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Contents

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other Acts are printed in bold type and preceded by an asterisk.

I

(Acts whose publication is obligatory)

DIRECTIVE 98/78/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 October 1998

on the supplementary supervision of insurance undertakings in an insurance group

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 57(2) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure laid down in Article 189b of the Treaty [3],

(1) Whereas the first Council Directive 73/239/EEC of 24 July 1973 on the coordination of laws, regulations and administrative provisions relating to the taking up and pursuit of the business of direct insurance other than life assurance [4] and the first Council Directive 79/267/EEC of 5 March 1979 on the coordination of laws, regulations and administrative provisions relating to the taking up and pursuit of the business of direct life assurance [5] require insurance undertakings to have solvency margins;

(2) Whereas, under Council Directive 92/49/EEC of 18 June 1992 on the coordination of laws, regulations and administrative provisions relating to direct insurance other than life assurance and amending Directives 73/239/EEC and 88/357/EEC [6] and Council Directive 92/96/EEC of 10 November 1992 on the coordination of laws, regulations and administrative provisions relating to direct life assurance and amending Directives 79/267/EEC and 90/619/EEC [7] the taking up and the pursuit of the business of insurance are subject to the granting of a single official authorisation issued by the authorities of the Member State in which an insurance undertaking has its registered office (home Member State); whereas such authorisation allows an undertaking to carry on business throughout the Community, under either the right of establishment or the freedom to provide services; whereas the competent authorities of home Member States are responsible for monitoring the financial health of insurance undertakings, including their solvency;

(3) Whereas measures concerning the supplementary supervision of insurance undertakings in an insurance group should enable the authorities supervising an insurance undertaking to form a more soundly based judgment of its financial situation; whereas such supplementary supervision should take into account certain undertakings which are not at present subject to supervision under Community Directives; whereas this Directive does not in any way imply that Member States are required to undertake supervision of those undertakings considered individually;

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[1] OJ C 341, 19.12.1995, p. 16, and OJ C 108, 7.4.1998, p. 48.

[2] OJ C 174, 17.6.1996, p. 16.

[3] Opinion of the European Parliament of 23 October 1997 (OJ C 339, 10.11.1997, p. 136), Council common position of 30 March 1998 (OJ C 204, 30.6.1998, p. 1), Decision of the European Parliament of 16 September 1998 (OJ C 313, 12.10.1998) and Council Decision of 13 October 1998.

[4] OJ L 228, 16.8.1973, p. 3. Directive as last amended by Directive 95/26/EC (OJ L 168, 18.7.1995, p. 7).

[5] OJ L 63, 13.3.1979, p. 1. Directive as last amended by Directive 95/26/EC.

[6] OJ L 228, 11.8.1992, p. 1. Directive as amended by Directive 95/26/EC.

[7] OJ L 360, 9.12.1992, p. 1. Directive as amended by Directive 95/26/EC.

(4) Whereas insurance undertakings in a common insurance market engage in direct competition with each other and the rules concerning capital requirements must therefore be equivalent; whereas, to that end, the criteria applied to determine supplementary supervision must not be left solely to the discretion of Member States; whereas the adoption of common basic rules will be in the best interests of the Community in that it will prevent distortions of competition; whereas it is necessary to eliminate certain divergences between the laws of the Member States as regards the prudential rules to which insurance undertakings that are part of an insurance group are subject;

(5) Whereas the approach adopted consists in bringing about such harmonisation as is essential, necessary and sufficient to achieve the mutual recognition of prudential control systems in this field; whereas the aim of this Directive is in particular to protect the interests of insured persons;

(6) Whereas certain provisions of this Directive define minimum standards; whereas a home Member State may lay down stricter rules for insurance undertakings authorised by its own competent authorities;

(7) Whereas this Directive provides for the supplementary supervision of any insurance company which is a participating undertaking in at least one insurance undertaking, reinsurance undertaking or non-member-country insurance undertaking and, under different rules, for the supplementary supervision of any insurance company whose parent undertaking is an insurance holding company, a reinsurance undertaking, a non-member-country insurance undertaking or a mixed-activity insurance holding company; whereas the supervision of individual insurance undertakings by the competent authorities remains the essential principle of insurance supervision;

(8) Whereas it is necessary to calculate an adjusted solvency situation for insurance undertakings forming part of an insurance group; whereas different methods are applied by the competent authorities in the Community to take into account the effects on the financial situation of an insurance undertaking attributable to the fact that it belongs to an insurance group; whereas this Directive lays down three methods to effect that calculation; whereas the principle is accepted that these methods are prudentially equivalent;

(9) Whereas the solvency of a related subsidiary insurance undertaking of an insurance holding company, reinsurance undertaking or non-member-country insurance undertaking may be affected by the financial resources of the group of which it is a part and by the distribution of financial resources within that group; whereas the competent authorities should be provided with the means of exercising supplementary supervision and of taking appropriate measures at the level of the insurance undertaking where its solvency is or may be jeopardised;

(10) Whereas the competent authorities should have access to all the information relevant to the exercise of supplementary supervision; whereas cooperation between the authorities responsible for the supervision of insurance undertakings as well as between those authorities and the authorities responsible for the supervision of other financial sectors should be established;

(11) Whereas intra-group transactions can affect the financial position of an insurance undertaking; whereas the competent authorities should be in a position to exercise general supervision over certain types of such intra-group operations and take appropriate measures at the level of the insurance undertaking where its solvency is or may be jeopardised,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Definitions

For the purposes of this Directive:

(a) *insurance undertaking* means an undertaking which has received official authorisation in accordance with Article 6 of Directive 73/239/EEC or Article 6 of Directive 79/267/EEC;

(b) *non-member-country insurance undertaking* means an undertaking which would require authorisation in accordance with Article 6 of Directive 73/239/EEC or Article 6 of Directive 79/267/EEC if it had its registered office in the Community;

(c) *reinsurance undertaking* means an undertaking, other than an insurance undertaking or a non-member-country insurance undertaking, the main business of which consists in accepting risks ceded by an insurance undertaking, a non-member-country insurance undertaking or other reinsurance undertakings;

(d) *parent undertaking* means a parent undertaking within the meaning of Article 1 of Directive 83/349/EEC [1] and any undertaking which, in the opinion of the competent authorities, effectively exercises a dominant influence over another undertaking;

(e) *subsidiary undertaking* means a subsidiary undertaking within the meaning of Article 1 of Directive 83/349/EEC and any undertaking over which, in the opinion of the competent authorities, a parent undertaking effectively exercises a dominant influence. All subsidiaries of subsidiary undertakings shall also be considered subsidiaries of the parent undertaking which is at the head of those undertakings;

(f) *participation* means participation within the meaning of Article 17, first sentence, of Directive 78/660/EEC [2] or the holding, directly or indirectly, of 20 % or more of the voting rights or capital of an undertaking;

(g) *participating undertaking* means an undertaking which is either a parent undertaking or another undertaking which holds a participation;

(h) *related undertaking* means either a subsidiary or other undertaking in which a participation is held;

(i) *insurance holding company* means a parent undertaking the main business of which is to acquire and hold participations in subsidiary undertakings, where those subsidiary undertakings are exclusively or mainly insurance undertakings, reinsurance undertakings or non-member-country insurance undertakings, one at least of such subsidiary undertakings being an insurance undertaking;

(j) *mixed-activity insurance holding company* means a parent undertaking, other than an insurance undertaking, a non-member-country insurance undertaking, a reinsurance undertaking or an insurance holding company, which includes at least one insurance undertaking among its subsidiary undertakings;

(k) *competent authorities* means the national authorities which are empowered by law or regulation to supervise insurance undertakings.

[1] Seventh Council Directive 83/349/EEC of 13 June 1983 based on Article 54(3)(g) of the Treaty on consolidated accounts (OJ L 193, 18.7.1983, p. 1). Directive as last amended by the 1994 Act of Accession.

[2] Fourth Council Directive 78/660/EEC of 25 July 1978 based on Article 54(3)(g) of the Treaty on the annual accounts of certain types of companies (OJ L 222, 14.8.1978, p. 11). Directive as last amended by the 1994 Act of Accession.

Article 2

Cases of application of supplementary supervision of insurance undertakings

1. In addition to the provisions of Directives 73/239/EEC and 79/267/EEC which lay down the rules for the supervision of insurance undertakings, Member States shall provide supervision of any insurance undertaking which is a participating undertaking in at least one insurance undertaking, reinsurance undertaking, or non-member-country insurance undertaking shall be supplemented in the manner prescribed in Articles 5, 6, 8 and 9.

2. Every insurance undertaking the parent undertaking of which is an insurance holding company, a reinsurance undertaking or a non-member-country insurance undertaking shall be subject to supplementary supervision in the manner prescribed in Articles 5(2), 6, 8 and 10.

3. Every insurance undertaking the parent undertaking of which is a mixed-activity insurance holding company shall be subject to supplementary supervision in the manner prescribed in Articles 5(2), 6 and 8.

Article 3

Scope of supplementary supervision

1. The exercise of supplementary supervision in accordance with Article 2 shall in no way imply that the competent authorities are required to play a supervisory role in relation to the non-member-country insurance undertaking, insurance holding company or mixed-activity insurance holding company or reinsurance undertaking taken individually.

2. The supplementary supervision shall take into account:

— related undertakings of the insurance undertaking,

— participating undertakings in the insurance undertaking,

— related undertakings of a participating undertaking in the insurance undertaking,

referred to in Articles 5, 6, 8, 9 and 10.

3. Member States may decide not to take into account in the supplementary supervision referred to in Article 2 undertakings having their registered office in a non-member country where there are legal impediments to the transfer of the necessary information, without prejudice to the provisions of Annex I, point 2.5, and of Annex II, point 4.

Furthermore, the competent authorities responsible for exercising supplementary supervision may in the cases listed below decide on a case-by-case basis not to take an undertaking into account in the supplementary supervision referred to in Article 2:

— if the undertaking which should be included is of negligible interest with respect to the objectives of the supplementary supervision of insurance undertakings,

— if the inclusion of the financial situation of the undertaking would be inappropriate or misleading with respect to the objectives of the supplementary supervision of insurance undertakings.

Article 4

Competent authorities for exercising supplementary supervision

1. Supplementary supervision shall be exercised by the competent authorities of the Member State in which the insurance undertaking has received official authorisation under Article 6 of Directive 73/239/EEC or Article 6 of Directive 79/267/EEC.

2. Where insurance undertakings authorised in two or more Member States have as their parent undertaking the same insurance holding company, reinsurance undertaking, non-member-country insurance undertaking or mixed-activity insurance holding company, the competent authorities of the Member States concerned may reach agreement as to which of them will be responsible for exercising supplementary supervision.

3. Where a Member State has more than one competent authority for the prudential supervision of insurance undertakings and reinsurance undertakings, such Member State shall take the requisite measures to organise coordination between those authorities.

Article 5

Availability and quality of information

1. Member States shall prescribe that the competent authorities shall require that every insurance undertaking subject to supplementary supervision shall have adequate internal control mechanisms in place for the production of any data and information relevant for the purposes of such supplementary supervision.

2. Member States shall take the appropriate steps to ensure that there are no legal impediments within their jurisdiction preventing the undertakings that are subject to the supplementary supervision and their related undertakings and participating undertakings from exchanging among themselves any information relevant for the purposes of such supplementary supervision.

Article 6

Access to information

1. Member States shall provide that their competent authorities responsible for exercising supplementary supervision shall have access to any information which would be relevant for the purpose of supervision of an insurance undertaking subject to such supplementary supervision. The competent authorities may address themselves directly to the relevant undertakings referred to in Article 3(2) to obtain the necessary information only if such information has been requested from the insurance undertaking and has not been supplied by it.

2. Member States shall provide that their competent authorities may carry out within their territory, themselves or through the intermediary of persons whom they appoint for that purpose, on-the-spot verification of the information referred to in paragraph 1 at:

— the insurance undertaking subject to supplementary supervision,

— subsidiary undertakings of that insurance undertaking,

— parent undertakings of that insurance undertaking,

— subsidiary undertakings of a parent undertaking of that insurance undertaking.

3. Where, in applying this Article, the competent authorities of one Member State wish in specific cases to verify important information concerning an undertaking situated in another Member State which is a related insurance undertaking, a subsidiary undertaking, a parent undertaking or a subsidiary of a parent undertaking of the insurance undertaking subject to supplementary supervision, they must ask the competent authorities of that other Member State to have that verification carried out. The authorities which receive such a request must act on it within the limits of their jurisdiction by carrying out the verification themselves, by allowing the authorities making the request to carry it out or by allowing an auditor or expert to carry it out.

Article 7

Cooperation between competent authorities

1. Where insurance undertakings established in different Member States are directly or indirectly related or have a common participating undertaking, the competent authorities of each Member State shall communicate to one another on request all relevant information which may allow or facilitate the exercise of supervision pursuant to this Directive and shall communicate on their own initiative any information which appears to them to be essential for the other competent authorities.

2. Where an insurance undertaking and either a credit institution as defined in Directive 77/780/EEC [1] or an investment firm as defined in Directive 93/22/EEC [2], or both, are directly or indirectly related or have a common participating undertaking, the competent authorities and the authorities with public responsibility for the supervision of those other undertakings shall cooperate closely. Without prejudice to their respective responsibilities, those authorities shall provide one another with any information likely to simplify their task, in particular within the framework of this Directive.

3. Information received pursuant to this Directive and, in particular, any exchange of information between competent authorities which is provided for in this Directive shall be subject to the obligation of professional secrecy defined in Article 16 of Directive 92/49/EEC and Article 15 of Directive 92/96/EEC.

