R-Nano

User Manual V.1.3. - November 2016

Contents

1 Introduction – The application's home page 3

2 Version / language 3

3 General rules 3

4 Registration 5

4.1 Description of the process 5

4.2 Account activation 8

5 Declarer dashboard 9

6 The declaration 13

6.1 Information on the declaration 13

6.1.1 Description of the fields to be completed 13

6.1.2 Derogation from the Ministry of Defence 16

6.1.3 Simplified declaration for public research organisations 17

6.2 Identity of the declarer 17

6.3 Identity of the substance, fields to be completed 18

6.4 Quantity 30

6.5 Uses 30

6.6 Clients (professional users) 31

6.7 View history 33

7 Scientific R&D without substances being placed on the market 33

8 Importing data by entering a declaration number 33

9 Loading/exporting in XML format 36

10 Duplicating a declaration 38

11 Modifying a submitted declaration 38

12 Declarant Assistance - Contact Box 40

1 Introduction – The application's home page

The home page includes a legislative and regulatory documentation section. The laws and regulatory documents governing annual declarations are as follows:

- **French Environment Code – legislative part**: Articles L. 523-1 to L. 523-5
- **French Environment Code – regulatory part**: Articles L. 523-12 to D. 523-22
- **Ministerial Decree no. 2012-232 of 17 February 2012** relating to annual declarations of substances with nanoparticle status pursuant to Article L. 523-4 of the French Environment Code
- **Ministerial Order of 6 August 2012** relating to the content and submission conditions of annual declarations of substances with nanoparticle status pursuant to Articles R. 523-12 and R. 523-13 of the French Environment Code
- **The notices in the Official Journal of the French Republic of 1 and 10 January 2013**
- **Ministerial Order of 24 January 2013** defining submission and examination conditions for derogation requests relating to the public disclosure of annual declarations of substances with nanoparticle status pursuant to Article R. 523-20 of the French Environment Code

2 Version / language

The R-Nano application is offered in French and English versions.
You can access the English/French version of the website by clicking on "English" or "Français" in the upper right hand corner of the banner on the home page and all other pages.

The text available on this site was written in French and has been translated into English to facilitate the dissemination of information. However only the French version shall prevail.

3 General rules

Prior to 30 April each year, a declarer must make a declaration for each substance with nanoparticle status manufactured, imported and/or distributed during the previous calendar year.

In accordance with Article 6 of the Ministerial Order of 6 August 2012 relating to the content and submission conditions of annual declarations of substances with nanoparticle status, the annual declaration should be submitted electronically, except when it comprises classified documents in accordance with Article R. 2311-2 of the French Defence Code.

Structure of the declaration

The declaration is divided into six main parts:

- Information on the declaration ;
- Declarer identity ;
- Substance identity (pure, contained in a mixture, or material);
- Quantity;
- Uses ;
- Users (professional users);

An additional tab:

- View history.

Mandatory nature of certain fields

Fields marked with an asterisk (*) are mandatory.

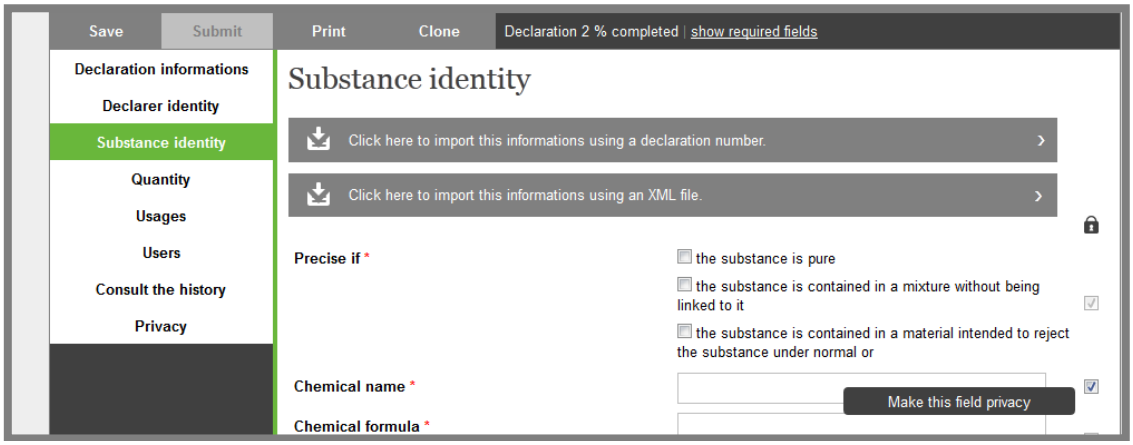
IMPORTANT: the mandatory nature of the fields may depend on the type of declarer or choices made in the declaration process. All mandatory fields must be completed to be able to submit the declaration.

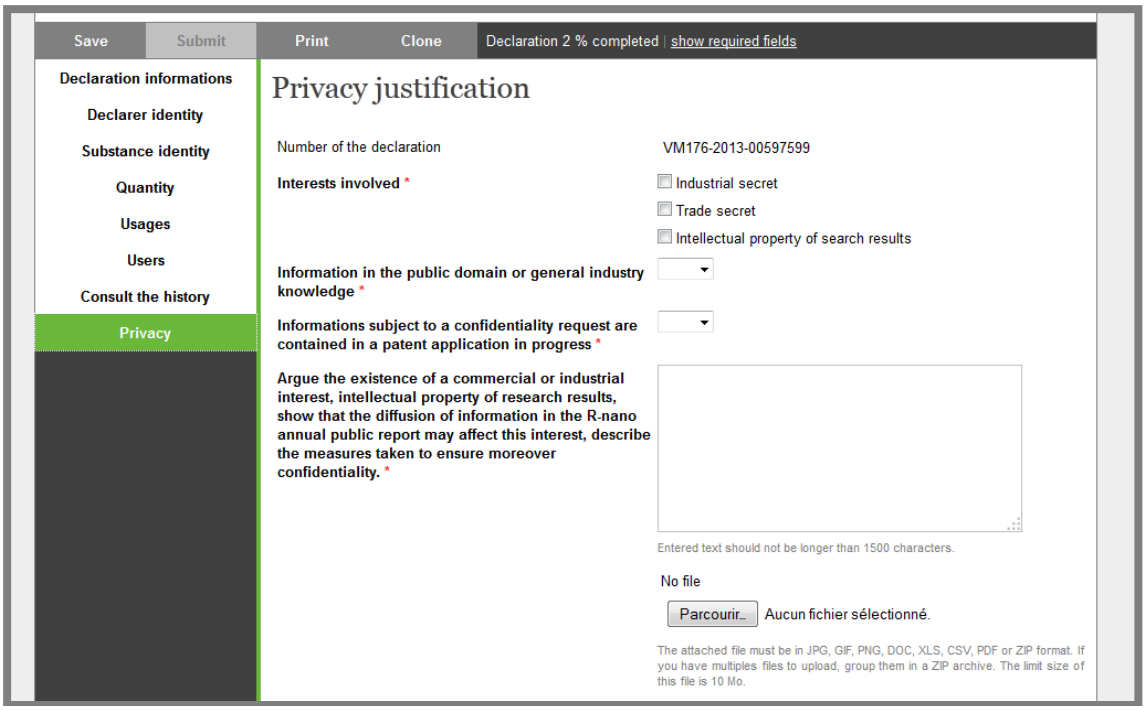
Confidentiality management

The information included in the annual declaration, mentioned in Sections II., III., IV., V., of the Annex to the Ministerial Order of 6 August 2012 (except for the chemical name of the substance, the properties for which the substance with nanoparticle status is used and its use), is regarded as confidential, and it is therefore unnecessary for the declarer to specifically request this confidential status.

To place a confidentiality request, you should tick the corresponding box as shown below:

Then fill in the corresponding tab to justify this request:





Important: the confidentiality request is not automatically transferred if the declaration number is used by a downstream user (professional client) to import data on the substance's identity.

4 Registration

4.1 Description of the process

Registration is done from the home page of the site by clicking on "Professional Access":

and then clicking on "Access the registration form":

Before registering, the future declarer must read the Legal Notice and accept the General Terms and Conditions.

The legal entity must make the declaration on behalf of all establishments concerned with the substance covered by the scope of the declaration. The entity is identified by its intra-community Value Added Tax (EU VAT) number. It must also attach a certificate of incorporation (KBIS).

In case that an identical EU VAT number has already been entered in the declaration database, the declaring administrator of the existing account will immediately be notified by email that a registration attempt has been made with that VAT number. The two users will be invited to contact one another to agree on the procedure to follow.

The fields to be completed for the entity are:

COMPANY IDENTIFICATION

Designation or company name*

Address of the entity*

Post Code*

Town/City*

EU VAT or UAI *

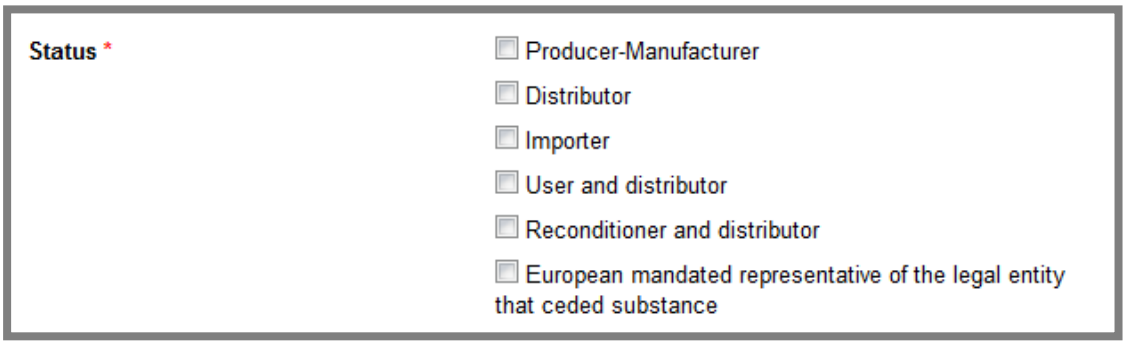
To fill this in: *enter text in the space provided (free text field).*

Country*

To fill this in: *choose only one option from the list provided*.

Capacity of the declarer*

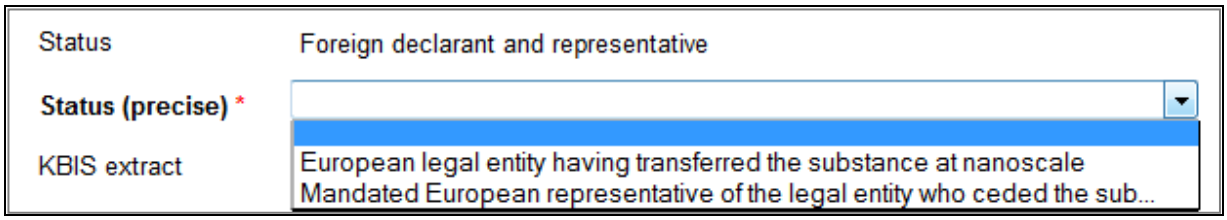
To fill this in: *choose from the list provided; several choices are possible.*



If the selected country is not France (mainland or overseas territories), the declarer must specify his/her capacity/status as shown below:

Capacity of the extranational legal entity / or authorised representative, if importer

To fill this in: *choose only one option from the list provided.*



Are you a public research organisation*

To fill this in: *choose only one option from the list provided.*

Certificate of incorporation (KBIS)*

Attach the KBIS document.

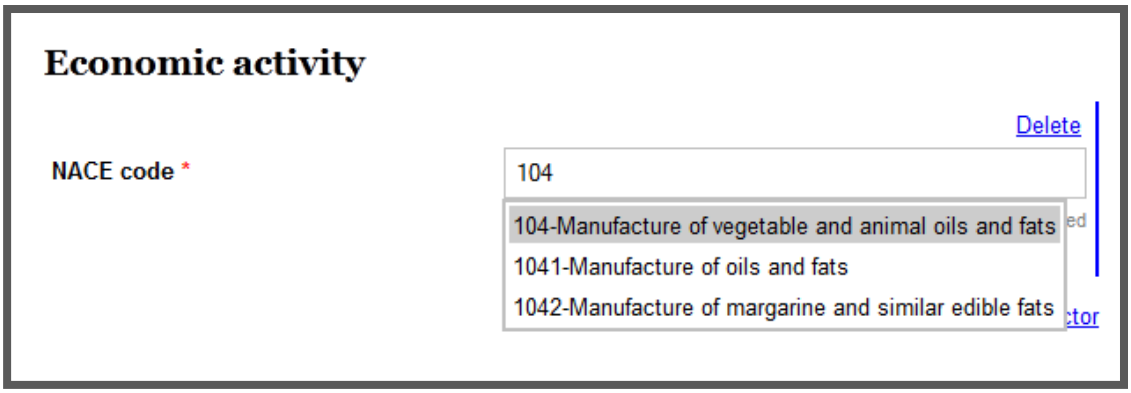
SECTOR OF BUSINESS

Nomenclature for Economic Activities (NACE) code*[1]

The list of NACE codes is available on the EUROSTAT site at the following address:

http://ec.europa.eu/competition/mergers/cases/index/nace_all.html

To fill this in: *after entering the first digits of the NACE code,* ***you must select an NACE code from the list provided.*** *If not, the validation button for the registration form will not be accessible (it will be grey).*



ESTABLISHMENTS CONCERNED

Name of the establishment*

Address of the establishment*

Additional address

Post Code*

Town/City*

Country*

To fill this in: *enter text in the space provided (free text field).*

[1] NACE: Statistical Nomenclature for Economic Activities in the European Community

You can add as many establishments as necessary if they are concerned with the substance covered by the declaration.
If the company has only one establishment altogether, you may delete the fields for "Establishments concerned".

