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Judgment of the Court (Fifth Chamber) of 24 October 2002. - Criminal proceedings against v Walter Hahn. - Reference for a preliminary ruling: Bezirksgericht Innere Stadt Wien - Austria. - Fisheries - Health policy - Directive 91/493/EEC and Decision 94/356/EC - Articles 28 EC and 30 EC - Principle of proportionality - Limit values for the presence of *Listeria monocytogenes* in smoked fish products. - Case C-121/00.

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Keywords

*Free movement of goods - Quantitative restrictions - Measures having equivalent effect - National legislation laying down zero tolerance for the presence of *Listeria monocytogenes* in certain fish products - Whether permissible*

(Arts 28 EC and 30 EC; Council Directive 91/493; Commission Decision 94/356)

Summary

*Neither Directive 91/493 laying down the health conditions for the production and the placing on the market of fishery products and Decision 94/356 laying down detailed rules for the application of Directive 91/493 as regards own health checks on fishery products nor Articles 28 EC and 30 EC preclude the application of national legislation laying down zero tolerance for the presence of *Listeria monocytogenes* in fish products which have not been chemically preserved.*

(see para. 47, operative part)

Parties

In Case C-121/00,

REFERENCE to the Court under Article 234 EC by the Bezirksgericht Innere Stadt Wien (Austria) for a preliminary ruling in the criminal proceedings before that court against Walter Hahn,

on the interpretation of Council Directive 91/493/EEC laying down the health conditions for the production and the placing on the market of fishery products (OJ 1991 L 268, p. 15),

THE COURT (Fifth Chamber),

composed of: A. La Pergola, acting as President of the Fifth Chamber, P. Jann and S. von Bahr (Rapporteur), Judges,

Advocate General: L.A. Geelhoed,

Registrar: H. von Holstein, Deputy Registrar,

after considering the written observations submitted on behalf of:

- Staatsanwaltschaft Wien, by H. Kellner, Erster Staatsanwalt,
- Mr Hahn, by C. Hauer, Rechtsanwalt,
- the Austrian Government, by C. Pesendorfer, acting as Agent,
- the Commission of the European Communities, by G. Berscheid and G. Braun, acting as Agents,

having regard to the Report for the Hearing,

after hearing the oral observations of Mr Hahn and the Commission at the hearing on 23 October 2001,

after hearing the Opinion of the Advocate General at the sitting on 13 December 2001,

gives the following

Judgment

Grounds

1 By order of 21 March 2000, received at the Court on 30 March 2000, the Bezirksgericht Innere Stadt Wien (Inner City of Vienna District Court) referred to the Court for a preliminary ruling under Article 234 EC a question on the interpretation of Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products (OJ 1991 L 268, p. 15).

2 That question was raised in criminal proceedings against Mr Hahn or, where appropriate, the senior staff of the company Nordsee GmbH (hereinafter Nordsee') for negligently placing on the market foodstuffs harmful to human health.

Legal background

Community law

3 Article 3(1)(d) of Directive 91/493 provides that:

The placing on the market of fishery products caught in their natural environment shall be subject to the following conditions:

...

(d) they must have undergone a health check in accordance with Chapter V of the Annex'.

4 Chapter V of the Annex to Directive 91/493, entitled 'Health control and monitoring of production conditions', contains, in addition to a Part I on general monitoring, a Part II which lists special checks, that is to say, organoleptic, parasite and chemicals checks and microbiological analyses. As regards the latter, Chapter V, Part II(4) of the Annex to Directive 91/493 provides that, '[i]n accordance with the procedure laid down in Article 15 of this directive, microbiological criteria, including sampling plans and methods of analysis, may be laid down when there is a need to protect public health'.

5 Article 2(14) of Directive 91/493 states that, to those ends, "establishment" means any premises where fishery products are prepared, processed, chilled, frozen, packaged or stored. Auction and wholesale markets in which only display and sale by wholesale takes place are not deemed to be establishments.'

6 Article 6 of Directive 91/493 provides that:

1. Member States shall ensure that persons responsible for establishments take all necessary measures, so that, at all stages of the production of fishery products, the specifications of this Directive are complied with.

