EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Numer powiadomienia : 2026/0273/FR (France)

Projet d'arrêté modifiant l'arrêté du 20 avril 2017 relatif au prétraitement par désinfection des déchets d'activités de soins à risques infectieux et assimilés

Data otrzymania : 02/06/2026
Koniec zawieszenia : 03/09/2026

Message

Message 001

Communication from the Commission - TRIS/(2026) 1478

Directive (EU) 2015/1535

Notification: 2026/0273/FR

Notification of a draft text from a Member State

Notification – Notification – Notifzierung – Нотификация – Oznámení – Notifikation – Γνωστοποίηση – Notificación – Teavitamine – Ilmoitus – Obavijest – Bejelentés – Notifica – Pranešimas – Paziņojums – Notifika – Kennisgeving – Zawiadomienie – Notificação – Notificare – Oznámenie – Obvestilo – Anmälan – Fógra a thabhairt

Does not open the delays - N'ouvre pas de délai - Kein Fristbeginn - Не се предвижда период на прекъсване - Nezahajuje prodlení - Fristerne indledes ikke - Καμμία έναρξη προθεσμίας - No abre el plazo - Viivituste perioodi ei avata - Määräaika ei ala tästä - Ne otvara razdoblje kašnjenja - Nem nyitja meg a késéseket - Non fa decorrere la mora - Atidėjimai nepradedami - Atlikšanas laikposms nesākas - Ma jiftaħx il-perijodi ta’ dewmien - Geen termijnbegin - Nie otwiera opóźnień - Não inicia o prazo - Nu deschide perioadele de stagnare - Nezačína oneskorenia - Ne uvaja zamud - Inleder ingen frist - Ní osclaíonn sé na moilleanna

MSG: 20261478.EN

1. MSG 001 IND 2026 0273 FR EN 02-06-2026 FR NOTIF

2. France

3A. Direction générale des entreprises
SQUALPI
Bât. Sieyès -Teledoc 151
61, Bd Vincent Auriol
75703 PARIS Cedex 13
d9834.france@finances.gouv.fr

3B. Ministère de la santé et de la prévention
Direction générale de la santé.
Sous-direction de la prévention des risques liés à l’environnement et à l’alimentation (SD-EA)
Bureau environnement extérieur et produits chimiques (EA1)
14 avenue Duquesne

75350 Paris 07 SP

Ministère de l'économie, des finances et de la souveraineté industrielle et numérique
Direction générale de la Concurrence, de la Consommation et de la Répression des fraudes
Bureau des produits et prestations de santé et des serv

4. 2026/0273/FR - S20E - Waste

5. Draft order amending the order of 20 April 2017 on the pre-treatment by disinfection of potentially infectious waste from healthcare activities and other comparable healthcare waste

6. Pre-treatment by disinfection of potentially infectious waste from healthcare activities and other comparable healthcare waste (DASRIA).

7.

8. The Order of 20 April 2017 on the pre-treatment by disinfection of potentially infectious waste from healthcare activities and other comparable healthcare waste (notified under number 2016/012/F) sets out the requirements for equipment used for the pre-treatment by disinfection of potentially infectious waste from healthcare activities and other comparable healthcare waste (DASRIA) and for the facilities that use such equipment. It makes the standard NF X 30-503-1:2016 on the 'reduction of microbiological and mechanical risks associated with potentially infectious waste from healthcare activities and other comparable healthcare waste through pre-treatment by disinfection – Part 1' mandatory.

Standard NF X30-503-1: 2016 was cancelled in April 2024 and replaced by standard NF X30-503-1: 2024 on 'Infectious waste (H9): reduction of microbiological and/or mechanical risks by physico-chemical treatment – Part 1: Specifications and tests for collectable solid and liquid waste'.

The amendments to the draft order relate to the change in the year of issue of this standard.
With effect from the day following the publication of the revised Order, standard X30-503-1: 2024 will become mandatory and standard NF X30-503-1: 2016 will be cancelled.

Summary of changes between standards NF X30-503: 2016 and NF X30-503: 2024

Standard NF X30-503: 2016
Title:
Waste from healthcare activities – Reduction of microbiological and mechanical risks associated with potentially infectious waste from healthcare activities and other comparable healthcare waste using disinfection pre-treatment equipment – Part 1: Specifications and tests

Standards references:
NF EN 13098:2000, Workplace atmospheres – Rules for the measurement of airborne microorganisms and endotoxin.

