FRENCH REPUBLIC

Ministry of […]

Order amending the Order of 22 June 2012 on conditions for the placing on the market and implementation of membrane filtration modules used in the treatment of water intended for human consumption

NOR:

Public concerned: *Manufacturers of membrane filtration modules, water treatment professionals, local authorities, and people responsible for the production and distribution of water.*

Subject: *Modification of the Order of 22 June 2012 on conditions for the placing on the market and implementation of membrane filtration modules used in the treatment of water intended for human consumption based on Article R. 1321-50 (I and II) of the French Public Health Code*

Entry into force: *the Order shall enter into force on […]*

The Minister of Health, Families, Autonomy and Persons with Disabilities,

Having regard to 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 Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption;

Having regard to the French Consumer Code and in particular Articles L. 121-1 and L. 212-1 thereof;

Having regard to the Public Health Code, in particular Articles L. 1321-4, R. 1321-48 and subsequent;

Having regard to the Order of 18 August 2009 on the conditions for authorising laboratories pursuant to Article R. 1321-52 of the French Public Health Code;

Having regard to the Order of 22 June 2012 on conditions for the placing on the market and implementation of membrane filtration modules used in the treatment of water intended for human consumption based on Article R.1321-50 (I and II) of the French Public Health Code;

Having regard to the Opinion of the French Agency for Food, Environmental and Occupational Health & Safety of 16 May 2025,

Having regard to notification No 2025/XXXX/F addressed to the European Commission on XX/XXX/2025,

Hereby orders:

Article 1

In Article 13 of the Order of 22 June 2012, the words: 'in the Official Journal' are replaced by the words: 'on the website of the Ministry of Health'.

Article 2

Article 21 of the same Order is amended as follows:

1° In section I, after the words: 'health authorities' the following shall be inserted: 'and the person responsible for the production and distribution of water,';

2° In the first subparagraph of section II, after the words: 'pilot trials', the following words are inserted: 'carried out in accordance with the procedures set out in Annex 7,'.

Article 3

Annexes 6 and 7 to the element: 'Annexes' to the same Order are replaced by two Annexes 6 and 7 worded as follows:

'Annex 6. - RECOGNISED CLAIMS OF EFFICACY OF MEMBRANE PROCESSES

WITH REGARD TO THE RETENTION OF TARGET PARAMETERS/COMPOUNDS

'The target parameters and compounds for treatment using membrane processes and recognised claims of efficacy are presented in the table below. The claims that are not mentioned relate to the provisions laid down in Article R. 1321-50-IV of the French Public Health Code.

'The installation of membrane filtration modules in a facility producing water intended for human consumption may not be considered as a disinfection stage for the water produced.

'

Type of membrane filtration // Parameters/compounds treatment targets (1)	Microfiltration (pore size between 0.05 and 0.5 µm (2))	Ultrafiltration (cut-off weight between 1,000 and 200,000 Daltons(2))	Nanofiltration (3) (cut-off weight between 100 and 1,000 Daltons(2))	Reverse osmosis (3) (cut-off threshold ≤ 100 Daltons(2))
Turbidity/suspended matter	X	X	X(4)	X(4)
Giardia cysts/Cryptosporidium oocysts	X	X	X	X
Bacteria	X	X	X	X
Virus		X	X	X
Monovalent and divalent ions, including micropollutants/inorganic molecules			X(5)	X
Micropollutants/Organic molecules			X	X
Dissolved organic matter			X	X

(1) Provided that a module integrity verification protocol is implemented for the filtration membrane with sufficient frequency, as defined in the instructions for use by the person responsible for market placement.

(2) Indicative data.

(3) It is important to remember that water treated by nanofiltration and reverse osmosis must be brought back to a balanced calcium-carbonate level: it is recommended that the water be restored to a hydrotimetric titre and a complete alkalimetric titre of at least 8°f (8°f = 80 mg.L-1 expressed in CaCO3 or 1.6 méq.L-1) and to a pH that allows for slight scaling and is close to 8.

(4) Considering the cut-off threshold of nanofiltration and reverse osmosis, these processes are capable of rejecting suspended solids responsible for turbidity. However, in order to avoid the risk of clogging, it is not customary to employ them for this purpose. Often pre-treatment is used upstream to prevent this clogging.

(5) With less efficiency than reverse osmosis for monovalent ions.

