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II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 26 April 2004

amending Decision 2001/471/EC as regards bacteriological tests in certain meat establishments

(notified under document number C(2004) 1519)

(Text with EEA relevance)

(2004/379/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 64/433/EEC of 26 June 1964 on health conditions for the production and marketing of fresh meat¹, and in particular Article 10(2) thereof,

Whereas:

- (1) Commission Decision 2001/471/EC² obliges operators of meat establishments to conduct regular checks on the general hygiene conditions of production in their establishments.
- (2) That Decision lays down rules for the bacteriological testing of carcasses of cattle, swine, sheep, goats and horses. It provides that the results of the bacteriological tests are to be converted into daily log mean values in order to compare them to the limits it lays down.

¹ OJ L 121, 29.7.1964, p. 2012/64. Directive as last amended by Directive 95/23/EC (OJ L 243, 11.10.1995, p. 7).

² OJ L 165, 21.6.2001, p. 48.

- (3) Member States are currently implementing two different methods of calculation to convert the test results into a log mean value, which results in different numerical values.
- (4) The implementation of bacteriological testing should be harmonised within the Community. The method of calculation for the conversion of the results of the bacteriological tests of meat set out in Decision 2001/471/EC should therefore be clarified.
- (5) Decision 2001/471/EC should therefore be amended accordingly.
- (6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 2001/471/EC is amended in accordance with the Annex to this Decision.

Article 2

This Decision shall apply from 20 May 2004

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 26 April 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX

Part 1 of the Annex to Decision 2001/471/EC is amended as follows:

1. In the Section entitled 'Applying microbiological criteria to excised-sample test results (Table 1)', the first sentence is replaced by the following:

'The daily mean of the log results should be allocated into one of three categories for process control verification: acceptable, marginal, and unacceptable.'

2. Table 1 is replaced by the following:

'Table 1

Daily mean of the log values¹ for marginal and unacceptable results for bacterial performance criteria for cattle, pig, sheep, goat and horse units (cfu/cm²) for samples taken by the destructive method.

		Acceptable range		Marginal range (> m but ≤ M)	Unacceptable range(> M)
		Cattle/sheep /goat/horse	Pig	Cattle/pig/sheep/ goat/horse	Cattle/pig/sheep/ goat/horse
Daily mean of the log values for	Total viable counts (TVC)	< 3,5	< 4,0	3,5 (pig: 4,0) - 5,0	> 5,0
	Entero- bacteria- cae	< 1,5	< 2,0	1,5 (pig: 2,0) - 2,5 (pig: 3,0)	> 2,5 (pig: > 3,0)

¹ The daily mean of the log values is calculated by first taking a log (log₁₀) value of each individual test result and then calculating the arithmetical mean of these log values.'

COMMISSION DECISION**of 26 April 2004****amending Decision 97/365/EC as regards the inclusion of establishments in Iceland in provisional lists of third-country establishments from which Member States authorise imports of meat products***(notified under document number C(2004) 1520)***(Text with EEA relevance)**

(2004/380/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 95/408/EC of 22 June 1995 on the conditions for drawing up, for an interim period, provisional lists of third-country establishments from which Member States are authorised to import certain products of animal origin, fishery products or live bivalve molluscs ¹, and in particular Article 2(4) thereof,

Whereas:

- (1) Provisional lists of establishments in third countries from which the Member States authorise imports of products prepared from meat of bovine animals, swine, equidae and sheep and goats have been drawn up by Commission Decision 97/365/EC ².
- (2) Iceland has sent list a of establishments producing meat products for which the competent authority certifies that the establishments comply with Community rules.
- (3) Those establishments should be included in the lists drawn up by Decision 97/365/EC.
- (4) As on-the-spot inspections have not yet been carried out, imports from such establishments are not eligible for reduced physical checks pursuant to Article 10 of Council Directive 97/78/EC ³.
- (5) Decision 97/365/EC should therefore be amended accordingly.

¹ OJ L 243, 11.10.1995, p. 17. Decision as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

² OJ L 154, 12.6.1997, p. 41. Decision as last amended by the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (OJ L 236, 23.9.2003, p. 381).

³ OJ L 24, 30.1.1998, p. 9.

- (6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 97/365/EC is amended in accordance with the Annex to this Decision.

Article 2

This Decision shall apply from 7 May 2004.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 26 April 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX

In the Annex to Decision 97/365/EC, the following text is inserted in accordance with the alphabetical order of the country ISO code:

‘País: Islandia / Land: Island / Land: Island / Χώρα: Ισλάνδία / Country: Iceland / Pays: Islande / Paese: Islanda / Land: Ijsland / País: Islandia / Maa: Islanti / Land: Island

1	2	3	4	5
22	Kaupfélag V-Hunvetninga	Hvammstangi		6
23	Sölufélag A-Hunvetninga	Blonduos		6
31	Nordlenska	Husavik		6
50	Kaupfélag Skagfirdinga	Saudarkrokur ⁷		6 ⁷

COMMISSION DECISION**of 26 April 2004****amending Decision 1999/710/EC as regards the inclusion of establishments in Iceland in provisional lists of third-country establishments from which Member States authorise imports of minced meat and meat preparations***(notified under document number C(2004) 1521)***(Text with EEA relevance)**

(2004/381/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 95/408/EC of 22 June 1995 on the conditions for drawing up, for an interim period, provisional lists of third-country establishments from which Member States are authorised to import certain products of animal origin, fishery products or live bivalve molluscs ¹, and in particular Article 2(4) thereof,

Whereas:

- (1) Provisional lists of establishments in third countries from which the Member States authorise imports of minced meat and meat preparations have been drawn up by Commission Decision 1999/710/EC ².
- (2) Iceland has sent a list of establishments producing minced meat and meat preparations for which the competent authority certifies that the establishments comply with Community rules.
- (3) Those establishments should be included in the lists drawn up by Decision 1999/710/EC.
- (4) As on-the-spot inspections have not yet been carried out, imports from such establishments are not eligible for reduced physical checks pursuant to Article 10 of Council Directive 97/78/EC ³.

¹ OJ L 243, 11.10.1995, p. 17. Decision as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

² OJ L 281, 4.11.1999, p. 82. Decision as last amended by the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (OJ L 236, 23.9.2003, p. 381).

- (5) Decision 1999/710/EC should therefore be amended accordingly.
- (6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 1999/710/EC is amended in accordance with the Annex to this Decision.

Article 2

This Decision shall apply from 7 May 2004.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 26 April 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX

In the Annex to Decision 1999/710/EC, the following text is inserted in accordance with the alphabetical order of the country ISO code:

‘País: Islandia / Land: Island / Land: Island / Χώρα: Ισλάνδια / Country: Iceland / Pays: Islande / Paese: Islanda / Land: Ijsland / País: Islandia / Maa: Islanti / Land: Island.

1	2	3	4	5	6
22	Kaupfelag V-Hunvetninga	Hvammstangi		MP	7
50	Kaupfelag Skagfirdinga	Saudarkrokur		MP	7'

COMMISSION DECISION**of 26 April 2004****adopting Community import decisions for certain chemicals pursuant to Regulation (EC) No 304/2003 of the European Parliament and of the Council****(Text with EEA relevance)**

(2004/382/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals ¹, and in particular Article 12(1) thereof,

Whereas:

- (1) Pursuant to Regulation (EC) No 304/2003 the Commission is to decide on behalf of the Community, whether or not to permit the import into the Community of each chemical subject to the prior informed consent (PIC) procedure.
- (2) The United Nations Environment Programme (UNEP) and the Food and Agriculture Organization (FAO) have been appointed to provide secretariat services for the operation of the interim PIC procedure established by the Final Act of the Conference of Plenipotentiaries on the Rotterdam Convention on the Prior Informed Consent (PIC) procedure for certain hazardous chemicals and pesticides in international trade, signed on 11 September 1998, and approved by the Community by Council Decision 2003/106/EC of 19 December 2002 concerning the approval, on behalf of the European Community, of the Rotterdam Convention on the Prior Informed Consent Procedure for certain hazardous chemicals and pesticides in international trade ², in particular the Resolution on interim arrangements laid down in the Final Act.
- (3) The Commission, acting as common designated authority, is required to forward decisions on chemicals to the Secretariat of the interim PIC procedure, on behalf of the Community and its Member States.

¹ OJ L 63, 6.3.2003, p. 1.

² OJ L 63, 6.3.2003, p. 27.

- (4) The interim Secretariat has requested that the participants in the PIC procedure use the special Importing Country Response form when reporting their import decisions.
- (5) The chemicals actinolite, amosite, anthophyllite and tremolite, which are all amphibole forms of asbestos fibres, have also been added to the interim PIC procedure and the Commission has received information from the interim secretariat in the form of a decision guidance document (which also covers crocidolite asbestos, which was already included in the interim PIC procedure and was subject to a final Community import decision that was reported in PIC circular IV reflecting the position as at 31 December 1994). All these chemicals have been progressively banned or severely restricted at Community level by means of a series of regulatory actions, the latest of which is Commission Directive 1999/77/EC of 26 July 1999³ adapting to technical progress for the sixth time 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 preparations⁴. Accordingly a final import decision should be taken for actinolite, amosite, anthophyllite and tremolite and a revised and updated final decision should be taken in respect of crocidolite.
- (6) The chemical DNOC has been added to the interim PIC procedure, as a pesticide, for which the Commission has received information from the interim Secretariat in the form of a decision guidance document. DNOC falls within the scope of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market⁵, as last amended by Regulation (EC) No 806/2003⁶. By Commission Decision 1999/164/EC of 17 February 1999 concerning the non-inclusion of DNOC of active substance in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance⁷, DNOC was excluded from Annex I to Directive 91/414/EEC and authorisations for plant protection products containing it were to be withdrawn by 16 August 1999. Accordingly a final import decision should be taken.
- (7) Certain pesticide formulations, in the form of dustable powder formulations containing a combination of benomyl at or above 7 %, carbofuran at or above 10 % and thiram at or above 15 %, have also been added to the interim PIC procedure. The Commission has received information from the interim secretariat in the form of a decision guidance document. The chemicals benomyl, carbofuran and thiram fall within the scope of Directive 91/414/EEC. By Commission Decision 2002/928/EC of 26 November 2002 concerning the non-inclusion of benomyl in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance⁸, benomyl has been excluded from Annex I to Directive 91/414/EEC and authorisations for plant protection products containing it had to be withdrawn by 25 May 2003. Carbofuran is currently subject to an ongoing assessment within the framework of Directive 91/414/EEC. That Directive provides for a transitional period during which Member States are allowed to take national

³ OJ L 262, 27.9.1976, 201.

⁴ OJ L 207, 6.8.1999, p. 18.

⁵ OJ L 230, 19.8.1991, p. 1.

⁶ OJ L 122, 16.5.2003, p. 1.

⁷ OJ L 54, 2.3.1999, p. 21.

⁸ OJ L 322, 27.11.2002, p. 53.

decisions on substances and products falling within its scope pending a Community decision. By Commission Directive 2003/81/EC of 5 September 2003 amending Directive 91/414/EEC to include molinate, thiram and ziram as active substances⁹, thiram has been included in Annex I to Directive 91/414/EEC and is authorised for use in plant protection products subject to certain conditions. Thiram has also been notified under Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market¹⁰, which provides for a transitional period during which Member States may, pending a Community decision, take a decision on substances and products falling within its scope. Consequently, an interim import decision should be taken for dustable powder formulations containing a combination of benomyl, carbofuran and thiram at or above the specified concentrations.

- (8) The measures provided for in this Decision are in accordance with the opinion of the Committee set up pursuant to Article 29 of Council Directive 67/548/EEC¹¹, as last amended by Commission Directive 2001/59/EC¹²,

HAS DECIDED AS FOLLOWS:

Article 1

The final decision on the import of the chemicals actinolite, amosite, anthophyllite, crocidolite and tremolite, as set out in the import response form contained in Annex I, is adopted.

Article 2

The final decision on the import of the chemical DNOC, as set out in the import response form contained in Annex II, is adopted.

Article 3

The interim decision on the import of dustable powder pesticide formulations containing a combination of benomyl at or above 7 %, carbofuran at or above 10 % and thiram at or above 15 %, as set out in the import response form in Annex III, is also adopted.

Done at Brussels, 26 April 2004.

For the Commission
Margot WALLSTRÖM
Member of the Commission

⁹ OJ L 224, 6.9.2003, p. 29.

¹⁰ OJ L 123, 24.4.1998, p. 1.

¹¹ OJ 196, 16.8.1967, p. 1.

¹² OJ L 225, 21.8.2001, p. 1.

ANNEX I

Final import decision for the chemicals actinolite, amosite, anthophyllite and tremolite, together with an updated final import decision for crocidolite replacing a previous 1994 import decision



*Interim Secretariat for the Rotterdam Convention on the Prior Informed
Consent Procedure for Certain Hazardous Chemicals and Pesticides in
International Trade*



**FORM
FOR IMPORTING COUNTRY RESPONSE**

IMPORTANT: See instructions before filling in the form

COUNTRY: European Community

(Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom)

SECTION 1. IDENTITY OF CHEMICAL

1.1	Common name	Asbestos in the following forms: Actinolite, Anthophyllite, Amosite, Crocidolite and Tremolite
1.2	CAS numbers	Actinolite 77536-66-4 Anthophyllite 77536-67-5 Amosite 12172-73-5 Crocidolite 12001-28-4 Tremolite 77536-68-6
1.3	Type of formulation and content of active ingredient	

SECTION 2. THE IMPORT RESPONSE PROVIDED IN THIS FORM APPLIES TO THE FOLLOWING CATEGORY OR CATEGORIES

Pesticide
X Industrial
Severely hazardous pesticide formulation

SECTION 3. INDICATION REGARDING PREVIOUS RESPONSE, IF ANY

3.1	X This is a first time import response for this chemical in the country.* * except for crocidolite, for which a final 1994 decision is updated.
3.2	This is a modification of a previous response.

	The previous response was a final decision.	Yes	No
	The previous response was an interim response.	Yes	No
	Date of issue of the previous response:		

SECTION 4. RESPONSE REGARDING FUTURE IMPORT

X Final decision (Fill in section 5, page 2) **OR** **Interim response (Fill in section 6, page 3-4)**

SECTION 5. FINAL DECISION, PURSUANT TO NATIONAL LEGISLATIVE OR ADMINISTRATIVE MEASURES

5.1	X No consent to import		
	Is the import of the chemical from all sources simultaneously prohibited?	X Yes	No
	Is domestic production of the chemical for domestic use simultaneously prohibited?	X Yes	No
5.2	Consent to import		
5.3	Consent to import only subject to specified conditions		
	Are the conditions for import of the chemical the same for all sources of import?	Yes	No
	Are the conditions for domestic production of the chemical for domestic use the same as for all imports?	Yes	No
5.4	NATIONAL LEGISLATIVE OR ADMINISTRATIVE MEASURE UPON WHICH THE FINAL DECISION IS BASED		
	Description of the national legislative or administrative measure: It is prohibited to place on the market and use all forms of asbestos fibres and products containing them. The chemicals were banned by a series of regulatory actions dating from 1983, the latest of which is Commission Directive 1999/77/EC (Official Journal of the European Communities(OJ) L207 of 6 August 1999, p. 18) adapting to technical progress for the sixth time Annex I to Council Directive 76/769/EEC relating to 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. The complete name and address of the institution/authority responsible for issuing this national legislative or administrative measure: European Community and its Member States (see address in section 8).		
5.5	Remarks See under point 5.3 and 5.4		
	Has there ever been a request of registration of this chemical in the country?	Yes	No
	Is this chemical currently registered in the country?	Yes	No

	Is this chemical manufactured in the country?		Yes	No
	Is this chemical formulated in the country?		Yes	No
	If yes to either one of these last two questions:	Is this intended for domestic use?	Yes	No
		Is this intended for export?	Yes	No
	Other remarks			
SECTION 6. INTERIM RESPONSE				
6.1	No consent to import Is the import of the chemical from all sources simultaneously prohibited? Yes No Is domestic production of the chemical for domestic use simultaneously prohibited? Yes No			
6.2	Consent to import			
6.3	Consent to import only subject to specified conditions The specified conditions are: Are the conditions for import of the chemical the same for all sources of import? Yes No Are the conditions for domestic production of the chemical for domestic use the same as for all imports? Yes No			
6.4	INDICATION OF ACTIVE CONSIDERATION IN ORDER TO REACH A FINAL DECISION			
	1.1. Is a final decision under active consideration? Yes No Approximate time needed before a final decision can be reached: The complete name and address of the responsible institution/authority actively considering a final decision:			
6.5	INFORMATION OR ASSISTANCE REQUESTED IN ORDER TO REACH A FINAL DECISION			

	The following additional information is requested from the Secretariat: The following additional information is requested from the country that notified the final regulatory action: The following assistance is requested from the Secretariat in evaluating the chemical:		
6.6	Remarks		
	Has there ever been a request of registration of this chemical in the country?		Yes No
	Is this chemical currently registered in the country?		Yes No
	Is this chemical manufactured in the country?		Yes No
	Is this chemical formulated in the country?		Yes No
	If yes to either one of these last two questions:	Is this intended for domestic use?	Yes No
		Is this intended for export?	Yes No
	Other remarks		

SECTION 7. RELEVANT ADDITIONAL INFORMATION

All forms of asbestos are classified under Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 196, 16.8.1967, p.1) as: Carc. Cat.1; R45 (Carcinogenic category 1; may cause cancer) – T; R 48/23 (Toxic; danger of serious damage to health by prolonged exposure through inhalation).

