JUDGMENT OF THE COURT (Third Chamber)

28 January 2010 *

In Case C-333/08,

ACTION under Article 226 EC for failure to fulfil obligations, brought on 18 July 2008,

European Commission, represented by B. Stromsky, acting as Agent, with an address for service in Luxembourg,

applicant,

v

French Republic, represented by G. de Bergues and R. Loosli-Surrans, acting as Agents,

defendant,

* Language of the case: French.

THE COURT (Third Chamber),

composed of J.N. Cunha Rodrigues, President of the Second Chamber, acting as President of the Third Chamber, P. Lindh, A. Rosas, A. Ó Caoimh (Rapporteur) and A. Arabadjiev, Judges,

Advocate General: J. Mazák,
Registrar: R. Grass,

after hearing the Opinion of the Advocate General at the sitting on 8 September 2009,

gives the following

Judgment

1 By its action, the Commission of the European Communities seeks a declaration from the Court that, by laying down, for processing aids and foodstuffs whose preparation involved the use of processing aids from other Member States where they are lawfully manufactured and/or marketed, a prior authorisation scheme not complying with the principle of proportionality, the French Republic has failed to fulfil its obligations under Article 28 EC.

Legal context

Community legislation

2 Processing aids are substances used in the process of elaborating or manufacturing a foodstuff, and the aim of which is to obtain a certain technical effect during that process.

3 Although Community law harmonises certain categories of processing aids, the latter are not subject to horizontal harmonisation at Community level, so that, in general, Member States remain free to regulate the use of processing aids while complying with the EC Treaty.

Directive 89/107

4 Article 1(3)(a) of Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption (OJ 1989 L 40, p. 27) defines processing aids, in a footnote, as being any substance not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.

5 It follows from that same provision of Directive 89/107 that processing aids are excluded from the scope of the latter.

Directive 98/34

6 Article 8 of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ 1998 L 204, p. 37) provides:

'1. Subject to Article 10, Member States shall immediately communicate to the Commission any draft technical regulation, except where it merely transposes the full text of an international or European standard, in which case information regarding the relevant standard shall suffice; they shall also let the Commission have a statement of the grounds which make the enactment of such a technical regulation necessary, where these have not already been made clear in the draft.

…

Where, in particular, the draft seeks to limit the marketing or use of a chemical substance, preparation or product on grounds of public health or of the protection of consumers or the environment, Member States shall also forward either a summary or the references of all relevant data relating to the substance, preparation or product concerned and to known and available substitutes, where such information may be available, and communicate the anticipated effects of the measure on public health and the protection of the consumer and the environment, together with an analysis of the risk carried out as appropriate …

…

2. The Commission and the Member States may make comments to the Member State which has forwarded a draft technical regulation; that Member State shall take such comments into account as far as possible in the subsequent preparation of the technical regulation.

…'

Directive 2000/13

7 Article 3(1) of 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), provides that, under the conditions and subject to the exceptions laid down in Articles 4 to 17 of that directive, the labelling of foodstuffs must contain certain information, including the list of ingredients.

8 However, according to Article 6(4)(c)(ii) of Directive 2000/13, additives used as processing aids are not regarded as ingredients.

9 Article 18 of Directive 2000/13 reads:

‘1. Member States may not forbid trade in foodstuffs which comply with the rules laid down in this Directive by the application of non-harmonised national provisions governing the labelling and presentation of certain foodstuffs or of foodstuffs in general.

2. Paragraph 1 shall not apply to non-harmonised national provisions justified on grounds of:

— protection of public health,

…’

Regulation (EC) No 178/2002

10 The third recital of 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) reads:

'The free movement of food and feed within the Community can be achieved only if food and feed safety requirements do not differ significantly from Member State to Member State.'

11 Pursuant to Article 1 of Regulation No 178/2002, that regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

12 Article 5 of Regulation No 178/2002, headed 'General objectives', provides:

'1. Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.

2. Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements in this Chapter.

…'

13 Article 6 of Regulation No 178/2002, headed 'Risk analysis', reads:

'1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the European Food Safety Authority, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5.'

14 Article 7 of Regulation No 178/2002, headed 'Precautionary principle', reads:

'1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.'