Article 8

Intra-group transactions

1. Member States shall provide that the competent authorities exercise general supervision over transactions between:

(a) an insurance undertaking and:

(i) a related undertaking of the insurance undertaking;

(ii) a participating undertaking in the insurance undertaking;

(iii) a related undertaking of a participating undertaking in the insurance undertaking;

(b) an insurance undertaking and a natural person who holds a participation in:

(i) the insurance undertaking or any of its related undertakings;

(ii) a participating undertaking in the insurance undertaking;

(iii) a related undertaking of a participating undertaking in the insurance undertaking.

These transactions concern in particular:

— loans,

— guarantees and off-balance-sheet transactions,

— elements eligible for the solvency margin,

— investments,

— reinsurance operations,

— agreements to share costs.

2. To this end, Member States shall require at least annual reporting by the insurance undertakings to the competent authorities of significant transactions as provided for in paragraph 1.

If, on the basis of this information, it appears that the solvency of the insurance undertaking is, or may be, jeopardised, the competent authority shall take appropriate measures at the level of the insurance undertaking.

Article 9

Adjusted solvency requirement

1. In the case referred to in Article 2(1), Member States shall require that an adjusted solvency calculation be carried out in accordance with Annex I.

2. Any related undertaking, participating undertaking or related undertaking of a participating undertaking shall be included in the calculation referred to in paragraph 1.

3. If the calculation referred to in paragraph 1 demonstrates that the adjusted solvency is negative, the competent authorities shall take appropriate measures at the level of the insurance undertaking in question.

Article 10

Reinsurance undertakings, insurance holding companies and non-member-country insurance undertakings

1. In the case referred to in Article 2(2), Member States shall require the method of supplementary supervision to be applied in accordance with Annex II.

2. In the case referred to in Article 2(2), the calculation shall include all related undertakings of the insurance holding company, the reinsurance undertaking or the non-member-country insurance undertaking, in the manner provided for in Annex II.

3. If, on the basis of this calculation, the competent authorities conclude that the solvency of a subsidiary insurance undertaking of the insurance holding company, the reinsurance undertaking or the non-member-country

[1] First Council Directive 77/780/EEC of 12 December 1977 on the coordination of the laws, regulations and administrative provisions relating to the taking up and pursuit of the business of credit institutions (OJ L 322, 17.12.1977, p. 30). Directive as last amended by Directive 96/13/EC (OJ L 66, 16.3.1996, p. 15).

[2] Council Directive 93/22/EEC of 10 May 1993 on investment services in the securities field (OJ L 141, 11.6.1993, p. 27). Directive as last amended by Directive 97/9/EC (OJ L 84, 26.3.1997, p. 22).

insurance undertaking is, or may be, jeopardised, they shall take appropriate measures at the level of that insurance undertaking.

Article 11

Implementation

1. Member States shall adopt not later than 5 June 2000 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall immediately inform the Commission thereof.

2. Member States shall provide that the provisions referred to in paragraph 1 shall first apply to the supervision of accounts for financial years beginning on 1 January 2001 or during that calendar year.

3. When Member States adopt the measures referred to in paragraph 1, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

4. Member States shall communicate to the Commission the main provisions of national law which they adopt in the field covered by this Directive.

5. Not later than 1 January 2006 the Commission shall submit to the Insurance Committee a report on the application of this Directive and, if necessary, on the need for further harmonisation.

Article 12

Entry into force

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Communities*.

Article 13

Addressees

This Directive is addressed to the Member States.

Done at Luxembourg, 27 October 1998.

For the European Parliament	*For the Council*
The President	*The President*
J. M. GIL-ROBLES	E. HOSTASCH

ANNEX I

CALCULATION OF THE ADJUSTED SOLVENCY OF INSURANCE UNDERTAKINGS

1. CHOICE OF CALCULATION METHOD AND GENERAL PRINCIPLES

A. Member States shall provide that the calculation of the adjusted solvency of insurance undertakings referred to in Article 2(1) shall be carried out according to one of the methods described in point 3. A Member State may, however, provide for the competent authorities to authorise or impose the application of a method set out in point 3 other than that chosen by the Member State.

B. **Proportionality**

The calculation of the adjusted solvency of an insurance undertaking shall take account of the proportional share held by the participating undertaking in its related undertakings.

'Proportional share' means either, where method 1 or method 2 described in point 3 is used, the proportion of the subscribed capital that is held, directly or indirectly, by the participating undertaking or, where method 3 described in point 3 is used, the percentages used for the establishment of the consolidated accounts.

However, whichever method is used, when the related undertaking is a subsidiary undertaking and has a solvency deficit, the total solvency deficit of the subsidiary has to be taken into account.

However, where, in the opinion of the competent authorities, the responsibility of the parent undertaking owning a share of the capital is limited strictly and unambiguously to that share of the capital, such competent authorities may give permission for the solvency deficit of the subsidiary undertaking to be taken into account on a proportional basis.

C. **Elimination of double use of solvency margin elements**

C.1. *General treatment of solvency margin elements*

Regardless of the method used for the calculation of the adjusted solvency of an insurance undertaking, the double use of elements eligible for the solvency margin among the different insurance undertakings taken into account in that calculation must be eliminated.

For this purpose, when calculating the adjusted solvency of an insurance undertaking and where the methods described in point 3 do not provide for it, the following amounts shall be eliminated:

— the value of any asset of that insurance undertaking which represents the financing of elements eligible for the solvency margin of one of its related insurance undertakings,

— the value of any asset of a related insurance undertaking of that insurance undertaking which represents the financing of elements eligible for the solvency margin of that insurance undertaking,

— the value of any asset of a related insurance undertaking of that insurance undertaking which represents the financing of elements eligible for the solvency margin of any other related insurance undertaking of that insurance undertaking.

C.2. *Treatment of certain elements*

Without prejudice to the provisions of section C.1:

— profit reserves and future profits arising in a related life assurance undertaking of the insurance undertaking for which the adjusted solvency is calculated, and

— any subscribed but not paid-up capital of a related insurance undertaking of the insurance undertaking for which the adjusted solvency is calculated,

may only be included in the calculation in so far as they are eligible for covering the solvency margin requirement of that related undertaking. However, any subscribed but not paid-up capital which represents a potential obligation on the part of the participating undertaking shall be entirely excluded from the calculation.

Any subscribed but not paid-up capital of the participating insurance undertaking which represents a potential obligation on the part of a related insurance undertaking shall also be excluded from the calculation.

Any subscribed but not paid-up capital of a related insurance undertaking which represents a potential obligation on the part of another related insurance undertaking of the same participating insurance undertaking shall be excluded from the calculation.

C.3. *Transferability*

If the competent authorities consider that certain elements eligible for the solvency margin of a related insurance undertaking other than those referred to in section C.2 cannot effectively be made available to cover the solvency margin requirement of the participating insurance undertaking for which the adjusted solvency is calculated, those elements may be included in the calculation only in so far as they are eligible for covering the solvency margin requirement of the related undertaking.

C.4. The sum of the elements referred to in sections C.2 and C.3 may not exceed the solvency margin requirement of the related insurance undertaking.

D. **Elimination of the intra-group creation of capital**

When calculating adjusted solvency, no account shall be taken of any element eligible for the solvency margin arising out of reciprocal financing between the insurance undertaking and:

— a related undertaking,

— a participating undertaking,

— another related undertaking of any of its participating undertakings.

Furthermore, no account shall be taken of any element eligible for the solvency margin of a related insurance undertaking of the insurance undertaking for which the adjusted solvency is calculated when the element in question arises out of reciprocal financing with any other related undertaking of that insurance undertaking.

In particular, reciprocal financing exists when an insurance undertaking, or any of its related undertakings, holds shares in, or makes loans to, another undertaking which, directly or indirectly, holds an element eligible for the solvency margin of the first undertaking.

E. The competent authorities shall ensure that the adjusted solvency is calculated with the same frequency as that laid down by Directives 73/239/EEC and 79/267/EEC for calculating the solvency margin of insurance undertakings. The value of the assets and liabilities shall be assessed according to the relevant provisions of Directives 73/239/EEC, 79/267/EEC and 91/674/EEC [1].

2. APPLICATION OF THE CALCULATION METHODS

2.1. Related insurance undertakings

The adjusted solvency calculation shall be carried out in accordance with the general principles and methods set out in this Annex.

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[1] Council Directive 91/674/EEC of 19 December 1991 on the annual accounts and consolidated accounts of insurance undertakings (OJ L 374, 31.12.1991, p. 7).

In the case of all methods, where the insurance undertaking has more than one related insurance undertaking, the adjusted solvency calculation shall be carried out by integrating each of these related insurance undertakings.

In cases of successive participations (for example, where an insurance undertaking is a participating undertaking in another insurance undertaking which is also a participating undertaking in an insurance undertaking), the adjusted solvency calculation shall be carried out at the level of each participating insurance undertaking which has at least one related insurance undertaking.

Member States may waive calculation of the adjusted solvency of an insurance undertaking:

— if the undertaking is a related undertaking of another insurance undertaking authorised in the same Member State, and that related undertaking is taken into account in the calculation of the adjusted solvency of the participating insurance undertaking, or

— if the insurance undertaking is a related undertaking either of an insurance holding company or of a reinsurance undertaking which has its registered office in the same Member State as the insurance undertaking, and both the holding insurance company or the reinsurance undertaking and the related insurance undertaking are taken into account in the calculation carried out.

Member States may also waive calculation of the adjusted solvency of an insurance undertaking if it is a related insurance undertaking of another insurance undertaking, a reinsurance undertaking or an insurance holding company which has its registered office in another Member State, and if the competent authorities of the Member States concerned have agreed to grant exercise of the supplementary supervision to the competent authority of the latter Member State.

In each case, the waiver may be granted only if the competent authorities are satisfied that the elements eligible for the solvency margins of the insurance undertakings included in the calculation are adequately distributed between those undertakings.

Member States may provide that where the related insurance undertaking has its registered office in a Member State other than that of the insurance undertaking for which the adjusted solvency calculation is carried out, the calculation shall take account, in respect of the related undertaking, of the solvency situation as assessed by the competent authorities of that other Member State.

2.2. **Related reinsurance undertakings**

When calculating the adjusted solvency of an insurance undertaking which is a participating undertaking in a reinsurance undertaking, this related reinsurance undertaking shall be treated, solely for the purposes of the calculation, by analogy with a related insurance undertaking, applying the general principles and methods described in this Annex.

To this end, a notional solvency requirement shall be established for each related reinsurance undertaking on the basis of the same rules as are laid down in Article 16(2) to (5) of Directive 73/239/EEC or Article 19 of Directive 79/267/EEC. However, in the event of significant difficulty in applying these rules, the competent authorities may permit the notional life solvency requirement to be calculated on the basis of the first result as set out in Article 16(3) of Directive 73/239/EEC. The same elements as are found in Article 16(1) of Directive 73/239/EEC and in Article 18 of Directive 79/267/EEC shall be recognised as eligible for the notional solvency margin. The value of the assets and liabilities shall be assessed according to the same rules as are laid down in those Directives and in Directive 91/674/EEC.

2.3. **Intermediate insurance holding companies**

When calculating the adjusted solvency of an insurance undertaking which holds a participation in an insurance undertaking, a related reinsurance undertaking, or an insurance undertaking in a non-member country through an insurance holding company, the situation of the intermediate insurance holding company is taken into account. For the sole purpose of this calculation, to be undertaken in accordance with the general principles and methods described in this Annex, this insurance holding company shall be treated as if it were an insurance undertaking subject to a zero solvency requirement and were subject to the same conditions as are laid down in Article 16(1) of Directive 73/239/EEC or in Article 18 of Directive 79/267/EEC in respect of elements eligible for the solvency margin.

2.4. **Related insurance or reinsurance undertakings having their registered office in non-member countries**

A. *Related non-member country insurance undertakings*

When calculating the adjusted solvency of an insurance undertaking which is a participating undertaking in a non-member-country insurance undertaking, the latter shall be treated solely for the purposes of the calculation, by analogy with a related insurance undertaking, by applying the general principles and methods described in this Annex.

However, where the non-member-country in which that undertaking has its registered office makes it subject to authorisation and imposes on it a solvency requirement at least comparable to that laid down in Directives 73/239/EEC or 79/267/EEC, taking into account the elements of cover of that requirement, Member States may provide that the calculation shall take into account, as regards that undertaking, the solvency requirement and the elements eligible to satisfy that requirement as laid down by the non-member country in question.

B. *Related non-member-country reinsurance undertakings*

Notwithstanding section 2.2, when calculating the adjusted solvency of an insurance undertaking which is a participating undertaking in a reinsurance undertaking with its registered office in a non-member country, and subject to the same conditions as those set out in point A above, Member States may provide that the calculation shall take account, as regards the latter undertaking, of the own-funds requirement and the elements eligible to satisfy that requirement as laid down by the non-member country in question. Where only the insurance undertakings of that non-member country are subject to such provisions, the notional own-funds requirement on the related reinsurance undertaking and the elements eligible to satisfy that notional requirement may be calculated as if the undertaking in question were a related insurance undertaking of that non-member country.

2.5. **Non-availability of the necessary information**

Where information necessary for calculating the adjusted solvency of an insurance undertaking, concerning a related undertaking with its registered office in a Member State or a non-member country, is not available to the competent authorities, for whatever reason, the book value of that undertaking in the participating insurance undertaking shall be deducted from the elements eligible for the adjusted solvency margin. In that case, the unrealised gains connected with such participation shall not be allowed as an element eligible for the adjusted solvency margin.

