KINGDOM OF BELGIUM

FEDERAL PUBLIC SERVICE HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT

Unofficial translation of

27 Mei 2014 – Koninklijk besluit betreffende het op de markt brengen van stoffen geproduceerd in nanoparticulaire toestand (B.S. 24-09-2014)

27 Mai 2014 – Arrêté royal relatif à la mise sur le marché des substances manufacturées à l'état nanoparticulaire (M.B. 24-09-2014)

May 27th 2014 - Royal Decree concerning the placing on the market of substances produced in nanoparticular state

PHILIPPE, King of the Belgians,

To all those present and to come, Greetings.

Having regard to the Law of August 4th, 1996 on the well-being of workers at work, Article 4, § 1, numbered by the Law of April 7th 1999 and amended by the Law of January 10th 2007;

Having regard to the Law of December 21st 1998 on standards for products intended for promotion of sustainable production and consumption methods and protection of the environment, health and workers, Article 5, § 1, first paragraph, 2°, amended by the Laws of December 27th 2004 and July 27th 2011, § 1, first paragraph, 6°, amended by the Law of July 27th 2011, and § 1, first paragraph, 11°, Article 5, amended by the Law of July 27th 2011, and Article 20, amended by the Law of September 10th 2009;

Having regard to the Commission Recommendation No 2011/696/EU of October 18th, 2011 on the definition of nanomaterial;

Having regard to the decision of the Council of Ministers of February 7th 2014 concerning the date of entry into force of Articles 11 to 17 of this Decree;

Having regard to the impact analysis of the regulation, conducted in accordance with Articles 6 and 7 of the Law of December 15th 2013 laying down various provisions on administrative simplification;

Having regard to the Communication to the European Commission, on July 4th 2013, in application of Article 8, first paragraph, of Directive 98/34/EC of the European Parliament and of the Council of June22nd 1998 laying down a procedure for the provision of information in the field of technical standards, and regulations and rules on Information Society services;

Having regard to the opinion of the Inspector of Finances, given on August 6th 2013;

Having regard to the involvement of the regional governments in the drafting of this Decree on September 24th 2013;

Having regard to the opinion of the National Labour Council, given on October 22nd 2013;

Having regard to the opinion of the Central Council for the Economy, given on October 23rd 2013;

Having regard to the opinion of the Federal Council for Sustainable Development, given on October 25th 2013;

Having regard to the opinion of the Superior Health Council, given on November 6th 2013;

Having regard to the opinion of the Consumption Council, given on November 7th 2013;

Having regard to the approval of the Minister of Budget, given on February 5th 2014;

Having regard to the opinion of the High Council for Prevention and Protection at Work, given on February 7th 2014;

Having regard to opinion 55.443/1 of the Council of State, given on March 21st 2014, in application of Article 84, § 1, first paragraph, 2°, of the laws on the Council of State, coordinated on January 12th 1973;

On the proposal of the Minister of Economy, the Minister of Internal Affairs, the Minister of Public Health, the Minister of Work and the Secretary of State for Environment and on the advice of the Ministers meeting in Council,

We have decreed and hereby decree:

Chapter 1. Scope and definitions

Article 1. The provisions of this Decree shall not apply to the following products:

1° Biocidal products and treated articles falling within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council of May 22nd 2012 concerning the making available on the market and use of biocidal products, and biocidal products that were registered or for which an authorisation was granted in accordance with the provisions of the

Royal Decree of May 22nd 2003 concerning the placing on the market and use of biocidal products;

2° Medicinal products falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council of March 31st 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;

3° Medicinal products for human use and veterinary medicinal products falling within the scope of the Royal Decree of December 14th 2006 concerning medicinal products for human use and veterinary medicinal products;

4° Foodstuffs, and substances and objects intended to come into contact with foodstuffs, as referred to in Article 1, 1° and 2°, b) of the Law of January 24th 1977 on the protection of the health of consumers in matters of foodstuffs and other products;

5° Feed, as defined in Article 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of January 28th 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;

6° Veterinary medicinal products and medicated feedingstuffs falling within the scope of the Law of June 21st 1983 on medicated feedingstuffs;

7° Processing aids and other products which may be used for the processing of ingredients of agricultural origin from organic production, referred to in Section B of Annex VIII to Commission Regulation (EC) No 889/2008 of September 5th 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control;

8° Pigments, when placed on the market in a mixture, an article or a complex object.

Article 2. For the purpose of this Decree, the following definitions apply:

1° Law of December 21st 1998: the Law of December 21st 1998 on standards for products intended for promotion of sustainable production and consumption methods and protection of the environment, health and workers;

2° REACH Regulation: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of December 18th 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC;

3° particle: a minute piece of matter with defined physical boundaries;

4° aggregate: a particle comprising of strongly bound or fused particles;

5° agglomerate: a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;

6° substances: substances as defined in Article 2, 4° of the Law of December 21st 1998;

7° substance produced in nanoparticular state: a substance containing 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 of one nanometer to one hundred nanometers, with the exception of natural, non-chemically modified substances and the substances of which the fraction between one nanometer and one hundred nanometers is a by-product of human activity. Fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below one nanometre shall be deemed to be substances produced in nanoparticular state.