IDENTIFICATION OF THE DECLARING ADMINISTRATOR

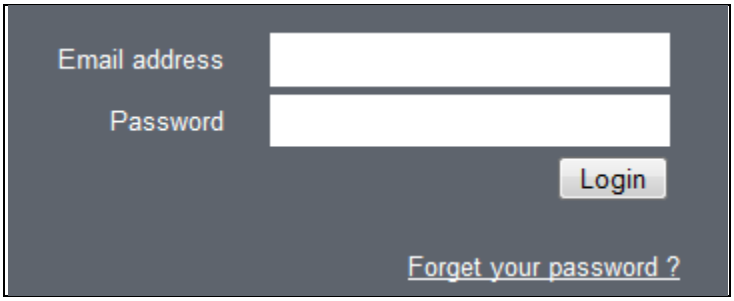
The fields to be completed concerning the identity of the individual making the declaration are:
First name*
Last name*
Title
Email address*
Position
Telephone
To fill this in: *enter text in the space provided (free text field).*

After creating an account, the administrator has the option of defining additional users linked to his/her entity in the "Administration" section of his/her account.

NOTE: all automatic emails generated by the R-Nano application, or sent by the site managers, will go to the email address of the user who completed the declaration, as applicable, as well as to the declaring administrator.

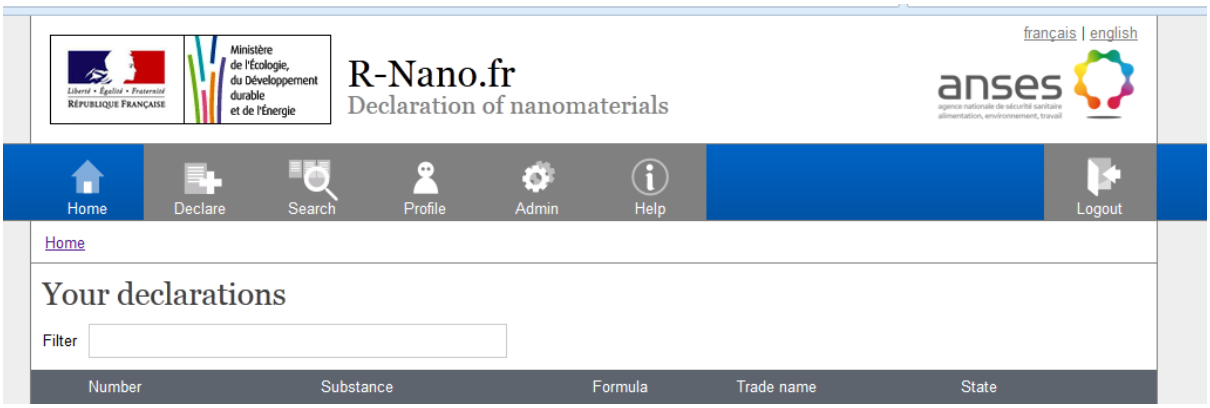
4.2 Account activation

Upon finalisation of his/her registration, the declarer will receive an email with a user name and password. **An activation link will also appear in the body of the email. The declarer must click on this link to activate the account.** Registration is the first step to creating an entity or company account and making an online declaration.
The password sent automatically by email during registration cannot be changed by the declarer. If the password is forgotten, a new one can be generated on the site login page, by clicking on "Forgot your password", and then following the instructions.



5 Declarer dashboard

The dashboard is the first page that appears after logging in.



In the upper banner, the declarer will find:

- Home: return to the declarer dashboard
- Declare: initiate a new declaration
- Search: perform multi-criteria searches for declarations
- Profile: manage and edit the entity profile
- Administration: create additional users linked to the same account
- Help: access all available information and documents in the "Help" section of the home page

The dashboard has the following columns:

- " " button for duplication
- Number: identity of declarations
- Substance: chemical name of the substance
- Formula: chemical formula
- Commercial name
- Status of the declaration (see table below)
- " " button to download proof of submission
- " " button to delete declarations

The table can be sorted by column when clicking on the column headers. Click on a declaration to access its content.

Review of the various declaration statuses shown in the dashboard and corresponding features:

- **Draft**: a declaration for the current year whose entry is not finalised and/or which has not yet been submitted. A draft may be a new declaration or a previously submitted declaration under review. This status has no regulatory value. A draft is not a declaration.
- **Submitted**: a declaration for the current or previous year that has been submitted to the regulatory authority.
- **Completed**: a declaration for the previous year that has not been submitted to the regulatory authority.
- **Derogation pending**: a declaration for which a derogation request has been submitted to the Ministry of Defence and for which the decision to accept or refuse has not yet been made.
- **Derogation refused**: a declaration whose derogation request has been refused by the Ministry of Defence. (This declaration returns to "Draft" status when it is first reopened and must be filled in and submitted on the R-Nano site).
- **Derogation accepted**: a declaration whose derogation request has been accepted by the Ministry of Defence.

Table of declaration statuses and corresponding actions and features for French entities

Y = YES; **N** = NO; **N.A.** = Not applicable

Declaration status	Draft			Submitted in current year			Submitted in previous year			Completed
R-Nano actions and features	Direct keyboard entry / Without importing by declaration number / Without importing by XML file	With importing by declaration number	With loading by XML file	Direct keyboard entry / Without importing by declaration number / Without importing by XML file	With importing by declaration number	With loading by XML file	Direct keyboard entry / Without importing by declaration number / Without importing by XML file	With importing by declaration number	With loading by XML file	
Delete	Y	Y	Y	N	N	N	N	N	N	N
Modify a submitted declaration	N.A.	N.A.	N.A.	Y Until 30/04			N	N	N	N.A.
Duplicate from the dashboard	Y	N	Y	Y	N	Y	Y	N	Y	Y
Duplicate from the "Substance identity" section	Y	N	Y	Y	N	Y	Y	N	Y	Y
Import the "Substance identity" section by declaration number	Y	Y	Y	Y After reopening for modification			N	N	N	N

Load the "Substance identity" section by XML file	Y	Y	Y	Y After reopening for modification			N	N	N	N
Export the "Substance identity" section by XML file	Y	Y But only data overwritten by entry	Y	Y	Y But only data overwritten by entry	Y	Y	Y But only data overwritten by entry	Y	Y
Overwrite by entry of "Substance identity" data imported by number or loaded by XML file	N.A.	Y	Y	Y After reopening for modification			N	N	N	N
Import a list of clients/users by .csv file	Y	Y	Y	Y After reopening for modification			N	N	N	N

6 The declaration

6.1 Information on the declaration

6.1.1 Description of the fields to be completed

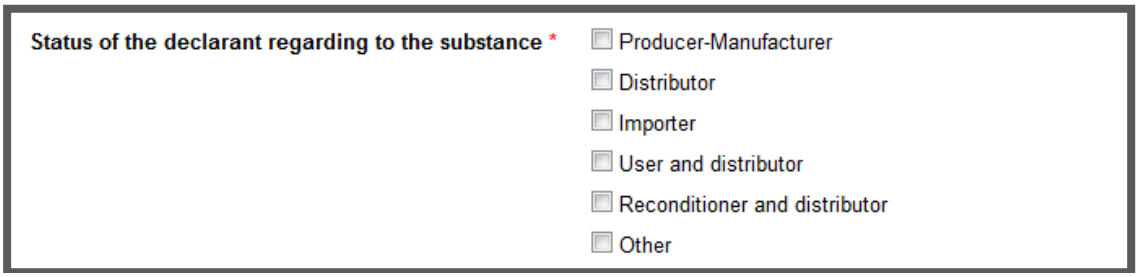
To make a request for derogation, see Section 6.1.2

To make a simplified declaration, see Section 6.1.3

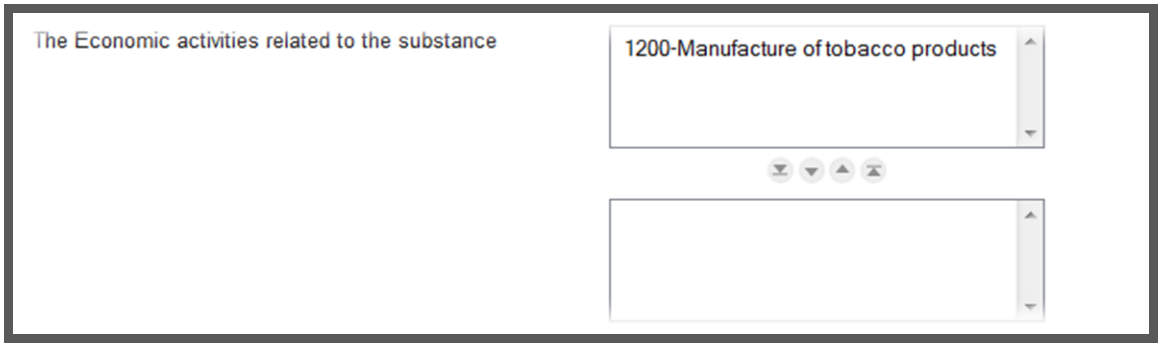
Declaration number: this is generated by the application, and is automatically filled in when a new declaration is opened.

Declaration year*: to be chosen from the dropdown list, it is the calendar year of the declaration concerned.

Capacity of the declarer with respect to the substance*: the declarer must indicate his/her capacity with respect to the substance covered by the declaration.
To fill this in: *choose from the list provided; several choices are possible.*



Activities concerned by the declaration
To fill this in: *the declarer shall specify which activity(ies), among those declared at registration, pertain(s) to the substance covered by the declaration. The list of business activities is displayed in the lower panel, and the activities concerned must be selected from the upper panel using the selection arrows.*



Establishments concerned by the declaration*:

To fill this in: the declarer should tick those of the company's establishments affected by the declaration.

The declarer should specify the users to whom ownership of the nanoparticle substance has been transferred either for payment or free of charge, by completing the "Clients - Professional users" tab

manually or by loading this list of users in CSV format. However, if the declarer has more than 30 professional end user clients for the same NACE activity category, it can indicate at this stage the NACE category(-ies) and the number of end users corresponding to each one.

Note: For a declaration of end user clients by NACE code, the declarer must keep the complete list of these users available for 10 years in case of a request/check by the authorities. Insofar as possible, the declarer should fully complete the "clients/users" tab.

For this substance, do you have more than 30 professional end user clients for one or more NACE activity categories? *

To fill this in: *choose only one option from the list provided.*

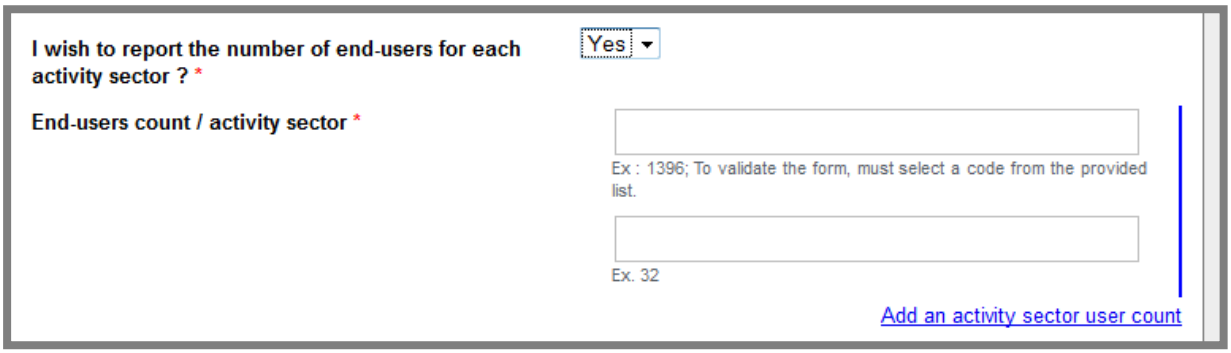
If yes

I wish to declare the number of end users by NACE category. *

To fill this in: *choose only one option from the list provided.*

Number of users/activity category*

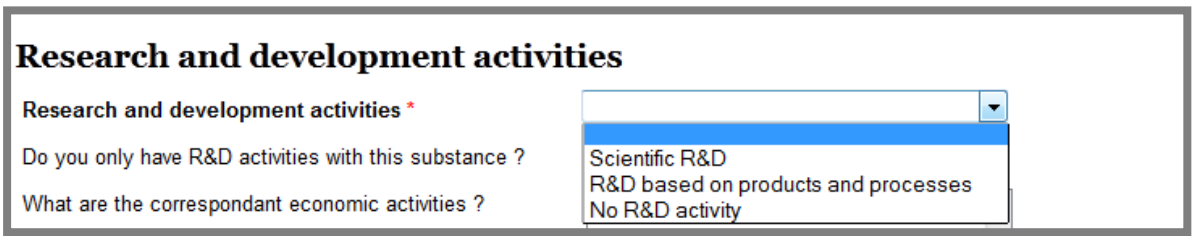
To fill this in: *after entering the first digits of the NACE code, you must select an NACE code from the list provided and then enter the number of users concerned*.



