



Reports of Cases

JUDGMENT OF THE COURT (Tenth Chamber)

16 October 2014*

(Protection of health — Regulation (EC) No 853/2004 — Hygiene rules for food of animal origin — Annex I, points 1.14 and 1.15 — Concepts of ‘mechanically separated meat’ and ‘meat preparations’ — Regulation (EC) No 999/2001 — Prevention, control and eradication of certain transmissible spongiform encephalopathies — Consumer protection — Directive 2000/13/EC — Labelling and presentation of foodstuffs)

In Case C-453/13,

REQUEST for a preliminary ruling under Article 267 TFEU from the High Court of Justice (England and Wales), Queen’s Bench Division (Administrative Court) (United Kingdom), made by decision of 7 August 2013, received at the Court on 12 August 2013, in the proceedings

The Queen, on the application of:

Newby Foods Ltd

v

Food Standards Agency,

THE COURT (Tenth Chamber),

composed of A. Rosas, acting for the President of the Chamber, E. Juhász and D. Šváby (Rapporteur),
Judges,

Advocate General: M. Szpunar,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

- Newby Foods Ltd, by T. Russ, Solicitor, H. Mercer QC, and A. Legg, Barrister,
- the United Kingdom Government, by V. Kaye, acting as Agent, and by J. Holmes, Barrister,
- the German Government, by T. Henze and A. Wiedmann, acting as Agents,
- the French Government, by C. Candat and D. Colas, acting as Agents,

* Language of the case: English.

— the European Commission, by D. Bianchi and K. Skelly, acting as Agents,
having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,
gives the following

Judgment

- 1 This request for a preliminary ruling concerns the interpretation of points 1.14 and 1.15 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ 2004 L 139, p. 55, and corrigendum OJ 2004 L 226, p. 22).
- 2 The request has been made in proceedings between Newby Foods Ltd ('Newby Foods') and the Food Standards Agency ('the FSA') concerning a decision of the FSA published on 4 April 2012 and entitled 'Moratorium on desinewed meat' ('the Moratorium').

EU law

The hygiene rules for food of animal origin: Regulation No 853/2004

- 3 Regulation No 853/2004 contains, inter alia, the following recitals in its preamble:

'...

- (2) Certain foodstuffs may present specific hazards to human health, requiring the setting of specific hygiene rules. This is particularly the case for food of animal origin, in which microbiological and chemical hazards have frequently been reported.

...

- (9) The principal objectives of the recasting are to secure a high level of consumer protection with regard to food safety, in particular by making food business operators throughout the Community subject to the same rules, and to ensure the proper functioning of the internal market in products of animal origin, thus contributing to the achievement of the objectives of the common agricultural policy.

...

- (20) The definition of mechanically separated meat (MSM) should be a generic one covering all methods of mechanical separation. Rapid technological developments in this area mean that a flexible definition is appropriate. The technical requirements for MSM should differ, however, depending on a risk assessment of the product resulting from different methods.

...'

- 4 The specific hygiene rules for food of animal origin, the drawing-up of which constitutes the purpose of Regulation No 853/2004, are set out in Annex II et seq. to that regulation. As a preliminary point, Annex I to that regulation provides a set of definitions, including the following definitions:

'...

1. Meat

1.1. “Meat” means edible parts of the animals referred to in points 1.2 to 1.8, including blood. ...

1.10. “Fresh meat” means meat that has not undergone any preserving process other than chilling, freezing or quick-freezing, including meat that is vacuum-wrapped or wrapped in a controlled atmosphere. ...

1.13. “Minced meat” means boned meat that has been minced into fragments and contains less than 1% salt.

1.14. “Mechanically separated meat” or “MSM” means the product obtained by removing meat from flesh-bearing bones after boning or from poultry carcasses, using mechanical means resulting in the loss or modification of the muscle fibre structure.

1.15. “Meat preparations” means fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat. ...

7. Processed products

7.1. “Meat products” means processed products resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat. ...’

- 5 In accordance with point 2 of Article 2 of Regulation No 853/2004, also applicable to that regulation are the definitions laid down in Article 2 of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ 2004 L 139, p. 1), paragraph 1 of which contains, inter alia, the following definitions:

‘...’

(m) “processing” means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes;

(n) “unprocessed products” means foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed;

(o) “processed products” means foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.’

- 6 The following specific requirements concerning, respectively, raw material and hygiene during and after production for minced meat, meat preparations and mechanically separated meat are laid down in Chapters II and III of Section V of Annex III to Regulation No 853/2004.

‘Chapter II: Requirements for raw material ...’

1. The raw material used to prepare minced meat must meet the following requirements.

- (a) It must comply with the requirements for fresh meat;
- (b) It must derive from skeletal muscle, including adherent fatty tissues;
- (c) It must not derive from:
 - (i) scrap cuttings and scrap trimmings (other than whole muscle cuttings);
 - (ii) MSM;
 - (iii) meat containing bone fragments or skin;or
 - (iv) meat of the head with the exception of the masseters, the non-muscular part of the *linea alba*, the region of the carpus and the tarsus, bone scrapings and the muscles of the diaphragm (unless the serosa has been removed).

2. The following raw material may be used to prepare meat preparations:

- (a) fresh meat;
 - (b) meat meeting the requirements of point 1;
- and
- (c) if the meat preparation is clearly not intended to be consumed without first undergoing heat treatment:
 - (i) meat derived from the mincing or fragmentation of meat meeting the requirements of point 1 other than point 1(c)(i);and
 - (ii) MSM meeting the requirements of Chapter III, point 3(d).

