

Who has to register?

Introduction

Not all substances produced in nanoparticulate state or mixtures containing such substances, have to be registered. In the next paragraphs, you will find the answer to the question whether or not you have to register your substance or your mixture.

The answer to the question in the title is given in a schematic way :

- [Decision tree for substances](#)
- [Decision tree for mixtures](#)

The main difference between these two decision trees follows from the exemption made in Art 1, 8° of the Royal Decree: *"The provisions of this Decree shall not apply to ... pigments, when placed on the market in a mixture, an article or a complex object"*.

The decision tree exists out of 9 questions. Depending on the answer you give to a specific question, you will receive an answer to the question whether you have to register or not, or will be referred to the next question.

For each question, reference is made to the list of FAQ's published on our website. The answer to these FAQ's can assist you with the interpretation of the Royal Decree or with the questions below. In case you don't find the answer to your specific question, please contact us at info@nanoregistration.be. The reference to the FAQ's is indicative and does not mean to exclude the other FAQ's.

Question 1:

I place a substance in nanoparticulate state (as such or in a mixture) on the market and this substance is a

- Biocide (reg. 528/2012 or RD 22.05.2003)
- Medicinal product for human or veterinary use (reg. 726/2004 or RD 14.12.2006 or law 21.06.1983)
- (Product intended to come into contact with) Foodstuff (law 24.01.1977)
- Animal feed (reg. 178/2002 or law 21.06.1983)
- Technological aid or other product that may be used for processing ingredients of agricultural origin (reg. 889/2008) ?

If the answer to this question = **yes**, there is **no obligation** to register.

If the answer to this question = **no**, go to [question 2](#)

More info about biocides?

See FAQ 1.1.a, FAQ 1.1.b at www.nanoregistration.be

Question 2:

I place a substance in nanoparticulate state (as such or in a mixture) on the market and I am the manufacturer or importer of that substance/mixture ?

If the answer to this question = **yes**, go to [question 4](#)

If the answer to this question = **no**, go to [question 3](#)

More info about manufacturers or importers?

See FAQ 2.17.a, FAQ 2.17.b, FAQ 2.17.c, FAQ 2.17.d, FAQ 2.17.e, FAQ 2.17.f, FAQ 3.3.a, FAQ 5.1.a, FAQ 6.a at www.nanoregistration.be

Question 3:

I place a substance in nanoparticulate state (as such or in a mixture) on the market as a distributor.
I am a Business to Business distributor, which means I sell exclusively to professional users ?

If the answer to this question = **yes**, go to [question 4](#)

If the answer to this question = **no**, you are a distributor but you sell your substance/mixture (also) to consumers, there is **no obligation** to register

More info about distributors?

See FAQ 3.a, FAQ 3.3.a, FAQ 3.3.b, FAQ 5.1.a, FAQ 10.c at www.nanoregistration.be

More info about professional users?

See FAQ 2.18.a, FAQ A.S5.b at www.nanoregistration.be



Question 4:

The substance I place on the market is composed of fullerenes, graphene flakes or single wall carbon nanotubes with one or several external dimensions less than 1 nanometer, or the mixture contains such substance(s) .

If the answer to this question = **yes**, go to [question 8](#)

If the answer to this question = **no**, go to [question 5](#)

More info about the definition of a substance produced in nanoparticulate state?

See FAQ 2.2.a at www.nanoregistration.be

Question 5:

The substance in nanoparticulate state (as such or contained in a mixture) is a non-chemically modified natural substance ?

If the answer to this question = **yes**, there is **no obligation** to register

If the answer to this question = **no**, go to [question 6](#)

More info about a natural substance in nanoparticulate state?

See FAQ 2.8.a at www.nanoregistration.be

Question 6:

The nanoparticulate state of the substance (as such or contained in a mixture) is a by-product of human activity (meaning that the substance in nanoparticulate state was not intentionally produced)?

If the answer to this question = **yes**, there is **no obligation** to register

If the answer to this question = **no**, go to [question 7](#)



Question 7:

The substance (as such or contained in a mixture) contains particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 to 100 nanometers ?

If the answer to this question = **yes**, go to [question 8](#)

If the answer to this question = **no**, there is **no obligation** to register

More info about the definition of a substance in nanoparticulate state?

See FAQ 2.2.a, FAQ 2.3.a, FAQ 2.7.a, FAQ 2.7.b at www.nanoregistration.be

Question 8:

The substance produced in nanoparticulate state is a pigment which is contained in a mixture ?

If the answer to this question = **yes**, there is **no obligation** to register the pigment

If the answer to this question = **no**, go to [question 9](#)

More info about pigments?