SECTION 8. DESIGNATED NATIONAL AUTHORITY

Institution	European Commission DG Environment
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Address	Rue de la Loi 200 B-1049 Brussels Belgium
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ANNEX II

Final import decision for the chemical DNOC



*Interim Secretariat for the Rotterdam Convention on the Prior Informed
Consent Procedure for Certain Hazardous Chemicals and Pesticides in
International Trade*



**FORM
FOR IMPORTING COUNTRY RESPONSE**

IMPORTANT: See instructions before filling in the form

COUNTRY: European Community

(Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom)

SECTION 1. IDENTITY OF CHEMICAL

1.1	Common name	DNOC and its salts (such as ammonium salt, potassium salt and sodium salt)
1.2	CAS number	DNOC 534-52-1 Ammonium salt 2980-64-5 Potassium salt 5787-96-2 Sodium salt 2312-76-7
1.3	Type of formulation and content of active ingredient	

SECTION 2. THE IMPORT RESPONSE PROVIDED IN THIS FORM APPLIES TO THE FOLLOWING CATEGORY OR CATEGORIES

☒ Pesticide
☐ Industrial
☐ Severely hazardous pesticide formulation

SECTION 3. INDICATION REGARDING PREVIOUS RESPONSE, IF ANY

3.1	☒ This is a first time import response for this chemical in the country.
3.2	This is a modification of a previous response. The previous response was a final decision. Yes No

	The previous response was an interim response. Yes No
	Date of issue of the previous response: _____

SECTION 4. RESPONSE REGARDING FUTURE IMPORT

☒ **Final decision** (*Fill in section 5, page 2*) **OR** **Interim response** (*Fill in section 6, page 3-4*)

SECTION 5. FINAL DECISION, PURSUANT TO NATIONAL LEGISLATIVE OR ADMINISTRATIVE MEASURES

5.1	X No consent to import Is the import of the chemical from all sources simultaneously prohibited? ☒ Yes No Is domestic production of the chemical for domestic use simultaneously prohibited? ☒ Yes No	
5.2	Consent to import	
5.3	Consent to import only subject to specified conditions The specified conditions are: Are the conditions for import of the chemical the same for all sources of import? Yes No Are the conditions for domestic production of the chemical for domestic use the same as for all imports? Yes No	
5.4	NATIONAL LEGISLATIVE OR ADMINISTRATIVE MEASURE UPON WHICH THE FINAL DECISION IS BASED Description of the national legislative or administrative measure: It is prohibited to use or place on the market all plant protection products containing DNOC. DNOC was excluded from Annex I to Council Directive 91/414/EEC and thus authorisations for plant-protection products containing this active substance have been withdrawn. (Commission Decision 1999/164/EC of 17 February 1999, OJ L54, 2.3.1999, p.21). The complete name and address of the institution/authority responsible for issuing this national legislative or administrative measure: European Community and its Member States (see address in section 8).	

5.5	Remarks		
	Has there ever been a request of registration of this chemical in the country?		Yes No
	Is this chemical currently registered in the country?		Yes No
	Is this chemical manufactured in the country?		Yes No
	Is this chemical formulated in the country?		Yes No
	If yes to either one of these last two questions:	Is this intended for domestic use?	Yes No
		Is this intended for export?	Yes No
Other remarks			
SECTION 6. INTERIM RESPONSE			
6.1	No consent to import		
	Is the import of the chemical from all sources simultaneously prohibited?		Yes No
6.2	Is domestic production of the chemical for domestic use simultaneously prohibited?		Yes No
	Consent to import		
6.3	Consent to import only subject to specified conditions		
	Are the conditions for import of the chemical the same for all sources of import?		Yes No
6.4	Are the conditions for domestic production of the chemical for domestic use the same as for all imports?		Yes No
	INDICATION OF ACTIVE CONSIDERATION IN ORDER TO REACH A FINAL DECISION		
6.5	Is a final decision under active consideration? Yes No		
	The complete name and address of the responsible institution/authority actively considering a final decision:		
INFORMATION OR ASSISTANCE REQUESTED IN ORDER TO REACH A FINAL DECISION			

	The following additional information is requested from the Secretariat: The following additional information is requested from the country that notified the final regulatory action: The following assistance is requested from the Secretariat in evaluating the chemical:		
6.6	Remarks		
	Has there ever been a request of registration of this chemical in the country?		Yes No
	Is this chemical currently registered in the country?		Yes No
	Is this chemical manufactured in the country?		Yes No
	Is this chemical formulated in the country?		Yes No
	If yes to either one of these last two questions:	Is this intended for domestic use?	Yes No
		Is this intended for export?	Yes No
Other remarks			

SECTION 7. RELEVANT ADDITIONAL INFORMATION

DNOC is classified under Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 196, 16.8.1967, p.1) as Muta. Cat.3; R68 (Mutagenic category 3; possible risks of irreversible effects) – T+; R26/27/28 (Very toxic; very toxic by inhalation, contact with skin and if swallowed) – Xi; R38, R41(Irritant; irritating to skin; risk of serious damage to eyes) – R43(may cause sensitisation by skin contact) – R44 (risk of explosion if heated under confinement) – N; R50/53 (Dangerous to the environment; very toxic to aquatic organisms, may cause long-term effects in the aquatic environment).

SECTION 8. DESIGNATED NATIONAL AUTHORITY

Institution	European Commission Directorate-General for the Environment
Address	Rue de la Loi Wetstraat 200, B-1049 Brussels

ANNEX III

Interim import decision for dustable powder pesticide formulations containing a combination of benomyl at or above 7 %, carbofuran at or above 10 % and thiram at or above 15 %



*Interim Secretariat for the Rotterdam Convention on the Prior Informed
Consent Procedure for Certain Hazardous Chemicals and Pesticides in
International Trade*



**FORM
FOR IMPORTING COUNTRY RESPONSE**

IMPORTANT: See instructions before filling in the form

COUNTRY: European Community

(Member States: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom)

SECTION 1. IDENTITY OF CHEMICAL

1.1	Common name	Dustable powder formulations containing a combination of: Benomyl at or above 7% Carbofuran at or above 10% Thiram at or above 15%
1.2	CAS numbers	Benomyl 17804-35-2 Carbofuran 1563-66-2 Thiram 137-26-8
1.3	Type of formulation and content of active ingredient	All dustable powder formulations containing a combination of: Benomyl at or above 7% Carbofuran at or above 10% Thiram at or above 15%

**SECTION 2. THE IMPORT RESPONSE PROVIDED IN THIS FORM APPLIES TO THE
FOLLOWING CATEGORY OR CATEGORIES**

Pesticide
Industrial
X Severely hazardous pesticide formulation

SECTION 3. INDICATION REGARDING PREVIOUS RESPONSE, IF ANY

3.1	X This is a first time import response for this chemical in the country.		
3.2	This is a modification of a previous response.		
	The previous response was a final decision.	Yes	No
	The previous response was an interim response.	Yes	No
	Date of issue of the previous response: _____		

SECTION 4. RESPONSE REGARDING FUTURE IMPORT

Final decision (Fill in section 5, page 2) OR X Interim response (Fill in section 6, page 3-4)

SECTION 5. FINAL DECISION, PURSUANT TO NATIONAL LEGISLATIVE OR ADMINISTRATIVE MEASURES

5.1	No consent to import		
	Is the import of the chemical from all sources simultaneously prohibited?	Yes	No
	Is domestic production of the chemical for domestic use simultaneously prohibited?	Yes	No
5.2	Consent to import		
5.3	Consent to import only subject to specified conditions		
	Are the conditions for import of the chemical the same for all sources of import?	Yes	No
	Are the conditions for domestic production of the chemical for domestic use the same as for all imports?	Yes	No
5.4	NATIONAL LEGISLATIVE OR ADMINISTRATIVE MEASURE UPON WHICH THE FINAL DECISION IS BASED		
	Description of the national legislative or administrative measure:		
	The complete name and address of the institution/authority responsible for issuing this national legislative or administrative measure:		
5.5	Remarks See under point 5.3 and 5.4		
	Has there ever been a request of registration of this chemical in the country?	Yes	No
	Is this chemical currently registered in the country?	Yes	No
	Is this chemical manufactured in the country?	Yes	No
	Is this chemical formulated in the country?	Yes	No

	If yes to either one of these last two questions:	Is this intended for domestic use?	Yes	No
		Is this intended for export?	Yes	No
	Other remarks			
SECTION 6. INTERIM RESPONSE				
6.1	X No consent to import Is the import of the chemical from all sources simultaneously prohibited? X Yes No Is domestic production of the chemical for domestic use simultaneously prohibited? X Yes No			
6.2	Consent to import			
6.3	Consent to import only subject to specified conditions The specified conditions are: Are the conditions for import of the chemical the same for all sources of import? Yes No Are the conditions for domestic production of the chemical for domestic use the same as for all imports? Yes No			
6.4	INDICATION OF ACTIVE CONSIDERATION IN ORDER TO REACH A FINAL DECISION			

	1.2. Is a final decision under active consideration? X Yes No The following administrative action is being undertaken during the period a final decision is being considered: It is prohibited to use or place on the market all plant protection products containing benomyl. Benomyl was excluded from Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p.1) and thus authorisations for plant-protection products containing this active substance have been withdrawn. (Commission Decision 2002/928/EC of 26 November 2002, OJ L322, 27.11.2002, p.53). Carbofuran is included in the Community programme for evaluation of existing active substances under Directive 91/414/EEC; The evaluation is not expected to be completed before the end of 2004. In the meantime it is for Member States to take national decisions whether or not to authorise its use in their territories. Pursuant to Commission Directive 2003/81/EC of 5 September 2003 (OJ L224, 6.9.2003, p.29), thiram has been included in Annex I to Council Directive 91/414/EEC and is authorised as an active substance for plant protection products for use as a fungicide or repellent. Member States may therefore authorise products containing the substance for such purposes subject to certain conditions. Furthermore thiram has been identified and notified within the framework of Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 (OJ L 123, 24.4.1998, p.1) concerning the placing of biocidal products on the market. According to Article 16.1 of that Directive it can be used in biocidal products in accordance with Member States' legislation pending a final Community decision. Approximate time needed before a final decision can be reached: by 2009, when Community evaluation for biocidal use of thiram will be completed. The complete name and address of the responsible institution/authority actively considering a final decision: European Community and its Member States (see address in section 8)
6.5	INFORMATION OR ASSISTANCE REQUESTED IN ORDER TO REACH A FINAL DECISION

	The following additional information is requested from the Secretariat: The following additional information is requested from the country that notified the final regulatory action: The following assistance is requested from the Secretariat in evaluating the chemical:		
6.6	Remarks		
	Has there ever been a request of registration of this chemical in the country?		Yes No
	Is this chemical currently registered in the country?		Yes No
	Is this chemical manufactured in the country?		Yes No
	Is this chemical formulated in the country?		Yes No
	If yes to either one of these last two questions:	Is this intended for domestic use?	Yes No
		Is this intended for export?	Yes No
	Other remarks		

SECTION 7. RELEVANT ADDITIONAL INFORMATION

In accordance with Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 196, 16.8.1967, p.1) the individual substances contained in the formulation are classified as follows:

Benomyl: Muta. Cat.3; R68 (Mutagenic category 3; possible risks of irreversible effects).

Carbofuran: T+; R26/28 (Very Toxic; very toxic by inhalation and if swallowed.) - N; R50-53 (Dangerous to the environment; Very Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment).

Thiram: Muta. Cat.3; R68 (Mutagenic category 3; possible risks of irreversible effects) – Xn; R20/22 (Harmful; harmful by inhalation and if swallowed) – Xi; R36/37(Irritant; irritating to eyes and respiratory system) – R43 (may cause sensitisation by skin contact)

SECTION 8. DESIGNATED NATIONAL AUTHORITY

Institution	European Commission DG Environment
Address	Rue de la Loi 200 B-1049 Brussels Belgium

COMMISSION RECOMMENDATION

of 27 April 2004

on the use of financial derivative instruments for undertakings for collective investment in transferable securities (UCITS)*(notified under document number C(2004) 1541/1)***(Text with EEA relevance)**

(2004/383/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 211, second indent, thereof,

Whereas

- (1) One of the aims of the amendments to Council Directive 85/611/EEC of 20 December 1985 on the coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS)¹, introduced by Directive 2001/108/EC, was to widen the scope of financial instruments in which a UCITS can invest and to enable UCITS to make use of modern investment techniques. This extension of permissible investments does not only include money market instruments, bank deposits, units of UCITS and other collective investments undertakings: UCITS are now also permitted to employ financial derivative instruments as part of their general investment policy, and not only for the purposes of hedging positions.
- (2) Another aim of those amendments was to ensure investor protection. Directive 85/611/EEC, as amended, therefore establishes an extensive system of risk-limitation: In order to ensure that the risks related to the new classes of financial instruments, in particularly regarding derivatives, are duly and accurately monitored, measured and managed, management companies or investment companies are required to apply sound risk measurement processes under the supervision of the competent authorities. In particular, these risk measurement processes should enable them to monitor, measure and manage at any time the risks of the positions and their contribution to the overall risk-profile of the portfolio. Management or investment companies have also to employ processes for the accurate and independent assessment of the value of over-the-counter (OTC)-derivative instruments. These requirements of Directive

¹ OJ L 375, 31.12.1985, p. 3; Directive as last amended by Directive 2001/108/EC of the European Parliament and of the Council(OJ L 41, 13.2.2002, p. 35).

85/611/EEC call for the establishment of an adequate framework for the risk-measurement and -management of a UCITS by Member States. In order to facilitate the development of such a framework and to ensure a harmonised approach, it is desirable to recommend some common basic principles for risk-measurement.

- (3) Agreement was reached in the UCITS Contact Committee on the benefits of formulating basic principles, which should be taken into account by Member States. Those principles should help Member States to ensure an equivalent and effective protection of investors throughout the Community and level the playing field for UCITS operators and products regulated under different jurisdictions.
- (4) With regard to the limit to global exposure relating to derivatives set out in the first subparagraph of Article 21(3) of Directive 85/611/EEC and the maximum limit to borrowing transactions laid down in Article 36(2) of that Directive, it should be made clear which maximum exposure in total may be incurred by a UCITS.
- (5) The total exposure of a UCITS needs to be assessed on the basis of both default risk of the UCITS and leverage produced by the use of financial derivative instruments. It should therefore be ensured that the market risk of a UCITS is adequately measured. It is therefore necessary to recommend possible approaches of market risk measurement, by clarifying the conditions for the use of the following types of methodologies: the commitment approach; the Value-at-risk approach (VaR-approach) and stress tests.
- (6) For the same reasons it is useful to recommend some elements for the method of assessing the leverage of a UCITS portfolio produced by the use of financial derivative instruments.
- (7) Pursuant to the second subparagraph of Article 21(3) of Directive 85/611/EEC, the exposure of a UCITS must be calculated taking into account not only the current value of the underlying assets, but also the counterparty risk, future market movements and the time available to liquidate the positions. As regards counterparty risk related to OTC-derivatives, specific requirements are laid down in the second subparagraph of Article 22(1) of that Directive. In view of these requirements it is desirable to clarify the method of calculating the counterparty risk associated with financial derivative instruments and the way in which it relates to the methods and criteria provided for in Directive 2000/12/EC of the European Parliament and of the Council of 20 March 2000 relating to the taking up and pursuit of the business of credit institutions².
- (8) Pursuant to the third subparagraph of Article 21(3) of Directive 85/611/EEC, the exposure to the underlying of the financial derivative instrument has to be included into the calculation of the issuer concentration limits laid down in Article 22 of that Directive. According to that same provision, Member States may allow that, when a UCITS invests in index-based derivatives, these investments do not have to be combined to the issuer concentration limits laid down in Article 22. It is therefore appropriate to recommend standards for the application of issuer concentration limits with regard to financial derivative instruments.

² OJ L 126, 26.5.2000, p.1

- (9) Uncovered sales are all transactions in which the UCITS is exposed to the risk of having to buy securities at a higher price than the price at which the securities are delivered and thus making a loss and the risk of not being able to deliver the underlying financial instrument for settlement at the time of the maturity of the transaction. These risks are always relevant for those operations in which the UCITS is forced to buy securities in the market to meet its obligations. In those cases the UCITS is exposed to the risk that it cannot meet all or a part of its commitments under the terms of a financial derivatives operation. Article 42 of Directive 85/611/EEC therefore generally prohibits the execution of uncovered sales in order to avoid heavy losses for UCITS. However, in the context of an operation with financial derivative instruments having the financial profile of an uncovered sale, the risks typically associated with uncovered sales may not always have the same relevance. It is therefore appropriate to clarify the concept of uncovered sales with regard to financial derivative instruments and to recommend criteria applicable to the cover of a derivatives transaction in order to facilitate compliance with Article 42.
- (10) This Recommendation is a first step towards a uniform understanding of risk measurement methodologies in the UCITS area. However, risk-measurement methodologies are submitted to a permanent progress. Further steps may therefore be necessary taking into account further developments such as the Basle Capital Accord (Basel II) and the future corresponding Community Directive on capital requirements for banks and investment firms.
- (11) This Recommendation provides some basic elements which should be taken into consideration by Member States for their implementation of Directive 85/611/EEC as amended by Directive 2001/108/EC. It should be noted that this Recommendation is not intended to provide exhaustive guidelines on the use of financial derivative instruments for UCITS but to outline some principles which can be considered as an essential basis of a common risk-measurement approach for UCITS,

HEREBY RECOMMENDS:

In the framework of implementing Directive 85/611/EEC Member States should apply the following:

1. Risk-measurement systems adapted to the relevant risk-profile of the UCITS

In applying Article 21(1) of Directive 85/611/EEC, Member States are recommended to ensure that management or investment companies employ risk measurement systems which are adapted to the relevant risk-profile of a UCITS in order to make sure that they accurately measure all material risks related to the UCITS under the supervision of the competent authorities.