Terms and definition:
Waste similar to household waste
Waste from healthcare activities
Potentially infectious waste from healthcare activities
Comparable potentially infectious waste from healthcare activities
Packaged potentially infectious waste from healthcare activities

Pathogenic microorganisms
Group 4 pathogenic microorganisms
Liquid waste
Pre-treatment by disinfection

Infectious risk
Psycho-emotional risk
Mechanical risk
Treatment of waste from pre-treatment by disinfection

Tests in the air:
3 days – 3 cycles – 4 sampling points

Waste discards:
3 days – 9 cycles – 27 tests

IB bacterial spores / Number of tests:
3 days – 9 cycles – 27 tests

IB Fungal viruses / Number of tests:
3 days – 9 cycles – 27 tests

Criteria:
5 log spores – 4 log virus and fungal

Annex:
/

Revival:
Number of tests:
3 days – 3 cycles – 15 tests on day 28

Criteria:
< 2 log and absence of indicators

Annex:
/

Particle size distribution:
Miscellaneous cycle: entire load
Controlled cycle: 10% of capacity and a minimum of 100 L

Criteria:
miscellaneous: 90% < 30 mm
Controlled: 60% < 30 mm
in total: 80% < 30 mm

Number of tests:
15 tests (9 random samples + 6 controlled samples)

Mechanical tests:
/

Standard NF X30-503: 2024
Title:
Infectious waste (H9): reduction of microbiological and/or mechanical risks by physico-chemical treatment – Part 1: Specifications and tests for collectable solid and liquid waste

Standards references:
NF EN 13098: 2000, Workplace atmospheres – Rules for the measurement of airborne micro-organisms and endotoxin.
NFEN 866-1 – General requirements for biological indicators
NFENISO 11138-1 – General requirements for biological indicators
NF EN ISO 7218: General requirements and recommendations for microbiological analyses relating to bacteria, yeasts and mould

Terms and definition:
Infectious waste
Collectable infectious waste
Potentially infectious waste from healthcare activities

Pathogenic microorganisms
Group 4 pathogenic microorganisms
Liquid waste
Treatment of infectious waste by physico-chemical disinfection (decontamination)

Germ carrier
Inoculated germ carriers
Primary packaging
Secondary packaging
Biological indicator

Infectious risk
Risk posed

9. This draft amending Order is intended for professionals placing on the market disinfection pre-treatment equipment for potentially infectious and other comparable waste from healthcare activities (DASRIA) and professionals using this equipment.
At local level, facilities that operate such equipment (disinfection pre-treatment facilities) must be registered with the regional health agency (ARS) and the regional directorate for the environment, planning and housing (DREAL) in the area where they are located.
With regard to the monitoring of these facilities, the draft order defines that the tests are carried out in accordance with standard NF X30-503-1: 2024, or any other equivalent technique described in a standard issued by an EU Member State or another State party to the Agreement establishing the EEA, designed to reduce microbiological and/or mechanical risks through a pre-treatment device that disinfects potentially infectious and other comparable waste from healthcare activities.
In France, potentially infectious and other comparable waste from healthcare activities (DASRIA) is either incinerated or pre-treated by disinfection. In the absence of a harmonised European standard, France is regulating the placement on the market of potentially infectious and other comparable waste from healthcare activities (DASRIA) disinfection pre-treatment equipment due to their potential health and environmental impacts.

9a. The public interest objective aims to combat health risks to people. Disinfection pre-treatment equipment reduces the microbiological contamination of potentially infectious and other comparable waste from healthcare activities (DASRIA). Consequently, it helps to reduce the risk of accidental exposure to blood for healthcare professionals and for those