8° natural substance: 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;

9° by-product of human activity: 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 the production of which is the result of a technical choice;

b) a substance that is not necessary for the production of the main product;

c) a substance the specific technical characteristics of which are the intended result of changes in the production process;

10° mixtures: mixtures as defined in Article 2, 6° of the Law of December 21st, 1998;

11° article: an article as defined in Article 2, 6°bis of the Law of December 21st ,1998;

12° complex object: an object consisting of a set of articles;

13° category of articles or complex objects: group of articles or complex objects that meet the following cumulative conditions:

a) the various articles or complex objects of the group that are intended for the same use and can be used in a similar manner;

b) the substances produced in nanoparticular state that were incorporated into the articles or complex objects of the group are the same for every article or complex object, and the characteristics referred to in Section 3 of Annex 5 are identical for each of these substances;

c) in articles or complex objects, the matrix of each of the substances referred to in b) is the same for all the articles or complex objects of the group;

14° products: tangible movable goods, as defined in Article 2, 1° of the Law of December 21st, 1998;

15° filler: a solid, immiscible and mechanically dispersed in a matrix in order to reduce the costs, improve certain properties or to modify the density of the matrix;

16° pigment: a substance that is insoluble in the standard suspension media and is used for its optical properties;

17° placing on the market: placing on the market as defined in Article 2, 3° of the Law of December 21st, 1998;

18° professional user: 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;

19° use: use as defined in Article 3 (24) of the REACH Regulation;

20° scientific research and development: scientific research and development as defined in Article 3 (23) of the REACH Regulation;

21° product and process oriented research and development: the activities listed in Article 3 (22) of the REACH Regulation;

22° registrant: a person subject to the registration obligation on foot of this Decree;

23° notifier: a person subject to the notification obligation on foot of this Decree;

24° calendar year: the period from January 1st to December 31st of any given year;

25° FPS HFCSE: Federal Public Service Health, Food Chain Safety and Environment.

Chapter 2. Registration of substances produced in nanoparticular state and of mixtures containing one or more substances produced in nanoparticular state

Article 3. Substances produced in nanoparticular state that meet the following cumulative conditions shall be placed on the market only if they were registered in conformity with this Chapter:

1° the substance is placed on the market as such or in a mixture;

2° a total quantity of more than one hundred grams of the substance is placed on the market by the company in question during the calendar year covered by the registration;

3° the person who places the substance or mixture on the market:

a) produced the substance or mixture himself; or

b) places the substance or mixture on the market exclusively for professional users.

Article 4. The registration of a substance produced in nanoparticular state placed on the market as such shall contain the information set out in Annex 1.

Where one or more of the substances produced in nanoparticular state referred to in Article 3 are placed on the market in a mixture, the mixture shall be subject to the registration obligation. This registration shall contain the information set out in Annex 2.

Article 5. § 1. The registration shall be performed by, or on behalf of, the person responsible for placing the substance or mixture in question on the market, before the substance or mixture is effectively placed on the market.

§ 2. The registration shall be submitted electronically to the FPS HFCSE. The Minister with competence for Public Health has the authority to lay down the detailed rules governing the registration.

If the information provided by the registrant is incomplete or inaccurate, the FPS HFCSE shall ask the registrant to complete it or to furnish the necessary clarifications.

The registrant shall be granted with two months to provide the information sought, unless the FPS HFCSE has imposed a different deadline.

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.

§ 3. The FPS HFCSE shall assign a unique number to every registration at the moment the registrant submits it electronically.

The registrant shall be notified of this number.

Article 6. § 1. Where one or more substances, as such or in a mixture, referred to in Article 3 have been supplied to the registrant by a person established outside the Belgian territory, the information referred to in Section 2 of Annex 1 or 2 concerning these substances may be registered either:

1° By the person placing the substance or mixture on the market;

2° By the person established in the European Economic Area outside the Belgian territory, who supplied the substances in question to the person placing them on the market;

3° By the representative in the European Economic Area of the person established outside the Belgian territory who supplied the substances in question to the person placing them on the market.

§ 2. In the cases referred to in paragraph 1, 2° and 3°, the person established outside the Belgian territory shall receive a registration number which he shall forward to the person placing the substance or mixture on the market.

Article 7. § 1. The registration may be limited to a simplified registration, provided the following cumulative conditions have been met:

1° The person who acquires the substance or the mixture from the registrant, uses it exclusively within the framework of scientific research and development or within the framework of product and process oriented research and development;

2° The acquirer does not subsequently place the substance, or one or several substances produced in nanoparticular state contained in the mixture, on the market in any form whatsoever or, if he subsequently proceeds to placing it/them on the market, this placing on the market shall be subject to the cumulative conditions listed in this paragraph.