2. A harmonised interpretation of limitations to the UCITS' risk- exposure

2.1 Limitation to a UCITS' global exposure on derivatives and overall risk exposure

Member States are recommended to ensure that the global exposure relating to financial derivative instruments may not exceed 100% of the UCITS' net asset value (NAV), and hence that the UCITS' overall risk exposure may not exceed 200% of the NAV on a permanent basis.

2.2 Limitation to possible temporary borrowing

Member States are recommended to ensure that the UCITS' overall risk exposure may not be increased by more than 10% by means of temporary borrowing, so that the UCITS' overall risk exposure may not exceed 210% of the NAV under any circumstances.

2.3 Joint application of points 3 and 4

For the application of the 100% global exposure limit relating to derivatives, Member States are recommended to ensure that both points 3 and 4 are respected.

3. Appropriately calibrated standards to measure market risk

3.1 Adaptation of risk-measurement methodologies to the risk-profile of a UCITS

In conformity with the overarching principle mentioned under point 1 and established in Article 21(1) of Directive 85/611/EEC, Member States are recommended to allow a differentiated methodological approach for the respective categories of "non-sophisticated UCITS", which have overall less and simpler derivative positions by using e.g. a few plain vanilla options, and "sophisticated UCITS". The distinction between, and exact definition of, these categories requires further work in accordance with point 3.4. Pending completion of such work, Member States should move towards a more calibrated approach for measuring market risk in accordance with points 3.2 and 3.3.

3.2 Non-sophisticated UCITS

3.2.1 Use of the commitment approach

Member States are recommended to request their competent authorities to ensure that, in the case of non-sophisticated UCITS, they are satisfied that market risk is adequately assessed by using the commitment approach, whereby the derivative positions of a UCITS are converted into the equivalent position in the underlying assets embedded in those derivatives. For the application of the commitment approach, Member States' competent authorities should also take into account criteria such as the UCITS' overall exposure deriving from the employment of financial derivative instruments, the nature, aim, number and frequency of the contracts entered into by the UCITS and the management techniques adopted.

3.2.2 Technical precisions

In the case of options, Member States are recommended to allow the application of the delta approach, which is derived from the sensitivity of the change in the option's price to marginal changes in the price of the underlying financial instruments. The conversion of forwards, futures and swaps positions should depend on the precise nature of the underlying contracts. In the case of simple contracts, the marked-to-market value of the contracts will usually be relevant.

3.2.3 Invitation to consider further additional safeguards

Member States are required to consider whether additional safeguards are requested in the context of the use of the commitment approach, such as an appropriate cap to the global exposure relating to financial derivative instruments below 100% of NAV for non-sophisticated UCITS.

3.3 *Sophisticated UCITS*

3.3.1 Standard use of Value-at-Risk (VaR) approach with stress tests

In the case of “sophisticated UCITS”, Member States are recommended to require management or investment companies to apply regularly VaR approaches. In the VaR-approaches, the maximum potential loss that a UCITS portfolio could suffer within a certain time horizon and a certain degree of confidence is estimated. Member States are recommended to require management or investment companies also to apply stress tests in order to help manage risks related to possible abnormal market movements. Stress tests measure how extreme financial or economic events affect the value of the portfolio at a specific point of time.

3.3.2 Invitation to develop common reference standards as a further step

For the application of VaR-approaches, Member States are recommended to require the use of appropriate standards in conformity with point 3.1. For this purpose, Member States should consider, as a possible reference the following parameters: a 99% confidence interval, a holding period of one month and “recent” volatilities, i.e. no more than one year from the calculation date without prejudice to further testing by the competent authorities. Once common standards have been developed by further work undertaken by Member States in accordance with point 3.4, Member States should allow management or investment companies to deviate from these standards only on a case-by-case basis, subject to the appropriate examination of the competent authorities in accordance with what is provided for in point 3.3.3.

3.3.3 Internal risk-measurement models

Member States are recommended to accept only those internal risk-measurement models proposed by a management or investment company which are subject to appropriate safeguards, including those set out in this recommendation. The models concerned should be subject to appropriate examination by the competent national authorities. Member States are also recommended to disclose a list of models recognised by the competent national authorities, and make them publicly available by appropriate means.

3.4 *Recommendation to carry out further work*

Considering that these risk-measurement methodologies need further refinement, Member States are recommended to encourage their competent authorities to undertake further work with a view to elaborating more advanced and elaborated methods of risk-measurement and thus develop a convergent Community-wide approach. This concerns in particular:

- a) the criteria to identify sophisticated and non-sophisticated UCITS;
- b) the conversion of financial derivative instruments into equivalent underlying assets and the netting of positions underlying the financial derivative instruments in case of the application of the commitment approach;
- c) best practices in the area of VaR and stress tests;
- d) the standards which internal models must meet in order to be used by UCITS.

4. *Appropriately calibrated standards to assess leverage*

4.1 Use of the commitment approach

In the absence of the advanced methodologies mentioned under point 4.2, Member States are recommended to request the use of the commitment approach to assess a UCITS' leverage, in combination with the VaR-approaches and the stress-tests required for the purpose of measuring market risk exposure of sophisticated UCITS under point 3.3.

Member States are also recommended to allow management or investment companies which use the commitment approach according to point 3.2 to also employ the commitment approach for the assessment of leverage.

4.2 Invitation to allow the use of further advanced methodologies

In the case of sophisticated UCITS under point 3.3, provided that the supervisory authorities are fully convinced that a given management or investment company has already developed and tested an appropriate method of assessing leverage by the means of VaR-approaches and stress tests and provided that this method is duly documented by the management or investment company, Member States should consider recognising it for the assessment of leverage. For this purpose, Member States are specifically recommended to consider approaches relying on a standard of comparison such as the VaR/stress test value of an appropriate reference portfolio which complies with the investment policy of a UCITS or the VaR/stress test value of an adequate benchmark.

4.3 Recommendation to carry out further work

Member States are recommended to take into account that the methods for assessing the leverage of a UCITS need further refinement, in particular with respect to the maximum VaR/stress-test value corresponding to a total exposure of 200% of a UCITS' NAV. Therefore they should encourage their competent national authorities to undertake further work to develop more advanced and sophisticated methods of assessing leverage aiming at the development of a convergent Community-wide approach.

5. Applying appropriate standards and recognised risk-mitigation techniques to limit counterparty risk

5.1 Criteria for the limitation of counterparty risk exposure to OTC derivatives

Member States are recommended to ensure that all the derivatives transactions which are deemed to be free of counterparty risk are performed on an exchange where the clearinghouse meets the following conditions: it is backed by an appropriate performance guarantee, and is characterised by a daily mark-to-market valuation of the derivative positions and an at least daily margining.

5.2 Recommendation to use maximum potential loss

Member States are recommended to require the exposure per counterparty on an OTC-derivative transaction to be measured on the maximum potential loss incurred by the UCITS if the counterparty defaults and not on the basis of the notional value of the OTC contract.

5.3 Invitation to use the standards laid down in Directive 2000/12/EC as a first reference

In compliance with the fixed quantitative prudential limits already imposed by Directive 2001/108/EC, Member States are recommended to require the assessment of counterparty risk with regard to OTC-derivatives in accordance with the marking-to-market method laid down in Directive 2000/12/EC of the European Parliament and of the Council³, notwithstanding the need of appropriate pricing models when the market price is not available. Member States should also require the use of the full credit equivalent approach laid down in Directive 2000/12/EC, including an add-on methodology to reflect the potential future exposure.

5.4 Recognition of collateral for the purpose of assessing a UCITS' counterparty risk exposure

5.4.1 General criteria

Member States are recommended to allow for the recognition of collateral in order to reduce a UCITS' counterparty risk provided that, in accordance with the prudential rules laid down in Directive 2000/12/EC and taking into account further developments, the collateral:

- a) is marked-to-market on a daily basis and exceeds the value of the amount at risk;
- b) is exposed only to negligible risks (e.g. government bonds of first credit rating or cash) and is liquid;
- c) is held by a third part custodian not related to the provider or is legally secured from the consequences of a failure of a related party;
- d) can be fully enforced by the UCITS at any time.

5.4.2 Risk concentration limits

In accordance with the general principle of risk-spreading, Member States are recommended to ensure that the exposure to counterparty risk on a given entity, respectively group, after taking into account any collateral received from that entity, or group, may not be higher than the 20% limit laid down in Directive 85/611/EEC, both at individual level, under the second sub-paragraph of Article 22(2) and at group level, under Article 22(5) of that Directive.

5.5 Recognition of netting

Member States are recommended to allow UCITS to net their OTC-derivative positions vis-à-vis the same counterparty, provided that the netting procedures comply with the conditions laid down in Directive 2000/12/EC and that they are based on legally binding agreements.

6. Using adequate methodologies when applying limitations to issuer risk

6.1 Adaptation of the risk-measurement methodologies to the derivatives typology

Considering that the fourth subparagraph of Article 21(3) of Directive 85/611/EEC provides that, in order to include financial derivative instruments into the issuer concentration limits foreseen by Article 22, they should be converted into equivalent underlying positions, Member States are recommended to require the use of methodologies adequate to the type of instrument considered. For example, Member States may allow the use of the delta approach for options. In cases where this approach is not relevant or technically impossible, due to the complexity of the concerned financial derivative instrument, Member States may then allow

³ OJ L 126, 26.5.2000, p.1

the use of an approach based on the maximum potential loss linked to that derivative as a maximum threshold assessment of the solvency risk.

6.2 Case of index-based derivatives

Member States are advised, in the use of their discretionary powers for the application of the option foreseen by the third subparagraph of Article 21(3) of Directive 85/611/EEC, to take into account whether the underlying index of a financial derivative instrument meets the requirements of Article 22a of that Directive. For the application of Article 21(2) and the third subparagraph of Article 21(3) of that Directive, Member States are recommended to consider that, a management or investment company should generally be prevented from using financial derivative instruments based on a self-composed index with the intent to circumvent the issuer concentration limits of Article 22. Member States are also recommended to consider that a management or investment company should be prevented from using financial derivative instruments based on indices which do not comply with the concentration limits set by Article 22a of Directive 85/611/EEC.

6.3 Risk-concentration limits

Member States are recommended to require management companies or investment companies to cumulate counterparty risk with issuer risk versus the same entity or group for the application of the 20% NAV-limit pursuant to the second subparagraph of Article 22(2) and Article 22(5) of Directive 85/611/EEC.

7. Applying relevant cover rules to transactions with both listed, and OTC, financial derivative instruments

7.1 Appropriate cover in the absence of cash-settlement

When the financial derivative instrument provides for, either automatically or at the counterpart's choice, physical delivery of the underlying financial instrument on maturity or exercise, and provided that physical delivery is common practice on the considered instrument, Member States are recommended to require UCITS to hold this underlying financial instrument as cover in their investment portfolios.

7.2 Exceptional substitution with an alternative underlying cover in the absence of cash settlement

In cases where the risks of the underlying financial instrument of a derivative can be appropriately represented by another underlying financial instrument and the underlying financial instrument is highly liquid, Member States should consider allowing UCITS to hold exceptionally other liquid assets as cover provided that they can be used at any time to purchase the underlying financial instrument to be delivered and that the additional market risk which is associated with that type of transaction is adequately measured.

7.3 Substitution with an alternative underlying cover in the case of cash-settlement

Where the financial derivative instrument is cash-settled automatically or at the UCITS discretion, Member States should consider allowing the UCITS not to hold the specific underlying instrument as cover. In this case, Member States are recommended to consider the following categories as acceptable cover:

- a) Cash;
- b) Liquid debt instruments (e.g. government bonds of first credit rating) with appropriate safeguards (in particular, haircuts);
- c) Other highly liquid assets which are recognised by the competent authorities considering their correlation with the underlying of the financial derivative instruments, subject to appropriate safeguards (e.g. haircuts where relevant).

In the context of the application of Article 42 of Directive 85/611/EEC, Member States should consider as “liquid” those instruments which can be converted into cash in no more than seven business days at a price closely corresponding to the current valuation of the financial instrument on its own market. Member States are recommended to ensure that the respective cash amount be at the UCITS’ disposal at the maturity/expiry or exercise date of the financial derivative instrument.

7.4 Calculation of the level of cover

Member States are recommended to require the level of cover to be calculated in line with the commitment approach.

7.5 Nature of the underlying financial instrument

Member States are recommended to require that the underlying financial instrument of financial derivative instruments, whether they provide for cash-settlement or physical delivery, as well as the financial instruments held for cover have to be compliant with the Directive and the individual investment policy of the UCITS.

7.6 Recommendation to undertake further common work

As regards cover of transactions with financial derivative instruments, Member States are recommended to encourage their competent authorities to identify a common typology of transactions with financial derivative instruments in which the risk profile of an uncovered sale may be identified.

8. The Member States are requested to inform the Commission, insofar as possible, by 30 September 2004 of any measures they have taken further to this Recommendation and to inform it of the first results of its implementation, in as far as they are able, no later than 28 February 2005.

9. This Recommendation is addressed to the Member States.

Done at Brussels, 27 April 2004.

For the Commission
Frederik BOLKESTEIN
Member of the Commission

COMMISSION RECOMMENDATION**of 27 April 2004****on some contents of the simplified prospectus as provided for in Schedule C of Annex I
to Council Directive 85/611/EEC***(notified under document number C(2002) 1541/2)***(Text with EEA relevance)**

(2004/384/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 211, second indent, thereof,

Whereas:

- (1) In order to enhance effective investor information, provisions concerning the simplified prospectus were introduced in Council Directive 85/611/EEC of 20 December 1985 on the coordination of laws, regulations, and administrative provisions relating to undertakings for collective investments in transferable securities (UCITS)¹ by Directive 2001/107/EC of the European Parliament and of the Council². The simplified prospectus is designed to provide clear information about the essentials the investor should know before investing in a fund, and be easily understood by the average retail investor. The simplified prospectus is also designed to facilitate the cross-border marketing of units of UCITS, and be used as a single marketing tool throughout the Community. Those provisions themselves stress that host Member States are not permitted to ask for any additions or modifications except translation.
- (2) In order to ensure the effectiveness of this key element of investor protection, it is desirable to clarify the contents and presentation of some of the elements of information which have to be included into the simplified prospectus pursuant to Schedule C of Annex I to Directive 85/611/EEC. This is critical to ensuring a common reading of the contents of Schedule C, and has to be achieved in the most appropriate and timely way available, taking into account the recent transposition process in the Member States and the need for appropriate implementation.
- (3) For that purpose, the mere clarification of definitions relating to the contents of the relevant indents of Schedule C would not be sufficient to achieve the necessary level of harmonisation, which is, in particular, intrinsically linked to the choice and

¹ OJ L 375, 31.12.1985, p. 3; Directive as last amended by Directive 2001/108/EC of the European Parliament and of the Council (OJ L 41, 13.2.2001, p. 35).

² OJ L 41, 13.2.2001, p. 20.

definition of some ratios relating to economic information (i.e. costs and portfolio turnover). Setting those ratios, which are critical to investor information, does not fall within the regulatory powers conferred upon the Commission by Article 53a of Directive 85/611/EEC. Since the implementing powers conferred upon the Commission by the Directive do not include the choice and structure of ratios, a Commission recommendation is for the moment the only available instrument to support a common, comprehensive reading of the relevant contents of Schedule C.

- (4) The description of the UCITS' investment objectives should inform investors about the investment goal the UCITS intends to pursue. Therefore, it is desirable that the simplified prospectus contain, in a concise form, an appropriate description of the outcomes sought for the investment, information on any third-party guarantees which protect investors, for example against a downfall or on a minimum level of increase of the value of their investment and information on index-tracking objectives.
- (5) In conformity with the requirements set forth under Article 24a(1) and (2) of Directive 85/611/EEC, the description of the UCITS' investment policy in the simplified prospectus should allow the average investor to understand the manner and method by which the investment goal is expected to be achieved and draw investors' attention on the UCITS' relevant characteristics. Therefore, it is desirable that the simplified prospectus briefly make clear the main categories of eligible instruments, the portfolio management strategy of the UCITS, by drawing attention to possible risk-concentration profiles where relevant, and the key characteristics of the bonds in which the UCITS invests. It is also desirable that the simplified prospectus contain information on the financial derivative instruments, the management style and the strategy to achieve the index-tracking objective in the case of index-tracking funds.
- (6) In keeping with the safeguards provided for in Article 24a(1) and (3) of Directive 85/611/EEC, the average investor should be enabled to understand the risk profile of a UCITS and be adequately informed of relevant risk characteristics. It is therefore desirable that the simplified prospectus contain a brief and easily comprehensible description, in narrative form, of all the risks material and relevant to the UCITS. It is also advisable to encourage Member States, where they deem it relevant in the light of customary disclosure practice and existing investor protection standards, to require that this information be supplemented by a quantitative risk indicator based on the UCITS volatility, but subject to further convergence work on such risk indicators.
- (7) To avoid misleading information for investors on historical performance and to advance the comparability of UCITS for investors within the Community, it is necessary to clarify the way past performance should be presented.
- (8) For the sake of clarity and concision of the simplified prospectus, it is desirable that information on the tax regime be limited to the tax regime applicable to the UCITS in its home Member State. To facilitate proper investor information, it is however appropriate that this information be supplemented by a warning that further taxation may apply to the individual investor taking into account that the taxation of individual investors will depend on the fiscal regulation applicable in their personal or particular case.

