Case C-51/21

Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice

Date lodged:

28 January 2021

Referring court:

Tallinna Halduskohus (Administrative Court, Tallinn, Estonia)

Date of the decision to refer:

28 January 2021

Applicant:

Aktsiaselts M.V.WOOL

Defendant:

Põllumajandus- ja Toiduamet (Agriculture and Food Board, formerly Veterinaar- ja Toiduamet, Veterinary and Food Board)

Subject matter of the main proceedings

Action brought by AS M.V.Wool seeking the annulment of the order in a control report of the Agriculture and Food Board dated 7 August 2019 (Order No 1) and seeking to have the order of 25 November 2019 (Order No 2) declared null and void on procedural grounds, or, in the alternative, annulled on substantive grounds and partially suspended for the duration of the present administrative proceedings

Subject matter and legal basis of the request

The request for a preliminary ruling seeks an interpretation of Article 3(1) of Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ 2005 L 338, p. 1) and point 1.2 of the table in Chapter 1 of Annex I thereto, read in conjunction with Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food

safety (OJ 2002 L 31, p. 1) and Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ 2004 L 165, p. 1).

Questions referred for a preliminary ruling

1. Must the second microbiological criterion 'Absence in 25 g' set out in Article 3(1) of Regulation No 2073/2005 and point 1.2 of the table in Chapter 1 of Annex I thereto be interpreted, having regard to that regulation, the protection of public health and the objectives pursued by Regulations No 178/2002 and No 882/2004, as meaning that in the case where the food business operator has been unable to demonstrate to the satisfaction of the competent authority that ready-to-eat foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes, will not exceed the limit of 100 cfu/g during their shelf-life, the microbiological criterion 'Absence in 25 g' then also applies in any event to products placed on the market during their shelf-life?

2. If Question 1 is answered in the negative: Must the second microbiological criterion 'Absence in 25 g' set out in Article 3(1) of Regulation No 2073/2005 and point 1.2 of the table in Chapter 1 of Annex I thereto be interpreted, having regard to that regulation, the protection of public health and the objectives pursued by Regulations No 178/2002 and No 882/2004, as meaning that, irrespective of whether the food business operator is able to demonstrate to the satisfaction of the competent authority that the food will not exceed the limit of 100 cfu/g during the shelf-life, two alternative microbiological criteria then apply to that food, namely (1) the criterion 'Absence in 25 g' while the food is under the control of the food business operator, and (2) the criterion '100 cfu/g' after the food has left the control of the food business operator?

Relevant provisions of EU law

Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, p. 1), recitals 1 to 3 and 5, Article 2(b), (c), (f), (g), (l), Article 3(1)(a) and (b) of the explanatory table in Chapter 1 of Annex I of Notes 5 and 7 to Annex I.

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1), recitals 2, 8, 10 and 12, Article 5(1), Article 7(1), Article 14(1) and (2), Article 14(3)(a) and (b), Article 14(5)

Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of

compliance with feed and food law, animal health and animal welfare rules (OJ 2004 L 165, p. 1, and corrigendum OJ 2004 L 191, p. 1), recitals 1, 4 and 6, Article 3(3)

Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ 2013 L 293, p. 1), Article 9(a) and (b)

Provisions of national law relied on

General Law on economic activities ('the MSÜS'), Paragraph 43(1)(1)

Law on foodstuffs ('the ToiduS'), Paragraph 49(4) and (5).

Succinct presentation of the facts and procedure in the main proceedings

1 On 7 August 2019, the Veterinary and Food Board ('the VLA' or 'the defendant') issued an order in a control report ('Order No 1') requiring AS M.V.Wool ('M.V.Wool' or 'the applicant') to suspend the further handling of its products (sliced cold smoked salmon, [use by 19 August 2019] and sliced cured trout [use by 10 August 2019]), to recall the entire batch from the market and to inform consumers of the recall of the non-compliant food from the market. The reasons given for Order No 1 were as follows.

2 VLA employees took food samples, in a Maxima store, from four products made in M.V.Wool's fish plant in Harku. The analysis of the samples revealed that *Listeria monocytogenes* ('*L.m.*') was present in 3 samples of cold smoked trout (use by 6 August 2019), 5 samples of sliced cold smoked salmon (use by 19 August 2019) and 1 sample of sliced cured trout (use by 10 August 2019).