Specific case of Research and Development

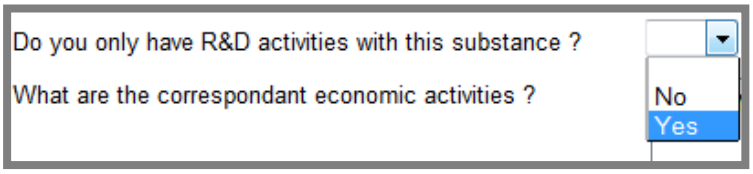
The declarer should specify whether he/she conducts research and development activities on the substance with nanoparticle status covered by the declaration.

To fill this in: *choose only one option from the list provided. This field must be filled in, to confirm that the dossier is complete.*

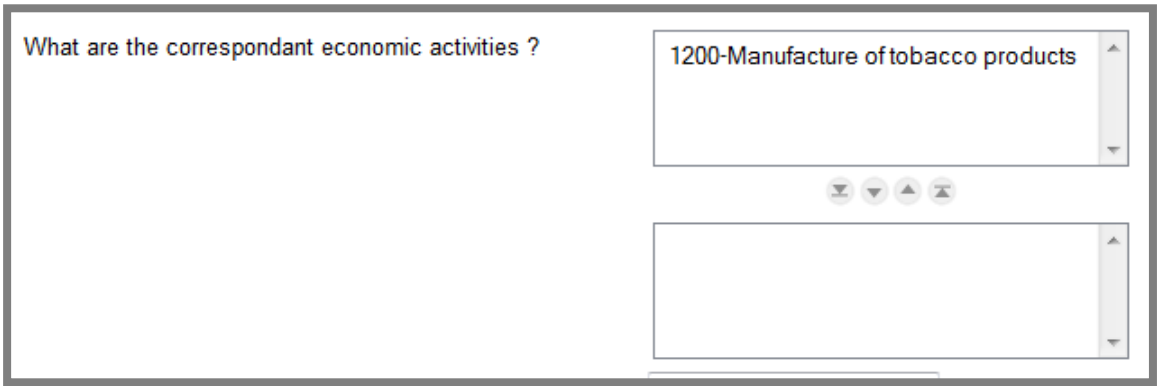


If the declarer is not engaged in any R&D activity for the substance covered by the declaration, he/she indicates this and then proceeds directly to the section "Substance identity".
If the declarer indicates that he/she is engaged in R&D activities ("scientific" or "focused on products and processes"), then the following three fields must be completed:

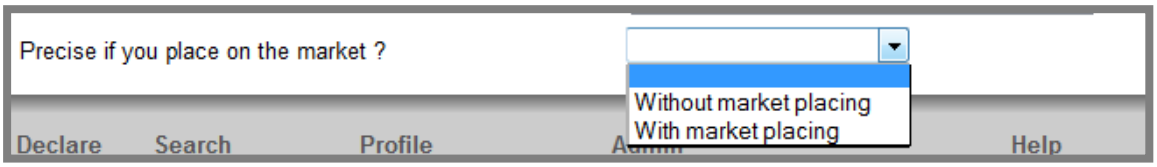
Have you engaged solely in R&D activities with regard to this substance?
To fill this in: *choose only one option from the list provided.*



Forms part of the activity sector
This is to indicate which activity sector(s) is (are) concerned by research and development work on the substance with nanoparticle status covered by the declaration.
To fill this in: *the declarer shall specify which activity(-ies), among those declared at registration, are concerned by R&D activities. The list of the company's activities is displayed in the lower panel, and the activities concerned must be selected from the upper panel using the selection arrows.*

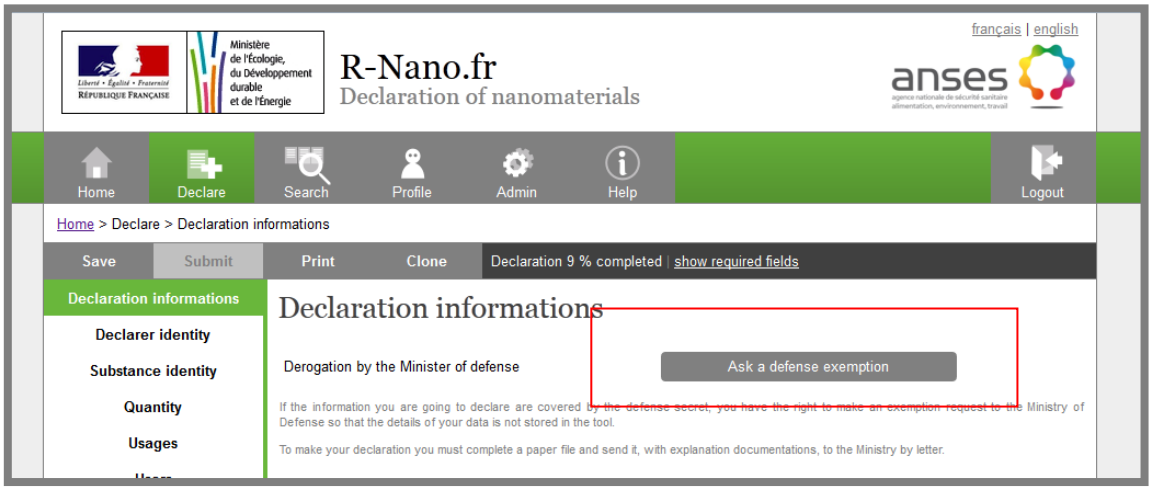


R&D with substances placed on the market
This is to indicate, in cases where the declarer engages in research and development activities on substances with nanoparticle status, whether such substances are placed on the market.
To fill this in: *choose only one option from the list provided. This field must be filled in, to confirm that the dossier is complete.*



6.1.2 Derogation from the Ministry of Defence

According to Article R523-20 of the French Environment Code: if a party required to submit a declaration in application of Article L. 523-1 of the French Environment Code wishes to benefit from the derogation from public disclosure provided for when necessary to safeguard national defence interests, it shall state this requirement in its declaration. In this case, the declarer should select the option "Request for derogation" in the first tab of the declaration.
To submit this declaration, he/she shall fill out a paper application and send it to the Ministry by registered letter together with supporting documents. A sample dossier is available in the "Help" section of the home page.



After a derogation request has been submitted by a declarer, the Ministry of Defence will be directly informed by email and will notify its decision to refuse or accept the request in the R-Nano application. The declarer will also receive a copy of the decision notification by email.

Reminder of the corresponding declaration statuses:

- Derogation pending: a declaration for which a derogation request has been submitted to the Ministry of Defence and for which the decision to accept or refuse has not yet been made.

- Derogation refused: a declaration whose derogation request has been refused by the Ministry of Defence. (This declaration returns to "Draft" status when it is first reopened and must be filled in and submitted on the R-Nano site).

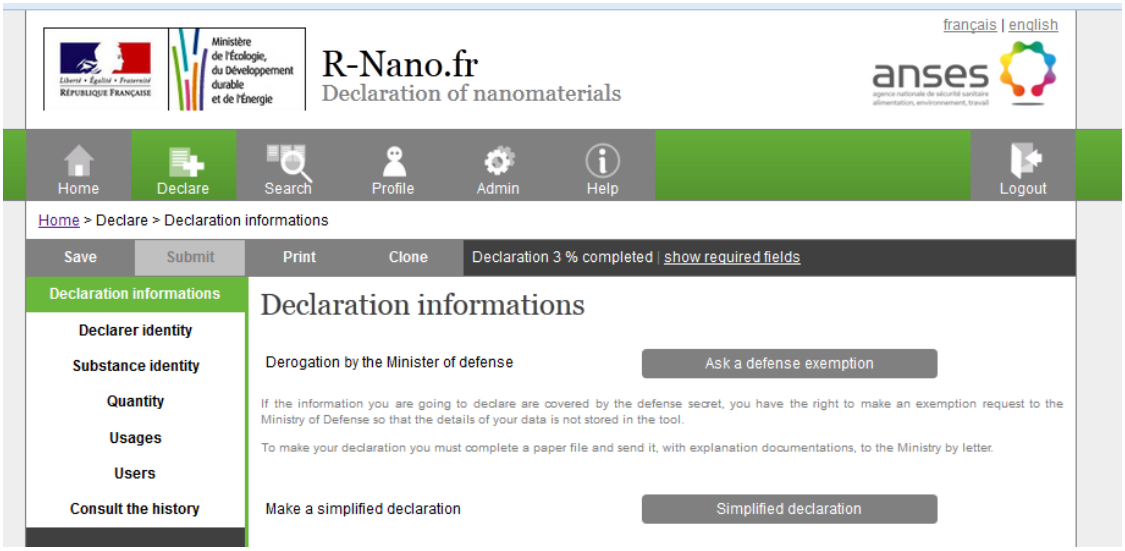
- Derogation accepted: a declaration whose derogation request has been accepted by the Ministry of Defence.

6.1.3 Simplified declaration for public research organisations

According to Article R. 523-15 of the French Environment Code: if the manufacturers, importers and distributors referred to in Article R. 523-13 are public research organisations, these bodies may submit a single declaration covering all of their research activities.

In this case, the declarer should select the option "Simplified declaration" in the first tab of the declaration. He/she will then have access to a simplified declaration form.

This option is only available if the entity declared itself as a public research organisation during registration.



6.2 Identity of the declarer

The entity profile entered during registration appears on this second tab of the declaration. Any declarations made will be linked to the displayed profile. It is important to make sure this information is accurate and up to date before continuing the declaration.

The information in the profile, shown in "Declarer identity", is linked to a legal entity identified by its VAT number. The information in the profile should not be changed to make declarations for several different legal entities with the same declarer account.

To update this information, go to the profile page, available via the banner at the top of the screen.

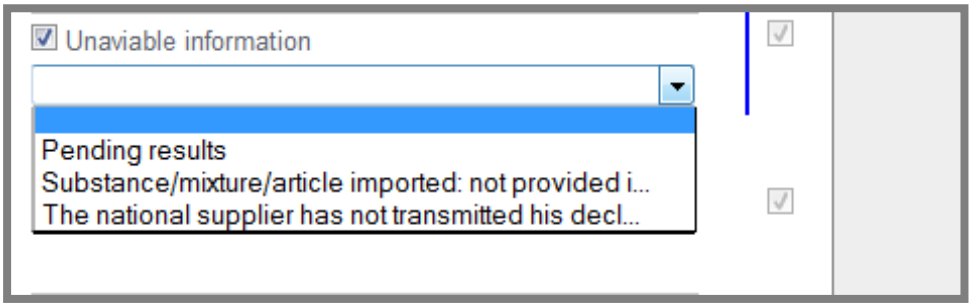
6.3 Identity of the substance, fields to be completed

On this tab, you can request confidentiality for the chemical name of the substance.

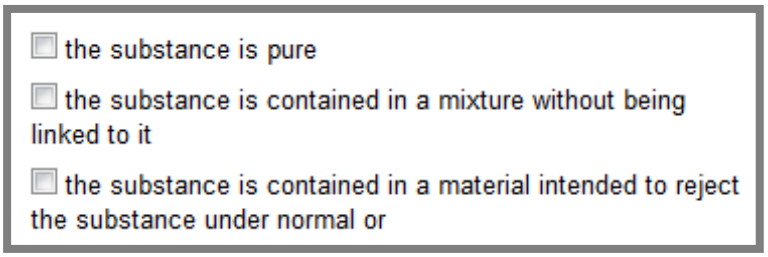
Importing the identity of the substance using a declaration number
Refer to Section 8.

Loading/exporting the identity of the substance using an XML file
Refer to Section 9.

If a field is mandatory and the information is not available, the declarer can tick the "Information unavailable" box and select a reason from the list provided.