3. CALCULATION METHODS

Method 1: **Deduction and aggregation method**

The adjusted solvency situation of the participating insurance undertaking is the difference between:

(i) the sum of:

(a) the elements eligible for the solvency margin of the participating insurance undertaking, and

b) the proportional share of the participating insurance undertaking in the elements eligible for the solvency margin of the related insurance undertaking

and

(ii) the sum of:

(a) the book value in the participating insurance undertaking of the related insurance undertaking, and

(b) the solvency requirement of the participating insurance undertaking, and

(c) the proportional share of the solvency requirement of the related insurance undertaking.

Where the participation in the related insurance undertaking consists, wholly or in part, of an indirect ownership, then item (ii)(a) shall incorporate the value of such indirect ownership, taking into account the relevant successive interests; and items (i)(b) and (ii)(c) shall include the corresponding proportional shares of the elements eligible for the solvency margin of the related insurance undertaking and of the solvency requirement of the related insurance undertaking, respectively.

Method 2: **Requirement deduction method**

The adjusted solvency of the participating insurance undertaking is the difference between:

(i) the sum of the elements eligible for the solvency margin of the participating insurance undertaking

and

(ii) the sum of:

(a) the solvency requirement of the participating insurance undertaking, and

(b) the proportional share of the solvency requirement of the related insurance undertaking.

When valuing the elements eligible for the solvency margin, participations within the meaning of this Directive are valued by the equity method, in accordance with the option set out in Article 59(2)(b) of Directive 78/660/EEC.

Method 3: **Accounting consolidation-based method**

The calculation of the adjusted solvency of the participating insurance undertaking shall be carried out on the basis of the consolidated accounts. The adjusted solvency of the participating insurance undertaking is the difference between:

the elements eligible for the solvency margin calculated on the basis of consolidated data, and

(a) either the sum of the solvency requirement of the participating insurance undertaking and of the proportional shares of the solvency requirements of the related insurance undertakings, based on the percentages used for the establishment of the consolidated accounts,

(b) or the solvency requirement calculated on the basis of consolidated data.

The provisions of Directives 73/239/EEC, 79/267/EEC and 91/674/EEC shall apply for the calculation of the elements eligible for the solvency margin and of the solvency requirement based on consolidated data.

ANNEX II

SUPPLEMENTARY SUPERVISION FOR INSURANCE UNDERTAKINGS THAT ARE SUBSIDIARIES OF AN INSURANCE HOLDING COMPANY, A REINSURANCE UNDERTAKING OR A NON-MEMBER-COUNTRY INSURANCE UNDERTAKING

1. In the case of two or more insurance undertakings referred to in Article 2(2) which are the subsidiaries of an insurance holding company, a reinsurance undertaking or a non-member-country insurance undertaking and which are established in different Member States, the competent authorities shall ensure that the method described in this Annex is applied in a consistent manner.

The competent authorities shall exercise the supplementary supervision with the same frequency as that laid down by Directives 73/239/EEC and 79/267/EEC for calculating the solvency margin of insurance undertakings.

2. Member States may waive the calculation provided for in this Annex with regard to an insurance undertaking:

— if that insurance undertaking is a related undertaking of another insurance undertaking and if it is taken into account in the calculation provided for in this Annex carried out for that other undertaking,

— if that insurance undertaking and one or more other insurance undertakings authorised in the same Member State have as their parent undertaking the same insurance holding company, reinsurance undertaking or non-member-country insurance undertaking, and the insurance undertaking is taken into account in the calculation provided for in this Annex carried out for one of these other undertakings,

— if that insurance undertaking and one or more other insurance undertakings authorised in other Member States have as their parent undertaking the same insurance holding company, reinsurance undertaking or non-member-country insurance undertaking, and an agreement granting exercise of the supplementary supervision covered by this Annex to the supervisory authority of another Member State has been concluded in accordance with Article 4(2).

In the case of successive participations (for example: an insurance holding company or a reinsurance undertaking which is itself owned by another insurance holding company, a reinsurance undertaking or a non-member-country insurance undertaking), Member States may apply the calculations provided for in this Annex only at the level of the ultimate parent undertaking of the insurance undertaking which is an insurance holding company, a reinsurance undertaking or a non-member-country insurance undertaking.

3. The competent authorities shall ensure that calculations analogous to those described in Annex I are carried out at the level of the insurance holding company, reinsurance undertaking or non-member-country insurance undertaking.

The analogy shall consist in applying the general principles and methods described in Annex I at the level of the insurance holding company, reinsurance undertaking or non-member-country insurance undertaking.

For the sole purpose of this calculation, the parent undertaking shall be treated as if it were an insurance undertaking subject to:

— a zero solvency requirement where it is an insurance holding company,

— a notional solvency requirement as provided for in section 2.2 of Annex I where it is a reinsurance undertaking, or as provided for in section 2.4(B) of Annex I where it is a reinsurance undertaking with its registered office in a non-member country,

— a solvency requirement determined according to the principles of section 2.4(A) of Annex I, where it is a non-member-country insurance undertaking,

and is subject to the same conditions as laid down in Article 16(1) of Directive 73/239/EEC or in Article 18 of Directive 79/267/EEC as regards the elements eligible for the solvency margin.

4. **Non-availability of the necessary information**

Where information necessary for the calculation provided for in this Annex, concerning a related undertaking with its registered office in a Member State or a non-member country, is not available to the competent authorities, for whatever reason, the book value of that undertaking in the participating undertaking shall be deducted from the elements eligible for the calculation provided for in this Annex. In that case, the unrealised gains connected with such participation shall not be allowed as an element eligible for the calculation.

COUNCIL DIRECTIVE 98/81/EC

of 26 October 1998

amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 103s(1) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure laid down in Article 189c of the Treaty [3],

(1) Whereas, within the meaning of the Treaty, action by the Community relating to the environment should be based on the principle that preventive action is to be taken and shall have as its objective to preserve, protect and improve the environment and to protect human health;

(2) Whereas contained uses of genetically modified micro-organisms (GMMs) should be classified in relation to the risks they present for human health and the environment; whereas such classification should be in line with international practice and based on an assessment of the risk;

(3) Whereas in order to ensure a high level of protection the containment and other protective measures applied to a contained use must correspond to the classification of the contained use; whereas in case of uncertainty the appropriate containment and other protective measures for the higher classification should be applied until less stringent measures are justified by appropriate data;

(4) Whereas appropriate measures should be adopted and used for the control of the disposal of material from contained uses of GMMs;

(5) Whereas GMMs which are disposed of without appropriate provisions for specific containment measures to limit their contact with the general population and the environment do not fall within the scope of the present Directive; other Community legislation such as Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [4] may apply;

(6) Whereas exemptions pursuant to this Directive do not entail exemptions pursuant to any other Community legislation that may apply, such as Directive 90/220/EEC;

(7) Whereas for all activities involving GMMs the principles of good microbiological practice and good occupational safety and hygiene should apply in accordance with relevant Community legislation;

(8) Whereas the containment and other protective measures applied to contained uses should be reviewed periodically;

(9) Whereas people employed in contained uses should be consulted in accordance with the requirements of relevant Community legislation, in particular Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) [5];

(10) Whereas weaknesses have been identified in Directive 90/219/EEC [6]; whereas the administrative procedures and notification requirements should be linked to the risk of the contained uses;

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(1) OJ C 356, 22.11.1997, p. 14 and OJ C 369, 6.12.1997, p. 12.
(2) OJ C 295, 7.10.1996, p. 52.
(3) Opinion of the European Parliament of 12 March 1997 (OJ C 115, 14.4.1997, p. 59), Council common position of 16 December 1997 (OJ C 62, 26.2.1998, p. 1) and Decision of the European Parliament of 16 June 1998 (OJ C 210, 6.7.1998).
(4) OJ L 117, 8.5.1990, p. 15. Directive as last amended by Commission Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72).
(5) OJ L 374, 31.12.1990, p.1. Directive as last amended by Commission Directive 97/59/EC (OJ L 282, 15.10.1997, p. 33).
(6) OJ L 117, 8.5.1990, p. 1. Directive as amended by Commission Directive 94/51/EC (OJ L 297, 18.11.1994, p. 29).

(11) Whereas Directive 90/219/EEC did not permit sufficient adaptation to technical progress; whereas the technical parts of that Directive need to be adapted to technical progress;

(12) Whereas the implementation of Directive 90/219/EEC could benefit from the addition of a list of GMMs that are safe for human health and the environment; whereas these GMMs should meet certain criteria in order to establish their safety;

(13) Whereas, to take account of the pace at which biotechnology is advancing, the nature of the criteria to be developed and the limited scope of this list, it is appropriate for the Council to define and revise these criteria;

(14) Whereas there is now considerable experience and knowledge of the risks associated with the contained use of GMMs;

(15) Whereas Directive 90/219/EEC should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 90/219/EEC is hereby amended as follows:

1. Articles 2 to 16 shall be replaced by the following:

'*Article 2*

For the purposes of this Directive:

(a) "micro-organism" shall mean any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cells in culture;

(b) "genetically modified micro-organism" (GMM) shall mean a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Within the terms of this definition:

(i) genetic modification occurs at least through the use of the techniques listed in Annex I, Part A;

(ii) the techniques listed in Annex I, Part B, are not considered to result in genetic modification;

(c) "contained use" shall mean any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with the general population and the environment;

(d) "accident" shall mean any incident involving a significant and unintended release of GMMs in the course of their contained use which could present an immediate or delayed hazard to human health or the environment;

(e) "user" shall mean any natural or legal person responsible for the contained use of GMMs;

(f) "notification" shall mean the presentation of the requisite information to the competent authorities of a Member State.

Article 3

Without prejudice to Article 5(1) this Directive shall not apply:

— where genetic modification is obtained through the use of the techniques/methods listed in Annex II, Part A, or

— for contained uses involving only types of GMMs meeting the criteria listed in Annex II, Part B which establish their safety to human health and the environment. These types of GMMs shall be listed in Annex II, Part C.

Article 4

Article 5(3) and 5(6) and Articles 6 to 12 shall not apply to the transport of GMMs by road, rail, inland waterway, sea or air.

This Directive shall not apply to the storage, culture, transport, destruction, disposal or use of GMMs which have been placed on the market in accordance with Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (*) or pursuant to other Community legislation, which provides for a specific environmental risk assessment similar to that laid down in the said Directive, provided that the contained use is in accordance with the conditions, if any, of the consent for placing on the market.

(*) OJ L 117, 8.5.1990, p. 15. Directive as last amended by Commission Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72).

Article 5

1. Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the contained use of GMMs.

2. To this end the user shall carry out an assessment of the contained uses as regards the risks to human health and the environment that these contained uses may incur, using as a minimum the elements of assessment and the procedure set out in Annex III, sections A and B.

3. The assessment referred to in paragraph 2 shall result in the final classification of the contained uses in four classes applying the procedure set out in Annex III, which will result in the assignment of containment levels in accordance with Article 6:

Class 1: activities of no or negligible risk, that is to say activities for which level 1 containment is appropriate to protect human health as well as the environment.

Class 2: activities of low risk, that is to say activities for which level 2 containment is appropriate to protect human health as well as the environment.

Class 3: activities of moderate risk, that is to say activities for which level 3 containment is appropriate to protect human health as well as the environment.

Class 4: activities of high risk, that is to say activities for which level 4 containment is appropriate to protect human health as well as the environment.

4. Where there is doubt as to which class is appropriate for the proposed contained use, the more stringent protective measures shall be applied unless sufficient evidence, in agreement with the competent authority, justifies the application of less stringent measures.

5. The assessment referred to in paragraph (2) shall especially take into account the question of disposal of waste and effluents. Where appropriate, the necessary safety measures shall be implemented in order to protect human health and the environment.

6. A record of the assessment referred to in paragraph (2) shall be kept by the user and made available in an appropriate form to the competent authority as part of the notification pursuant to Articles 7, 9 and 10 or on request.

Article 6

1. The user shall apply, except to the extent that paragraph 2 of Annex IV allows other measures to be applied, the general principles and the appropriate containment and other protective measures set out in Annex IV corresponding to the class of the contained use, so as to keep workplace and environmental exposure to any GMMs to the lowest reasonably practicable level, and so that a high level of safety is ensured.

2. The assessment referred to in Article 5(2) and the containment and other protective measures applied shall be reviewed periodically, and forthwith if:

(a) the containment measures applied are no longer adequate or the class assigned to the contained uses is no longer correct, or

(b) there is reason to suspect that the assessment is no longer appropriate judged in the light of new scientific or technical knowledge.

Article 7

When premises are to be used for the first time for contained uses, the user shall be required to submit to the competent authorities, before commencing such use, a notification containing at least the information listed in Annex V, Part A.

Article 8

Following the notification referred to in Article 7, subsequent class 1 contained use may proceed without further notification. Users of GMMs in class 1 contained uses shall be required to keep the record of each assessment referred to in Article 5(6), which shall be made available to the competent authority on request.

Article 9

1. For first and subsequent class 2 contained uses to be carried out in premises notified in accordance with Article 7, a notification containing the information listed in Annex V, Part B shall be submitted.

2. If the premises have been the subject of a previous notification to carry out class 2 or a higher class of contained uses and any associated consent requirements have been satisfied, the class 2 contained use may proceed immediately following the new notification.

The applicant can, however, himself request a decision on a formal authorisation from the competent authority. The decision must be made within a maximum of 45 days from the notification.

