

Number	Ref. RD	FAQ	Answer
1 (1.1.a)	Art 1, 1°	The Royal Decree excludes products which are covered under the scope of the Biocidal Product Regulation EU No 582/2012, including treated articles. Does this mean that, whatever the purpose of the substance in nanoparticulate state, we do not need to register the product if the product is in the scope of EU 582/2012?	This is correct, in the sense that the biocide or the treated articles are exempted from the Royal Decree of 27 <sup>th</sup> May 2014, according to Art 1, 1°. However, one needs to consider the stages before the product (substance, mixture or article) has been treated with the biocide. If that product contains substances in nanoparticulate state and is placed on the market before it has been treated with the biocide, that product falls under the scope of the Royal Decree of 27 <sup>th</sup> May 2014.
2 (1.1.b)	Art 1, 1°	Are plant protection products or pesticides exempted?	Please note that 'pesticides' are biocides and plant protection products. According to Art 1, 1° of the Royal Decree, only the biocides are exempted. The plant protection products are not exempted.
3 (1.8.a)	Art 1, 8°	Do pigments have to be registered when they are placed on the market as a substance and not in a mixture.	Yes. If the pigments, as a substance, fulfill the conditions of the definition of a substance produced in nanoparticulate state (Art 2, 7°) and the conditions of Art 3 of the Royal Decree, they have to be registered. According to Art 1, 8°, pigments are exempted only when they are placed on the market in a mixture, an article or a complex object.
4 (1.8.b)	Art 1, 8°	I am a manufacturer of pigments, marketing them to the Belgian territory. The pigments fulfill the conditions of the definition of a substance in nanoparticulate state as described in the Royal Decree and I have to register them. Does the registration number have to be cascaded to the professional users in the supply chain, when these users place the pigment on the market as a mixture?	Yes. According to Art 10 of the Royal Decree, the registrant must communicate, amongst others, the registration number to his customers if they are professional users of the registered substance.
5 (1.8.c)	Art 1, 8°	(a) Are fillers also considered as pigments (e.g. because they improve the opacity of the paint)? (b) How can one distinguish between a filler (such as talc) and a pigment, if they have a similar function in the paint?	(a) Not in all cases. Art 2, 16° gives the definition of a pigment: "a substance insoluble in the standard suspensions and used for its optical properties"; Art 2, 15° gives the definition of a filler: "a solid, immiscible and mechanically dispersed in a matrix in order to reduce costs, improve certain properties or to modify the density of the matrix". When the substance in nanoparticulate state is added mainly for its optical properties, it is considered to be a pigment.

Number	Ref. RD	FAQ	Answer
			(b) The reason why the substance is added, will be decisive for the difference between a filler and a pigment. If the substance is added specifically for its optical properties, it is considered to be a pigment. In case of any doubt, feel free to contact the helpdesk at " <a href="mailto:info@nanoregistration.be">info@nanoregistration.be</a> "
6 (2.2.a)	Art 2, 2°	(a) Will the Belgian definition in the Royal Decree be adapted each time when the recommendation of the EU Commission (18 <sup>th</sup> October 2011) on the definition of nanomaterials changes? (b) What will be the consequences if REACH or the REACH Annexes are changed in relation to nanomaterials?	(a) Since the Royal Decree is a part of the Belgian legislation, it is as such independent of the Commission's recommendation. However, since the definition is based on this recommendation, changes will be evaluated for their impact on the definition in the Royal Decree. (b) Changes in REACH or the REACH annexes will have no consequences for the definition of a substance produced in nanoparticulate state in the Royal Decree.
7 (2.3.a)	Art 2, 3°	The Royal Decree defines a particle as a minute piece of matter with defined physical boundaries. (a) What are "defined physical boundaries"? (b) Is it a 'very small piece of material' or 'any piece of material'?	(a) A "defined physical boundary" is a boundary which delimitates a piece of matter and which can be determined with a physical method. The standard physical method to determine the boundaries of particles in the nanorange is electron microscopy (b) 'minute' does not really specify a size of the particle, it should be read as a 'discrete' or a 'separate' particle.
8 (2.7.a)	Art 2, 7°	Is a (very) long polymer fiber with a diameter within the nanorange a particle or is it considered to be an article with dimensions in the nanorange? Is a broad pellet with thickness within the nanorange a particle or is it an article having one dimension in the nanorange?	According to the definition in the Royal Decree a substance produced in nanoparticulate state is 'a substance containing particles, ... where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range of one nanometer to one hundred nanometers...'. Therefore high aspect ratio particles with less than 3 dimensions in the range between 1 – 100 nm, are considered to fulfill the conditions of the definition of the Royal Decree. For the definition of an article, the Royal Decree refers to the law of 21 <sup>st</sup> December 1998. This law defines an article as : "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition". If the fiber or the pellet have no function other than being further processed, it is not to be considered as an article.

