

Ministerial Order of 6 August 2012

on the content and the conditions for the presentation of the annual declaration on substances at nanoscale, in application of articles R. 523-12 and R. 523-13 of the Environment code

NOR: DEVP1227946A

Publics concerned: Companies producing, distributing and importing substances at nanoscale or nanomaterials, private and public research laboratories.

Object: Content and the conditions for the presentation of the annual declaration on substances at nanoscale, in application of articles R. 523-12 and R. 523-13 of the Environment code

Entry into force: 1st January 2013.

Notice: Articles L. 523-1 to 5 of the Environment code provide for the implementation of a mandatory declaration procedure for the quantities and uses of substances at nanoscale produced, distributed or imported in France. This procedure is intended to improve the knowledge of nanomaterials and their uses, to ensure the traceability of sectors using these substances, to improve the knowledge of the market and the volumes sold, and to obtain available information on toxicological and ecotoxicological characteristics. The procedure for the application of these articles is defined in articles R. 523-12 to 20 of the Environment code. These articles particularly specify the definitions, minimum threshold for and frequency of declarations, and provisions on the protection and confidentiality of data and sanctions.

In application of articles R. 523-12 and R. 523-13 of the Environment code, this order, co-signed by the Ministers of the environment, agriculture, health, labour and industry, specifies the **content and conditions for the presentation of the declaration of substances at nanoscale**, provided for in article L. 523-4. This order particularly defines the information to be provided to characterise the identity of the declaring party, the identity of the substance at nanoscale, its uses and the quantities of the substance at nanoscale produced, distributed or imported. This order also provides that the declaration must generally be submitted electronically.

References: this order can be consulted at the Légifrance site (www.legifrance.gouv.fr).

The Minister of Social Affairs and Health, the Minister for Productive Recovery, the Minister of Ecology, Sustainable Development and Energy, the Minister of Labour, Employment, Professional Training and Social Dialogue and the Minister of Agriculture, Agrofood and Forestry,

Having regard to directive 98/34/EC of the European Parliament and the Council of 22 June 1998 amended, providing for the distribution of information in the field of standards and technical regulations and rules on the information Society;

Having regard to the Environment code, in particular its articles L. 523-1 to L. 523-4, R. 523-12 and R. 523-13;

Having regard to the Defence code, particularly article L2311-2;

Having regard to notification no. 2011/673/F of 29 December 2011 addressed to the European Commission in application of the aforementioned directive 98/34/EC (and the response by the European Commission of 30 March 2012),

Orders:

SECTION I SCOPE

Article 1

I - According to this decree, the term:

Declaring party: any party which must submit the declaration mentioned in article R. 523-13 of the Environment code.

II – The minimum proportion mentioned in article R. 523-12 of the Environment code, of particles with one or more external dimensions in the size range 1 nm - 100 nm, is defined as 50% of the number size distribution.

SECTION II CONTENT OF THE DECLARATION

Article 2

I – The information included in the annual declaration mentioned in the aforementioned article R. 523-13 is defined in appendix to this order. Some of the items of information identified as such in the appendix are considered as confidential, without need for the declaring party to specifically request this status.

II – The items of information mentioned in II-2 of the appendix to this order must be supplied by the declaring party, if the latter holds this information, particularly in application of other regulatory provisions. Should the declaring party not hold this information, the former must provide justification for the non-availability.

III – If the items of information mentioned in II of the appendix to this order are based on a determination method, the declaring party shall retain the detailed results and hold these results at the disposal of the administrative authority.

SECTION III CONDITIONS FOR THE DECLARATION

Article 3

I – A unique declaration reference is allocated to all declarations submitted. This reference shall be provided to the declaring party.

II – If the declaring party transfers a substance at nanoscale free of charge or for consideration, on its own or contained in a mixture without being linked to it, or a material intended to reject such a substance under normal or reasonably foreseeable conditions of use, to a professional user or a distributor, the declaring party shall transmit the corresponding declaration reference.

III – If the declaring party is a distributor, the former may provide a declaration reference which it obtained instead of the information mentioned in II of the appendix to this order, in its declaration.

This declaring party may not access the content of the corresponding information, with the exception of point II 1-a) (i) of the appendix to this order. If a substance at nanoscale is contained in a mixture with a mass concentration equal to or higher than the applicable minimum threshold for consideration for the purposes of classification, the information mentioned in II 1-a) (ii) may be accessed by distributors.

IV – If the declaring party is an importer, and at its request, the information mentioned in II of the appendix to this order may be declared:

- by the European legal entity having transferred the substance at nanoscale, on its own or contained in a mixture without being linked to it, or in a material intended to reject such a substance under normal or reasonably foreseeable conditions of use, or by its mandated European representative.
- by the mandated European representative of the legal entity, if the latter is based outside of European territory.

In this case, the importer may provide a declaration reference, provided by the legal entity having transferred the substance or by its mandated representative, in the declaration instead of the information mentioned in II of the appendix to this order.

The importer may not access the content of the corresponding information, with the exception of point II 1-a) (i) of the appendix to this order. If a substance at nanoscale is contained in a mixture with a concentration equal to or higher than the applicable minimum threshold for consideration for the purposes of classification, the information mentioned in II 1-a) (ii) may be accessed by distributors.

