COMMISSION DECISION

of 25 November 2003

concerning national provisions on the use of azodyes notified by Germany under Article 95(4) of the EC Treaty

(notified under document number C(2003) 4356)

(Only the German text is authentic)

(Text with EEA relevance)

(2003/829/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 95(6) thereof,

Whereas:

I. FACTS

(1) By letter of the Permanent Representation of the Federal Republic of Germany to the European Union of 21 May 2003, the German Government, referring to Article 95(4) of the EC Treaty, notified to the Commission its national provisions on the use of azodyes that it deems necessary to maintain after the adoption of Directive 2002/61/EC of the European Parliament and of the Council of 19 July 2002 amending for the nineteenth time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (azocolourants) ([1]).

1. Community legislation

1.1. *Article 95(4) and (6) of the EC Treaty*

(2) Article 95(4) of the EC Treaty provides that 'If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.'

(3) According to Article 95(6), the Commission shall, within six months of the notification, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

([1]) OJ L 243, 11.9.2002, p. 15.

1.2. *Directive 2002/61/EC*

(4) Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations ([2]), as last amended by Directive 2003/53/EC of the European Parliament and of the Council ([3]), establishes rules restricting the marketing and use of certain dangerous substances and preparations. According to Article 1(1), the Directive applies to the dangerous substances and preparations listed in Annex I.

(5) Article 2 provides that Member States shall take all necessary measures to ensure that the dangerous substances and preparations listed in Annex I may only be placed on the market or used subject to the conditions specified therein.

(6) Directive 76/769/EEC has been amended on several occasions, *inter alia*, to add new dangerous substances and preparations to Annex I thereto, thereby introducing the restrictions on their marketing or use that are necessary to protect human health or the environment. In certain cases, restrictions are also placed on the marketing or use of products treated with or containing those substances and preparations.

(7) Adopted on the legal basis of Article 95 of the EC Treaty, Directive 2002/61/EC of the European Parliament and of the Council has inserted in Annex I to Directive 76/769/EEC a new point 43 concerning azocolourants, laying down rules on the marketing and use of these substances.

([2]) OJ L 262, 27.9.1976, p. 201.
([3]) OJ L 178, 17.7.2003, p. 24.

(8) Recitals 2 to 4 of the Directive recall the background of the Directive, stating that 'Textile and leather articles containing certain azodyes have the capacity to release certain arylamines, which may pose cancer risks' ([1]), that 'Limitations already adopted or planned by certain Member States on the use of azodyed textile and leather articles concern the completion and functioning of the internal market. It is therefore necessary to approximate the laws of the Member States in this field and, consequently, to amend Annex I to Council Directive 76/769/EEC' ([2]) and that 'The Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE), after being consulted by the Commission, has confirmed that cancer risks posed by textile and leather goods coloured by certain azodyes, give cause for concern' ([3]).

(9) Consequently, as stated in recital 5, 'In order to protect human health, the use of dangerous azodyes and the placing on the market of some articles coloured with such dyes should be prohibited'.

(10) According to point 43.1, azodyes which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amines listed in the Appendix ([4]), in detectable concentrations, i.e. above 30 ppm in the finished articles or in the dyed parts thereof, according to the testing method established in accordance with Article 2a of this Directive, may not be used in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity, such as:

— clothing, bedding, towels, hairpieces, wigs, hats, nappies and other sanitary items, sleeping-bags,

— footwear, gloves, wristwatch straps, handbags, purses/wallets, briefcases, chair covers, purses worn round the neck,

— textile or leather toys and toys which include textile or leather garments,

— yarn and fabric intended for use by the final consumer ([5]).

(11) Point 43.2 states that 'Furthermore, the textile and leather articles referred to in point 1 above may not be placed on the market unless they conform to the requirements set out in that point', while providing for a time-limited exemption for textile articles made of recycled fibres previously dyed with azodyes.

(12) In addition, point 43.3 provides that not later than 11 September 2005, the Commission shall, in the light of new scientific knowledge, review the provisions on azocolourants, in accordance with recital 9 stating that 'In the light of new scientific knowledge, the provisions on certain azocolourants should be reviewed, in particular with regard to the need to include other materials not covered by this Directive, as well as other aromatic amines. Special attention should be paid to possible risks to children'.