Number	Ref. RD	FAQ	Answer
9 (2.7.b)	Art 2, 7°	A supplier of nanomaterials delivers his products as aggregates or agglomerates. Does he have to register?	(a) The definition of a substance in nanoparticulate state in the Royal Decree includes its agglomerates and aggregates. If the supplier fulfills the conditions of Art 3 of the Royal Decree, he will have to register.
10 (2.8.a)	Art 2, 8°	What is a natural substance? Are they exempted from registration?	Natural substances are exempted from registration. The definition in the Royal Decree of a substance in nanoparticulate state excludes natural, non-chemically modified substances. Article 2, 8° defines a natural substance as a “naturally occurring substance as such, unprocessed or processed only by manual or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means”. If other products and/or processes (e.g. processes using mechanical means like crushing machines) are used in its production process, the substance cannot be considered as a "natural product".
10 bis (2.9.a)	Art. 2, 9°	Manufactured substances are treated by mechanical means such as crushing, milling or grinding before they are placed on the market. During this treatment, non-intentional produced nanoparticles are generated. Can these nanoparticles in this case be considered as by-product of human activity?	No. Article 2, 9° defines a by-product of human activity as a substance derived from an activity or production process whose primary objective is not the production of that substance. The following shall not be deemed to be by-products of human activity: (a) a substance of which the production is the result of a technical choice ... In this example, although it may not be the primary objective to generate the substance in nanosize, it is the result of a specific technical choice in the production process and you need to register. A by-product of human activity can be e.g. the production of dust particles when driving a car or the production of nanoparticles when welding metal components.
11 (2.16.a)	Art 2, 16°	What if a pigment is not mainly used for its optical properties but for other properties, like stronger binding, more wear resistance, ... and also giving color? Do these have to be registered?	The Royal Decree defines a pigment in Art 2, 16°: “a substance insoluble in the standard suspensions and used for its optical properties”. When the pigment is not used for its optical properties, it is not considered as a pigment in this Royal Decree, and therefore the exemption given in Art 1, 8° does not apply.

Number	Ref. RD	FAQ	Answer
12 (2.16.b)	Art 2, 16°	The Royal Decree defines a pigment as: “a substance insoluble in the standard suspensions and used for its optical properties”. (a) What is understood under 'standard suspensions'? (b) How is 'insoluble' defined?	a) A distinction is made between a pigment, which is insoluble in its matrix and thus resulting in a suspension, and a dye, which either is itself a liquid or is soluble in the matrix and thus resulting in a solution. Usual suspension matrices include water, alcohols, hydrocarbon compounds, etc. that are used to disperse the pigment in the mixture. (b) A substance which is insoluble in the matrix will form a separate phase in the mixture, in the conditions (e.g. temperature, ion concentration,...) at which the product is normally used.
13 (2.17.a)	Art 2, 17°	What is 'placing on the market'?	Placing on the market is defined in Art 2, 3° of the Law of December 21st 1998 on standards for products intended for promotion of sustainable production and consumption methods: “The introduction, the import or the precarious possession for the purpose of selling or making available to third parties, the offer to sell, the sale, the offer to rent, the renting, or the cession, free or against payment’ (unofficial translation of article 2, 3° of the law of December 21 <sup>st</sup> , 1998)
14 (2.17.b)	Art. 2, 17° & 3, 3°	I am a Belgian firm, and I import, in Belgium, a mixture containing substances produced in nanoparticulate state. Then I sell it to consumers. I do not produce or modify the mixture. Do I have to register?	Yes, you must register your mixture. Placing on the market is defined in FAQ 2.17.a. In the described case, we actually have two placings on the market: the importation and the sale to consumers. For more information see also question 13. The first placing on the market (importation) triggers the obligation to register according to Art 3, 3°b. The import is a form of placing on the market, and that placing on the market is done exclusively to professional user(s); in this specific case, there is only one professional user: the importer. The second placing on the market is exempted, since the mixture is not exclusively placed on the market to professional users.
15 (2.17.c)	Art 2, 17°	I am a Belgian manufacturer of substances produced in nanoparticulate state and I use my own production for further processing, after which the substance produced in nanoparticulate state is no longer in nanoparticulate state. Do I have to register?	The first criteria to determine whether you need to register or not is the placing on the Belgian market. In this case, you do not place the substance(s) produced in nanoparticulate state (or mixture(s) containing them) on the market, since you use it all yourself. So you do not have to register.