To that end, the said persons responsible must carry out their own checks based on the following principles:

- identification of critical points in their establishment on the basis of the manufacturing processes used;
- establishment and implementation of methods for monitoring and checking such critical points;
- taking samples for analysis in [a] laboratory [approved] by the competent authority for the purpose of checking cleaning and disinfection methods and for the purpose of checking

compliance with the standards established by this Directive;

- keeping a written record or a record registered in an indelible fashion of the preceding points with a view to submitting them to the competent authority. The results of the different checks and tests will in particular be kept for a period of at least two years.

2. If the results of own checks or any information at the disposal of the persons responsible referred to in paragraph 1 reveal the risk of a health risk or suggest one might exist and without prejudice to the measures laid down in the fourth subparagraph of Article 3(1) of Directive 89/662/EEC, the appropriate measures shall be taken, under official supervision.

3. Rules for the application of the second subparagraph of paragraph 1 shall be established in accordance with the procedure laid down in Article 15.'

7 Article 2(1) of Commission Decision 94/356/EC of 20 May 1994 laying down detailed rules for the application of Council Directive 91/493/EEC as regards own health checks on fishery products (OJ 1994 L 156, p. 50) provides that:

"Critical point" as referred to in the first indent of the second subparagraph of Article 6(1) of Directive 91/493/EEC means any point, step or procedure at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels. All critical points which are useful for ensuring compliance with the hygiene requirements of that Directive must be identified.

For the purpose of identifying these critical points, Chapter I of the Annex hereto shall apply.'

8 Chapter I of the Annex to Decision 94/356, entitled 'Identification of critical points', specifies, in its part 6, entitled 'Listing of hazards and control measures', that a multidisciplinary team should:

(a) list all potential biological, chemical or physical hazards that may be reasonably expected to occur at each process step ...

A hazard is a potential to cause harm to health and is anything covered by the hygiene objectives of Directive 91/493/EEC. Specifically, it can be any of the following:

- unacceptable contamination (or recontamination) of a biological (micro-organisms, parasites), chemical or physical nature of raw materials, intermediate products or final products,

- unacceptable survival or multiplication of pathogenic micro-organisms and unacceptable generation of chemicals in intermediate products, final products, production line or line environment,

...'

9 Under Chapter I(6)(b) of the Annex to Decision 94/356, the multidisciplinary team should: consider and describe what control measures, if any, exist which can be applied for each hazard.

Control measures are those actions and activities that can be used to prevent hazards, eliminate them or reduce their impact or occurrence to acceptable levels.

More than one control measure may be required to control an identified hazard and more than one hazard may be controlled by one control measure. For instance, pasteurization or controlled heat treatment may provide sufficient assurance of reduction of the level of both salmonella and listeria.

...'

National law

10 Paragraph 7(1)(a) of the Lebensmittelgesetz 1975 (1975 Law on Foodstuffs, BGBl. 1975/86), as amended in BGBl. 1988/226 (hereinafter the LMG'), read in conjunction with Paragraph 8(a) of the same law, prohibits the placing on the market of foodstuffs, products intended for human consumption and additives which are harmful to health, that is, which are likely to endanger or harm health'.

11 It follows from Paragraphs 56(1)(1) and 57(1) of the LMG that any person who negligently places on the market foodstuffs, products intended for human consumption or additives which are harmful to health is subject to up to six months' imprisonment or a fine of up to 360 on the scale of daily penalty units'.

12 Article 51 of the LMG provides that:

The Bundesminister für Gesundheit und Umweltschutz [Federal Minister for Health and Environmental Protection] is responsible for the publication of the Austrian Foodstuffs Manual (Codex Alimentarius Austriacus). The manual sets out the technical designations, definitions,

methods of analysis and assessment criteria as well as guidelines for the placing on the market of the goods which are subject to this federal law.'

