COMMISSION DECISION

of 26 October 1999

on the national provisions concerning mineral wool notified by Germany derogating from Directive 97/69/EC adapting to technical progress for the 23rd time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances

(notified under document number C(1999) 3490)

(Only the German text is authentic)

(Text with EEA relevance)

(1999/836/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. THE FACTS

1. Community legislation

(1) Annex I to Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [1], as last amended by Directive 1999/33/EC of the European Parliament and the Council [2], contains a list of dangerous substances displaying the harmonised classification and labelling that apply to such substances. All manufacturers, importers or distributors are required to use the harmonised classification and labelling when placing a dangerous substance on the Community market. The list is regularly updated to take account of the continuous increase in scientific and technical knowledge. This is done by revising specific entries in the list and by adding new entries to the list.

The foreword to Annex I describes particular aspects of the list of dangerous substances such as the interpretation of notes that may be added to specific entries. The foreword is also updated when necessary.

Updates of Annex I are adopted by adaptations to technical progress in accordance with Article 28 of Directive 67/548/EEC.

(2) Commission Directive 97/69/EC of 5 December 1997 adapting to technical progress for the 23rd time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [3] was adopted on 5 December 1997. The latest date for Member States to comply with this was 16 December 1998. *Inter alia*, the 23rd adaptation introduced:

— a general entry on mineral wool into the list of dangerous substances in Annex I,

— a specific Note Q relating to mineral wool into the foreword to Annex I.

The draft for the 23rd adaptation was discussed for more than seven years among the Commission, Member State experts such as the Commission Working Group on Classification and Labelling — Health Effects, and experts from the industry involved. The results of these in-depth discussions were taken into account when drafting the draft. Member States delivered a favourable opinion when voting on the draft, with the exception of Germany who voted against.

(3) The general entry on mineral wool defines mineral wool as consisting of man-made vitreous (silicate) fibres with random orientation with an alkaline oxide and an alkaline earth oxide content greater than 18% by weight. All mineral wools are classified as:

— carcinogenic, category 3, risk phrase R 40; and irritant; symbol Xi, R 38,

— or labelled with the symbol Xn, R 38-40, safety phrases S (2-)36/37.

An exception to this general entry would be a specific wool which was given an individual entry in Annex I. The general entry exempts any such possible individual entries by using the descriptor 'with the exception of those specified elsewhere in this Annex'.

[1] OJ 196, 16.8.1967, p. 1.
[2] OJ L 199, 30.7.1999, p. 57.
[3] OJ L 343, 13.12.1997, p. 19.

Directive 97/69/EC further provides for the addition of a Note Q to the foreword to Annex I. According to Note Q, the classification of a specific mineral wool as carcinogenic, category 3, need not apply if the result of an animal test with the wool is 'negative'. Note Q offers the option of four such tests. If a mineral wool were to meet this requirement it would not have to be labelled as carcinogenic. However, the classification and labelling as 'irritant' would remain.

2. **National provisions**

(4) The national provisions at issue consist of a proposal by Germany that the Note Q referred to in Article 1(1)(c) of Directive 97/69/EC, and the classification of mineral wools set out in the Annex to that Directive, should be incorporated into its national laws, amending these as follows (see item I in that request):

'Note Q_1:

The classification as category 2, carcinogenic, need not apply if it can be established that the substance meets one of the following conditions:

— an appropriate test involving intraperitoneal injection of a dose of 1×10^9 WHO fibres, in the size distribution of a typical workplace has shown no evidence of excess carcinogenicity,

— the chemical composition of the substances is such that the algebraic sum of the percentages of weight of the oxides $Na_2O + K_2O + CaO + MgO + BaO + B_2O_3 - 2Al_2O_3$ is greater than 30.

Note Q_2:

The classification as a category 3 carcinogen need not apply if it can be shown that the substance fulfils one of the following conditions:

— an appropriate intraperitoneal test at a dose of 5×10^9 WHO fibres, in the size distribution of a typical workplace, has shown no evidence of excess carcinogenicity,

— the half life after intra-tracheal instillation of 2 mg of a fine suspension for fibres with a length of 5 μm, a diameter of less than 3 μm and a length-to-diameter ratio of more than 3:1 (WHO fibres) is not more than 40 days, or

— the chemical composition of the substance is such that the algebraic sum of the percentages of weight of the oxides $Na_2O + K_2O + CaO + MgO + BaO + B_2O_3 - 2Al_2O_3$ is greater than 40.

