Message 303

Communication from the Commission - TRIS/(2023) 01336
Directive (EU) 2015/1535
Notification: 2023/0070/B

Observations from the Commission (article 5, paragraph 2, of Directive (EU) 2015/1535). These observations do not have the effect of extending the standstill period.

Observaciones - připomínky - Bemärkninger - Bemerkungen - Märkused - Παρατηρήσεις - Comments - Observations - Osservazioni - Piezīmes - Komentarai - Megjegyzések - Kummenti - Opmerkingen - Uwagi - Observacoes - Komentáre- Pripombe - Huomautuksia - Synpunkter - Коментари - Comentarii.

Sin plazo de statu quo - Doba pozastavení prací se neaplikuje - Ingen status quo frist - Keine Stillhaltefrist - Ooteaeg ei ole kohaldatav - Δεν υπάρχει statu quo - Standstill period does not apply - Pas de délai de statu quo - Termine di status quo non previsto - Bezdarbības periods netiek piemērots - Atidėjimo periodas netaikomas - A halasztási időszak nem alkalmazandó - Il-perijodu ta' waqfien ma japplikax - Geen status quo-periode - Okres odroczenia nie ma zastosowania - Prazo do statu quo não previsto - Perióda pozastavenia neplatí - Obdobje mirovanja ne velja - Ei status quon määräaikaa - Ingen tidfrist för status quo - Не се прилага период на прекъсване - Perioada de stagnare nu se aplică.

(MSG: 202301336.EN)
1. MSG 303 IND 2023 0070 B EN 22-05-2023 12-05-2023 COM 5.2 22-05-2023

2. Commission

3. DG GROW/E/3 - N105 04/63

4. 2023/0070/B - C00C

5. article 5, paragraph 2, of Directive (EU) 2015/1535

6. Within the framework of the notification procedure laid down by Directive (EU) 2015/1535 ( ), the Belgian authorities notified to the Commission on 20 February 2023 the draft "Royal Decree amending the Royal Decree of 27 May 2014 on the placing on the market of nanoparticle-manufactured substances" (hereinafter, "the notified draft").

According to the notification message, the notified draft aims at expanding the scope of the Royal Decree of 27 May 2014 (hereinafter, "the Royal Decree of 2014"), in order to cover biocidal products, substances and articles intended to come into contact with foodstuffs, pigments and cosmetic products. It results from the notified draft that those products would be subject to the registration procedure provided for in the Royal Decree of 2014.

The examination of the notified draft has prompted the Commission to issue the following comments.

1. Placing on the market of biocidal products containing nanomaterials and definition of nanomaterials

Article 1 of Regulation (EU) No 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products ( ), provides that the purpose of that Regulation is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and the use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment. It results from Article 17 of that Regulation that biocidal products shall not be made available on the market or used unless authorised in accordance with that Regulation. Article 89 of the same Regulation provides for the transitional regime for Member States, under certain conditions, to continue applying their current system or practice of making available on the market or using a given biocidal product, in accordance with their national framework pending the approval of the existing active

substances under the working programme under that Regulation.

Regulation (EU) No 528/2012 contains a certain number of provisions specifically applicable to nanomaterials.

Nanomaterial is defined under Article 3(1), point (z), of that Regulation as “a natural or manufactured active substance or non-active 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 1-100 nm”. A new definition of nanomaterial, covering natural, incidental or manufactured materials was recently set out in the Commission Recommendation of 10 June 2022, on the definition of nanomaterial (2022/C 229/01). The recommended definition reads: “natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions: (a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm; (b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm; (c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm”. The Commission is considering updating Regulation (EU) No 528/2012 in the light of this new definition, pursuant to Article 3(4) of that Regulation, empowering the Commission to adapt the definition of nanomaterial for the purpose of that Regulation in view of technical and scientific progress, as reflected in the above-mentioned recommendation.

It results from Article 19(1), point (f), of Regulation (EU) No 528/2012 that, where nanomaterials are used in a biocidal product, such a product may be authorised provided that the risk to human health, animal health and the environment has been assessed separately. Besides, it results from Article 25 of that Regulation that biocidal products containing nanomaterials are not eligible for the simplified authorisation procedure. Articles 69 and 58(3) of Regulation (EU) No 528/2012 also provide for specific requirements concerning the labelling of biocidal products containing nanomaterial or articles treated with such biocidal products.