3. The raw material used to produce MSM must meet the following requirements.

- (a) It must comply with the requirements for fresh meat;
- (b) The following material must not be used to produce MSM:
 - (i) for poultry, the feet, neckskin and head;and
 - (ii) for other animals, the bones of the head, feet, tails, femur, tibia, fibula, humerus, radius and ulna.

Chapter III: Hygiene during and after production ...

2. The following requirements apply to the production of minced meat and meat preparations.

- (a) Unless the competent authority authorises boning immediately before mincing, frozen or deep-frozen meat used for the preparation of minced meat or meat preparations must be boned before freezing. It may be stored only for a limited period.
- (b) When prepared from chilled meat, minced meat must be prepared:
 - (i) in the case of poultry, within no more than three days of their slaughter;
 - (ii) in the case of animals other than poultry, within no more than six days of their slaughter;or
 - (iii) within no more than 15 days from the slaughter of the animals in the case of boned, vacuum-packed beef and veal.
- (c) Immediately after production, minced meat and meat preparations must be wrapped or packaged and be:
 - (i) chilled to an internal temperature of not more than 2 °C for minced meat and 4 °C for meat preparations;or
 - (ii) frozen to an internal temperature of not more than –18 °C.

These temperature conditions must be maintained during storage and transport.

- 3. The following requirements apply to the production and use of MSM produced using techniques that do not alter the structure of the bones used in the production of MSM and the calcium content of which is not significantly higher than that of minced meat.
 - (a) Raw material for deboning from an on-site slaughterhouse must be no more than seven days old; otherwise, raw material for deboning must be no more than five days old. However, poultry carcasses must be no more than three days old.
 - (b) Mechanical separation must take place immediately after deboning.
 - (c) If not used immediately after being obtained, MSM must be wrapped or packaged and then chilled to a temperature of not more than 2 °C or frozen to an internal temperature of not more than –18 °C. These temperature requirements must be maintained during storage and transport.
 - (d) If the food business operator has carried out analyses demonstrating that MSM complies with the microbiological criteria for minced meat adopted in accordance with Regulation (EC) No 852/2004 it may be used in meat preparations that are clearly not intended to be consumed without first undergoing heat treatment and in meat products.
 - (e) MSM not shown to comply with the criteria referred to in (d) may be used only to manufacture heat-treated meat products in establishments approved in accordance with this Regulation.
- 4. The following requirements apply to the production and use of MSM produced using techniques other than those mentioned in point 3.

- (a) Raw material for deboning from an on-site slaughterhouse must be no more than seven days old; otherwise, raw material for deboning must be no more than five days old. However, poultry carcasses must be no more than three days old.
- (b) If mechanical separation does not take place immediately after deboning the flesh-bearing bones must be stored and transported at a temperature of not more than 2 °C or, if frozen, at a temperature of not more than –18 °C.
- (c) Flesh-bearing bones obtained from frozen carcasses must not be refrozen.
- (d) If not used within one hour of being obtained, MSM must be chilled immediately to a temperature of not more than 2 °C.
- (e) If, after chilling, MSM is not processed within 24 hours, it must be frozen within 12 hours of production and reach an internal temperature of not more than –18 °C within six hours.
- (f) Frozen MSM must be wrapped or packaged before storage or transport, must not be stored for more than three months and must be maintained at a temperature of not more than –18 °C during storage and transport.
- (g) MSM may be used only to manufacture heat-treated meat products in establishments approved in accordance with this Regulation. ...'

7 Before the entry into force of Regulation No 853/2004, health aspects related to the production of mechanically separated meat were governed by Council Directive 64/433/EEC on health conditions for the production and marketing of fresh meat (OJ, English Special Edition 1963-1964, p. 185), as last amended by Council Directive 95/23/EC of 22 June 1995 (OJ 1995 L 243, p. 7). In accordance with Articles 2(c) and 6(1)(c) of that directive, 'mechanically recovered meat' was defined as 'meat obtained by mechanical means from flesh-bearing bones apart from the bones of the head, the extremities of the limbs below the carpal and tarsal joints and, in the case of swine, the coccygeal vertebrae, and intended for establishments approved in accordance with Article 6 of [Council] Directive 77/99/EEC [of 21 December 1976 on health problems affecting the production and marketing of meat products and certain other products of animal origin (OJ 1977 L 26, p. 85), as amended and updated by Council Directive 92/5/EEC (OJ 1992 L 57, p. 1),]' and had to undergo heat treatment as provided for in the latter directive.

The rules on the labelling and presentation of foodstuffs: Directive 2000/13/EC

8 Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ 2000 L 109, p. 29), as amended by Commission Directive 2001/101/EC of 26 November 2001 (OJ 2001 L 310, p. 19) ('Directive 2000/13'), contains, inter alia, the following recitals:

'...

- (2) Differences between the laws, regulations and administrative provisions of the Member States on the labelling of foodstuffs may impede the free circulation of these products and can lead to unequal conditions of competition.

...

(6) The prime consideration for any rules on the labelling of foodstuffs should be the need to inform and protect the consumer.

...

(8) Detailed labelling, in particular giving the exact nature and characteristics of the product which enables the consumer to make his choice in full knowledge of the facts, is the most appropriate since it creates fewest obstacles to free trade.

...

(14) The rules on labelling should also prohibit the use of information that would mislead the purchaser ...