ANNEX

CAS No	EC No	No 650-016-00-2
		Note A
		Note Q_1
		Note R

Mineral wool, unless specified elsewhere in this Annex:

[Man-made vitreous (silicate) fibres with random orientation and an alkaline oxide and an alkaline earth oxide content ($Na_2O + K_2O + CaO + MgO + BaO$) greater than 18 % by weight]

Classification

Carc. Cat 2; R 49

Labelling

T



R: 49
S: 53/45

CAS No	EC No	No 650-016-00-2
		Note A
		Note Q_2
		Note R

Mineral wool, unless otherwise specified in this Annex:

[Man-made vitreous (silicate) fibres with random orientation and an alkaline oxide and an alkaline earth oxide content ($Na_2O + K_2O + CaO + MgO + BaO$) greater than 18 % by weight]

Classification

Carc. Cat 3; R 40

Labelling

Xn



R: 40
S: (2-)22'

3. **Comparing the national provisions with Community legislation**

(5) The communication from Germany is in line with Directive 97/69/EC in that mineral wool consists of man-made vitreous (silicate) fibres with random orientation and an alkaline oxide and alkaline earth oxide content greater than 18 % by weight.

However, the communication considers that mineral wools need to be divided into two categories. The first of these should be:

— classified as carcinogenic, category 2, R 49, and be

— labelled with symbol T, R 49, S 53-45.

Inter alia Note Q_1 should exempt these mineral wools from the classification as carcinogenic, category 2 on condition that either:

— the result of an animal test has been 'negative', or

— the carcinogenicity index 'KI' which is a number calculated from the chemical composition of the wool, exceeds 30.

lt can be assumed that such wools should then be classified as carcinogenic, category 3.

The second category of mineral wools should be

— classified as carcinogenic, category 3, R 40, and be

— labelled with symbol Xn, R 40, S (2-)22.

Inter alia Note Q_2 should exempt these mineral wools from the classification as carcinogenic, category 3 on condition that either:

— the result of an animal test has been 'negative' and the communication offers the option of two such tests, or

— the KI exceeds 40.

Such wools should then not be classified and labelled at all, not even as irritant, R 38.

II. **PROCEDURE**

(6) On 11 December 1998, the Office of the Permanent Representative of the Federal Republic of Germany to the European Communities informed the Secretariat-General of the European Commission, by fax, of a request based on former Article 100a(4) of the Treaty establishing the European Community that the Commission should confirm the proposal made by the Federal Government to incorporate the Note Q referred to in Article 1(1)(c) of Directive 97/69/EC and the classification of mineral wool in the Annex to that Directive into its national laws in an amended form (see above). Germany feels that the intended national provisions are justified by 'the major requirements referred to in Article 36, namely the protection of health and of human and animal lives, and the protection of the working environment' (see Item II of the request and the amplifications therein).

On 17 December 1998, the Office of the Permanent Representative of the Federal Republic of Germany to the European Communities sent that request to the Secretariat-General of the European Commission in an official letter that was received on 21 December 1998.

(7) The German request was passed on to the other Member States for comment. No comment was received from the Member States with regard to the content of the notification transmitted to them.

III. **ASSESSMENT**

1. **Rules applying**

(8) The Treaty of Amsterdam has substantially amended the provisions of former Article 100a of the Treaty establishing the European Community by replacing paragraphs 3, 4 and 5 of that Article with eight new paragraphs numbered 3 to 10. Owing to the renumbering of all of the Articles the amended Article has now become Article 95 of the Treaty establishing the European Community.

The Treaty of Amsterdam does not contain any specific transitional provisions on the rules applying to the earlier notifications concerning the time of entry into force of this Treaty, such as the German notification, which is the subject of this Decision.

In the absence of specific provisions extending their scope, the former provisions of Article 100a(4) of the EC Treaty are to be regarded as repealed from the date of entry into force of the new provisions (1 May 1999). Instead the new provisions of the Treaty apply to the examination of this notification with immediate effect from that date.

(9) It emerges from Germany's notification that this is aimed at approval by the Commission of provisions which Germany is intending to introduce after Directive 97/69/EC has been adopted. However, those provisions are not compatible with that Directive. The Commission should therefore examine that notification in the light of Article 95(5) EC that apply if this were the case. Moreover, the Commission must, where appropriate, carry out the checks provided for by Article 95(6) EC. The provisions of Article 95(4) EC cannot be applied in this instance since they solely relate to a situation where a Member State wishes to receive approval to maintain national provisions already adopted before the harmonisation measure concerned has been adopted, this not being the case in this instance.

(10) It must be stressed that, on the date Germany sent its notification, the Treaty rules applying did not make any provision that this notification had to be based on new scientific proof relating to the protection of the environment or workplace because a specific problem in that Member State had arisen after the harmonisation measure had been adopted. This notification must be examined in the light of that specific situation.