§ 2. The simplified registration is in conformity with Annex 6.

In addition, the registrant shall enclose an affidavit, signed by the person responsible for the scientific research and development or product and process oriented research and development, stating that the substances shall subsequently not be placed on the market or, if so, that the cumulative conditions listed in paragraph 1 shall apply to that placing on the market.

Article 8. § 1. The registration may be limited to a limited registration in any one of the following cases:

1° The substance or mixture in question was already the subject of a registration similar to the registration specified in Annex 1 or 2 with a foreign national authority with whom Belgium has a mutual agreement concerning the registration of substances produced in nanoparticular state;

2° The registrant received a registration number in application of Article 6, § 2;

3° At least one of the substances produced in nanoparticular state referred to in Article 3 which the registrant is placing on the market was registered in accordance with Annex 1 or 2 when it was placed on the market on a previous occasion, and the registrant did not modify the

characteristics of the particles of the aforementioned substance before placing it on the market as such or in a mixture.

§ 2. The limited registration is in conformity with Annex 1 and 2, with the exception of Section 2 of the Annex in question.

In said Section 2, the registrant can replace the information required for each of the substances produced in nanoparticular state he received a registration number for, by entering that registration number.

In the case referred to in paragraph 1, 1°, the registrant shall enter the reference number he was issued with by the foreign national authority and the name of the State that corresponds to that national authority.

Article 9. The registrant shall update or, where appropriate, correct the information registered in accordance with the provisions of Articles 4 to 6 and 8 at the latest by March 31st of the calendar year following the year in which the substance was placed on the market.

The aforementioned update shall contain the information specified in:

1° Annex 3, in the case of registrations relating to a substance produced in nanoparticular state placed on the market as such;

2° Annex 4, in the case of registrations relating to a mixture.

The registrant shall subsequently update the information every year before March 31st, in conformity with the same Annexes.

Article 10. When a registrant places on the market, for a professional user, a substance or mixture which he registered, he shall furnish the latter with:

1° The registration number of the substance or the mixture;

2° The chemical name, the CAS number and, if available, the EINECS or ELINCS number of the substances produced in nanoparticular state described in Section 2 of Annexes 1 or 2;

3° If the registration concerns a mixture: the chemical formula of every substance produced in nanoparticular state registered in Section 2 and contained in the mixture with a mass concentration higher than or equal to the lowest threshold value applicable to classification referred to in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of December 16th 2008 on classification, labeling and packaging of substances and mixtures.

The registrant shall, upon request, furnish the statutory or contract personnel referred to in Article 15, § 1, and Article 15bis of the Law of December 21st ,1998 with proof of said transmission.

The person who receives a registration number within the framework of the first sentence of this Article or of Article 6, § 2, does not have any access to the content of the registration identified by means of the aforementioned registration number.

Chapter 3. Notification of articles and complex objects containing one or more substances produced in nanoparticular state

Article 11. § 1. Articles or complex objects that meet the following cumulative conditions shall be placed on the market only if they were the subject of a notification in accordance with this Chapter:

1° One or more substances produced in nanoparticular state were integrated into the article or complex object during any one of the production stages;

2° A quantity of more than one hundred grams of at least one of the substances produced in nanoparticular state is placed on the market during the calendar year in which the notification was effectuated;

3° It cannot be excluded that, within the framework of a foreseeable and reasonably appropriate use, a fraction of at least one of the substances produced in nanoparticular state exceeding 0.1 per cent of the mass originally contained in the article or complex object is released; and

4° The article or complex object is produced by the person who places it on the market or is placed on the market exclusively to professional users.

§ 2. A release higher than the threshold specified in paragraph 1, 3° cannot be excluded if the substance produced in nanoparticular state:

1° is in a state of suspension;

2° is integrated in any phase other than the solid phase, including suspension in a liquid, a gas or a gel and the mesophases;

3° is integrated, on its own or as a mixture, in the surface layer of an article or complex object, hereby understanding that the surface to be taken into consideration is the surface that can come into contact with the user and the surfaces that can lead to an indirect exposure of humans via the environment, and this within the framework of a foreseeable and reasonably appropriate use.

§ 3. By way of derogation from paragraph 1, the notification obligation shall however not apply to articles and complex objects containing carbon black, synthetic amorphous silicon dioxide or precipitated calcium carbonate, used as fillers.

Article 12. The notifier is authorised to submit one single notification:

1° by article;

2° by complex object; or

3° by category of articles or complex objects.

The notification shall contain the information specified in Annex 5.

Article 13. § 1. The notification shall be submitted by or on behalf of the person responsible for placing the article or complex object in question on the market, before it is effectively placed on the market.

§ 2. The notification shall be submitted electronically to the FPS HFCSE. The Minister with competence for Public Health has the authority to lay down the detailed rules governing the notification.