...'

9 Under Article 2(1) of Directive 2000/13:

'The labelling and methods used must not:

(a) be such as could mislead the purchaser to a material degree, particularly:

(i) as to the characteristics of the foodstuff and, in particular, as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production;

...'

10 In accordance with Annex I to Directive 2000/13, the designation '... meat' in the labelling and presentation of products containing meat as an ingredient corresponds to the following definition:

'Skeletal muscles ... of mammalian and bird species recognised as fit for human consumption with naturally included or adherent tissue, where the total fat and connective tissue content does not exceed the values indicated below and where the meat constitutes an ingredient of another foodstuff. The products covered by the Community definition of "mechanically recovered meat" are excluded from this definition.

...'

11 The insertion of that definition is explained by the following recitals in the preamble to Directive 2001/101:

'(1) ... [The] definition [of meat which was drawn up for the purposes of hygiene and the protection of public health] covers all parts of animals which are fit for human consumption. It does not correspond, however, to the consumer's perception of meat and does not inform the consumer as to the real nature of the product designated by the term "meat".

...

(7) Mechanically recovered meat differs significantly from "meat" as perceived by consumers. It should therefore be excluded from the scope of the definition.

(8) Consequently, it should be designated by its specific name, “mechanically recovered meat”, and by the name of the species, in compliance with the rule set out in Article 6(6) of Directive 2000/13/EC. This labelling rule applies to the products covered by the Community definition of “mechanically recovered meat”.

...’

- 12 As from 13 December 2014, Directive 2000/13 will be replaced by Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ 2011 L 304, p. 18), in accordance with Articles 53 and 55 of Regulation No 1169/2011.
- 13 In addition, point 17 of Annex VII to that regulation reproduces the definition of the designation ‘... meat’ as set out in Annex I to Directive 2000/13, while point 18 of Annex VII states that ‘[a]ll types of products covered by the definition of “mechanically separated meat” must be designated by the indication “mechanically separated meat” and the name(s) of the animal species from which it comes’; for labelling in English, the name of an animal species may be replaced by the generic name of the ingredient for the animal species concerned.

The rules on transmissible spongiform encephalopathies: Regulation (EC) No 999/2001

- 14 The concept of ‘mechanically separated meat’ as defined in point 1.14 of Annex I to Regulation No 853/2004 also corresponds to the definition set out in Article 3(n) of Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ 2001 L 147, p. 1), as amended by Commission Regulation (EC) No 722/2007 of 25 June 2007 (OJ 2007 L 164, p. 7) (‘Regulation No 999/2001’), with the exception that, having regard to its purpose, that latter definition does not refer to poultry carcasses amongst the raw material for mechanically separated meat.
- 15 Recital 5 in the preamble to Regulation (EC) No 1923/2006 of the European Parliament and of the Council of 18 December 2006 amending Regulation No 999/2001 (OJ 2006 L 404, p. 1), which inserted that definition into Regulation No 999/2001, reads as follows:
- ‘In the interests of clarity of Community legislation, it is appropriate to clarify that the definition of “mechanically separated meat” provided for in other Community legislation on food safety should be applicable in Regulation (EC) No 999/2001 in the context of [transmissible spongiform encephalopathy] eradication measures.’
- 16 Recital 11b in the preamble to Regulation No 999/2001 states:
- ‘Mechanically separated meat is obtained by removing meat from bones in such a way that the muscle fibre structure is destroyed or modified. It can contain parts of the bones and the periosteum (bone skin). Thus, mechanically separated meat is not comparable with regular meat. Consequently its use for human consumption should be reviewed.’

17 Point 5 of Annex V to Regulation No 999/2001 states:

‘Notwithstanding the individual decisions referred to in Article 5(2), and by way of derogation from Article 9(3), it shall be prohibited in all Member States to use bones or bone-in cuts of bovine, ovine and caprine animals for the production of mechanically separated meat.’

The dispute in the main proceedings and the questions referred for a preliminary ruling

18 In a guidance note issued in 2003, the FSA stated the following in respect of a product called ‘desinewed meat’:

‘Products obtained by mechanical deboning, which remove[s] definitive pieces of meat from meaty bones or carcass, which may or may not have had the primal muscles previously removed, such that the muscle fibre structure of the meat is substantially intact are not considered to be [mechanically separated meat]. This meat may then be desinewed and have the appearance of finely minced meat.

These products may still be considered meat, and may be counted towards the [Quantitative Ingredient] declaration.’

19 In a guidance paper following that guidance note, issued in 2010, the FSA provided the following information with regard to the distinction between ‘desinewed meat’ and mechanically separated meat:

‘1. Desinewed meat is meat from which the sinews and tendons have been removed. It may be obtained from a number of sources including meat trim [(that is to say, the preparation of a piece of meat by removing the non-edible parts)] and the removal of residual meat from bones.

2. It is produced by passing trim or meaty bones through a low pressure machine where the material obtained appears to retain its muscle fibre structure. Some machines remove and desinew the meat as part of a continuous process; others do it in a two-stage operation. The resulting product is variously known as Baader meat, 3 mm meat or desinewed meat; for the purposes of this document it is called “desinewed meat”. ... Such material would appear to fall within the definition of a meat preparation ([point] 1.15, Annex I [to] Regulation (EC) No 853/2004), which includes “fresh meat that has been reduced to fragments ... or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat”. As the muscle fibre structure is maintained, the material falls outside the definition of [mechanically separated meat] in Regulation ... No 853/2004 (i.e. where the mechanical process results in the loss or modification of the muscle fibre structure). It cannot be considered to be minced meat because it is produced under pressure and not by cutting.

