



Notification Number: 2008/514/E

SCO order/ / on alternative methods for the microbiological analysis of water for human consumption.

Date received : 17/11/2008

End of Standstill : 18/02/2009

Message

Message 002

Communication from the Commission - SG(2008) D/52230

Directive 98/34/EC

Translation of the message 001

Notification: 2008/0514/E

No abre el plazo - Nezahajuje odklady - Fristerne indledes ikke - Kein Fristbeginn - Viivituste perioodi ei avata - Καμμία έναρξη προθεσμίας - Does not open the delays - N'ouvre pas de délais - Non fa decorrere la mora - Neietekmē atlikšanu - Atidėjimai nepradedami - Nem nyitja meg a késések - Ma' jiftaħ il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Nao inicia o prazo - Neotvorí oneskorenia - Ne uvaja zamud - Määräaika ei ala tästä - Inleder ingen frist - He ce предвижда период на прекъсване - Nu deschide perioadele de stagnare - Nu deschide perioadele de stagnare.

(MSG: 200802230.EN)

1. Structured Information Line

MSG 002 IND 2008 0514 E EN 18-02-2009 17-11-2008 E NOTIF 18-02-2009

2. Member State

E

3. Department Responsible

Subdirección General de Asuntos Industriales, Energéticos, de Transportes, Comunicaciones y Medio Ambiente.

Dirección General de Coordinación del Mercado Interior y otras Políticas Comunitarias.

Secretaría de Estado de Asuntos Europeos.

Ministerio de Asuntos Exteriores.

C/ Serrano Galvache, 26, 4ª planta, Torre Sur (28071 Madrid)

Teléfonos: 91 379 84 64, 91 379 83 98 y 91 394 88 04

Fax: 91 379 84 01

Dirección correo electrónico: d83-189@ue.mae.es



3. Originating Department

SUBDIRECCION GENERAL DE SANIDAD AMBIENTAL Y SALUD LABORAL DE LA DIRECCION GENERAL DE SALUD PUBLICA Y SANIDAD EXTERIOR DEL MINISTERIO DE SANIDAD Y CONSUMO..

4. Notification Number

2008/514/E - C00A

5. Title

SCO order/ / on alternative methods for the microbiological analysis of water for human consumption.

6. Products Concerned

Quality of water for human consumption, analysis, alternative methods, laboratories, Escherichia coli and coliform bacteria.

7. Notification Under Another Act

-

8. Main Content

Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption, and its transposition in Royal Decree 140/2003 of 7 February setting out the health criteria for the quality of water for human consumption, specify the methodology to be used for its bacteriological analysis. In the case of coliform bacteria and Escherichia coli, the methodology specified is as described in the standard UNE EN ISO 9308-1:2000: Membrane filtration method using lactose TTC Agar with Tergitol incubated at $36\pm 2^{\circ}\text{C}$.

However, the European directive and national legislation allow for the use of other methodologies provided that data is provided to confirm that the alternative method is equivalent to or better than the reference methodology. In consideration of the difficulties in using this method experienced in the past by quality control laboratories for water for human consumption, a group of laboratories in the related sectors undertook to carry out an equivalency study based on the procedure ISO 17994:2004 (Water quality - Criteria for establishing equivalency of two microbiological methods) in accordance with the recommendations of the Expert Group on Microbiology, a consultative body of the European Commission.

The methods tested as alternatives for the analysis of coliform bacteria and Escherichia coli were the most-probable-number (MPN) method in liquid using defined substrate technology and the chromogenic agar method for coliforms. The results of this study, carried out using the culture methods and reagents described in the annex, demonstrated that both alternative methods produced results that were at least as reliable as the results obtained using the reference method.

Given that the Spanish exercise was ratified by the Expert Group on Microbiology in October 2007 and examined by the Environmental Health Working Group of the Inter-Regional Council of the National Health System, this order is proposed as an amendment to Royal Decree 140/2003 of 7 February to authorize the use of said methods as alternatives to the reference method in European and national legislation.

As a result and henceforth, in addition to the method provided for in Part A of Annex IV of the aforementioned royal decree, the methods provided for in this order may be used for the microbiological analysis of coliform bacteria and Escherichia coli.

Quality of water for human consumption, analysis, alternative methods, laboratories, Escherichia coli and coliform bacteria.



9. Brief Statement of Grounds

Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption specifies the methodology to be used for its bacterial analysis. In the case of coliform bacteria and *Escherichia coli*, the methodology specified is as described in the standard UNE EN ISO 9308-1:2000.

In consideration of the difficulties in using these methods experienced in the past by quality control laboratories for water for human consumption, it was necessary to carry out an equivalency exercise to confirm that the alternative method is equivalent to or better than the reference method.