13 Paragraph 52(1) of the LMG establishes a Codex Commission for the purpose of advising the Bundesminister für Gesundheit und Umweltschutz on matters covered by the LMG and preparing the Codex Alimentarius Austriacus. Paragraph 53 of the LMG provides that the Codex Commission is to designate a permanent hygiene committee.

14 Directive 91/493 and Decision 94/356 have been implemented in Austria by the Verordnung über Hygienebestimmungen für das Inverkehrbringen von Fischerzeugnissen (Fischhygieneverordnung) (Regulation on health requirements for the placing on the market of fish products (Fish Hygiene Regulation), BGBl. II. 1997/260). The second paragraph of Chapter I(6)(a) and the second and third paragraphs of Chapter I(6)(b) of Annex 2 to the Regulation correspond to the second paragraph of Chapter I(6)(a) and the second and third paragraphs of I(6)(b) of Decision 94/356.

The main proceedings and the question referred for a preliminary ruling

15 Mr Hahn or, as the case may be, the senior staff of Nordsee are charged with negligently placing on the market products harmful to human health. The foodstuffs at issue are various smoked-fish products, in particular Danish smoked salmon.

*16 The order for reference indicates that a series of samples was taken, in particular, at the end of 1998 and at the beginning of 1999, on the premises of Nordsee and in grocery shops which had been supplied with fish products from that company, both by way of routine checks carried out by health inspectors and as the result of complaints from parties suffering symptoms of food poisoning. Organoleptic checks (appearance, smell and taste) of the samples taken did not reveal any characteristic worth noting, and the expiry date had not yet been reached. None the less, contamination by *Listeria monocytogenes* was found in samples of 25 g. The qualitative analysis was not followed by a quantitative analysis.*

*17 The referring court points out that, at its meeting on 9 February 1998, the permanent hygiene committee drew up a guide for assessing *Listeria monocytogenes*, based on zero tolerance. According to that guide, for both products which have not been further treated but rather stabilised - for example by smoking, salting or vacuum packaging - and uncooked, ready-to-eat foodstuffs, and for food products which have been heat treated, a negative finding is possible only if the presence of the pathogen is not detectable in 25 grams'. If, on the contrary, *Listeria monocytogenes* is present, the food product must be considered harmful to health.*

18 The choice of zero tolerance was expressly confirmed in the meeting of the permanent hygiene committee on 30 March 1998. Subsequently, however, the committee determined that for products which had not been heat treated but had been chemically preserved, exceeding a threshold of 100 cfu (colony-forming units)/g entails a risk to public health.

*19 In this connection, the referring court observes that a large number of scientific studies indicate that there is no scientific basis for the concept of zero tolerance. *Listeria monocytogenes* is extremely widespread in the environment and in food products, whereas the number of clinical cases is quite low. Moreover, it is impossible to achieve a total absence of *Listeria monocytogenes* for many uncooked substances in the current state of the production and treatment of foodstuffs, even if production or manufacture takes place under good conditions.*

*20 Taking the view that the decision by the permanent hygiene committee which sets zero tolerance for *Listeria monocytogenes* conflicts with Directive 91/493, according to which risks must be reduced to an acceptable level, the court decided to stay proceedings and to refer the following question to the Court of Justice for a preliminary ruling:*

*Is Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products, which has been implemented in national law by the Regulation of the Federal Minister for Women and for Consumer Protection concerning health regulations for the placing on the market of fish products (Fish Hygiene Regulation), published in BGBl No 260/1997, to be interpreted generally as precluding the application of provisions of national law which, in respect of fish products which are not chemically preserved (in particular, smoked salmon), lay down zero tolerance as regards the contamination of such foodstuffs by *Listeria monocytogenes*?'*

The question referred for a preliminary ruling

21 Since the Court has jurisdiction to provide the national court with all the criteria for the interpretation of Community law which may enable that court to decide the issue, in the case

before it, of compatibility with the EC Treaty of provisions of national law (see, *inter alia*, Case C-42/90 Bellon [1990] ECR I-4863, paragraph 6), it is necessary, in the light of the observations submitted to the Court and the discussions which have taken place before it, to understand the question referred for a preliminary ruling as relating to whether Directive 91/493 and Decision 94/356 or, as the case may be, Articles 28 EC and 30 EC preclude the application of provisions of national law which lay down zero tolerance for the presence of *Listeria monocytogenes* in fish products which are not chemically preserved.

