Message 316

Communication from the Commission - SG(2012) D/50880
Directive 98/34/EC
Translation of the message 315
Notification: 2011/0673/F

Detailed opinion from the Commission (article 9, paragraph 2, second indent of Directive 98/34/EC). This detailed opinion extends the standstill period until 02-07-2012.

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ОГРАНИЧЕН - OMEZENÝ PŘÍSTUP - BEGRÆNSET - ZUGANGSBESCHRÄNKT - ΕΣΩΤΕΡΙΚΗ ΧΡΗΣΗ - LIMITED - LIMITADO - PIIRATUD - RAJOITETTU - LIMITÉ - KORLÁTOZOTT HOZZÁFÉRÉS - RISERVATO - RIBOTO NAUDOJIMO DOKUMENTAS - IEROBEŽOTAS PIEEJAMĪBAS DOKUMENTS - RISTRETT - RESTRITO - LIMITAT - OBMEDZENÝ - OMEJENO - BEGRÄNSAT

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1. MSG 316 IND 2011 0673 F EN 02-07-2012 30-03-2012 COM 9.2(2) 02-07-2012

2. Commission

3. DG ENTR/C/3 - BREY 08/94

4. 2011/0673/F - C00C

5. Article 9 (2), second point, of Directive 98/34/EC

6. On 29 December 2011, the Commission received the draft Order relating to the content and submission conditions of annual declarations of nanoparticle substances, adopted pursuant to Articles R. 523-12 and R. 523-13 of the Environment Code.

The draft Order is issued pursuant to the Decree on the annual declaration of nanoparticle substances, notified as part of Directive 98/34/EC under reference 2011/307/F, before being adopted on 17 February 2012 and published on 19 February 2012 (Decree No 2012 232 on the annual declaration of nanoparticle substances, laid down in implementation of Article L. 523-4 of the Environment Code., OJFR No 0043 of 19 February 2012).

The draft notified sets out the content and submission conditions for annual declarations relating

to nanoparticle substances, as single substances or as part of a mixture without being bound, or a material intended to reject such substances that are produced, distributed or imported nationally.

The Appendix to the draft notified sets out the information to be declared annually, grouped into five parts: identity of declarant, identity of nanoparticle substance, quantity of nanoparticle substance, uses and identity of professional users.

It is specified that the provisions shall enter into force on 1 January 2013 and that the first declarations shall relate to 2012.

As a preliminary point, the Commission wishes to recall the observations it made as part of notification 2011/307/F with respect to preparing a Communication on regulatory aspects for nanomaterials and a working document of the Commission's departments on the types of nanomaterials and their uses, including safety aspects. In this context, the Commission would like to inform the French authorities that the current position of this work shows that uses of nanomaterials could be greater than the calculations used by the French government for assessing the impact on French legislation would seem to indicate.

The Commission points out that in its Communication it will give a decision on the regulatory aspects for nanomaterials further to the request of the Environment Council on 20 December 2010, particularly the request to assess "the necessity of establishing specific measures for nanomaterials with respect to the assessment and management of the risk that they present, and information and monitoring, including the development of a harmonised database for nanomaterials, while taking into consideration the potential impact".

Furthermore, with respect to Decree No 2012-232 adopted on 17 February 2012, the Commission notes that, pursuant to Article R.523-13 of the Environment Code, the first declaration would be due by May 2013, for the 2012 calendar year. Insofar as the obligation to declare would at least partially apply to a period falling before the adoption of the draft notified under reference 2011/673/F defining the content of the declaration, the obligation is likely to apply retrospectively to a period where manufacturers, importers and distributors were not expected to collect certain information.

Pursuant to Article 9 (2) and Article 8 (2) of Directive 98/34/EC, and following examination of the draft notified, the Commission hereby makes the following detailed notification and observations:

I. Detailed notification

1.1. Disclosure to the public of certain information considered to be confidential pursuant to Articles 118(2) (b) to (d) and 119(2) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, evaluation and authorisation of chemical substances, as well as the restrictions applicable to these substances (REACH Regulation).

As part of notification 2011/307/F, the Commission had already highlighted the importance of protecting confidential commercial information.

On the one hand, points III and IV of Appendix I of the draft notified, when read in conjunction with Article R. 523-18 of the Environment Code, as adopted on 17 February 2012, would result in certain information, which, according to Article 118(2) (b) and (c) of REACH is in principle considered to be confidential, being disclosed to the public, unless the declarant requests confidentiality on the grounds of damaging trade or commercial secrets or intellectual property on research results. The Commission notes that such a request will be dealt with in accordance

with Article L. 521-7 of the Environment Code and with Article 21 of Law No 2000-321 of 12 April 2000 on the rights of citizens in their relations with administrations, which provides that if the administrative authority does not make a decision within two months, the request is considered to be rejected. Moreover, the competent administrative authority has the power to assess the validity of the request.