Number	Ref. RD	FAQ	Answer
16 (2.17.d)	Art 2, 17°	I am a Belgian manufacturer of substances produced in nanoparticulate state and I export all these substances. Do I have to register?	No, you do not have to register. In this case, you do not place the substance(s) produced in nanoparticulate state on the Belgian market.
17 (2.17.e)	Art 2, 17°	(a) I am a Belgian manufacturer of substances produced in nanoparticulate state and I export part of these substances. The other part is sold to professional users in Belgium. Do I have to register? (b) I am a Belgian manufacturer of substances produced in nanoparticulate state and I export part of these substances. The other part is sold to consumers in Belgium. Do I have to register?	(a) Yes, you need to register since you place the substance(s) produced in nanoparticulate state on the Belgian market. (b) Yes. If the manufacturer places his products on the market, either to professional users, either to consumers or both categories of users, he has to register.
17bis (2.17.f)	Art 2, 17°	A Belgian company buys a substance in nanoparticulate state in France and sells it in Spain. The substance never enters the Belgian territory physically. Does that company have to register?	No. Only the substances produced in nanoparticulate state (or mixtures containing these substances) that physically enter the Belgian territory need to be registered.
18 (2.18.a)	Art 2, 18°	Who is a “professional user”?	A professional user is defined in Art 2, 18° of the Royal Decree as: ‘a person registered with the Enterprise Crossroads Bank or engaged in a commercial activity in a country other than Belgium, and who, in the course of business, uses a product subject to registration or notification on foot of this Decree’. The reference to the type of use in this definition is there to make sure that the only products that are used by the acquirer in the framework of its professional activity is included in the scope, while products acquired by professionals for private use only are not. The notion of “use” is defined largely, as “any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation” (Art 2, 19° of the Royal Decree - reference to Article 3 (24) of the REACH regulation). This definition explicitly includes “storage” and “keeping”. There is no mention in that definition that would infer,

Number	Ref. RD	FAQ	Answer
			for example, that “storage or keeping in relation to distribution” would not enter the definition of “use”.
19 (2.19.a)	Art 2, 19°	The Royal Decree defines 'Use' as the use defined in Article 3, 24° of the REACH Regulation, i.e. use means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation. Is it only own use or also use by downstream users?	It is the own use and the intended use by professional users.
20 (3.a)	Art 3	When does a distributor have to register?	If a distributor places on the market a substance or a mixture which meets the definition of a substance produced in nanoparticulate state (Art 2, 7° of the Royal Decree), and fulfills the conditions of Art 3 of the Royal Decree, he will have to register his substance or mixture. For distributors, Art 3 of the Royal Decree states that they have to place the substance or mixture on the market <u>exclusively</u> to professional users. If a distributor places the substance or mixture on the market (also) to consumers, he does not have to register.
21 (3.3.a)	Art 3, 3°	(a) I am a manufacturer of substances produced in nanoparticulate state, or mixtures containing such substance(s). I place my products on the market to professional users and to consumers. Do I have to register? (b) The substance or mixture is consequently placed on the market by one of the customers, exclusively to professional users. Does he have to register? Can he ask for a registration number from his supplier?	(a) According to Art 3 of the Royal Decree, manufacturers must register in all cases, whatever the quality of their customers. (b) In this example, the customer places the substance or mixture on the market to professional users, so he will have to register also. According to Art 10 of the Royal Decree, the manufacturer has to give, amongst others, the registration number to his professional user(s). According to Art 8, §1 of the Royal Decree, the customer in this example can register the substance or mixture using a limited registration.
22 (3.3.b)	Art 3, 3°	I buy a substance produced in nanoparticulate state that fulfills the conditions for registration, and then I resell it to other distributors, without modifying the substance. Do I have to register?	Yes, you must register your substance. One of the conditions to be subject to the obligation of registration stated in Art 3 of the Royal Decree is that the company places the product on the market to professional users. A professional user is, in short, a company or a person who acquires the product, and uses the product in the framework of its economic activities.

