. 5.

deliver in the first half of 1999 with regard to cyclamate; and (iii) under Article 8 of Directive 94/35/EC, which requires Member States and the Commission to monitor sweetener consumption. This revision could take place on the basis of any new piece of information, such as a detailed study of the levels of consumption of foodstuffs liable to contain cyclamate and of the possible need for additional restrictions on the conditions of use of cyclamate, so that consumers do not exceed the ADI. This is not the case with the information communicated by Sweden in its derogation request. Moreover, not one Member State has so far sent the Commission any such information.

(39) The Commission therefore considers that, while the Swedish measures are aimed at protecting public health, they are excessive in relation to this aim.

*(b) The absence of arbitrary discrimination*

(40) Since the measures in question are not justified by the need to protect public health, the Commission does not have to verify whether this condition is satisfied.

*(c) The absence of a disguised restriction on trade between Member States*

(41) Since the measures in question are not justified by the need to protect public health, the Commission does not have to verify whether this condition is satisfied.

## CONCLUSION

(42) In the light of the above considerations the Commission concludes that the national provisions notified by the Kingdom of Sweden pursuant to Article 100a(4) of the EC Treaty, concerning the conditions of use of azo dyes and cyclamate in foodstuffs, though pursuing the objective of protecting public health, which is one of the major needs referred to in Article 36 in the Treaty, are not justified since they are not strictly necessary for achieving that objective.

(43) The Commission therefore has reason to consider that the national provisions notified cannot be confirmed,

HAS ADOPTED THIS DECISION:

*Article 1*

The Swedish national provisions derogating from Directives 94/35/EC and 94/36/EC notified pursuant to Article 100a(4) of the EC Treaty are not confirmed.

*Article 2*

This Decision is addressed to the Kingdom of Sweden.

Done at Brussels, 21 December 1998.

*For the Commission*

Martin BANGEMANN

*Member of the Commission*