15 Article 14 of Regulation No 178/2002, headed 'Food safety requirements', reads:

'1. Food shall not be placed on the market if it is unsafe.

2. Food shall be deemed to be unsafe if it is considered to be:

(a) injurious to health;

(b) unfit for human consumption.

…

7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

…

9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.'

National legislation

The 1912 Decree

16 Under Article 1 of the Decree of 15 April 1912 laying down administrative regulations for implementing the Law of 1 August 1905 to prevent deception in the sale of goods and adulteration of foodstuffs, as amended on numerous occasions ('the 1912 Decree'):

'It is prohibited to hold with a view to sale, to offer for sale or to sell any goods or foodstuffs intended for human consumption when they have undergone the addition of chemical products other than those the use of which is declared lawful by decrees issued in concert by the Ministry of Agriculture and Rural Development, the Ministry of the Economy and Finance, the Ministry of Scientific and Industrial Development and the Ministry of Public Health, having heard the advice of the Conseil supérieur d'hygiène publique de France [CSHPF] and the national academy of medicine.'

17 The CSHPF is an expert scientific and technical body, under the auspices of the health ministry.

18 Article 2 of the 1912 Decree reads:

'It is also prohibited to introduce, even temporarily, during the preparation of goods and foodstuffs intended for human consumption, chemical products other than those the use of which is declared lawful by the decrees issued in accordance with Article 1 above.'

19 A series of decrees was adopted pursuant to the 1912 Decree laying down the conditions in which processing aids may be used in the manufacturing process.

20 Those decrees generally regulate the authorised substance and the use and the foodstuff for which it is authorised. They specify the purity criteria and other characteristics with which the processing aid used must comply, and determine, in addition to the conditions for using the processing aid concerned in the manufacturing process, the maximum residual amounts of the processing aid used in the finished foodstuff.

21 Only four of those decrees contain a mutual recognition clause, namely the Decree of 6 February 1989 laying down the list of processing aids which may be used in confectionery, the Decree of 24 March 1993 concerning the use of ß cyclodextrine as a processing aid, the Decree of 23 February 1995 on the use of various processing aids in human foodstuffs, and the Decree of 9 March 1995 concerning the use of antifoaming agents for washing potatoes and mushrooms.

The 2001 Decree

22 The first paragraph of Article 1 of Decree No 2001-725 of 31 July 2001, concerning the processing aids which may be used in the manufacture of foodstuffs intended for human consumption (JORF of 5 August 2001; 'the 2001 Decree') defines processing aids as 'any substance not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foodstuffs or their ingredients, to fulfil a given technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that those residues do not present any health risk and do not have any technological effect on the finished product'.

23 The second paragraph of Article 1 of that decree provides:

'The provisions of this Decree apply to processing aids belonging to the categories listed in the Annex to this Decree, used or intended to be used in the manufacture of foodstuffs intended for human consumption.

They do not apply:

1. to processing aids used for the production of food additives, aromas, vitamins and other nutritional additives;

2. to substances used during operations for processing natural mineral water or spring water where those operations precede the marketing of those waters under one of the product names laid down by the Decree of 6 June 1989 …;

3. to substances used during the implementation of methods for improving water intended for human consumption, where those methods are laid down pursuant to the regulations based on Article L. 1321-4 of the Public Health Code.'

24 Article 2 of the 2001 Decree reads:

'An order of the Ministers for Consumer Affairs, Agriculture, Health, and Industry, issued after taking the advice of the Agence française de sécurité sanitaire des aliments (French Food Safety Agency; "AFSSA") shall determine, for the categories mentioned in the Annex to this Decree:

1. The list of processing aids the use of which is authorised, and, where appropriate, the conditions for their use and the permissible maximum residue limits;

2. The identity and purity criteria which they must meet;

3. The rules governing substances used as supporting and diluting products.

Processing aids must be used in compliance with good hygiene and manufacturing practices, particularly in cases where no condition for use is imposed by the order for which this article provides.

The dose of processing aids used must not exceed the quantity strictly necessary to obtain the desired effect and must not mislead the consumer.