3. If the premises have not been the subject of a previous notification to carry out class 2 or a higher class of contained uses, the class 2 contained use may, in the absence of any indication to the contrary from the competent authority, proceed 45 days after submission of the notification referred to in paragraph 1, or earlier with the agreement of the competent authority.

Article 10

1. For first and subsequent class 3 or class 4 contained uses to be carried out in premises notified in accordance with Article 7, a notification containing the information listed in Annex V, Part C shall be submitted.

2. A class 3 or higher class of contained use may not proceed without the prior consent of the competent authority which shall communicate its decision in writing:

(a) at the latest 45 days after submission of the new notification, in the case of premises which have been the subject of a previous notification to carry out class 3 or a higher class of contained uses and where any associated consent requirements have been satisfied for the same or a higher class than the contained use with which it is intended to proceed;

(b) at the latest 90 days after submission of the notification, in other cases.

Article 11

1. Member States shall designate the authority or authorities competent to implement the measures which they adopt in application of this Directive and to receive and acknowledge the notifications referred to in Articles 7, 9 and 10.

2. The competent authorities shall examine the conformity of the notifications with the requirements of this Directive, the accuracy and completeness of the information given, the correctness of the assessment referred to in Article 5(2) and the class of contained uses and, where appropriate, the suitability of the containment and other protective measures, the waste management, and emergency response measures.

3. If necessary, the competent authority may:

(a) ask the user to provide further information or to modify the conditions of the proposed contained use or to amend the class assigned to the contained use(s). In this case the competent authority may require that the contained use, if proposed, does not begin, or, if in progress, is suspended or terminated, until the competent authority has given its approval on the basis of the further information obtained or of the modified conditions of the contained use;

(b) limit the time for which the contained use should be permitted or subject it to certain specific conditions.

4. For the purpose of calculating the periods referred to in Articles 9 and 10, any period of time during which the competent authority:

— is awaiting any further information which it may have requested from the notifier in accordance with paragraph 3(a), or

— is carrying out a public inquiry or consultation in accordance with Article 13

shall not be taken into account.

Article 12

If the user becomes aware of relevant new information or modifies the contained use in a way which could have significant consequences for the risks posed by it, the competent authority shall be informed as soon as possible and the notification pursuant to Articles 7, 9 and 10 shall be modified.

If information subsequently becomes available to the competent authority which could have significant consequences for the risks posed by the contained use, the competent authority may require the user to modify the conditions of, or suspend or terminate, the contained use.

Article 13

Where a Member State considers it appropriate, it may provide that the public shall be consulted on aspects of the proposed contained use, without prejudice to Article 19.

Article 14

The competent authorities shall ensure that before a contained use commences:

(a) an emergency plan is drawn up for contained uses where failure of the containment measures could lead to serious danger, whether immediate or delayed, to humans outside the premises and/or to the environment, except where such an emergency plan has been drawn up under other Community legislation;

(b) information on such emergency plans, including the relevant safety measures to be applied, is supplied in an appropriate manner, and without their having to request it, to bodies and authorities liable to be affected by the accident. The information shall be updated at appropriate intervals. It shall also be made publicly available.

The Member States concerned shall at the same time make available to other Member States concerned, as a basis for all necessary consultation within the framework of their bilateral relations, the same information as that which is disseminated to their nationals.

Article 15

1. Member States shall take the necessary measures to ensure that, in the event of an accident, the user shall be required to inform immediately the competent authority specified in Article 11 and provide the following information:

— the circumstances of the accident,

— the identity and quantities of the GMMs concerned,

— any information necessary to assess the effects of the accident on the health of the general population and the environment,

— the measures taken.

2. Where information is given pursuant to paragraph 1, the Member States shall be required to:

— ensure that any measures necessary are taken, and immediately alert any Member States which could be affected by the accident,

— collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit the effects thereof.

Article 16

1. Member States shall be required to:

(a) consult with other Member States, likely to be affected in the event of an accident, on the proposed implementation of emergency plans;

(b) inform the Commission as soon as possible of any accident within the scope of this Directive, giving details of the circumstances of the accident, the identity and quantities of the GMMs concerned, the response measures taken and their effectiveness and an analysis of the accident, including recommendations to limit its effects and avoid similar accidents in the future.

2. The Commission, in consultation with the Member States, shall establish a procedure for the exchange of information pursuant to paragraph 1. It shall also set up and keep at the disposal of the Member States a register of accidents within the scope of this Directive, including an analysis of the causes of the accidents, experience gained and measures taken to avoid similar accidents in the future.'

2. Articles 18, 19 and 20 shall be replaced by the following:

'Article 18

1. Member States shall send to the Commission, at the end of each year, a summary report on class 3 and class 4 contained uses notified during that year pursuant to Article 10 including the description, purpose and risks of the contained use(s).

2. Every three years, Member States shall send the Commission a summary report on their experience with this Directive, the first time being on 5 June 2003.

3. Every three years, the Commission shall publish a summary based on the reports referred to in paragraph 2, the first time being on 5 June 2004.

4. The Commission may publish general statistical information on the implementation of this Directive and related matters, as long as it contains no information likely to cause harm to the competitive position of a user.

Article 19

1. Where its disclosure affects one or more of the items mentioned in Article 3(2) of Council Directive 90/313/EEC of 7 June 1990 on the freedom of access to information on the environment (*), the notifier may indicate the information in the notifications submitted pursuant to this Directive that should be treated as confidential. Verifiable justification must be given in such cases.

2. The competent authority shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decision.

3. In no case may the following information, when submitted according to Articles 7, 9 or 10, be kept confidential:

— the general characteristics of the GMMs, name and address of the notifier, and location of use,

— class of contained use and measures of containment,

— the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment.

4. The Commission and the competent authorities shall not divulge to third parties any information decided to be confidential according to paragraph 2 and notified or otherwise provided pursuant to this Directive, and shall protect intellectual property rights relating to the data received.

5. If, for whatever reasons, the notifier withdraws the notification, the competent authority must respect the confidentiality of the information supplied.

(*) OJ L 158, 23.6.1990, p. 56.

Article 20

Amendments necessary to adapt Annex II, Part A, and Annexes III to V to technical progress and to adapt Annex II, Part C, shall be decided in accordance with the procedure laid down in Article 21.'

3. The following Article shall be inserted:

'Article 20a

Before 5 December 2000 Annex II, Part B, listing the criteria for inclusion of types of GMMs into Annex II, Part C, shall be adopted by the Council acting by qualified majority on a proposal from the Commission. Amendments to Annex II, Part B, shall be adopted by the Council acting by qualified majority on a proposal from the Commission.'

4. The Annexes are replaced by the Annexes shown in the Annex hereto.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 18 months after the date of its entry into force. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive enters into force on the day of its publication in the *Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Luxembourg, 26 October 1998.

For the Council

The President

W. SCHÜSSEL

ANNEX

'ANNEX I

PART A

Techniques of genetic modification referred to in Article 2(b)(i) are, *inter alia*:

1. Recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.

2. Techniques involving the direct introduction into a micro-organism of heritable material prepared outside the micro-organism including micro-injection, macro-injection and micro-encapsulation.

3. Cell fusion or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART B

Techniques referred to in Article 2(b)(ii) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs made by techniques/methods other than techniques/methods excluded by Annex II, PART A:

(1) *in vitro* fertilisation;

(2) natural processes such as: conjugation, transduction, transformation;

(3) polyploidy induction.

ANNEX II

PART A

Techniques or methods of genetic modification yielding micro-organisms to be excluded from the Directive on the condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs other than those produced by one or more of the techniques/methods listed below:

1. Mutagenesis.
2. Cell fusion (including protoplast fusion) of prokaryotic species that exchange genetic material by known physiological processes.
3. Cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions.
4. Self-cloning consisting in the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent) with or without prior enzymic or mechanical steps, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes where the resulting micro-organism is unlikely to cause disease to humans, animals or plants.

   Self-cloning may include the use of recombinant vectors with an extended history of safe use in the particular micro-organisms.

PART B

Criteria establishing the safety of GMMs to human health and the environment:

. . . (to be completed in accordance with the procedures in Article 20a)

PART C

Types of GMMs which meet the criteria listed in Part B:

. . . (to be completed in accordance with the procedure in Article 21)

ANNEX III

PRINCIPLES TO BE FOLLOWED FOR THE ASSESSMENT REFERRED TO IN ARTICLE 5(2)

This Annex describes in general terms the elements to be considered and the procedure to be followed to perform the assessment referred to in Article 5(2). It will be supplemented, as regards in particular section B, by guidance notes to be developed by the Commission in accordance with the procedure set out in Article 21.

These guidance notes shall be completed no later than 5 June 2000.

A. ELEMENTS OF ASSESSMENT

1. The following should be considered as potentially harmful effects:

   — disease to humans including allergenic or toxic effects,

   — disease to animals or plants,

   — deleterious effects due to the impossibility of treating a disease or providing an effective prophylaxis,

   — deleterious effects due to establishment or dissemination in the environment,

   — deleterious effects due to the natural transfer of inserted genetic material to other organisms.

2. The assessment referred to in Article 5(2) should be based on the following:

   (a) the identification of any potentially harmful effects, in particular those associated with:

      (i) the recipient micro-organism;

      (ii) the genetic material inserted (originating from the donor organism);

      (iii) the vector;

      (iv) the donor micro-organism (as long as the donor micro-organism is used during the operation);

      (v) the resulting GMM;

   (b) the characteristics of the activity;

   (c) the severity of the potentially harmful effects;

   (d) the likelihood of the potentially harmful effects being realised.

B. PROCEDURE

3. The first stage in the assessment process should be to identify the harmful properties of the recipient and, where appropriate, the donor micro-organism, any harmful properties associated with the vector or inserted material, including any alteration in the recipient's existing properties.

4. In general, only GMMs which show the following characteristics would be considered appropriate for inclusion in class 1 as defined in Article 5:

   (i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants [1];

[1] This would only apply to animals and plants in the environment likely to be exposed.

(ii) the nature of the vector and the insert is such that they do not endow the GMM with a phenotype likely to cause disease to humans, animals or plants [1], or likely to cause deleterious effects in the environment;

(iii) the GMM is unlikely to cause disease to humans, animals or plants [1] and is unlikely to have deleterious effects on the environment.

5. In order to obtain the necessary information to implement this process the user may firstly take into account relevant Community legislation (in particular Council Directive 90/679/EEC [2]). International or national classification schemes (e.g. WHO, NIH, etc.) and their revisions due to new scientific knowledge and technical progress may also be considered.

These schemes concern natural micro-organisms and as such are usually based on the ability of micro-organisms to cause disease to humans, animals or plants and on the severity and transmissibility of the disease likely to be caused. Directive 90/679/EEC classifies micro-organisms, as biological agents, into four classes of risk on the basis of potential effects on a healthy human adult. These classes of risk can be used as guidance to the categorisation of the contained use activities in the four classes of risk referred to in Article 5(3). The user may also take into consideration classification schemes referring to plant and animal pathogens (which are usually established on a national basis). The abovementioned classification schemes give only a provisional indication of the risk class of the activity and the corresponding set of containment and control measures.

6. The hazard identification process carried out in accordance with paragraphs 3 to 5, should lead to the identification of the level of risk associated with the GMM.

7. Selection of the containment and other protective measures should then be made on the basis of the level or risk associated with the GMMs together with consideration of:

(i) the characteristics of the environment likely to be exposed (e.g. whether in the environment likely to be exposed to the GMMs there are known biota which can be adversely affected by the micro-organisms used in the contained use activity);

(ii) the characteristics of the activity (e.g. its scale; nature);

(iii) any non-standard operations (e.g. the inoculation of animals with GMMs; equipment likely to generate aerosols).

Consideration of items (i) to (iii) for the particular activity may increase, reduce or leave unaltered the level of risk associated with the GMM as identified under paragraph 6.

8. The analysis carried out as described above will finally lead to the assignment of the activity to one of the classes described in Article 5(3).

9. The final classification of the contained use should be confirmed by reviewing the completed assessment referred to in Article 5(2).

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[1] This would only apply to animals and plants in the environment likely to be exposed.

[2] OJ L 374, 31.12.1990, p. 1. Directive as last amended by Commission Directive 97/59/EC (OJ L 282, 15.10.1997, p. 33).

ANNEX IV

CONTAINMENT AND OTHER PROTECTIVE MEASURES

General principles

1. These tables present the normal minimum requirements and measures necessary for each level of containment.

   Containment is also achieved through the use of good work practices, training, containment equipment and special installation design. For all activities involving GMMs the principles of good microbiological practice and the following principles of good occupational safety and hygiene, shall apply:

   (i) to keep workplace and environmental exposure to any GMM to the lowest practicable level;

   (ii) to exercise engineering control measures at source and to supplement these with appropriate personal protective clothing and equipment when necessary;

   (iii) to test adequately and maintain control measures and equipment;

   (iv) to test, when necessary, for the presence of viable process organisms outside the primary physical containment;

   (v) to provide appropriate training of personnel;

   (vi) to establish biological safety committees or subcommittees, if required;

   (vii) to formulate and implement local codes of practice for the safety of personnel, as required;

   (viii) where appropriate to display biohazard signs;

   (ix) to provide washing and decontamination facilities for personnel;

   (x) to keep adequate records;

   (xi) to prohibit eating, drinking, smoking, applying cosmetics or the storing of food for human consumption in the work area;

   (xii) to prohibit mouth pipetting;

   (xiii) to provide written standard operating procedures where appropriate to ensure safety;

   (xiv) to have effective disinfectants and specified disinfection procedures available in case of spillage of GMMs;

   (xv) to provide safe storage for contaminated laboratory equipment and materials, when appropriate.