If the notification provided by the notifier is incomplete or inaccurate, the FPS HFCSE shall ask the notifier to complete it or to furnish the necessary clarifications.

The notifier shall be granted with two months to furnish the information sought, unless the FPS HFCSE has imposed a different deadline.

If the information sought is not furnished within the period specified in the third sentence of the second paragraph of this Article, the notification requirement shall be deemed not to have been complied with.

§ 3. The FPS HFCSE shall assign a unique number to every notification at the moment the notifier submits it electronically.

The notifier shall be notified of this number.

Article 14. § 1. Where one or more substances produced in nanoparticular state as such or in a mixture, an article or complex object, have been supplied to the notifier by a person established outside the Belgian territory, the information referred to in Section 3 of Annex 5 concerning these substances may be furnished either:

1° by the notifier;

2° by the person established in the European Economic Area outside the Belgian territory, who supplied the substances in question to the person placing them on the market;

3° by the representative in the European Economic Area of the person established outside the Belgian territory who supplied the substances in question to the person placing them on the market.

§ 2. In the cases referred to in paragraph 1, 2° and 3°, the person concerned shall receive a notification number which he shall forward to the person placing the article or complex object on the market.

Article 15. § 1. The notification can be limited to a simplified notification, provided the following cumulative conditions have been met:

1° The person who acquires the article or complex object from the notifier uses it exclusively within the framework of scientific research and development or within the framework of product and process oriented research and development;

2. The acquirer does not subsequently place the substances produced in nanoparticular state contained in the article or complex object on the market in any form whatsoever or, if he subsequently proceeds to placing them on the market, this placing on the market shall be subject to the cumulative conditions listed in this paragraph.

§ 2. The simplified notification shall be in conformity with Annex 6.

In addition, the notifier shall enclose an affidavit with said simplified notification, signed by the person responsible for the scientific research and development or product and process oriented research and development, stating that the substances shall subsequently not be placed on the market or, if so, that the cumulative conditions listed in paragraph 1 shall apply to that placing on the market.

Article 16. § 1. The notification may be limited to a limited notification in any one of the following cases:

1° The article or complex object in question was already the subject of a notification containing at least the information specified in Annex 5 with a foreign national authority with whom Belgium has a mutual agreement concerning the registration of substances produced in nanoparticular state;

2° The notifier received a registration or notification number in application of Article 6, § 2 or Article 14, § 2;

3° The notifier places a substance produced in nanoparticular state on the market, that was already registered or notified in accordance with Annex 1, 2 or 5 by, or on behalf of, the person who previously placed the substance on the market, and the notifier did not modify the characteristics of the particles of the aforementioned substance before placing it on the market as a constituent of the article or complex object in question.

§ 2. The limited notification is in conformity with Annex 5, with the exception of section 3. In said section 3, the notifier can replace the information required for each substance produced in nanoparticular state he received a registration or notification number for, by entering that registration or notification number.

In the cases referred to in paragraph 1, 1°, the notifier shall enter the reference number he was issued with by the foreign national authority and the name of the State that corresponds to that national authority.

Article 17. When a notifier places on the market for a professional user, an article or complex object, which he notified, he shall furnish the latter with:

1° the corresponding notification number;

2° the chemical name, the CAS number and, if available, the EINECS or ELINCS number of the substances produced in nanoparticular state described in Section 3 of Annex 5;

3° The chemical formula of each substance produced in nanoparticular state listed in Section 3 and contained in the article or complex object with a mass concentration higher than or equal to the lowest threshold value applicable to classification referred to in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of December 16th 2008 on classification, labelling and packaging of substances and mixtures.

The notifier shall, upon request, furnish the statutory or contract personnel referred to in Article 15, § 1, and Article 15bis of the Law of December 21st 1998 with proof of said transmission.

The person who receives a notification number within the framework of the first sentence of this Article or Article 14, § 2, does not have any access to the content of the notification identified by means of the aforementioned notification number.

Chapter 4. Common provisions

Article 18. If there is evidence that a substance produced in nanoparticular state may pose a risk to public health or the health of workers, the FPS HFCSE may, on the basis of a request referring to said evidence, require that the registrant or notifier furnishes it with all the information the latter has in his possession with regard to:

1° the potential hazards of the substances produced in nanoparticular state which he places on the market as such or as a constituent of a product;

2° the direct or indirect exposures of persons these substances may give way to;

3° any information that may be useful in terms of assessing the risks these substances may pose to public health and the health of workers.

Article 19. The information supplied to the FPS HFCSE on foot of the provisions of the present Decree shall be recorded under their registration and notification number in a registry managed by the FPS HFCSE under the supervision of the Minister with competence for Public Health.