Information establishing that those substances have been used in compliance with good manufacturing practices must be kept available for official inspection by manufacturers.'

25 It is apparent from Article L. 1323-1 of the Public Health Code that AFSSA is a public institution of the State, under the tutelage of the Agriculture, Consumer Affairs, and Health Ministries.

26 Article 3 of the 2001 Decree provides:

'Applications to amend or add to the provisions of the order referred to in Article 2 can be made by any natural or legal person. They are to be addressed to the Directorate-General for Competition Policy, Consumer Affairs and Fraud Control (Direction générale de la concurrence, de la consommation et de la répression des fraudes), together with the file necessary for their investigation, with a view to their transmission to AFFSA.

An order of the Ministers for Consumer Affairs, Agriculture, Health, and Industry shall determine the rules concerning the preparation and content of files.

When the file is complete, the Directorate-General for Competition Policy, Consumer Affairs and Fraud Control shall acknowledge receipt thereof and ensure its transmission to AFFSA. The Agency has a period of four months from receipt of the application to issue an opinion.

The Directorate-General for Competition Policy, Consumer Affairs and Fraud Control shall notify the applicant of the opinion of AFFSA and the reasoned decision of the Minister based on that opinion. Such notification shall be made within one month following the adoption of the opinion.'

27 In accordance with Article 4 of that Decree:

'The order referred to in Article 2 shall be updated, in particular in order to comply with the Community obligations of France and proposals formulated by AFFSA as a result of new information concerning possible toxicity of processing aids.'

28 Article 6 of the 2001 Decree provides:

'It is prohibited to hold, exhibit for sale, offer for sale, sell, or distribute free of charge:

1. Foodstuffs intended for human consumption in the preparation of which processing aids have been used which do not comply with the provisions of Article 2 hereof, or with the provisions of Decree No 2004-187 of 26 February 2004 transposing Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market;

2. Processing aids which do not comply with the provisions of Articles 2 and 5 or with the provisions of Decree No 204-187 of 26 February 2004 implementing Directive 98/8...;

However, these provisions shall not hinder the principle of free movement:

(a) of the foodstuffs referred to in paragraph (1) of this article from other Member States of the European Community, or other contracting parties to the agreement on the European Economic Area, where those States have put in place a method for evaluating the risks presented by the use of processing aids, ensuring an equivalent level of safety to that guaranteed by this directive;

(b) of processing aids from other Member States of the European Community, or other contracting parties to the Agreement on the European Economic Area, with purity criteria different from those set by the order referred to in Article 2, where those criteria have been fixed by one of those States, or have been subject to a favourable opinion of a competent body in one of those States, officially published.'

29 According to Article 7 of the 2001 Decree:

'The provisions of this Decree shall enter into force as from the publication date of the order referred to in Article 2 above. The persons responsible for placing processing aids on the market have a period of six months as from the publication date of that order to comply with the requirements of Article 5 above.'

30 The Annex to the 2001 Decree lists the categories of processing aids covered by that decree. The aids in question are antifoaming agents, catalysts, clarifying agents/filtering additives, discolouring agents, washing and peeling agents, plucking and hair removal agents, ion exchanging resins, contact freezing and cooling agents, desiccating/

anticaking agents, enzymes, acidifying, alcalysing or neutralising agents, release agents, flocculating and coagulating agents, biocides, anti-scaling agents, extracting solvents, and a category headed 'Miscellaneous'.

The ministerial order of 19 October 2006

31 A draft ministerial order was notified to the Commission and the Member States on 5 October 2005 pursuant to the provisions of Article 8 of Directive 98/34.

32 The documents on file show that that draft order did not form the subject-matter of observations by the Commission, but gave rise to detailed submissions from the United Kingdom of Great Britain and Northern Ireland and the Kingdom of Denmark.

33 The order of 19 October 2006 on the use of processing aids in certain foodstuffs (JORF of 2 December 2006), repealed the provisions of the orders made pursuant to the 1912 Decree.

34 That order contains, in an annex, a list of the processing aids authorised for use in France. It lays down the conditions for using those processing aids, the maximum authorised residual doses, and the applicable purity criteria.

