EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Message 103

Communication from the Commission - TRIS/(2023) 1832

Directive (EU) 2015/1535

Notification: 2023/0116/F

Forwarding of the observations of a Member State (Spain) (article 5, paragraph 2, of Directive (EU) 2015/1535). These observations do not have the effect of extending the standstill period.

MSG: 20231832.EN

1. MSG 103 IND 2023 0116 F EN 19-06-2023 16-06-2023 ES COMMS 5.2 19-06-2023

2. Spain

3A. Ministerio de Asuntos Exteriores, Unión Europea y Cooperación
D.G de Coordinación del Mercado Interior y Otras Políticas Comunitarias
Subdirección General de Asuntos Industriales, Energéticos, de Transportes y Comunicaciones, y de Medio Ambiente

3B. Comisión Interministerial para la Ordenación Alimentaria
Agencia Española de Seguridad Alimentaria y Nutrición.
Ministerio de Consumo.

4. 2023/0116/F - C00C - Chemicals

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

6.

In the framework of Directive 2015/1535, France notified, on 17 March 2023, the draft Order specifying the details relating to the content and conditions for the submission of the information provided for in Article L. 5232-5, paragraphs I and II, of the Public Health Code. Examination of the draft has led the Spanish authorities to submit the following comments, as set out in Article 5(2) of said Directive:

That draft order is part of the development of the requirements laid down in Decree No 2021-1110 of 23 August 2021 on the provision of information to identify endocrine disruptors in a product and which provides for the publication of three separate orders which the French authorities wish to publish simultaneously:

• an order establishing the list of substances with endocrine disrupting properties referred to in Article L. 5232-5, paragraphs I and II of the Public Health Code and the categories of products presenting a particular risk of exposure referred to in Article L. 5232-5, paragraph II, of the Public Health Code: Draft order subject to prior notification (2021/0680/F).
• a joint order of the Ministers of Health and the Environment specifying the details concerning the content and conditions for the submission of the information provided for in Article L. 5232-5, paragraphs I and II, of the Public Health Code, which is referred to in this notification (2023/116/F).
• a joint order of the Ministers of Health and the Environment designating the application that can be used as an alternative for the presentation of information on the presence of substances with endocrine disrupting properties in a product on a specific website: Draft order subject to notification at the same time as this notification (2023/117/F).

In particular, this draft order (2023/116/F) specifies the details regarding the content and conditions for the submission of the expected information on the presence of substances with proven or presumed endocrine disrupting properties in products intended for consumers. It applies to products referred to in Article R. 5232-19 of the Public Health Code, intended for consumers.

The provision of this information shall apply to the entire product and its primary packaging or sales packaging within the meaning of Article R. 543-43 of the Environmental Code (e.g.: a container, a bottle, a vial) where the concentration of a substance with proven or presumed endocrine disrupting properties exceeds 0.1 % by mass.

The information (referred to in Article L. 5232-5 of the Public Health Code) shall be expressed in the form of the indication 'containing a substance or substances with proven or presumed endocrine disrupting properties:'. Or for certain categories of products presenting a particular risk of exposure (Article L. 5232-5 II(II) of the Public Health Code), in the form of the indication 'containing a substance or substances suspected to have endocrine disrupting properties:'. The information shall be supplemented by the name of the relevant substance(s) present in the product. This name corresponds to the name of the substance referred to in Tables A, Aa, B or Ba of Annex I to the Joint Order of the Ministers of Health and the Environment establishing the list of substances with endocrine disrupting properties referred to in Article L. 5232-5, paragraphs I and II, of the Public Health Code, adopted in accordance with Article R. 5232-19 of the Public Health Code.

Where the substance is listed in Table Aa and the product containing that substance is a food (according to Article 2 of Regulation (EC) No 178/2002) or a medical device (Article 2 of Regulation (EU) 2017/745), the information provided for in Article L. 5232-5(I) of the Public Health Code shall be expressed in the form of the indication 'contains the substance [insert the name of the substance in Table Aa referred to above]: this substance has health benefits when used in accordance with the precautions and dosage specified in the package leaflet or on the product labelling. In case of doubt, seek the advice of a health professional.'