See FAQ 1.8.a, FAQ 1.8.b, FAQ 1.8.c, FAQ 2.16.a, 2.16.b at www.nanoregistration.be

Question 9:

I place more than 100 grams per year of the substance in nanoparticulate state (as such or contained in a mixture) on the market ?

If the answer to this question = **yes**, you have to register. You find [more information](#) in the next paragraph

If the answer to this question = **no**, there is **no obligation** to register

More info about the quantity placed on the market?

See FAQ A.S3.a at www.nanoregistration.be

I have to register. Where can I find more information?

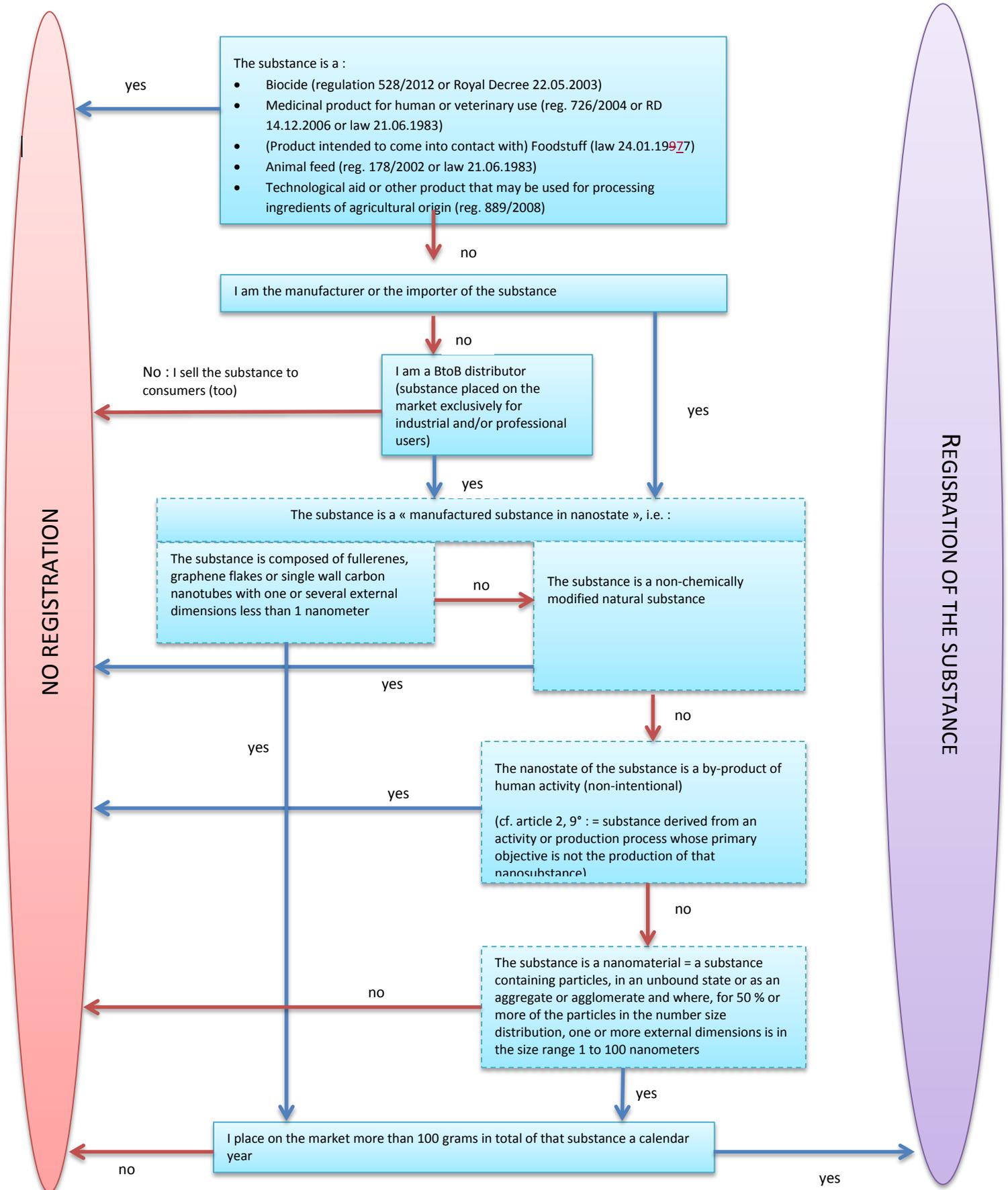
On the website www.nanoregistration.be, you can find more guidance documents:

- When do I have to register
- Different types of accounts
- Different types of registrations
- Creation of an account: which information has to be provided
- Registrations: which information has to be provided
- The Royal Decree
- FAQs
- The link to the registration tool

In case of questions, contact the helpdesk via info@nanoregistration.be



Decision tree for substances





Decision tree for mixtures