The notice to undertakings

35 On 19 January 2002, the French authorities published a notice to undertakings in the food sector (JORF of 19 January 2002, p. 1234; the notice to undertakings).

36 That notice to undertakings states:

'Article 7 of [the 2001 Decree] provides that "the provisions of this Decree shall enter into force as from the publication date of the order referred to in Article 2". …

However, there shall be no barrier, as from the date of publication of this notice, to the application of the provisions on the submission of files (Art. 3) and concerning the principle of free movement (Art. 6) of the [2001 Decree] referred to above.'

The pre-litigation procédure

37 Following a first letter of formal notice dated 3 July 1996 and a reasoned opinion dated 27 March 1998, the Commission sent the French Republic an additional letter of formal notice, dated 12 October 2005, annulling and replacing the earlier letter of formal notice and reasoned opinion.

38 In that letter, the Commission argued that the French legislation, both in the 1912 Decree and in the 2001 Decree, conflicted with Article 28 EC, first, by imposing a prior authorisation scheme on processing aids and foodstuffs where their manufacturing

process used processing aids from other Member States where they were legally manufactured and/or marketed; and, in the alternative, by failing to establish, for the purpose of obtaining authorisations for the use of processing aids, a procedure which was sufficiently clear, easily accessible and transparent, and met the requirements of legal certainty.

39 As regards the 2001 Decree, the Commission took the view that, as a ministerial order had not been adopted, that decree had not yet entered into force. The Commission maintains, concerning the notice to undertakings, that, as the latter is not binding by nature, it did not offer the legal certainty necessary for economic operators.

40 It is apparent from the application and from the additional letter of formal notice that the latter was sent by reason of the extensive correspondence between the French Republic and the Commission, of the time which had elapsed since the sending of the first letter of formal notice, of attempted reform of the French legislation which subsequently proved abortive, and of further reflections of the Commission.

41 After an extension of the period for replying to the additional letter of formal notice, the French Republic replied thereto by letter of 16 February 2006. It sent the Commission all the orders issued pursuant to the 1912 Decree and pointed out that it was essentially because of the lack of an operative clause ensuring mutual recognition that reform of that decree, leading to the adoption of the 2001 Decree, had been undertaken. The French Republic insisted that a notice to undertakings already permitted the implementation of the principle of free movement in practice, even if the ministerial order envisaged by the 2001 Decree had not yet been adopted.

42 Concerning new national legislation intended to govern the use of processing aids in the future, the French Republic stated its willingness to adopt that order implementing the

2001 Decree as soon as possible, attempted to justify the prior authorisation scheme for processing aids, and proposed to amend the drafting of the mutual recognition clause appearing in the 2001 Decree.

43 By letter of 4 July 2006, the Commission sent that Member State an additional reasoned opinion.

44 By letter of 8 September 2006, the French Republic replied to the additional reasoned opinion, indicating that it had started the procedure for signing the order implementing the 2001 Decree. Recalling that certain categories of processing aids were governed or in the course of harmonisation at Community level, it maintained that a prior authorisation scheme for processing aids was justified. It drew the Commission's attention in particular to the risks posed by processing agents used as biocides or decontaminating agents in products of vegetable origin and by the use of antifoaming agents in certain conditions. Regarding the mutual recognition clause, the French Republic indicated that it had begun a process of reflection concerning amendment of the relevant provision of the 2001 Decree in order to answer the Commission's arguments.

45 Being dissatisfied with the reply given by that Member State, the Commission decided to bring the present action.

The action

46 In its application, the Commission raises, essentially, three pleas against the legislation in question, namely, first, lack of justification on grounds of protecting public health for the obstacles to the free movement of goods created by the prior authorisation schemes enacted by that legislation; second, and in the alternative, as regards the 2001 Decree, the existence of an obstance to Article 28 EC resulting from the legal uncertainty

created by that decree; and, third, the lack of simplified procedures for entering processing aids on the national list of authorised processing aids.

Preliminary observations on the scope of the action

47 It should be noted, first, that the Commission's action regarding infringement of Article 28 EC concerns all processing aids save for those for which harmonisation measures exist at Community level.