2. **Conditions attached to acceptability**

(11) The notification of Germany is intended to obtain an authorisation to introduce national provisions that are incompatible with Commission Directive 97/69/EC. That Directive constitutes one of the harmonisation measures referred to in Article 95(5) EC, the scope of which deliberately includes harmonisation measures that have been adopted by the Commission.

As required by Article 95(5) EC, Germany notified the Commission of the actual wording of the provisions that they were intending to introduce, accompanying their request by an explanation of the reasons which, they felt, justified the introduction of those provisions.

In view of the above, the Commission feels that the notification prepared by Germany in order to obtain approval for the introduction of national provisions that were incompatible with Directive 97/69/EC, on the basis of the provisions of former Article l00a(4) of the EC Treaty, can be acceptable pursuant to Article 95(5) EC.

3. **Assessment of merits**

(12) It emerges from Article 95 of the Treaty that the Commission must satisfy itself that all of the conditions enabling a Member State to avail itself of the scope for divergence offered by that Article are met.

The Commission must therefore assess whether the conditions provided for by Article 95(5) EC are met. This requires (a) 'new scientific proof with regard to the protection of the environment and workplace', (b) which causes the applicant Member State to consider the introduction of national provisions to be necessary 'as a result of a problem that is specific to that Member State', (c) where the problem concerned arose 'after the harmonisation measure had been adopted'.

In addition, pursuant to Article 95(6) EC, where it feels that the introduction of such national provisions is justified the Commission must check whether those national provisions are, or are not a means of arbitrary discrimination or a hidden restriction of trade between the Member States and whether they do, or do not, constitute 'an impediment to the functioning of the internal market'.

3.1 ***New scientific evidence concerning the protection of the environment or workplace following a specific problem in the Member State concerned arising after the harmonisation measure has been adopted***

(13) Germany is basing its request on the 'major requirements referred to in Article 36, namely the protection of health and of human and animal life, and the protection of the workplace'.

The national provisions that Germany intends to apply to the classification and labelling of mineral wool are in conformity with Directive 97/69/EC with regard to the chemical composition that such a wool must have. Furthermore, those provisions are in conformity with Notes A and R, which are attached to the classification of mineral wool both in the German provisions and in Directive 97/69/EC.

However, the German draft provisions provide for two classes of mineral wool which, with reference to carcinogenicity, are classified as category 2 (stronger carcinogen) and category 3 (weaker carcinogen), whereas Directive 97/69/EC only classifies mineral wool in category 3. It is therefore not possible to evaluate the criteria for exemption from category 2 in the notification from Germany as compared with the exemption criteria in Directive 97/69/EC.

For mineral wool classified as 'category 3, carcinogenic' the German notification places the exemption criteria in a Note Q_2, whereas Directive 97/69/EC places such criteria in Note Q.

The first exemption criterion in Note Q_2 gives more details concerning an intra-peritoneal test than Note Q in Directive 97/69/EC, which simply requires an 'appropriate intra-peritoneal test'. The criteria in both notes could be considered as equivalent, at least in certain cases.

The second criterion in Note Q_2 describes a test with intra-tracheal instillation in detail. Again, the description of the intra-tracheal instillation test in Note Q in Directive 97/69/EC is less detailed. A notable difference is, however, that Note Q_2 also includes relatively short mineral wool fibres, whereas Note Q in Directive 97/69/EC concentrates on longer fibres.

The third criterion in Note Q_2 refers to the chemical composition of a wool required for exemption from the classification as carcinogenic. This is an application of the KI (CI) index which, according to the opinion [4] adopted by the Scientific Committee for Toxicology, Ecotoxicology and the Environment (CSTEE) by written procedure on 10 September 1999, has 'not been extensively tested to confirm that the chemical composition of a fibre is informative with regard to its carcinogenicity'. There is no equivalent to the KI (CI) index in Note Q in Directive 97/69/EC.

Finally, Note Q in Directive 97/69/EC also lists a short-term biopersistence test by inhalation and a long term inhalation test as criteria for exempting mineral wool from classification as carcinogenic. Neither of these two tests is referred to in Note Q_2 in the notification from the German authorities.

This being the case it follows that the criteria for exempting mineral wool from the classification as a carcinogen proposed in the German notification differ to a considerable extent from the criteria laid down in Directive 97/69/EC. One of the proposed criteria, namely the use of the chemical composition has, in the opinion of the CSTEE, not been extensively tested and therefore does not appear to be acceptable.