(13) Article 3(1) of the Directive provides that Member States shall adopt and publish, not later than 11 September 2003, the laws, regulations and administrative provisions necessary to comply with this Directive, they shall forthwith inform the Commission thereof and shall apply these provisions from 11 September 2003.

2. **National provisions notified**

(14) The national provisions notified by the Federal Government of Germany were introduced by the second ordinance amending the Consumer Goods Ordinance [Bedarfsgegenständeverordnung] of 15 July 1994. The ban of the use of harmful azodyes in eight groups of articles, which are in prolonged contact with the body, was introduced to protect the consumer against health risks, given the fact that these dyes can break down into substances which are potentially carcinogenic.

(15) Subsection 3 of the Consumer Goods Ordinance headed 'Prohibited substances' states that 'The commercial manufacture or treatment of the materials and articles set out in Annex 1 may not employ substances mentioned therein'. Annex 1 deals with the substances which may not be used in the manufacture or processing of certain articles. Point 7 of Annex 1 lists among the prohibited substances 'Azodyes which can form one of the following amines ([6]) by breaking down into one or more azo groups, with the exception of pigments in which none of the amines specified below can be detected using the methods in accordance with the procedure given in Annex 10(7)'. These azodyes may not be employed in the manufacture or treatment of the following categories of products, listed in Annex 1:

1. Clothing, materials for the manufacture of clothing;

2. Bed linen, blankets, pillows, sleeping bags;

([1]) See recital 2 of Directive 2002/61/EC.
([2]) See recital 3 of Directive 2002/61/EC.
([3]) See recital 4 of Directive 2002/61/EC.
([4]) Directive 2002/61/EC introduced in the Appendix to Directive 76/769/EEC, under 'Point 43 — Azocolourants' a list of 22 aromatic amines.
([5]) Point 43.1 provides for a non-exhaustive list of articles.
([6]) Point 7 of Annex 1 includes thereafter a list of 20 amines.

3. Hand towels, beach mats, air mattresses;

4. Masks, hair-pieces, wigs, artificial eyelashes;

5. Articles of jewellery which are worn on the skin, armbands;

6. Money bags, rucksacks;

7. Crawling mats, covers for seats and loungers for infants and small children;

8. Nappies, sanitary towels, panty liners, tampons.

II. PROCEDURE

(16) By letter of 21 May 2003, the German Permanent Representation to the European Union informed the Commission that, in accordance with Article 95(4) of the EC Treaty, the Federal Republic of Germany intended to maintain its national provisions regarding the use of azodyes which deviate from those provided for in Directive 2002/61/EC amending Directive 76/769/EEC regarding the marketing and use of azocolourants. The Commission received the letter on 26 May 2003.

(17) By letter of 12 June 2003, the Commission informed the German Government that it had received the notification under Article 95(4) of the EC Treaty and that the six-month period for its examination under Article 95(6) started on 27 May 2003, the day following the day on which the notification was received.

(18) By letter of 1 August 2003, the Commission informed the other Member States of the notification received from the Federal Republic of Germany. The Commission also published a notice regarding the notification in the *Official Journal of the European Union* [1] in order to inform other interested parties of the national provisions that Germany intended to maintain as well as the grounds invoked to that effect.

III. LEGAL ASSESSMENT

1. Consideration of admissibility

(19) Article 95(4) concerns cases in which the national provisions are notified in relation to a Community harmonisation measure where these provisions were adopted and entered into force before the adoption of the latter and the maintenance of which would be incompatible with it.

(20) The German notification received by the Commission on 26 May 2003 is intended to obtain approval for the maintenance of national provisions derogating from those of Directive 2002/61/EC, which constitutes a measure concerning the approximation of the laws, regulations and administrative provisions of the Member States, aiming at the establishment and operation of the Internal Market, adopted on the basis of Article 95 of the EC Treaty. In addition, these national provisions were adopted and entered into force in 1994, therefore before the adoption of that Directive.

(21) The need for harmonisation in the field of azocolourants arose from the cancer risks posed by textile and leather goods coloured by certain azodyes, giving cause for concern, as confirmed by the SCTEE in its opinion of 18 January 1999, and from the national legislations banning certain carcinogenic azocolourants introduced or notified by several Member States. Therefore, Directive 2002/61/EC introduced restrictions on the use of azocolourants by banning certain azodyes in articles containing dangerous substances that have clearly been shown, on the basis of sufficient data, to pose risks, i.e. articles made of textiles or leather.