Number	Ref. RD	FAQ	Answer
			Selling a product is covered by the notion of placing on the market and your clients are exclusively professional users, you must therefore register.
23 (5.1.a)	Art 5, §1	Who are the actors involved in the registration of substances produced in nanoparticulate state, or mixtures containing such substances? Belgian and non-Belgian importers, distributors or manufacturers?	The obligation to register is triggered by the placing on the Belgian market of the product. Manufacturers who place the product on the Belgian market must always register, while distributors must only register if they place on the Belgian market exclusively to professional users. The notion of placing on the market includes import, so Belgian or non-Belgian importers have to register as well (see also FAQ 2.17.a and 2.17.b)
24 (5.2.a)	Art 5, §2	Art 5, §2 of the Royal Decree states that: "The registrant shall be granted with two months to provide the information sought, unless the FPS HFCSE has imposed a different deadline". Can one ask for a longer period (e.g. in case of a long complex international supply chain)?	For the first registration, the registrant can explain why he does not yet have all the information required, in order to submit his registration. At the moment of the first annual update, it is expected that the required information is available. Requests for a longer period can be considered by the FPS, but will have to be thoroughly justified (e.g. through a written and dated order for a laboratory analysis).
25 (5.2.b)	Art 5, §2	Art 5, §2 of the Royal Decree states "If the information sought is not furnished within the period specified in the third sentence of the second paragraph of this Article, the registration requirement shall be deemed not to have been complied with.." What about the social consequences when e.g. a car assembly line has to shut down due to one missing mixture or component because the registration is not fulfilled? Is there a procedure to cover the social consequences?	Article 21 of the Royal Decree states how violations of the provisions of this Royal Decree will be treated. It refers to the Articles 15 to 18 of the law of December 21 <sup>st</sup> 1998 relative to products' norms. The sanctions stated in Art 17 and Art 18, §4 of the law, as well as other corrective measures (such as seizures or shut down of installations) must always be proportionate to the gravity of the infringement. Moreover, there are two different processes to impose the measures (some measures are specifically linked with one of the processes, while some other may be imposed in the framework of both processes): <ul style="list-style-type: none"> <li>- Action by the administrative inspectors defined in Articles 15 to 15quinquies, following procedures specified in the Royal Decree of July 2<sup>nd</sup> 2014 organising the execution of controls about the application of the law of December 21<sup>st</sup> 1998 and in the Royal Decree of December 6<sup>th</sup> 2012 relative to administrative fines;</li> <li>- Action by the State Attorney, on the basis of the Code on criminal proceedings.</li> </ul>

Number	Ref. RD	FAQ	Answer
			Both these processes include protective measures for the involved company.
26 (5.2.c)	Art 5, §2	Article 5, §2 of the Royal Decree states that “The registration shall be submitted electronically to the FPS HFCSE” What if a supplier in the supply chain cannot deal with the (electronic) procedures?	If you encounter problems with the registration tools, we invite you to: <ul style="list-style-type: none"> <li>- Consult the guidance, where you may find information on these issues;</li> <li>- Contact our helpdesk for further help: <a href="mailto:info@nanoregistration.be">info@nanoregistration.be</a></li> <li>- Contact the FPS Contact Center at +32 (0)2 524.97.97</li> </ul>
27 (5.2.d)	Art 5, §2	What is meant by 'incomplete or inaccurate information'?	As mentioned in the annexes, some information is mandatory, other information can be provided when available. In this context, 'incomplete' means that not all the mandatory information is given. Inaccurate information is for instance information which is contradictory or which is not technically or scientifically reliable.
28 (5.3.a)	Art 5, §3	Art 5, §3 of the Royal Decree states: “The FPS HFCSE shall assign a unique number to every registration at the moment the registrant submits it electronically”. (a) Will the same number be maintained when an annual update has been done according to annex 3 or 4? (b) Are the initial data still accessible after submission? (c) If changes/corrections are done in the initial submission, will a new registration number be generated?	(a) Yes. The first registration according to annex 1 or 2 (or annex 6) will generate a unique number (e.g. 123456). When performing an annual update, the same number will be kept, but an indication of the trade year will be added (e.g. 123456_2017). It is the first number (123456) that has to be transferred along the supply chain. (b) Yes. The initial data will always be accessible, even after the submission. It will be possible to correct these data, as long as no annual update has been done. When an annual update has been done, you will have to correct the data in the updated registration. (c) No. Changing or correcting data in the initial submission does not have any influence on the registration number – as far as these changes do not concern a change in the registered substance or the registered mixture.
29 (6.a)	Art 6	What needs to be done if substances produced in nanoparticulate state or mixtures containing these substances, are imported into Belgium? Does the foreign supplier who sells to a Belgian customer have to register,	The person or entity who legally imports the substance(s) or the mixture(s), has to register. If the supplier did not register, the importer will have to make a full registration.