3 The control report of 18 March 2018 had already imposed on M.V.Wool the obligation to establish the absence of *L.m.* for each product batch (absence in 25 g, in 5 samples) before the food had left the immediate control of the food business operator. In the event of a positive result, the batches were not allowed to depart the company (the 'zero tolerance' requirement). The applicant has not challenged the orders on which the abovementioned form of order sought by it was based.

4 Since the applicant did not duly demonstrate to the VLA that the quantity of *L.m.* present at the end of the shelf-life would not exceed 100 cfu/g, only criterion II, provided for in point 1.2 of the table in Chapter 1 of Annex I to Regulation No 2073/2005, namely that *L.m.* must be absent in 25 g in five product samples, can apply. The applicant breached its obligation of self-regulation by placing on the market products that did not meet food safety criteria.

5 On 25 November 2019 the VLA issued an order ('Order No 2') to M.V.Wool requiring it to suspend completely its activities (including manufacturing,

brokering, storage, import of raw materials, export of raw materials and of goods) at two operating sites: the Harku fish plant and the Vihterpalu fish plant. The operative part of Order No 2 also states that if the action plan to improve the operations of M.V.Wool includes the production of a sample batch, the VLA must be informed of this and a corresponding action plan must be submitted to the VLA for coordination purposes. In addition, M.V.Wool was required to inform the VLA of the following on 25 November 2019: a) the stock level determined at the relevant establishments, and b) where and in what way the Category-2 animal by-products to be disposed of at the establishment are handled. Part of that order was mandatory from the time of service. The suspension of activities was to apply until M.V.Wool had demonstrated to the VLA that the *L.m.* strain ST1247 of the outbreak had been eliminated from M.V.Wool's operating sites, the VLA had been informed of this and the VLA had confirmed it on the basis of the results of rinse samples taken as part of a government control measure. The reasons given for Order No 2 were as follows.

6 After analysing samples taken from the Harku fish plant and Vihterpalu fish plant and the products made there, the VLA found *L.m.* in six samples taken from the production areas in the Harku fish plant, in one sample taken from the warehouse and in six samples taken from a reseller's store. At the Vihterpalu fish plant, *L.m.* was detected in four samples taken from the production areas.

7 The previously imposed restrictions had failed. In 2019, M.V.Wool had been issued with eight separate orders obliging it to withdraw from the market the product contaminated with *L.m.*, which had been produced at the Harku fish plant. The VLA also found further non-conformities in the products of the Vihterpalu fish plant and asked M.V.Wool to clarify that it itself had withdrawn the products from the market or had not placed them on the market. In the course of the control measures, attention was also repeatedly drawn to cross-contamination at the Vihterpalu fish plant.

8 According to the sequencing results, the *L.m.* strain ST1247 was isolated in the products of M.V.Wool and in the rinse samples.

9 On 15 October 2019, M.V.Wool informed the VLA that it planned to completely sterilise the Harku fish plant from 17 October 2019 to 18 October 2019 in order to eliminate the *L.m.* strain ST1247. It was also considering a significant reduction of the shelf-life of products that did not contain *L.m.*-inhibiting preservatives. Nevertheless, after the large-scale cleaning and disinfection operation carried out by M.V.Wool at the fish plant, *L.m.* was found both in rinse samples and in the products, in both Vihterpalu and Harku. The ST1247 strain poses a risk to the public.

10 M.V.Wool has failed to comply with food law and there has been non-compliance on its part within the meaning of point 10 of Article 2 of Regulation No 882/2004, with the result that there are grounds, pursuant to Article 54(1) of that regulation, for applying the measure provided for in Article 54(2)(e) of that regulation,

namely the suspension of the entire operation of the Harku and Vihterpalu fish plants. At the same time, pursuant to point 1 of Paragraph 43(1) of the MSÜS, there are grounds for suspending the company's operating licence, as it has breached essential requirements of an economic activity, entailing a significant risk to public health. The measures applicable to M.V.Wool are lawful, appropriate, necessary and proportionate to achieve the objective pursued, that is to say, they are necessary for the protection of human health and life. The shelf-life established by the company is not sufficient to ensure the safety of the products until the end of the shelf-life.