(22) According to a well-established case law, a Community measure has to be interpreted in the light of the objectives pursued. Directive 2002/61/EC is based on Article 95(1) of the Treaty, which is the legal basis for the adoption of harmonisation measures having as their object the establishing and functioning of the internal market. It is clear from recital 3 of that Directive that its main objective is to remove the obstacles to the completion and the functioning of the internal market resulting from the limitations already adopted or planned by certain Member States on the use of certain azocolourants.

(23) The Commission therefore considers that Directive 2002/61/EC has to be interpreted as having introduced a harmonisation of all the current uses of azodyes, thus preventing Member States from introducing or maintaining national restrictions on the use of azodyes going further than those laid down in that Directive.

(24) When comparing the provisions of Directive 2002/61/EC and the national measures notified by Germany, it emerges that the national ban on the use of azodyes considered as harmful to health in certain articles, differs from the requirements of Directive 2002/61/EC. The German provisions (Subsection 3 together with Annex 1(7)) ban the use of azodyes in eight groups of articles without limiting these to textile and leather as required by Directive 2002/61/EC.

(25) Furthermore Article 95(4) requires that the notification of the national provisions be accompanied by a description of the grounds relating to one or more of the major needs referred to in Article 30 or to the protection of the environment or the working environment.

[1] OJ C 185, 5.8.2003, p. 3.

(26) As required by Article 95(4) of the EC Treaty, Germany notified the Commission of the exact wording of the provisions going beyond those set out in Directive 2002/61/EC, including with the application a short explanation of the reasons relating to the protection of consumer health which, in its opinion, justify the maintenance of those provisions.

(27) In the light of the foregoing, the Commission considers that the application submitted by Germany with a view to obtaining authorisation to maintain its national provisions on azodyes is admissible under Article 95(4) of the EC Treaty.

2. **Assessment of merits**

(28) In accordance with Article 95(4) and (6), first subparagraph, of the EC Treaty, the Commission must ascertain that all the conditions enabling a Member State to maintain its national provisions derogating from a Community harmonisation measure provided for in that Article are fulfilled. In particular, the national provisions have to be justified by the major needs referred to in Article 30 of the Treaty or relating to the protection of the environment or the working environment, must not be a means of arbitrary discrimination or a disguised restriction on trade between Member States and must not constitute an obstacle to the functioning of the internal market.

(29) It should be pointed out that the Court's case law is consistent in requiring that the conditions for granting a derogation from the fundamental rules of Community law must be interpreted restrictively. As the provision in question creates an exception to the principles of uniform application of Community law and the unity of the market, Article 95(4) of the EC Treaty must, as with all measures relating to derogations, be interpreted in such a way that its scope is not extended beyond the cases expressly foreseen. As Article 95 is precisely the expression of such a derogation, it must be interpreted strictly and only be applied under strict conditions with regard to the justification required.

2.1. *The burden of proof*

(30) It has to be noted that, in the light of the time frame established by Article 95(6) of the EC Treaty, the Commission, when examining whether the national measures notified under Article 95(4) are justified, has to take as a basis 'the grounds' put forward by the notifying Member State. This means that, according to the provisions of the EC Treaty, the responsibility of proving that the national measures are justified lies with the requesting Member State which seeks to maintain them. Given the procedural framework established by Article 95 of the EC Treaty, including in particular a strict deadline for a decision to be adopted, the Commission normally has to limit itself to examining the relevance of the elements which are submitted by the requesting Member State, without having to seek itself possible reasons of justifications.

(31) It is up to the notifying Member State to provide enough grounds, facts and scientific evidence so that it can be given authorisation to make a derogation [1]. It is thus in the Member State's interest to attach to the notification any substantive or legal elements which could support the application [2]. Failure to include in the notification to maintain or introduce national provisions such elements shall lead the Commission to consider the notification not founded.

(32) In their letter of notification, the German authorities invoke the objective of safeguarding consumer health. The Commission therefore must check whether the national provisions are commensurate with the aim, i.e. necessary and proportionate to the objective pursued, given that the harmonisation measure already adopted, i.e. Directive 2002/61/EC, has itself taken as its basis a high level of protection in accordance with Article 95(3) and pursues this objective in a proportionate way.

