The Kingdom of Belgium

FEDERAL PUBLIC SERVICE, PUBLIC HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT

Draft Royal Decree determining the conditions for the placing on the market of air purification systems for the control of aerosol-transmissible viruses for purposes other than medical purposes.

PHILIPPE, King of the Belgians,

To all present, and those to come, Greetings.

Having regard to the Law of 21 December 1998 on product standards for the promotion of sustainable production and consumption patterns and the protection of the environment, health and workers, Article 5, §1, subparagraph 1(1), (2), (5) and (12), as amended by the Laws of 27 July 2011 and 16 December 2015;

Having regard to the Ministerial Decree of 23 November 2021 extending the measures taken in the Ministerial Decree of 12 May 2021 provisionally determining the conditions for placing air purification products on the market in the context of the fight against SARS-CoV-2 other than for medical uses;

Having regard to the opinion of the Data Protection Authority No 200/2022 of 9 September 2022;

Having regard to the involvement of regional governments in the preparation of this Decree, within the framework of the Interministerial Conference on the Environment of 29 September 2022;

Having regard to the communication to the European Commission of 28 October 2022, pursuant to Article 5(1) of Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services;

Having regard to the opinion of the Consumer Council, given on 23 November 2022;

Having regard to the opinion of the Central Economic Council, given on 23 November 2022;

Having regard to the opinion of the Federal Council for Sustainable Development, given on 23 November 2022;

Having regard to the opinion of the Finance Inspector, given on 28 November 2022;

Having regard to the opinion of the Superior Health Council, given on 4 January 2023;

Having regard to the opinion xx.xxx/x of the Council of State, given on dd-mm-yyyy, pursuant to Article 84(1), subparagraph 1(2) of the laws on the Council of State, consolidated on 12 January 1973;

Whereas the retention period referred to in Article 8 of this Decree is determined by Law of 21 December 1998 on product standards for the promotion of sustainable consumption and protection of the environment and health;

On the proposal of the Minister of Public Health and the opinion of the Ministers who have deliberated it in the Council;

I HAVE DECREED AND HEREBY DECREE:

Article 1. This Decree lays down the conditions for placing on the market air purification systems in the context of the fight against aerosol viruses, other than for medical uses;

Article 2. For the purposes of this Decree, the following definitions shall apply:

1. Aerosol: A collection of fine particles, solid or liquid, suspended in the air;

2. Contaminated air: indoor air that may contain aerosols contaminated by viruses;

3. Air purification system: technology capable of removing aerosols from contaminated air or deactivating viruses present, in accordance with the efficacy levels laid down in Articles 3 and 4;

4. Medical uses: products covered by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC;

5. Integrated air purification system: a combination consisting of one or more air purification techniques as referred to in points 7, 8, 9 and 10 and which can be installed in the ventilation, heating or air-conditioning system of a building or vehicle;

6. Autonomous air purification system: a combination consisting of one or more air purification techniques as referred to in points 7, 9 and 10, whether or not coupled in a regulatory manner to a ventilation, heating or air-conditioning system, moveable or fixed to a wall or ceiling, operating independently, and which may be installed in a room in a building or in a vehicle;

7. HEPA filter: HEPA filter class H13 or higher with a retention efficacy of at least 99.95 % according to standards NBN EN 1822:2019 or EN ISO 29463-5;

8. EPA filter: EPA filter class E12 or higher with a retention efficacy of at least 99.5 % according to standards NBN EN 1822:2019 or EN ISO 29463-5;

9. Electrostatic precipitator: air purification system equipped with a capture system for collecting suspended particles and aerosols by electrostatic effect. The efficacy levels are determined in Article 3 for integrated air purification systems and in Article 4 for autonomous air purification systems;

10. UV-C system: air purification system that uses UV-C light with a wavelength of between 240 and 280 nanometres. Systems can be open or closed. The efficacy levels are determined in Article 3 for integrated air purification systems and in Article 4 for autonomous air purification systems;