- (9) To ensure effective investor protection and enhance investor confidence in the fund industry, it is desirable that the simplified prospectus provide for full transparency of all the costs actually borne by investors in relation to their investment. To this end, it is necessary to disclose a total expense ratio (TER) calculated as an indicator of the fund's total operating costs. It is therefore also necessary to clarify how the TER should be calculated. Since entry and exit commissions and other expenses directly paid by the investor are not included in the TER, it is desirable that they be shown separately as well as all the other costs not included in the TER, including disclosure of transaction costs when these are deemed to be available by the home Member State competent authorities. In any case, it is desirable to disclose the portfolio turnover rate calculated on a standardised basis, as an additional indicator of the relevance of transaction costs.
- (10) In view of the current differences in market practice on fee-sharing agreements and comparable fee arrangements, it is appropriate that these be adequately disclosed to investors. To improve transparency for investors, it is therefore necessary that the simplified prospectus indicate the existence of any such agreements or arrangements. It is also advisable to invite investors to consult the full prospectus for detailed information on this kind of arrangement, which should enable them to understand to whom the expenses are paid and whether possible conflicts of interest will be resolved in their best interest.
- (11) The understanding of investors' needs in terms of product information and cross-border comparability has to be made subject to further progress, also in the light of consumer studies on national markets, in order to underpin the completion of a true, investor-friendly, internal market for UCITS. Member States should therefore carry out, in so far as possible, further testing of measures taken in this field, in particular following this recommendation, and to report accordingly to the Commission. The Commission may consider in due time whether there is a need to propose legislative measures to leverage on experience and Member States' feedback on the implementation of this recommendation,

HEREBY RECOMMENDS:

1. As regards the investment information referred to in the second heading of Schedule C in Annex I to Directive 85/611/EEC it is recommended that Member States apply the following interpretations.

1.1. Interpretation of 'short definition of UCITS' objectives'

In the first indent, Member States are recommended to interpret '*a short definition of UCITS' objectives*' as meaning the following information:

- (a) a concise and appropriate description of the outcomes sought for any investment in the UCITS;
- (b) a clear statement of any guarantees offered by third parties to protect investors and any restrictions on those guarantees;
- (c) a statement, where relevant, that the UCITS is intended to track an index/indices, and sufficient indications to enable investors both to identify the

relevant index/indices and to understand the extent or degree of tracking pursued.

1.2. Interpretation of 'the unit trust's/common fund's or the investment company's investment policy'

In the second indent Member States are recommended to interpret '*the unit trust's/common fund's or the investment company's investment policy*' as meaning the following information, provided it is material and relevant:

- (a) the main categories of eligible financial instruments which are the object of investment;
- (b) whether the UCITS has a particular strategy in relation to any industrial, geographic or other market sectors or specific classes of assets, e.g. investments in emerging countries' financial instruments;
- (c) where relevant, a warning that, whilst the actual portfolio composition is required to comply with the broad legal and statutory rules and limits, risk-concentration may occur in regard of certain tighter asset classes, economic and geographic sectors;
- (d) if the UCITS invests in bonds, an indication of whether they are corporate or government, their duration and the rating requirements;
- (e) if the UCITS uses financial derivative instruments, an indication of whether this is done in pursuit of the UCITS' objectives, or for hedging purposes only;
- (f) whether the UCITS' management style contemplates some reference to a benchmark; and in particular whether the UCITS has an 'index tracking' objective, with an indication of the strategy to be pursued to achieve this;
- (g) whether the UCITS' management style is based on a tactical asset allocation with high frequency portfolio adjustments.

1.3. Joint presentation of the UCITS' objectives and investment policy

Home Member States are recommended to allow the information required under points 1.1 and 1.2 to be set out as a single item in the simplified prospectus (e.g. for the information on index tracking), provided that the information so combined does not lead to confusion of the objectives and policies of the UCITS. The order of the information items may be adapted to reflect the UCITS' specific investment objectives and policy.

1.4. Interpretation of 'a brief assessment of the fund's risk profile'

In the second indent, Member States are recommended to interpret '*a brief assessment of the fund's risk profile*' as meaning the following information:

1.4.1. Overall structure of the information provided:

- (a) a statement to the effect that the value of investments may fall as well as rise and that investors may get back less than they put in;
- (b) a statement that details of all the risks actually mentioned in the simplified prospectus may be found in the full prospectus;
- (c) a textual description of any risk investors have to face in relation to their investment, but only where such risk is relevant and material, based on risk impact and probability.

1.4.2. Precisions regarding the textual description of risks

1.4.2.1. Specific risks

The description referred to in point 1.4.1(c) should include a brief and understandable explanation of any specific risk arising from particular investment policies or strategies or associated with specific markets or assets relevant to the UCITS such as:

- (a) the risk that the entire market of an asset class will decline thus affecting the prices and values of the assets (market risk);
- (b) the risk that an issuer or a counterparty will default (credit risk);
- (c) only where strictly relevant, the risk that a settlement in a transfer system does not take place as expected because a counterparty does not pay or deliver on time or as expected (settlement risk);
- (d) the risk that a position can not be liquidated in a timely manner at a reasonable price (liquidity risk);
- (e) the risk that the investment's value will be affected by changes in exchange rates (exchange or currency risk);
- (f) only where strictly relevant, the risk of loss of assets held in custody that could result from the insolvency, negligence or fraudulent action of the custodian or of a subcustodian (custody risk);
- (g) risks related to a concentration of assets or markets.

1.4.2.2. Horizontal risk factors

The description referred to in point 1.4.1(c) should also mention, where relevant and material, the following factors that may affect the product:

- (a) performance risk, including the variability of risk levels depending on individual fund selections, and the existence, absence of, or restrictions on any guarantees given by third parties;
- (b) risks to capital, including potential risk of erosion resulting from withdrawals/cancellations of units and distributions in excess of investment returns;

- (c) exposure to the performance of the provider/third-party guarantor, where investment in the product involves direct investment in the provider, rather than assets held by the provider;
- (d) inflexibility, both within the product (including early surrender risk) and constraints on switching to other providers;
- (e) inflation risk;
- (f) lack of certainty that environmental factors, such as a tax regime, will persist.

1.4.2.3. Possible prioritisation of information disclosure

In order to avoid conveying a misleading image of the relevant risks, Member States are also recommended to consider requiring the presentation of the information items to prioritize, based on scale and materiality, the risks so as to better highlight the individual risk profile of the UCITS.

1.4.3. Additional disclosure of a synthetic risk indicator

Where the UCITS has been set up at least one year before, home Member States are also invited to consider as a possible option requiring that the description referred to in point 1.4.1.c) be supplemented by a synthetic indicator of risk in just one figure or word, based on the volatility of the UCITS' portfolio, in which case:

- (a) the volatility of the UCITS' portfolio should be intended as measuring the dispersion of the UCITS' return;
- (b) the UCITS' return should be calculated taking into account all the UCITS' net asset values (NAVs) of the period, e.g. daily NAVs where this is the normal frequency of NAV calculation as approved by the UCITS competent authorities, computed by assessing the UCITS assets on that same frequency.

1.5. Interpretation of 'historical performance of the unit trust/common fund/investment company (where applicable)'

In the third indent, Member States are recommended to interpret the 'historical performance of the unit trust/common fund/investment company (where applicable)' with 'a warning that this is not an indicator of future performance' as meaning the following information:

1.5.1 Disclosure of past performance:

- (a) the UCITS' past performance, as presented using a bar chart showing annual returns for the last 10 full consecutive years. If the UCITS has been in existence for fewer than 10 years but at least for a period of one year, it is recommended that the annual returns, calculated net of tax and charges, be given for as many years as are available;
- (b) if a UCITS is managed according to a benchmark or if its cost structure includes a performance fee depending on a benchmark, the information on the past performance of the UCITS should include a comparison with the past

performance of the benchmark according to which the UCITS is managed or the performance fee is calculated. Member States are recommended to require that comparison to be achieved by representing the past performance of the benchmark and that of the UCITS on the same bar-chart and/or separately.

1.5.2. Disclosure of cumulative (average) performance

Additionally, Member States are recommended to consider requiring disclosure, either of the cumulative performance, or the cumulative average performance of the fund over specific periods of time (such as on three, five and 10 years). In case they use either of these options, Member States are recommended to require also a comparison with the cumulative performance, or cumulative average performance (where relevant) of a benchmark, when comparison to a benchmark is required in accordance with point 1.5.1(b).

1.5.3. Exclusion of subscription and redemption fees, subject to appropriate disclosure

Taking into account existing regulatory standards, Member States are recommended to consider, whether or not to require subscription and redemption fees to be included in the calculation of the fund performance. However, Member States should require the exclusion of that information (where relevant) to be subject to an appropriate statement drawing attention to this fact. Member States are also recommended to encourage their competent authorities to ensure progressive convergence to standards aligned on best practice in performance calculation.

1.5.4. Disclosure of a benchmark

Member States are also invited to consider as a possible option requiring disclosure of a benchmark for all UCITS authorised in their jurisdiction, regardless of the fact that the UCITS' investment objective does not explicitly refer to a benchmark.

2. As regards the economic information referred to in the third heading of Schedule C in Annex I to Directive 85/611/EEC it is recommended that Member States apply the following interpretations:

2.1. Interpretation of 'tax regime'

In the first indent, Member States are recommended to interpret '*tax regime*' as meaning the following information:

- (a) the tax regime applicable to the UCITS in its home Member State;
- (b) a statement which recalls that the regime of taxation of the income or capital gains received by individual investors depends on the tax law applicable to the personal situation of each individual investor and/or to the place where the capital is invested and that if investors are unclear as to their fiscal position, they should seek professional advice or information from local organisations, where available.

2.2 Interpretation of 'entry and exit commissions' and 'other possible expenses or fees'

2.2.1. Overall contents of the information provided

In the second and third indents, Member States are recommended to interpret the '*entry and exit commissions*' of the fund and '*other possible expenses or fees, distinguishing between those to be paid by the unit-holder and those to be paid out of the unit trust's/common fund's or the investment company's assets*' as meaning the following information:

- (a) disclosure of a total expense ratio (TER), calculated as indicated in Annex I, except for newly created UCITS where a TER cannot yet be calculated;
- (b) on an ex ante basis, disclosure of the expected cost structure, i.e. an indication of all costs available according to the list set forth in Annex I so as to provide investors, insofar as possible, with a reasonable estimate of expected costs;
- (c) all entry and exit commissions and other expenses directly paid by the investor;
- (d) an indication of all the other costs not included in the TER, including disclosure of transaction costs when these are deemed to be available by the home Member State competent authorities;
- (e) as an additional indicator of the importance of transaction costs, the portfolio turnover rate, calculated as shown in Annex II;
- f) an indication of the existence of fee-sharing agreements and soft commissions.

The requirement set out in point (f) of the first paragraph should not be interpreted as a general validation of the compliance of any individual agreement or commission with Directive 85/611/EEC, and especially with Article 5f(1)(b) thereof, or with national regulations. Taking into account current market practice, Member States are therefore invited to require UCITS to consider how far existing fee-sharing agreements and comparable fee-arrangements are for the exclusive benefit of the UCITS.

Member States are recommended to provide for the simplified prospectus to make a reference to the full prospectus for detailed information on that kind of arrangements, which should allow any investor to understand to whom expenses are to be paid and how possible conflicts of interest will be resolved in his/her best interest. Member States are therefore recommended to ensure that the information provided in the simplified prospectus remains concise.

2.2.2 Precisions on the notions of 'fee-sharing agreements' and 'soft commissions'

2.2.2.1 Identification of 'fee-sharing agreements'

Member States are recommended to identify and classify as fee-sharing agreements those agreements whereby a party remunerated, either directly or indirectly, out of the assets of a UCITS agrees to split its remuneration with another party and which result in that other party meeting expenses through this fee-sharing agreement that should normally be met, either directly or indirectly, out of the assets of the UCITS.

Furthermore, Member States are recommended to consider the following as fee-sharing agreements within the meaning of the above paragraph:

- (a) fee-sharing agreements on transaction costs between a UCITS' management company and a broker whereby the broker agrees to split with the management

company the transactions fees paid by the UCITS to the broker for processing transactions for the UCITS;

- (b) fee-sharing agreements in funds of funds between a UCITS management company and another fund (or its management company) whereby, if that UCITS invests in the fund, part of the fees charged to that UCITS (either directly – subscription/redemption fees – or indirectly – TER) because of this investment will be paid by the target fund (or its management company) to the UCITS management company.

2.2.2.2. Identification of 'soft commissions'

Member States are recommended to identify as soft commissions any economic benefit, other than clearing and execution services, that an asset manager receives in connection with the fund's payment of commissions on transactions that involve the fund's portfolio securities. Soft commissions are typically obtained from, or through, the executing broker.

2.2.3. Presentation of TER and portfolio turnover rate

Member States are invited to allow both the TER and the portfolio turnover rate to be either included in or attached to the simplified prospectus in the same paper as information on past performance.

3. The Member States are requested to inform the Commission, in so far as possible, by 30 September 2004 of any measures they have taken further to this recommendation and to inform it of the first results of its implementation, in as far as they are able, no later than 28 February 2005.

4. This recommendation is addressed to the Member States.

Done at Brussels, 27 April 2004.

For the Commission
Frederik BOLKESTEIN
Member of the Commission

*ANNEX I***Total expense ratio (TER)****1. Definition of the TER:**

The total expense ratio (TER) of a UCITS is equal to the ratio of the UCITS' total operating costs to its average net assets calculated as according to paragraph 3.

2. Included/Excluded costs

2.1 The total operating costs are all the expenses which come in deduction of a UCITS' assets. These costs are usually shown in a UCITS' statement of operations for the relevant fiscal period. They are assessed on an 'all taxes included' basis, which means that the gross value of expenses should be used.

2.2 They include any legitimate expenses of the UCITS, whatever their basis of calculation (e.g. flat-fee, asset-based, transaction-based³), such as:

- management costs including performance fees;
- administration costs;
- fees linked to depository duties;
- audit fees;
- payments to shareholder services providers including payments to the UCITS' transfer agent and payments to broker-dealers that are record owners of the UCITS' shares and that provide sub-accounting services for the beneficial owners of the UCITS shares;
- payments to lawyers;
- any distribution or unit cancellation costs charged to the fund;
- registration fees, regulatory fees and similar charges;
- any additional remuneration of the management company (or any other party) corresponding to certain fee-sharing agreements in accordance to point 4 below.

2.3 The total operating costs do not include:

- transaction costs which are costs incurred by a UCITS in connection with transactions on its portfolio. They include brokerage fees, taxes and linked charges and the market impact of the

³ This non-exhaustive typology of calculation bases reflects the diversity of recent commercial practice across Member States (i.e. at the end of 2003) and should not be interpreted as a general validation of the compliance of any individual agreement or commission with Directive 85/611/EEC, as last amended by Directives 2001/107/EC and 2001/108/EC, and especially with Article 5f(1)(b) thereof, regarding conflicts of interest, or with national regulations.

transaction taking into account the remuneration of the broker and the liquidity of the concerned assets;

- interest on borrowing;
- payments incurred because of financial derivative instruments;
- entry /exit commissions or any other fees paid directly by the investor;
- soft commissions in accordance with point 4.

3. Calculation method and disclosure:

3.1 The TER is calculated at least once a year on an ex post basis, generally with reference to the fiscal year of the UCITS. For specific purposes it may also be calculated for other time periods. The simplified prospectus should in any case include a clear reference to an information source (e.g. the fund's website) where the investor may obtain previous years'/periods' TER figures.

3.2 The average net assets must be calculated using figures that are based on the UCITS' net assets at each calculation of the net asset value, e.g. daily NAVs where this is the normal frequency of NAV calculation as approved by the UCITS competent authorities. Further circumstances or events which could lead to misleading figures have equally to be taken into consideration.

Tax relief should not be taken into account.

The calculation method of the TER must be validated by the UCITS' auditors and/or competent authorities.

4. Fee-sharing agreements and soft commissions:

It regularly results from fee-sharing agreements on expenses that are generally not included in the TER, that the management company or another party is actually meeting, in all or in part, operating costs that should normally be included in the TER. They should therefore be taken into account when calculating the TER, by adding to the total operating costs any remuneration of the management company (or another party) that derives from such fee-sharing agreements.

There is no need to take into account fee-sharing agreements on expenses that are already in the scope of the TER. Soft commissions should also be left outside the scope of the TER.

Thus:

- the remuneration of a management company through a fee-sharing agreement with a broker on transaction costs and with other fund management companies in the case of funds of funds (if this remuneration has not been already been taken into account in the synthetic TER or through other costs already charged to the fund and therefore directly included into the TER) should anyway be taken into account in the TER;

- conversely, the remuneration of a management company through a fee-sharing agreement with a fund (except when this remuneration falls under the scope of the specific fund-of-fund case covered in the previous indent) should not be taken into account.

5. Performance fees:

Performance fees should be included in the TER and should also be disclosed separately as a percentage of the average net asset value.

6. UCITS investing in UCITS or in non-UCITS:

When a UCITS invests at least 10 % of its net asset value in other UCITS or in non-UCITS which publish a TER in accordance with this Annex, a synthetic TER corresponding to that investment should be disclosed.

The synthetic TER is equal to the ratio of:

- the UCITS' total operating costs expressed by its TER and all the costs suffered by the UCITS through holdings in underlying funds (i.e. those expressed by the TER of the underlying funds weighted on the basis of the UCITS investment proportion), plus the subscription and redemption fees of these underlying funds, divided by
- the average net assets of the fund.

As mentioned in the previous subparagraph, subscription fees and redemption fees of the underlying funds should be included into the TER. Subscription and redemption fees may not be charged when the underlying funds belong to the same group in accordance with Article 24 (3) of Directive 85/611/EEC.