'Annex 7. - OPERATIONAL CONDITIONS FOR EVALUATING THE EFFICACY

'OF PROCESSES IMPLEMENTING MEMBRANE FILTRATION MODULES

'I. – Implementation of pilot tests

'The pilot tests shall be carried out on water which may be changed by artificial doping. Doping is adjusted to the upper limit of use of the membrane filtration module, as defined by the person responsible for placing the product on the market in his instructions for use, that is to say, to the limit beyond which the modules are likely to undergo abnormal degradation or the efficacy of the process is not guaranteed. Failing this, the adjustment of the contamination is made at a level so that the claims and reduction rates recommended are demonstrated by a statistical analysis of the data obtained for each parameter concerned.

'The implementation of tests and the monitoring of the operational parameters of the module and of the quality of the water (in particular the continual sensors) shall be conducted under quality assurance. All outsourced analyses are carried out by a laboratory accredited for sampling operations and for the analysis of all monitored physical-chemical and microbiological parameters (or European equivalent).

'II. — Expression of results

'The test results shall be presented as a concentration of the quantified fraction of the elements present in the permeate compared to the concentration present in the water supplying the pilot, using reduction or the retention rate:

Abatement is defined as the ratio between the concentrations of a compound in the filtrate and in the retentate. The decimal logarithm of this value (marked as "LRV", maximum retention rate) is defined as:

'LRV = log (100/[100-R]),

where R is the retention rate in %.

The retention rate is defined as the fraction of elements retained, relative to the fraction that would pass through the permeate if the membrane offered no selectivity:

'R(%) = 100 × (1-Cpermeate/Cretentate)

'or

'R(%) = 100 × (1 — exp [-LRV])

'Two categories of claims may be considered, concerning:

'— either on a reduction of viruses, bacteria, algae, parasites, suspended solids, colloids, etc.;

'— or a reduction, selective or not, of dissolved molecules and ions in the water to be treated.

'The efficacy claims shall be presented for each parameter target, with the operating conditions.

'III. — Demonstration of the efficacy of processes implementing membrane filtration modules in the case of retention

'III.-1. Retention of microorganisms:

In the case of a claim regarding the retention of microorganisms by the membrane filtration module, the person responsible for placing the product on the market shall present the results of tests carried out under various operating conditions, following protocols validated by an accredited laboratory.

'The operating conditions chosen to carry out each test (permeate output, pressure, conversion rates) correspond to the conditions in which the membrane filtration module should operate in the actual facilities.

'All the tests shall be carried out in accordance with the recommendations of the person responsible for the market placement. Doping of water by microorganisms can lead to the addition of agglomerated microorganisms that can bias the retention rate. The laboratory carrying out the tests shall specify the installation conditions. Non-filtered water must be contaminated to a sufficiently high level in order to determine the reductions obtained by the membrane filtration module.

'III.-2. Retention of particles and colloids:

'The membrane treatments which form the physical stages for water clarification (surface waters or waters affected by surface waters) and the turbidity of filtered water shall comply with the regulations in force and should strictly be less than 0.5 NFU which shall include the uncertainty of the analytical method. This limit shall be verified for the maximum permissible raw water turbidities on the membrane filtration module claimed by the person responsible for placing the product on the market.

'The operating conditions chosen to carry out each test (permeate output, pressure, conversion rates) correspond to the conditions in which the membrane filtration module should operate in the actual facilities.

IV. — Demonstration of the efficiency of the processes installing the membrane filtration modules in the case of selective membranes of dissolved compounds

'Selective membranes contribute to modify the composition of dissolved elements in water (macromolecules, mineral or organic ions, molecules) and also to the reduction in microorganisms. In this respect, they shall undergo the tests referred to in the previous paragraph. However, leaks from

the joints of the membrane system remain possible and are even more likely as the pressure applied is increased.

'For each target parameter, the person responsible for placing the product on the market shall present the results of tests carried out under various operating conditions, in accordance with protocols validated by an accredited laboratory. The results for the retention of solutes obtained by the pilot tests shall be provided in the form of retention rates under the following conditions:

'— use of water with identical quality for all the tests. The definition of water quality is left to the discretion of the person responsible for placing the product on the market, under the supervision of the laboratory. The variables, such as temperature, ionic force or conductivity, turbidity and the pH of each test should be specified. The person responsible for the market placement shall ensure that these conditions are representative of real situations;

'Definition of operating conditions (permeate flow, pressure, hydrodynamic conditions in the module) corresponding to conditions recommended by the person responsible for placing the product on the market.

'The elements, including the retention rate recommended, are those which may affect the quality of water (major ions or micropollutants). Extrapolation of the results for other elements/compounds or molecules that have not been tested is not possible. '

Article 4

This order shall be published in the Official Journal of the French Republic.

Dated

For and on behalf of the Minister:

The Director-General for Health;