Message 201

Communication from the Commission - TRIS/(2025) 0992

Directive (EU) 2015/1535

Notification: 2024/0678/NL

Forwarding of the response of the Member State notifying a draft (Netherlands) to comments (5.2) of Sweden.

MSG: 20250992.EN

1. MSG 201 IND 2024 0678 NL EN 17-03-2025 03-04-2025 NL ANSWER 17-03-2025

2. Netherlands

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4. 2024/0678/NL - C50A - Foodstuffs

5.

6. Reaction on the comments on the policy rule on precautionary allergen labelling.

Comment 1:
The Commission, Spain, Sweden and EFTA ask to consider the need to include in the notified draft a single market clause.

Reaction to comment 1:
In the notified draft a single market clause has been included.

Comment 2:
The Commission and EFTA surveillance ask for an explanation for the deviations from reference doses for mustard and lupin in the Dutch regulation from the latest FAO/WHO recommendations.
Belgium refers to the difference in reference dose for lupin as well.

Reaction to comment 2:
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.

Comment 3:
Sweden and Belgium notice a non-consistent use of PAL-terms compared to the Codex proposal.

Reaction to comment 3:
In article 2, paragraph 4, we refer to the wordings which can be used when precautionary labelling is applied. In this paragraph we have included both wordings 'may contain' and 'not suitable for xxx' which can be used in this situation. This decision is based upon discussion with the stakeholders and input from the Codex proposal. With this, we have included the Codex proposal for the wording of 'may contain'.

Comment 4:
Belgium asks to include the possibility to use the PAL-wording as referred to in comment 3 for multiple allergens.

Reaction to comment 4:
The Dutch policy rule includes this possibility.

Comment 5:
All Member States and organisations notice some minor differences in the Dutch policy versus the Codex proposal on allergen labelling.

Reaction to comment 5:
Once the Codex proposal on allergen labelling has been adopted into European legislation, we will will make sure the Dutch policy is similar to the European legislation.

Comment 6:
The EFTA surveillance authority mentions an omit to (Annex II of) Regulation (EC) No. 1169/2011.

Reaction to comment 6:
A link to the Regulation 1169/2011 is included in the policy rule.

Comment 7:
The EFTA surveillance authority regrets that preventive measures as described in the guideline on cross-contamination of allergens has not been included in the draft.

Reaction to comment 7:
This guideline has been included in the policy rule.

Comment 8:
Spain asks to include a note that a PAL may not be used as alternative for HACCP-measures.

Reaction to comment 8:
This information is included in the policy rule.

Comment 9:
Spain asks for an additional explanation to the term 'ambachtelijk levensmiddelen'.

Reaction to comment 9:
The Dutch Food Safety Authority uses the explanation as given in article 1 and is known within the Netherlands. We therefore won't extent or adapt the currently used definition.

EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
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