Article 20. § 1. The following information shall be treated as confidential information, and its dissemination shall be deemed prejudicial to the protection of the commercial interests of the person concerned:

1° the information referred to in Sections 1, 2 and 5 of Annexes 1 and 2, with the exception of Section 2, § 1, 1°, and in Sections 1 and 3 of Annex 5, with the exception of Section 3, § 2, 1° and 5°;

2° the precise use, function or application of the registered or notified substance, mixture, article or complex object;

3° the precise quantities of the registered or notified substance produced in nanoparticular state concerning a product or category of products;

4° the existing links between the registrant or notifier and the latter's suppliers or users whom the registrant or notifier supplies with the substance, mixture, article or complex object to which the registration or notification applies.

Where urgent action is essential to protect safety or health, the authorities may disclose the information referred to in paragraph 1.

§ 2. The authorities shall furthermore treat one or several datum or data referred to in paragraph 2 as confidential information if the registrant or notifier justifies how the publication of said information is potentially harmful to his commercial interests or to that of any other parties concerned, and if the authorities recognise the validity of the provided justification.

This paragraph shall apply to the following information:

1° the total tonnage band, i.e. 100 grams to 500 grams, 500 grams to 1 kilo, 1 kilo to 100 kilos, 100 kilos to 1 tonne, 1 to 10 tonnes, 10 to 100 tonnes, 100 to 1,000 tonnes or more than 1,000 tonnes, the substance produced in nanoparticular state was registered in;

2° the trade name or trade names of the notified or registered substance, the notified or registered mixture, article or complex object;

3° the information furnished on foot of Article 18.

§ 3. The federal, regional and community authorities may seek access to information contained in the register referred to in Article 19 within the framework of the exercise of their competences by informing the FPS HFCSE of the exact objective of their demand.

Without prejudice to the provision of the first sentence of this paragraph, the staff of the Federal Public Service Employment, Labour and Social Dialogue and the Federal Public Service Economy, SMEs, Self-employed and Energy, who were, each for their part, designated by the Minister with competence for Employment or by the Minister with competence for Economy,

shall have direct and systematic access to the information contained in the register referred to in Article 19.

The federal, regional and community authorities shall, within the framework of the use of the data they are furnished with, pay due regard to paragraphs 1 and 2 and shall ensure that these data are protected.

Article 21. Infringements of the provisions of the present Decree shall be identified, established and prosecuted in accordance with Articles 15 to 18 of the Law of December 21st, 1998.

The sanctions imposable for the violation of the provisions of this Decree shall exclusively be the sanctions referred to in Article 17 and Article 18, §4bis of that same Law.

Article 22. The Minister with competence for Public Health has the authority to complete and amend the annexes to this Decree.

Chapter 5. Amending provision

Article 23. Article 14 of the Royal Decree of May 3rd, 1999 concerning the tasks and the functioning of the Committees for Prevention and Protection at Work is completed with a paragraph that reads:

"The information referred to in the first paragraph shall more specifically comprise the information concerning products the employer registered or notified, or in respect of which he received a registration or notification number within the framework of the Royal Decree of May 27th, 2014 concerning the placing on the market of substances produced in nanoparticular state. This information also concerns information about products referred to in Article 1 of the aforementioned Decree, which in application of a specific regulation, are subject to a notification or authorisation in view of the presence of nanomaterials."

Chapter 6. Entry into force and final provision

Article 24. § 1. The provisions of Articles 3 to 10 shall enter into force on January 1st 2016 with regard to substances produced in nanoparticular state placed on the market as such.

The provisions of Articles 3 to 10 shall enter into force on January 1st 2017 with regard to mixtures.

Articles 11 to 17 shall enter into force at a later date, to be set by the King, following an evaluation for the articles.

§ 2. Substances produced in nanoparticular state that are already on the market as such prior to January 1st, 2016 shall be subject to the registration referred to in the present Decree before January 1st, 2016.

Mixtures that are already on the market prior to January 1st, 2017 shall be subject to the registration referred to in the present Decree before January 1st, 2017.

§ 3. As regards the substances referred to in paragraph 1, the updating referred to in Article 9 shall be performed before March 31st, 2017.

As regards the mixtures referred to in paragraph 1, second sentence, the updating referred to in Article 9 shall be performed before March 31st 2018.

Article 25. The Minister with competence for Public Health, the Minister with competence for Employment, the Minister with competence for Economy and the Minister with competence for the Environment are, each for as far as they are concerned, tasked with the implementation of this Decree.

On behalf of the King:

The Deputy Prime Minister and Minister of Economy, Consumer Affairs and the North Sea,

JOHAN VANDE LANOTTE

The Deputy Prime Minister and Minister of the Interior and Equal Opportunities,

JOËLLE MILQUET

The Deputy Prime Minister and Minister of Social Affairs and Public Health, with competence for Beliris and the Federal Cultural Institutions,

LAURETTE ONKELINX

The Minister of Employment,

MONICA DE CONINCK

The Secretary of State for the Environment, Energy and Mobility,

MELCHIOR WATHELET

ANNEX 1

Information to be included when registering a substance produced in nanoparticular state (Article 4 Paragraph 1)

Section 1: Registrant identification

1. Name of the person/company placing the substance on the market.

2. Enterprise Crossroads Bank identification number, if the registrant has one.

3. Sector of activity.

4. Address of registered office.

5. For companies with their registered offices outside the European Economic Area: indication of the quality of the extra-national legal entity or of the mandated representative.