2. The titles of the tables are indicative:

   Table I A presents minimum requirements for laboratory activities.

   Table I B presents additions to and modifications of Table I A for glasshouse/growth-room activities involving GMMs.

   Table I C presents additions to and modifications of Table I A for activities with animals involving GMMs.

   Table II presents minimum requirements for activities other than laboratory activities.

   In some particular cases, it might be necessary to apply a combination of measures, from Table I A and Table II, of the same level.

   In some cases users may, with the agreement of the competent authority, not apply a specification under a particular containment level or combine specifications from two different levels.

   In these tables "optional" means that the user may apply these measures on a case-by-case basis, subject to the assessment referred to in Article 5(2).

3. Member states may, in implementing this Annex, incorporate in addition the general principles in paragraphs 1 and 2 in the following tables for the sake of clarity of the requirements.

Table I A

Containment and other protective measures for laboratory activities

	Specifications	Containment levels			
		1	2	3	4
1	Laboratory suite: isolation (1)	Not required	Not required	Required	Required
2	Laboratory: sealable for fumigation	Not required	Not required	Required	Required
Equipment					
3	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required (bench)	Required (bench)	Required (bench, floor)	Required (bench, floor, ceiling, walls)
4	Entry to lab via airlock (2)	Not required	Not required	Optional	Required
5	Negative pressure relative to the pressure of the immediate environment	Not required	Not required	Required except for (3)	Required
6	Extract and input air from the laboratory should be HEPA-filtered	Not required	Not required	Required (HEPA) (4) — extract air except for (3)	Required (HEPA) (5) — input and extract air
7	Microbiological safety post	Not required	Optional	Required	Required
8	Autoclave	On site	In the building	En suite (6)	In lab = double-ended
System of work					
9	Restricted access	Not required	Required	Required	Required
10	Biohazard sign on the door	Not required	Required	Required	Required
11	Specific measures to control aerosol dissemination	Not required	Required minimise	Required prevent	Required prevent
13	Shower	Not required	Not required	Optional	Required
14	Protective clothing	Suitable protective clothing	Suitable protective clothing and (optional) footwear	Suitable protective clothing	Complete change of clothing and footwear before entry and exit

	Specifications	Containment levels			
		1	2	3	4
15	Gloves	Not required	Optional	Required	Required
18	Efficient vector control (e.g. for rodents and insects)	Optional	Required	Required	Required
Waste					
19	Inactivation of GMMs in effluent from hand-washing sinks or drains and showers and similar effluents	Not required	Not required	Optional	Required
20	Inactivation of GMMs in contamined material and waste	Optional	Required	Required	Required
Other measures					
21	Laboratory to contain its own equipment	Not required	Not required	Optional	Required
23	An observation window or alternative is to be present so that occupants can be seen	Optional	Optional	Optional	Required

(1) Isolation = the laboratory is separated from other areas in the same building or is in a separated building.
(2) Airlock = entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.
(3) Activities where transmission does not occur via airborne route.
(4) HEPA = High efficiency particulate air.
(5) Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.
(6) With validated procedures, allowing the safe transfer of material into an autoclave outside the lab, and providing an equivalent level of protection.

Table I B

Containment and other protective measures for glasshouses and growth-rooms

The terms "glasshouse" and "growth-room" refer to a structure with walls, a roof and a floor designed and used principally for growing plants in a controlled and protected environment.

All provisions of Table I A shall apply with the following additions/modifications:

	Specifications	Containment levels			
		1	2	3	4
Building					
1	Greenhouse: permanent structure (1)	Not required	Required	Required	Required
Equipment					
3	Entry via a separated room with two interlocking doors	Not required	Optional	Optional	Required
4	Control of contaminated run-off water	Optional	Minimise (2) run-off	Prevent run-off	Prevent run-off
System of work					
6	Measures to control undesired species such as insects, rodents, arthropods	Required	Required	Required	Required
7	Procedures for transfer of living material between the glasshouse/growth-room, protective structure and laboratory shall control dissemination of genetically modified micro-organisms	Minimise dissemination	Minimise dissemination	Prevent dissemination	Prevent dissemination

(1) The glasshouse shall consist of a permanent structure with a continuous waterproofed covering, located on a site graded to prevent entry of surface-water run-off having self-closing lockable doors.
(2) Where transmission can occur through the ground.

Table I C

Containment and other protective measures for activities in animal units

All provisions of Table I A shall apply with the following additions/modifications:

	Specifications	Containment levels			
		1	2	3	4
Facilities					
1	Isolation of animal unit (1)	Optional	Required	Required	Required
2	Animal facilities (2) separated by lockable doors	Optional	Required	Required	Required
3	Animal facilities designed to facilitate decontamination (waterproof and easily washable material (cages, etc.))	Optional	Optional	Required	Required
4	Floor and/or walls easily washable	Optional	Required (floor)	Required (floor and walls)	Required (floor and walls)
5	Animals kept in appropriate containment facilities such as cages, pens or tanks	Optional	Optional	Optional	Optional
6	Filters on isolators or isolated room (3)	Not required	Optional	Required	Required

(1) Animal unit: a building, or separate area within a building containing facilities and other areas such as changing rooms, showers, autoclaves, food storage areas, etc.
(2) Animal facility: a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures.
(3) Isolators: transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

Table II

Containment and other protective measures for other activities

	Specifications	Containment levels			
		1	2	3	4
General					
1	Viable micro-organisms should be contained in a system which separates the process from the environment (closed system)	Optional	Required	Required	Required
2	Control of exhaust gases from the closed system	Not required	Required, minimise dissemination	Required, prevent dissemination	Required, prevent dissemination
3	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	Optional	Required, minimise dissemination	Required, prevent dissemination	Required, prevent dissemination
4	Inactivation of bulk culture fluids before removal from the closed system	Optional	Required, by validated means	Required, by validated means	Required, by validated means
5	Seals should be designed so as to minimise or prevent release	No sepecific requirement	Minimise dissemination	Prevent dissemination	Prevent dissemination
6	The controlled area should be designed to contain spillage of the entire contents of the closed system	Optional	Optional	Required	Required
7	The controlled area should be sealable to permit fumigation	Not required	Optional	Optional	Required
Equipment					
8	Entry via airlock	Not required	Not required	Optional	Required
9	Surfaces resistant to water, acids, alkalis, solvents, disinfectants, decontamination agents and easy to clean	Required (bench if any)	Required (bench if any)	Required (bench if any, floor)	Required (bench, floor, ceiling, walls)
10	Specific measures to adequately ventilate the controlled area in order to minimise air contamination	Optional	Optional	Optional	Required
11	The controlled area should be maintained at an air pressure negative to the immediate surroundings	Not required	Not required	Optional	Required
12	Extract and input air from the controlled area should be HEPA filtered	Not required	Not required	Required (extract air, optional for input air)	Required (input and extract air)

	Specifications	Containment levels			
		1	2	3	4
System of work					
13	Closed systems should be located within a controlled area	Not required	Optional	Required	Required
14	Access should be restricted to nominated personnel only	Not required	Required	Required	Required
15	Biohazard signs should be posted	Not required	Required	Required	Required
17	Personnel should shower before leaving the controlled area	Not required	Not required	Optional	Required
18	Personnel should wear protective clothing	Required (work clothing)	Required (work clothing)	Required	Complete change before exit and entry
Waste					
22	Inactivation of GMMs in effluent from handwashing sinks and showers or similar effluents	Not required	Not required	Optional	Required
23	Inactivation of GMMs in contaminated material and waste including those in process effluent before final discharge	Optional	Required, by validated means	Required, by validated means	Required, by validated means

ANNEX V

PART A

Information required for the notification referred to in Article 7:

— name of user(s) including those responsible for supervision and safety,

— information on the training and qualifications of the persons responsible for supervision and safety,

— details of any biological committees or subcommittees,

— address and general description of the premises,

— a description of the nature of the work which will be undertaken,

— the class of the contained uses,

— only for class 1 contained uses, a summary of the assessment referred to in Article 5(2) and information on waste management.

PART B

Information required for the notification referred to in Article 9:

— the date of submission of the notification referred to in Article 7,

— the name of the persons responsible for supervision and safety and information on the training and qualification,

— the recipient, donor and/or parental micro-organism(s) used and, where applicable, the host-vector system(s) used,

— the source(s) and the intended function(s) of the genetic material(s) involved in the modification(s),

— identity and characteristics of the GMM,

— the purpose of the contained use including the expected results,

— approximate culture volumes to be used,

— description of the containment and other protective measures to be applied, including information about waste management including the wastes to be generated, their treatment, final form and destination,

— a summary of the assessment referred to in Article 5(2),

— the information necessary for the competent authority to evaluate any emergency response plans if required under Article 14.

PART C

Information required for the notification referred to in Article 10:

(a) — the date of submission of the notification referred to in Article 7,

— the name of the persons responsible for supervision and safety and information on the training and qualification;

(b) — the recipient or parental micro-organism(s) to be used,

— the host-vector system(s) to be used (where applicable),

— the source(s) and intended functions(s) of the genetic material(s) involved in the modification(s),

— identity and characteristics of the GMM,

— the culture volumes to be used;

(c) — description of the containment and other protective measures to be applied, including information about waste management including the type and form of wastes to be generated, their treatment, final form and destination,

— the purpose of the contained use including the expected results,

— description of the parts of the installation;

(d) information about accident prevention and emergency response plans, if any:

— any specific hazards arising from the location of the installation,

— the preventive measures applied such as safety equipment, alarm systems and containment methods,

— procedures and plans for verifying the continuing effectiveness of the containment measures,

— a description of information provided to workers,

— the information necessary for the competent authority to evaluate any emergency response plans if required under Article 14;

(e) a copy of the assessment referred to in Article 5(2).'

COUNCIL DIRECTIVE 98/83/EC

of 3 November 1998

on the quality of water intended for human consumption

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community and, in particular, Article 130s(1) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Having regard to the opinion of the Committee of the Regions [3],

Acting in accordance with the procedure laid down in Article 189c [4],

(1) Whereas it is necessary to adapt Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption [5] to scientific and technological progress; whereas experience gained from implementing that Directive shows that it is necessary to create an appropriately flexible and transparent legal framework for Member States to address failures to meet the standards; whereas, furthermore, that Directive should be re-examined in the light of the Treaty on European Union and in particular the principle of subsidiarity;

(2) Whereas in keeping with Article 3b of the Treaty, which provides that no Community action should go beyond what is necessary to achieve the objectives of the Treaty, it is necessary to revise Directive 80/778/EEC so as to focus on compliance with essential quality and health parameters, leaving Member States free to add other parameters if they see fit;

(3) Whereas, in accordance with the principle of subsidiarity, Community action must support and supplement action by the competent authorities in the Member States;

(4) Whereas, in accordance with the principle of subsidiarity, the natural and socio-economic differences between the regions of the Union require that most decisions on monitoring, analysis, and the measures to be taken to redress failures be taken at a local, regional or national level insofar as those differences do not detract from the establishment of the framework of laws, regulations and administrative provisions laid down in this Directive;

(5) Whereas Community standards for essential and preventive health-related quality parameters in water intended for human consumption are necessary if minimum environmental-quality goals to be achieved in connection with other Community measures are to be defined so that the sustainable use of water intended for human consumption may be safeguarded and promoted;

(6) Whereas, in view of the importance of the quality of water intended for human consumption for human health, it is necessary to lay down at Community level the essential quality standards with which water intended for that purpose must comply;

(7) Whereas it is necessary to include water used in the food industry unless it can be established that the use of such water does not affect the wholesomeness of the finished product;

(8) Whereas to enable water-supply undertakings to meet the quality standards for drinking water, appropriate water-protection measures should be applied to ensure that surface and groundwater is kept clean; whereas the same goal can be achieved by appropriate water-treatment measures to be applied before supply;

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[1] OJ C 131, 30.5.1995, p. 5 and OJ C 213, 15.7.1997, p. 8.
[2] OJ C 82, 19.3.1996, p. 64.
[3] OJ C 100, 2.4.1996, p. 134.
[4] Opinion of the European Parliament of 12 December 1996 (OJ C 20, 20.1.1997, p. 133), Council common position of 19 December 1997 (OJ C 91, 26.3.1998, p. 1) and Decision of the European Parliament of 13 May 1998 (OJ C 167, 1.6.1998, p. 92).
[5] OJ L 229, 30.8.1980, p. 11. Directive as last amended by the 1994 Act of Accession.