With respect to Article 118(2) (d) of REACH which refers to links existing between a manufacturer or an importer and its distributors or users down the line, the Commission recognises that Article L. 523-1, last paragraph of the Environment Code, when read in conjunction with Article L. 521-7 II of the same Code, provides in principle for a higher level of confidentiality concerning information relating to the identity of professional users (point V of Appendix I of the draft notified). However, the aforementioned Article L. 521-7 II refers to the criterion of "trade and commercial secret", which does not correspond to the criterion provided for in Article 118(2) of REACH, namely "breach of the protection of commercial interests" of the person concerned.

The Commission therefore considers that disclosure of information required under points III to V of Appendix I of the draft notified would go against Article 118 (2) (b) to (d) of REACH which provides that such information is in principle protected from being disclosed. Even if the administrative authority granted confidentiality to this data systematically, it would remain difficult to understand the usefulness of the confidentiality request procedure and of the individual decision of the competent administrative authority. The Commission considers that the data in question should be treated in accordance with REACH and, consequently, that confidentiality should in principle be granted to them.

In view of the foregoing, the Commission invites the French authorities to amend the draft notified in order to ensure the confidentiality of the information required by points III to V of Appendix I in the same conditions as the protection granted by Article 118 (2) (b) to (d) of REACH. In this context, the Commission sets out that the application of Article 118 (2) of REACH is not limited to data contained in registration dossiers.

On the other hand, points I and II (a) to (m) of Appendix I of the draft notified, when read in conjunction with Article R. 523-18 of the Environment Code, as adopted on 17 February 2012, would result in certain information, which, according to Article 119(2) of REACH is in principal considered to be confidential when a party submitting the required information puts forward reasons whose validity is recognised by the European Chemicals Agency ("the Agency") on the grounds of damaging the commercial interests of the declarant or of other interested parties, being disclosed to the public, unless the declarant requests confidentiality on the grounds of damaging trade or commercial secrets or intellectual property on research results in accordance with Article R. Article L. 521-7 II of the Environment Code would seem to indicate that a decision by the Agency to accept a request for confidentiality shall be respected by the French administrative authority. Conversely, in the absence of such a request being addressed to the Agency, for example for substances which benefit from the deadlines of Article 23 of REACH, or which have not reached the registration limits of the Regulation, the disclosure of information, following a negative decision by the French administrative authority which does not accept the justification that the information falls within the "trade and commercial secret" (different criterion to that provided for by REACH, see above), could subsequently deprive the parties of making use of their right to invoke confidentiality under Article 119 (2) of REACH.

The Commission therefore invites the French authorities to amend the draft notified in order to ensure the confidentiality of the information concerned by points I and II (a) to (m) of Appendix I of the draft notified, in such a way as to ensure that the protection offered by Article 119 (2) of REACH is not denied. In this context, the Commission specifies that the application of Article 119 (2) of REACH is not limited to data contained in registration dossiers.

1.2. Disclosure within the supply chain of certain information which may damage the manufacturer's commercial interests or the interests of other parties in the supply chain

The Commission also reminds the French authorities that any manufacturer or any other actor in the supply chain could consider some of the information requested by point II (a) to (m) of Appendix I of the draft notified as commercially sensitive or in need of protection from being shared with any of its clients in the supply chain. Importers in France would then be unable to obtain the required data from a manufacturer situated in another Member State or in a third country.

This problem could also arise regarding information required by point II (a), which provides for the transmission of the REACH Number for registered substances, and by point II (b) relating to the possible presence of impurities. In effect, this information corresponds to information which is to be shared along the supply chain in a limited manner in accordance with points 1.1, third paragraph and 3.1, second paragraph of Appendix II of REACH. These two clauses allow for the part of the REACH Number specific to the manufacturer to be omitted in order to avoid confidentiality problems and practical problems along supply chains where suppliers change often and quickly. Moreover, other information could also be considered to be commercially sensitive by the manufacturer supplying, directly or indirectly, a French importer, and the manufacturer could refuse to share it with said importer. Such could be the case particularly for information relating to the commercial name of the mixture or material required by point II (m), for example for a mixture which would add particular value to the end product in which it is used and that the manufacturer of the end product wants to keep confidential from its competitors, including the French importers of its products.

1.3. Possible hindrance to the free movement of goods prohibited by Article 34 TFEU

It emerges from the text of the draft notified that a distributer that is supplied directly or indirectly by a French manufacturer would be exempt from the obligation to declare the information required by point II of Appendix I of the draft Order, by having the possibility, in accordance with Article 3 of said draft, to only declare the declaration number that has been transmitted to it. Consequently, in such an event, no information would be transmitted which could damage the commercial interests of the French manufacturer.