11 On 5 September 2019, M.V.Wool brought an action before the Tallinna Halduskohus (Administrative Court, Tallinn, Estonia) seeking to have Order No 1 of the VLA declared null and void and, on 26 November 2019, it brought an action before that court seeking to have Order No 2 of the VLA declared null and void on procedural grounds, or, in the alternative, annulled on substantive grounds and partially suspended for the duration of the present administrative proceedings. The actions were joined for the purposes of the judgment.

Essential arguments of the parties in the main proceedings

12 The applicant seeks to have Order No 1 declared null and void on the ground that the defendant was not entitled either to prohibit the sale of foodstuffs which had not been shown to be dangerous in accordance with point 1.2 of the table in Chapter 1 of Annex I to Regulation No 2073/2005 or to require the applicant to withdraw those foodstuffs from the market. The applicant takes the view that Order No 1 is unlawful and must be declared null and void on the grounds that (1) the defendant was not entitled to analyse the samples taken from the store on the basis of the zero tolerance criterion (absence of *L.m.* in 25 g); (2) the content of *L.m.* in the fish products is not clear from the defendant's control report; (3) the defendant prohibited the sale of fish products which had not been found to be dangerous and it therefore misinterpreted the food safety criteria provided for in Regulation No 2073/2005; (4) the deficiencies in the order do not allow the defendant to prohibit the sale of foodstuffs which comply with the food safety criteria set out in Regulation No 2073/2005.

13 With regard to Order No 1, the defendant states that, since the applicant did not duly demonstrate to the VLA that the amount of *L.m.* present in the applicant's products would not exceed 100 cfu/g at the end of the shelf-life, only criterion II, provided for in point 1.2 of the table in Chapter 1 of Annex I to Regulation No 2073/2005, namely that *L.m.* must be absent in 25 g in five product samples, could apply. According to the defendant, the applicant was not able to carry out appropriate endurance tests (challenge tests) to show that the amount of *L.m.* in the products did not exceed 100 cfu/g at the end of the implementation period. The applicant breached the obligation of self-regulation incumbent on food business operators by placing on the market products that do not meet food safety criteria.

14 According to the applicant, Order No 2 is unlawful because a total suspension of the company's operations is disproportionate, given that there were no cases of illness related to strain ST1247 in Estonia when that order was issued. The absence of such cases of illness was confirmed by representatives of the VLA and by the Health Board.

15 The applicant takes the view that it is clear from Order No 2 that the purpose of that administrative act was to ensure that production hygiene requirements were met at the applicant's company. Regulation No 2073/2005 makes a very clear distinction between food safety criteria (that is to say, whether food is compliant, or safe) and production hygiene criteria (that is to say, whether production areas are clean). In the event of non-compliance with production hygiene requirements (which can be proven by means of surface samples and rinse samples), the inspection body can take measures to improve hygiene or improve the selection of raw materials. In the event of non-compliance with production hygiene requirements, it is not possible to take measures intended for the identification of non-compliant food.

16 The applicant takes the view that the criterion set out in point 1.2 of the table in Chapter 1 of Annex I to Regulation No 2073/2005, namely that a food is safe if the content of *L.m.* in the food is less than 100 cfu/g at the end of the shelf-life, is applicable. It is not apparent from the contested administrative act that the applicant placed on the market foodstuffs that exceeded the food safety criterion of 100 cfu/g during the shelf-life as provided for in Regulation No 2073/2005. The samples taken from the applicant's products were never found to contain *L.m.* in excess of the limit.

17 The applicant submits that it complied with the defendant's order of 18 March 2019 in relation to the Harku fish plant and the order of 5 November 2019 in relation to the Vihterpalu fish plant, according to which: 'The operator must carry out a test for *L. monocytogenes* for each product batch (presence in 25 g, in 5 sub-samples) before the food has left the immediate control of the food business operator, who has produced it (the 'zero tolerance' criterion). In the event of a positive result, the batches are not allowed to depart the company.' According to the applicant, it is not clear from the contested administrative act why that measure is not sufficient to ensure product safety. It takes the view that the ST1247 strain was not found in any of the product samples taken at the Vihterpalu plant in 2019.

18 The applicant submits that the defendant relies solely on positive samples analysed by the Veterinary and Food Laboratory (VTL), despite the fact that two other state-accredited laboratories had produced negative results for the same batches and surfaces. The defendant refused the applicant's request for the appointment of a third, independent laboratory in such a situation. The applicant claims that such conduct infringes Article 11(5) of Regulation No 882/2004. This therefore constitutes a procedural irregularity which, according to the applicant, renders the order unlawful.