Specify whether*
At this stage, it is necessary to indicate whether the substance covered by the declaration is pure, contained in a mixture, or intended to be released by a material in normal or reasonably foreseeable conditions of use.
To fill this in: *choose from the list provided; several choices are possible. Note: This field must be filled in, to confirm that the dossier is complete.*



Note: the same substance may be produced or placed on the market in its pure state and/or contained in a mixture and/or in an article. Several choices are thus possible.

Chemical name of the substance*
To fill this in: *enter the name of the substance in the space provided (free text field). For example: titanium dioxide. This name should be entered in English whenever possible. The name as it is declared will appear in the annual report made available to the public.*

Chemical formula*
The chemical formula is the representation by composition and number of atoms. By convention, cations are noted on the left, followed by the anionic group, then the hydroxyl ions.
To fill this in: *enter the chemical formula in the space provided (free text field). For example, for titanium dioxide: TiO_2.*
This field must be filled in, to confirm that the dossier is complete.

If this information is unavailable, tick the "Information unavailable" box and select a reason from the list provided.

Chemical Abstract Service (CAS) number*

The CAS number is a computer-determined identifier. The algorithm identifies the structural diagrams and automatically assigns a unique CAS number to each chemical entity (molecule, mixture of isomers, industrial product).

To fill this in: *enter the CAS number of the substance in the space provided (free text field). This number is divided into three parts, separated by dashes. It is thus in the form: YYYYYY-XX-X where Y is 3 to 6 digits. For example, for titanium dioxide: 13463-67-7.*

CAS number not available

To fill this in: *if the CAS number is not available, indicate it here.*

At least one of the two fields for the CAS number must be filled in.

Note: the CAS number must be entered if it exists, particularly so that the substances may be properly identified when analysing the data.

European Commission (EC) Number (EINECS/ELINCS/INCI)*

This is an identification number related to European legislation, which must appear on the packaging of hazardous substances (EC number).

EINECS: European Inventory of Existing Commercial Chemical Substances ("existing" chemical substances sold on the European market between 1/01/1971 and 18/09/1981).

ELINCS: European List of Notified Chemical Substances ("new" chemical substances introduced on the European market after 18/09/1981).

To fill this in: *enter the EC number of the substance in the space provided (free text field), a 7-digit number, which will be written in the form: XXX-XXX-X. For example, for titanium dioxide: 236-675-5.*

EC number not available

To fill this in: *if the EC number is not available, indicate it here*.

At least one of the two fields for the EC number must be filled in.

Trade name of the substance where applicable*

To fill this in: *enter the trade name of the substance (free text field).*

No trade name: If there is no trade name, indicate it here.

At least one of the two fields for the trade name must be filled in.

IUPAC name

IUPAC nomenclature is a system for naming and for describing the science of chemistry in general. It was developed and is updated under the auspices of the "International Union of Pure and Applied Chemistry."

To fill this in: *enter the IUPAC name of the substance in the space provided (free text field).*

REACH No. (Registration)*

The term "REACH number" refers to the registration number of the REACH dossier for the same substance. Accordingly, once the REACH registration is complete, ECHA assigns a registration number to the substance concerned along with a registration date that is identical to the submission date. The Agency immediately communicates the registration date and number to the declarer concerned. The registration number is then used in all future correspondence relating to the registration.

To fill this in: *enter the REACH number of the substance in the space provided (free text field). The number is in the following format: <TYPE> - <BASE-NUMBER> - <CHECKSUM> - <INDEX-NUMBER> where:*

<TYPE>	- **01** Registration - **02** C&L notification (CLP) - **03** Substance in article notification (Art. 7(2) - SVHC) - **04** PPORD - **05** Pre-registration - **06** Inquiry - **07** On-site isolated intermediates - **08** Transported on-site isolated intermediates - **09** Data holder notification - **17** Late pre-registration (Art. 28(6))
<BASE-NUMBER>	is a 10-digit number
<CHECKSUM>	is a 2-digit number
<INDEX-NUMBER>	is a 4-digit number giving the index of a member in a joint submission

No registration

At least one of the two fields for the REACH registration number must be completed.

Multiple registration numbers

If several registration numbers are available, enter one of the numbers in the space provided (free text field).

Confidential number

If some declarers do not wish to provide the last 4 digits of the registration number, corresponding to the identity of a member of a joint submission, they may enter 00-0000000000-00-XXXX.

IMPURITIES

What is involved at this stage is clarifying the chemical composition of the impurities and the corresponding quantities.

Composition of the impurities and information as to their quantity, when the mass concentration is greater than 0.1%

Composition of the impurities, and information as to their quantity, when the mass concentration is less than 0.1% but required for other regulatory provisions

To fill this in: *enter the chemical composition of the impurities as well as the corresponding percentages in the space provided (free text field). Different impurities are to be separated by a comma. For example, Impurity 1: XX [CAS], XX% and Impurity 2: XX, [CAS] XX%.*

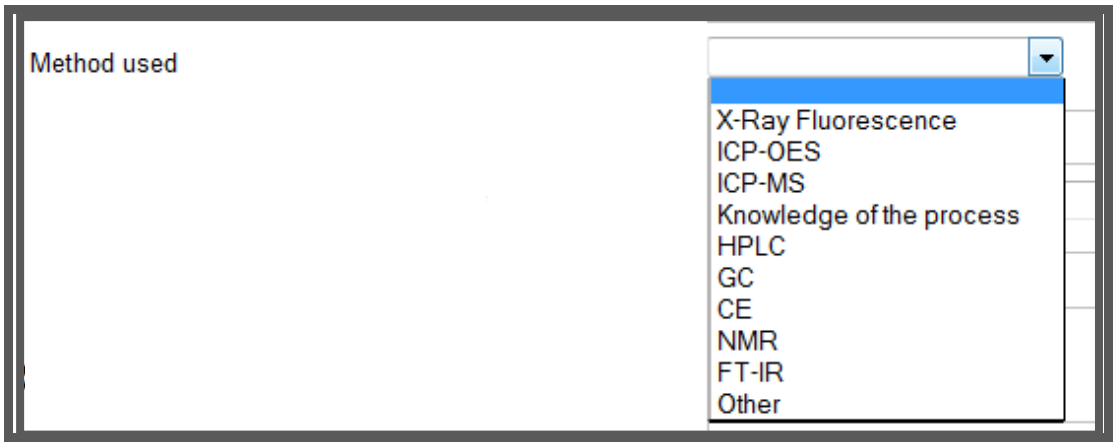
Test guidelines

To fill this in: *enter the guidelines (free text field).*

Method of identifying impurities

This is to specify the method that was used to determine the composition of the impurities as well as information on their quantity.

To fill this in: *choose only one option from the list provided. If the option selected is "other", an empty field will be provided to enter details for clarification.*



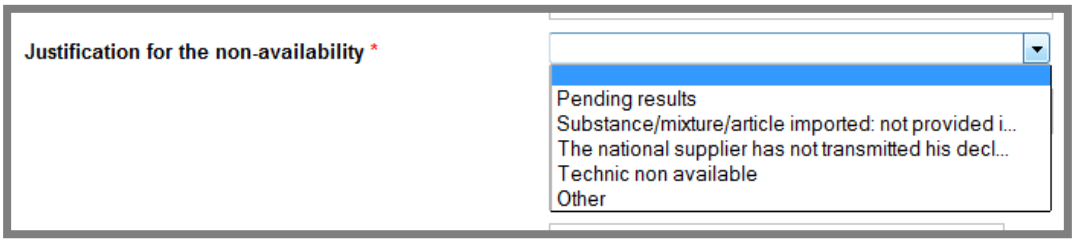
If other method, specify

To fill this in: *enter the method in the space provided (free text field).*

If information is unavailable, justify*

To fill this in: *choose only one option from the list provided.*

If the composition of the impurities has not been entered, this field must be filled in, to confirm that the dossier is complete.



If other reason, specify

PRIMARY PARTICLE SIZE

The unit for expressing the mean diameter(s) is the **nanometre**.

Mean particle size and standard deviation 1*

This is to specify one or more numerical values corresponding to the mean size(s) of the primary particles, which could be one, two or three values according to the shape.

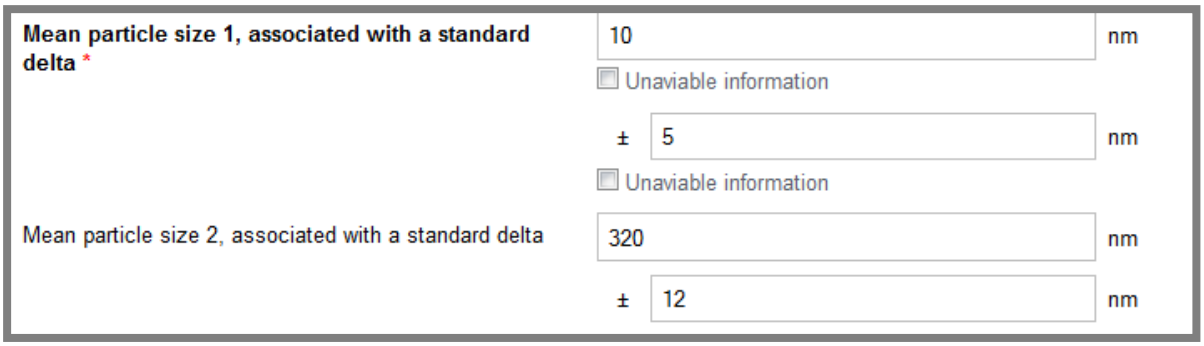
To fill this in: *enter the mean diameter(s) and standard deviations in the spaces provided (free text fields). For example, for a bimodal distribution:*

Mean diameter 1: 10 nm

Standard deviation 1: ± 5 nm

Mean diameter 2: 320 nm

Standard deviation 2: ± 12 nm

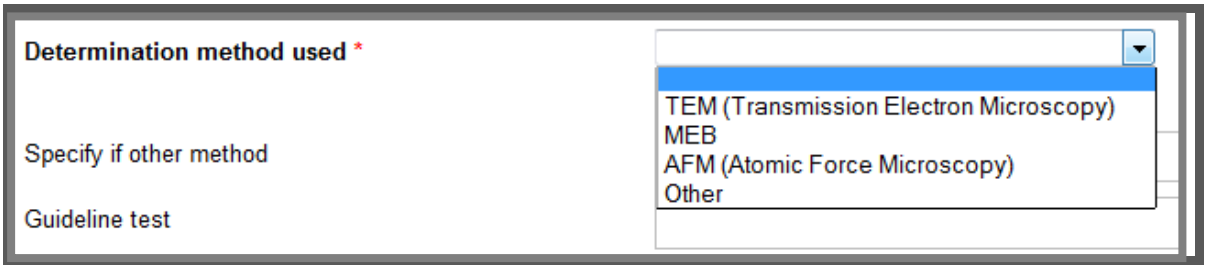


This field must be filled in, to confirm that the dossier is complete.
If this information is unavailable, tick the "Information unavailable" box and select a reason from the list provided.

Mean particle size and standard deviation 2

Mean particle size and standard deviation 3

Method of determining size*
This is to specify the method that was used to determine the diameter(s) of the primary particles.
To fill this in: *choose only one option from the list provided.*
This field must be filled in, to confirm that the dossier is complete.



If this information is unavailable, tick the "Information unavailable" box and select a reason from the list provided.

If other method, specify
To fill this in: *free text field, mandatory if "other" was chosen for the previous question.*

Test guidelines:
To fill this in: *enter the guidelines (free text field).*

Documents related to size analysis
To fill this in: *attach a file using the function created for this. The attached file must be in JPG, GIF, PNG, DOC, XLS, CSV, PDF or ZIP format. If the declarer has multiple files to attach, he/she shall group them together in a ZIP archive. The size limit for this attachment is 10 MB.*

PRIMARY PARTICLE SIZE DISTRIBUTION

Method of determining distribution*
This is to specify the method that was used to determine the distribution of the primary particle sizes.
To fill this in: *choose from the list provided; several choices are possible. If the option selected is "other", an empty field will be provided to enter details for clarification.*

This field must be filled in, to confirm that the dossier is complete.

Determination method used *	☐ DLS ☐ Laser diffraction ☐ Gravitational sedimentation ☐ Differential Centrifugal sedimentation ☐ Raman (NTC) ☐ Other

Note: The Raman method must be preferred for the specific case of carbon nanotubes (CNT).
If this information is unavailable, tick the "Information unavailable" box and select a reason from the list provided.

If other method, specify
To fill this in: *free text field, mandatory if "other" was chosen for the previous question.*

Test guidelines
To fill this in: *enter the guidelines (free text field).*

Documents related to the distribution analysis*
Attach the file(s) corresponding to the analytical results for the distribution of the primary particle sizes.
To fill this in: *attach a file using the function created for this. The attached file must be in JPG, GIF, PNG, DOC, XLS, CSV, PDF or ZIP format. If the declarer has multiple files to attach, he/she shall group them together in a ZIP archive. The size limit for this attachment is 10 MB.*
This field must be filled in, to confirm that the dossier is complete.
If this information is unavailable, tick the "Information unavailable" box and select a reason from the list provided.