6. Contact details of a physical contact person: first name, surname, address, telephone number, e-mail address.

Section 2: Identification of the substance

§ 1 Mandatory information:

1°. Chemical identification of the substance, i.e.:

a) Chemical name

b) Chemical formula

c) CAS number

d) And the EC number (EINECS or ELINCS), where applicable.

2°. Average and median particle size in relation to a standard deviation.

3. Number based distribution curve for the particle size.

4. Average size of the aggregates and, if the substance is placed on the market in agglomerate form, average size of the agglomerates, in relation to a standard deviation if the latter is available.

5. Qualitative description of the shape of the particles.

6. Qualitative description of the particle coating, where applicable.

Regarding points 2° to-5°, the registrant shall also specify the determination method used, explain why this method is applicable to the substance in question and report the experimental circumstances.

The measurements used to provide the information required under points 2° to 5° shall be traceable, meaning that these measurements can be related to a reference through an unbroken and documented chain of calibrations, each contributing to the measurement uncertainty.

§2 Information to be provided if available at the registration date:

1° If the substance has been registered by the registrant under the REACH-regulation, the registration number. However, the part of the registration number which identifies the individual registrant can be omitted.

2° Where applicable, the type and quantity of each impurity present in the substance produced in nanoparticular state with a mass concentration above 0.1% and, in cases where this information must be furnished for the purpose of other regulatory provisions, each impurity present in the substance produced in nanoparticular state with a mass concentration of less than 0.1%.

3° Nature of the crystallographic phases and, in case of mixed phases, proportion of each of the phases, including the amorphous phase if it exists.

4° Average specific surface area in relation to a standard deviation, specifying the determination method used, explaining why this method is applicable to the substance in question and reporting the experimental circumstances .

5. Zeta potential, with indication of the medium and the conditions of pH and ionic strength.

Section 3: Quantity of the substance produced in nanoparticular state placed on the market during the period under consideration

Estimated total quantity of the registered substance to be placed on the market by the registrant between the registration date and the end of the calendar year (expressed in kilograms).

As an exception, where the substance must be registered before January 1st, 2016 on foot of Article 24, § 1, the period to consider is between January 1st and December 31st, 2016.

Section 4: Uses of the substance produced in nanoparticular state

§ 1 All foreseeable uses of the registered substance.

§2 Trade name or trademark of the substance for the purpose of the placing on the market by the registrant.

§ 3 Optional indication of the properties claimed for which the registered substance is used.

Section 5: Identity of the professional users to whom the registrant will transfer the substance produced in nanoparticular state between the registration date and the end of the calendar year (if known at the time of registration)

For each professional user, the registrant shall specify:

1°. Name of acquirer of the registered substance;

2°. Enterprise Crossroads Bank identification number, if the acquirer has one

3°. Address of registered office;

As an exception, where the substance must be registered before January 1st, 2016 on foot of the provisions of Art. 24, § 1, the period to consider is between January 1st and December 31st, 2016.

To be annexed to the Royal Decree of May 27th, 2014 concerning the placing on the market of substances produced in nanoparticular state

FILIP

On behalf of the King:

The Deputy Prime Minister and Minister of Economy, Consumer Affairs and the North Sea,

JOHAN VANDE LANOTTE

The Deputy Prime Minister and Minister of the Interior and Equal Opportunities,

JOËLLE MILQUET

The Deputy Prime Minister and Minister of Social Affairs and Public Health, with competence for Beliris and the Federal Cultural Institutions,

LAURETTE ONKELINX

The Minister of Employment,

MONICA DE CONINCK

The Secretary of State for the Environment, Energy and Mobility,

MELCHIOR WATHELET

ANNEX 2

Information to be included when registering a mixture (Article 4 Paragraph 2)

Section 1: Registrant identification

1. Name of the person/company placing the substance on the market.

2. Enterprise Crossroads Bank identification number, if the registrant has one.

3. Sector of activity.

4. Address of registered office.

5. For companies with their registered offices outside the European Economic Area: indication of the quality of the extra-national legal entity or of the mandated representative.

6. Contact details of a physical contact person: first name, surname, address, telephone number, e-mail address.

Section 2: Identification of the substances produced in nanoparticular state contained in the registered mixture

§ 1 The registrant shall provide the information set out in this section for each substance referred to in Article 3 and that is contained in the registered mixture

The technical data shall relate, at the registrant's choice,

1°. Either to information relating to the substances produced in nanoparticular state as they are contained in the mixture;

2°. Or to information relating to the substances produced in nanoparticular state as they were before being incorporated into the mixture.