19 The applicant challenges Order No 2 in so far as it relates to the ineffectiveness of the large-scale cleaning operation carried out at its fish plant in Harku. On 23 October 2019, the VLA took samples showing the presence of *L.m.* from production areas at the factory while production activities were being carried out, and found that it had 'reasonable grounds to believe that the *L.m.* found both in rinse samples taken after the cleaning operation and in product samples is still strain ST1247'. M.V.Wool submits, in essence, that the presence of strain ST1247 cannot be assumed, because its presence must be properly established by means of analysis, and that, after the large-scale cleaning operation, it provided the defendant with rinse and product samples in which no *L.m.* was detected, that is to say, evidence that the cleaning had been effective. The applicant further asserts that the defendant did not take the post-cleaning samples until the third day after the start of production, and not before the start of production, which would have been the correct approach. Furthermore, at the time when the samples were taken, raw fish had been processed on the production line on which *L.m.* had been found, which is why *L.m.* had also been found on that line.

20 According to the applicant, the so-called zero tolerance requirement (absence of *L.m.* in 25 g before the food leaves the food business operator's control) does not extend to food at retail level. The applicant had analyses of all product batches carried out in approved laboratories in order to determine the presence of *L.m.* in 25 g. The goods were dispatched from the plant for sale only if the result of the analysis was 0 in 25 g in all 5 sub-samples, submits the applicant. According to Annex I to Regulation No 2073/2005 (Interpretation of the test results), a result of 0 is satisfactory. According to point 1.1 of the table in Chapter 1 of Annex I to Regulation No 2073/2005, a zero-tolerance limit is provided for ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes, that is to say, 'absence in 25 g in 5 samples'. The stage where the criterion applies is specified as being 'Products placed on the market during their shelf-life'. According to point 1.2 of the table in Chapter 1 of Annex I to Regulation No 2073/2005, zero tolerance for *L.m.* applies to other ready-to-eat foods, that is to say, 'Absence in 25 g' in 5 samples, for the stage 'Before the food has left the immediate control of the food business operator, who has produced it'. It is clear from the comparison that, when it comes to the application of zero tolerance for *L.m.*, provision is made for different stages where that criterion applies.

21 The applicant considers that the VLA is incorrect in its assessment that, if strain ST1247 is detected, the food is dangerous even if the *L.m.* does not exceed 100 cfu/g. Regulation No 2073/2005 does not distinguish between different strains, since all highly pathogenic and virulent strains are taken into account when establishing the criterion in the interest of public health.

22 According to the applicant, Article 14(8) of Regulation No 178/2002 does not permit food which complies with Community microbiological requirements to be regarded as dangerous. In the guidance document on the interpretation of Regulation No 882/2004, which forms the legal basis for the order, the following explanation can be found under the heading 'Absence of Community criteria': 'In

the absence of Community microbiological criteria the evaluation of the food can be done in accordance with Article 14 of Regulation (EC) No 178/2002, which provides that unsafe food products must not be placed on the market.' According to the guidance document for Regulation No 178/2002, Article 14(8) is aimed at cases where a food contains a piece of glass or a hazardous chemical not specifically identified by legislation on contaminants in food. Even if it were accepted that Article 14(8) of Regulation No 178/2002 allows a food which complies with the microbiological requirements to be regarded as dangerous, the only conceivable measure would be the imposition of restrictions on the placing of the food on the market and its withdrawal from the market, but not the suspension of the company's operations.

23 The applicant considers that the operative part of the order is contradictory, according to which the food does not comply with the microbiological requirements within the meaning of Regulation No 2073/2005, but is also dangerous even if it does comply with the microbiological requirements (Article 14(8) of Regulation No 178/2002).

24 According to M.V.Wool, there was no cross-border threat to health, because the criteria set out in Article 9(a) and (b) of Decision No 1082/2013/EU of the European Parliament and of the Council have not been met, and, therefore, the measures taken to contain the threat by Order No 2 were unlawful.

25 The disproportionate nature of Order No 2 is also confirmed by the fact that, with regard to the various activities (import of raw materials, storage, production, dispatch of goods and brokering), no consideration was given to the possibility of taking alternative measures (for example, temporary suspension of sales of unheated goods because *L.m.* is eliminated when heated; product recall; shortening of the shelf-life of the products by way of an order, or similar). The applicant claims that, since Regulation No 2073/2005 establishes microbiological requirements only for ready-to-eat food, it is unlawful to prohibit the import and storage of the raw materials. The danger posed by the imported or stored raw materials has not been proven.