...

4. ... [Mechanically separated meat] is different to, and should not be confused with, meat preparations or desinewed meat.

...

6. If the pressure used to remove the meat from the bone (paragraph 2 refers) is too great the resulting product may be [mechanically separated meat]. Microscopy analysis can be used to assess whether there has been a loss or modification of the internal fibre structure to determine whether the product meets the definition of [mechanically separated meat]. Once a product has been classified as [mechanically separated meat] it cannot be reclassified as a meat preparation or as desinewed meat.

Defining Muscle fibre structure

7. Neither the definition of meat preparations nor that of [mechanically separated meat] in the food hygiene regulations provides a clear indication of what is meant by “loss or modification of the muscle fibre structure” or the level of modification or loss necessary before a product ceases to be “fresh meat” and becomes [mechanically separated meat]. Recent enquiries to the European Commission indicate that any modification of the muscle fibre structure of the “meat” during the removal process would cause the product to be classified as [mechanically separated meat] ...
8. It is worth noting that there is, generally, no muscle fibre structure present in samples of pork, chicken and turkey [mechanically separated meat] examined under a microscope. However, even mincing processes and passing through a 3mm plate can result in some modification of muscle fibre structure. Microscopic analysis therefore allows only a subjective assessment of the appropriate categorisation of a product. ...

Identifying desinewed meat and [mechanically separated meat]

10. It is the food business operator’s responsibility to ... demonstrate ... that [its] product ... meets the criteria for desinewed meat and, in particular, that the muscle fibre structure of the product has not been lost or modified. Microscopic analysis can be used to assess the destruction of muscle fibre structure and hence assist in the decision as to whether a product falls within the definition of a “meat preparation” and can be considered to be desinewed meat, or whether it is [mechanically separated meat]. If the food business operator is unable to demonstrate that the product is desinewed meat then, in the case of [a] product from cattle, sheep or goats, it could be illegal under Community [transmissible spongiform encephalopathy] legislation ...

...

20. As the law currently stands, production of desinewed meat on the bones of cattle, sheep and goats is legal, provided no [specified risk material] is included in the production process. The production of [mechanically separated meat] from the same bones is illegal.’

20 Newby Foods was approved by the FSA to produce ‘desinewed’ lamb meat, in 2006, and beef, in 2008.

21 The referring court states that Newby Foods has developed a machine which is capable of removing the residual meat attached to the bones after the main part of the meat had been removed from them, without crushing those bones or liquefying the residual tissues. That machine, which operates essentially by means of shearing, can be distinguished from those operating at high pressure, which turn the residual tissues into a viscous paste. The resulting product, which, at the end of the first production stage, passes through a perforated plate with 10 mm diameter apertures, is then processed in another machine which minces it by making it pass through a filter with 3 mm diameter apertures. This product, which looks like ordinary minced meat, is marketed in the United Kingdom as ‘desinewed meat’. As regards its appearance, that product is clearly distinguishable from mechanically separated meat obtained at high pressure. According to the applicant in the main proceedings, no one would classify the product obtained by means of its machine as anything other than meat.

22 Also according to the applicant in the main proceedings, the ‘desinewed meat’ which it produces contains only very rarely particles of bones, bone skin or bone marrow; however, the presence of occasional shards of bone cannot be excluded.

23 According to the applicant in the main proceedings and the FSA, by reference to the documents mentioned in paragraphs 18 and 19 of the present judgment, the product obtained by means of that process does not correspond to the definition of ‘mechanically separated meat’ within the meaning of

Regulation No 853/2004, in the absence of ‘significant’ loss or modification of the muscle fibre structure, that is to say, in the absence of a change which is sufficient to eliminate the characteristics of fresh meat. That product should rather be classified as ‘meat preparations’ within the meaning of point 1.15 of Annex I to that regulation.

24 According to Newby Foods, to permit the marketing of the product at issue only as mechanically separated meat would result in a substantial waste of meat that is acceptable for human consumption as fresh meat. The referring court adds that this would lead to a significant reduction in that product’s commercial value. The referring court also notes that that classification has three other technical consequences, namely:

- the prohibition of the use of ruminant bones, which is not allowed for the production of mechanically separated meat pursuant to point 5 of Annex V to Regulation No 999/2001, in view of the risks linked to certain transmissible spongiform encephalopathies;
- the obligation to comply with the specific requirements concerning raw material and hygiene during and after production which apply to mechanically separated meat, as laid down by Regulation No 853/2004; and
- the prohibition of labelling the product concerned as ‘meat’.

25 According to the referring court, loss or modification of the muscle fibre structure can just as well result from the chopping or mincing and from the freezing and thawing of the skeletal muscles. However, those treatments do not usually eliminate the characteristics of fresh meat. The position adopted by the Commission, which is not to take account of the fact that a method of mechanical separation may not damage the processed bones or extract the bone marrow, has the advantage of being simple, whereas, if the argument of the applicant in the main proceedings were to be followed, an individual assessment of the final product would be necessary in order to identify it as mechanically separated meat or otherwise.

