



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/(2024) 1458

Directive (EU) 2015/1535

Notification: 2024/0003/IT

Forwarding of the response of the Member State notifying a draft (Italy) to of European Commission.

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1. MSG 201 IND 2024 0003 IT EN 04-07-2024 04-06-2024 IT ANSWER 04-07-2024

2. Italy

3A. Ministero delle Imprese e del Made in Italy

Dipartimento Mercato e Tutela

Direzione Generale Consumatori e Mercato

Divisione II - Normativa tecnica - Sicurezza e conformità dei prodotti, qualità prodotti e servizi

3B. Ministero delle Imprese e del Made in Italy

Direzione generale per la politica industriale, la riconversione e la crisi industriale, l'innovazione, le PMI e il made in Italy

Div. XIII - Agroindustria, industrie culturali e creative, industria del turismo

4. 2024/0003/IT - C50A - Foodstuffs

5.

6. In the framework of the notification procedure provided for in Directive (EU) 2015/1535, the Italian authorities notified the Commission on 3 January 2024 of the draft Interministerial Decree repealing and replacing the Decree of 21 September 2005 of the Minister of Productive Activities and the Minister of Agricultural and Forestry Policies concerning the production and sale specifications for certain cured meat products (notification 2024/0003/IT).

The following clarifications are provided in relation to what is stated in the Commission's detailed opinion on Article 10a of the notified text.

Premise

The European Commission has indicated that Article 10a of the notified draft, as set out in the preamble thereto, is not compatible with Article 17(5) of Regulation (EU) No 1169/2011, read in conjunction with point 6 of Part A of Annex VI to that Regulation, in so far as the indication of the presence of added water is required.

In particular in cases where failure to provide such information could lead to misleading the consumer, in all cases where the added water constitutes more than 5 % of the weight of the finished product, as required by Union law.

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The text of point 6 of Annex VI to Regulation No 1169/2011 – concerning added water – is one of the most controversial points, which has created the most problems of interpretation. There have been a number of interpretative measures taken by the European Commission to provide clear operational guidance and uniform application in all Member States.



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Specifically, point 1 of part A of Annex VII – on indication and designation of ingredients, with reference to added water and volatile ingredients – provides that added water is to be declared in the list of ingredients if, in terms of weight, it exceeds 5 % of the finished product.

Point 6 of Annex VI to the Regulation provides that ‘In the case of meat products and meat preparations which have the appearance of a cut, joint, slice, portion or carcase of meat, the name of the food shall include an indication of the presence of added water if the added water makes up more than 5 % of the weight of the finished product [...]’.

1) What is meant by: meat products and meat preparations which have the appearance of a cut, joint, slice, portion or carcase of meat.

The content of this distinction is not immediately clear.

Indeed, this provision has been the subject of a number of ‘Questions and Answers on the application of the Regulation (EU) on the provision of food information to consumers’, formulated by the Commission to identify the cases in which the sales denomination must be supplemented by the indication of the added water if it exceeds 5 %.

In the Q&A 2.11.1 published in January 2013, the Commission stated that “it is up to food business operators, and subsequently Member States, in the context of their control activities, to verify on a case-by-case basis whether a product meets these requirements. In this regard, the “appearance” of the food has to be taken into account. As an indication, this indication is not mandatory for foods ‘such as sausages (e.g., bologna, hot dogs), blood sausages, meat bread, pate (meat or fish), and meatballs (meat)’.

Thus, according to the Commission, it is up to Member States to identify which products are covered by that provision. In view of the diversity of production between the cured meat products (in particular cooked ham) in the various countries, the Commission has referred to Member States the assessment of whether the conditions for the application of the provision in question were met.

On this issue, the Commission’s in-depth work with the Member States has continued and can be found in the draft work of the Q&A meat & fish labelling 30.10.2014. Specifically in the latest draft of the works in circulation, the Commission, in addition to the requirement of ‘appearance’, on the basis of the questions asked, assessed whether the provision was normally applicable to heat-treated products (smoked, cooked) obtained from whole cuts or produced from two or more muscles combined together (e.g. canned cooked ham).