When any of the underlying non-UCITS does not publish a TER in accordance with this Annex, disclosure of costs should be adapted in the following way:

- the impossibility of calculating the synthetic TER for that fraction of the investment must be disclosed;
- the maximum proportion of management fees charged to the underlying fund(s) must be disclosed in the simplified prospectus.
- a synthetic figure of total expected costs, by calculating:
 - a truncated synthetic TER incorporating the TER of each of those underlying funds for which the TER is calculated according to this Annex, weighted on the basis of the UCITS investment proportion, and
 - by adding, for each of the other underlying funds, the subscription and redemption fees plus the best available upper-bound assessment of TER-eligible costs. This should include the maximum management fee and the last available performance fee for that fund, weighted on the basis of the UCITS investment proportion.

6. Umbrella funds/multiclass funds:

In the case of umbrella funds, the TER should be calculated for each subfund. If, in the case of multiclass funds, the TER differs between different share classes, a separate TER should be calculated and disclosed for each share class. Furthermore, in keeping with the principle of equality among investors, where there are differences in fees and expenses across classes, these different fees/expenses should be disclosed separately in the simplified prospectus. An additional statement should indicate that the objective criteria (e.g. the amount of subscription), on which these differences are based, are available in the full prospectus.

*ANNEX II***Portfolio turnover rate**

A fund's or, where relevant, a compartment's portfolio turnover rate should be calculated in the following way:

Purchases of securities = X

Sales of securities = Y

Total 1 = Total of transactions in securities = X + Y

Issues/Subscriptions of units of the fund = S

Cancellations/Redemptions of units of the fund = T

Total 2 = Total transactions in units of the fund = S + T

Reference average of total net assets = M

Turnover = [(Total 1 - Total 2)/M]*100

The reference average of total net assets corresponds to the average of net asset values calculated with the same frequency as under Annex I, Article 1(3). The turnover rate disclosed should correspond to the period(s) for which a TER is disclosed. The simplified prospectus should in any case include a clear reference to an information source (e.g. the fund's website) where the investor may obtain previous periods' p

COMMISSION DECISION**of 27 April 2004****conferring management of aid on implementing agencies for preaccession measures in agriculture and rural development in Hungary in the preaccession period**

(2004/385/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1266/1999 of 21 June 1999 on coordinating aid to the applicant countries in the framework of the preaccession strategy and amending Regulation (EEC) No 3906/89¹, and in particular Article 12(2) thereof,

Having regard to Council Regulation (EC) No 1268/1999 of 21 June 1999 on Community support for preaccession measures for agriculture and rural development in the applicant countries of central and eastern Europe in the preaccession period², and in particular Article 4(5) and (6) thereof,

Whereas:

- (1) The Special Programme for Agriculture and Rural Development for Hungary (hereinafter Sapard) was approved by Commission decision of 18 October 2000³, as last amended by Commission decision of 25 February 2004, in accordance with Article 4(5) and (6) of Regulation (EC) No 1268/1999.
- (2) The Government of Hungary and the Commission, acting on behalf of the European Community, signed on 1 March 2001 the Multiannual Financing Agreement laying down the technical, legal and administrative framework for the execution of Sapard, as last amended by the Annual Financing Agreement for 2003, signed on 28 July 2003, which finally entered into force on 22 December 2003.
- (3) The Agriculture and Rural Development Agency (hereinafter ARDA), public institution with legal status, under the subordination of the Ministry of Agriculture and Rural Development has been appointed by the competent authority of Hungary for the implementation of some of the measures defined in Sapard. The National Fund within the Ministry of Finance has been appointed for the financial functions it is due to perform in the framework of the implementation of Sapard.

¹ OJ L 161, 26.6.1999, p. 68.

² OJ L 161, 26.6.1999, p. 87; Regulation as last amended by Regulation (EC) No 696/2003 (OJ L 99, 17.4.2003, p. 24).

³ C(2000) 2738 final.

- (4) On the basis of a case-by-case analysis of the national and sectorial programme/project management capacity, financial control procedures and structures regarding public finance, as provided for in Article 12(2) of Regulation (EC) No 1266/1999, the Commission adopted Decision 2002/927/EC of 26 November 2002 conferring management of aid on implementing agencies for preaccession measures in agriculture and rural development in Hungary in the preaccession period⁴ with regard to certain measures provided for in Sapard.
- (5) The Commission has undertaken a further analysis under Article 12(2) of Regulation (EC) No 1266/1999 in respect of measure 1305 'Renovation and development of villages and the protection and conservation of rural heritage' and measure 1306 'Development and diversification of economic activities providing for multiple activities and alternative income' (hereinafter 'measures 1305 and 1306') as provided for in Sapard. The Commission considers that, also with regard to those measures, Hungary complies with the provisions of Articles 4 to 6 and of the Annex to Commission Regulation (EC) No 2222/2000 of 7 June 2000 laying down financial rules for the application of Council Regulation (EC) No 1268/1999 on Community support for preaccession measures for agriculture and rural development in the applicant countries of central and eastern Europe in the preaccession period⁵, and with the minimum conditions set out in the Annex to Regulation (EC) No 1266/1999.
- (6) It is therefore appropriate to waive the ex ante approval requirement referred to in Article 12(1) of Regulation (EC) No 1266/1999 and to confer with regard to measures 1305 and 1306 on the ARDA and on the Ministry of Finance, National Fund, in Hungary the management of aid on a decentralised basis.
- (7) Since the verifications carried out by the Commission for measures 1305 and 1306 are based on a system that is not yet fully operating with regard to all relevant elements, it is therefore appropriate to confer the management of Sapard on the ARDA and on the National Fund according to Article 3(2) of Regulation No 2222/2000, on a provisional basis.
- (8) Full conferral of management of Sapard is only envisaged after further verification to ensure that the system operates satisfactorily has been carried out and after any recommendations the Commission may issue, with regard to the conferral of management of aid on the ARDA and on the National Fund have been implemented.
- (9) On 2 April 2004, the Hungarian authorities proposed the rules for eligibility of expenditure in accordance with Article 4(1) of section B of the Multiannual Financing Agreement. The Commission is called upon to take a decision in this respect,

HAS DECIDED AS FOLLOWS:

⁴ OJ L 322, 27.11.2002, p. 51.

⁵ OJ L 253, 7.10.2000, p. 5; Regulation as last amended by Regulation (EC) No 188/2003 (OJ L 27, 1.2.2003, p. 14).

Article 1

The requirement of ex ante approval by the Commission of project selection and contracting for measures 1305 and 1306 by Hungary provided for in Article 12(1) of Regulation (EC) No 1266/1999 is hereby waived.

Article 2

Management of Sapard is conferred on a provisional basis to:

1. the ARDA under the subordination of the Ministry of Agriculture and Rural Development of Hungary, Alkotmány út 29, District V, Budapest, for the implementation of measures 1305 and 1306 as defined in the Programme for Agriculture and Rural Development that was approved in accordance with Commission Decision C(2000) 2738 final of 18 October 2000, as last amended by the Commission decision, adopted on 25 February 2004;
2. the National Fund within the Ministry of Finance in Hungary, József Nádor tér 2-4., District V, Budapest, for the financial functions it is due to perform in the framework of the implementation of Sapard for measures 1305 and 1306 for Hungary.

Article 3

Expenditure pursuant to this decision shall be eligible for Community co-financing only if incurred by beneficiaries from the date of this decision, or if later, the date of the instrument making them a beneficiary for the project in question, except for feasibility and related studies, where this date shall be 18 October 2000, provided in all cases it has not been paid by the ARDA prior to the date of this decision.

Article 4

Without prejudice to any decisions granting aid under Sapard to individual beneficiaries, the rules for eligibility of expenditure proposed by Hungary by letter of 2 April 2004 and registered in the Commission under No AGR A 11682 of 6 April 2004, shall apply.

Done at Brussels, 27 April 2004.

For the Commission
Franz FISCHLER
Member of the Commission

COMMISSION DECISION**of 28 April 2004****on the financial contribution by the Community towards the World Organisation for Animal Health for the OIE mediated process in 2004****(Text with EEA relevance)**

(2004/386/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field¹, and in particular Article 20 thereof,

Whereas:

- (1) Pursuant to Decision 90/424/EEC the Community is to undertake or assist the Member States in undertaking the technical and scientific measures necessary for the development of Community veterinary legislation and for the development of veterinary education or training.
- (2) At the request of both the European Union and the United States of America, the World Organisation for Animal Health (OIE) convened a meeting at its headquarters on 11 February 2004 with representatives of both parties. The discussions were conducted under the auspices of the OIE in order to solve the problems associated with the interpretation of and the adherence to the current OIE standards in the Terrestrial Animal Health Code of the OIE on BSE (Terrestrial Code).
- (3) The final outcome of the discussions could be of use for further proposals for amendment of the Terrestrial Code on BSE and subsequently be part of the further development of Community veterinary legislation.
- (4) The Community should consequently support the participation by the European Union in the OIE delegated process for which the costs are budgeted at EUR 8 000 for each delegation.
- (5) The financial resources necessary for the Community contribution to the OIE mediated process in February 2004 should therefore be engaged.

¹ OJ L 224, 18.8.1990, p. 19; Decision as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

- (6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS DECIDED AS FOLLOWS:

Sole Article

The participation by the European Union in the OIE mediated process to be financed from budget heading 17 04 02 of the budget of the European Union for 2004 to a maximum amount of EUR 8 000, is hereby approved.

Done at Brussels, 28 April 2004.

For the Commission

David BYRNE

Member of the Commission

COMMISSION DECISION**of 28 April 2004**

on the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the United Mexican States concerning amendments to Annex I to the Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks, taking into account the enlargement

(2004/387/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 97/361/EC of 27 May 1997 concerning the conclusion of an Agreement between the European Community and the United Mexican States on mutual recognition and protection of designations for spirit drinks¹, and in particular Article 4 thereof,

Whereas:

- (1) Taking account of the enlargement, it is necessary to amend Annex I to the Agreement between the European Community and the United Mexican States on the mutual recognition and protection of spirit drinks in order to protect the new spirit terms of the new Member States with effect from 1 May 2004.
- (2) Therefore, the Community and the United Mexican States have negotiated, in accordance with Article 18 of the abovementioned Agreement, an agreement in the form of an Exchange of Letters to amend its Annex I. This Exchange of Letters should therefore be approved.
- (3) The measures provided for in this decision are in accordance with the opinion of the Implementation Committee for Spirit Drinks,

¹ OJ L 152, 11.6.1997, p. 15.

HAS DECIDED AS FOLLOWS:

Article 1

The Agreement in the form of an Exchange of Letters between the European Community and the United Mexican States amending Annex I to the Agreement between the European Community and the United Mexican States on mutual recognition and protection of designations for spirit drinks is hereby approved on behalf of the Community.

The text of the Agreement is attached to this Decision.

Article 2

The Commissioner of Agriculture is hereby empowered to sign the Exchange of Letters in order to bind the Community.

Done at Brussels, 28 April 2004.

For the Commission
Franz FISCHLER
Member of the Commission

ANNEX

AGREEMENT IN THE FORM OF AN EXCHANGE OF LETTERS

between the European Community and the United Mexican States concerning amendment of Annex I to the Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks

*Letter No 1**Letter from the European Community*

Brussels, ... 2004

Sir,

I have the honour to refer to meetings related to technical adaptations which have been held under Article 18 of the Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks, of 27 May 1997, which provides that the Contracting Parties may, by mutual consent, amend this Agreement.

As you are already aware the enlargement of the European Union will take place on 1 May 2004. Therefore, in this context it is necessary to make technical adaptations to Annex I to the abovementioned Agreement, in order to include the recognition and protection of designations for spirit drinks of the new Member States with a view to be applied by the Parties with effect from 1 May 2004.

I have therefore the honour to propose that Annex I to the Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks be replaced by the Annex attached hereto, with effect as of 1 May 2004, subject to the entry into force on the same date of the Treaty of Accession to the European Union of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia.

I should be obliged if you would confirm that your Government is in agreement with the contents of this letter.

Please accept, Sir, the assurance of my highest consideration.

On behalf of the European Community

*Letter No 2**Letter from the United Mexican States*

(Mexico City/Brussels, ... 2004)

Sir,

I have the honour to acknowledge receipt of your letter of (date) which reads as follows:

"I have the honour to refer to meetings related to technical adaptations which have been held under Article 18 of the Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks, of 27 May 1997, which provides that the Contracting Parties may, by mutual consent, amend this Agreement.

As you are already aware the enlargement of the European Union will take place on 1 May 2004. Therefore, in this context it is necessary to make technical adaptations to Annex I to the abovementioned Agreement, in order to include the recognition and protection of designations for spirit drinks of the new Member States with a view to be applied by the Parties with effect from 1 May 2004.

I have therefore the honour to propose that Annex I to the Agreement between the European Community and the United Mexican States on the mutual recognition and protection of designations for spirit drinks be replaced by the Annex attached hereto, with effect as of 1 May 2004, subject to the entry into force on the same date of the Treaty of Accession to the European Union of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia.

I should be obliged if you would confirm that your Government is in agreement with the contents of this letter."

I have the honour to inform you that the United Mexican States are in agreement with the content of your letter.

Please accept, Sir, the assurance of my highest consideration.

On behalf of the United Mexican States

*‘ANNEX 1***to the Agreement between the European Community and the United Mexican States
on the mutual recognition and protection of designations for spirit drinks****1. Rum**

Rhum de la Martinique/Rhum de la Martinique traditionnel
Rhum de la Guadeloupe/Rhum de la Guadeloupe traditionnel
Rhum de la Réunion/Rhum de la Réunion traditionnel
Rhum de la Guyane/Rhum de la Guyane traditionnel
Ron de Málaga
Ron de Granada
Rum da Madeira

2. (a) Whisky

Scotch Whisky
Irish Whisky
Whisky español
(These designations may be supplemented by the terms “malt” or “grain”)

2. (b) Whiskey

Irish Whiskey
Uisce Beatha Eireannach/Irish Whiskey
(These designations may be supplemented by the term “pot still”)

3. Grain spirit

Eau-de-vie de seigle de marque nationale luxembourgeoise
Korn
Kornbrand

4. Wine spirit

Eau-de-vie de Cognac
Eau-de-vie des Charentes
Cognac
(The designation “Cognac” may be supplemented by the following terms:
- Fine
- Grande Fine Champagne
- Grande Champagne
- Petite Champagne
- Petite Fine Champagne
- Fine Champagne
- Borderies
- Fins Bois
- Bons Bois)
Fine Bordeaux
Armagnac

Bas-Armagnac
Haut-Armagnac
Ténarèse
Eau-de-vie de vin de la Marne
Eau-de-vie de vin originaire d'Aquitaine
Eau-de-vie de vin de Bourgogne
Eau-de-vie de vin originaire du Centre-Est
Eau-de-vie de vin originaire de Franche-Comté
Eau-de-vie de vin originaire du Bugey
Eau-de-vie de vin de Savoie
Eau-de-vie de vin originaire des Coteaux de la Loire
Eau-de-vie de vin des Côtes-du-Rhône
Eau-de-vie de vin originaire de Provence
Eau-de-vie de Faugères/Faugères
Eau-de-vie de vin originaire du Languedoc
Aguardente do Minho
Aguardente do Douro
Aguardente da Beira Interior
Aguardente da Bairrada
Aguardente do Oeste
Aguardente do Ribatejo
Aguardente do Alentejo
Aguardente do Algarve

5. Brandy

Brandy de Jerez
Brandy del Penedés
Brandy italiano
Brandy Αττικής/Brandy of Attica
Brandy Πελοποννήσου/Brandy of the Peloponnese
Brandy Κεντρικής Ελλάδας/Brandy of central Greece
Deutscher Weinbrand
Wachauer Weinbrand
Weinbrand Dürnstein
Karpatské brandy špeciál

6. Grape marc spirit

Eau-de-vie de marc de Champagne ou
Marc de Champagne
Eau-de-vie de marc originaire d'Aquitaine
Eau-de-vie de marc de Bourgogne
Eau-de-vie de marc originaire du Centre-Est
Eau-de-vie de marc originaire de Franche-Comté
Eau-de-vie de marc originaire de Bugey
Eau-de-vie de marc originaire de Savoie
Marc de Bourgogne
Marc de Savoie
Marc d'Auvergne
Eau-de-vie de marc originaire des Coteaux de la Loire

Eau-de-vie de marc des Côtes du Rhône
Eau-de-vie de marc originaire de Provence
Eau-de-vie de marc originaire du Languedoc
Marc d'Alsace Gewürztraminer
Marc de Lorraine
Bagaceira do Minho
Bagaceira do Douro
Bagaceira da Beira Interior
Bagaceira da Bairrada
Bagaceira do Oeste
Bagaceira do Ribatejo
Bagaceiro do Alentejo
Bagaceira do Algarve
Orujo gallego
Grappa
Grappa di Barolo
Grappa piemontese/Grappa del Piemonte
Grappa lombarda/Grappa di Lombardia
Grappa trentina/Grappa del Trentino
Grappa friulana/Grappa del Friuli
Grappa veneta/Grappa del Veneto
Südtiroler Grappa / Grappa dell'Alto Adige
Τσικουδιά Κρήτης/Tsikoudia of Crete
Τσίπουρο Μακεδονίας/Tsipouro of Macedonia
Τσίπουρο Θεσσαλίας/Tsipouro of Thessaly
Τσίπουρο Τυρνάβου/Tsipouro of Tyrnavos
Τσιπουρο Τυρναβου/Tsipouro of Tyrnavos
Eau-de-vie de marc de marque nationale luxembourgeoise
Zivania
Pálinka

7. Fruit spirit

Schwarzwälder Kirschwasser
Schwarzwälder Himbeergeist
Schwarzwälder Mirabellenwasser
Schwarzwälder Williamsbirne
Schwarzwälder Zwetschgenwasser
Fränkisches Zwetschgenwasser
Fränkisches Kirschwasser
Fränkischer Obstler
Mirabelle de Lorraine
Kirsch d'Alsace
Quetsch d'Alsace
Framboise d'Alsace
Mirabelle d'Alsace
Kirsch de Fougerolles
Südtiroler Williams/Williams dell'Alto Adige
Südtiroler Aprikot/Südtiroler
Marille/Aprikot dell'Alto Adige/Marille dell'Alto Adige