Number	Ref. RD	FAQ	Answer
		or is it the Belgian customer who sells the substances or mixtures further, has to register?	If the supplier has registered and transferred the registration number to the importer, the importer can use the option for a limited registration according to Art 8 of the Royal Decree. However, there is no obligation for the supplier to do so.
30 (6.1.a)	Art 6, §1, 3°	(a) How is a representative defined? (b) Who can appoint a representative?	(a) A representative is any person that has been mandated by the supplier to register on its behalf. The mandated representative must be established inside the EEA. (b) The supplier designates his representative.
31 (6.1.b)	Art 6, §1, 2°	What if the supplier, who transmits substances produced in nanoparticulate state or mixtures containing such substances, to the person who places them on the Belgian market, isn't established in the EEA? Who must declare in that case?	The person or entity who places the substances produced in nanoparticulate state on the Belgian market, is responsible for the registration.  However, according to Art. 6 §1 the information of section 2 of the annexes 1 and 2 of the Royal Decree can be given by (but this is not an obligation) 1) The representative in the EEA of the supplier 2) The foreign supplier
32 (8.a)	Art 8	If a registrant obtains the same substance produced in nanoparticulate state, from different suppliers, which previous registration number does he have to use in the limited registration?	A substance produced in nanoparticulate state is considered to be the same only if the substance and its properties, as described in the Royal Decree, are identical According to Art 8 of the Royal Decree, the registrant can use the possibility of a limited registration when he has a previous registration number concerning the registration of the same substance or mixture. If the registrant has more than one previous registration number, the registrant is free to choose which previous registration number he uses. It is recommended to use the previous registration number from his major supplier. It is also recommended to add the other previous registration numbers in the comment box as additional information.
33 (8.1.a)	Art 8, §1, 1°	How will the registrants know with whom Belgium has a mutual agreement as mentioned in Art 8, §1, 1°?	Information on the agreements will be available on the website and via the registration tool.

Number	Ref. RD	FAQ	Answer
			In the software, only the countries with whom Belgium has an agreement can be chosen
34 (8.1.b)	Art 8 §1, 3°	I place non-hazardous substances, produced in nanoparticulate state, or mixtures containing these substances, on the Belgian market. Do I have to register?	Yes. All the substances, produced in nanoparticulate state, and mixtures containing these substances, that are not exempted in Art 1, fall under the definitions of Art 2 and fulfill the conditions of Art 3 of the Royal Decree, have to be registered. There is no correlation between the potential hazards of the substances and mixtures and the obligation to register.
35 (10.a)	Art 10	To which data do the registrants have access? It could be useful, for example, to have access to the information of the registered substances and to copy it for the registration of a mixture.	The registrants have only access to their own registrations – created within one account. The registrant can export his own registration data to a pdf-file. The use of a limited registration, as described in Art 8 of the Royal Decree, prevents the need to copy the information of section 2 of the annexes. In case the registrant needs the information required in the other annexes, he can consult his own registration files or his own exported pdf-files.
36 (10.b)	Art 10	Is information on registration needed for labeling? If requirement of labelling is not included where should we display the registration details?	There is no requirement to include the registration number of the Belgian nanoregistry on the label. Companies are free to choose the appropriate way of communication to pass on the registration number to their customer. This could be integrated in a SDS, an invoice, a technical data sheet, a separate mailing,... Please note that the communication of the registration number needs to be traceable, this means that it must be possible to show this communication if asked for by an enforcement officer.
37 (10.c)	Art 10	Are suppliers required to inform their customers that the product they supply is a substance produced in nanoparticulate state, or that the mixture they supply contains these substances? Or is it the customer's responsibility to ask this information from all his suppliers?	The person or entity who places the substances, produced in nanoparticulate state, or mixtures containing these substances, on the Belgian market has to register his products if he fulfills the criteria of the Royal Decree. According to Art 10, it is the registrant who has to transfer, amongst others, the registration number to his customers.