48 Second, even if the subject-matter of the Commission's action has been described as concerning French legislation in general, it follows from the pre-litigation procedure and the grounds of the application that the action is directed at the two prior authorisation schemes laid down by the 1912 and 2001 Decrees.

49 Concerning the 2001 Decree, as the documents before the Court show, the Commission and the French Republic are at issue as to whether the notice to undertakings already permitted, particularly at the expiry of the time-limit laid down by the reasoned opinion, the implementation of the principle of free movement laid down by the 2001 Decree, the ministerial order referred to in Article 2 of that decree having not yet been adopted at that date. According to that Member State, the notice to undertakings permitted, at the expiration of that time-limit, the implementation of that principle and of Articles 3 and 6 of the 2001 Decree.

50 The Court considers, in that respect, that, on the basis of the information sent to it concerning the legal value and the scope of the notice to undertakings, and taking account of the very wording of the 2001 Decree, that notice cannot be regarded as compensating for the failure to adopt the ministerial decree referred to in Article 2 of

that decree, permitting the entry into force, in particular, of Articles 3 and 6 of the 2001 Decree and its definitive substitution for the 1912 Decree.

51 First, in reply to the Commission's arguments concerning the notice to undertakings, the French Republic has not demonstrated that that notice does not constitute a simple administrative circular devoid of obligatory character and not legally binding. In its reply to the Commission's letter of formal notice, that Member State acknowledged that full implementation of the 2001 Decree required the publication of a ministerial order determining the list of all authorised substances and their conditions for use, and stated that it was not until such a list was published that the 2001 Decree would definitively replace the 1912 Decree.

52 Second, nothing in the clear and explicit wording of Articles 2 and 7 of the 2001 Decree appears to support the effects accorded by the French Republic to that notice. For example, in accordance with Article 2 of that decree, a ministerial order has to be adopted laying down the list of processing aids the use of which is authorised. As regards Article 7 of that decree, its wording shows that 'the provisions of this Decree shall enter into force as from the publication date of the order referred to in Article 2'. Therefore, the publication of such a ministerial order appears to be a necessary condition for the entry into force of the 2001 Decree, as has been explicitly stated in the notice to undertakings itself.

53 Third, whilst that notice indicates that there is no barrier to the application as from 19 January 2002, its publication date, of the provisions of the 2001 Decree concerning, for example, the submission of files by economic operators pursuant to Article 3 of that decree, it is difficult to see how an economic operator might submit a file requesting amendment of the list of authorised processing aids laid down by a ministerial order when that list has not yet been established, owing to the failure to adopt the order in question.

54 In those circumstances, this Court finds that the notice to undertakings has not remedied the failure to adopt the ministerial order referred to in Article 2 of the 2001 Decree, and that, at the expiry of the time-limit laid down by the reasoned opinion, the 1912 Decree had not yet ceased to have effect.

55 In an action under Article 226 EC for failure to fulfil obligations, the question whether a Member State has failed to fulfil its obligations must be determined by reference to the situation prevailing in the State at the end of the period laid down in the reasoned opinion, and subsequent changes cannot be taken into account by the Court (Case C-214/96 *Commission* v *Spain* [1998] ECR I-7661, paragraph 25).

56 In the context of the present action, the Commission has maintained many times that the 2001 Decree makes its entry into force conditional on the publication of a ministerial order and that, failing such publication, that decree has not entered into force. In its application, for example, it stated that 'two schemes have successively been applicable in France to processing aids. The first of those schemes remained in force during the pre-litigation procedure and did not come to an end until 2 December 2006. The [second] scheme was definitively adopted on 31 July 2001, but its entry into force was deferred until the first scheme came to an end'.

57 The time-limit laid down by the reasoned opinion expired on 4 September 2006. The ministerial order referred to in Article 2 of the 2001 Decree was adopted on 19 October 2006 and published in the *Journal officiel de la République française* on 2 December 2006.

58 It follows that, because the ministerial order referred to in Article 2 of the 2001 Decree was not adopted, the Commission's action concerning that decree can be examined by the Court only in relation to its claim based on the existence of an obstacle to Article 28 EC arising from the legal uncertainty created by the latter.