Südtiroler Kirsch/Kirsch dell'Alto Adige
Südtiroler Zwetschgeler/Zwetschgeler dell'Alto Adige
Südtiroler Obstler/Obstler dell'Alto Adige
Südtiroler Gravensteiner/Gravensteiner dell'Alto Adige
Südtiroler Golden Delicious/Golden Delicious dell'Alto Adige
Williams friulano/Williams del Friuli
Sliwovitz del Veneto
Sliwovitz del Friuli-Venezia Giulia
Sliwovitz del Trentino-Alto Adige
Distillato di mele trentino / Distillato di mele del Trentino
Williams trentino/Williams del Trentino
Sliwovitz trentino/Sliwovitz del Trentino
Aprikot trentino/Aprikot del Trentino
Medronheira do Algarve
Medronheira do Buçaco
Kirsch Friulano/Kirschwasser Friulano
Kirsch Trentino/Kirschwasser Trentino
Kirsch Veneto/Kirschwasser Veneto
Aguardente de pêra da Lousã
Eau-de-vie de pommes de marque nationale luxembourgeoise
Eau-de-vie de poires de marque nationale luxembourgeoise
Eau-de-vie de kirsch de marque nationale luxembourgeoise
Eau-de-vie de quetsch de marque nationale luxembourgeoise
Eau-de-vie de mirabelle de marque nationale luxembourgeoise
Eau-de-vie de prunelles de marque nationale luxembourgeoise
Wachauer Marillenbrand
Bošacka Slivovica
Szatmári Szilvapálinka
Kecskeméti Barackpálinka
Békési Szilvapálinka
Szabolcsi Almapálinka
Slivovice
Pálinka

8. Cider spirit and perry spirit

Calvados
Calvados du Pays d'Auge
Eau-de-vie de cidre de Bretagne
Eau-de-vie de poiré de Bretagne
Eau-de-vie de cidre de Normandie
Eau-de-vie de poiré de Normandie
Eau-de-vie de cidre du Maine
Aguardiente de sidra de Asturias
Eau-de-vie de poiré du Maine

9. Gentian spirit

Bayerischer Gebirgsenzian
Südtiroler Enzian/Genzians dell'Alto Adige
Genziana trentina/Genziana del Trentino

10. Fruit spirit drinks

Pacharán

Pacharán navarro

11. Juniper-flavoured spirit drinks

Ostfriesischer Korngenever

Genièvre Flandres Artois

Hasseltse jenever

Balegemse jenever

Péket de Wallonie

Steinhäger

Plymouth Gin

Gin de Mahón

Vilniaus Džinas

Spišská Borovička

Slovenská Borovička Juniperus

Slovenská Borovička

Inovecká Borovička

Liptovská Borovička

12. Caraway-flavoured spirit drinks

Dansk Akvavit/Dansk Aquavit

Svensk Aquavit/Svensk Akvavit/Swedish Aquavit

13. Aniseed-flavoured spirit drinks

Anis español

Évoca anisada

Cazalla

Chinchón

Ojén

Rute

Oύζο/Ouzo

14. Liqueur

Berliner Kümmel

Hamburger Kümmel

Münchener Kümmel

Chiemseer Klosterlikör

Bayerischer Kräuterlikör

Cassis de Dijon

Cassis de Beaufort

Irish Cream

Palo de Mallorca

Ginjinha portuguesa

Licor de Singeverga

Benediktbeurer Klosterlikör

Ettaler Klosterlikör

Ratafia de Champagne
Ratafia catalana
Anis português
Finnish berry/Finnish fruit liqueur
Grossglockner Alpenbitter
Mariazeller Magenlikör
Mariazeller Jagasaftl
Puchheimer Bitter
Puchheimer Schlossgeist
Steinfelder Magenbitter
Wachauer Marillenlikör
Jägertee/Jagertee/Jagatee
Allažu Kimelis
Čepkeliu
Demänovka Bylinný Likér
Polish Cherry
Karlovarská Hořká

15. Spirit drinks

Pommeau de Bretagne
Pommeau du Maine
Pommeau de Normandie
Svensk Punsch/Swedish Punch
Slivovice

16. Vodka

Svensk Vodka/Swedish Vodka
Suomalainen Vodka/Finsk Vodka/Vodka of Finland
Polska Wódka/Polish Vodka
Laugarício Vodka
Originali Lietuviška degtinė
Wódka zioowa z Niziny Pónocnopodlaskiej aromatyzowana ekstraktem z trawy żubrowej /
Herbal Vodka from the North Podlasie Lowland aromatised with an extract of bison grass
Latvijas Dzidrais
Rīgas Degvīns
LB Degvīns
LB Vodka

17. Bitter-tasting spirit drinks

Rīgas melnais Balzāms/Riga Black Balsam
Demänovka bylinná horká

COMMISSION RECOMMENDATION**of 29 April 2004**

**on the results of the risk evaluation and the risk reduction strategies for the substances:
Acetonitrile; Acrylamide; Acrylonitrile; Acrylic acid; Butadiene; Hydrogen fluoride;
Hydrogen peroxide; Methacrylic acid; Methyl methacrylate; Toluene; Trichlorobenzene**

(notified under document number C(2004) 1446)

(Text with EEA relevance)

(2004/394/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community

Having regard to Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances ⁽¹⁾ and in particular Article 11(2) thereof,

Whereas:

- (1) In the framework of Council Regulation (EEC) No 793/93 the following substances have been identified as priority substances for evaluation in accordance with Commission Regulation (EC) No 1179/94 of 25 May 1994 concerning the first list of priority substances as foreseen under Council Regulation (EEC) No 793/93 ⁽²⁾, which also designates for those substances the following rapporteur Member States:
- Acetonitrile, rapporteur Member State: Spain,
 - Acrylamide, rapporteur Member State: the United Kingdom,
 - Acrylonitrile, rapporteur Member State: Ireland,
 - Acrylic acid, rapporteur Member State: Germany,
 - Butadiene, rapporteur Member State: the United Kingdom,
 - Hydrogen fluoride, rapporteur Member State: the Netherlands,
 - Methacrylic acid, rapporteur Member State: Germany,

¹ OJ L 84, 5.4.1993, p. 1.

² OJ L 131, 26.5.94, p. 3.

- Methyl methacrylate, rapporteur Member State: Germany.
- (2) In the framework of Council Regulation (EEC) No 793/93 the following substances have been identified as a priority substances for evaluation in accordance with Commission Regulation (EC) No 2268/95 of 28 September 1995 concerning the second list of priority substances as foreseen under Council Regulation (EEC) No 793/93 ⁽³⁾, which also designates for those substances the following rapporteur Member States:
- Hydrogen peroxide, rapporteur Member State: Finland;
 - Toluene, rapporteur Member State: Denmark;
 - Trichlorobenzene, rapporteur Member State: Denmark;
- (3) Those rapporteur Member States have completed all the risk evaluation activities with regard to man and the environment for those substances and have suggested a strategy for limiting the risks in accordance with Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93 ⁽⁴⁾.
- (4) The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) has been consulted and has issued an opinion with respect to the risk evaluations carried out by the Member States rapporteurs.
- (5) The results of the risk evaluation are set out in the Annex.
- (6) On the basis of the measures recommended by the rapporteur, the Member States and the interested sector should where appropriate take into account the agreed risk evaluation and implement the relevant recommendations, to ensure risk to human health and the environment is controlled for each of the substances for which a risk assessment has been carried out. The Commission has also listed community legislative measures to which priority should be given.
- (7) The measures provided for in this recommendation are in accordance with the opinion of the Committee set up pursuant to Article 15 of Regulation (EEC) No 793/93,

HEREBY RECOMMENDS:

1. All sectors importing, producing, transporting, storing, formulating into a preparation or other processing, using, disposing or recovering the following substances:
 - (1) Acetonitrile;
CAS No 75-05-8
Einecs No 200-835-2

³ OJ L 231, 28.9.1995, p. 18.

⁴ OJ L 161, 29.6.1994, p. 3.

- (2) Acrylamide;
CAS No 79-06-1
Einecs No 201-173-7
- (3) Acrylonitrile;
CAS No 107-13-1
Einecs No 203-466-5
- (4) Acrylic acid;
CAS No 79-10-7
Einecs No 201-177-9
- (5) Butadiene;
CAS No 106-99-0
Einecs No 203-450-8
- (6) Hydrogen fluoride;
CAS No 7664-39-3
Einecs No 231-634-8
- (7) Hydrogen peroxide;
CAS No 7722-84-1
Einecs No 231-765-0
- (8) Methacrylic acid;
CAS No 79-41-4
Einecs No 201-204-4
- (9) Methyl methacrylate;
CAS No 80-62-6
Einecs No 201-297-1
- (10) Toluene;
CAS No 108-88-3
Einecs No 203-625-9
- (11) Trichlorobenzene;
CAS No 120-82-1
Einecs No 204-428-0

should take into account the results of the risk evaluation set out in the Section Risk assessment of parts 1 to 11 of the Annex for each of the substances mentioned.

2. The strategy for limiting risks set out in the Section Strategy for limiting risks of Parts 1 to 11 of the Annex to this recommendation should be implemented. Where it is considered that no risks are expected, the information should be used to ensure the current risk reduction measures are maintained.

This Recommendation is addressed to all sectors importing, producing, transporting, storing, formulating into a preparation or other processing, using, disposing or recovering the following substances and to the Member States.

Done at Brussels, 29 April 2004.

For the Commission
Margot WALLSTRÖM
Member of the Commission

ANNEX

PART ONE

CAS-NO. 75-05-8

Einecs-No. 200-835-2

Structural Formula: **$\text{CH}_3\text{-C}\equiv\text{N}$**

Einecs Name: Acetonitrile

IUPAC Name: **Acetonitrile**

Rapporteur: Spain

Classification ⁵:
F: R11
Xn: R20/21/22
Xi: R36

The risk assessment is based on current practices related to the life cycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State Rapporteur ⁶. The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate for synthesis of industrial chemicals, pharmaceuticals and pesticides, and in the manufacturing of photographic film. Other uses include as a solvent in various extraction processes and in research and analytical laboratories. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

The risk assessment has identified other sources of exposure of the substance to man and the environment, in particular, the substance is produced during biomass burning and is present in automobile exhaust, which do not result from the life-cycle of the substance produced in or imported into the European Community. The assessment of the risks arising from these exposures are not part of this risk assessment. The comprehensive Risk Assessment Reports as forwarded to the Commission by the Member State Rapporteur does however provide information about these risks.

⁵ The classification of the substances is established by Commission Directive 2000/32/EC of 19 May 2000 adapting to technical progress for the 26th 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 (OJ L 136, 8.6..2000, p. 1).

⁶ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for general systemic toxicity as a consequence of dermal exposure arising from use as a solvent and as an intermediate.

The conclusions of the evaluation of the risks to

CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient

The conclusions of the evaluation of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient

B. Environment

The conclusions of the evaluation of the risks to the environment for

ATMOSPHERE

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusions of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM and TERRESTRIAL ECOSYSTEM

is that there is a need for specific measure to limit the risks. The conclusion is reached because of:

- concerns for the aquatic and terrestrial ecosystems as a consequence of exposure arising from use of the substance in the pharmaceutical industry.

The conclusions of the evaluation of the risks to the environment for

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for effects on sewage treatment plants as a consequence of exposure arising from the use of the substance in the pharmaceutical industry.

STRATEGY FOR LIMITING RISKS

The risk assessment has identified other sources of acetonitrile emissions (eg burning of fossil fuels). This is outside the scope of Council Regulation (EEC) 793/93 and has not been considered in the Risk Reduction Strategy.

for WORKERS

The legislation for workers protection currently in force at Community level is considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

Within this framework it is recommended:

- to consider revising the current occupational exposure limit value adopted under Commission Directive 91/322/EEC ⁷ to provide an indication that dermal exposure can make a contribution to the worker body burden.

for ENVIRONMENT

- that the European Commission should consider the inclusion of acetonitrile in the priority list of Annex X to Council and Parliament Directive 2000/60/EC ⁸ (Water Framework Directive) during the next review of this Annex.

⁷ Commission Directive 91/322/EEC on establishing indicative limit values by implementing Council Directive 80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work (OJ L 177, 5.7.1991, p. 22).

⁸ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, (OJ L 327, 22.12.2000, p. 1).

- to facilitate permitting under Council Directive 96/61/EC ⁹ (Integrated Pollution Prevention and Control) this substance should be included in the ongoing work to develop guidance on ‘Best Available Techniques’ (BAT). It is recommended that Member States should carefully monitor the implementation of BAT by permitting and report any important developments to the Commission in the framework of the exchange of information on BAT.
- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

⁹ Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control (OJ L 257, 10.10.1996, p. 26).

ANNEX

PART TWO

CAS-NO. 79-06-1

Einecs-No. 201-173-7

Structural Formula: **CH₂=CH-CONH₂**Einecs Name: **Acrylamide**

IUPAC Name: 2-propenamide

Rapporteur: United Kingdom

Classification ¹⁰:
Carc.Cat.2:R45
Muta.Cat.2:R46
Repro.Cat.3:R62
T:R25
T:R48/23/24/25
Xn:R20/21
Xi:R36/38
R43

The risk assessment is based on current practices related to the life-cycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State Rapporteur ¹¹.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate in the chemical industry for the production of polyacrylamide. Other uses are as on-site preparation of polyacrylamide gels and as grouting agents. The main uses of polyacrylamide are in waste water treatment, paper and pulp processing and mineral processing; minor uses include as cosmetic additives and as soil conditioners. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore some uses may exist which are not covered by this risk assessment.

¹⁰ The classification of the substance is established by Commission Directive 2001/59/EC of 6 August, adapting to technical progress for the 28th 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 (OJ L 225, 21.8.2001, p. 1).

¹¹ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for mutagenicity and carcinogenicity as a consequence of exposure arising from production of the substance, use as an intermediate in the chemical industry for the production of polyacrylamide, use of polyacrylamide, use of polyacrylamide gels for electrophoresis and use of acrylamide based grouts (small and large scale applications).
- concerns for neurotoxicity and reproductive toxicity as a consequence of exposure arising from the small and large scale use of acrylamide based grouts.

The conclusions of the evaluation of the risks to

CONSUMERS

- is that risks can not be excluded at any exposure, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

The conclusions of the evaluation of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for neurotoxicity, reproductive toxicity, mutagenicity and carcinogenicity as a consequence of exposure resulting from the use of acrylamide based grouts in large scale construction applications.

In addition to the conclusion given above, risks cannot be excluded considering the remaining uses, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusions of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM

is that there is a need for specific measures to limit the risks. The conclusion is reached because of:

- concerns for the aquatic ecosystem as a consequence of exposure arising from the use of acrylamide based grouts in construction applications, and to indirect exposure of other organisms through contaminated water from the same use.

The conclusion of the assessment of the risks to the

ATMOSPHERE

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to the

TERRESTRIAL ECOSYSTEM

is that there is a need for further information and/or testing. This conclusion is reached because of:

- concerns for use of acrylamide-based grouts in construction applications. The information and/or testing requirement is:
- information to refine the risk evaluation for the environment.

The need to obtain this information was re-evaluated in light of the risk reduction strategy and is no longer required (see section II Strategy for limiting risks).

The conclusion of the assessment of the risks to the

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

for HUMAN HEALTH and the ENVIRONMENT

It is recommended:

- to consider at Community level marketing and use restrictions in Council Directive 76/769/EEC¹² for the use of acrylamide¹³ in grouts for small and large-scale applications.
- Further work may be necessary to determine if derogations can be justified
- The marketing and use restrictions proposed will eliminate the need for more information to refine the risk evaluation for the environment

for WORKERS

The legislation for worker protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

Within this framework it is recommended:

- to establish at community level occupational exposure limit values for acrylamide.

for CONSUMERS

- The existing legislative measures for consumer protection, in particular the provisions under Directive 76/769/EEC (Marketing and Use Directive) as regards substances that are carcinogenic, mutagenic and toxic to reproduction (CMR

¹² OJ L 262, 27.9.1976, p. 201.

¹³ N-methylolacrylamide-based grouts are also a potential source of free acrylamide in the grouting process and consideration should be given to examining the risks from this chemical.

substances), and Council Directive 2001/95/EC (General Product Safety) ¹⁴ as regards products are considered sufficient to address the risks identified.

¹⁴

OJ L 11, 15.1.2002, p. 4.

ANNEX

PART THREE

CAS-NO. 107-13-1

Einecs-No.203-466-5

Structural Formula: **$\text{CH}_2 = \text{CH} - \text{C} \equiv \text{N}$** Einecs Name: **Acrylonitrile**

IUPAC Name: 2-propenenitrile

Rapporteur: Ireland

Classification ¹⁵

F:R11
Carc.Cat.2:R45
T:R23/24/25
Xi:R37/38
R41
R43
N:R51/53

The risk assessment is based on current practices related to the lifecycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State rapporteur ¹⁶.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as a monomer in the production of polymeric materials, primarily acrylic and modacrylic fibres, acrylonitrile-butadiene-styrene plastics and styrene-acrylonitrile plastics. Other uses are as a monomer in the synthesis of novel polymeric materials, production of acrylamide, adiponitrile, fatty amines and fatty alcohols.