Article 4

I – If the declaring party produces, imports, or distributes a substance at nanoscale, on its own or contained in a mixture without being linked to it, or in a material intended to reject such a substance under normal or reasonably foreseeable conditions of use, in the context of scientific research and development activities or product and process-orientated research and development activities, the party concerned shall specify if this substance is placed on the market.

II – If the substance is produced, imported or distributed in the context of scientific research and development activities without being placed on the market, the declaration may be limited to the information mentioned in I of the appendix to this order.

Article 5

Without prejudice to the provisions of article 4, the annual declaration mentioned in the aforementioned article R. 523-13 shall be considered complete if all of the mandatory items of information mentioned in the appendix to this order have been provided by the declaring party, as well as the justification mentioned in II of article 2 of this order.

SECTION IV PROCEDURE FOR THE TRANSMISSION OF THE DECLARATION

Article 6

The annual declaration mentioned in the aforementioned article R. 523-13 must be addressed electronically, with the exception of classified documents as defined in article R. 2311-2 of the Defence code, which shall be transmitted by the appropriate means.

Article 7

The provisions of this order shall enter into force on 1st January 2013.

Article 8

The Director General of health, the Director General of competitiveness, industry and services, the Director General of risk prevention, the Director General of labour and the Director General of food are all responsible for, each in their respective domains, the execution of this order, which shall be published in the French *Journal officiel* (JORF).

On 06 August 2012.

The Minister of social affairs and health
On behalf of the Minister and by delegation:
The Director General of health,

J-Y. GRALL

The Minister for productive recovery;
On behalf of the Minister and by delegation:
The Director General of competitiveness, industry and services,

L. ROUSSEAU

The Minister of ecology, sustainable Development and energy
On behalf of the Minister and by delegation:
The Director General of risk prevention,

L. MICHEL

The Minister of labour, employment, professional
training and social dialogue
On behalf of the Minister and by delegation:
The Director General of labour,

J-D. COMBEXELLE

The Minister of agriculture, agrofood and forestry
On behalf of the Minister and by delegation:
The Director General of food,

P. DEHAUMONT

Appendix: information to be declared

I – Identity of the declaring party

I-1. The declaring party provides specific identification data for the company and the sites concerned by the declaration.

I-2. The declaring party indicates its status (manufacturer, distributor, importer) and the business segment.

In the circumstances provided for in IV of article 3, extra-national legal entity or mandated representative shall be indicated as the status.

I-3. If the declaring party performs scientific research and development activities or product- and process-orientated research and development activities, the declaring party shall specify if the substance is placed on the market.

II – Identity of the substance at nanoscale. This entry shall correspond to the following items:

II-1 Mandatory information:

a) Chemical identification of the substance: the substance shall be identified using:

(i) its chemical name,

(ii) its chemical formula, CAS number and, if applicable, its EC reference (EINECS or ELINCS).

b) If this substance is placed on the market as such under a commercial name, specify the latter.

c) Size of the particles: mean particle size, associated with a standard delta, with indication of the determination method used.

d) Number size distribution for particles: a graph showing the number size distribution shall be provided, with indication of the determination method used.

e) Aggregation and agglomeration state: mean size of aggregates and, if the substance is sold in an agglomerated form, mean agglomerate size, with standard delta for each if available. The declaring party shall specify the determination method used.

f) Shape: qualitative description of the shape of the particle, with indication of the determination method used.

g) If necessary, qualitative description of any coating of the particle.

h) The declaring party shall specify if:

- the substance is pure

- the substance is contained in a mixture without being linked to it, or

- if the substance is contained in a material intended to reject the substance under normal or reasonably foreseeable conditions of use.

For mixtures, the declaring party shall specify the state of the mixture containing the substance (solid, liquid, gas, powder).

II-2 Information to be disclosed if available at the time of the declaration:

- a) If the substance has been registered by the declaring party in the context of EC regulation no. 1907/2006 (REACH), the registration number must also be provided. The part of the registration number referring to the individual declaring party is not mandatory.
- b) The presence of any impurities: nature and quantity of each impurity with a mass concentration in the substance at nanoscale equal to or higher than 0.1%, or lower than this threshold if this information is mandatory according to other regulatory provisions.
- c) Crystalline state: nature of crystallographic phases and, if phases are mixed, the proportion of each phase, including the amorphous phase if existing.
- d) Specific surface: mean specific surface, associated with a standard delta, with indication of the determination method used.
- e) Surface charge: zeta potential, specify the medium and pH conditions.
- f) The information provided for in II, with the exception of point II-1 a) (i), is considered as confidential, without need for the declaring party to request this status.

III – Quantity of the substance at nanoscale produced, distributed or imported during the year covered by the declaration: expressed in kilograms.

Quantity information is considered as confidential, without need for the declaring party to request this status.

IV – Uses of the substance at nanoscale:

- a) Without prejudice to the provisions of article R 2311-2 of the Defence code, the declaring party must specify the planned uses of the substance at nanoscale.
- b) The declaring party must indicate, as applicable, the commercial names of the mixture or the material, which it places on the market itself.
- c) The declaring party may also indicate the claimed properties, on which basis the substance at nanoscale is used, however this information is optional.

Information on the commercial name of the mixture or the material shall be systematically considered as confidential, without need for the declaring party to request this status.

V – Identity of professional users to which the declaring party has transferred the substance at nanoscale

Information on the identity of professional users shall be considered as confidential, without need for the declaring party to request this status.