The first head of claim, concerning lack of justification based on the objective of protecting public health

Arguments of the parties

59 The Commission argues that it is for the French Republic to justify the existence of a prior authorisation scheme for the various categories of processing aids. Recourse to a prior authorisation scheme, whilst not excluded in principle, should be targeted and precisely justified on a scientific basis. The French prior authorisation scheme, the Commission submits, is based on a generalised presumption of risk, the principle of which is not compatible with Article 28 EC.

60 The general prior authorisation scheme as laid down by the 1912 Decree is, the Commission argues, disproportionate in relation to the possible risks which processing aids may pose for human health. Requiring compliance with certain conditions for using an authorised processing aid or with certain purity criteria cannot be justified on a public health ground where the finished products do not contain any residues of processing aids, or where the residues do not present any danger for human health when ingested by consumers.

61 According to the Commission, the presumption of risk on which the French scheme is based is all the more difficult to justify having regard to Regulation No 178/2002. In accordance with that regulation, other Member States normally carry out an assessment of the risks posed by foodstuffs and control that their food legislation has been complied with.

62 The Commission observes that the French Republic appears to be one of the rare Member States to make the use of processing aids subject to a prior authorisation procedure. Whilst that circumstance does not in itself imply that the prior authorisation scheme established by the French Republic is incompatible with Article 28 EC, it does demonstrate that the risk alleged by that Member State is far

from being generally acknowledged and that a scheme systematically making all processing aids subject to prior authorisation goes beyond the legitimate objective pursued by the latter.

63 The Commission maintains, as regards the mutual recognition clauses included in certain orders adopted pursuant to the 1912 Decree, that the latter cannot have any practical effect since France appears to be one of the rare Member States to lay down a prior authorisation procedure for the use of processing aids. In those circumstances, any reference to a higher residual content recognised in other Member States is of only theoretical use. It is the French legislation which is applied in all cases.

64 It argues that, since other Member States must comply with the requirements, in particular, of Article 14 of Regulation No 178/2002 in relation to the rules concerning foodstuffs placed on the market, and an infringement of Community law by the latter cannot be presumed, a mutual recognition clause should be limited to providing that the provisions of the relevant national legislation shall not hinder the principle of the free movement of foodstuffs in the preparation of which processing aids have been used which do not comply with the provisions of that legislation but which come from other Member States of the Community where they are lawfully manufactured and/or marketed.

65 The French Republic acknowledges that processing aids may, at first sight, present fewer health risks than nutritional substances such as vitamins and food additives which are added to a foodstuff, where they remain until the latter is ingested by the consumer. The fact remains, however, that processing aids may present risks for public health, arising from the presence of residues of the processing aids themselves and/or the presence of 'newly-formed' products. In that latter respect, the French Republic explains that, under the influence of certain processing procedures, the processing aids may cause changes in the structure of the molecules constituting the foodstuff, and those new molecules are capable of producing toxic effects for the health of the consumer.

66 The French Republic refers to the note of 13 August 2008 from AFSSA to the Director-General for Competition Policy, Consumer Affairs and Fraud Control, summarising its findings over eight years of assessing applications for authorisation to use processing aids. In that letter, AFSSA stated that, in the majority of cases, the residual quantities of processing aids in the final foodstuff are not known and that exposing the consumer to processing aids runs the risk of exceeding in certain cases the reference toxicological values, where they have been established. It also raised the issue of the formation of neoformed products arising from the use of certain processing aids in the manufacturing process.

67 According to the French Republic, in order to ensure that a product does not contain residues of processing aids, it is necessary for that processing aid to be known and for it to have been identified by the operative part of an authorisation or a declaration. Moreover, in order to be sure that residues do not pose risks to human health, the processing aid must itself have given rise to a health assessment of the residues present in certain foodstuffs, bearing in mind the conditions under which such foodstuffs are normally consumed. That sort of assessment of the final health risk posed by a foodstuff containing a processing aid is effective only in the context either of a marketing authorisation procedure or of a relevant scientific assessment before international, Community or national bodies. Given the potential risks for public health of certain categories of processing aids, a Member State is perfectly entitled, in respect of aids belonging to those categories which are not subject to Community harmonisation provisions, to require an authorisation procedure prior to their being placed on the market. The French Republic further maintains that, having regard to the permanent evolution of manufacturing processes, it is not possible to identify in advance categories of processing aids which are inoffensive.