(9) Whereas the coherence of European water policy presupposes that a suitable water framework Directive will be adopted in due course;

(10) Whereas it is necessary to exclude from the scope of this Directive natural mineral waters and waters which are medicinal products, since special rules for those types of water have been established;

(11) Whereas measures are required for all parameters directly relevant to health and for other parameters if a deterioration in quality has occurred; whereas, furthermore, such measures should be carefully coordinated with the implementation of Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1] and Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market [2];

(12) Whereas it is necessary to set individual parametric values for substances which are important throughout the Community at a level strict enough to ensure that this Directive's purpose can be achieved;

(13) Whereas the parametric values are based on the scientific knowledge available and the precautionary principle has also been taken into account; whereas those values have been selected to ensure that water intended for human consumption can be consumed safely on a life-long basis, and thus represent a high level of health protection;

(14) Whereas a balance should be struck to prevent both microbiological and chemical risks; whereas, to that end, and in the light of a future review of the parametric values, the establishment of parametric values applicable to water intended for human consumption should be based on public-health considerations and on a method of assessing risk;

(15) Whereas there is at present insufficient evidence on which to base parametric values for endocrine-disrupting chemicals at Community level, yet there is increasing concern regarding the potential impact on humans and wildlife of the effects of substances harmful to health;

(16) Whereas in particular the standards in Annex I are generally based on the World Health Organisation's 'Guidelines for drinking water quality', and the opinion of the Commission's Scientific Advisory Committee to examine the toxicity and ecotoxicity of chemical compounds;

(17) Whereas Member States must set values for other additional parameters not included in Annex I where that is necessary to protect human health within their territories;

(18) Whereas Member States may set values for other additional parameters not included in Annex I where that is deemed necessary for the purpose of ensuring the quality of the production, distribution and inspection of water intended for human consumption;

(19) Whereas, when Member States deem it necessary to adopt standards more stringent than those set out in Annex I, Parts A and B, or standards for additional parameters not included in Annex I but necessary to protect human health, they must notify the Commission of those standards;

(20) Whereas Member States are bound, when introducing or maintaining more stringent protection measures, to respect the principles and rules of the Treaty, as they are interpreted by the Court of Justice;

(21) Whereas the parametric values are to be complied with at the point where water intended for human consumption is made available to the appropriate user;

(22) Whereas the quality of water intended for human consumption can be influenced by the domestic distribution system; whereas, furthermore, it is recognised that neither the domestic distribution system nor its maintenance may be the responsibility of the Member States;

(23) Whereas each Member State should establish monitoring programmes to check that water intended for human consumption meets the requirements of this Directive; whereas such monitoring programmes should be appropriate to local needs and should meet the minimum monitoring requirements laid down in this Directive;

(24) Whereas the methods used to analyse the quality of water intended for human consumption should be such as to ensure that the results obtained are reliable and comparable;

[1] OJ L 230, 19.8.1991, p. 1. Directive as last amended by Commission Directive 96/68/EC (OJ L 277, 30.10.1996, p. 25).

[2] OJ L 123, 24.4.1998, p. 1.

(25) Whereas, in the event of non-compliance with the standards imposed by this Directive the Member State concerned should investigate the cause and ensure that the necessary remedial action is taken as soon as possible to restore the quality of the water;

(26) Whereas it is important to prevent contaminated water causing a potential danger to human health; whereas the supply of such water should be prohibited or its use restricted;

(27) Whereas, in the event of non-compliance with a parameter that has an indicator function, the Member State concerned must consider whether that non-compliance poses any risk to human health; whereas it should take remedial action to restore the quality of the water where that is necessary to protect human health;

(28) Whereas, should such remedial action be necessary to restore the quality of water intended for human consumption, in accordance with Article 130r(2) of the Treaty, priority should be given to action which rectifies the problem at source;

(29) Whereas Member States should be authorised, under certain conditions, to grant derogations from this Directive; whereas, furthermore, it is necessary to establish a proper framework for such derogations, provided that they must not constitute a potential danger to human health and provided that the supply of water intended for human consumption in the area concerned cannot otherwise be maintained by any other reasonable means;

(30) Whereas, since the preparation or distribution of water intended for human consumption may involve the use of certain substances or materials, rules are required to govern the use thereof in order to avoid possible harmful effects on human health;

(31) Whereas scientific and technical progress may necessitate rapid adaptation of the technical requirements laid down in Annexes II and III; whereas, furthermore, in order to facilitate application of the measures required for that purpose, provision should be made for a procedure under which the Commission can adopt such adaptations with the assistance of a committee composed of representatives of the Member States;

(32) Whereas consumers should be adequately and appropriately informed of the quality of water intended for human consumption, of any derogations granted by the Member States and of any remedial action taken by the competent authorities; whereas, furthermore, consideration should be given both to the technical and statistical needs of the Commission, and to the rights of the individual to obtain adequate information concerning the quality of water intended for human consumption;

(33) Whereas, in exceptional circumstances and for geographically defined areas, it may be necessary to allow Member States a more extensive timescale for compliance with certain provisions of this Directive;

(34) Whereas this Directive should not affect the obligations of the Member States as to the time limit for transposition into national law, or as to application, as shown in Annex IV,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Objective

1. This Directive concerns the quality of water intended for human consumption.

2. The objective of this Directive shall be to protect human health from the adverse effects of any contamination of water intended for human consumption by ensuring that it is wholesome and clean.

Article 2

Definitions

For the purposes of this Directive:

1. 'water intended for human consumption' shall mean:

   (a) all water either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, from a tanker, or in bottles or containers;

   (b) all water used in any food-production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption unless the competent national authorities are satisfied that the quality

of the water cannot affect the wholesomeness of the foodstuff in its finished form;

2. 'domestic distribution system' shall mean the pipework, fittings and appliances which are installed between the taps that are normally used for human consumption and the distribution network but only if they are not the responsibility of the water supplier, in its capacity as a water supplier, according to the relevant national law.

Article 3

Exemptions

1. This Directive shall not apply to:

(a) natural mineral waters recognised as such by the competent national authorities, in accordance with Council Directive 80/777/EEC of 15 July 1980 on the approximation of the laws of the Member States relating to the exploitation and marketing of natural mineral waters [1];

(b) waters which are medicinal products within the meaning of Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products [2].

2. Member States may exempt from the provisions of this Directive:

(a) water intended exclusively for those purposes for which the competent authorities are satisfied that the quality of the water has no influence, either directly or indirectly, on the health of the consumers concerned;

(b) water intended for human consumption from an individual supply providing less than 10 m^3 a day as an average or serving fewer than 50 persons, unless the water is supplied as part of a commercial or public activity.

3. Member States that have recourse to the exemptions provided for in paragraph 2(b) shall ensure that the population concerned is informed thereof and of any action that can be taken to protect human health from the adverse effects resulting from any contamination of water intended for human consumption. In addition, when a potential danger to human health arising out of the quality of such water is apparent, the population concerned shall promptly be given appropriate advice.

Article 4

General obligations

1. Without prejudice to their obligations under other Community provisions, Member States shall take the measures necessary to ensure that water intended for human consumption is wholesome and clean. For the purposes of the minimum requirements of this Directive, water intended for human consumption shall be wholesome and clean if it:

(a) is free from any micro-organisms and parasites and from any substances which, in numbers or concentrations, constitute a potential danger to human health, and

(b) meets the minimum requirements set out in Annex I, Parts A and B;

and if, in accordance with the relevant provisions of Articles 5 to 8 and 10 and in accordance with the Treaty, Member States take all other measures necessary to ensure that water intended for human consumption complies with the requirements of this Directive.

2. Member States shall ensure that the measures taken to implement this Directive in no circumstances have the effect of allowing, directly or indirectly, either any deterioration of the present quality of water intended for human consumption so far as that is relevant for the protection of human health or any increase in the pollution of waters used for the production of drinking water.

Article 5

Quality standards

1. Member States shall set values applicable to water intended for human consumption for the parameters set out in Annex I.

2. The values set in accordance with paragraph 1 shall not be less stringent than those set out in Annex I. As regards the parameters set out in Annex I, Part C, the values need be fixed only for monitoring purposes and for the fulfilment of the obligations imposed in Article 8.

3. A Member State shall set values for additional parameters not included in Annex I where the protection

[1] OJ L 229, 30.8.1980, p. 1. Directive as last amended by Directive 96/70/EC (OJ L 299, 23.11.1996, p. 26).

[2] OJ 22 9.2.1965, p. 369. Directive as last amended by Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).

of human health within its national territory or part of it so requires. The values set should, as a minimum, satisfy the requirements of Article 4(1)(a).

Article 6

Point of compliance

1. The parametric values set in accordance with Article 5 shall be complied with:

(a) in the case of water supplied from a distribution network, at the point, within premises or an establishment, at which it emerges from the taps that are normally used for human consumption;

(b) in the case of water supplied from a tanker, at the point at which it emerges from the tanker;

(c) in the case of water put into bottles or containers intended for sale, at the point at which the water is put into the bottles or containers;

(d) in the case of water used in a food-production undertaking, at the point where the water is used in the undertaking.

2. In the case of water covered by paragraph 1(a), Member States shall be deemed to have fulfilled their obligations under this Article and under Articles 4 and 8(2) where it can be established that non-compliance with the parametric values set in accordance with Article 5 is due to the domestic distribution system or the maintenance thereof except in premises and establishments where water is supplied to the public, such as schools, hospitals and restaurants.

3. Where paragraph 2 applies and there is a risk that water covered by paragraph 1(a) would not comply with the parametric values established in accordance with Article 5, Member States shall nevertheless ensure that:

(a) appropriate measures are taken to reduce or eliminate the risk of non-compliance with the parametric values, such as advising property owners of any possible remedial action they could take, and/or

other measures, such as appropriate treatment techniques, are taken to change the nature or properties of the water before it is supplied so as to reduce or eliminate the risk of the water not complying with the parametric values after supply;

and

(b) the consumers concerned are duly informed and advised of any possible additional remedial action that they should take.

Article 7

Monitoring

1. Member States shall take all measures necessary to ensure that regular monitoring of the quality of water intended for human consumption is carried out, in order to check that the water available to consumers meets the requirements of this Directive and in particular the parametric values set in accordance with Article 5. Samples should be taken so that they are representative of the quality of the water consumed throughout the year. In addition, Member States shall take all measures necessary to ensure that, where disinfection forms part of the preparation or distribution of water intended for human consumption, the efficiency of the disinfection treatment applied is verified, and that any contamination from disinfection by-products is kept as low as possible without compromising the disinfection.

2. To meet the obligations imposed in paragraph 1, appropriate monitoring programmes shall be established by the competent authorities for all water intended for human consumption. Those monitoring programmes shall meet the minimum requirements set out in Annex II.

3. The sampling points shall be determined by the competent authorities and shall meet the relevant requirements set out in Annex II.

4. Community guidelines for the monitoring prescribed in this Article may be drawn up in accordance with the procedure laid down in Article 12.

5 (a) Member States shall comply with the specifications for the analyses of parameters set out in Annex III.

(b) Methods other than those specified in Annex III, Part 1, may be used, providing it can be demonstrated that the results obtained are at least as reliable as those produced by the methods specified. Member States which have recourse to alternative methods shall provide the Commission with all relevant information concerning such methods and their equivalence.

(c) For those parameters listed in Annex III, Parts 2 and 3, any method of analysis may be used provided that it meets the requirements set out therein.

6. Member States shall ensure that additional monitoring is carried out on a case-by-case basis of substances and micro-organisms for which no parametric value has been set in accordance with Article 5, if there is reason to suspect that they may be present in amounts or

numbers which constitute a potential danger to human health.

Article 8

Remedial action and restrictions in use

1. Member States shall ensure that any failure to meet the parametric values set in accordance with Article 5 is immediately investigated in order to identify the cause.

2. If, despite the measures taken to meet the obligations imposed in Article 4(1), water intended for human consumption does not meet the parametric values set in accordance with Article 5, and subject to Article 6(2), the Member State concerned shall ensure that the necessary remedial action is taken as soon as possible to restore its quality and shall give priority to their enforcement action, having regard *inter alia* to the extent to which the relevant parametric value has been exceeded and to the potential danger to human health.

3. Whether or not any failure to meet the parametric values has occurred, Member States shall ensure that any supply of water intended for human consumption which constitutes a potential danger to human health is prohibited or its use restricted or such other action is taken as is necessary to protect human health. In such cases consumers shall be informed promptly thereof and given the necessary advice.

4. The competent authorities or other relevant bodies shall decide what action under paragraph 3 should be taken, bearing in mind the risks to human health which would be caused by an interruption of the supply or a restriction in the use of water intended for human consumption.

5. Member States may establish guidelines to assist the competent authorities to fulfil their obligations under paragraph 4.

6. In the event of non-compliance with the parametric values or with the specifications set out in Annex I, Part C, Member States shall consider whether that non-compliance poses any risk to human health. They shall take remedial action to restore the quality of the water where that is necessary to protect human health.

7. Member States shall ensure that, where remedial action is taken, consumers are notified except where the competent authorities consider the non-compliance with the parametric value to be trivial.

Article 9

Derogations

1. Member States may provide for derogations from the parametric values set out in Annex I, Part B, or set in accordance with Article 5(3), up to a maximum value to be determined by them, provided no derogation constitutes a potential danger to human health and provided that the supply of water intended for human consumption in the area concerned cannot otherwise be maintained by any other reasonable means. Derogations shall be limited to as short a time as possible and shall not exceed three years, towards the end of which a review shall be conducted to determine whether sufficient progress has been made. Where a Member State intends to grant a second derogation, it shall communicate the review, along with the grounds for its decision on the second derogation, to the Commission. No such second derogation shall exceed three years.

2. In exceptional circumstances, a Member State may ask the Commission for a third derogation for a period not exceeding three years. The Commission shall take a decision on any such request within three months.

3. Any derogation granted in accordance with paragraphs 1 or 2 shall specify the following:

(a) the grounds for the derogation;

(b) the parameter concerned, previous relevant monitoring results, and the maximum permissible value under the derogation;

(c) the geographical area, the quantity of water supplied each day, the population concerned and whether or not any relevant food-production undertaking would be affected;

(d) an appropriate monitoring scheme, with an increased monitoring frequency where necessary;

(e) a summary of the plan for the necessary remedial action, including a timetable for the work and an estimate of the cost and provisions for reviewing;

(f) the required duration of the derogation.

4. If the competent authorities consider the non-compliance with the parametric value to be trivial, and if action taken in accordance with Article 8(2) is sufficient to remedy the problem within 30 days, the requirements of paragraph 3 need not be applied.