STATES OF AGGREGATION AND AGGLOMERATION

The unit for entering the sizes of aggregates and agglomerates is the **nanometre**.

Mean size of aggregates (order of magnitude or interval) with standard deviation*
This is to specify a numerical value corresponding to the size of the aggregates.
To fill this in: *enter the size of the aggregates in the space provided (free text field). For example, for a unimodal distribution:*

Mean diameter 1: 1,200 nm;
Standard deviation 1: ± 40 nm

This field must be filled in, to confirm that the dossier is complete.
If this information is unavailable, tick the "Information unavailable" box and select a reason from the list provided.

Method of determination*
To fill this in: *enter the method of determination used to calculate the mean size of the aggregates (free text field).*

This field must be filled in, to confirm that the dossier is complete.
If this information is unavailable, tick the "Information unavailable" box and select a reason from the list provided.

Is this substance sold in agglomerated form?*

To fill this in: *choose only one option from the list provided.*
This field must be filled in, to confirm that the dossier is complete.

If this information is unavailable, tick the "Information unavailable" box and select a reason from the list provided.

Size of agglomerates with standard deviation

This is to specify a numerical value corresponding to the size of the agglomerates as well as its standard deviation.
To fill this in: *enter the size and standard deviation of the agglomerates in the space provided (free text field). For example, for a bimodal distribution:*

Mean diameter 1: 3,000 nm
Standard deviation 1: ±500 nm
Mean diameter 2: 12,000 nm
Standard deviation 2: ± 1,000 nm

This field must be filled in when the response to the question "Is the substance sold in agglomerated form?" is yes.
If this information is unavailable, tick the "Information unavailable" box and select a reason from the list provided.

Method of determination (of the state of agglomeration)

This is to specify the method for determining the size of the agglomerates.
To fill this in: *enter the method of determination (free text field).*
This field must be filled in when the response to the question "Is the substance sold in agglomerated form?" is yes.
If this information is unavailable, tick the "Information unavailable" box and select a reason from the list provided.

Test guidelines

To fill this in: *enter the guidelines (free text field).*

Documents related to characterisation of the state of aggregation

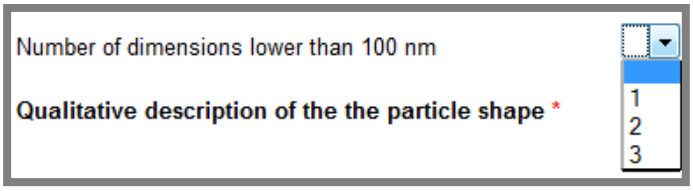
Attach the file(s) corresponding to the analytical results for characterisation of the aggregation level by TEM, SEM, AFM or any other method.
To fill this in: *attach a file using the function created for this. The attached file must be in JPG, GIF, PNG, DOC, XLS, CSV, PDF or ZIP format. If the declarer has multiple files to attach, he/she shall group them together in a ZIP archive. The size limit for this attachment is 10 MB.*

SHAPE

Number of dimensions less than 100 nm

This is to specify the number of dimensions of the substance that measure less than 100 nanometres.

To fill this in: *choose only one option from the list provided.*

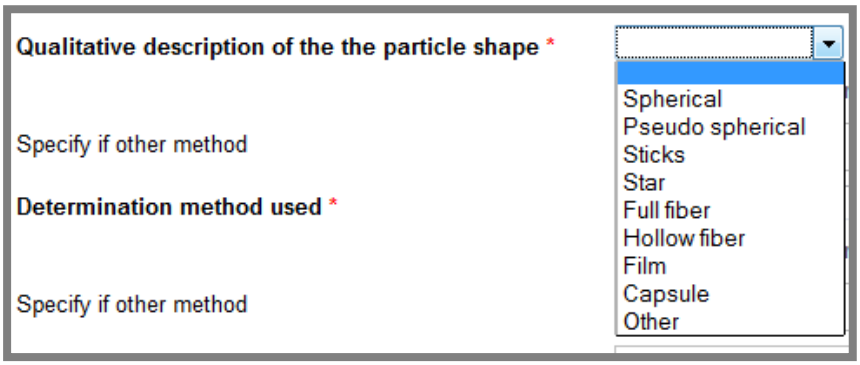


Qualitative description of the shape of the particle*

This is to characterise the shape of the particle qualitatively.

To fill this in: *choose only one option from the list provided. If the option selected is "other", an empty field will be provided to enter details for clarification.*

This field must be filled in, to confirm that the dossier is complete.



If this information is unavailable, tick the "Information unavailable" box and select a reason from the list provided.

If other shape, specify

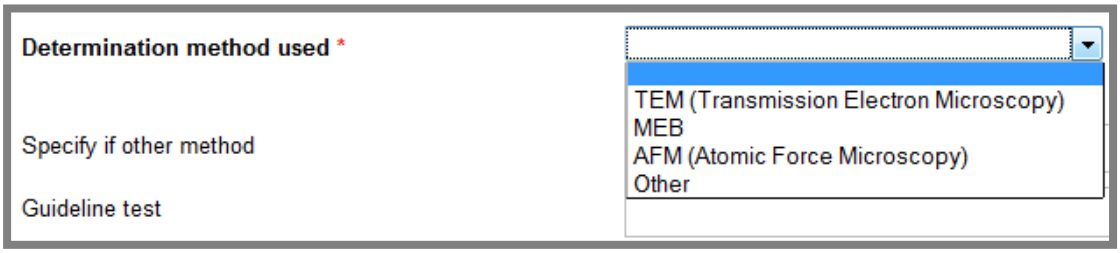
To fill this in: *free text field, must be filled in if the option "other" was chosen in response to the previous question.*

Method of characterising shape*

This is the method that was used to characterise the shape.

To fill this in: *choose only one option from the list provided.*

This field must be filled in, to confirm that the dossier is complete.



If this information is unavailable, tick the "Information unavailable" box and select a reason from the list provided.

If other method, specify

To fill this in: *free text field, must be filled in if the option "other" was chosen in response to the previous question.*

Test guidelines

To fill this in: *enter the guidelines (free text field).*

Documents related to the characterisation of the shape:

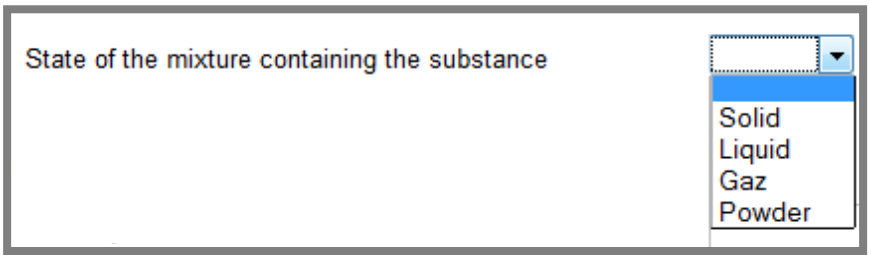
Attach the file(s) corresponding to the analytical results for the characterisation of the shape.

To fill this in: *attach a file using the function created for this. The attached file must be in JPG, GIF, PNG, DOC, XLS, CSV, PDF or ZIP format. If the declarer has multiple files to attach, he/she shall group them together in a ZIP archive. The size limit for this attachment is 10 MB.*

STATE OF THE MIXTURE/MATRIX

State of the mixture containing the substance

To fill this in: *choose only one option from the list provided.*



SPECIFIC SURFACE AREA

The specific surface area value must be filled in as **m^2/g**.

Value of the mean specific surface area and standard deviation

This is to specify a numerical value corresponding to the value of the specific surface area and its standard deviation.

To fill this in: *enter the specific surface area and its standard deviation in the space provided (free text field). For example: Specific surface area (powder): 52 m^2/g*
± 10 m^2/g

Method of determining the specific surface area

This is the method that was used to characterise the specific surface area.

To fill this in: *choose only one option from the list provided. If the option selected is "other", an empty field will be provided to enter details for clarification.*

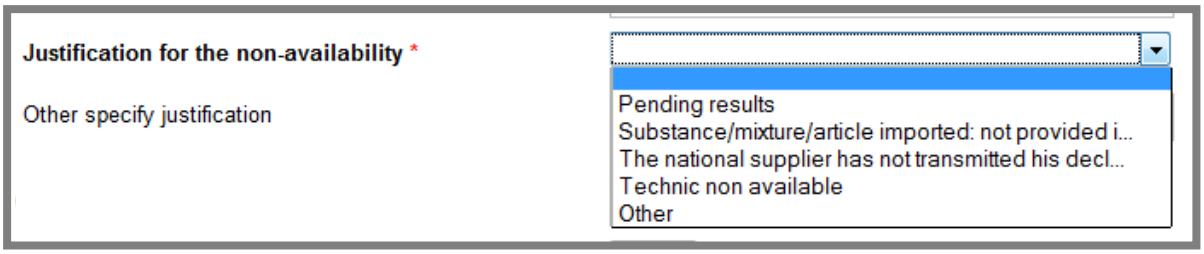
If other method, specify

To fill this in: *enter the method in the space provided (free text field).*

If information is unavailable, justify*

To fill this in: *choose only one option from the list provided.*

This field must be filled in if the specific surface area value is not filled in, to confirm that the dossier is complete.



If other reason, specify

CRYSTALLINE STATE

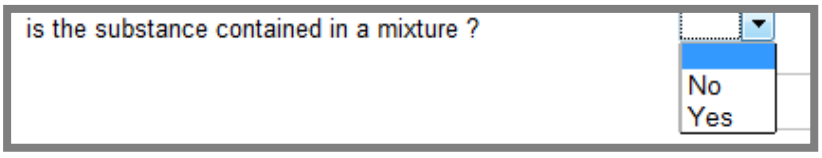
The X-ray diffraction method must be used to analyse the crystalline state.

I have this information*

To fill this in: *choose only one option from the list provided. This field must be filled in, to confirm that the dossier is complete.*

The substance is in the form of a mixture

To fill this in: *choose only one option from the list provided.*



If the substance is not in the form of a mixture (answer "NO" to the previous question)

Common name, if any

If not, indicate the type of Bravais lattice

To fill this in: *choose only one option from the list provided.*

If the substance is in the form of a mixture (answer "YES" to the previous question)

Common name, if any

If not, indicate the type of Bravais lattice

To fill this in: *choose only one option from the list provided.*

Percentages of this phase (including the amorphous phase when there is one)

Test guidelines

To fill this in: *enter the guidelines (free text field).*

Documents related to the analysis of the crystalline state

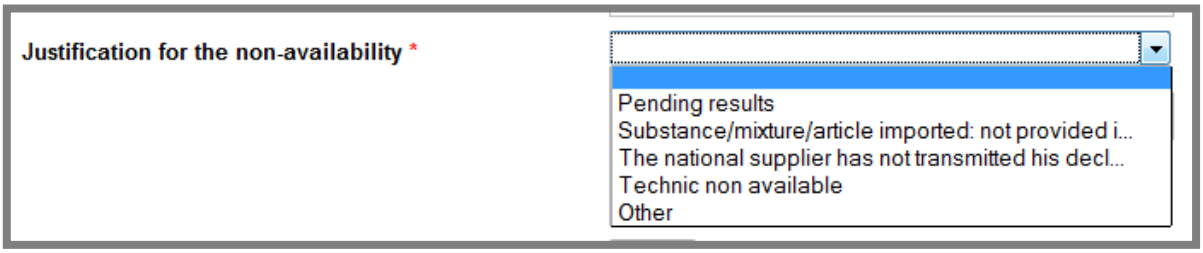
Attach the file(s) corresponding to the analytical results for the determination of the crystalline state.

To fill this in: a*ttach a file using the function created for this. The attached file must be in JPG, GIF, PNG, DOC, XLS, CSV, PDF or ZIP format. If the declarer has multiple files to attach, he/she shall group them together in a ZIP archive. The size limit for this attachment is 10 MB.*

If information is unavailable, justify*

To fill this in: *choose only one option from the list provided.*

If the nature of the phases has not been entered, this field must be filled in, to confirm that the dossier is complete.



If other reason, specify

COATING

Presence of a coating*

This is to specify whether there is a coating on the substance.

To fill this in: *choose only one option from the list provided.*

This field must be filled in, to confirm that the dossier is complete.

If this information is unavailable, tick the "Information unavailable" box and select a reason from the list provided.

Composition of the coating

This is to specify whether the composition of the coating is organic or inorganic.

To fill this in: *choose only one option from the list provided.*

This field must be filled in when the response to the question on the "presence of a coating" is yes.

If other type of coating, specify

Details of the coating

To fill this in: *choose only one option from the list provided. If the option selected is "other", an empty field will be provided to enter details for clarification.*

This field must be filled in when the response to the question on the "presence of a coating" is yes.