26 M.V.Wool considers that it is incorrect to conclude that the food was dangerous on the basis of the *L.m.* found in the production areas, as no limits for *L.m.* have been set for the production environment.

27 The applicant contests the VLA's view that, in the event of the presence of the ST1247 strain, which is allegedly more dangerous than others, it is not necessary to comply with the food safety criteria provided for in Regulation No 2073/2005. All *L.m.* strains have been declared pathogenic by the Scientific Panel operating under the auspices of the European Union. According to the applicant, the application of a special measure is based on the fact that a food does not comply with the food safety criteria under EU and national law, which, in the present case, is to be assessed on the basis of the *L.m.* content and not on the basis of the strain.

The VLA fails to recognise that *L.m.* can be harmful to human health only in quantities that exceed the food safety criteria.

28 The defendant takes the view that Order No 2 is not invalid. Unlike Article 54 of Regulation No 882/2004, Paragraph 49(4) and (5) of the ToiduS does not require that a food business operator has failed to comply with the requirements, but, rather, it requires only that there is reason to believe that a specific food may pose a risk.

29 According to the VLA, that order is lawful because the applicant has failed to comply with food law. According to point 10 of Article 2 of Regulation No 882/2004, 'non-compliance' means non-compliance with feed or food law, and with the rules for the protection of animal health and welfare. According to Article 54(1) of Regulation No 882/2004, when the competent authority identifies non-compliance, it is to take action to ensure that the operator remedies the situation. When deciding which action to take, the competent authority is to take account of the nature of the non-compliance and that food business operator's past record with regard to non-compliance. Therefore, the application of the measure depends on whether the food business operator has failed to comply with food law and not only, as the applicant claims, the food safety criteria applicable to the food. According to the VLA, food law also includes the requirements provided for in other food law provisions.

30 The VLA states that point 1.2 of the table in Chapter 1 of Annex I to Regulation No 2073/2005 lays down two criteria for the presence of *L.m.* with regard to products manufactured by the food business operator and able to support the growth of *L.m.* With regard to the first criterion – the limit – the table explains that 'this criterion applies if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life.' The applicant did not demonstrate to the VLA by challenge/endurance tests that the products would not exceed the value of 100 cfu/g throughout the shelf-life. In addition, submits the VLA, the report concerned states that the applicant carried out a total of 589 shelf-life tests for the period from January 2016 to April 2019, of which 55, or 9%, exceeded 100 cfu/g.

31 According to Order No 3 of 27 March 2019, the applicant was required to check for the presence of *L.m.* in each product batch at the Harku fish plant, that is to say, to carry out batch-by-batch checks ('zero tolerance' requirement), and to do the same at the Vihterpalu fish plant from 23 October 2019. Notwithstanding the zero tolerance measure, the VLA had to recall from the market the applicant's products in which *L.m.* had been found, and it was later found that the products contained strain ST1247.

32 According to the VLA, it took new samples after the cleaning operation had been carried out in October 2019 at the Harku and Vihterpalu fish plants. *L.m.* was found in those samples, and *L.m.* strain ST1247 was found at the Vihterpalu fish plant at the beginning of October. The VLA submits that, during that sampling,

L.m. was detected in the products that had left the production areas at both the Harku and Vihterpalu fish plants. In that regard, the order of 25 November 2019 states that, with respect to the *L.m.* found in the products of the Vihterpalu fish plant (herring fillets), the applicant breached either its obligation to take subsamples from each batch in accordance with the order of 5 November 2019 or its obligation to recall the entire non-compliant batch. According to Paragraph 22 of the ToiduS, the food business operator is responsible for ensuring that food is handled and processed properly; it must use all means to ensure this and must not receive, use in processing or deliver food that does not comply with the requirements.

33 The VLA states that, to date, the applicant has not identified the source of the infection, and that even after the cleaning operation carried out in the fish plants in October, *L.m.* – once again strain ST1247 – was found in rinse samples, as was demonstrated at the beginning of December. The VLA correctly assumed that it would not be possible for the *L.m.* strain ST1247 to be eliminated by a couple of days of cleaning carried out by the applicant. Strain ST1247 poses a significant risk to public health that cannot be definitively eliminated until the *L.m.* strain ST1247 has been eliminated.