2.2. *Justification on grounds of major needs referred to in Article 30 or relating to the protection of the environment or the working environment*

2.2.1. German position

(33) The Federal Government intends to retain the national ban on certain azodyes for the eight groups of articles which come into direct and prolonged contact with the body, in so far as these do not consist of textile or leather thereby going beyond the restrictions contained in Directive 2002/61/EC which is limited to articles made of textile and leather.

(34) To justify the maintenance of their national provisions, the German authorities have submitted an explanatory statement which provides the following justifications.

[1] See, in relation to Article 30 of the EC Treaty, the European Court of Justice judgment of 23 September 2003 in case C-192/01, *Commission* v. *Kingdom of Denmark*, paragraph 46.

[2] See the 'Communication from the Commission concerning Article 95 (paragraphs 4, 5 and 6) of the Treaty establishing the European Community' (COM(2002)760 final, 23.12.2002), in particular its paragraph 13.

(35) The German authorities point out that 'the ban on azodyes which are harmful to health in certain articles which have prolonged contact with the body, enacted in the Federal Republic of Germany in 1994, was for the protection of consumer health'. The German authorities state that 'even at this point in time it was known that certain azodyes could break down into carcinogenic amines'. They consider that 'consequently, any direct contact with the body with these azodyes should be prevented, regardless of the material of which the article, with which the consumer comes into prolonged contact, is made'.

(36) The Federal Government takes the view that the danger to health from azodyes, which can break down into harmful amines, applies regardless of whether the dyed objects are produced from textiles, leather or another material.

(37) As scientific data, Germany simply mentions two opinions of the SCTEE (Scientific Committee for Toxicity, Ecotoxicity and the Environment): the opinion on 'Risk of cancer caused by textiles and leather goods coloured with azodyes' of 18 January 1999 and the opinion on the Report (final draft) on 'Assessment of the risks to human health posed by azocolourants in toys, writing inks and paper products, and analysis of the advantages and drawbacks of restrictions on their marketing and use' of 12 June 2001.

(38) In the following, the statements and positions of the German authorities will be evaluated in the light of the criteria established by Article 95(4). In particular the two opinions of the SCTEE on which Germany bases its request will be analysed.

2.2.2. The SCTEE opinion of 1999

(39) The Commission would like to recall that the effects of azodyes have been assessed both in the study commissioned by the Commission and in the opinion of the SCTEE of 1999 during the preparation of Directive 2002/61/EC.

(40) On 18 January 1999, the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) delivered its opinion ([1]), concluding that the cancer risks associated with the use of certain azodyes give cause for concern ([2]). The Committee confirmed that azodyes which on cleavage form any of the carcinogenic amines classified as carcinogenic category 1 or 2, and in addition 8 amines on the German MAK list, were of special concern. The SCTEE considered that the report commissioned by the Commission adequately reviewed the situation regarding the risk of cancer for consumers as a result of the use of fabrics dyed with azo compounds and that its conclusions were in general acceptable. The Committee supported the report's recommendation that use of azodyes should be restricted without distinguishing between the 14 amines classified by the EU as category I or II carcinogens and the eight amines classified by the MAK Commission, and considered that the restriction should not be subject to prior development of validated analytical methodology.

(41) Therefore, in line with these recommendations, Directive 2002/61/EC has banned the use of dangerous azocolourants and the placing on the market of textiles and leather articles coloured with such substances that have clearly been shown, on the basis of sufficient data, to pose risks. Therefore Germany cannot rely on the SCTEE opinion of 1999 for restricting the use of azodyes in materials other than textiles and leather.

2.2.3. The SCTEE opinion of 2001

(42) The SCTEE, in its opinion of June 2001 ([3]) stated that even if some products made of other materials dyed with azodyes could be possible sources of exposure to azodyes, there is a serious lack of quantitative data. Germany therefore cannot rely on this opinion for justifying its restriction of azodyes in materials other than textiles and leather.

(43) This second SCTEE opinion was known before Directive 2002/61/EC was adopted.

(44) To extend the scope of the ban to other materials, which have not clearly been shown by sufficient data to pose risks, would therefore not be justified.

