



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Enforcement

Notification of Regulatory Barriers

Notification Number : 2021/0664/E (Spain)

Royal Decree laying down sanitary requirements for the prevention and control of legionellosis.

Date received : 15/10/2021

End of Standstill : 17/01/2022 (closed)

Message

Message 002

Communication from the Commission - TRIS/(2021) 03768

Directive (EU) 2015/1535

Translation of the message 001

Notification: 2021/0664/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 késéket - Ma' jiftaħx il-perijodi ta' dawmien - Geen termijnbegin - Nie otwiera opóźnień - Não 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: 202103768.EN)

1. MSG 002 IND 2021 0664 E EN 15-10-2021 E NOTIF

2. E

3A. Ministerio de Asuntos Exteriores, Unión Europea y Cooperación

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4. 2021/0664/E - S00S

5. Royal Decree laying down sanitary requirements for the prevention and control of legionellosis.

6. This decree affects any facility (fixed or mobile) in which Legionella is able to proliferate and spread and which are identified by the concurrence of two factors: using water and producing, or being susceptible to produce, aerosols.



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7. -

8. This Royal Decree has been drafted in order to protect the population from exposure to Legionella in facilities susceptible to its proliferation and spread by updating Royal Decree 865/2003 of 4 July 2003 laying down hygiene and health measures for the prevention and control of legionellosis in accordance with current technical and epidemiological knowledge of the disease and based on the experience acquired through its application.

This decree affects any facility (fixed or mobile) in which Legionella is able to proliferate and spread and which are identified by the concurrence of two factors: using water and producing, or be susceptible to produce, aerosols. Since there are other factors (e.g. design, maintenance, location, etc.) that affect a facility's level of risk, the classification of facilities according to their probability of proliferation and dispersion of Legionella has been eliminated. Instead, the risk category of each facility will be determined by its corresponding assessment results.

The obligation to notify these facilities (cooling towers or evaporative condensers) has been maintained as in the current legislation. However, it is possible for regional health authorities to extend the scope of this requirement to other facilities.

The regulations emphasise the responsibilities with regard to the design and materials used in the equipment and appliances used by facilities susceptible to multiplication and spread of the germ in question. Similarly, the use and maintenance instructions for aerosol cooling equipment or humidifiers for home use must include cleaning or disinfection guidelines to be observed by users.

Furthermore, the obligation to monitor Legionella extends to all facilities subject to the circumstances covered by the Royal Decree and not only to those identified as high-risk (facilities referred to in Article 2.2.1 of Royal Decree 865/2003 of 4 July 2003).

The two instruments identified for the control of Legionella are the Health Plan (PSL) (established on a voluntary basis) and the Legionella Prevention and Control Plan (PPCL). The first is based on continuous risk assessment of the facility following the recommendations of the World Health Organisation and adaptation of measures and controls according to the assessment results). For the first plan, the aspects to be integrated are set out (Evaluation of the system: identification of hazards, ranking of risks and identification of critical areas where improvements need to be made and a description of corrective and preventive measures to mitigate risks; Control and verification measures; Management and communication and evaluation of the PSL). Furthermore, for the second plan, the articles and corresponding annexes set out the general and specific aspects to be observed and the measures and actions to be taken by the facility manager or the companies responsible for the prevention and control of Legionella at a facility.

9. The proposal is based on the need to update the national legislation on Legionella prevention in accordance with the current science and the latest epidemiological information.

In addition, UNE 100030:2017 was updated in 2017 on the prevention and control of Legionella proliferation and dissemination in facilities. This regulation is complementary to the provisions of Royal Decree 865/2003 of 4 July 2003, currently in force in Spain, which has led to uncertainty as to the application of different aspects of the regulation, leading to legal uncertainty for the administration and for official control officers.

10. References from the basic texts: Royal Decree 865/2003 of 4 July 2003 laying down hygiene and health criteria for the prevention and control of legionellosis.

11. No

12. -

13. No



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14. No

15. Yes

16. TBT aspect

NO - The draft will have no discernible effect on international trade.

SPS aspect

NO - The draft will have no discernible effect on international trade.

European Commission

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