Conversely, in the event of a supply chain where the manufacturer is situated in another Member State, the French importer could not benefit from the facility provided for by the aforementioned Article 3 and would be obliged to provide the information required by point II of Appendix I. As a result, the manufacturer situated in another Member State must supply the information required to its clients importing in France. In the event that the manufacturer considers the information required to be commercially sensitive or should be protected from being shared with its clients in the supply chain, the French importer would not be able to obtain this information from the manufacturer or from another actor in the supply chain originating from another Member State or from a third country, unless it analyses the imported product itself to satisfy the obligations of the draft notified. This would lead to further delays and additional costs. The Commission has no information on the possibility of carrying out such analyses on mixtures or materials and wishes to know if the French authorities have any information on this subject.

Even though the parameters of the Appendix of the draft Decree have been identified by the Commission as characterising nanoparticle forms and the European Chemicals Agency advises on a technical basis to specify the way in which these forms are covered by the REACH registration dossier and allows it from a technical perspective, REACH does not require that information over and above the "granulometry" standard be provided for REACH registration.

In this context, as regards the information required by the draft notified, the clauses relating to the free movement of goods provided for in Articles 34 to 36 of the Treaty on the Functioning of the European Union (TFEU) apply. Article 34 TFEU prohibits quantitative restrictions on imports, and all measures having equivalent effect, on trade within the European Union. Any regulation of the Member States capable of hindering, directly or indirectly, actually or potentially, intra-Union trade constitutes a measure having equivalent effect to quantitative restrictions (CJEU, 11 July 1974, Dassonville case, 8/74).

The French authorities indicate that the proposed plan is not a prerequisite for the development of the activities in question which can continue unhindered. However, as the annual declaration is compulsory and Decree No 2012-232 notified under reference 2011/307/F and adopted on 17 February 2012 provides for financial penalties in the event of failure to comply with the declaration obligation, the aspect causing hindrance to imports is reinforced. Therefore, it should be noted that the content of the annual declaration could dissuade some importers on the French market from importing products containing nanomaterials originating from other Member States on grounds linked to further costs, additional administrative charges or the protection of commercial interests.

As a result, the information required by point II of Appendix I of the draft notified could constitute a hindrance to the free movement of goods, prohibited by Article 34 TFEU.

A measure having equivalent effect may however be justified under Article 36 TFEU and the overriding requirements of general interest recognised by the EU Court of Justice. These measures must be necessary and proportionate to the objective being pursued and must be the means to obtaining this objective that are the least harmful to the free movement of goods.

The Commission therefore asks the French authorities to explain the need for the information required by point II of Appendix I of the draft notified and their proportionality in relation to the objective being pursued.

Moreover, the Commission considers that the hindrance to free movement could be avoided by allowing manufacturers, or other actors in the supply chain situated in other Member States, to provide the information required by point II of Appendix I through an "exclusive representative" following the example of the system provided for by Article 8 of REACH. The same system could also apply to imports from third countries.

For the foregoing reasons, the Commission issues, in accordance with Article 9 (2) of Directive 98/34/EC, the detailed notification according to which the draft regulation would violate Article 34 of TFEU and Articles 118 (2) and 119 (2) of REACH, as well as points 3.1, second paragraph, and 1.1, third paragraph, of Appendix II of REACH, if it were to be adopted without the foregoing observations being taken into consideration.

The Commission reminds the French government that under the terms of the aforementioned Article 9 (2) of Directive 98/34/EC, issuance of a detailed notification carries with it the incumbent obligation upon the author State of a draft technical rule to defer its adoption for six months from the date of its communication.

This period expires on 2 July 2012.

It draws the French government's attention to the fact that, under the terms of this provision, the Member State receiving a detailed notification is required to submit a report to the Commission on the course of action it intends to take in response to said notification.

If the draft technical rule in question were to be adopted without consideration of the

aforementioned objections, the Commission could find itself under obligation to send a letter of formal notice in accordance with Article 258 of the TFEU. It also reserves the possibility of sending a letter of formal notice if the response of the French government were not to reach it prior to adoption of the draft technical rule in question.

The Commission invites the French Government to send the final text of the draft technical rule as soon as it is adopted. Failure to send this text would constitute a breach of Article 4 (3) of the Treaty of the European Union (TEU), as well as a breach of Article 8 (3) of Directive 98/34/EC, which the Commission reserves the right to act upon.

II. Observations

The Commission considers that it is possible that nanomaterials are subject to modifications once incorporated into mixtures or into materials intended to reject such substances. This would mean that, even if the information had been obtained from the supplier of the nanomaterials, it would no longer be correct once incorporated into mixtures or materials. In this context, the Commission would like to know the consequences for downstream distributors/users and importers. In particular, the Commission would like to know if they will be required to carry out additional analyses in order to submit correct information on the presence of nanomaterials in mixtures or materials intended to reject such substances.

Compared to the information required by Section II) points (b) to (m) of Appendix I, the draft Decree seems to be based on well-defined nanomaterials, for example in terms of large scale particle size distribution. It should however be noted that the same nanomaterial placed on the market can vary. Insofar as the Commission's interpretation is correct, it asks the French authorities if such variants shall be covered by a single declaration for all, or if it will be necessary to make separate declarations for each of the variants.

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