If there are other details on the coating, specify

SURFACE CHARGE

The method that must be used for the analysis of surface charge is **zetametry**.

Zeta potential value

This is to provide a numerical value corresponding to the value of the Zeta potential.

To fill this in: *enter the Zeta potential value in the space provided (free text field).*

pH at which the value was measured

This is to specify a numerical value corresponding to the pH value.

To fill this in: *enter the pH value in the space provided (free text field).*

Medium in which the value was measured

This is to specify the type of medium in which the value was measured.

To fill this in: *enter the type of medium in the space provided (free text field).*

Test guidelines

To fill this in: *enter the guidelines (free text field)*

Documents related to the determination of surface charge

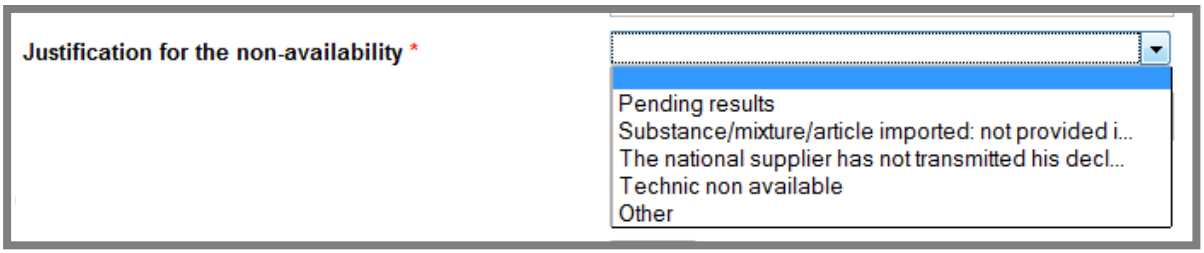
Attach the file(s) corresponding to the analytical results for the determination of surface charge.

To fill this in: *enter the value of the proportions of each phase in the space provided (free text field).*

If unavailable, justify

To fill this in: *choose only one option from the list provided*

This field must be filled in if the Zeta potential value has not been filled in, to confirm that the dossier is complete.



If other reason, specify

6.4 Quantity

IMPORTANT: The quantities to be entered are quantities of substances with nanoparticle status and not quantities of mixture, materials, articles, etc.
Quantities must be expressed in **kilograms**.

Quantity*
This is to specify annual quantities of the substance manufactured, distributed, imported, used, formulated, or other.
To fill this in: *enter the quantities in the space provided (free text field).*
*The mandatory fields on quantity are those **under the capacity(ies) declared in the "Information on the declaration" section**. For example, for a declared substance, if the declarer indicated he/she is a "manufacturer", it must fill in the "quantity manufactured" field.*
For quantities of the substance imported, distributed, distributed after use or repackaging, or other, if this information is unavailable, tick the "Information unavailable" box and select a reason from the list provided.

6.5 Uses

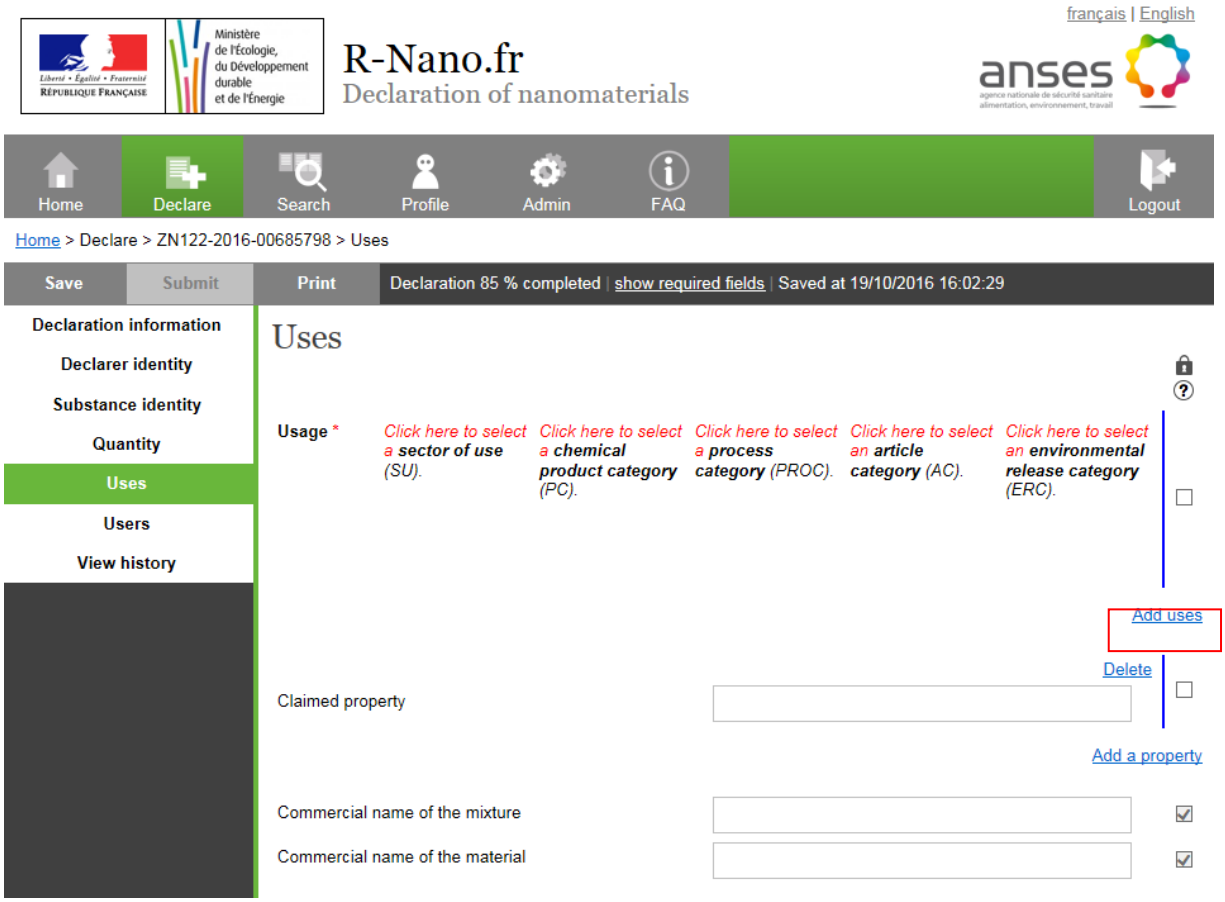
On this tab, you can request confidentiality for the uses and/or the property(ies) for which the substance is used.

The detailed list of uses is provided in Annex II.
This is to specify different uses of the substance. For each use, the declarer must fill in four fields:
Descriptors for sectors of use (SU)
Descriptors for the chemical product category (PC)
Descriptors for process categories (PROC)
Descriptors for substances in articles (AC)
Descriptors for environmental release category (ERC)
To fill this in: *For each descriptor, choose one option from the list provided. Note: all the descriptors must be filled in, to confirm that the dossier is complete.*

ECHA has made a guide available on the internet for providing this usage information according to the REACH model:

https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

To describe several uses, click on "Add a use":



Properties for which the substance with nanoparticle status is used

To fill this in: *enter the property(ies) for which the substance is used (free text field).*

If a mixture, trade name of the mixture(s)

To fill this in: *the declarer must specify the trade name of the mixture(s), or when several mixtures contain the same substance, he/she provides a list of trade names.*

If a material, trade name of the material(s)

To fill this in: *the declarer must specify the trade name of the material (article), or when several materials (articles) contain the same substance, must provide a list of trade names.*

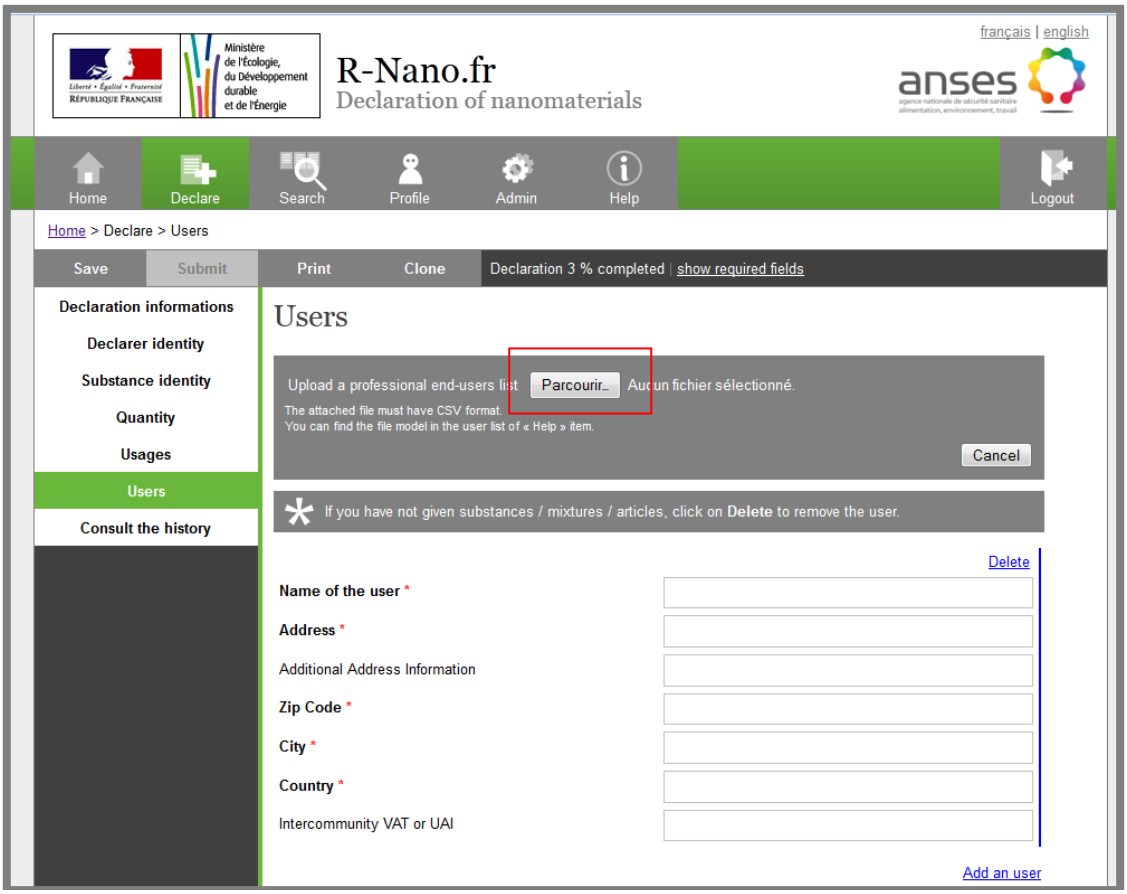
6.6 Clients (professional users)

The following fields are to be filled in as many times as there are professional users to whom ownership of the substances, mixtures and/or materials (*articles*) has been transferred either for payment or free of charge.

Name of the clients (professional users) to whom ownership of the substances, mixtures or articles has been transferred*

If you have not transferred ownership of any substances/mixtures/articles, click on "Delete" to remove the user.

To fill this in: *enter the names of the professional users to whom ownership of the substances, mixtures and/or articles has been transferred in the space provided (free text field) or load the list of clients by importing a file. The attached file must be in CSV format. The user list sample file can be retrieved/found in the "Help" section. The available model must be followed or else it will not be recognised by the application: column order, column names, CSV format, etc. In order to optimise loading, it is best not to use special characters (e.g. $, " , #, %, etc.).*



Address, Post Code, Country*

To fill this in: *in the space provided, enter the mailing address of the professional users to whom ownership of the substances, mixtures and/or articles has been transferred (free text field). These fields must be filled in, to confirm that the dossier is complete.*

Intra-community VAT

To fill this in: *in the space provided, enter the intra-community VAT number of the professional users to whom ownership of the substances, mixtures and/or products has been transferred (free text field). This field does not necessarily have to be filled in, to confirm that the dossier is complete.*

Note: If there are more than 30 professional end user clients for the same NACE code and they have been declared by NACE code (see § 6.1.1 page 12), the "Clients (professional users)" section does not need to be filled in. You must delete the users' part.

6.7 View history

You can use this screen to view actions taken by users on each declaration:

- Initialise
- Register
- Submit
- Delete
- Consult
- Modify

All actions taken by the declarer or declaring administrator are traced/recorded.