34 However, Article 14(8) of Regulation No 178/2002 provides that conformity of a food with specific provisions applicable to that food is not to bar the competent authorities from taking appropriate measures to impose restrictions on that food being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe. The VLA is therefore entitled to impose restrictions on the applicant's products, as the *L.m.* strain ST1247 has repeatedly been found in the applicant's fish plants in Vihterpalu and Harku, that is to say, in the products, and *L.m.* had also previously been found in the products of the Vihterpalu fish plant.

35 The defendant takes the view that the analyses carried out by the VTL comply with the applicable requirements. Only one laboratory can analyse one and the same sample, with the result that it cannot be claimed that the results of the analyses differ.

36 According to the defendant, the order is proportionate and the defendant also explained in the order why it is not possible to suspend the activity separately at specific stages.

37 The defendant takes the view that the applicant failed to fulfil its obligation as a food business operator to ensure that the consumer receives safe food. *L.m.* had already been found in the applicant's products in 2013, and it later emerged that the strain was ST1247, but the facts show that the applicant has not addressed the *L.m.* problem in a timely manner and has not paid sufficient attention to production hygiene in order to ensure that the consumer receives safe food. It is therefore reasonable to conclude that, as a result, the strain of bacteria in the applicant's production environment became more contagious and resistant,

subsequently causing an international outbreak of listeriosis. Between 2014 and 2019, several cases of illness and death in Estonia and Europe were linked to strain ST1247, and samples taken at retail level showed that the applicant's products proved to be a common denominator in the spread of the outbreak.

38 The VLA disagrees with the applicant's view that all *L.m.* strains are equally contagious. According to the VLA, *L.m.* is a dangerous bacterium and can cause listeriosis, which can be fatal for humans, so there is no such thing as a 'safe' strain. However, the VLA considers strain ST1247 to be more pathogenic, has provided relevant evidence and expert opinions, and draws attention to related cases of illness and death in Estonia and elsewhere in Europe.

39 The VLA submits that point 1.2 of the table in Chapter 1 of Annex I to Regulation No 2073/2005 has established two criteria for the presence of *L.m.*: (i) 0/25 g and (ii) 100 cfu/g, the latter applying under the regulation where the food business operator is not able to demonstrate that its products will not exceed the limit of 100 cfu/g throughout the shelf-life. The applicant has not provided evidence of this. If the 0/25 g criterion applies to the food business operator's products (as it does to the applicant's products in the present case), it applies irrespective of whether the product is located in the applicant's plant or its retailer. This is also confirmed by the practice of other countries and, for example, by the Codex Alimentarius guidelines. Otherwise, the purpose of that criterion would be incomprehensible if the detection of *L.m.* before departure from the applicant's warehouse were to constitute a reason for requiring the withdrawal of the goods from the market, whereas if *L.m.* has been detected in samples taken immediately after departure from the warehouse, the applicant would still be entitled to market the product. *L.m.* cannot come into being by itself in the applicant's products after they have left the applicant's warehouse, with the result that if *L.m.* were found in a sample taken at retail level, it must have been there before the product left the warehouse.

Succinct presentation of the reasoning in the request for a preliminary ruling

40 The key issue in the dispute between the parties is whether or not it is permissible to take samples in a store in order to determine the absence of *L.m.* in 25 g. The answer to this question also depends on the merits of the applicant's complaint that the defendant prohibited the sale of fish products which had not been proven to be dangerous to the consumer. This is a question that has a direct impact on the lawfulness of the two contested orders. The parties are ultimately in dispute as to how the criterion of the stage of application in explanatory note 5 of the table in Chapter 1 of Annex I to Regulation No 2073/2005 is to be understood.

41 According to the applicant, a clear distinction must be made between two different stages: (1) products placed on the market during their shelf-life, and (2), 'Before the food has left the immediate control of the food business operator, who has

produced it'. The limit of '100 cfu/g' applies to the first case, while 'absence in 25 g' applies to the second case.