responsible for waste collection, whose work may involve handling waste generated by this equipment. Proper management of the disinfection process of this equipment contributes to the safety of healthcare professionals and waste disposal professionals.
The public interest objective also seeks to combat damage to the protection of the environment.
Making these appliances safe helps to limit the environmental dispersion, via potentially infectious and other comparable waste from healthcare activities (DASRIA), of germs from hospital flora, for example germs from known infectious illnesses, but also germs specifically associated with hospital flora (germs that are resistant to antibiotics or certain disinfectant biocides, and new strains of highly resistant bacteria). The emergence of new pathogens (e.g. human immunodeficiency virus, non-conventional transmissible agents, severe acute respiratory syndrome virus, Ebola virus, etc.) broadens the range of biological agents that may be present in these potentially infectious and other comparable waste from healthcare activities (DASRIA), and in the environment if appropriate treatment is not provided. ’
Industrialists wishing to place on the market equipment for the pre-treatment by disinfection of potentially infectious and other comparable healthcare waste (DASRIA) on the market are obliged to undergo tests to verify that thesis equipment guarantees a sufficient reduction in microbiological contamination of this waste and a level of safety that does not adversely affect the protection of the environment.
That framework and those objectives are those already provided for by the Order of 20 April 2017 and are based on standard NF X30-503-1:2016.
The purpose of the amendment to the 2017 Order is to update the references of standard NF X30-503-1: 2024, published in April 2024, replacing the 2016 version.
To confirm that these objectives have been met, manufacturers may refer to the tests set out in standard NF X30-503-1 on Healthcare waste – Reduction of microbiological and mechanical risks in potentially infectious and comparable healthcare waste through pre-treatment by disinfection (following the amended draft of 20 April 2017 relating to the pre-treatment by disinfection of DASRIA) or on any standard issued by an EU Member State or another State party to the Agreement establishing the EEA and aimed at reducing microbiological and/or mechanical risks through a device for the pre-treatment by disinfection of DASRIA.

9b. In France, potentially infectious and other comparable waste from healthcare activities (DASRIA) is either incinerated or pre-treated by disinfection. In the absence of a harmonised European standard, France is regulating the placement on the market of DASRIA disinfection pretreatment equipment due to its potential health and environmental impacts.
Manufacturers wishing to place equipment for the pre-treatment by disinfection of DASRIA on the French market may rely on the tests set out in standard NF X30-503-1 Waste from healthcare activities (as set out in the amended draft of 20 April 2017 relating to the pre-treatment by disinfection of waste from healthcare activities posing an infectious risk and similar waste) or on any standard issued by an EU Member State or another State party to the Agreement establishing the EEA and aimed at reducing microbiological and/or mechanical risks through a device for the pre-treatment by disinfection of DASRIA.
Furthermore, once published, the amended draft order of 20 April 2017 on the pre-treatment of DASRIA by disinfection will make standard NF X30-503-1 mandatory. Manufacturers wishing to consult the tests listed there may do so free of charge on the AFNOR website.
This draft order is compatible with the principles of the internal market. It is justified on grounds of public interest relating to the protection of consumers and the environment.
First, the purpose of the regulation is to enable a health risk to be controlled for individuals. Disinfection pre-treatment equipment reduces the microbiological contamination of potentially infectious and other comparable waste from healthcare activities (DASRIA). Consequently, it helps to reduce the risk of accidental exposure to blood for healthcare professionals and for those responsible for waste collection, whose work may involve handling waste generated by this equipment. Proper management of the disinfection process of this equipment contributes to the safety of healthcare professionals and waste disposal professionals.
Secondly, these regulations are designed to ensure that environmental risks are kept under control. Making these appliances safe helps to limit the environmental dispersion, via potentially infectious and other comparable waste from healthcare activities (DASRIA), of germs from hospital flora, for example germs from known infectious illnesses, but also germs specifically associated with hospital flora (germs that are resistant to antibiotics or certain disinfectant biocides, and new strains of highly resistant bacteria). The emergence of new pathogens (e.g. human immunodeficiency virus,

non-conventional transmissible agents, severe acute respiratory syndrome virus, Ebola virus, etc.) broadens the range of biological agents that may be present in these potentially infectious and other comparable waste from healthcare activities (DASRIA), and in the environment if appropriate treatment is not provided.

9c. It is the responsibility of any manufacturer wishing to market their medical waste pre-treatment equipment on the French market to base their testing – which must ensure the equipment's operational suitability in terms of managing infectious risks and protecting the environment – on the tests described in standard NF X30-503-1 (available free of charge on the AFNOR website once the amended order has been published) or those derived from any standard issued by an EU Member State or another State party to the Agreement establishing the EEA, the aim of which is to reduce microbiological and/or mechanical risks through the use of a pre-treatment device for the disinfection of potentially infectious and other comparable waste from healthcare activities (DASRIA).

In this respect, this measure is compatible with the internal market and proportionate in view of the objective of consumer and environmental protection set out above (see the section on 'necessity').

10. References to the basic texts:

11. No

12.

13. No

14. No

15. No

16.
TBT aspects: No

SPS aspects: No

****
European Commission
Contact point Directive (EU) 2015/1535
email: grow-dir2015-1535-central@ec.europa.eu