26 Citing the Communication of 2 December 2010 from the Commission to the European Parliament and the Council on the future necessity and use of mechanically separated meat in the European Union, including the information policy towards consumers (COM(2010) 704 final), which was drawn up pursuant to Regulation No 999/2001, the referring court observes that the first paragraph of point 2 and the fourth and fifth paragraphs of point 5.1 of that communication are worded as follows:

‘2. Introduction Mechanically separated meat ... is a product, obtained by removing meat from bones or poultry carcasses using mechanical means, where the normal structure of the muscle fibre is mostly lost or modified in such a way that it is not comparable with regular meat. ...

5.1. Production methods of [mechanically separated meat] ... Visually, high-pressure [mechanically separated meat] results in a product with a characteristic and particularly pasty texture resulting from the loss or modification of the muscle fibre structure. Other technologies (low-pressure [mechanically separated meat]) may result in a product that cannot or [can] hardly be differentiated visually from minced meat ... Microscopically, an evaluation of “the loss or modification of the muscle fibre structure” is possible using microscopic sections of meat. A large variation of the modification of [the] internal structure of the product can be observed depending on the different production parameters used.’

27 The report drawn up following an inspection carried out in the United Kingdom in March 2012 by an audit team from the European Commission’s Food and Veterinary Office (‘the FVO’) mentioned the use in that Member State of the designation ‘desinewed meat’, which, it is stated, is unknown in EU legislation, for a category of products which are incorrectly considered to be ‘meat preparations’

within the meaning of that legislation, although they correspond in actual fact to mechanically separated meat. That report referred in detail to the document published by the FSA in 2010 and mentioned in paragraph 19 of the present judgment. It was stated therein that that document required a microscopy analysis to be carried out in order to demonstrate that the muscle fibre structure has not been lost or modified as a result of the process for the production of the product concerned and that the results of the analyses carried out, where available, never indicated that there was no loss or no modification of the muscle fibre structure.

- 28 According to the referring court, the disagreement between the FVO auditors and the FSA related to the question whether the classification as ‘mechanically separated meat’ within the meaning of point 1.14 of Annex I to Regulation No 853/2004 is dependent on any loss or modification of the muscle fibre structure or, on the contrary, on a loss or modification to a certain extent.
- 29 On 4 April 2012 the FSA published the Moratorium, by which it took note of the position of the Commission’s Services as regards the classification of ‘desinewed meat’ under EU law but distanced itself from that position. In documents or subsequent position papers sent to United Kingdom undertakings or authorities, or even in response to the FVO report, the FSA confirmed its disagreement in principle with the interpretation advocated by the Commission’s Services, drawing attention in particular to the innovative nature of the method used by undertakings such as Newby Foods in order mechanically to process bones which may have a large amount of flesh and which were previously processed by hand.
- 30 Newby Foods brought an action before the referring court challenging the Moratorium.
- 31 According to that court, the dispute in the main proceedings concerns solely the labelling of the product obtained by the process used by Newby Foods as regards pig and poultry bones, but also presents a public-health aspect in the case of its application to ruminant bones in that there is a risk that the bones will be damaged, which is inherent in the use of any mechanical process. Although it takes the view that the position of the Commission’s Services is hardly accurate in this regard and observes that that position is contested by the FSA, the referring court accepts that it is a legitimate concern. However, in its view, the only relevant question is whether ruminant bones can be used in the process applied by the applicant in the main proceedings, and not whether the resulting product must be classified as mechanically separated meat.
- 32 Scientific analyses commissioned by Newby Foods from an undertaking specialising in the foodstuffs sector led to the following conclusions:
- the product obtained at the end of the first stage of the process used by Newby Foods looked like pieces of meat;
 - meat from poultry and pigs, hand de-boned and minced meat, on the one hand, and Newby Foods’ product, on the other, showed differences, since the muscle fibre structure was nearly intact in some areas and showed some damage and dispersion of the protein in other areas; however, Newby Foods’ product was more like minced meat than mechanically separated meat obtained at high pressure; blind tests allowed that product to be distinguished from minced meat, but not invariably; in conclusion, Newby Foods’ product, which kept the muscle fibre structure sufficiently intact by comparison with minced meat, could be considered as a meat preparation, a classification which would be excluded for mechanically separated meat having regard, in that case, to the too great modification of that structure;
 - as for beef and lamb meat, a comparative microscopy examination of Newby Foods’ product and of mechanically separated meat obtained at high pressure did not result in a distinction which was as evident because, with the meat of those species, that process did not give rise to a large destruction

of muscle fibre structure; the destruction of that structure was, however, less significant in the case of that product and was similar to that obtained with minced meat, the quality being almost equivalent.