Observations submitted to the Court

22 Mr Hahn observes that the Austrian authorities automatically characterise a product as harmful to human health when *Listeria* can be detected in a sample of 25 g. He maintains that that rule is contrary to Directive 91/493, read in the light of the implementing provisions contained in Decision 94/356, which do not set tolerance at zero. The second paragraph of Chapter I(6)(a) and the second and third paragraphs of I(6)(b) of the Annex to Decision 94/356 refer to 'unacceptable contamination' and to sufficient ... reduction of the level of ... *Listeria*'.

23 In the alternative, Mr Hahn maintains that the national provisions at issue in the main proceedings are in breach of Articles 28 EC and 30 EC and the related case-law. He claims, on the basis of the judgment in Case 178/84 Commission v Germany [1987] ECR 1227, that while it is for the Member States, in the absence of harmonisation, to decide to what degree they intend to assure the protection of the health and life of humans, the principle of proportionality nevertheless requires that marketing prohibitions be limited to what is actually necessary for the protection of public health.

24 Nothing objectively establishes that a total prohibition on the placing on the market of all fishery products containing *Listeria*, whatever the concentration, observes the principle of proportionality. In that regard, Mr Hahn cites, in particular, the results of research carried out by the US Center for Disease Control and Prevention (CDC), published in February 1996, which concludes that the population of the United States of America often consumes low to moderate amounts of *Listeria monocytogenes* in foodstuffs but that only a very low proportion of that population becomes ill as a result (in 1993, only 1092 cases were registered in the entire population of the United States).

25 Mr Hahn claims that it may be considered as certain that *Listeria* poses a health threat only to an extremely limited number of people and that, even for those people, the risk posed by a *Listeria* concentration below 100 cfu/g may be questioned. The immunocompromised, the very elderly, and pregnant women, whose foetus may be affected, are susceptible.

26 The Austrian Government observes that Directive 91/493 does not fully harmonise the contamination limit values which are considered harmful to human health, but merely sets objectives for basic health protection expressed as general clauses. Their implementation is the responsibility of the Member States, which rely on experts' reports for that purpose.

27 Decision 94/356 merely specifies the concepts and procedures provided for in Directive 91/493. Since the terms 'unacceptable contamination' and 'acceptable levels' used in Chapter I (6)(a) and (b) of the Annex to the decision were not further defined in Directive 91/493 or Decision 94/356, Community rules give Member States discretion both to specify the organisms and fields concerned and to define the limit values through a set of statutory framework provisions in combination with experts' reports.

28 As regards the application of Articles 28 EC and 30 EC, the Austrian Government, on the basis of the judgments in Case 97/83 Melkunie [1984] ECR 2367 and Case 94/83 Heijn [1984] ECR 3263, maintains that national measures such as those at issue in the main proceedings satisfy the requirements of Article 30 EC, including in the light of the principle of proportionality, and that they therefore are not in breach of the provisions relating to the free movement of goods.

29 The Commission points out that, under the Community law in force, there is no specific provision that sets microbiological criteria for *Listeria monocytogenes* for the fishery products at issue in the main proceedings. Consequently, it is necessary to consider the general rules of the Treaty.

30 In that regard, having determined that the national measures at issue in the main proceedings constitute a measure having equivalent effect to a quantitative restriction within the meaning of Article 28 EC, the Commission refers by analogy, as regards the application of Article 30 EC, to the Court's case-law on additives (Joined Cases C-13/91 and C-113/91 Debus [1992] ECR I-3617, and Case C-344/90 Commission v France [1992] ECR I-4719), from which it emerges that the determination of whether an additive is necessary, which must be carried

out under the principle of proportionality, must focus on the risk it poses to health, taking account of both the results of international scientific research, in particular the work of the Scientific Committee for Food and of the Codex Alimentarius Committee of the FAO (United Nations Food and Agriculture Organisation) and the WHO (World Health Organisation), and the eating habits in the importing Member State, as well as the existence of a genuine need, in particular a technological need.