68 As regards the Commission's argument that the national authorities must demonstrate the existence of a precise risk for each category of processing aid, the French Republic points out that the precautionary principle applies in the area of public health. In its submission, in accordance with that principle, it is for the Member States to establish the risk which the use of processing aids may pose, but they are not obliged to establish precisely and scientifically the existence of the risk which they pose.

69 In the absence of an assessment mechanism for processing aids in the great majority of Member States, the fact that a substance has been marketed in another Member State cannot exonerate it from an examination by AFSSA and the French administration. The fact that a Member State imposes rules which are less strict than those applicable in another Member State does not in itself mean that the latter are disproportionate.

70 Regarding mutual recognition clauses, the French Republic merely argues that it is precisely in order to respond to the Commission's complaint that the 1912 Decree did not contain such mutual clauses that the 2001 Decree was adopted.

71 As for the possibility of informing and protecting consumers by means of labelling, the French Republic argues, first, that labelling is no substitute for the result of a risk analysis for consumer health. Moreover, since Directive 2000/13 exempts processing aids from the labelling obligation, to require those substances to be mentioned in labelling would constitute an infringement of that directive.

72 Concerning the AFSSA study report of April 2007 annexed for the first time to its rejoinder, the French Republic argues that, even if that report is focused on certain products and procedures, as the Commission has observed, such a focus is logical bearing in mind the particular problem posed by the production of neoformed products. In its submission, an exhaustive examination of processing aids cannot be envisaged, given the considerable quantity of usable processing aids. In any event, contrary to what the Commission claims, the French legislation was not adopted without a prior, in-depth, overall study of the impact of processing aids on health, such a study having been begun between 2001 and 2003 and the second phase of that study being envisaged for the period from 2009 to 2011.

Findings of the Court

73 It should be recalled, as a preliminary observation, that the free movement of goods between Member States is a fundamental principle of the Treaty which finds its expression in the prohibition, set out in Article 28 EC, of quantitative restrictions on imports between Member States and all measures having equivalent effect.

74 The prohibition on measures having an effect equivalent to restrictions set out in Article 28 EC covers all commercial rules enacted by the Member States which are capable of hindering, directly or indirectly, actually or potentially, intra-Community trade (see, in particular, Case 8/74 *Dassonville* [1974] ECR 837, paragraph 5; Case C-192/01 *Commission* v *Denmark* [2003] ECR I-9693, paragraph 39; and Case C-24/00 *Commission* v *France* [2004] ECR I-1277, paragraph 22).

75 It is undisputed that the prior authorisation scheme laid down by the 1912 Decree constitutes a measure having equivalent effect to a quantitative restriction within the meaning of Article 28 EC.

76 The prior authorisation scheme laid down by that decree makes it more costly and difficult, or, in certain cases, impossible, to market processing aids and foodstuffs in the preparation of which processing aids lawfully manufactured and/or marketed in other Member States have been used.

77 First, that scheme hinders the free movement of processing aids, intended to be used in the preparation of foodstuffs, coming from other Member States where they are lawfully manufactured and/or marketed, in so far as they are subjected to criteria of purity or other characteristics, such as maximum authorised residual doses, established by the French legislation.

78 Second, it hinders the free movement of finished foodstuffs from other Member States in which the presence, however infinitesimal, of residues of a processing aid not authorised in France can be found, or in which the presence of residues of processing aids authorised in France can be found, where the maximum residual amounts determined by the French authorisation decisions have been exceeded.

79 Third, that prior authorisation scheme hinders the free movement of finished foodstuffs from other Member States whose preparation involved the use of a processing aid not authorised in France, or authorised there but not satisfying the criteria as to purity or other characteristics laid down by the French legislation, or authorised there but used in a different manner from that authorised by the French legislation, even where there are no residues in the finished foodstuff, or residues are present only in the authorised quantities.