11. Test organism: *Bacillus subtilis* spores are used as a substitute for the various viruses present in aerosols.

12. CADR or Clean Air Delivery Rate: quantity of purified air per hour (expressed in m^3 per hour);

13. Ionisation: the process by which an atom or molecule loses or gains an electron from a neutral state by means of energy, becoming a charge-bearing particle, also known as an ion;

14. Public service: Federal Public Service, Health, Food Chain Safety and Environment, Directorate-General for Environment, Chemical Products and Substances Policy Division;

15. Efficacy and safety claim: written communication, including by means of symbols, concerning the levels of efficacy against aerosol viruses of autonomous and integrated air purification systems and the safety of these air purification systems for the health of the user, installer and the public, in spaces where the effects of these systems are expected.

    This communication shall be affixed to the packaging or any other information medium accompanying autonomous and integrated air purification systems, including online communication elements if reference is made to this online communication on the systems themselves or on their packaging, with the exception of references to the company's website which do not concern the efficacy against aerosol viruses and the safety of the system;

16. Minister: the Minister for Public Health.

Article 3. § 1. The integrated air purification systems meet technical requirements that guarantee system efficacy levels against aerosol viruses and ensure the safety of the product for the health of the user, installer and the public.
§ 2. The air purification systems to be integrated meet the following conditions:

1. In the case of the use of (H)EPA filters, they meet the EPA standard of class E12 or higher;

2. In the case of the use of (H)EPA filters, they are integrated into the ventilation, heating or air conditioning system, in a sealed enclosure to prevent any possible leakage, so that the total efficacy of the system is equal to the efficacy of the filter alone, throughout the unit's operating flow rate range.
   The manufacturer or person responsible for placing the system on the market shall provide instructions and conditions for its replacement in the technical documentation;

3. In the case of the use of electrostatic precipitators for the purification of contaminated air, the efficacy shall be at least that of EPA filters, throughout the operating flow rate range of the unit in which it will be installed;

4. In the event that an electrostatic precipitator is used, the precipitate collection system shall be replaceable. The manufacturer or person responsible for placing the system on the market shall provide instructions and conditions for its replacement in the technical documentation.
   The ozone production is displayed on the air purification system and must comply with the approved safety standard IEC 60335-2-65;

5. In the case of the use of a UV-C system, the wavelength of UV-C lamps must be guaranteed by the manufacturer or person responsible for placing the system on the market;

6. In the case of the use of a UV-C system for the purification of contaminated air, they must disable the test organism with an efficacy of at least 99.5 % over the entire operating flow range of the unit in which the UV-C system will be installed;

7. In the case of the use of a UV-C system, they shall comply with the EN ISO 15858 safety standards and be designed in such a way that the lamps are placed there in a housing from which no UV-C light can escape. The manufacturer or person responsible for placing the system on the market shall provide in the technical manual the instructions on the maintenance, the frequency of replacement of UV-C lamps and the preventive measures to be taken with regard to exposure in the event of any opening of the housing.

Article 4. § 1. Autonomous air purification systems meet technical requirements that guarantee system efficacy levels against aerosol viruses and ensure the safety of the system for the health of the user, installer and the public.
§ 2. Autonomous air purification systems meet the following conditions:

1. In the case of the use of HEPA filters for the purification of contaminated air, they meet class H13 or higher;

2. In the case of the use of HEPA filters, they are integrated into a hermetically sealed housing to prevent any possible leakage, so as to ensure that the total system efficacy is equal to the efficacy of the filter alone, throughout the range of the unit's operating flow rate range;

3. In the case of the use of HEPA filters, the manufacturer or person responsible for placing the system on the market shall provide instructions and conditions for its replacement in the technical documentation;

4. In the case of the use of an electrostatic precipitator for the purification of contaminated air, the efficacy shall be at least equal to that of HEPA class H13 filters, throughout the unit's operating flow rate range;

5. In the event that an electrostatic precipitator is used, the precipitate collection system shall be replaceable. The manufacturer or person responsible for placing the system on the market shall provide instructions and conditions for its replacement in the technical documentation. The ozone production is displayed on the air purification system and must comply with the approved safety standard IEC 60335-2-65;

6. Air flow rates of air purification systems that use a HEPA filter or electrostatic precipitator are:
   a. guaranteed by the manufacturer or person responsible for placing the system on the market;
   b. expressed in m^3 per hour under reference conditions of temperature at 20°C and atmospheric pressure of 1013.25 mbar;
   c. measured at the system outlet and with all the components provided by the manufacturer, according to standard NBN-EN-ISO 5801, Annex A "Determination of air flow", Article A.3 "Methods by exploration of the velocity field" and in accordance with Annex 1 to this Decree.