Traces are shown as a table with the following columns:

- Email address
- Role
- Date
- Time
- (Declaration) Number
- Action taken

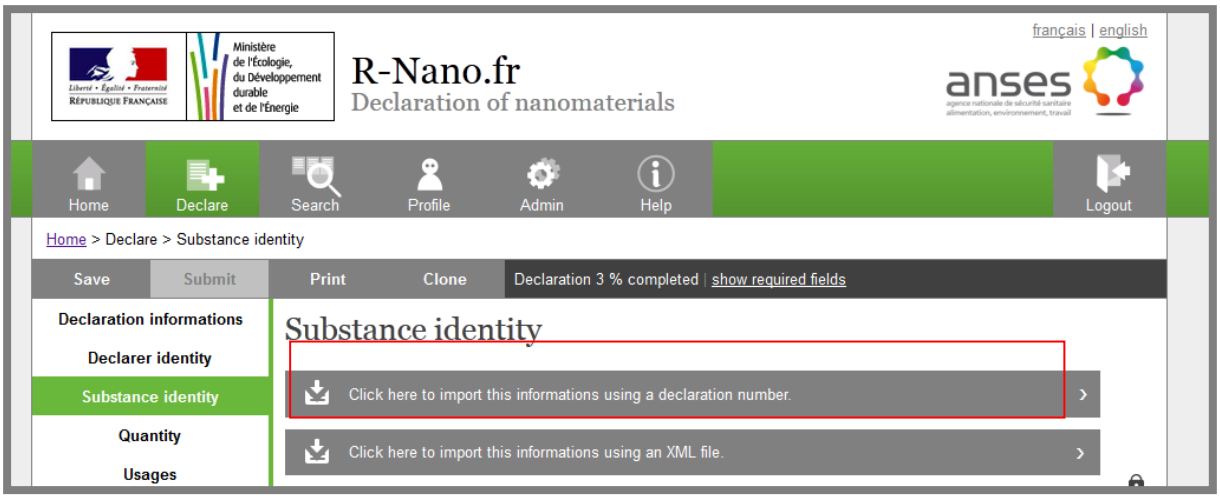
7 Scientific R&D without substances being placed on the market

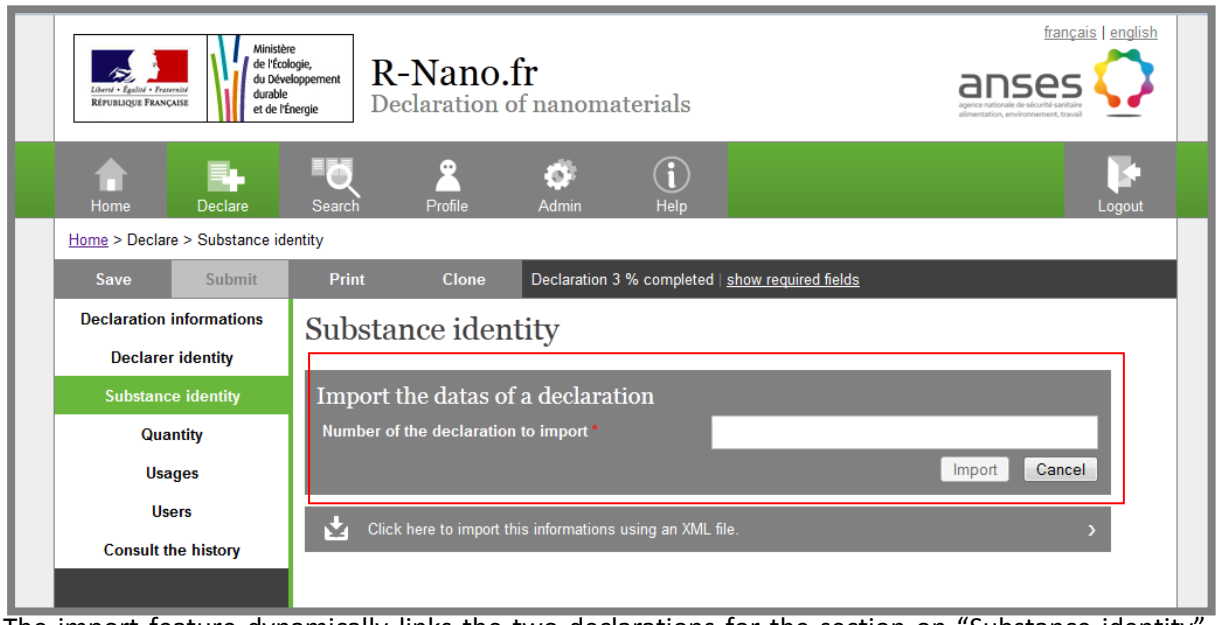
According to Article R. 523-14 of the French Environment Code: if the manufacture, import or distribution of substances with nanoparticle status, pure or as part of a mixture without being bound to it, or of materials intended to release such a substance under normal or reasonably foreseeable conditions of use, are in the context of research and development activity without such substances being placed on the market, the declarer is only required to declare its identity and the sector of business concerned.
Note: This does not apply to public research organisations (referred to in Article R. 523-15 of the French Environment Code), which can use the simplified declaration (see § 6.1.3).

8 Importing data by entering a declaration number

The declarer has the option of importing part of its declaration (Substance identity) by entering the number of a declaration made by his/her supplier for the same substance.

Note: transmission of the declaration number by suppliers to their professional clients is a regulatory requirement.





The import feature dynamically links the two declarations for the section on “Substance identity”. The declarer importing the data will not have access to these, with the exception of the chemical name of the substance.

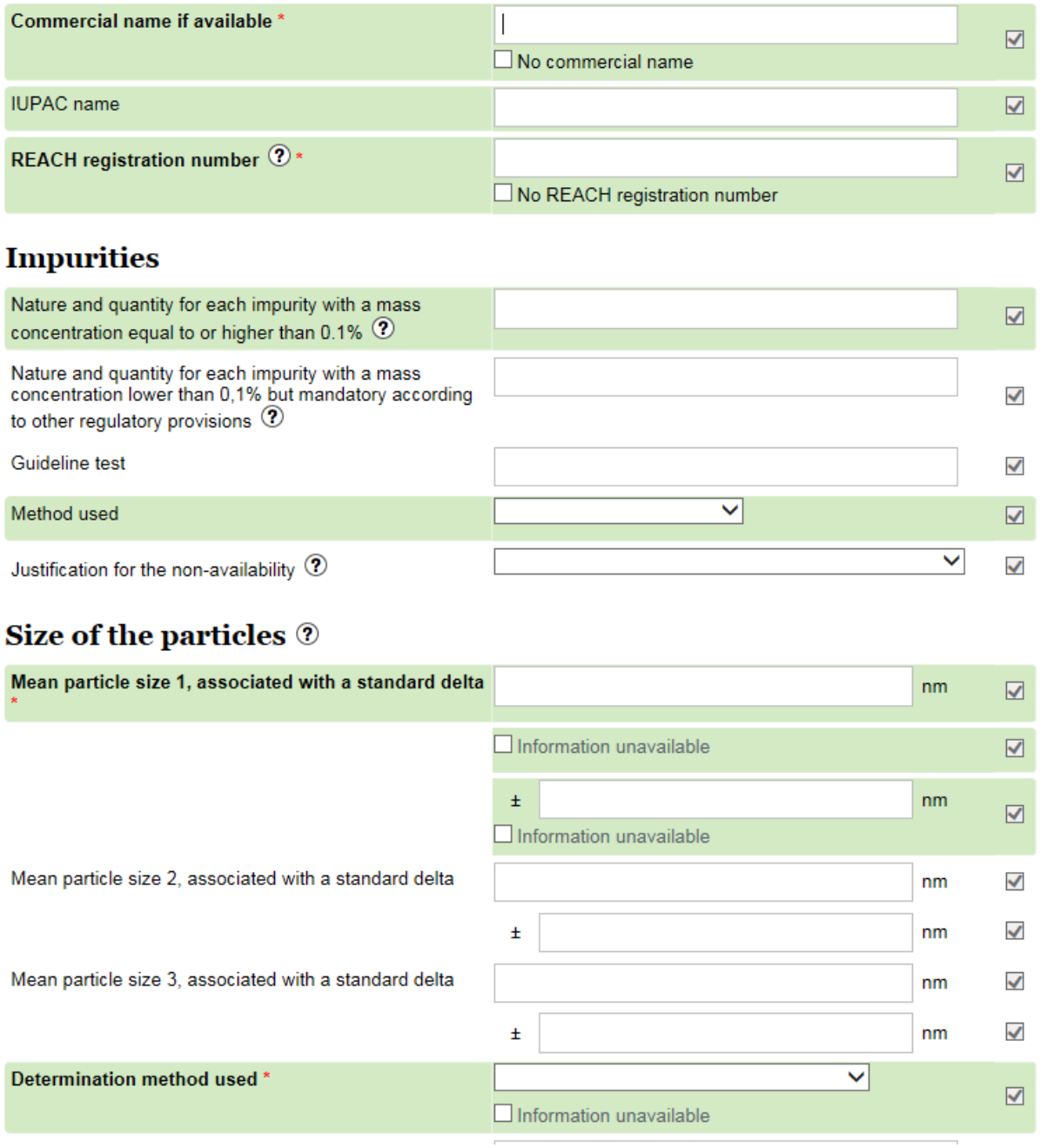
Note: exchanges of declaration numbers for transmission of information within the supply chain take place outside of the declaration system.

After importing, the imported data on the identity of the substance can be modified (e.g. modification of a coating). To do so, enter the updated data in the corresponding fields.

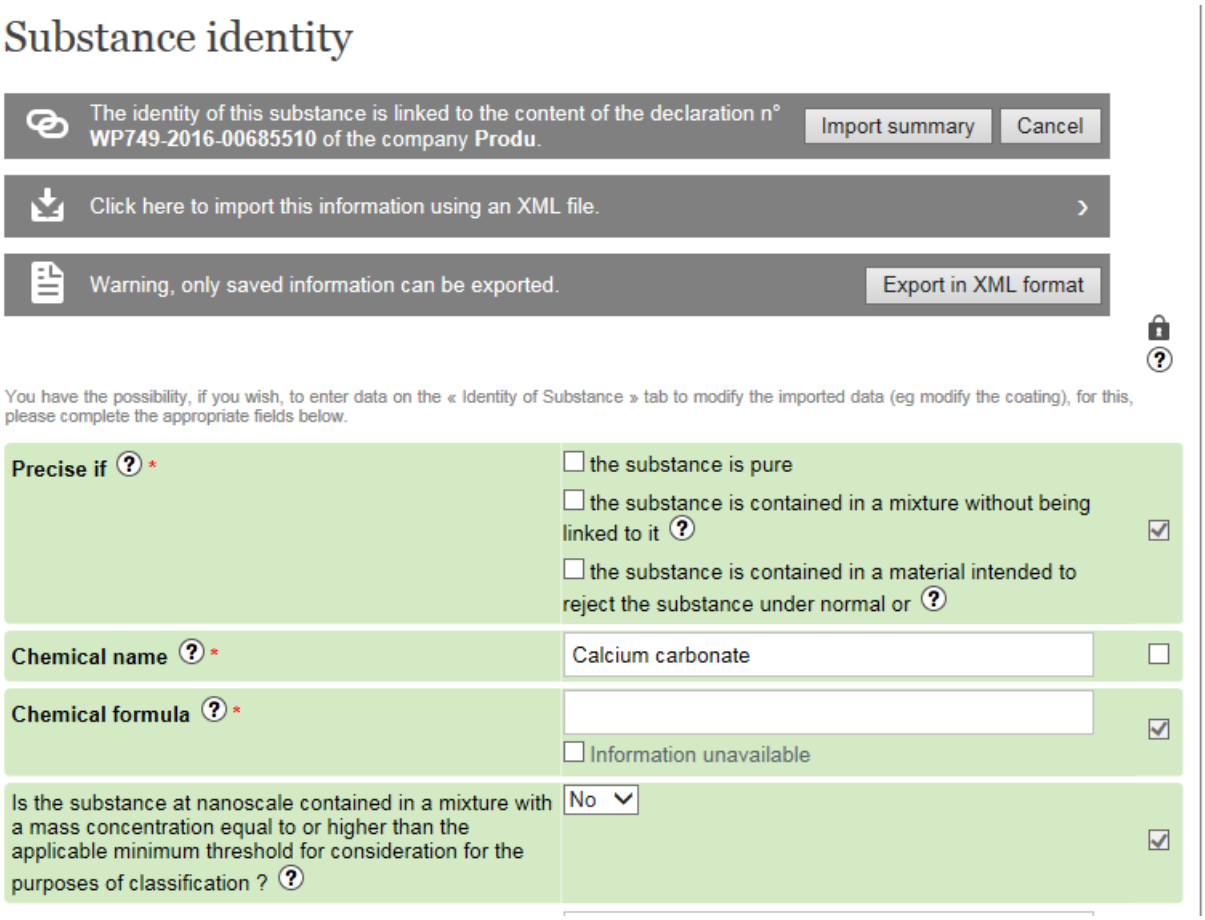
Data cannot be imported using a declaration number:

- if it does not correspond to any existing declarations,
- if it is the same as that of the current declaration,
- if it is the number of a daughter declaration of the current declaration,
- if the number corresponds to an archived declaration,
- if the number corresponds to a completed declaration,
- if the number corresponds to the initial declaration before modification.