2.2.4. Further considerations

(45) In this context, the Commission would also like to stress that even if a Member State may base an application to maintain its already existing national provisions on an assessment of the risk to public health different from that accepted by the Community legislature when it adopted the harmonisation measure from which the national provisions derogate, it falls to the applicant Member State to prove the necessity and proportionality of the national provisions in question.

([1]) Opinion on Risk of cancer caused by textiles and leather goods coloured with azodyes expressed at the seventh SCTEE plenary meeting, Brussels, 18 January 1999.

([2]) The concern from the point of view of carcinogenic risks arises from the potential of azodyes to undergo in vivo reductive cleavage to aromatic amines, including the 22 amines classified by the EU or the MAK Commission as proven or suspected human carcinogens.

([3]) Opinion on: Report (final draft) on 'Assessment of the risks to human health posed by azocolourants in toys, writing inks and paper products, and analysis of the advantages and drawbacks of restrictions on their marketing and use'. Opinion expressed at the 24th SCTEE plenary meeting, Brussels, 12 June 2001.

(46) The German authorities have not provided any element to demonstrate the existence of a known risk to human health going beyond the risk already identified by the Community legislature, nor have they demonstrated that the national measures concerned do not go beyond what is necessary to attain the objective foreseen [1].

(47) As demonstrated above, the material and data submitted by the German authorities in support to their request for application of Article 95(4) is very limited. In their explanatory statement, the German authorities justify the maintenance of their national provisions on the ground of consumer protection. However, no further information or data is provided to substantiate their arguments. They have not submitted any scientific data on the risks which would demonstrate the inadequacy of the Community harmonisation measure, nor any evaluation of the risks for health — such as an estimation of the consumer exposure — enabling them to justify the maintenance of their national provision. They have not even provided any information on the use of such azodyes in the manufacture of products with materials other than textile and leather.

(48) Concerning the remaining arguments put forward by the German authorities, the Commission would like to recall that a ban on products constitutes a restriction to trade in the internal market and thus a serious impediment to the fundamental objective of the free circulation of goods. Any restriction of that kind would therefore have to be based on very solid grounds, and the examination of the German application has shown that no such grounds have been presented.

(49) Overall it can be seen that the documentation and arguments submitted by the German authorities in support of their request for a derogation under Article 95(4) do not allow to conclude that the national measures are justified by a major need referred to in Article 30 of the EC Treaty. Consequently, the request from Germany for maintaining its national measures does not fulfil all the conditions set out in Article 95(4) of the EC Treaty.

2.3. *Absence of any arbitrary discrimination, any disguised restriction of trade between Member States or any obstacle to the functioning of the internal market*

(50) Pursuant to Article 95(6) of the EC Treaty, the Commission shall approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

(51) It should be recalled that an application under Article 95(4) of the EC Treaty must be assessed in the light of the conditions laid down in both that paragraph and paragraph 6 of that Article. If any one of those conditions is not met, the application must be rejected without there being a need to examine the others.

(52) Since the request made by Germany does not fulfil the basic conditions set out in Article 95(4) (see Part III, section 2.2, of this Decision), the Commission is not obliged to verify whether or not the notified national provisions are a means of arbitrary discrimination or a disguised restriction on trade between Member States, and whether or not they constitute an obstacle to the functioning of the internal market.

IV. **CONCLUSION**

(53) In light of the elements which it had available to assess the merits of the justifications put forward for the national measures notified, and in light of the considerations set out above, the Commission considers that the request of Germany for maintaining national provisions derogating from Directive 2002/61/EC amending Directive 76/769/EEC with regard to the marketing and use of certain azodyes, submitted on 21 May 2003:

— is admissible,

— does not fulfil all the conditions set out in Article 95(4) of the EC Treaty, as Germany did not justify the maintenance of its national provisions by the major need to protect consumer health.

(54) The Commission therefore has grounds to consider that the national provisions notified cannot be approved in accordance with Article 95(6) of the EC Treaty,

HAS ADOPTED THIS DECISION:

Article 1

The national provisions on restriction on the use and marketing of azodyes notified by the Federal Republic of Germany pursuant to Article 95(4) of the EC Treaty are rejected.

[1] See the European Court of Justice judgment of 20 March 2003 in case C-3/00, paragraphs 63 and 64.

Article 2

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels, 25 November 2003.

For the Commission
Erkki LIIKANEN
Member of the Commission