Number	Ref. RD	FAQ	Answer
			In case the supplier does not place the product on the Belgian market ('foreign supplier'), he may (but is not obliged) to register the data described in section 2 of annex 1 or 2.
38 (10.2.a)	Art 10, 2°	<p>The chemical name, the CAS number and, if available, the EINECS or ELINCS number of the substances produced in nanoparticulate state; are described in Section 2 of Annexes 1 or 2.</p> <p>(a) Which chemical name has to be given in case there is more than one?</p> <p>(b) What if the substance produced in nanoparticulate state has no CAS number?</p> <p>(c) What if the substance has a whole series of CAS numbers?</p> <p>(d) What if one substance (with only one CAS number) has several different nano-forms?</p> <p>(e) Can the REACH registration number be provided instead if the substance is registered under REACH?</p>	<p>As a general rule, the registration data should be similar to those mentioned on the SDS of the substance or the mixture.</p> <p>(a) If the substance produced in nanoparticulate state has several chemical names, the English IUPAC name is preferred.</p> <p>(b) in the registration tool, there is an option to indicate that there is no CAS-number available</p> <p>(c) one CAS-number is sufficient, but please note that it is the registered CAS-number that should be transferred to the professional user. You can mention the other CAS-numbers in a comment box for additional info.</p> <p>(d) Depending on the differences, different registrations may be required. Please contact the helpdesk in case of doubt at <a href="mailto:info@nanoregistration.be">info@nanoregistration.be</a></p> <p>(e) No, the REACH registration number can be given in the registration tool, but it does not replace the CAS- or EC-number.</p>
39 (10.2.b)	Art 10, 2°, 3°	<p>The registration number received during the registration of a mixture containing substances produced in nanoparticulate state, should be communicated to the professional downstream chain.</p> <p>The substances produced in nanoparticulate state are however not classified under the regulation (EC) n° 1272/2008 and consequently do not drive any classification when used in a mixture (whatever the concentration in the mixture). Should the concentration of the substances produced in nanoparticulate state, in the mixture be communicated to the professional downstream chain?</p>	<p>The concentration of these substances in the mixture may be communicated to the professional downstream chain. This would certainly help the next economic actor on the chain to fulfill their obligations under the decree. However, this is not an obligation.</p>
40 (20.a)	Art 20	<p>What are the guarantees that confidential info will not be misused?. To whom may the information be disclosed? Who decides? Who has access?</p>	<p>The data as mentioned in Art 20 of the Royal Decree are considered to be confidential. There is a log of who accesses the data through the back office (registration only with FPS-account).</p>

Number	Ref. RD	FAQ	Answer
			The same rules are applicable for the access given to the governmental departments as mentioned in Art 20, §3 of the Royal Decree.
40 bis (21.a)	Art. 21	What kind of proof needs to be presented to demonstrate the absence of nanomaterials, especially for importers (who do not produce the substance or mixture themselves)?	<p>As an importer, you can ask your supplier (who does not need to register, as he does not place the product on the Belgian market) whether the substance or mixture you place on the market, contains nanomaterials. If he confirms the presence of nanomaterials, he can register (on a voluntary basis) the substance or mixture imported (as a 'foreign supplier').</p> <p>More indications about the presence of nanomaterials can be found via:</p> <ul style="list-style-type: none"> <li>- The name of the product</li> <li>- Specific properties or price</li> <li>- The safety data sheet</li> <li>- Other information of the supplier.</li> </ul> <p>If the answer to the questions above is negative, the importer does not need to register. As a proof to demonstrate the absence, the documentation/motivation of the answers to the questions above can be used.</p> <p>If however, there is a reasonable suspicion of the presence of nanomaterials and no relevant information is available, a laboratory analysis could be advisable.</p>
41 (24.a)	Art 24	Will the deadlines be established according to the position in the supply chain? It may be necessary to establish a closer deadline for upstream users, in order to enable downstream users to fulfill their obligations.	<p>Substances already on the market have to be registered before January 1<sup>st</sup>, 2016. Mixtures already on the market have to be registered before January 1<sup>st</sup>, 2017.</p> <p>This gives a year for passing the registration number to the formulators of mixtures.</p> <p>New substances or mixtures have to be registered before they are placed on the market.</p> <p>Furthermore, at the first registration of a substance or a mixture, the registrant can indicate that not all the data required have been provided and justify why this is. The required data will however have to be provided at the first annual update.</p>