24 hours after the import, the imported fields appear in green in the declaration. Below on the screenshot we see that the fields EC reference, commercial name of the substance, REACH number, etc. in green have been filled following the import. However, their content is hidden.



The list of imported fields is also available through the import summary available at the top of the page containing the substance identity as described in the screenshot below:



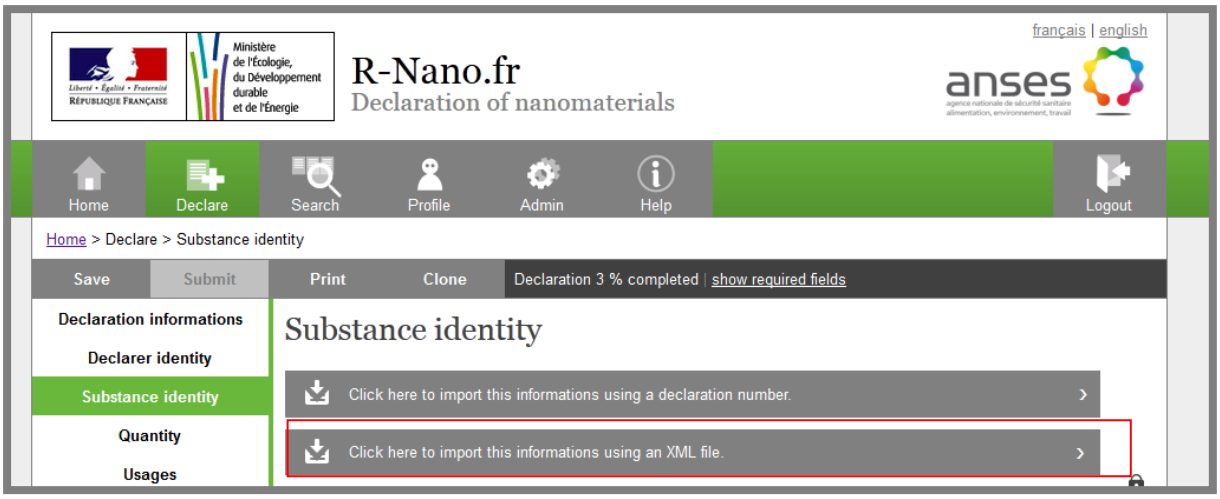
9 Loading/exporting in XML format

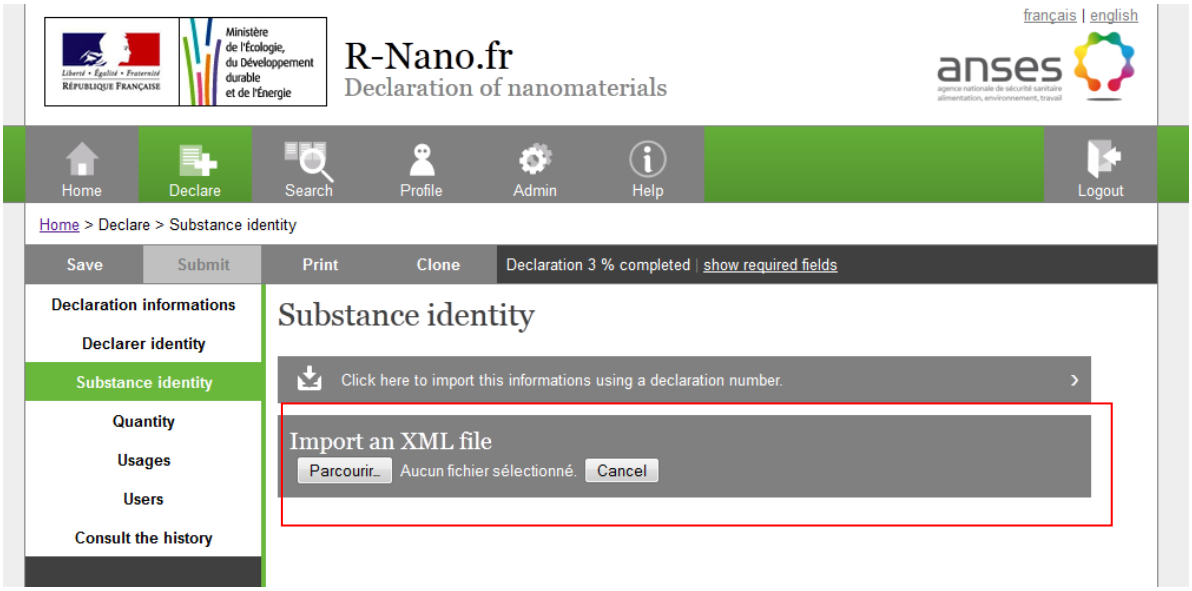
The declarer can import part of his/her declaration (Substance identity) by loading an XML file.

Unlike when importing by declaration number, this type of operation does not link the data in the two declarations but only loads data from an XML file so that all or some of the data in the "Identity of the substance" form do not need to be directly entered.

The XML file structure is available in the "Help" section of the R-Nano site.

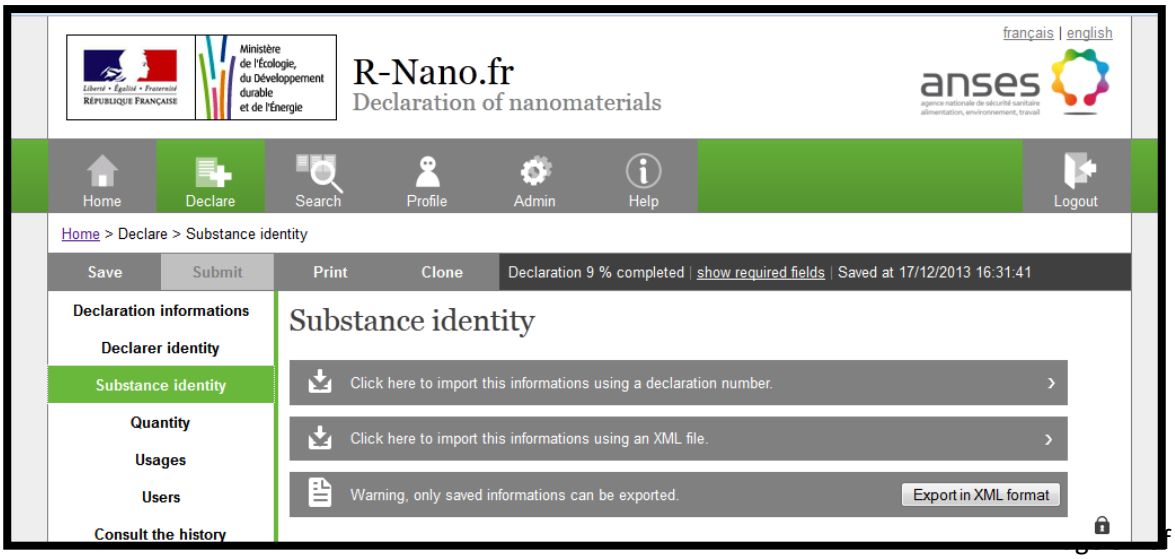
Note: The data contained in an XML file are visible, just as the data are visible after they have been loaded to R-Nano. This type of data exchange and loading format does not guarantee data confidentiality between declarers.





The "Substance identity" section can also be exported in XML format.

Data imported by declaration number (and not overwritten by entry after importing) are not taken into account by the XML export in order to guarantee data confidentiality between declarers.



10 Duplicating a declaration

The duplication feature can be accessed from two different locations:

- In the upper banner, next to the "Print" insert in an open declaration
- From the "Your declarations" dashboard on the home page after logging in, where a duplication option will be available across from each unique declaration identification number through the icon.

The duplication feature lets you create a new identical declaration. The fields will be completed with the information contained in the declaration you want to duplicate.

Duplication copies the data in the "Substance identity", "Uses" and "Clients - Professional users" tabs for declarers in France. Duplication copies the "Substance identity" tab for foreign declarers. Duplication copies all data entered as well as any attachments (.jpg, Word, Excel, PDF attachments, etc.).

Duplication is available for declarations with the following statuses:

- Submitted
- Draft
- Completed

Simplified and imported declarations and declarations that are or have been the subject of a derogation request cannot be duplicated. Confidentiality requests are not transferred to the new declaration.

11 Modifying a submitted declaration

The "Modify" button is located in the upper banner, next to the "Print" insert in an open declaration, for all declarations submitted in the current year.

This button can be used to modify the content of a submitted declaration throughout the declaration period. This feature is available for the following roles:

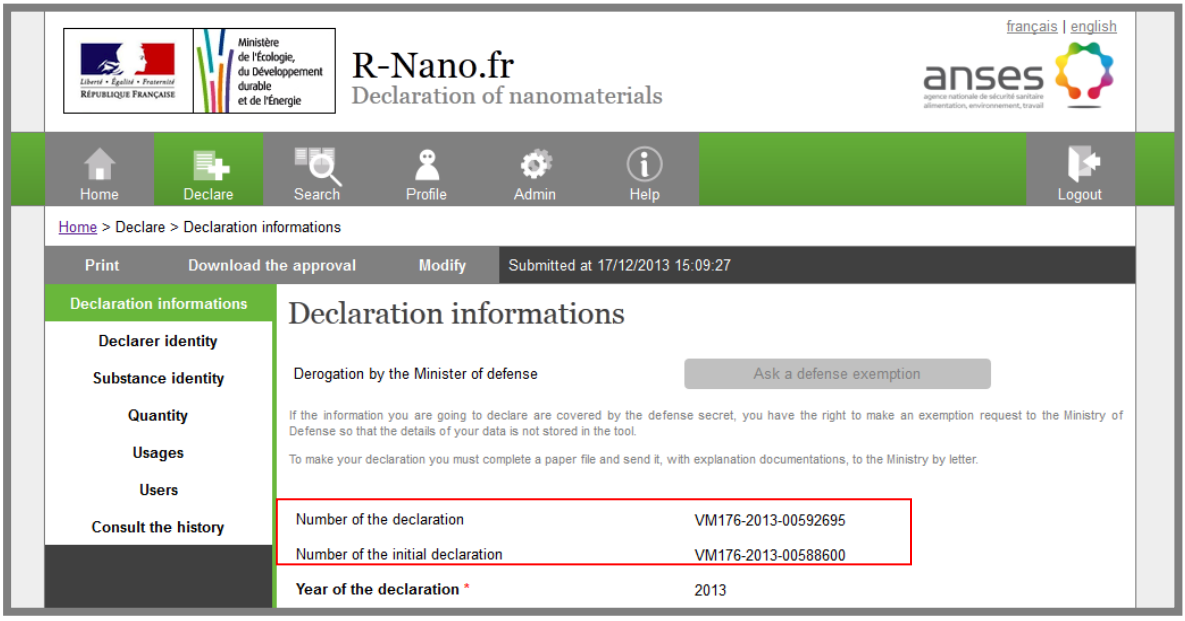
- Declaring administrator
- Declarer
- Foreign declarer and authorised European representative

Only one version of a submitted declaration can be modified. If the new version of the declaration with "Draft" status is deleted, the "Modify" button becomes available again on the initial submitted declaration.

When a user clicks on the "Modify" button, a confirmation message appears.

If the user decides to continue, he/she is redirected to a new declaration with "Draft" status containing the same data as the initial submitted declaration. The new declaration has its own declaration number. In the "Information on the declaration" section, the initial declaration number is shown in the "Initial declaration number" field.

All other fields can be modified except for the "Declaration year" field



The new declaration then appears in dashboards and in the multi-criteria search.

When the new declaration is submitted, an alert message informs that the new declaration number should be transferred to clients and users that have not used the old number and wish to import the data it contains. Once the submission has been confirmed, the status of the initial declaration changes to "Archived" and its reference and content are no longer visible in the application.

Note: the modified version does not take effect until it has been submitted. A modified version left in "draft" status has no regulatory value.

The information in the "View history" and "Request additional information" tabs is now retrieved from the initial declaration and saved on the new one. If the initial declaration has been used downstream, in other declarations, to import data from the "Substance identity" section, this link is transferred to the new declaration. In this way, daughter declarations are linked to the new

declaration irrespective of their status (draft or submitted) and the new declaration's reference appears in the imported information area ("Identity of the substance" tab).

A submitted declaration cannot be modified after the declaration period. If the declarer clicks on the "Modify" button after this period, an alert message appears: "The declaration period is over; you cannot re-open and modify submitted declarations".

12 Declarant Assistance - Contact Box

In addition to the present tutorial, the FAQs document is available on the homepage of the site. However, if the declarant does not find the answer to his request, he can contact the r-nano team by mail by clicking on the contact at the bottom of the homepage.