As set out below, the issue of cooked, canned, netted or bone-in hams, according to the different production traditions of the various countries, has been directly taken into account by the Commission, since they are products of the highest quality, where water can be added by more than 5 %.

The Working Party at the European Commission asked the following:

- does the obligation laid down in point 6 of Annex VI to the Regulation also apply to heat-treated products (smoked, cooked) consisting of whole cuts?
- does this obligation also apply to heat-treated products which may give the impression that they are made of a whole piece of meat but were actually made by two or more muscles together (e.g. boiled ham or canned ham)?

The Commission proposed as a reply to both questions “normally NO”, referring to Q&A 2.11.1 above (which has been published).

Without prejudice to the purpose of the provision, it follows from the above that it is up to the Member States to assess and decide to which of their products the Community legislation is applicable, taking into account the national rules governing cured meat products.

2) The purpose of the obligation to indicate the presence of added water next to the sales denomination

In the course of the work of Q&A meat & fish labelling 30.10.2014, in order to clarify the scope of this obligation, the Commission had argued that the objective of this indication is to protect consumers from unfair and misleading practices when water has been added to meat products in the form of cuts, slices, portions or carcasses which are not justified by technological reasons during the production process. (Q&A meat & fish labelling 31.10.2014).



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When asked to give some examples of what “technologically justified” means, the Commission replied that: ‘Some products require the addition of brine (water and salt) to distribute salt and other ingredients uniformly in the product, through water. In such cases, water may account for more than 5 % of the final product, but has a technological function.’

### 3) Italian legislation on cooked ham: the technological function of the added water

The current Ministerial Decree of 21 September 2005, as latest amended in 2016, defines the production of cooked ham (cooked ham, selected cooked ham, high-quality cooked ham) and other cured meat products, introducing strict rules as regards the technological and qualitative characteristics and parameters in order to ensure the high level of Italian cooked ham.

According to this provision, the designation ‘cooked ham’ is reserved for the cured meat product obtained from the pork leg, possibly cut, boneless, defatted, using water, salt, sodium and potassium nitrite, etc.

The addition of water is governed by the Decree and has a precise technological function.

The injection of an aqueous brine is a technologically necessary stage in the production of cooked ham for the safety and quality of the finished product. The composition and volume of the brine are aimed at evenly distributing the appropriate concentrations of salt and nitrite, and possibly other permitted ingredients such as ascorbate, wine, sugars, proteins, flavorings, etc.

By subsequent churning, a mechanical massage by which the brine is distributed, the salt must reach the suitable concentration at all points of the product for the swelling of muscle fibers and the extraction of myofibrillar proteins, which are necessary requirements for the texture and cohesion of cooked ham. At this stage, nitrite dissolved in brine, reaching all the points of the ham, ensures the adequate concentration of the nitrosant agent for microbiological and oxidative stability as well as the nitrosation of pigments for the development of the typical pink colour.

If the described processes do not occur or occur partially, the finished product may have problems related to safety, color development, slice tightness, and texture.

### 4) The changes introduced by the draft decree

The draft Interministerial Decree repealing and replacing the Ministerial Decree has led to significant changes to the rules governing cooked ham compared to the original text.

In fact, Article 1 on “cooked ham,” by totally changing the previous text, stipulates that:

‘It is permissible not to use nitrite or to replace synthetic nitrite with nitrite obtained from natural sources, under the responsibility of the food business operator who is required to demonstrate, to the satisfaction of the competent health authority, that the procedures used are supported by scientific justifications and that they ensure that the expected microbiological criteria for process acceptability and food safety are met as defined by the current legislation.’

The possibility of using the name ‘cooked ham’ without the use of nitrite, which has never been granted to date, is consistent with recent developments in Community legislation on the quantities of nitrites and nitrates in meat products.

The new Regulation (EU) 2023/2108, by amending Regulation (EC) No 1333/2008, allows the use of nitrite in heat-treated meat products in reduced quantities compared to the previous legislation.

As a result, producers of cooked ham have initiated technological changes [1] aimed at reducing salt and nitrite or adding natural replacement ingredients.