§ 2 Mandatory information:

1°. Chemical identification of the substances, i.e.:

a) Chemical name

b) Chemical formula

c) CAS number

d) And the EC number (EINECS or ELINCS), where applicable.

2°. Average and median particle size, in relation to a standard deviation.

3°. Number based distribution curve for the particle size.

4°. Average size of the aggregates and, if the substance is placed on the market in agglomerate form, average size of the agglomerates, in relation to a standard deviation if the latter is available.

5°. Qualitative description of the shape of the particles.

6°. Qualitative description of the particle coating, where applicable.

Regarding points 2° to 5°, the registrant shall also specify the determination method used, explain why this method is applicable to the substance in question and report the experimental circumstances.

The measurements used to provide the information required under points 2° to 5° shall be traceable, meaning that these measurements can be related to a reference through an unbroken and documented chain of calibrations, each contributing to the measurement uncertainty.

§ 3 Information to be provided if available at the registration date

1° If the substance has been registered by the registrant under the REACH-regulation, the registration number. However, the part of the registration number which identifies the individual registrant can be omitted.

2° Where applicable, the type and quantity of each impurity present in the substance produced in nanoparticular state with a mass concentration above 0.1% and, in cases where this information must be furnished for the purpose of other regulatory provisions, each impurity present in the substance produced in nanoparticular state with a mass concentration of less than 0.1%.

3°. Nature of the crystallographic phases and, in case of mixed phases, proportion of each of the phases, including the amorphous phase if it exists.

4° Average specific surface area in relation to a standard deviation, specifying the determination method used, explaining why this method is applicable to the substance in question and reporting the experimental circumstances .

5°. Zeta potential, with indication of the medium and the conditions of pH and ionic strength.

Section 3: Quantity of the substances placed on the market during the period under consideration

§1 Estimated total quantity of each substance identified in Section 2 to be placed on the market by the registrant between the registration date and the end of the calendar year (expressed in kilograms).

As an exception, where the mixture must be registered before January 1st, 2017 on foot of Article 24, § 1, the period to consider is between January 1st and December 31st, 2017.

§ 2 Mass concentration of the substances identified in Section 2, contained in the registered mixture.

§ 3 State in which the substances identified in Section 2, are contained in the registered mixture (solid, liquid, gas, powder, mesophase or other)

Section 4: Uses of the mixture

§ 1 Brief description of the uses of the substances produced in nanoparticular state contained in the mixture and all foreseeable uses of the registered mixture.

§ 2 Trade name or trademark of the mixture for the purpose of the placing on the market by the registrant.

§ 3 Optional indication of the properties claimed for which the registered substances are used.

Section 5: Identity of the professional users to whom the registrant will transfer the mixture between the registration date and the end of the calendar year (if known at the time of registration)

For each professional user, the registrant shall specify:

1°. Name of acquirer of the registered mixture;

2°. Enterprise Crossroads Bank identification number, if the acquirer has one

3°. Address of registered office;

As an exception, where the substance must be registered before January 1st, 2017 on foot of the provisions of Art. 24, § 1, the period to consider is between January 1st and December 31st , 2017.

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MONICA DE CONINCK

The Secretary of State for the Environment, Energy and Mobility,

MELCHIOR WATHELET

ANNEX 3

Annual update of information provided when registering a substance produced at nanoparticular state (Article 9)

Section 1: Registrant identification

The registrant shall indicate any changes made to the information provided during registration or during the latest update.

Section 2: Identification of the substance

The registrant shall indicate any changes made to the information provided during registration or during the latest update including the reason for these changes (for example, use of a new determination method).

Section 3: Quantity of the substance placed on the market during the period under consideration

Total quantity of the registered substance placed on the market by the registrant during the calendar year preceding the end date laid down in Article 9 for the relevant update (expressed in kilograms).

Section 4: Uses of the substance produced in nanoparticular state

The registrant shall indicate any changes made to the information provided during registration or during the latest update.

Section 5: Identity of the professional users to whom the registrant transferred the substance produced in nanoparticular state during the calendar year preceding the end date laid down in Article 9 for the relevant update

For each professional user, the registrant shall specify:

1. Name of acquirer of the registered substance;

2. Enterprise Crossroads Bank identification number, if the acquirer has one

3. Address of registered office.

To be annexed to the Royal Decree of May 27th, 2014 concerning the placing on the market of substances produced in nanoparticular state

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On behalf of the King:

The Deputy Prime Minister and Minister of Economy, Consumer Affairs and the North Sea,

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MONICA DE CONINCK

The Secretary of State for the Environment, Energy and Mobility,

MELCHIOR WATHELET

ANNEX 4

Annual update of information provided when registering a mixture

Section 1: Registrant identification

The registrant shall indicate any changes made to the information provided during registration or during the latest update.