The risk assessment has identified other sources of exposure to the substance, relevant for man and the environment, which do not result from the life cycle of the substance produced in or imported into the European Community, in particular, the substance is produced during combustion of fossil fuels. The assessment of the risks arising from these exposures are not part of this risk assessment. The comprehensive Risk Assessment Report, as forwarded to the

¹⁵ The classification of the substance is established by Commission Directive 2000/32/EC of 19 May 2000 adapting to technical progress for the 26th 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 (OJ L 136, 8.6.2000, p.1).

¹⁶ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

Commission by the Member State Rapporteur, does however provide information which could be used to assess these risks.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for general systemic effects and carcinogenicity as a consequence of exposure arising during the production and processing of the substance.

The conclusions of the evaluation of the risks to

CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

are that there is a need for specific measures to limit the risks. This conclusion is reached because :

- Risks can not be excluded for all exposure scenarios, as the substance is currently regarded as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusions of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM

is that there is a need for specific measure to limit the risks. The conclusion is reached because of:

- concerns for effects on the local aquatic sphere as a consequence of exposure arising from production of acrylic fibres at a particular site.

The conclusion of the assessment of the risks to the
ATMOSPHERE and TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks for

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental sphere mentioned above are not expected. Risk reduction measures already being applied are considered sufficient

STRATEGY FOR LIMITING RISKS

The risk assessment has identified other sources of acrylonitrile emissions (e.g. burning of fossil fuels). This is outside the scope of Council Regulation (EEC) 793/93 and has not been considered in the Risk Reduction Strategy.

for WORKERS

The legislation for workers protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

Within this framework it is recommended:

- to establish at community level occupational exposure limit values for Acrylonitrile

for CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

- The existing legislative measures for the protection of consumers and humans exposed via the environment, in particular the provisions under the Council Directive 76/769/EEC (Marketing and Use Directive) as regards CMR substances, Council Directive 2001/95/EC (General Product Safety) as regards products, and Council Directive 96/61/EC (Integrated Pollution Prevention and Control) are considered sufficient to address the risks identified.

for the ENVIRONMENT

- to facilitate permitting under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) this substance should be included in the ongoing work to

develop guidance on 'Best Available Techniques' (BAT). It is recommended that Member States should carefully monitor the implementation of BAT by permitting and report any important developments to the Commission in the framework of the exchange of information on BAT.

- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

ANNEX**PART FOUR**

CAS NO. 79-10-7

Einecs-No.201-177-9

Structural Formula: **CH₂=CH-COOH**Einecs Name: **Acrylic Acid**

IUPAC Name: 2-propenoic acid

Rapporteur: Germany

Classification ¹⁷

C:R35
Xn:R20/21/22
R10
N:R50

The risk assessment is based on current practices related to the life cycle of the substance produced in or imported into European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State rapporteur ¹⁸.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate in the production of polyacrylates. Other uses are as an ingredient in adhesives and its occurrence as a residual monomer in adhesives, paints, binding agents, printing inks, sanitary towels, panty-liners and nappy pants. Polyacrylates are mainly used as co-builders in phosphate free washing agents, in flocculating agents and for treatment of drinking and waste water. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

The risk assessment has identified other sources of exposure to the substance, relevant for man and the environment, in particular, during the use of acrylate based grouting agents, as a decomposition product during the production of printed circuit boards and during the removal of paints using gas flames, which do not result from the life-cycle of the substance produced

¹⁷ The classification of the substance is established by Commission Directive 2000/32/EC of 19 May 2000 adapting to technical progress for the 26th 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 (OJ L 136, 8.6.2000, p.1).

¹⁸ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

in or imported into the European Community. The assessment of the risks arising from these exposures are part of this risk assessment.

RISK ASSESSMENT

A. Human health

The conclusion of the assessment of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for respiratory tract irritation and corrosivity as a consequence of single inhalation exposure arising from production and processing, production of adhesives containing the substance and use of adhesives containing the substance,
- concerns for local effects as a consequence of repeated inhalation exposure arising from production of adhesives containing the substance and use of adhesives containing the substance,
- concerns for general systemic toxicity as a consequence of repeated inhalation exposure arising from production and use of adhesives containing the substance.

The conclusion of the assessment of the risks to

CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusions of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM

is that there is a need for specific measures to limit the risks. The conclusion is reached because of:

- concerns for effects on the local aquatic ecosystem as a consequence of exposure arising from wet polymerisation processes including wet production of super absorber polymers and the use of acrylate based grouts.

The conclusion of the assessment of the risks to the

ATMOSPHERE and TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is a need for further information and/or testing. This conclusion is reached because

- there is a need for better information to adequately characterise the risk to municipal waste water treatment plants as a consequence of exposure from the use of the substance for wet polymerisation including the production of super absorber polymers.

The information and/or test requirements are

- Further data reflecting integrity of native ciliate populations in sewage.

STRATEGY FOR LIMITING RISKS

for WORKERS

The legislation for workers' protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

Within this framework it is recommended:

- to establish at community level occupational exposure limit values for acrylic acid.
- that employers using adhesives containing acrylic acid should take note of the practical non-binding guidance, to be developed by the Commission as foreseen under Article 12(2) of Council Directive 98/24/EC¹⁹ (Chemical Agents Directive),

¹⁹

OJ L 131, 5.5.1998, p. 11.

and of any sector specific guidance developed at national level based on this guidance.

for ENVIRONMENT

it is recommended that:

- for Acrylic Acid released from chemical grouts:
- to establish a harmonised European testing and assessment scheme for chemical grouts.
- to regulate general conditions for use of chemical grouts at EU level, including requirements on comprehensive training of planners and field personnel, whereas local aspects should be considered by the respective local supervisory authorities.
- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.
- for Acrylic Acid used in wet polymerisation processes at downstream user sites (processing capacity > 500 t/a) and in SAP production:
- that the European Commission should consider the inclusion of acrylic acid in the priority list of Annex X to Directive 2000/60/EC (Water Framework Directive) during the next review of this Annex and should consider measures such as harmonised requirements for prior authorisation of discharges and emissions into water for the respective plants.
- to facilitate permitting under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) this substance should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT). It is recommended that Member States should carefully monitor the implementation of BAT by permitting and report any important developments to the Commission in the framework of the exchange of information on BAT.
- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

ANNEX

PART FIVE

CAS-NO. 106-99-0

Einecs-No. 203-450-8

Structural Formula: **$\text{CH}_2 = \text{CH} - \text{CH} = \text{CH}_2$** Einecs Name: **Butadiene**

IUPAC Name: 1,3-Butadiene

Rapporteur: UK

Classification²⁰ F+:R12
Carc.Cat.1:R45
Muta.Cat.2:R46

The risk assessment is based on current practices related to the life cycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State Rapporteur²¹

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate in the polymer industry. The major uses of 1,3-butadiene are in the manufacture of synthetic rubber such as styrene-butadiene rubber (SBR) and polybutadiene rubber, thermoplastic resins such as acrylonitrile-butadiene-styrene (ABS), and styrene-butadiene latex. It is also used as a chemical intermediate in the production of neoprene for automotive and industrial rubber goods, in the production of methylmethacrylate-butadiene-styrene (MBS) polymer, which is used as a polyvinyl chloride (PVC) reinforcing agent, and for producing adiponitrile, a nylon precursor. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

²⁰ The classification of the substance is established by Commission Directive 2001/59/EC of 6 August, adapting to technical progress for the 28th 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 (OJ L 225, 21.8.2001, p. 1).

²¹ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for mutagenicity and carcinogenicity as a consequence of exposure arising from production and use as an intermediate in the polymer industry.

The conclusions of the evaluation of the risks to

CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is a need to limit the risks. This conclusion is reached because:

- Risks can not be excluded for all exposure scenarios, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.
- The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusions of the evaluation of the risks to the environment for

ATMOSPHERE, AQUATIC ECOSYSTEM and TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusions of the evaluation of the risks to the environment for

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

for WORKERS

The legislation for workers' protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

Within this framework it is recommended:

- to establish at community level occupational exposure limit values for butadiene .

for CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

- the existing legislative measures for the protection of consumers and humans exposed via the environment, in particular the provisions under the Council Directive 76/769/EEC (Marketing and Use Directive) as regards CMR substances, Council Directive 2001/95/EC (General Product Safety) as regards products, and Council Directive 96/61/EC (Integrated Pollution Prevention and Control) are considered sufficient to address the risks identified.

ANNEX

PART SIX

CAS-NO. 7664-39-3

Einecs-No.231-634-8

Structural Formula:	HF
Einecs Name:	Hydrofluoric acid , anhydrous hydrofluoric acid
IUPAC Name:	Hydrogen fluoride
Rapporteur:	Netherlands
Classification ²²	T+:R26/27/28 C: R34

The risk assessment is based on current practices related to the life cycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State rapporteur ²³.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate in the chemical industry for the synthesis of organofluoride compounds and inorganic fluorides. Other uses are as a pickling agent for metal surfaces, an etching agent for glass surfaces and surface cleaning. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

The risk assessment has identified other sources of exposure of the substance to man and the environment, in particular, releases of hydrogen fluoride from iron/steel and aluminium industry, glass, ceramic and brick industry, power plants and phosphate chemical producers, which does not result from the life-cycle of the substance produced in or imported into the European Community. The assessment of the risks arising from these exposures are not part of this risk assessment. The risk assessment forwarded to the Commission by the Member State Rapporteur does however provide information which could be used to assess these risks.

²² The classification of the substance is established by Commission Directive 2000/32/EC of 19 May 2000, adapting to technical progress for the 26th 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 (OJ L 136, 8.6.2000, p. 1).

²³ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for skin, eye and respiratory tract irritation and/or corrosivity, depending on the concentration, as a consequence of repeated exposure to gaseous hydrogen fluoride at production and use as an intermediate in the chemical industry and use of aqueous solutions of the substance,
- concerns for general systemic toxicity as a consequence of repeated inhalatory exposure arising from the use of aqueous solutions of the substance,
- concerns for skin irritation and/or corrosivity, depending on concentration, as a consequence of single exposure to the hydrogen fluoride liquid arising from the use of aqueous solutions of the substance,
- concerns for respiratory tract irritation and/or corrosivity, depending on concentration, as a consequence of single exposure to gaseous hydrogen fluoride at production and use as an intermediate in the chemical industry and at the use of aqueous solutions of the substance.

The conclusion of the evaluation of the risks to

CONSUMERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for skin irritation and/or corrosivity, depending on concentration, as a consequence of single and repeated exposure to the hydrogen fluoride liquid arising from the consumer use of preparations containing the substance.

The conclusions of the evaluation of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for general systemic toxicity due to repeated inhalatory exposure in the vicinity of production and processing sites of the substance.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected although concerns for risks related to the violent behaviour of the concentrated substance on contact with water and the potential formation of hydrogen on reaction of less than 65 % solutions of the substance with metals have been raised.

B. Environment

The conclusions of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM and ATMOSPHERE

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for effects on local aquatic and atmospheric environmental spheres as a consequence of exposure arising from some production and use sites of the substance.

The conclusion of the assessment of the risks to the

TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks for

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

for WORKERS

The legislation for workers' protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed.

Within this framework it is recommended:

- to consider at the Community level prohibition of the use in building surface cleaning (including floors) at work of hydrogen fluoride by including it in Annex III of Directive 98/24/EC (Chemical Agents Directive);
- that the Commission Scientific Committee on Occupational Exposure Limits (SCOEL) review the new information contained in the risk assessment report and recommend whether there is a need to revise the current occupational exposure limit (OEL).

for CONSUMERS

It is recommended:

- to remove hydrogen fluoride preparations classified as corrosive or toxic from the consumer market ²⁴These products do not comply with the general safety requirement of the Directive 92/59/EEC on General Product Safety ²⁵and should be immediately withdrawn. Member States should carry out an active and effective market surveillance of the situation in their territories concerning the presence of hydrogen fluoride containing consumer products, to remove these products from the market as being unsafe under the general safety obligation provisions of the Directive 92/59/EEC (General Product Safety) and to notify the Commission through the Rapid Alert System of Directive 92/59/EEC.

²⁴ Minutes of the meeting of 2 April 2003 of the Emergencies Committee of Directive 92/59/EEC (General Product Safety).

²⁵ OJ L 228, 11.8.1992, p. 24.

for the ENVIRONMENT

- to facilitate permitting under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) this substance should be included in the ongoing work to develop guidance on ‘Best Available Techniques’ (BAT). It is recommended that Member States should carefully monitor the implementation of BAT by permitting and report any important developments to the Commission in the framework of the exchange of information on BAT.
- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

ANNEX

PART SEVEN

CAS-NO. 7722-84-1

Einecs-No. 231-765-0

Structural Formula: **H₂O₂**

Einecs Name: **Hydrogen peroxide**

IUPAC Name: Hydrogen peroxide

Rapporteur: Finland

Classification ²⁶ O:R8
C:R35

The risk assessment is based on current practices related to the life cycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report as forwarded to the Commission by the Member State Rapporteur ²⁷.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as in pulp bleaching and chemicals manufacture. Other uses are in textile bleaching, disinfection in the foods processing industry, etching in the electronics industry, metal plating, degrading of proteins, tooth bleaching, professional hair dyeing and bleaching, treatment of drinking water and waste water, in numerous consumer products for hair dyeing and bleaching, household textile bleaching products, cleaning agents, contact lens disinfection, and tooth bleaching products.

²⁶ The classification of the substance is established by Commission Directive 91/325/EEC of 1 March 1991, adapting to technical progress for the 12th 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 (OJ L180, 8. 7. 1991, p. 1).

²⁷ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for skin, eye and respiratory tract irritation and/or corrosivity, depending on concentration, as a consequence of exposure arising from loading operations.
- concerns for skin and eye irritation and/or corrosivity, depending on concentration, as a consequence of exposure arising from bleaching of textiles (batch process), aseptic packaging (old types of immersion bath machines), peracetic acid use in breweries, etching of circuit boards (old process), metal plating, degrading of proteins.
- concerns for eye irritation and/or corrosivity, depending on concentration, as a consequence of exposure arising from hairdresser's work.
- concerns for repeated inhalation toxicity in loading operations and aseptic packaging (all machines types), etching of circuit boards (old process) and waste water treatment.

The conclusions of the evaluation of the risks to

CONSUMERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for eye irritation as a consequence of exposure arising from hair dying and bleaching and concerns for eye irritation/corrosivity in use of textile bleaches and cleaning agents, if the actual concentration of hydrogen peroxide is >5 %.
- concerns for specific adverse effects on tooth pulp and teeth as a consequence of exposure arising from tooth bleaching with 35% of hydrogen peroxide by a dentist.

The conclusions of the evaluation of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is a need for specific measures to limit the risks (applies to the workers and to the consumers) This conclusion is reached because:

- concerns for the risk of fire hazard caused by spills of the more concentrated (>25 %) hydrogen peroxide solutions on combustible materials.

B. Environment

The conclusions of the evaluation of the risks to the environment for

ATMOSPHERE and TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to the

AQUATIC ECOSYSTEM

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for effects on aquatic ecosystem as a consequence of exposure arising from four production sites and use in manufacture of other chemicals.

The conclusion of the assessment of the risks for

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks related to the environmental spheres mentioned above are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

for WORKERS

The legislation for workers' protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

Within this framework it is recommended that:

- employers review any risk assessments produced according to Directive 98/24/EC (Chemical Agents Directive) to take into account the information contained in the risk assessment and risk reduction strategy for hydrogen peroxide produced under Regulation (EEC) 739/93, and take any necessary measures that are required.
- employers using hydrogen peroxide for the uses identified as a concern in the risk assessment (part I) should take note of the practical non-binding guidance, to be developed by the Commission as foreseen under Article 12(2) of Directive 98/24/EC, and of any sector specific guidance developed at national level based on this guidance.

for CONSUMERS

It is recommended that:

- in the framework of Commission Directive (EC) 2003/83²⁸ regarding the maximum acceptable percentage of hydrogen peroxide for tooth bleaching products used under supervision of a dentist, a concentration limit of up to 6 % hydrogen peroxide should be considered, provided appropriate conditions of use and warning are printed on the label.
- textile bleaching agents and cleaning agents which contain ≥ 5 % of hydrogen peroxide should be formulated so that the risk of eye irritation/corrosivity is diminished (e.g. viscous suspensions, cream). In the instructions, the risk of eye irritation/corrosivity should be emphasised and the percentage of H₂O₂ in the product should be indicated. For hair dyes/bleaches the above mentioned recommendations, including the percentage limit, should be considered within the framework of Community legislation on cosmetic products.
- the requirement for child-resistant fastenings in the Directive 1999/45/EC (Dangerous Preparations Directive) should be extended to all household chemicals, which may be accessible to children and contain hydrogen peroxide.

for ENVIRONMENT

It is recommended that:

- to facilitate permitting under Directive 96/61/EC (Integrated Pollution Prevention and Control) this substance should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT). It is recommended that Member States should carefully monitor the implementation of BAT by permitting and report any important developments to the Commission in the framework of the exchange of information on BAT.

²⁸

OJ L 238 25.9.2003, p. 27.

ANNEX

PART EIGHT

CAS-NO.79-41-4

Einecs-No. 201-204-4

Structural Formula: **$\text{CH}_2 = \text{C}(\text{CH}_3) - \text{COOH}$**

Einecs Name: **Methacrylic acid (MAA)**

IUPAC Name: 2-Propenoic acid, 2-methyl

Rapporteur: Germany

Classification ²⁹: C: R35
Xn: R21/22

The risk assessment is based on current practices related to the lifecycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State rapporteur ³⁰

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an internal and external intermediate in the chemical industry for the production of methacrylic acid esters and as co-monomer in different kinds of polymers. Other uses are as an ingredient in adhesives and its occurrence as a residual monomer in paints and products for textile processing. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

The risk assessment has identified other sources of exposure to the substance, relevant for man and the environment, in particular during the use of methacrylate based grouts, which do not result from the life-cycle of the substance produced in or imported into the European Community. The assessment of the risks arising from these exposures are part of this risk assessment.