The implementation of these changes requires injecting into cooked ham volumes of brine that can ensure a rapid and homogeneous distribution of salt and nitrite (synthesised or from natural sources) used at reduced doses.

In this context, because nitrite is consumed quickly, to ensure sufficient concentration to inhibit *Clostridium botulinum* development [2] and nitrosate pigments in all areas of the muscle, diffusion must be fast and uniform, a condition achievable with adequate brine volumes and churning times.



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In addition, the reduction/elimination of nitrite, which also has antioxidant functions, requires a higher amount of antioxidants, including natural ones, conveyed and distributed through the injected brine [3]. This technological development makes it possible to improve the nutritional properties of cooked ham without compromising its safety and quality, but could be compatible with more than 5 % water in the finished product.

The addition of water therefore has a precise technological function, even if it is above 5 %.

In this case, the need for the words 'with added water' to the sales description could discourage producers from pursuing the objectives of reducing nitrite and salt in cooked ham.

In addition, the consumer is correctly informed about its use through the words 'water' in the list of ingredients to which the percentage indication of the quantity of meat in the product is added.

### 5) French legislation on cooked ham

The same interpretation was also given by France, which did not consider the provision in question applicable to cooked hams, since they are governed by the 'Code des Usages de la Charcuterie', a production code approved by the 'Direction General de la concurrence de la consommation et de la repression des fraudes' of the transalpine Ministry of Economic Affairs and Industry, which governs the main French cured meat products.

### 3.4) Présence d'eau ajoutée

(règlement UE n°1169/2011 annexe VI, Partie A allinéa 6)

Dans le cas des produits à base de viande et des préparations de viandes qui prennent l'apparence d'un morceau, d'un rôti, d'une tranche, d'une portion ou d'une carcasse de viande, la dénomination de la denrée alimentaire doit comporter l'indication de la présence d'eau ajoutée si celle-ci représente davantage que 5 % du poids du produit fini.

Les produits définis par la réglementation ou le présent code des usages ne sont pas concernés car astreints à des limites technologiques (HPD...). Pour les autres produits, cette indication de la présence d'eau pourra être indiquées sous la forme par exemple\_

- « saumuré »

- « mention du pourcentage d'eau ».

The non-application of the provision in point 6 of Annex VI to the Regulation, is justified as follows: 'Les produits définis par la réglementation ou le présent code des usages ne sont pas concernés car astreints à des limites technologiques (HPD, ...).'

In fact, it is argued that cooked hams covered by the Code are necessarily of high quality thanks to their regulation, and their method of production is known to consumers.

The analogy with the Italian measure that pursues the same purpose as the French "Code" is clear.

### Conclusions

On the basis of the above considerations and on the basis of the European Commission's interpretations, it is considered that the provision in Annex VI is not applicable to cooked ham because of the technological function of the water used in the production of cooked ham.

Its application would unfairly penalise Italian cooked ham compared to other non-national cooked hams, including the French standard Jambon cuit.

### Bibliography

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3. M. Armenteros, D. Morcuende, J. Ventanas, M. Estévez. (2016). The application of natural antioxidants via brine injection protects Iberian cooked hams against lipid and protein oxidation. *Meat Science*, 116, 253-259.

Clarifications are provided below with respect to what is highlighted in the Commission's comments regarding the "sixth citation" and what is provided in Article 18 of the notified text.

In order to clarify the text of the "sixth citation", it is proposed to amend the text as follows:

"Having regard to Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives;"

With reference to Article 18, taking into account the Commission's comments, it is hereby proposed the following amendment in analogy with what has already been stated in the second paragraph of Article 9 of the notified text: 'Wine, vinegar (including balsamic vinegar), brandy and other spirits, honey, truffles, cheese, nuts, pepper, garlic, spices and aromatic plants, sugar, dextrose, fructose, lactose, low-fat milk powder, milk proteins, fermentation starter microbial cultures, flavourings, permitted additives are allowed in the preparation of salami. No other additives are allowed, except for those permitted by Regulation 1333/2008 as long as they represent a real technological necessity, they do not mislead the consumer and their use benefits consumers, as envisaged by said Regulation.'

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