Section 2: Identification of the substances produced in nanoparticular state contained in the registered mixture

The registrant shall indicate any changes made to the information provided during registration or during the latest update and the reason for these changes (for example, use of a new determination method).

Section 3: Quantity of the substances placed on the market during the period under consideration

§ 1 Total quantity of each substance, identified in Section 2, placed on the market by the registrant during the calendar year preceding the end date laid down in Article 9 for the relevant update (expressed in kilograms).

§ 2 Mass concentration of each substance identified in Section 2, contained in the registered mixture

§ 3 State in which the substances identified in Section 2, are contained in the registered mixture (solid, liquid, gas, powder, mesophase or other)

Section 4: Uses of the mixture

The registrant shall indicate any changes made to the information provided during registration or during the latest update.

Section 5: Identity of the professional users to whom the registrant transferred the mixture during the calendar year preceding the end date laid down in Article 9 for the relevant update

For each professional user, the registrant shall specify:

1°. Name of acquirer of the registered mixture;

2°. Enterprise Crossroads Bank identification number, if the acquirer has one

3°. Address of registered office;

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The Secretary of State for the Environment, Energy and Mobility,

MELCHIOR WATHELET

ANNEX 5

Information to be included in the notification of an article, a complex object or category of articles or complex objects (Article 12)

Section 1: Notifier identification

1. Name of the person/company placing the article(s) or complex object(s) on the market.

2. Enterprise Crossroads Bank identification number, if the notifier has one.

3. Sector of activity.

4. Address of registered office.

5. For companies with their registered offices outside the European Economic Area: indication of the quality of the extra-national legal entity or of the mandated representative.

6. Contact details of a physical contact person: first name, surname, address, telephone number, e-mail address.

Section 2: Identification of the notified article(s) or complex object(s)

1. Identification of the article, the complex object or the category of articles or complex objects that are the subject of the notification.

2. Brief description of the uses of the substances produced in nanoparticular state incorporated in the article and the uses of the articles.

3. Trade name or trademark of the articles or complex objects for the purpose of the placing on the market by the notifier.

Section 3: Identification of the concerned substances produced in nanoparticular state

§ 1 The notifier shall provide the information set out in this section for each substance produced in nanoparticular state incorporated in the notified articles or complex objects and meeting the conditions laid down in Article 11.

The technical data shall relate, at the notifier's choice:

1°. Either to information relating to the substances produced in nanoparticular state as they are incorporated in the article or complex object in question

2° Or to information relating to the substances produced in nanoparticular state as they were before being incorporated into the article or complex object in question;

§ 2 Mandatory information:

1°. Chemical identification of the substances, i.e.:

a) Chemical name

b) Chemical formula

c) CAS number

d) And the EC number (EINECS or ELINCS), where applicable.

2°. Number based distribution curve for the particle size.

3°. Qualitative description of the shape of the particles.

4°. Identification of the matrix in which the substances produced in nanoparticular state are incorporated.

5°. Concentration of each substance produced in nanoparticular state identified in this section and incorporated in the notified articles or complex objects. The concentration shall be assessed for each notified article or for each article containing one or more of said substances, present in the notified complex objects.

Regarding points 2° and 3°, the notifier shall also specify the determination method used, explain why this method is applicable to the substance in question and report the experimental circumstances.

The measurements used to provide the information required under points 2° to 4° shall be traceable, meaning that these measurements can be related to a reference through an unbroken and documented chain of calibrations, each contributing to the measurement uncertainty.

To be annexed to the Royal Decree of May 27th, 2014 concerning the placing on the market of substances produced in nanoparticular state

FILIP

On behalf of the King:

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The Secretary of State for the Environment, Energy and Mobility,

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ANNEX 6

Simplified registration/notification relating to the placement on the market of a product exclusively used for scientific research and development or product and process oriented research and development (Articles 7 and 15)

Section 1: Registrant/notifier identification

1. Name of the person/company placing the product on the market.

2. Enterprise Crossroads Bank identification number, if the registrant or notifier has one.

3. Sector of activity.

4. Address of registered office.

5 For companies with their registered offices outside the European Economic Area: indication of the quality of the extra-national legal entity or of the mandated representative.

6. Contact details of a physical contact person: first name, surname, address, telephone number, e-mail address.

Section 2: Identification of the notified or registered product (unless it is a substance)

Brief description of the registered mixture or the notified article, complex object or category of articles or complex objects

Section 3: Identification of the substances produced in nanoparticular state

§ 1 The registrant/notifier shall provide the information set out in this section relating to:

1°. The registered substance;

2°. Each substance referred to in Article 3contained in the registered mixture; or

3. Each substance produced in nanoparticular state incorporated in the notified article(s) or complex object(s).

§ 2 Chemical identification of the substance, i.e.:

a) Chemical name

b) Chemical formula

c) CAS number

d) And the EC number (EINECS or ELINCS), where applicable.

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