- 33 A consultant approved that analysis, taking the view (i) that, as regards composition and structure, mechanically separated meat obtained at high pressure, which passes through a 1 mm filter to prevent bone particles and connective tissue from passing through, is significantly different from minced meat and (ii) that Newby Foods' product is itself significantly different from mechanically separated meat obtained at high pressure.
- 34 According to the referring court, since the product obtained by application of the process used by the applicant in the main proceedings — albeit significantly different from mechanically separated meat obtained at high pressure as regards its appearance and texture — nevertheless undergoes a modification of the muscle fibre structure, the central question is whether the classification as mechanically separated meat is linked to any modification whatsoever of that structure.
- 35 Referring to the definition of the concept of 'meat preparations' set out in point 1.15 of Annex I to Regulation No 853/2004, the referring court draws two conclusions from this. Firstly, the words 'and thus' indicate that there is a causal link between the loss or modification of the muscle fibre structure and the elimination of the characteristics of fresh meat. Secondly, that definition cannot be interpreted as meaning that any diminution of the characteristics of fresh meat implies that those characteristics have been eliminated, since that elimination stems only from a significant diminution of those characteristics. In addition, the referring court takes the view that the 'characteristics of fresh meat', as referred to in that definition, are its organoleptic properties, such as taste, smell and texture.
- 36 The referring court considers that the product obtained as a result of the process used by Newby Foods sufficiently retains the characteristics of fresh meat to be placed in the category of meat preparations within the meaning of point 1.15 of Annex I to Regulation No 853/2004.
- 37 Finally, the referring court reiterates the argument of the applicant in the main proceedings that it would be inconsistent for the Commission to refuse such a classification by claiming that, because of the use of mechanical means and the existence of a modification of the muscle fibre structure, that product has to be classified as mechanically separated meat, whilst accepting that the use of mechanical means to separate chicken breasts from carcasses, which nevertheless inevitably gives rise to such a modification at the point where the cutting is carried out, does not imply that the resulting meat has lost the characteristics of fresh meat.
- 38 It was in this context that the High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court), decided to stay the proceedings and to refer the following questions to the Court for a preliminary ruling:
- '(1) Do the words "loss or modification of the muscle fibre structure" in [point] 1.14 of Annex I [to] Regulation (EC) No 853/2004 [(the same words appearing also in Article 3(n) of Regulation No 999/2001)] mean "any loss or modification of the muscle fibre structure" that is visible using standard techniques of microscopy? ...
- (2) Can a meat product be classified as a meat preparation within [point] 1.15 of Annex I [to Regulation No 853/2004] where there has been some loss or modification of its muscle fibre structure that is visible using standard techniques of microscopy?

- (3) If the answer to [the first question] is no and the answer to [the second question] is yes, is the degree of loss or modification of the muscle fibre structure that is sufficient to require the meat product to be classified as [mechanically separated meat] within [point] 1.14 of Annex I [to Regulation No 853/2004] the same as that required to eliminate the characteristics of fresh meat within [point] 1.15 [of that annex]?
- (4) To what extent must the characteristics of fresh meat have been diminished before they can be said to have been eliminated within the meaning of [point] 1.15 [of Annex I to Regulation No 853/2004]?
- (5) If the answer to [the first question] is no, but the answer to [the third question] is also no[, w]hat degree of modification to the muscle fibre structure is required in order for the product in question to be classified as [mechanically separated meat]?
- (6) [On the same assumption, w]hat criteria should be used by national courts in determining whether or not the muscle fibre structure of the meat has been modified by that degree?

39 By letters of 1 and 11 October 2013, received at the Court Registry on 16 October 2013, the referring court requested that the present request for a preliminary ruling be dealt with under the expedited procedure provided for in Article 105 of the Court's Rules of Procedure. That request was refused on 7 February 2014 by order of the President of the Court in *Newby Foods* (C-453/13, EU:C:2014:87).

Consideration of the questions referred

- 40 By its questions, which it is appropriate to examine together, the referring court is essentially asking whether points 1.14 and 1.15 of Annex I to Regulation No 853/2004, which contain the definitions of the concepts of 'mechanically separated meat' and 'meat preparations' respectively, must be interpreted as meaning that the product obtained by the mechanical removal of meat from flesh-bearing bones after boning or from poultry carcasses must be classified as 'mechanically separated meat' within the meaning of that point 1.14 only where the process used results in a loss or modification of the muscle fibre structure which is significant, while the classification as 'meat preparations' within the meaning of point 1.15 must be chosen where that loss or modification is not significant. Secondly, in the event that that interpretation should prevail, the referring court seeks to ascertain what degree of modification or loss is required for that modification or loss to have to be regarded as significant and what process should be used in order to determine whether the degree thus required has been attained.
- 41 It must be stated at the outset that the definition of the concept of 'mechanically separated meat' set out in point 1.14 of Annex I to Regulation No 853/2004 is based on three cumulative criteria which must be read in conjunction with one another, namely (i) the use of bones from which the intact muscles have already been detached, or of poultry carcasses, to which meat remains attached, (ii) the use of methods of mechanical separation to recover that meat, and (iii) the loss or modification of the muscle fibre structure of the meat thus recovered by reason of the use of those processes. In particular, that definition does not make any distinction as regards the degree of loss or modification of the muscle fibre structure, with the result that any loss or modification of that structure is taken into consideration within the context of that definition.
- 42 Consequently, any meat product which satisfies those three criteria must be classified as 'mechanically separated meat', irrespective of the degree of loss or modification of the muscle fibre structure, in so far as, by reason of the process used, that loss or modification is greater than that which is strictly confined to the cutting point.