²⁹ The classification of the substance is established by Commission Directive 2001/59/EC of 19 August 2001 adapting to technical progress for the 28th 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 (OJ L 225, 21.8.2001, p. 1).

³⁰ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusion of the assessment of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for respiratory tract irritation as a consequence of short term inhalation exposure arising from the production, further processing as a chemical intermediate in the chemical industry, the manufacture of adhesives in the industrial area and the industrial and skilled trade use of adhesives,
- concerns for local respiratory effects as a consequence of repeated inhalation exposure arising from manufacture and use of adhesives.

The conclusion of the assessment of the risks to

CONSUMERS and HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusion of the assessment of the risks to the environment for

AQUATIC ECOSYSTEM

is that there is a need for specific measures to limit the risks. The conclusion is reached because of:

- concerns for effects on the aquatic ecosystem as a consequence of exposure arising from the use of acrylate based grouting agents.

The conclusion of the assessment of the risks to the

ATMOSPHERE and TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

for WORKERS

The legislation for workers' protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

Within this framework it is recommended:

- to establish at community level occupational exposure limit values for Methacrylic acid.
- that employers using adhesives containing methacrylic acid should take note of the practical non-binding guidance, to be developed by the Commission as foreseen under Article 12(2) of Directive 98/24/EC (Chemical Agents Directive) and of any sector specific guidance developed at national level based on this guidance .

for ENVIRONMENT

For methacrylic acid released from chemical grouts it is recommended:

- to establish a harmonised European testing and assessment scheme for chemical grouts.
- to regulate general conditions for use of chemical grouts at EU level, including requirements on comprehensive training of planners and field personnel, whereas local aspects should be considered by the respective local supervisory authorities.
- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

ANNEX

PART NINE

CAS-NO.80-62-6

Einecs-No.201-297-1

Structural Formula:	$\text{CH}_2 = \text{C}(\text{CH}_3) - \text{COOCH}_3$
Einecs Name:	Methyl methacrylate (MMA)
IUPAC Name:	2-methyl-propenoic acid, methyl ester
Rapporteur:	Germany
Classification ³¹	F:R11 Xi:R37/38 R43

The risk assessment is based on current practices related to the lifecycle of the substance as described in the risk evaluation forwarded to the Commission by the Member State rapporteur ³².

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate in production of polymers, copolymers, adhesives, reactive resins, in transesterification and in cast sheet production. Other uses are in the production of emulsion, dispersion and solvent polymers, acrylic sheet type polymers, as an ingredient in reactive adhesives and embedding resins, floor coatings, casting resins used for dental and medical applications and the substance occurs as residual monomer in paints, as well as in other polymers used for consumer products. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

The risk assessment has identified other sources of exposure to the substance, relevant for man and the environment, in particular, as a decomposition product during the thermal processing of polymethyl methacrylate (PMMA), which do not result from the life-cycle of the substance produced in or imported into the European Community. The assessment of the risks arising from these exposures are part of this risk assessment.

³¹ The classification of the substance is established by Commission Directive 2000/32/EC of 19 May 2000 adapting to technical progress for the 26th 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 (OJ L 136, 8.6.2000, p. 1).

³² The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusion of the assessment of the risks to

WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for respiratory tract irritation and corrosivity as a consequence of inhalation exposure arising from cast sheet production, production of reactive resins, production and use of adhesives, production of paints, skilled trade area: floor coating, use of casting resins in medical applications and in orthopaedic workshops, dental laboratories and surgeries as well as in ornamental decoration,
- concerns for skin sensitisation as a consequence of dermal exposure arising from production of methyl methacrylate, polymethyl methacrylate, transesterification, cast sheet production, production of adhesives and reactive resins in chemical industry, production of adhesives, casting resins and floor coating materials, production of paints and varnishes, use of adhesives in plastics, electronics and glass industry, use of adhesives and floor coating in skilled trade area, use of casting resins in medical applications, orthopaedic workshops, dental laboratories and surgeries, manufacturing of lenses and ornamental decoration,
- concerns for local effects as a consequence of repeated inhalation exposure arising from cast sheet production, production of reactive resins, production and use of adhesives and as well as production of paints, use of casting resins in orthopaedic workshops and dental laboratories and surgeries,
- concerns for general systemic effects as a consequence of inhalation exposure arising from cast sheet production, production of adhesives, production of paints, skilled trade area: floor coating, use of casting resins in orthopaedic workshops and in ornamental decoration.

The conclusion of the assessment of the risks to

CONSUMERS

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusion of the assessment of the risks to the

AQUATIC ECOSYSTEM

is that there is a need for specific measures to limit the risks. The conclusion is reached because of:

- concerns for effects on the local aquatic ecosystem as a consequence of exposure arising from wet polymerisation processes.

The conclusion of the assessment of the risks to the

ATMOSPHERE and TERRESTRIAL ECOSYSTEM

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

STRATEGY FOR LIMITING RISKS

for WORKERS

The legislation for workers' protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

Within this framework it is recommended:

- to establish at community level occupational exposure limit values for methyl methacrylate
- that employers using methyl methacrylate for the uses identified as a concern in the risk assessment (part I) should take note of the practical non-binding guidance to be developed by the Commission as foreseen under Article 12(2) of 98/24/EC (Chemical Agents Directive), and of any sector specific guidance developed at national level based on this guidance.

for ENVIRONMENT

for Methyl methacrylate used in wet polymerisation processes at downstream user sites (processing capacity > 5000 t/a) it is recommended:

- that the European Commission should consider whether to include methyl methacrylate on the priority list of Annex X to Directive 2000/60/EC (Water Framework Directive) during the next review of this Annex and should consider measures such as harmonised requirements for prior authorisation of discharges and emissions into water for the respective plants.
- to facilitate permitting under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) this substance should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT). It is recommended that Member States carefully monitor the implementation of BAT by permitting and report any important developments to the Commission in the framework of the exchange of information on BAT
- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

ANNEX

PART TEN

CAS-NO. 108-88-3

Einecs-No. 203-625-9

Structural Formula: **C₆H₅ – CH₃**Einecs Name: **Toluene**

IUPAC Name: Toluene

Rapporteur: Denmark

Classification³³
F:R11
Xn:R20

The risk assessment is based on current practices related to the lifecycle of the substance produced in or imported into the European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State rapporteur³⁴.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate for synthesis of other chemicals, in solvents, and adhesives, paints, lacquers, varnishes and in the mineral oil, fuel and polymer industries. Other uses reported are in the pulp, paper and board industry, textile industry, agricultural industry and electrical and electronic industry.

The risk assessment has identified other sources of exposure of the substance to man and the environment, in particular the use and combustion of petroleum products, which do not result from the life-cycle of the substance produced in or imported into the European Community. The assessment of the risks arising from these exposures is not part of this risk assessment. The comprehensive Risk Assessment Reports as forwarded to the Commission by the Member State Rapporteur does however provide information that could be used to assess these risks.

³³ The classification of the substance is established by Commission Directive 91/325/EEC of 1 March 1991, adapting to technical progress for the 12th 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 (OJ L 180, 8. 7. 1991, p. 1).

³⁴ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to WORKERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for acute toxicity as a consequence of dermal exposure arising from spraying painting or the use of adhesives,
- concerns for acute toxicity (headache, dizziness, feeling of intoxication, sleepiness and impaired functional performance) as a consequence of inhalation exposure arising from production and use as an intermediate, production of products containing the substance and use of products containing the substance,
- concerns for eye irritation as a consequence of exposure arising from production of products containing the substance and use of products containing the substance in the sectors of manual cleaning, use of adhesives, printing and painting (mechanical coating),
- concerns for general systemic toxicity as a consequence of inhalation exposure arising from production of products containing the substance and use of products containing the substance in the sectors of manual cleaning, use of adhesives, printing and painting (mechanical coating),
- concerns for general systemic toxicity as a consequence of dermal exposure arising from use of products containing the substance in the sectors of manual cleaning, use of adhesives and spray painting,
- concerns for general systemic toxicity as a consequence of the combined dermal and inhalatory exposure arising the use of products containing the substance in the sectors of manual painting,
- concerns for specific organ toxicity (auditory system toxicity) as a consequence of inhalation exposure arising from production of products containing the substance and use of products containing the substance in the sectors of manual cleaning, use of adhesives, printing and painting (mechanical coating),
- concerns for fertility and developmental effects and spontaneous abortions as a consequence of inhalation exposure arising from production of products and use of toluene containing products in the sectors of manual cleaning, use of adhesives, printing and painting (mechanical coating).

The conclusions of the evaluation of the risks to

CONSUMERS

1. is that there is a need for specific measures to limit the risks. This conclusion is reached because of:
 - concerns for acute toxicity (headache, dizziness, feeling of intoxication, sleepiness and impaired functional performance) and eye irritation as a consequence of inhalation exposure or eye exposure to vapours arising from spray painting and carpet laying.
2. is that there is a need for further information and/or testing. This conclusion is reached because
 - concerns for effects on reproduction as a consequence of inhalation exposure.

The information and/or test requirement is:

- information on the relationship between the observed effects on reproduction and the duration of the exposure leading to these effects.

The need to obtain this information was re-evaluated in light of the risk reduction strategy and is no longer required (see section II Strategy for limiting risks).

The conclusions of the evaluation of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for effects on humans due to the contribution of commercial product toluene to the formation of ozone and other harmful substances, i.e., smog formation.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusions of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for the aquatic ecosystem as a consequence of exposure arising from some sites of production and combined production and processing of the substance, as well as exposure arising from processing and the use sectors of basic chemicals (including processing aid, “extraction” agent and solvent), processing and formulation, mineral oil and fuel formulation, formulation of polymers, formulation of paints and textile processing.

The conclusion of the assessment of the risks to the

TERRESTRIAL ECOSYSTEM

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for terrestrial ecosystem as a consequence of exposure arising from processing as well as exposure arising from the use sectors of basic chemicals (including processing aid, “extraction” agent and solvent), processing and formulation, mineral oil and fuel formulation, formulation of polymers, formulation of paints and textile processing.

The conclusion of the assessment of the risks for

ATMOSPHERE

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for the contribution of the commercial product toluene to the formation of ozone and other harmful substances, i.e. smog formation.

The conclusion of the assessment of the risks for

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for sewage treatment plants as a consequence of exposure arising from processing of the substance as well as in the use sectors of industry use as basic chemicals.

STRATEGY FOR LIMITING RISKS

The risk assessment has identified other sources of toluene emissions (e.g. gasoline and crude oil). This is outside the scope of Council Regulation (EEC) 793/93 and has not been considered in the Risk Reduction Strategy.

for WORKERS

The legislation for workers’ protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

Within this framework it is recommended:

- that the Commission Scientific Committee on Occupational Exposure Limits (SCOEL) review the new information contained in the risk assessment report and recommend whether there is a need to revise the current OEL.

for CONSUMERS

It is recommended:

- to consider at Community level marketing and use restrictions in Directive 76/769/EEC for the substance as such or in preparations for use in adhesives and spray paint.
- The marketing and use restrictions proposed will eliminate the need for more information on reproduction as a consequence of inhalation exposure.

for ENVIRONMENT and HUMANS EXPOSED VIA THE ENVIRONMENT

It is recommended:

- that the European Commission should consider the inclusion of toluene in the priority list of Annex X to Directive 2000/60/EC (Water Framework Directive) during the next review of this Annex but that, in the meantime, toluene should be considered as a relevant List II substance in Council Directive 76/464/EEC³⁵ on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community, thus requiring the establishment of national quality objectives, monitoring and eventual reduction measures, as to ensure that concentrations in surface water systems do not exceed the quality objective.
- to facilitate permitting under Council Directive 96/61/EC (Integrated Pollution Prevention and Control) that this substance is included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT). It is recommended that Member States should carefully monitor the implementation of BAT by permitting and report any important developments to the Commission in the framework of the exchange of information on BAT.
- local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected.

³⁵

OJ L 129, 18.5.1976, p 23.

The proposal from the Commission to limit the content of solvents in certain products would further limit the risk from toluene to man via the environment ³⁶

³⁶

Proposal for a Directive on the limitation of emissions of volatile organic compounds due to the use of organic solvents in decorative paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC (COM(2002) 750 final).

ANNEX

PART ELEVEN

CAS-NO. 120-82-1

Einecs-No. 204-428-0

Structural Formula: **C₆H₃Cl₃**

Einecs Name: **1,2,4-Trichlorobenzene (TCB)**

IUPAC Name: 1,2,4-Trichlorobenzene

Rapporteur: Denmark

Classification³⁷ Xn:R22
Xi:R38
N:50-53

The risk assessment is based on current practices related to the lifecycle of the substance produced in or imported into European Community as described in the comprehensive Risk Assessment Report forwarded to the Commission by the Member State rapporteur³⁸.

The risk assessment has, based on the available information, determined that in the European Community the substance is mainly used as an intermediate for synthesis of herbicides and as a process solvent in closed systems. Other uses reported include as a solvent, dye carrier in textile industry, additive in dielectric fluids and corrosion inhibitor. It was not possible to obtain information on the use of the total volume of substance produced in or imported into the European Community, therefore, some uses may exist which are not covered by this risk assessment.

The risk assessment has identified other sources of exposure of the substance to man and the environment, in particular, from certain 1,2,4-trichlorobenzene containing dielectric fluids still in use in existing electrical equipment and environmental formation of 1,2,4-trichlorobenzene as a decomposition product of other, more complex organo-chlorine compounds, which do not result from the life-cycle of the substance produced in or imported into the European Community. The assessment of the risks arising from these exposures are not part of this risk assessment.

The comprehensive Risk Assessment Reports as forwarded to the Commission by the Member State Rapporteur does however provide information that could be used to assess these risks.

³⁷ The classification of the substance is established by Commission Directive 2001/59/EC of 6 August, adapting to technical progress for the 28th 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 (OJ L 225, 21. 8.2001, p. 30).

³⁸ The comprehensive Risk Assessment Report, as well as a summary thereof, can be found on the internet site of the European Chemicals Bureau: <http://ecb.jrc.it/existing-substances/>.

The risk assessment indicates that it should be further investigated if the substance should be considered in relation to national or international programmes addressing persistent organic pollutants.

RISK ASSESSMENT

A. Human health

The conclusions of the evaluation of the risks to

WORKERS

is that there is a need for further information and/or testing. This conclusion is reached because:

- concerns for effects as a consequence exposure

The information and/or test requirements are

- information on occupational exposure during the use of the substance as a dye carrier and as a process solvent, during production of products containing the substance in the sector of production of dielectric fluids and during the use of products containing the substance in the sector of production of wire and cabling.

The need to obtain this information was re-evaluated in light of the risk reduction strategy and is no longer required (see section II Strategy for limiting risks).

that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for general systemic toxicity as a consequence of repeated inhalation exposure arising from drumming activities in the production of the substance, from the production of products containing the substance in the sector of pigment production and from the use of products containing the substance in the sector of spray painting,
- concerns for eye and respiratory tract irritation as a consequence of repeated exposure to the vapour of the substance arising from the production of products containing the substance in the sector of pigment production and from the use of products containing the substance in the sector of production of plastic pellets,
- concerns for general systemic toxicity and local dermal effects as a consequence of repeated dermal exposure arising from the use of the products containing the substance in the sectors of spray painting, dismantling transformers and polishing,

The conclusions of the evaluation of the risks to

CONSUMERS

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for eye and respiratory tract irritation as a consequence of repeated exposure to vapours and general systemic toxicity as a consequence of repeated inhalation and dermal exposure arising from spray painting and car polishing.

The conclusions of the evaluation of the risks to

HUMANS EXPOSED VIA THE ENVIRONMENT

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for indirect exposure as calculated exposures can exceed WHO TDIs, and WHO guideline values in drinking water for local use scenarios.

The conclusion of the assessment of the risks to

HUMAN HEALTH (physicochemical properties)

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient.

B. Environment

The conclusions of the evaluation of the risks to the environment for

AQUATIC ECOSYSTEM and TERRESTRIAL ECOSYSTEM is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for the aquatic ecosystem and terrestrial ecosystem as a consequence of exposure arising from the use of the substance as a dye carrier and other uses (including as a process solvent, additive in dielectric fluids and a corrosion inhibitor).

The conclusion of the assessment of the risks to the

ATMOSPHERE

is that there is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied. This conclusion is reached because:

- the risk assessment shows that risks are not expected. Risk reduction measures already being applied are considered sufficient

The conclusion of the assessment of the risks to

MICRO-ORGANISMS IN THE SEWAGE TREATMENT PLANT

is that there is a need for specific measures to limit the risks. This conclusion is reached because of:

- concerns for sewage treatment plants as a consequence of exposure arising from use as an intermediate, as well as from the use sectors of basic chemicals as a solvent, textile industry as dye carrier and other downstream uses.

STRATEGY FOR LIMITING RISKS

for WORKERS

The legislation for workers' protection currently in force at Community level and in particular the provisions under Commission Directive 2000/39/EC ³⁹ establishing a first list of indicative exposure limit values are generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

The marketing and use restrictions proposed for the environment will also reduce the risk for human health (workers) and eliminate the need for more information on the occupational exposure scenarios.

for CONSUMERS, the ENVIRONMENT and HUMANS EXPOSED VIA THE ENVIRONMENT

It is recommended:

- to consider marketing and use restrictions at Community level in Council Directive 76/769/EEC for all uses of TCB except as an intermediate to protect the environment and to reduce the indirect exposure via the environment. Where appropriate, marketing and use restrictions of articles containing TCB should also be considered.

³⁹

OJ L 142, 16.6.2000, p. 47.