10. Reference Documents - Basic Texts

a) Royal Decree 140/2003 of 7 February on health criteria relating to the quality of water for human consumption.

11. Invocation of the Emergency Procedure

Yes

12. Grounds for the Emergency

As the drinking-water quality control laboratories are awaiting approval of this regulation so that they can use the new alternative methods.

13. Confidentiality

No

14. Fiscal measures

No

15. Impact assessment

The financial report, supporting report and gender impact report were submitted to the departmental secretariat in mid May 2008.

16. TBT and SPS aspects

TBT and SPS aspects

TBT aspects:

a) Yes

SPS aspects:

a) No

The draft is not a sanitary or phytosanitary measure pursuant to Annex A of the SPS Agreement.

Catherine Day
Secretario General



Comisión Europea

Punto de contacto Directiva 98/34

Fax: (32-2) 296 76 60

email: dir83-189-central@ec.europa.eu

sent to :

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1
Frau MARKL Iris

European Free Trade Association
.

Malta standards Authority
Sarah Jane Meli

Kommerskollegium
Ms Gunnel Fälth

Slovenian Institute for Standardization SIST
Mrs Vesna Stazisar

Service de l' Energie de l' Etat
M.Romain Nies

Ministerio de Asuntos Exteriores DG de Coordinación del Mercado Interior
Sra. De Lezcano-Mújica Núñez, Margarita

Ministerio dell'industria
Sr. CASTIGLIONI Enrico

Ministry of Economy Dept for Economic Regulations
Mrs Barbara H. Kozłowska

Ministry of Economy and Commerce Division for Internal Market
Catalina Groza

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1
Frau Brigitte WIKGOLM

Erhvervs- og Byggestyrelsen/ National Agency for Enterpr.& Construct.
Bjarne Bang Christensen

Min. of Economic Affairs & Communication



Mr. Karl Stern

Min. of Industry, Energy & Technology
Mr K. Polychronidis

CU N Lovseth Hanne Leen

.

Ministerie van Financiën Belastingdienst - Douane Noord / CDIU
De Heer IJ.G. van der Heide

Instituto Português da Qualidade
Sra Eng^a. Anete Freitas

Bundesministerium für Wirtschaft und Bund Arbeit - Abteilung C2/1
Franz BORTH

Institut Belge de Normalisation
Mme F. Hombert

EU internal market coordination (Ministry of Economics)
Mr. Dainis Matulis

Dept for Innovation Univ & Skills Innovation Unit
Mr Philip Plumb

BELNotif (Qualité et Sécurité) SPF Economie, PME, Classes moyennes, Energ
M. Paul Caruso

Cyprus org. for the promotion of quality Ministry of Commerce, Industry & Tourism
M. Antonis Ioannou

Délégation Interministérielle aux Normes
Mme Piau

ELOT
Mrs. Tzolou Afroditi

NSAI
Mr Tony Losty

Service de l'Energie de l'Etat (ILNAS)
Mr Richard Berg

Lithuanian Standards Board
Daiva Lesickiene

Undersecretariat of Foreign Trade General Directorate of Standardisation
Mr Mehmet COMERT

Czech Office for Standards, Metrology and testing
Mrs Lucie Ruzickova



EFTA Surveillance Authority
Mr. Gunnar Thor PETURSSON

Työ- ja elinkeinoministeriö
Ms. Leila Orava

Bundesministerium für Wirtschaft und Arbeit - Abteilung C2/1
Ida CSISZAR

State Agency for Metrological and Technical Surveillance
Violetta Veleva

BundesMinisterium für Wirtschaft und Technologie (Referat EA3)
Frau Christina Jäckel

Hungarian Notification Centre Ministry of National Development and Eco
Mr Zsolt Fazekas

Ministero dello sviluppo economico Dipartimento per regolazione del mercato
Mr. Vincenzo Correggia

Office of standards, metrology & Testing Director of the department of European I
Mrs Kvetoslava STEINLOVA

sent to :

European Free Trade Association
.

Malta standards Authority
Sarah Jane Meli

Ministry of Economy and Commerce Division for Internal Market
Catalina Groza

CU N Lovseth Hanne Leen
.

Dept for Innovation Univ & Skills Innovation Unit
Mr Philip Plumb

NSAI
Mr Tony Losty

Undersecretariat of Foreign Trade General Directorate of Standardisation
Mr Mehmet COMERT



EFTA Surveillance Authority
Mr. Gunnar Thor PETURSSON

Työ- ja elinkeinoministeriö
Ms. Leila Orava

Représentation Permanente du Royaume-Uni
.

State Agency for Metrological and Technical Surveillance
Violetta Veleva

SL
.

Hungarian Notification Centre Ministry of National Development and Eco
Mr Zsolt Fazekas

Représentation Permanente de l'Irlande
Denis Colfer