The air flow value expressed is equal to the measured air flow corrected in relation to the reference conditions according to the formula:

$$Dcorr = Dmes * \left(\frac{\frac{pa}{1013,25} * 293,15}{273,15 + ta} \right)$$

d. D_{corr} is the maximum air flow corrected to the reference conditions of 20°C and 1013.25 mbar, in m^3/h;
e. D_{mes} is the maximum measured air flow, in m^3/h;
f. *pa* is the atmospheric pressure in mbar;
g. *ta* is the average air temperature in °C;

The air flows of the system shall be indicated on the device or in the technical manual. If multiple air flows can be achieved, they must all be mentioned on the device or in the technical manual.

CADR is the result of the multiplication between efficacy and air flow of the air purification system. The manufacturer or person responsible for placing the system on the market shall communicate the CADR of his system.

The sound power level (Lw,A) of each air flow is mentioned in the technical manual. The sound level is expressed in decibels (dB(A)) and measured according to standards NBN EN ISO 3741 or NBN EN ISO 3743-2;

7. In the case of the use of a UV-C system, the manufacturer or the person responsible for placing the product on the market shall ensure compliance with points a to e.
   a. If the UV-C source is enclosed in the housing in which the air is treated (closed system), the system shall comply with the approved safety standard EN IEC 60335-2-65.
   b. If the system disinfects the air outside the housing with UV-C light (open system), the approved safety standards EN ISO 15858, EN IEC 62471 and IEC PAS 63313 shall be complied with.
   c. The purification of contaminated air shall be carried out with an efficacy of at least 99.95 % inactivation of the test organism throughout the system flow range, which is determined as described in AHAM AC-5 with the test organism, or in an equivalent international or national standard that also uses the test organism.
   d. Maintenance instructions and replacement intervals of UV-C lamps are given in the technical manual.
   e. The ozone production is displayed on the system and must comply with the approved safety standard IEC 60335-2-65;
   f. The system is only used in a room where the ventilation is at least equal to two air changes per hour. This installation requirement is mentioned on the system packaging and in the technical manual;

8. The air flows of UV-C systems with fan, are:
   a. guaranteed by the manufacturer or person responsible for placing on the market;
   b. expressed in m^3 per hour compared to the reference conditions of temperature at 20°C and atmospheric pressure of 1013.25 mbar;

c. measured at the system outlet and with all the components provided by the manufacturer, according to standard NBN-EN-ISO 5801, Annex A "Determination of air flow", A.3 "Methods by exploration of the velocity field" and in accordance with Annex 1 to this Decree. The air flow value expressed is equal to the measured air flow corrected in relation to the reference conditions according to the formula:

$$Dcorr = Dmes * \left(\frac{\frac{pa}{1013,25} * 293.15}{273,15 + ta} \right)$$

d. D_{corr} is the maximum air flow corrected to the reference conditions of 20°C and 1013.25 mbar, in m^3/h;
e. D_{mes} is the maximum measured air flow, in m^3/h;
f. *pa* is the atmospheric pressure in mbar;
g. *ta* is the average air temperature in °C;

The air flows of the system shall be indicated on the device or in the technical manual. If multiple air flows may be available, they must all be mentioned on the device or in the technical manual;

The manufacturer or person responsible for placing the system on the market must communicate the CADR. For closed and open UV-C air purification systems, CADR is determined as described in the AHAM AC-5 standard with the test organism, or in an equivalent internationally or nationally approved standard that also uses the test organism;

The sound power level (Lw,A) of each air flow is mentioned in the technical manual. The sound level is expressed in decibels (dB(A)) and measured according to standards NBN EN ISO 3741 or NBN EN ISO 3743-2.

