



**MINISTÈRE
DE LA TRANSITION
ÉCOLOGIQUE**

*Liberté
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Fraternité*

<https://www.r-nano.fr>

**Information on French prescriptions
relating to the annual notification**

**of manufacturing, importing and
distributing of nanomaterials
in the nanomaterial register**

WHAT IS the R-Nano notification and its aim?

Because of their specific and innovative properties, substances at nanoscale are used in numerous industrial sectors such as aeronautics, cosmetics or health. However, some of them display risks for human health and the environment. In France, this leads to the implementation of an **annual** mandatory declaration of these substances based on the data of the **previous civil year**. It came into force on 1st January 2013 and aims at:

- ▶ tracking nanomaterials on the French territory: from the manufacturer to the distributor to the last professional user: the quantities exchanged and the sites where exposures can occur,
- ▶ improving knowledge on nanomaterials (their identity, their uses and the fields of application) and gathering knowledge that can be useful in risk assessments of these substances in order to ensure protection of human health and the environment,
- ▶ gathering knowledge in order to inform consumers about these substances and their uses.

The management of the register of notifications, called "R-Nano" and of the data it contains has been assigned to the French Agency for Food, Environmental and Occupational Health and Safety (ANSES).

This mandatory notification is different from European regulations, including the obligation under REACH regulation, for any manufacturer and importer more than 1 ton per year of a substance at nanoscale on the territory of the European Union to provide specific information related to its nanoform as part of its registration dossier, from 1st January 2020.

French prescription is also in line and contributes to the European Chemicals Strategy for Sustainability¹, published on 14th October 2020 and aiming at strengthening the protection of human health and the environment against chemicals with hazardous properties, in particular by improving knowledge of the effects of chemicals.

WHAT DO YOU NEED to do?

As a professional based outside of the French territory, it is not mandatory to notify French authorities if you distributes substances at nanoscale –on their own, contained in a mixture without being bonded to it, or a material intended to release such substances under normal or reasonably foreseeable conditions of use– (substances so called "nanomaterials") to a client located on the French territory or if you import such substances from a supplier inside the French territory. However, you should still support your French client by providing him with information about the substance (chemical name, physical properties ...) and with relevant information to determine if the product

supplied contains nanomaterials (under French legislation). Two options are available to share data:

- ▶ direct transmission to your client (no condition) e.g. via e-mail,
- ▶ if you wish to keep this data confidential, you can create a notification on the French register (<https://www.r-nano.fr/>), fill it and transmit the notification number to your clients. They will then import the information you provided them with. However, if you are located outside of the European Economic Area (EEA), you need to mandate a legal entity based inside the EEA to do it for you.

¹ Communication: Chemicals Strategy for Sustainability. Towards a toxic-free environment

WHAT INFORMATION can be provided to help your clients on the French territory?

Your client established in France needs information about the physical and chemical characteristics of the substance defined as a nanomaterial, whether on their own, in a mixture or in a material/article:

- ▶ The substance name (chemical name and formula, CAS and EC number ...),
- ▶ Impurities,
- ▶ The size and number size distribution for particles,
- ▶ Surface properties (specific surface, coating ...).

The French Ministerial Order of 6th August 2012² details more precisely the information that is compulsory.

HOW IS data confidentiality managed?

Most information is confidential to protect business secrecy, except the chemical name of the substance and its uses. All security measures are taken to protect data.

This means that:

- ▶ only authorised person can access to the data,
- ▶ in application of the law, a public report is published every year on the site <https://www.r-nano.fr>
- ▶ dissemination of data (different from chemical names and uses) is only possible to inspectors and to mandated public agencies for risk assessment only,
- ▶ if a client imports the data you provide, he will only be able to see the name of the substance.

For further information: you can refer to a [Q&A](#) and if you do not find an answer to your question, a contact [link](#) is available.

² English version available on R-Nano website at the following [link](#)