42 The applicant's position is supported by a systematic interpretation of the regulation. It is clear throughout that regulation that in cases where it is intended to set the limit of 'Absence in 25 g', this is expressly done. This also applies to ready-to-eat foods intended for infants or for special medical purposes, which are listed in the first column of the table in Chapter 1 of Annex I to Regulation No 2073/2005. It is clear from the judgment of the Court of Justice in Case C-443/13 that the linking of the criterion 'Absence in 25 g' to products placed on the market during their shelf-life was intentional.

43 If the applicant's interpretation is correct, the defendant applied an incorrect method (the VLA did not quantify the presence of *L.m.* in the samples taken in the store) and an incorrect limit (that is to say, absence of *L.m.* in 25 g, in 5 samples) in relation to the applicant, on the basis of which it concluded in the two contested administrative acts that the applicant had marketed a product dangerous to the health of consumers. In this respect, the applicant rightly takes the view that a food cannot be deemed to be unsafe without quantifying *L.m.*

44 The defendant, on the other hand, takes the view that the criteria are not to be applied simultaneously, but that the conditions provided for in Regulation No 2073/2005 must be met in order for a specific criterion to apply. According to Note 5 to the table in Chapter 1 of Annex I to Regulation No 2073/2005, the application of the first criterion is subject to the following condition: 'This criterion applies if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life.' The control report of 27 March 2019 also explains that a 'zero tolerance' limit applies to the applicant's products (*L.m.* must be absent in 25 g, in five subsamples, before the food has left the immediate control of the food business operator) until the applicant has been able to carry out proper endurance/challenge tests to show that the amount of *L.m.* in the products did not exceed 100 cfu/g at the end of the implementation period. The applicant has not demonstrated to the VLA that the products do not exceed the limit of 100 cfu/g throughout the shelf-life.

45 The VLA's position is supported by a teleological interpretation of the regulation. Article 3 of Regulation No 2073/2005 lays down the general requirements under which food business operators are to ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I. To this end the food business operators at each stage of food production, processing and distribution, including retail, are to take measures, as part of their procedures based on HACCP [hazard analysis and critical control point] principles together with the implementation of good hygiene practice, to ensure the following: (1) that the supply, handling and processing of raw materials and foodstuffs under their control are carried out in such a way that the process hygiene criteria are met; (2) that the food safety criteria applicable throughout the shelf-life of the products can be met under

reasonably foreseeable conditions of distribution, storage and use. As necessary, the food business operators responsible for the manufacture of the product are to conduct studies in accordance with Annex II in order to investigate compliance with the criteria throughout the shelf-life. In particular, this applies to ready-to-eat foods that are able to support the growth of *Listeria monocytogenes* and that may pose a *Listeria monocytogenes* risk for public health.

46 It follows from the foregoing that the purpose of the regulation is to ensure food safety at all stages throughout its shelf-life, paying particular attention to the risk posed by *L.m.* The defendant's interpretation is also supported by the fact that, with regard to the first criterion – the limit – the table explains that that criterion applies if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The defendant's interpretation is also consistent with the objective set out in the recitals in the preamble to Regulation No 178/2002, of ensuring a high level of protection of human life and health and ensuring that feed and food should be safe and wholesome. Taking into account Articles 5(1), Article 7(1) and Article 14(1) to (3) and (5) of Regulation No 178/2002, a high level of health protection can be ensured, in particular, by a risk management measure ensuring the high level of health protection provided for in the Community. This is better ensured by the defendant's interpretation, which is supported, inter alia, by the provisions of recitals 1, 4 and 6 and Article 3(3) of Regulation No 882/2004, which refer specifically to the stage of placing on the market.

47 As regards the view of the law taken by the defendant, the applicant failed to comply with the obligation incumbent on it to ensure the safety of its products because a food containing *L.m.* had entered the market. In other words, the requirement that *L.m.* must be absent in 25 g in 5 subsamples is not met.

48 It follows from the foregoing that the provisions of the regulation at issue are open to different interpretations, which means that they cannot be regarded as clear (*acte claire*), and that there is no relevant case-law providing appropriate interpretative guidance (*acte éclairé*). Since this is a directly binding regulation of the European Union, the referring court is obliged in such a situation to seek a preliminary ruling from the Court of Justice. In so doing, the referring court takes note of the defendant's submissions that the relevant provisions of Regulation No 2073/2005 should be amended at European Union level and that the new wording would make it clearer that the interpretation proposed by the defendant is correct. This strengthens the referring court's conviction that a request for a preliminary ruling is necessary.