9. For UV-C systems without fans, the manufacturer or person responsible for placing the system on the market shall specify:
   a. The CADR of his UV-C system. For closed and open UV-C air purification systems, the CADR is determined as described in the AHAM AC-5 standard or in an equivalent internationally or nationally approved standard that also uses the test organism;
   b. The sound power level (Lw,A) for each position is given in the technical manual. The sound power level is expressed in decibels (dB(A)) and measured according to standards NBN EN ISO 3741 or NBN EN ISO 3743-2.

Article 5. § 1. Autonomous and integrated air purification systems which consist of one or more of the following techniques, with or without ventilation, shall not be placed on the market:
1. Systems using the generation and dosed release of ozone in a given location;
2. Systems using cold plasma;
3. Systems using UV-C light with a wavelength below and above the limit of 240-280 nm;
4. Systems that combine UV and photo-catalytic solids (mainly TiO_2);
5. Systems using air ionisation without capturing precipitates;
6. Systems using the dosed release of hydrogen peroxide into space or air flow.

§ 2. The Minister may authorise exemptions on the basis of the opinion of the public service.

The exemptions concern autonomous and integrated air purification products referred to in paragraph 1 and are obtained individually. Exemptions shall be valid for three years from the date on which they are obtained.

Requests for exemption shall be submitted to the public service on the following website:
http.//.....
Requests for exemption shall be assessed on the basis of a complete, detailed and structured file as follows:

1. A summary of the file structured according to points 2 to 9. The evidence and other documents which validate the conformity of the air purification system shall be appended to the summary;
2. Identification of the applicant: surname and first name, business address, telephone number, business email address;
3. A description of the complete system, its constituents, a technical drawing and the mode of operation of the complete product;
4. System manual in which the conditions of maintenance, use and installation are described.
5. Tests, trials and reports on the levels of efficacy against aerosol viruses of the complete system, as well as the conclusions which the manufacturer or the person responsible for placing on the market ensures that his product is effective according to the following standards, carried out by an accredited laboratory:
    a. at least the efficacy of an EPA class E12 filter if the technology referred to in §1, points 1-6 shall be installed in an integrated system;
    b. at least the efficacy of a HEPA H13 filter if the technology referred to in §1, points 1-6 shall be installed in an autonomous device;
6. Ensuring the levels of efficacy of the system against aerosol viruses for a given time of use and the measures taken to ensure these levels of efficacy over time;
7. Scientific evidence of the safety of the product to the health of the user, installer and the public so that no adverse health effect can be identified. This evidence is provided by the results of tests carried out in an accredited laboratory;
8. A description of the conditions for installation, maintenance and use of the product in an environment to be treated;
9. A description of the conditions of installation and use under which the system cannot be used;
10. A description of the conditions for disposing of equipment contaminated with the virus.

Only complete applications will be accepted and processed.
The public service shall communicate its reasoned opinion to the Minister within 30 working days of the application for exemption.

The Minister may refuse an application for exemption due to the lack of evidence of efficacy of the product against aerosol viruses or the lack of evidence of the safety of the product to the health of the user, installer or public, in spaces where the effects of the product are expected.

When the Minister accepts an application for exemption, it shall be notified to the applicant and published on the public service website. Only data relating to products that benefit from an exemption are published on the website, no personal data.

Article 6. § 1. For the purposes of market surveillance, the manufacturer or person responsible for placing on the market autonomous or integrated air purification systems who make claims of efficacy or safety against aerosol viruses shall use the label provided by the public service.

This label attests that the air purification system has been recognised by the public service as complying with the obligations set out in this Decree. The public service publishes a list of recognised air purification systems on the FPS Public Health website.

The above-mentioned label is the only way to communicate about the recognition process.

§2. To obtain a recognition label, the manufacturer or person responsible for placing an air purification system on the market must submit a technical file via the website http.//.....

The label awarded confirms that the technical file submitted by the manufacturer or the person responsible for placing the system on the market complies with the obligations set out in this Decree.