- 43 In the case of use of mechanical processes, that third criterion allows ‘mechanically separated meat’ within the meaning of point 1.14 of Annex I to Regulation No 853/2004 to be distinguished from the product obtained by cutting intact muscles; the latter product does not show a more general loss or modification of the muscle fibre structure, but reveals a loss or modification of the muscle fibre structure which is strictly confined to the cutting point. Consequently, chicken breasts which are detached from the carcase of the animal by mechanically operated cutting rightly do not constitute mechanically separated meat.
- 44 As regards the products which meet those criteria and thus satisfy the definition of ‘mechanically separated meat’, Regulation No 853/2004 does not make any other distinction than that stemming from points 3 and 4 of Chapter III of Section V of Annex III to that regulation.
- 45 That distinction concerns, first, mechanically separated meat referred to in point 3, produced using techniques that do not alter the structure of the bones used, immediately after those bones have had removed from them the intact muscles which were initially attached to them, provided that the resulting product has a calcium content close to that of minced meat and respects the microbiological criteria applicable to minced meat.
- 46 This type of product, which corresponds to mechanically separated meat obtained at low pressure, like the product at issue in the main proceedings, may, by way of exception, be used in certain ‘meat preparations’ within the meaning of point 1.15 of Annex I to Regulation No 853/2004, namely those intended to undergo heat treatment prior to consumption, whereas, in accordance with the definition given in point 1.15, meat preparations may in principle be obtained only from fresh meat, possibly minced into fragments — that is to say, meat deriving from intact muscles — to the exclusion of bone scrapings. The same type of product may also be used in all of the ‘meat products’ within the meaning of point 7.1 of that annex.
- 47 That distinction concerns, secondly, mechanically separated meat referred to in point 4 of Chapter III of Section V of Annex III to Regulation No 853/2004, produced by means of other techniques, which corresponds to mechanically separated meat obtained at high pressure, which can be used only in meat products which are subjected to heat treatment in an establishment approved in accordance with Regulation No 853/2004.
- 48 The distinction thus made in points 3 and 4 of Chapter III of Section V of Annex III to Regulation No 853/2004 is reflected in the definition of the concept of ‘mechanically separated meat’ set out in point 1.14 of Annex I to that regulation, particularly in the words ‘resulting in the loss or modification of the muscle fibre structure’, since that distinction within the category of mechanically separated meat and those words in the definition of that category of products were inserted at the same time in the process of the drafting of that regulation. The presence of the term ‘modification’ in that definition implies that products obtained through the use of methods of mechanical separation operating at low pressure come, in any event, within the scope of that definition.
- 49 That scheme, which consists in the arrangement of all mechanically separated meat into a single category subdivided into two subcategories of products which present different health risks and may consequently be intended for different uses, is explained in recital 20 in the preamble to Regulation No 853/2004, which was also inserted at the same stage of the drafting of that regulation. That recital announces, for that category of products, (i) a generic definition stated in flexible terms in such a way as to cover all methods of mechanical separation and to remain appropriate notwithstanding the rapid technological developments in that area, and (ii) technical requirements which differ depending on a risk assessment of the product resulting from different methods.
- 50 That recital, which clarifies perfectly the EU legislature’s intentions, adequately demonstrates that the EU legislature took into consideration from the outset the possibility that new low-pressure methods for the production of mechanically separated meat might be developed, such as, as the case may be,

that used by the applicant in the main proceedings, assuming that that process demonstrates some innovation vis-à-vis methods using techniques which do not alter the structure of the bones used, of which the EU legislature was aware at the time when Regulation No 853/2004 was drafted.

- 51 As regards the argument of the applicant in the main proceedings that not every loss or modification of the muscle fibre structure has the result that a product has to be considered to be mechanically separated meat, since a product must be considered as such only in the event of 'significant' loss or modification of that structure, it should be borne in mind that the classification as 'mechanically separated meat' within the meaning of point 1.14 of Annex I to Regulation No 853/2004 results from the combination of three cumulative criteria, as has been stated in paragraph 41 of the present judgment.
- 52 By contrast, a classification as 'meat preparations', within the meaning of point 1.15 of Annex I to Regulation No 853/2004, of products which, like that at issue in the main proceedings, satisfy the criteria for mechanically separated meat is excluded by the definition laid down in that point.
- 53 In this regard, it should be noted that the production of mechanically separated meat involves neither of the two processes provided for in that definition, namely the addition of foodstuffs, seasonings or additives, or a 'processing' within the meaning of Article 2(1)(m) of Regulation No 852/2004; on the contrary, a product such as that at issue in the main proceedings corresponds to the notion of an 'unprocessed product' within the meaning of Article 2(1)(n) of that regulation.
- 54 Furthermore, the concept of 'meat preparations' has a direct link, not with the concept of 'mechanically separated meat', but rather, first, with the concepts of 'fresh meat' and 'minced meat', which are, in principle, the only usable raw material, and, secondly, with the concept of 'meat products' within the meaning of point 7.1 of Annex I to Regulation No 853/2004, which combines with the concept of 'meat preparations' in the event of the processing of the fresh meat used as a raw material. In that event, those two latter concepts are alternative in the sense that, depending on whether a procedure for the processing of fresh meat modifies the internal muscle fibre structure by thus eliminating the characteristics of fresh meat or does not result in such a modification, the resulting product is either a meat product or a meat preparation.
- 55 In addition, as the French Government suggests, a classification of products, such as that at issue in the main proceedings, as 'fresh meat' within the meaning of point 1.10 of Annex I to Regulation No 853/2004 is also excluded. Disregarding their other characteristics, such products consisting in fragmented meat would be capable of coming only within the concept of 'minced meat' within the meaning of point 1.13 of that annex, a concept from which they must, however, be excluded by reason of point 1(c)(iv) of Chapter II of Section V of Annex III to that regulation as products obtained from bone scrapings.
- 56 Regardless of the health requirements laid down in Regulation No 853/2004, the classification of products obtained through the use of a given industrial method as 'mechanically separated meat' within the meaning of point 1.14 of Annex I to that regulation also has consequences with regard, first, to Regulation No 999/2001 relating to transmissible spongiform encephalopathies and, secondly, to Directive 2000/13, which concerns, inter alia, the labelling and presentation of foodstuffs.
- 57 That classification implies, in the first place, that that method cannot be used for the processing of bovine, ovine and caprine raw material, in accordance with point 5 of Annex V to Regulation No 999/2001 relating to transmissible spongiform encephalopathies.
- 58 Contrary to the view advanced in this regard by the applicant in the main proceedings, the application of that classification to products such as that at issue in the main proceedings in order to conclude that their production from raw material obtained from ruminants is prohibited follows from the implementation of the intention expressed in clear terms by the EU legislature within the context of