31 As regards the case in the main proceedings, the current scientific discussions concerning the correct microbiological standards for the bacterial pathogens present in various foodstuffs, *inter alia*, *Listeria monocytogenes*, and the different criteria which must be taken into account when defining those standards are such that it is not possible automatically to conclude from them, when considering proportionality, that stringent standards are not useful and that more flexible standards would constitute measures which are equally effective but less restrictive of intra-Community trade. As long as the provisional results of those scientific discussions have not been translated into Community law, Member States have the right, by way of precaution, to set more stringent microbiological standards in order to protect human health and in particular the health of susceptible groups.

Findings of the Court

32 At the outset, it should be stated that, as the Austrian Government rightly pointed out, although Directive 91/493 harmonises, *inter alia*, the handling, treatment and packaging of fishery products as well as the health checks to be carried out at the production stage for those products, it does not exhaustively harmonise limit values for restricting contamination by *Listeria monocytogenes* in smoked fish products. Directive 91/493 does not set microbiological criteria, but rather confers on the Community legislature the authority to do so, if needed, in order to protect public health in accordance with the procedure laid down in Article 15. Until now, microbiological criteria have been set in accordance with that procedure only for cooked crustaceans and molluscan shellfish, by Commission Decision 93/51/EEC of 15 December 1992 on the microbiological criteria applicable to the production of cooked crustaceans and molluscan shellfish (OJ 1993 L 13, p. 11).

33 As for the use of the terms 'unacceptable contamination', 'unacceptable survival or multiplication' and 'acceptable levels' in Chapter I(6)(a) and (b) of the Annex to Decision 94/356, as the Advocate General observed in paragraph 30 of his Opinion, those provisions do not prevent Member States from considering zero tolerance as the only acceptable level for certain risks.

34 However, although, in the absence of complete harmonisation in the field, the Member States may prescribe the standards which products intended for human consumption must satisfy in their own territories, the national provisions in question cannot be exempt from the application of Articles 28 EC and 30 EC (see *Melkunie*, cited above, paragraphs 9 and 10).

35 It is therefore necessary to consider whether Articles 28 EC and 30 EC preclude the application of national provisions setting zero tolerance for *Listeria monocytogenes* in fish products which are not chemically preserved.

36 It is common ground that, as regards products coming from another Member State, the application of a national provision such as that at issue in the main proceedings, which effectively prohibits the placing on the market of a fish product if *Listeria monocytogenes* can be detected in 25 g of the product, is likely to obstruct intra-Community trade and therefore constitutes a measure having equivalent effect to a quantitative restriction within the meaning of Article 28 EC.

37 None the less, it should be determined whether such a prohibition can be justified on the grounds of protection of the health and life of humans.

38 The Court has consistently held that, among the grounds which may justify derogations from Article 28 EC, the protection of the health and life of humans ranks foremost and, in so far as there are uncertainties at the present state of scientific research, it is for the Member States, within the limits imposed by the Treaty, to decide what degree of protection they wish to assure and, in particular, the stringency of the checks to be carried out (see, *inter alia*, to that effect, *Commission v Germany*, cited above, paragraph 41, and *C-347/89 Eurim-Pharm* [1991] ECR I-1747, paragraph 26).

39 However, national rules or practices which restrict intra-Community trade or are capable of doing so are compatible with the Treaty only to the extent to which they are necessary for the effective protection of the health and life of humans. They do not qualify for a derogation if the health and life of humans can be protected as effectively using measures which are less restrictive of intra-Community trade (see, *inter alia*, *Eurim-Pharm*, cited above, paragraph 27).

40 In addition, the existence of a risk to public health must be assessed in the light of international scientific research, in particular the work of the Community's scientific committees, and the eating habits in the Member State concerned (see, to that effect, Bellon, cited above, paragraph 17, and *Commission v France*, paragraph 13).

