



EUROPEAN COMMISSION

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

Message 791

Communication from the Commission - TRIS/(2025) 0169

Directive (EU) 2015/1535

Notification: 2024/0003/IT

Reaction of the Commission to the response of a Member State/Country notifying a draft regarding comments (5.2)/request for supplementary information (INFOSUP)

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1. MSG 791 IND 2024 0003 IT EN 04-07-2024 22-01-2025 COM REACTION COM 04-07-2024

2. Commission

3. DG GROW/E/3 - N105 04/63

4. 2024/0003/IT - C50A - Foodstuffs

5.

6. On 3 January 2024 the Italian authorities notified to the Commission the DRAFT INTERMINISTERIAL DECREE REPEALING AND REPLACING THE DECREE OF 21 SEPTEMBER 2005 OF THE MINISTER OF PRODUCTIVE ACTIVITIES AND OF THE MINISTER OF AGRICULTURAL AND FORESTRY POLICIES CONCERNING THE PRODUCTION AND SALE SPECIFICATIONS [...].

On 15 March 2024 the Commission issued a detailed opinion with comments. Pursuant to Article 6.2 of Directive (EU) 2015/1535 of 9 September 2015, the Member State concerned should report to the Commission on the action it proposes to take on such detailed opinions. The Commission should comment on this reaction.

The Commission services would like to thank the Italian authorities for their reply of 4 June 2024 and would like to make the following remarks.

Reply with regards to the issues highlighted in related to Regulation (EU) No 1169/2011

With regard to the reply from the Italian authorities on the issues highlighted in relation to point 6 of Part A of Annex VI to the FIC Regulation, the Commission services have the following remarks.

The COMMISSION NOTICE on Questions and Answers on the application of the Regulation (EU) No 1169/2011 (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2018:196:FULL>), which has been adopted by the Commission, does not refer to technological function as a condition for the application of point 6 of Part A of Annex VI to Regulation (EU) No 1169/2011 (herein after 'FIC Regulation'). It clarifies that:

"An indication of the presence of added water which makes up more than 5 % of the weight of the finished product must be included in the name of the food in the following cases:

— meat products and meat preparations which have the appearance of a cut, joint, slice, portion or carcase of meat (...)
The determination of whether a food product fulfils these requirements must be carried out on a case-by-case basis by the food business operators. In this regard, the appearance of the food has to be taken into account. Indicatively, foods like sausages (e.g. mortadella, hot dog), black pudding, meat loaf, meat/fish pate, meat/fish balls would not require such indication".



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The function served by the addition of the water, based on the wording of the provision, would not appear relevant for the application of point 6 of Part A of Annex VI to the FIC Regulation.

How much water is added during the production process and how much water is in the final product is at the discretion of a business operator, by adjusting the manufacturing process and recipe (i.e. ingredients used and their amounts). The determination of whether a food product fulfils the requirements of point 6 of Part A of Annex VI to the FIC Regulation must therefore be carried out on a case-by-case basis by the food business operators, and subject to the monitoring of the competent national control authorities.

Member States are responsible for the enforcement of the EU food law and can assist food business operators in the application of rules on food information to consumers by providing clarifications and instructions. It is also for them to assess on a case-by-case basis whether this obligation applies to specific meat products and in particular to cooked ham, as well as to ensure compliance with the EU provisions.

For the reasons above, the Commission services invite the Italian authorities to align with the points raised in the detailed opinion.

Reply to the comments as regards Regulation (EC) No 1333/2008

The Commission services take note of further explanation pointing at the newly included Article 1 of the notified draft on 'cooked ham' and clarifying that producers of cooked ham have initiated technological changes, aimed at reducing salt and nitrite or adding natural replacement ingredients. The Commission services also note that Article 45 of the notified draft sets out that "the use of food additives is defined as the use in meat products of ingredients that provide nitrates, nitrites or both, in order to obtain a preservative effect in the finished product and that in the presence of ingredients that have a preservative function, with the exception of salt, it is not possible to claim the absence of preservatives even if nitrites are not used".

As regards the use of 'natural replacement ingredients', we draw the attention of the Italian authorities to the statement of the Standing Committee on Plants, Animal, Food and Feed, endorsed unanimously by the Member States on 17 September 2018, on the use of plant extracts rich in constituents performing a technological function[1].

The statement clarifies that the use of plant extracts, which deliver a technological function (e.g. preservative, antioxidant, stabiliser -colour stabiliser-, etc.) in foods to which they are added is deemed a deliberate use of such extracts as a food additive and that such use is to comply with the conditions set out in the food additives legislation, including relevant specifications. The statement represents the views of Member States, and it intends to assist national authorities in the harmonised application of Regulation (EC) No 1333/2008.

As regards nitrite obtained from natural sources, the Commission services would like to highlight that Regulation (EC) No 1333/2008 together with Regulation (EU) No 231/2012 do not authorise the use of nitrites from natural sources. It follows from the specifications laid down in Regulation (EU) No 231/2012 and from the respective scientific opinions of the European Food Safety Authority that nitrites and nitrates authorised for use as food additives (potassium nitrite (E 249), sodium nitrite (E 250), sodium nitrate (E 251), potassium nitrate (E 252)) are purified industrially produced chemicals. Hence the use of nitrite obtained from natural sources is not compatible with Regulation (EC) No 1333/2008. Therefore, the text 'or to replace synthetic nitrite with nitrite obtained from natural sources' should be removed from Article 1, and Article 45 should also be reworded so that it refers only to the authorised nitrite food additives, i.e. potassium nitrite (E 249) and sodium nitrite (E 250).

1 <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4786>

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European Commission

Contact point Directive (EU) 2015/1535

email: grow-dir2015-1535-central@ec.europa.eu