Number	Ref. RD	FAQ	Answer
42 (24.b)	Art 24	What if the REACH registration is only due in June 2018? Some data requested might not (yet) be available? How to proceed?	The data required in the Belgian nanoregistry are not the same as the data required in REACH. As set out in the Royal Decree, some data have to be provided at the time specified in this Decree, some data have to be provided if available. There is no correlation with the deadlines in REACH.
42 bis (A.2)	Annex 2	Do I always have to register each mixture separately?	No, if you have a group of mixtures which fulfill the definition of a category of mixtures, you can register them together. A category of mixtures is a group of mixtures that meet the following cumulative conditions: <ul style="list-style-type: none"> <li>- The different mixtures in the group are intended for the same use and can be used in a similar way AND</li> <li>- The substances produced in nanoparticulate state contained in the mixtures of the group are the same for each of these mixtures, and the characteristics described in Section 2 of Annex 2 of the Royal Decree are identical for each of these substances AND</li> <li>- The mass concentration of the substances produced in nanoparticulate state is the same for all the mixtures in the group, a maximum variation of 20% (meaning + 10% and -10%) is allowed for each of these substances.</li> </ul>
43 (A.S1.b)	Section 1 of the annexes	The registration is done by a non-Belgian company (EU or non-EU). Which identification number must be used when the company does not have an Enterprise Crossroads Bank identification number?	Section 1, 2° asks for the Enterprise Crossroads Bank identification number, if the registrant has one. There are two options to create an account for a registrant in the register: (a) if the registrant has an identification number from the CBE, he can use this number and some of the data as described in section 1 will be retrieved from the CBE. (b) if the registrant does not have an identification number from the CBE, he will have to enter the data as described in section 1, manually.
44 (A.S1.b)	Section 1 of the annexes	Can a company register for its different establishments ?	Yes, if the different establishments are a part of the same legal entity. An account contains the information concerning the identification of the registrant, and is created for or by the headquarter of the company. Within this account, it is also possible to create one or more

Number	Ref. RD	FAQ	Answer
			<p>establishments (in case of use of CBE-number, these data will also be retrieved).</p> <p>Within one account, several registration files (for different substances, for different mixtures) can be created. At the level of the registration of the substance or the mixture, there is an option to indicate the establishment concerned with this substance or mixture.</p>
45 (A.S2.a)	Section 2 of the annexes	What has to be done when not all information about the nanomaterial is available, e.g. when a non-EU supplier does not provide the information requested, like the registration number or the technical information of the material?	<p>For the first registration, the registrant can explain why he does not yet have all the information required in order to submit his registration. At the moment of the first annual update, the information is expected to be available, either provided by the supplier or as a result of having the substance or mixture analysed.</p> <p>Furthermore, it will be possible for a foreign supplier to submit the technical data of the substance or the mixture (section 2 of the annexes 1 or 2) and transfer the registration number to his customers. In this way, the foreign supplier does not have to release the technical data to his customers.</p>
46 (A.S2.b)	Section 2 of the annexes	How do I know which determination methods are used for the technical properties (e.g. specific surface area,...)	<p>In the registry software, you will be able to choose from a list of possible determination methods. If your determination method is not in the list, you can choose the option 'other' and specify the method used. Even if the method used is chosen from the list, you still need to motivate why you have used this method for this specific substance or mixture, describe the experimental circumstances and document the traceability of the calibration chain and the measurement uncertainty.</p>
46 bis (A.S2.c)	Section 2 of the annexes	What is the difference between the average and the median value?	<p>The average is the sum of all the observations, divided by the number of observations; the median is defined as the observation for which 50% of the observations have a lower result.</p> <p>The average is sensible for extreme observations, where the median is not. If the distribution curve of the observations is asymmetric or if there are extreme observations, a difference between the average and the median can be expected.</p>