Where the substance is listed in Table Ba and the product containing that substance is a food (according to Article 2 of Regulation (EC) No 178/2002) or a medical device (Article 2 of Regulation (EU) 2017/745, the information provided for in paragraph II of Article L. 5232-5 of the Public Health Code shall be expressed in the form of the indication 'contains the substance [insert name of the substance as set out in the mentioned table Ba]: this substance has health benefits when used in accordance with the precautions and dosage specified in the package leaflet or on the product labelling. In case of doubt, seek the advice of a health professional.'

Spain would like to request information on a number of issues related to this draft order, as well as comment on certain aspects that may affect the free movement of goods in the EU:

1. First, this draft order indicates the way in which the information is to be expressed according to the inclusion of the substance in one table or another in Annex I to the draft order notified in accordance with notification 2021/0680F. However, the latter project, in the version notified under Directive 2015/1535, did not include Tables Aa and Ba mentioned in this project which is being evaluated (2023/116/F). Not having this information creates a situation of uncertainty among operators as to what indication should be included in the labelling of their products since it depends on the table in which the product has been included. In Spain's view, France should clarify both the substances included in each of the tables included in the list of products and the criteria they have used to establish such classification.

2. Secondly, it is well known that labelling requirements involve the production of labels specifically tailored to a country's market, putting at a disadvantage operators in other Member States who will have to incur additional costs that are difficult to bear, in particular as regards small and medium-sized producers. In practice, they constitute an obstacle to trade in the internal market and lead to a fragmentation of trade.

However, as set out in Article 36 TFEU, if there are justifiable grounds of public policy, public morality and public security or the protection of health, among others, Member States may introduce such restrictions, provided that they do not constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States. In this regard,

ignoring the criteria that have led the French authorities to determine that a substance is considered to have suspected endocrine disrupting properties or that it is suspected to have endocrine-disrupting properties, or even those which may present a particular risk depending on its exposure, does not allow a proper assessment of whether the indication is established on the basis of substantiated reasons or on the contrary, there is insufficient evidence and is going beyond what can reasonably be justified in accordance with the exceptions in Article 36 TFEU. In the latter case, the indication could be considered too alarmist in relation to the current situation of knowledge in that area. In addition, since the draft order does not incorporate any recognition clause, nor was it included in Decree No 2021-1110 of 23 August 2021, or of some kind of equivalence, the risk that this draft order will end up generating unnecessary barriers to trade is not reduced, especially since we can currently find substances that for some Member States are considered as endocrine disruptors while in other Member States they do not have this consideration.

3. Thirdly, and in relation to the implementation deadline, given the current circumstances in which there are still no clear fundamental aspects for the implementation of this legislation (e.g. the products included in each of the lists and the criteria for their inclusion), it would be desirable for economic operators to correctly adapt to the period of implementation of the order, which is longer than that initially included in Decree No 2021-1110 (6 months). It is proposed to set a period of 18 months to facilitate the implementation of this measure and confirmation is requested that the publication of the three orders that depend on the Decree will be at least simultaneous.

4. Finally, Spain lacks that this draft order (notified under the symbol 2023/116/F) does not include a depletion of stocks clause. Since the labelling requirements will affect, among others, non-perishable products, the storage time may be longer than the one set for the implementation of the measure, forcing or relabelling products that are already on the market or ready for marketing, which would entail additional costs, in many cases unaffordable, for operators.

In conclusion, and as explained throughout this letter, Spain considers that the draft order specifying the details relating to the content and conditions for the submission of the information provided for in Article L. 5232-5, paragraphs I and II, of the Public Health Code, constitutes an obstacle to the free movement of goods, with the inclusion of a mutual recognition clause being necessary and also granting a reasonable additional period for the application of this order. On the other hand, it is necessary for France to clarify information regarding the list of substances and the criteria for inclusion in each of them before the publication of this draft Order.

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