(14) In order to address the scientific/technical reasons put forward in the notification from Germany for applying national provisions which diverge from the requirements of Directive 97/69/EC, the Commission called on experts in the field of classification and labelling to draw up a technical report. In short the arguments from Germany can be summarised as:

— the classification of mineral wool as laid down in Directive 97/69/EC conflicts with the provisions of Directive 67/548/EEC and is not toxicologically sound,

— the exemption criteria in Note Q in Directive 97/69/EC contradict scientific knowledge,

— the planned national provisions tie in with the principles laid down at Community level for avoiding unnecessary animal experiments.

The technical report refuted each individual argument presented. This included reference to the year long, in depth scientific/technical discussions that had taken place during the preparation of Directive 97/69/EC: 'The Communication from the Federal Government is not considered to contain any evidence that has not previously been considered by the Commission and other Member States in the meetings leading to the development and adoption of Directive 97/69/EC'.

Thus, with regard to the scientific arguments presented by Germany, the situation is the same as before the adoption of Directive 97/69/EC. These arguments had not convinced the experts from the other Member States during the preparatory scientific discussions.

It can therefore be concluded that the scientific/technical arguments put forward in the German notification cannot be considered a better basis for the classification of mineral wool than the provisions in Directive 97/69/EC.

The technical report was forwarded to the CSTEE for assessment as to whether it correctly addressed the reasons put forward in the notification from Germany. In its opinion of 10 September 1999 the CSTEE considered in a general comment that 'A scientific evaluation of either document (the German communication and the technical report) is made difficult by the lack of references to the scientific literature. The text of both documents (particularly that of the technical report) mixes allusions to scientific findings and to their potential normative consequences, without drawing a clear distinction between the two'.

Furthermore, in evaluating the scientific basis for the classification of mineral wool the CSTEE opinion refers, among other things, to scientific findings that were dismissed in both the notification from Germany and also the technical report.

Thus, the scientific arguments in the German notification are considered incomplete and cannot serve as a sound basis for the classification of mineral wool. Similarly the technical report is of unsatisfactory quality. It can therefore be concluded that the scientific developments in the field of man-made mineral fibres need further evaluation.

(15) In addition, in the light of the requirements laid down in Article 95(5) the Commission asked the CSTEE whether the reasons put forward by Germany in its communication:

(a) represented or contained new scientific evidence which had arisen after 5 December 1997 (the date of adoption of Directive 97/69/EC);

(b) related to the protection of the environment or the workplace;

[4] *http://europa.eu.int/comm/dg24/health/sc/sct/out48_en.html*

(c) constituted a justification based on a problem which was specific to the Federal Republic of Germany.

The CSTEE included its response in its abovementioned opinion of 10 September 1999.

(a) with regard to the first requirement of Article 95(5) mentioned above, the opinion of the CSTEE was that the reasons put forward in the notification from the German authorities did not specifically allude to any scientific evidence which had arisen after 5 December 1997.

The Commission therefore considers that the requirement concerning new scientific evidence in Article 95(5) is not fulfilled.

(b) With regard to the second requirement of Article 95(5) mentioned above, the opinion of the CSTEE stated that the scientific evidence provided by Germany did indeed relate to the protection of the workplace.

Consequently, the second requirement of Article 95(5) can be considered as fulfilled.

(c) With regard to the third requirement of Article 95(5) mentioned above, the opinion of the CSTEE was that the problem of protecting the workplace which Germany intend to tackle with its notification is not specific to Germany.

The Commission therefore considers that the third requirement of Article 95(5) is likewise not fulfilled.

In view of the opinion of the CSTEE, the Commission feels that the basic conditions set out in Article 95(5) are not met in this particular instance.

3.2. *Arbitrary means of discrimination/hidden restriction of trade between the Member States/impairment of the functioning of the internal market*

(16) Under Article 95(6), the Commission will either approve or reject any given national provisions 'after having checked whether these are or are not a means of arbitrary discrimination or a hidden barrier to trade between Member States and if they either do or do not constitute an impairment of the functioning of the internal market'.

(17) Since the request made by Germany is not justified in the light of the basic conditions set out in Article 95(5) (see point 3.1), the Commission is not obliged to check whether the national provisions referred to are, or are not, a means of arbitrary discrimination or a hidden barrier to trade between Member States and if they either do or do not constitute an impairment of the functioning of the internal market.

IV. **CONCLUSION**

(18) In view of the above factors, the Commission feels that the request made by Germany:

— is acceptable,

— but is not justified.

The Commission therefore concludes by rejecting that request in accordance with Article 95(6) of the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

The national provisions concerning mineral wool, of which the Commission was notified by Germany by fax on 11 December and by a letter dated 17 December 1998, and which diverge from Directive 97/69/EC are hereby rejected.

Article 2

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels, 26 October 1999.

For the Commission

Margot WALLSTRÖM

Member of the Commission