Article 1 of the notified draft would amend the scope of the Royal Decree of 2014, by repealing subparagraph 1° (“biocidal products and treated articles falling within the scope of Regulation (EU) No 528/2012”) of Article 2 of the Royal Decree of 2014, which sets out the substances excluded from the scope of that Decree. Biocidal products would therefore be included in the scope of the said Decree.

In accordance with Article 3 of the Royal Decree of 2014, biocidal products containing substances manufactured in a nanoparticulate state could only be placed on the market if registered in accordance with Chapter 2 of that Decree, if the total quantity of substances manufactured in a nanoparticulate state to be put on the market would be above one hundred grams, and if the person placing the substance or mixture on the market would produce itself that substance, or if it would place it on the market exclusively for use by professional users.

The Commission notes that Article 65(3), point (d), of Regulation (EU) No 528/2012 requires Member States to submit to the Commission, every five years, a report on the implementation of this Regulation. This report shall include “information on the use of nanomaterials in biocidal products and the potential risks thereof”. In that regard, where biocidal products are authorised in accordance with Article 19 of Regulation (EU) No 528/2012, information on nanomaterials in these products is already available to the Belgian authorities, and an additional registration requirement would duplicate obligations on market operators. The Belgian authorities are therefore invited to amend the notified draft so as to exclude from the registration requirement nanomaterials contained in biocidal products authorised in accordance with Regulation (EU) No 528/2012. Nevertheless, the Commission acknowledges that national rules may apply to nanomaterials in biocidal products subject to the transitional regime established by Article 89 of Regulation (EU) No 528/2012, where the level of knowledge may be different.

2. Definition of food contact materials

Article 1 of Regulation (EC) No 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food ( ), defines as follows the scope of application of that Regulation:

“1. The purpose of this Regulation is to ensure the effective functioning of the internal market in relation to the placing on the market in the Community of materials and articles intended to come into contact directly or indirectly with food, whilst providing the basis for securing a high level of protection of human health and the interests of consumers.

2. This Regulation shall apply to materials and articles, including active and intelligent food contact materials and articles, (hereinafter referred to as materials and articles) which in their finished state:

(a) are intended to be brought into contact with food; or

(b) are already in contact with food and were intended for that purpose; or

(c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

3. This Regulation shall not apply to:

(a) materials and articles which are supplied as antiques;

(b) covering or coating materials, such as the materials covering cheese rinds, prepared meat products or fruits, which form part of the food and may be consumed together with this food;

(c) fixed public or private water supply equipment”.

Article 2 of the notified draft would introduce subparagraph 28 in Article 2(1) of the Royal Decree of 2014, in which materials and articles intended to come into contact with food are defined as follows:

“materials and articles, including active and intelligent materials and articles intended to come into contact with food, which, in the finished state:

— are intended to come into contact with food, or

— are already in contact with foodstuffs and are intended for that purpose, or

— which can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.”

The definition included in the notified draft only partially reflects the scope of application of Regulation (EC) No 1935/2004, as laid down in Article 1 of that Regulation. In particular, it omits to include the notion that food contact materials are materials intended to come into contact “directly or indirectly” with food and it does not refer to the restrictions to the scope of application of Regulation (EC) No 1935/2004 laid down in its Article 1(3).

Therefore, in order to ensure clarity and avoid legal uncertainty, which could hamper the direct application of EU law, the Commission recommends that the Belgian authorities rephrase Article 2 of the notified draft, for what concerns point 28, by defining materials and articles intended to come into contact with food by using the phrase “food contact materials mean materials and articles falling within the scope of application of Regulation (EC) No 1935/2004”, rather than by only partially repeating the wording of Article 1 of Regulation (EC) No 1935/2004.

The Commission invites the Belgian authorities to take the above comments into account.

The Commission furthermore reminds the Belgian authorities that once the definitive text has been adopted, they are required to communicate it to the Commission in accordance with Article 5(3) of Directive (EU) 2015/1535.

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