In that event, only the maximum permissible value for the parameter concerned and the time allowed to remedy the problem shall be set by the competent authorities or other relevant bodies.

5. Recourse may no longer be had to paragraph 4 if failure to comply with any one parametric value for a given water supply has occurred on more than 30 days on aggregate during the previous 12 months.

6. Any Member State which has recourse to the derogations provided for in this Article shall ensure that the population affected by any such derogation is promptly informed in an appropriate manner of the derogation and of the conditions governing it. In addition the Member State shall, where necessary, ensure that advice is given to particular population groups for which the derogation could present a special risk.

These obligations shall not apply in the circumstances described in paragraph 4 unless the competent authorities decide otherwise.

7. With the exception of derogations granted in accordance with paragraph 4 a Member State shall inform the Commission within two months of any derogation concerning an individual supply of water exceeding 1 000 m^3 a day as an average or serving more than 5 000 persons, including the information specified in paragraph 3.

8. This Article shall not apply to water intended for human consumption offered for sale in bottles or containers.

Article 10

Quality assurance of treatment, equipment and materials

Member States shall take all measures necessary to ensure that no substances or materials for new installations used in the preparation or distribution of water intended for human consumption or impurities associated with such substances or materials for new installations remain in water intended for human consumption in concentrations higher than is necessary for the purpose of their use and do not, either directly or indirectly, reduce the protection of human health provided for in this Directive; the interpretative document and technical specifications pursuant to Article 3 and Article 4 (1) of Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products [1] shall respect the requirements of this Directive.

[1] OJ L 40, 11.2.1989, p. 12. Directive as last amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).

Article 11

Review of Annexes

1. At least every five years, the Commission shall review Annex I in the light of scientific and technical progress and shall make proposals for amendments, where necessary, under the procedure laid down in Article 189c of the Treaty.

2. At least every five years, the Commission shall adapt Annexes II and III to scientific and technical progress. Such changes as are necessary shall be adopted in accordance with the procedure laid down in Article 12.

Article 12

Committee procedure

1. The Commission shall be assisted by a committee composed of representatives of the Member States and chaired by a Commission representative.

2. The Commission representative shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

3. The Commission shall adopt measures which shall apply immediately. However, if those measures are not in accordance with the committee's opinion, the Commission shall communicate them to the Council forthwith. In that event:

(a) the Commission shall defer application of the measures which it has adopted for a period of three months from the date of communication;

(b) the Council, acting by a qualified majority, may take a different decision within the time limit referred to in point (a).

Article 13

Information and reporting

1. Member States shall take the measures necessary to ensure that adequate and up-to-date information on the

quality of water intended for human consumption is available to consumers.

2. Without prejudice to Council Directive 90/313/EEC of 7 June 1990 on the freedom of access to information on the environment [1], each Member State shall publish a report every three years on the quality of water intended for human consumption with the objective of informing consumers. The first report shall cover the years 2002, 2003 and 2004. Each report shall include, as a minimum, all individual supplies of water exceeding 1 000 m^3 a day as an average or serving more than 5 000 persons and it shall cover three calendar years and be published within one calendar year of the end of the reporting period.

3. Member States shall send their reports to the Commission within two months of their publication.

4. The formats and the minimum information for the reports provided for in paragraph 2 shall be determined having special regard to the measures referred to in Article 3(2), Article 5(2) and (3), Article 7(2), Article 8, Article 9(6) and (7) and 15(1), and shall if necessary be amended in accordance with the procedure laid down in Article 12.

5. The Commission shall examine the Member States' reports and, every three years, publish a synthesis report on the quality of water intended for human consumption in the Community. That report shall be published within nine months of the receipt of the Member States' reports.

6. Together with the first report on this Directive as mentioned in paragraph 2, Member States shall also produce a report to be forwarded to the Commission on the measures they have taken or plan to take to fultil their obligations pursuant to Article 6(3) and Annex I, Part B, note 10. The Commission shall submit, as appropriate, a proposal on the format of this report in accordance with the procedure laid down in Article 12.

Article 14

Timescale for compliance

Member States shall take the measures necessary to ensure that the quality of water intended for human consumption complies with this Directive within five years of its entry into force, without prejudice to Notes 2, 4 and 10 in Annex I, Part B.

[1] OJ L 158, 23.6.1990, p. 56.

Article 15

Exceptional circumstances

1. A Member State may, in exceptional circumstances and for geographically defined areas, submit a special request to the Commission for a period longer than that laid down in Article 14. The additional period shall not exceed three years, towards the end of which a review shall be carried out and forwarded to the Commission which may, on the basis of that review, permit a second additional period of up to three years. This provision shall not apply to water intended for human consumption offered for sale in bottles or containers.

2. Any such request, grounds for which shall be given, shall set out the difficulties experienced and include, as a minimum, all the information specified in Article 9(3).

3. The Commission shall examine that request in accordance with the procedure laid down in Article 12.

4. Any Member State which has recourse to this Article shall ensure that the population affected by its request is promptly informed in an appropriate manner of the outcome of that request. In addition, the Member State shall, where necessary, ensure that advice is given to particular population groups for which the request could present a special risk.

Article 16

Repeal

1. Directive 80/778/EEC is hereby repealed with effect from five years after the entry into force of this Directive. Subject to paragraph 2, this repeal shall be without prejudice to Member States' obligations regarding deadlines for transposition into national law and for application as shown in Annex IV.

Any reference to the Directive repealed shall be construed as a reference to this Directive and shall be read in accordance with the correlation table set out in Annex V.

2. As soon as a Member State has brought into force the laws, regulations and administrative provisions necessary to comply with this Directive and has taken the measures provided for in Article 14, this Directive, not Directive 80/778/EEC, shall apply to the quality of water intended for human consumption in that Member State.

Article 17

Transposition into national law

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive within two years of its entry into force. They shall forthwith inform the Commission thereof.

When the Member States adopt those measures, these shall contain references to this Directive or shall be accompanied by such references on the occasion of their official publication. The methods of making such references shall be laid down by the Member States.

2. The Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

Article 18

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Communities*.

Article 19

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 3 November 1998.

For the Council

The President

B. PRAMMER

ANNEX I

PARAMETERS AND PARAMETRIC VALUES

PART A

Microbiological parameters

Parameter	Parametric value (number/100 ml)
Escherichia coli (E. coli)	0
Enterococci	0

The following applies to water offered for sale in bottles or containers:

Parameter	Parametric value
Escherichia coli (E. coli)	0/250 ml
Enterococci	0/250 ml
Pseudomonas aeruginosa	0/250 ml
Colony count 22 °C	100/ml
Colony count 37 °C	20/ml

PART B

Chemical parameters

Parameter	Parametric value	Unit	Notes
Acrylamide	0,10	μg/l	Note 1
Antimony	5,0	μg/l	
Arsenic	10	μg/l	
Benzene	1,0	μg/l	
Benzo(a)pyrene	0,010	μg/l	
Boron	1,0	mg/l	
Bromate	10	μg/l	Note 2
Cadmium	5,0	μg/l	
Chromium	50	μg/l	
Copper	2,0	mg/l	Note 3
Cyanide	50	μg/l	
1,2-dichloroethane	3,0	μg/l	
Epichlorohydrin	0,10	μg/l	Note 1
Fluoride	1,5	mg/l	
Lead	10	μg/l	Notes 3 and 4
Mercury	1,0	μg/l	
Nickel	20	μg/l	Note 3
Nitrate	50	mg/l	Note 5
Nitrite	0,50	mg/l	Note 5
Pesticides	0,10	μg/l	Notes 6 and 7
Pesticides — Total	0,50	μg/l	Notes 6 and 8
Polycyclic aromatic hydrocarbons	0,10	μg/l	Sum of concentrations of specified compounds; Note 9
Selenium	10	μg/l	
Tetrachloroethene and Trichloroethene	10	μg/l	Sum of concentrations of specified parameters
Trihalomethanes — Total	100	μg/l	Sum of concentrations of specified compounds; Note 10
Vinyl chloride	0,50	μg/l	Note 1

Note 1: The parametric value refers to the residual monomer concentration in the water as calculated according to specifications of the maximum release from the corresponding polymer in contact with the water.

Note 2: Where possible, without compromising disinfection, Member States should strive for a lower value.

For the water referred to in Article 6(1)(a), (b) and (d), the value must be met, at the latest, 10 calendar years after the entry into force of the Directive. The parametric value for bromate from five years after the entry into force of this Directive until 10 years after its entry into force is 25 μg/l.

Note 3: The value applies to a sample of water intended for human consumption obtained by an adequate sampling method [1] at the tap and taken so as to be representative of a weekly average value ingested by consumers. Where appropriate the sampling and monitoring methods must be applied in a harmonised fashion to be drawn up in accordance with Article 7(4). Member States must take account of the occurrence of peak levels that may cause adverse effects on human health.

Note 4: For water referred to in Article 6(1)(a), (b) and (d), the value must be met, at the latest, 15 calendar years after the entry into force of this Directive. The parametric value for lead from five years after the entry into force of this Directive until 15 years after its entry into force is 25 μg/l.

Member States must ensure that all appropriate measures are taken to reduce the concentration of lead in water intended for human consumption as much as possible during the period needed to achieve compliance with the parametric value.

When implementing the measures to achieve compliance with that value Member States must progressively give priority where lead concentrations in water intended for human consumption are highest.

Note 5: Member States must ensure that the condition that [nitrate]/50 + [nitrite]/3 $\leq$ 1, the square brackets signifying the concentrations in mg/l for nitrate (NO_3) and nitrite (NO_2), is complied with and that the value of 0,10 mg/l for nitrites is complied with ex water treatment works.

Note 6: 'Pesticides' means:

— organic insecticides,

— organic herbicides,

— organic fungicides,

— organic nematocides,

— organic acaricides,

— organic algicides,

— organic rodenticides

— organic slimicides,

— related products (*inter alia*, growth regulators)

and their relevant metabolites, degradation and reaction products.

Only those pesticides which are likely to be present in a given supply need be monitored.

Note 7: The parametric value applies to each individual pesticide. In the case of aldrin, dieldrin, heptachlor and heptachlor epoxide the parametric value is 0,030 μg/l.

Note 8: 'Pesticides — Total' means the sum of all individual pesticides detected and quantified in the monitoring procedure.

Note 9: The specified compounds are:

— benzo(b)fluoranthene,

— benzo(k)fluoranthene,

— benzo(ghi)perylene,

— indeno(1,2,3-cd)pyrene.

Note 10: Where possible, without compromising disinfection, Member States should strive for a lower value.

The specified compounds are: chloroform, bromoform, dibromochloromethane, bromodichloromethane.

For the water referred to in Article 6(1)(a), (b) and (d), the value must be met, at the latest, 10 calendar years after the entry into force of this Directive. The parametric value for total THMs from five years after the entry into force of this Directive until 10 years after its entry into force is 150 μg/l.

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[1] To be added following the outcome of the study currently being carried out.

Member States must ensure that all appropriate measures are taken to reduce the concentration of THMs in water intended for human consumption as much as possible during the period needed to achieve compliance with the parametric value.

When implementing the measures to achieve this value, Member States must progressively give priority to those areas where THM concentrations in water intended for human consumption are highest.

PART C

Indicator parameters

Parameter	Parametric value	Unit	Notes
Aluminium	200	μg/l	
Ammonium	0,50	mg/l	
Chloride	250	mg/l	Note 1
Clostridium perfringens (including spores)	0	number/100 ml	Note 2
Colour	Acceptable to consumers and no abnormal change		
Conductivity	2 500	μS cm^{-1} at 20 °C	Note 1
Hydrogen ion concentration	$\geq$ 6,5 and $\leq$ 9,5	pH units	Notes 1 and 3
Iron	200	μg/l	
Manganese	50	μg/l	
Odour	Acceptable to consumers and no abnormal change		
Oxidisability	5,0	mg/l O_2	Note 4
Sulphate	250	mg/l	Note 1
Sodium	200	mg/l	
Taste	Acceptable to consumers and no abnormal change		
Colony count 22°	No abnormal change		
Coliform bacteria	0	number/100 ml	Note 5
Total organic carbon (TOC)	No abnormal change		Note 6
Turbidity	Acceptable to consumers and no abnormal change		Note 7

RADIOACTIVITY

Parameter	Parametric value	Unit	Notes
Tritium	100	Bq/l	Notes 8 and 10
Total indicative dose	0,10	mSv/year	Notes 9 and 10

Note 1: The water should not be aggressive.

Note 2: This parameter need not be measured unless the water originates from or is influenced by surface water. In the event of non-compliance with this parametric value, the Member State concerned must investigate the supply to ensure that there is no potential danger to human health arising from the presence of pathogenic micro-organisms, e.g. cryptosporidium. Member States must include the results of all such investigations in the reports they must submit under Article 13(2).

Note 3: For still water put into bottles or containers, the minimum value may be reduced to 4,5 pH units.

For water put into bottles or containers which is naturally rich in or artificially enriched with carbon dioxide, the minimum value may be lower.

Note 4: This parameter need not be measured if the parameter TOC is analysed.

Note 5: For water put into bottles or containers the unit is number/250 ml.

Note 6: This parameter need not be measured for supplies of less than 10 000 m^3 a day.

Note 7: In the case of surface water treatment, Member States should strive for a parametric value not exceeding 1,0 NTU (nephelometric turbidity units) in the water ex treatment works.

Note 8: Monitoring frequencies to be set later in Annex II.

Note 9: Excluding tritium, potassium -40, radon and radon decay products; monitoring frequencies, monitoring methods and the most relevant locations for monitoring points to be set later in Annex II.