the measures adopted with a view to combatting those diseases. It is apparent from recital 5 in the preamble to Regulation No 1923/2006, which inserted the definition of ‘mechanically separated meat’ into Regulation No 999/2001, that the EU legislature wished to reproduce, in that area, the definition previously adopted in the context of food safety within the framework of Regulation No 853/2004.

- 59 Furthermore, it is apparent from recital 11b in the preamble to Regulation No 999/2001 that, within the context of that regulation, the legislature particularly had in mind the fact that mechanically separated meat could contain portions of bones and of the periosteum. It follows precisely from the decision making the reference that the same applies in the case of a product such as that produced by the applicant in the main proceedings.
- 60 In the second place, in accordance with Annex I to Directive 2000/13, the classification as ‘mechanically separated meat’ within the meaning of point 1.14 of Annex I to Regulation No 853/2004 implies a prohibition on labelling the product concerned under the term ‘... meat’ followed by the name of the animal species from which it comes, since that product can be designated only under the term ‘mechanically separated meat’ followed by the name of the animal species from which it comes.
- 61 Within the context of Directive 2000/13, which, in accordance with recital 6 in the preamble thereto, is based primarily on the need to inform and protect the consumer, that prohibition constitutes an implementation of the general rule set out in Article 2(1)(a)(i) of that directive, according to which the labelling must not be such as could mislead the purchaser to a material degree as to the characteristics of the foodstuff and, in particular, as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production.
- 62 As is apparent from recitals 1 and 7 in the preamble to Directive 2001/101, the definition of the concept of ‘meat’ which was drawn up in Regulation No 853/2004 for the purposes of hygiene and the protection of public health, which covers all parts of animals which are fit for human consumption, does not correspond to the consumer’s perception of meat and therefore does not make it possible to inform the consumer as to the real nature of the products which are covered by that definition in that regulation, with the result that mechanically separated meat, which differs significantly from ‘meat’ as perceived by consumers, must be excluded from the scope of that concept for the purposes of the labelling and presentation of foodstuffs.
- 63 Those recitals express the finding that, although mechanically separated meat is technically fit for human consumption in so far as it is not obtained from ruminants, it is none the less a product of inferior quality because it consists of residual meat, fat and connective tissue which remain attached to the bones after the main part of the meat has been removed.
- 64 In that regard, the fact, from which the applicant in the main proceedings seeks to derive an argument in favour of a designation other than that of ‘mechanically separated meat’, that a product such as that which it produces, known in the industry concerned as ‘Baader meat’, ‘3 mm meat’ or ‘desinewed meat’, has an appearance comparable to that of minced meat, from which it cannot easily be differentiated by consumers because the mixture of the various tissues obtained at the end of the production process does not allow their identification, constitutes, in reality, an illustration of the type of mistake which the EU legislature sought to prevent by adopting Directive 2000/13.
- 65 Not to require that that product of inferior quality be subject to specific labelling which informs consumers in clear terms by removing any ambiguity as to its exact nature, but, on the contrary, to allow it to be labelled in a manner which suggests that it is fragmented meat, like minced meat, would be tantamount to overlooking an essential objective pursued by Directive 2000/13, namely that of ensuring detailed labelling indicating the exact nature and characteristics of the product which

enables the consumer to make his choice in full knowledge of the facts, as stated in recital 8 in the preamble to that directive. This is all the more the case where that product is an ingredient which cannot be identified by the consumer.

- 66 Laxity of this kind would also have the effect of jeopardising the attainment of the other essential objective pursued by Directive 2000/13, expressed in recital 2 in the preamble thereto, which is to prevent differences in the labelling of foodstuffs which might impede the free circulation of those products and lead to unequal conditions of competition.
- 67 Having regard to all of the foregoing considerations, the answer to the questions referred is that points 1.14 and 1.15 of Annex I to Regulation No 853/2004 must be interpreted as meaning that the product obtained by the mechanical removal of meat from flesh-bearing bones after boning or from poultry carcasses must be classified as ‘mechanically separated meat’ within the meaning of that point 1.14, since the process used results in a loss or modification of the muscle fibre structure which is greater than that which is strictly confined to the cutting point, irrespective of the fact that the technique used does not alter the structure of the bones used. Such a product cannot be classified as a ‘meat preparation’ within the meaning of that point 1.15.

Costs

- 68 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Tenth Chamber) hereby rules:

Points 1.14 and 1.15 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin must be interpreted as meaning that the product obtained by the mechanical removal of meat from flesh-bearing bones after boning or from poultry carcasses must be classified as ‘mechanically separated meat’ within the meaning of that point 1.14, since the process used results in a loss or modification of the muscle fibre structure which is greater than that which is strictly confined to the cutting point, irrespective of the fact that the technique used does not alter the structure of the bones used. Such a product cannot be classified as a ‘meat preparation’ within the meaning of that point 1.15.

[Signatures]