

L.N. 169 of 2002

**ENVIRONMENT PROTECTION ACT, 2001
(ACT NO. XX OF 2001)**

**Contained use of Genetically Modified Micro-Organisms
Regulations, 2002**

BY virtue of the powers conferred by articles 9 and 11 of the Environment Protection Act, 2001, hereinafter referred to as 'the Act', the Minister for Home Affairs and the Environment has made the following regulations:-

1. (1) The title of these regulations is Contained use of genetically modified micro-organisms Regulations, 2002. Citation and commencement.

(2) (a) These regulations shall come into force on such date as the Minister responsible for the environment may by notice in the Gazette appoint and different dates may be so appointed for different provisions and different purposes of these regulations.

(b) A notice under paragraph (a) of this sub-regulation may make such transitional provisions as appear to the Minister to be necessary or expedient in connection with the provisions thereby brought into force.

2. The objective of these regulations is to lay down measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment. Objectives.

3. In these regulations, unless the context otherwise requires: Interpretation.

“micro-organism” means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, animal and plant cells in culture;

“genetically modified micro-organism” (GMM) means 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:

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(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;

“contained use” means 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;

“accident” means 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;

“user” means any natural or legal person responsible for the contained use of GMMs;

“notification” means the presentation of the requisite information to the Authority;

“Minister” means the Minister responsible for the environment

“Authority” means the Malta Environment and Planning Authority as prescribed by the notice entitled Nomination of the Malta Environment and Planning authority as the competent authority, and such other body or person as the Minister responsible for the environment may by order in the Gazette prescribe and different bodies or persons may be designated as the competent authority for different provisions and different purposes of these regulations;

Exemptions.

4. (1) Without prejudice to Article 6(1) these regulations 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.

(2) Article 5(2), 5(5), 5(6), 5(7) and Articles 6 to 11 shall not apply to the transport of GMMs by rail, by road, sea or air.

(3) To the storage, culture, transport, destruction, disposal or use of GMMs which have been placed on the market in accordance with the deliberate release into the environment of genetically modified organisms regulations, 2002 or pursuant to other relevant legislation, which provides for a specific environmental risk assessment similar to that laid down in the said regulations, provided that the contained use is in accordance with the conditions, if any, of the consent for placing on the market.

5. (1) In order to ensure that the contained use of GMMs does not produce adverse effects on human health and the environment 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. ^{Assessment.}

(2) The assessment referred to in sub-article (1) 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 sub-articles (6) and (7) :

Class 1 : activities of no or negligible risk, for which level 1 containment is appropriate.

Class 2 : activities of low risk, for which level 2 containment is appropriate.

Class 3 : activities of moderate risk, for which level 3 containment is appropriate.

Class 4 : activities of high risk, for which level 4 containment is appropriate.

(3) 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.

(4) The assessment referred to in sub-article (1) 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.

(5) A record of the assessment referred to in sub-article (1) 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 6, 8 and 9 or on request.

(6) 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.

(7) The assessment referred to in sub-article 5(1) 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.

Premises used for the first time.

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

Class 1 contained use.

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

Class 2 contained use.

8. (1) For first and subsequent class 2 contained uses to be carried out in premises notified in accordance with Article 6, a notification containing the information listed in Annex V, Part B shall be submitted to the competent authority.

(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.

Provided that the applicant can, however, himself request a decision on a formal authorisation from the 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 sub-article (1), or earlier with the agreement of the competent authority.

9. (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. Class 3 and class 4 contained use.

(2) A class 3 or higher class of contained use may not proceed without the prior consent of the 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.

10. (1) The competent authority 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(1) 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. Notifications to the competent authority.

(2) If necessary, the 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).

Provided that in this case the Authority may require that the contained use, if proposed, does not begin, or, if in progress, is suspended

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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.

(3) For the purpose of calculating the periods referred to in Articles 8 and 9, any period of time during which the Authority:

- is awaiting any further information which it may have requested from the notifier in accordance with sub-article 2(a), or

- is carrying out a public inquiry or consultation in accordance with Article 12 shall not be taken into account.

New information on risks of contained use.

11. 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 Authority shall be informed as soon as possible and the notification pursuant to Articles 6, 8 and 9 shall be modified.

Provided that 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.

Public consultation.

12. Where the competent authority considers it appropriate, it may hold public consultations on aspects of the proposed contained use, without prejudice to Article 18.

Emergency plans.

13. The competent authority 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 relevant 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 authority shall at the same time make available to other States concerned, the same information as that which is disseminated to their nationals.