Only complete files will be accepted and processed.
The file contains the following information:

§ 2. The following information is requested:

1. The name of the product/trade name;
2. The person responsible for placing on the market/manufacturer: surname and first name/company name, business address, telephone number, business email address;
3. The contact person: first name, surname, telephone number and business email address;
4. System manual in the national languages in which the conditions of maintenance, use and installation are described;
5. Information on how to combat viruses: HEPA filter/EPA filter/electrostatic precipitator/UV-C;
6. Tests, trials and reports on the levels of efficacy against aerosol viruses on the complete system as well as the conclusions that lead the manufacturer or the person responsible for placing the product on the market to ensure that his product is effective according to the standards listed in Article 3, § 2 or in Article 4 § 2 carried out by an accredited laboratory;
7. Scientific evidence of the safety of the product to the health of the user, installer and the public, so that no adverse health effect can be identified. This evidence is demonstrated by results of tests carried out in an accredited laboratory;
8. The results and reports of the tests, trials and measurements referred to in Article 4(2), 6., 7. and 8. ;
9. Product dimensions (length x width x height);
10. The weight of the product, in kg;
11. The electric voltage used, in volt (V), and the power at rated power, in kW.

Only complete files will be accepted and processed.
Article 7. § 1. Checking the compliance of systems referred to in Articles 3 and 4 and systems referred to in Article 5 which have benefited from an exception by the public service in shops or online shopping platforms shall require tests and measurements by an accredited laboratory.

§ 2. For the purposes of the tests and measurements referred to in paragraph 1, the manufacturer or person responsible for placing autonomous or integrated air purification systems makes two identical devices available to the public service free of charge;

§ 3. The public service shall affix seals to the two systems referred to in paragraph 2. The manufacturer or person responsible for placing autonomous or integrated air purification systems on the market,

deliver the first device to the approved laboratory; the second device is kept by the manufacturer or the person responsible for placing autonomous or integrated air purification systems on the market;

§ 4. The second device shall be delivered to the accredited laboratory for a second opinion.

In this case, all costs are borne by the manufacturer or person responsible for placing autonomous or integrated air purification systems on the market;

§ 5. The accredited laboratory shall forward the analysis report to the competent department.

Article 8. The public service shall be solely responsible for the processing of personal data under Articles 5, 6 and 7.

The maximum retention period for personal data to be processed is provided for in Article XX of the Law of 21 December 1998 on product standards for the promotion of sustainable consumption and protection of the environment and health.

Article 9. This Decree shall enter into force 30 days after its publication in the Moniteur Belge.

Article 10. The Minister for Public Health shall be responsible for the implementation of this Decree.

Made at Brussels, on ….

PHILIPPE,
By the King:

The Minister for Public Health,

Frank VANDENBROUCKE

Annex 1 pursuant to Articles 3 and 4: Methodology for measuring air flow

The measurement of the air flow consists in the measurement of the average air velocity (in m/sec) at the device outlet multiplied by the blowing surface in m^2 and multiplied by 3600. The result is expressed in m^3/h.

The determination of the average air velocity consists in measuring the air velocity in at least 10 points distributed logically and geometrically to cover the entire blowing surface.
The series of at least 10 different points will give an initial average value of the air velocity. This series has to be repeated twice more to enable the robustness of the measurement carried out by the operator to be assessed. A difference in average velocities between series of maximum ± 5% relative is acceptable. The final value taken into account is the average of all three series.

For devices that expel air with a turbulent flow, it is necessary for measurement purposes to apply an accessory to reduce disturbances in the outflow. Either use a flow rectifier or use a straight nozzle whose length is at least 3 times the diameter of the nozzle and which extends the flow to ensure a less turbulent speed in order to measure a realistic average speed.

Seen to be annexed to our Royal Decree of ...../...../..... determining the conditions for the placing on the market of air purification products for the control of aerosol-transmissible viruses for purposes other than medical purposes.

Philippe,
By the King:

The Minister for Public Health,

Frank VANDENBROUCKE