



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/(2025) 0632

Directive (EU) 2015/1535

Notification: 2024/0678/NL

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.

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1. MSG 103 IND 2024 0678 NL EN 17-03-2025 07-03-2025 ES COMMS 5.2 17-03-2025

2. Spain

3A. Ministerio de Asuntos Exteriores, Unión Europea y Cooperación
Dirección General de Coordinación del Mercado Interior y Otras Políticas Comunitarias
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Agencia Española de Seguridad Alimentaria y Nutrición.
Ministerio de Derechos Sociales, Consumo y Agenda 2030

4. 2024/0678/NL - C50A - Foodstuffs

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

6. In the context of Directive 2015/1535, on 10 December 2024, the Netherlands Government notified its draft 'Policy Rule on Precautionary Allergen Labelling'.

Examination of the draft has led the Spanish authorities to submit the comments set out below, pursuant to Article 5(2) of said Directive.

On the one hand, Article 1 of this draft legislation includes the following: 'In this Policy Rule, the following terms and definitions shall apply:

- "artisan food products": food products supplied directly by the producer in small quantities to the final consumer, or to local retail establishments directly supplying the final consumer'.

In this regard, Spain understands that, in order for a food to be considered artisanal, some mention should be made of the existence of a manual component that predominates in the production process. The supply, as described in the current definition, does not necessarily have to be artisanal and may lead to confusion on the part of the consumer.

Similarly, Article 2 states that:

'1. Precautionary allergen labelling is based on findings of a risk assessment carried out by food-business operators.
2. Precautionary allergen labelling shall only be applied if the risk assessment referred to in paragraph 1 reveals that one or more of the reference values set out in the Annex have been exceeded'.



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Based on the wording of this Article, Spain is of the opinion that, although the explanatory note already mentions that precautionary labelling should not be applied as an alternative to preventive measures, this requirement should also be included in the articles so that this legal obligation is emphasised.

On the other hand, it is understood from the proposed wording of the draft legislation that those foods originating in other Member States of the European Union that include precautionary allergen labelling (PAL), following the conclusion that there is a likelihood of the accidental and unavoidable presence of a food allergen subject to mandatory declaration within the framework of good hygiene practice (GHP) and the application of procedures based on a hazard analysis and critical control point (HACCP) system, but not based on the risk assessment model set out in the Dutch proposal, could be subject to coercive measures on the Dutch market.

This disparity in the criteria established in different countries could have an impact on the traffic of goods, something that cannot be defended on the grounds of protection of health and human life, since the operator would be making use of PAL to report an unavoidable risk, based on its HACCP and GHP.

For these reasons, the following are requested.

- Inclusion in the draft of some mention of the existence of a manual component predominating in the production process if the supply referred to in the draft is 'artisanal'. If this is not the case, it is suggested that reference be made to the term 'proximity food', for example.
- Inclusion in Article 2 of the draft legislation of reference to the fact that PAL should not be applied as an alternative to preventive measures, in addition to the mention of this fact in the explanatory note.
- Inclusion of a mutual recognition clause in the body of the draft legislation, thus preventing it from becoming an unnecessary barrier to intra-Community trade in the foodstuffs concerned until allergen thresholds have been harmonised at European Union level.

European Commission
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