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) 1801

Directive (EU) 2015/1535

Notification: 2023/0116/F

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

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1. MSG 103 IND 2023 0116 F EN 19-06-2023 14-06-2023 HU COMMS 5.2 19-06-2023

2. Hungary

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4. 2023/0116/F - C00C - Chemicals

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

6. As we interpret it, the underlying Draft of notification No 2023/116/F does not make any changes to the requirement laid down in Decree No 2021-1110 of 23 August 2021 on the provision of information identifying endocrine disruptors in a product, which states that manufacturers, importers and distributors should inform consumers, in respect of products placed on the market under their own brand, if the food contains a substance which is proven to possess or is suspected of possessing endocrine disrupting properties and is included in the list of substances with endocrine disrupting properties. The list of substances with endocrine disrupting properties was established in the Decree on which notification 2021/680/F is based, which included cholecalciferol (vitamin D) among the substances that are proven to possess or are suspected of possessing endocrine disrupting properties.

The Decree under notification number 2023/116/F amends the notification obligation to the extent that the information provision for the said products should be supplemented by the following text: ‘cholecalciferol has health benefits when used according to the precautions and dosage specified on the package leaflet or product labelling. If in doubt, seek the advice of a health professional.’

In our view, the amended information provision obligation may still be able to influence the choices that final consumers make and to discourage them in their decision, given the difference and contradictory nature of the information. We continue to maintain all our professional comments on notification No 2021/680/F and our view that the legislation challenges fundamentally the safety of cholecalciferol, regardless of the quantity used, and creates total uncertainty and confusion for consumers. The extension of the information provision obligation to cholecalciferol unduly hampers the free

movement of goods, and neither will the notified draft improve this situation. In addition, for foodstuffs the regulation seems to challenge EFSA's scientific assessment of vitamin D with regard to higher safety limits (UL). (https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2813)

In addition, the term 'presents health benefits' is a health claim within the meaning of Article 10(3) of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods, which can only be used in accordance with the provisions of that Regulation. Thus, in our view, the warning text which this draft prescribes for products containing cholecalciferol is not in line with EU law.

We would like to ask the Government of France to take into account our position as described above.

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