

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

Message 201

Communication from the Commission - TRIS/(2025) 0131

Directive (EU) 2015/1535

Notification: 2024/0678/NL

Forwarding of the response of the Member State notifying a draft (Netherlands) to request for supplementary information (INFOSUP) of European Commission.

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1. MSG 201 IND 2024 0678 NL EN 17-03-2025 20-01-2025 NL ANSWER 17-03-2025

2. Netherlands

3A. Ministerie van Volksgezondheid, Welzijn en Sport Directie Voeding, Gezondheidsbescherming en Preventie

3B. Douane Groningen, Centrale dienst voor In- en Uitvoer

4. 2024/0678/NL - C50A - Foodstuffs

5.

6. Reaction on the request for supplementary information on the policy rule on precautionary allergen labelling. The Commission asks (1) to provide an explanation for the deviations from the reference values proposed by the FAO/WHO in the cases of mustard and lupin, and (2) to explain the reasons for the deviation on concentration value set for cereals containing gluten.

(1) Provide an explanation for the deviations from the reference values proposed by the FAO/WHO in the cases of mustard and lupin

The discussion on our national policy rule regarding allergen started some years ago. At that moment, not all current proposed reference values were published yet. Among other things, the reference values for mustard and lupin were not set, as they were only published in the FAO/WHO report late in 2023, and only discussed in Codex-context by the end of 2024. At the moment we discussed the reference values with all our stakeholders, we therefore concluded to take for the time being 0.40 mg and 15.0 mg as reference values for mustard and lupin.

This was based on the literature review published by Turner et al (Turner et al., 2022a) regarding reports of fatal reactions for intakes at or below ED05. For mustard and lupin however, there was no data available. Therefore, we based our conclusions on the available data from Remington et al. (2022) and Houben et al. (2020) in which an ED05 of respectively 0.4 mg and 15.0 mg was set.

During the process of finalizing our national policy rule, some additional reference values and/or data has been published. As we wanted to continue with our national policy rule including only information which had already been accepted in Codex-context, we decided to continue without awaiting all new data and Codex-discussions. Once the Codex-discussions and Codex-policy rule has been finalized and adopted, we will review our national policy rule and see where we have to adapt our policy rule.

(2) Explain the reasons for the deviation on concentration value set for cereals containing gluten At the moment of drafting, cereals containing gluten were not included in the FAO/WHO report, as IgE mediated allergies (e.g. coeliac) were out of scope. Therefore, cereals containing gluten are not included in the table of our national policy rule.



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As we discussed this would may cause problems for people suffering from coeliac, we included this deviation with an astrix below the tabel. In the current Codex-table, you see our deviation is already included in the table.

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