14. (1) In the event of an accident, the user shall be required to inform immediately the competent authority and provide the following information: Occurrences of accidents.

- 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 sub-article (1), the competent authority shall be required to:

- ensure that any measures necessary are taken, and immediately alert other 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.

15. The competent authority shall consult with other States, likely to be affected in the event of an accident, on the proposed implementation of emergency plans. Communication with other states.

16. The competent authority shall organise inspections and other control measures to ensure user compliance with these regulations. Inspection and control measures

17. (1) Where disclosure of data affects one or more of the following: Disclosure of confidential data.

- the confidentiality of the proceedings of public authorities, international relations and national defence,

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- public security,
- matters which are, or have been, *sub judice*, or under enquiry (including disciplinary enquiries), or which are the subject of preliminary investigation proceedings,
- commercial and industrial confidentiality, including intellectual property,
- the confidentiality of personal data and/or files,
- material supplied by a third party without that party being under a legal obligation to do so,
- material, the disclosure of which would make it more likely that the environment to which such material related would be damaged, the notifier may indicate the information in the notifications submitted pursuant to these regulations that should be treated as confidential.

Provided that a verifiable justification must be given in such cases.

(2) The 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 6, 8 or 9, 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 competent authority shall not divulge to third parties any information decided to be confidential according to sub-article 2 and notified or otherwise provided pursuant to these regulations, and shall protect intellectual property rights relating to the data received.

(5) If, for whatever reasons, the notifier withdraws the notification, the Authority must respect the confidentiality of the information supplied.

18. Any person shall be guilty of an offence under these regulations if: Offences.

(a) he fails to comply with any provision of these regulations or fails to comply with permit conditions or with any order lawfully given in terms of any provision of these regulations; or

(b) he contravenes any restriction, prohibition or requirement imposed by or under these regulations; or

(c) he acts in contravention of any of the provisions of these regulations; or

(d) he conspires or attempts, or aids, or abets, any other person by whatever means, including advertising, counselling or procurement to contravene the provisions of these regulations or to fail to comply with any such provisions, including any order lawfully given in terms of any of the provision of these regulations, or to contravene any restriction, prohibition or requirement imposed by or under the said regulations.

19. Any person who commits an offence against these regulations shall, on conviction, be liable: Penalties.

(a) on a first conviction to a fine (multa) of not less than five hundred Maltese liri but not exceeding one thousand Maltese liri;

(b) on a second or subsequent convictions, to a fine (multa) of not less than one thousand Maltese liri, but not exceeding two thousand Maltese liri or to imprisonment for a term not exceeding two years, or to both such fine and imprisonment:

Provided that the court shall order any person who has been found guilty of committing an offence against these regulations to pay for the expenses incurred by the competent authority as a result of the said offence, the revocation of the permit issued by the competent authority and the confiscation of the *corpus delicti*.

20. (1) The provisions of articles 23 and 30 of the Criminal Code shall, *mutatis mutandis*, apply to proceedings in respect of offences against these regulations, so however that the disqualification from holding or obtaining a licence, permit or authority shall in no case be for less than one year. Applicability of the Criminal Code Cap.9.

(2) Notwithstanding the provisions of article 370 of the Criminal Code, proceedings for an offence against these regulations

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shall be held before the Court of Magistrates (Malta) or the Court of Magistrates (Gozo), as the case may be, and shall be in accordance with the provisions of the Criminal Code regulating the procedure before the said courts as courts of criminal judicature.

(3) Notwithstanding the provisions of the Criminal Code, the Attorney General shall always have a right of appeal to the Court of Criminal Appeal from any judgement given by the Court of Magistrates (Malta) or the Court of Magistrates (Gozo) in respect of proceedings for any offence against these regulations.

Language of
schedules.

21. The Schedules I to IV to these regulations are being published in the English language with the English text of these regulations.

ANNEX I

PARAMETERS AND PARAMETRIC VALUES

PART A

Microbiological parameters

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

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

Parameter	Parametric value
<i>Escherichia coli</i> (<i>E. coli</i>)	0/250 ml
Enterococci	0/250 ml
<i>Pseudomonas aeruginosa</i>	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 $[\text{nitrate}]/50 + [\text{nitrite}]/3 \leq 1$, the square brackets signifying the concentrations in mg/l for nitrate (NO₃) and nitrite (NO₂), 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.

⁽¹⁾ To be added following the outcome of the study currently being carried out.

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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
<i>Clostridium perfringens</i> (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	≥ 6,5 and ≤ 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 m³ 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.

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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 · 7H ₂ O	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 · 6H ₂ O	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.

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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 characteristics 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

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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