Note 10:

1. The proposals required by Note 8 on monitoring frequencies, and Note 9 on monitoring frequencies, monitoring methods and the most relevant locations for monitoring points in Annex II shall be adopted in accordance with the procedure laid down in Article 12. When elaborating these proposals the Commission shall take into account *inter alia* the relevant provisions under existing legislation or appropriate monitoring programmes including monitoring results as derived from them. The Commission shall submit these proposals at the latest within 18 months following the date referred to in Article 18 of the Directive.

2. A Member State is not required to monitor drinking water for tritium or radioactivity to establish total indicative dose where it is satisfied that, on the basis of other monitoring carried out, the levels of tritium of the calculated total indicative dose are well below the parametric value. In that case, it shall communicate the grounds for its decision to the Commission, including the results of this other monitoring carried out.

ANNEX II

MONITORING

TABLE A

Parameters to be analysed

1. *Check monitoring*

The purpose of check monitoring is regularly to provide information on the organoleptic and microbiological quality of the water supplied for human consumption as well as information on the effectiveness of drinking-water treatment (particularly of disinfection) where it is used, in order to determine whether or not water intended for human consumption complies with the relevant parametric values laid down in this Directive.

The following parameters must be subject to check monitoring. Member States may add other parameters to this list if they deem it appropriate.

Aluminium (Note 1)

Ammonium

Colour

Conductivity

Clostridium perfringens (including spores) (Note 2)

Escherichia coli (E. coli)

Hydrogen ion concentration

Iron (Note 1)

Nitrite (Note 3)

Odour

Pseudomonas aeruginosa (Note 4)

Taste

Colony count 22 °C and 37 °C (Note 4)

Coliform bacteria

Turbidity

Note 1: Necessary only when used as flocculant (*).

Note 2: Necessary only if the water originates from or is influenced by surface water (*).

Note 3: Necessary only when chloramination is used as a disinfectant (*).

Note 4: Necessary only in the case of water offered for sale in bottles or containers.

(*) In all other cases, the parameters are in the list for audit monitoring.

2. *Audit monitoring*

The purpose of audit monitoring is to provide the information necessary to determine whether or not all of the Directive's parametric values are being complied with. All parameters set in accordance with Article 5(2) and (3) must be subject to audit monitoring unless it can be established by the competent authorities, for a period of time to be determined by them, that a parameter is not likely to be present in a given supply in concentrations which could lead to the risk of a breach of the relevant parametric value. This paragraph does not apply to the parameters for radioactivity, which, subject to Notes 8, 9 and 10 in Annex I, Part C, will be monitored in accordance with monitoring requirements adopted under Article 12.

TABLE B1

Minimum frequency of sampling and analyses for water intended for human consumption supplied from a distribution network or from a tanker or used in a food-production undertaking

Member States must take samples at the points of compliance as defined in Article 6(1) to ensure that water intended for human consumption meets the requirements of the Directive. However, in the case of a distribution network, a Member State may take samples within the supply zone or at the treatment works for particular parameters if it can be demonstrated that there would be no adverse change to the measured value of the parameters concerned.

Volume of water distributed or produced each day within a supply zone (Notes 1 and 2) m^3	Check monitoring number of samples per year (Notes 3, 4 and 5)	Audit monitoring number of samples per year (Notes 3 and 5)
≤ 100	(Note 6)	(Note 6)
> 100 ≤ 1 000	4	1
> 1 000 ≤ 10 000	4 + 3 for each 1 000 m^3/d and part thereof of the total volume	1 + 1 for each 3 300 m^3/d and part thereof of the total volume
> 10 000 ≤ 100 000		3 + 1 for each 10 000 m^3/d and part thereof of the total volume
> 100 000		10 + 1 for each 25 000 m^3/d and part thereof of the total volume

Note 1: A supply zone is a geographically defined area within which water intended for human consumption comes from one or more sources and within which water quality may be considered as being approximately uniform.

Note 2: The volumes are calculated as averages taken over a calendar year. A Member State may use the number of inhabitants in a supply zone instead of the volume of water to determine the minimum frequency, assuming a water consumption of 200 l/day/capita.

Note 3: In the event of intermittent short-term supply the monitoring frequency of water distributed by tankers is to be decided by the Member State concerned.

Note 4: For the different parameters in Annex I, a Member State may reduce the number of samples specified in the table if:

(a) the values of the results obtained from samples taken during a period of at least two successive years are constant and significantly better than the limits laid down in Annex I, and

(b) no factor is likely to cause a deterioration of the quality of the water.

The lowest frequency applied must not be less than 50 % of the number of samples specified in the table except in the particular case of note 6.

Note 5: As far as possible, the number of samples should be distributed equally in time and location.

Note 6: The frequency is to be decided by the Member State concerned.

TABLE B2

Minimum frequency of sampling and analysis for water put into bottles or containers intended for sale

Volume of water produced for offering for sale in bottles or containers each day (1) m^3	Check monitoring number of samples per year	Audit monitoring number of samples per year
≤ 10	1	1
> 10 ≤ 60	12	1
> 60	1 for each 5 m^3 and part thereof of the total volume	1 for each 100 m^3 and part thereof of the total volume

(1) The volumes are calculated as averages taken over a calendar year.

ANNEX III

SPECIFICATIONS FOR THE ANALYSIS OF PARAMETERS

Each Member State must ensure that any laboratory at which samples are analysed has a system of analytical quality control that is subject from time to time to checking by a person who is not under the control of the laboratory and who is approved by the competent authority for that purpose.

1. PARAMETERS FOR WHICH METHODS OF ANALYSIS ARE SPECIFIED

The following principles for methods of microbiological parameters are given either for reference whenever a CEN/ISO method is given or for guidance, pending the possible future adoption, in accordance with the procedure laid down in Article 12, of further CEN/ISO international methods for these parameters. Member States may use alternative methods, providing the provisions of Article 7(5) are met.

Coliform bacteria and *Escherichia coli (E. coli)* (ISO 9308-1)

Enterococci (ISO 7899-2)

Pseudomonas aeruginosa (prEN ISO 12780)

Enumeration of culturable microorganisms — Colony count 22 °C (prEN ISO 6222)

Enumeration of culturable microorganisms — Colony count 37 °C (prEN ISO 6222)

Clostridium perfringens (including spores)

Membrane filtration followed by anaerobic incubation of the membrane on m-CP agar (Note 1) at 44 ± 1 °C for 21 ± 3 hours. Count opaque yellow colonies that turn pink or red after exposure to ammonium hydroxide vapours for 20 to 30 seconds.

Note 1: The composition of m-CP agar is:

Basal medium	
Tryptose	30 g
Yeast extract	20 g
Sucrose	5 g
L-cysteine hydrochloride	1 g
$MgSO_4 \cdot 7H_2O$	0,1 g
Bromocresol purple	40 mg
Agar	15 g
Water	1 000 ml

Dissolve the ingredients of the basal medium, adjust pH to 7,6 and autoclave at 121 °C for 15 minutes. Allow the medium to cool and add:

D-cycloserine	400 mg
Polymyxine-B sulphate	25 mg
Indoxyl-β-D-glucoside to be dissolved in 8 ml sterile water before addition	60 mg
Filter — sterilised 0,5% phenolphthalein diphosphate solution	20 ml
Filter — sterilised 4,5 % $FeCl_3 \cdot 6H_2O$	2 ml

2. PARAMETERS FOR WHICH PERFORMANCE CHARACTERISTICS ARE SPECIFIED

2.1. For the following parameters, the specified performance characteristics are that the method of analysis used must, as a minimum, be capable of measuring concentrations equal to the parametric value with a trueness, precision and limit of detection specified. Whatever the sensitivity of the method of analysis used, the result must be expressed using at least the same number of decimals as for the parametric value considered in Annex I, Parts B and C.

Parameters	Trueness % of parametric value (Note 1)	Precision % of parametric value (Note 2)	Limit of detection % of parametric value (Note 3)	Conditions	Notes
Acrylamide				To be controlled by product specification	
Aluminium	10	10	10		
Ammonium	10	10	10		
Antimony	25	25	25		
Arsenic	10	10	10		
Benzo(a)pyrene	25	25	25		
Benzene	25	25	25		
Boron	10	10	10		
Bromate	25	25	25		
Cadmium	10	10	10		
Chloride	10	10	10		
Chromium	10	10	10		
Conductivity	10	10	10		
Copper	10	10	10		
Cyanide	10	10	10		Note 4
1,2-dichloroethane	25	25	10		
Epichlorohydrin				To be controlled by product specification	
Fluoride	10	10	10		
Iron	10	10	10		
Lead	10	10	10		
Manganese	10	10	10		
Mercury	20	10	20		
Nickel	10	10	10		
Nitrate	10	10	10		
Nitrite	10	10	10		
Oxidisability	25	25	10		Note 5
Pesticides	25	25	25		Note 6
Polycyclic aromatic hydrocarbons	25	25	25		Note 7

Parameters	Trueness % of parametric value (Note 1)	Precision % of parametric value (Note 2)	Limit of detection % of parametric value (Note 3)	Conditions	Notes
Selenium	10	10	10		
Sodium	10	10	10		
Sulphate	10	10	10		
Tetrachloroethene	25	25	10		Note 8
Trichloroethene	25	25	10		Note 8
Trihalomethanes — Total	25	25	10		Note 7
Vinyl chloride				To be controlled by product specification	

2.2. For hydrogen ion concentration the specified performance characterisatics are that the method of analysis used must be capable of measuring concentrations equal to the parametric value with a trueness of 0,2 pH unit and a precision of 0,2 pH unit.

Note 1 (*): Trueness is the systematic error and is the difference between the mean value of the large number of repeated measurements and the true value.

Note 2 (*): Precision is the random error and is usually expressed as the standard deviation (within and between batch) of the spread of results about the mean. Acceptable precision is twice the relative standard deviation.

(*) These terms are further defined in ISO 5725.

Note 3: Limit of detection is either:

— three times the relative within batch standard deviation of a natural sample containing a low concentration of the parameter,

or

— five times the relative within batch standard deviation of a blank sample.

Note 4: The method should determine total cyanide in all forms.

Note 5: Oxidation should be carried out for 10 minutes at 100 °C under acid conditions using permanganate.

Note 6: The performance characteristics apply to each individual pesticide and will depend on the pesticide concerned. The limit of detection may not be achievable for all pesticides at present, but Member States should strive to achieve this standard.

Note 7: The performance characteristics apply to the individual substances specified at 25 % of the parametric value in Annex I.

Note 8: The performance characteristics apply to the individual substances specified at 50 % of the parametric value in Annex I.

3. PARAMETERS FOR WHICH NO METHOD OF ANALYSIS IS SPECIFIED

Colour
Odour
Taste
Total organic carbon
Turbidity (Note 1)

Note 1: For turbidity monitoring in treated surface water the specified performance characteristics are that the method of analysis used must, as a minimum, be capable of measuring concentrations equal to the parametric value with a trueness of 25 %, precision of 25 % and a 25 % limit of detection.

ANNEX IV

DEADLINES FOR TRANSPOSITION INTO NATIONAL LAW AND FOR APPLICATION

Directive 80/778/EEC Transposition 17.7.1982 Application 17.7.1985 All Member States except Spain, Portugal and new *Länder* of Germany	Directive 81/858/EEC (Adaptation due to accession of Greece)	Act of Accession of Spain and Portugal Spain: transposition 1.1.1986 application 1.1.1986 Portugal: transposition 1.1.1986 application 1.1.1989	Directive 90/656/EEC for new *Länder* of Germany	Act of Accession of Austria, Finland and Sweden Austria: transposition 1.1.1995 application 1.1.1995 Finland: transposition 1.1.1995 application 1.1.1995 Sweden: transposition 1.1.1995 application 1.1.1995	Directive 91/692/EEC
Articles 1 to 14			Application 31.12.1995		
Article 15	Amended with effect from 1.1.1981	Amended with effect from 1.1.1986		Amended with effect from 1.1.1995	
Article 16					
Article 17					Article 17(a) inserted
Article 18					
Article 19		Amended	Amended		
Article 20					
Article 21					

ANNEX V

CORRELATION TABLE

This Directive	Directive 80/778/EEC
Article 1(1)	Article 1(1)
Article 1(2)	—
Article 2(1) (a) and (b)	Article 2
Article 2(2)	—
Article 3(1) (a) and (b)	Article 4(1)
Article 3(2) (a) and (b)	—
Article 3(3)	—
Article 4(1)	Article 7(6)
Article 4(2)	Article 11
Article 5(1)	Article 7(1)
Article 5(2) first sentence	Article 7(3)
Article 5(2) second sentence	—
Article 5(3)	—
Article 6(1)	Article 12(2)
Article 6(2) to (3)	—
Article 7(1)	Article 12(1)
Article 7(2)	—
Article 7(3)	Article 12(3)
Article 7(4)	—
Article 7(5)	Article 12(5)
Article 7(6)	—
Article 8	—
Article 9(1)	Article 9(1) and Article 10(1)
Article 9(2) to (6)	—
Article 9(7)	Article 9(2) and Article 10(3)
Article 9(8)	—
Article 10	Article 8

This Directive	Directive 80/778/EEC
Article 11(1)	—
Article 11(2)	Article 13
Article 12(1)	Article 14
Article 12(2) and (3)	Article 15
Article 13(1)	—
Article 13(2) to (5)	Article 17(a) (inserted by Directive 91/692/EEC)
Article 14	Article 19
Article 15	Article 20
Article 16	—
Article 17	Article 18
Article 18	—
Article 19	Article 21