Number	Ref. RD	FAQ	Answer
46 tris (A.S2.d)	Section 2 of the annexes	When is a measurement traceable?	<p>A measurement is traceable when:</p> <ul style="list-style-type: none"> <li>- An unbroken and documented chain of calibrations can link the instrument used for this measurement, with an international reference AND</li> <li>- In each link in the chain an estimation of the uncertainty of the measurement is available AND</li> <li>- The user of the instrument puts in place procedures which maintain over time the performance guaranteed by calibration AND</li> <li>- Factors that influence the measurement are identified and quantified, and a total measurement uncertainty is calculated, documented and mentioned in the measurement report.</li> </ul> <p>Measurements made in a production line can meet these criteria, if the on-line measuring instruments were calibrated.</p>
46 quater (A.S2.e)	Section 2 of the annexes	What is measurement uncertainty?	<p>A measurement result is expressed as a numerical value, a unit and an uncertainty. Many factors can cause variations in the measurement result and contribute to this uncertainty:</p> <ul style="list-style-type: none"> <li>- Drift of the instrument</li> <li>- Calibration corrections</li> <li>- Sensitivity of the instrument to environmental conditions (e.g. temperature, humidity,...)</li> <li>- Sample preparation</li> <li>- Different operators</li> <li>- ...</li> </ul> <p>To assess the uncertainty of the measurement results, internationally recognized rules exist. They are described in the 'Guide to the expression of uncertainty in measurement' that includes many practical examples (GUM, <a href="http://www.bipm.org/en/publications/guides/gum.html">http://www.bipm.org/en/publications/guides/gum.html</a>). These rules explain how to calculate/estimate the uncertainty for each source contributing to the uncertainty of the result, how to combine these uncertainties according to a measurement model and finally how to express the uncertainty associated with the result.</p>

Number	Ref. RD	FAQ	Answer
46 cinquies (A.S2.f)	Section 2 of the annexes	How can I enter the REACH registration number?	A REACH registration number has the following format: <TYPE> - <BASE-NUMBER> - <CHECKSUM> - <INDEX-NUMBER>. In the Belgian nanoregistry, you should only enter <TYPE><BASE-NUMBER><CHECKSUM> (note the absence of hypens), since the index number only refers to the index of a member in a joint submission.
47 (A.S3.a)	Section 3 of the annexes	How can I determine the quantity of the substance placed on the market for my registration?	The registrant has to indicate the quantity placed on the Belgian market. This means <ul style="list-style-type: none"> <li>• the quantities exported do not have to be registered.</li> <li>• In the case of a manufacturer, the quantity sold to consumers also needs to be taken into account</li> <li>• In the case of a manufacturer, the stock also has to be taken into account if the stock is intended to be sold to third parties</li> </ul> <p>At the first registration, the registrant makes an estimation of the quantity that will be placed on the market in the calendar year concerned by the registration.</p> <p>At the annual update, the registrant gives the exact quantity which was placed on the market during the calendar year preceding the annual update.</p> <p>Please note that, when a company has different roles in the supply chain, the quantity for each role in the supply chain can be registered. This could be useful, for example, for a company that buys a substance in nanoparticulate state (or mixtures containing them) and sells some 'as bought' (distributor) and sells the rest in other packages (refills).</p>
48 (A.S4.a)	Section 4 of the annexes	How are the uses of the substance(s) produced in nanoparticulate state, or mixture(s) containing such substances, described ?	The registrant will be able to choose the applicable uses from a list. This list is based on the European use descriptor system.
49 (A.S5.a)	Section 5 of the annexes	How do we have to register the professional users if the list is very long?	The registrant can choose whether he wants to enter the data concerning the professional users manually, or whether he wants to upload a list of professional users, or a combination of both methods. The format of this

Number	Ref. RD	FAQ	Answer
			list is free, but it has to be provided in one of the current applications (pdf, word, excel,...).
50 (A.S5.b)	Section 5 of the annexes	Are my professional users always located in Belgium?	Not necessarily. Every professional user has to be mentioned in the context of the placing on the market in Belgium.