41 It is particularly important in that regard to consider the work of the Scientific Committee on Veterinary Measures Relating to Public Health (SCVPH) on *Listeria monocytogenes*, which resulted in the Opinion produced by the Committee on 23 September 1999, cited by the Commission. It is clear from that Opinion, whose conclusions were supported by the Scientific Committee on Food in an Opinion of 22 June 2000, that *Listeria monocytogenes* is a bacterial pathogen liable to cause serious illness in humans. It can cause a variety of infections, but listeriosis most often affects the uterus of pregnant women, the central nervous system and the bloodstream. Although listeriosis can occur in healthy adults and children, the most commonly affected populations are pregnant women, neonates, the elderly and those persons whose immune systems have been suppressed by medication or illness.

42 The Opinion also makes clear that, while the incidence of human listeriosis is relatively low - from 2 to 15 cases per million population - the fatality rate is reported to be between 20% and 40% and might approach 75% in immunocompromised individuals. The SCVPH concludes from those data that listeriosis represents an infrequent but serious threat to public health, in particular for the high-risk groups referred to in the preceding paragraph.

43 Even if, as the Commission indicates, the report of the SCVPH concludes that according to outbreak data available it would seem that the presence of *L[isteria] monocytogenes* in food represents a very low risk for all population groups when the *L[isteria] monocytogenes* concentration is below 100 cfu/g', it should be noted that the SCVPH takes a very cautious approach, even using the conditional tense ('it would seem' in English, the language of the Opinion), and that it refers on several occasions to the large number of uncertainties which remain concerning the issue owing to the limited number of cases for which information is available. The SCVPH also observes that the information concerning eating habits for the foodstuffs in question is not directly available and therefore could not be taken into consideration.

44 In addition, the SCVPH states that, given the uncertainties concerning the assessment of risk to the consumer and the fact that studies appear to demonstrate a very high potential for reproduction by *Listeria monocytogenes* in foodstuffs, it is possible that limit values below 100 cfu/g should be applied to foodstuffs where such reproduction can take place. In that regard, the SCVPH indicates that it is even possible that, for products which have been treated by certain methods, it might be necessary to require that *Listeria monocytogenes* cannot be detected in 25 g at the time of production.

45 It therefore appears, from the available data, that the current state of scientific research does not make it possible to determine with any certainty the precise concentration of *Listeria monocytogenes* pathogens above which a fish product poses a threat to human health. Therefore, it is for the Member States, in the absence of harmonisation, to decide what degree of protection of the health and life of humans they wish to assure, while taking account of the requirements for the free movement of goods.

46 In that regard, national legislation seeking to ensure that the pathogen cannot be detected in 25 g of fish product, simply because, for certain products, even low concentrations of *Listeria monocytogenes* may constitute a risk to the health of particularly susceptible consumers, must be considered compatible with the requirements of the Treaty (see, to that effect, *Melkunie*, cited above, paragraph 18, and *Case C-17/93 Van der Veldt [1994] ECR I-3537*, paragraph 17).

47 Therefore, the response to the question referred for a preliminary ruling must be that neither Directive 91/493 and Decision 94/356 nor Articles 28 EC and 30 EC preclude the application of national legislation laying down zero tolerance for *Listeria monocytogenes* in fish products which have not been chemically preserved.

Decision on costs

Costs

48 The costs incurred by the Austrian Government and the Commission, which have submitted observations to the Court, are not recoverable. Since these proceedings are, for the parties to

the main proceedings, a step in the proceedings pending before the national court, the decision on costs is a matter for that court.

Operative part

On those grounds,

THE COURT (Fifth Chamber),

in answer to the question referred to it by the Bezirksgericht Innere Stadt Wien by order of 21 March 2000, hereby rules:

*Neither Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products and Commission Decision 94/356/EC of 20 May 1994 laying down detailed rules for the application of Council Directive 91/493/EEC as regards own health checks on fishery products nor Articles 28 EC and 30 EC preclude the application of national legislation laying down zero tolerance for the presence of *Listeria monocytogenes* in fish products which have not been chemically preserved.*

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