80 According to consistent case-law, national legislation making the addition of a nutritive substance to a foodstuff lawfully manufactured and/or marketed in other Member States subject to prior authorisation is not in principle contrary to Community law provided certain conditions are fulfilled (see, to that effect, Case C-344/90 *Commission* v *France* [1992] ECR I-4719, paragraph 8, and *Commission* v *Denmark*, paragraph 44).

81 First, such legislation must be accompanied by a procedure allowing economic operators to obtain the entry of that nutritive substance in the national list of authorised substances. That procedure must be easily accessible, must be capable of being concluded within a reasonable time, and, if it leads to a refusal, the refusal decision must be capable of review before the courts (see, to that effect, Case C-344/90 *Commission* v *France*, paragraph 9, and Case C-24/00 *Commission* v *France*, paragraph 26).

82 Second, an application for the entry of a nutritive substance on the national list of authorised substances may be rejected by the competent national authorities only if

that substance poses a genuine threat to public health (*Commission* v *Denmark*, paragraph 46, and Case C-24/00 *Commission* v *France*, paragraph 27).

83 In this case, the Commission argues that, unlike additives and nutritive substances, such as vitamins, which formed the subject-matter of the abovementioned judgments in *Commission* v *Denmark* and Case C-24/00 *Commission* v *France*, processing aids are not substances added to foodstuffs but merely substances used in the process of elaborating and manufacturing a foodstuff, of which traces may be detected in certain cases. In contrast with vitamins and additives, their presence in the finished foodstuff is rare and involuntary. Having regard to those differences, the Commission considers that a prior authorisation scheme is not justified for processing aids, since the latter do not threaten the same harmfulness to public health as additives or vitamins.

84 It should be noted in this respect that those differences between nutritive substances voluntarily and intentionally added to foodstuffs and processing aids are not capable of excluding the possibility of a Member State relying, in principle, on Article 30 EC and the objective of protecting public health in order to justify prior authorisation schemes such as those at issue in this case. If such differences existed in relation to substances subject to a prior authorisation scheme, they would be relevant not for determining whether the choice of such a scheme is in principle excluded in Member States but as regards the means of applying the principle of proportionality in relation to the scheme which is applicable to them.

85 As regards the objective of protecting public health, it is for the Member States, in the absence of harmonisation and in so far as doubts subsist in the current state of scientific research, to decide at which level they intend to ensure the protection of the health and life of persons, and whether to require prior authorisation for the marketing of processing aids and foodstuffs in the preparation of which such aids have been used, whilst at the same time taking into account the requirements of the free movement of

goods within the Community (see, to that effect, Case 174/82 *Sandoz* [1983] ECR 2445, paragraph 16; Case C-42/90 *Bellon* [1990] ECR I-4863, paragraph 11; *Commission* v *Denmark*, paragraph 42; and Case C-24/00 *Commission* v *France*, paragraph 49).

86 That discretion relating to the protection of public health is particularly wide where it is shown that uncertainties continue to exist in the current state of scientific research as to certain substances used in the preparation of foodstuffs (*Commission* v *Denmark*, paragraph 43, and Case C–24/00 *Commission* v *France*, paragraph 50).

87 Since Article 30 EC contains an exception, which must be narrowly interpreted, to the rule of the free movement of goods within the Community, it is for the national authorities which invoke it to demonstrate in each case, taking account of the results of international scientific research, that their legislation is necessary in order effectively to protect the interests referred to in that provision, and, in particular, that the marketing of the products in question poses a genuine threat to public health (see, to that effect, *Commission* v *Denmark*, paragraph 46, and Case C-24/00 *Commission* v *France*, paragraph 53 and case-law cited).

88 A prohibition on marketing processing aids or foodstuffs in which processing aids have been used which have been lawfully manufactured and/or marketed in other Member States must therefore be based on an in-depth assessment of the risk alleged by the Member State invoking Article 30 EC (see, to that effect, *Commission* v *Denmark*, paragraph 47; Case C-24/00 *Commission* v *France*, paragraph 54; and Case C-41/02 *Commission* v *Netherlands* [2004] ECR I-11375, paragraph 48).

89 A decision to prohibit marketing, which indeed constitutes the most restrictive obstacle to trade in products lawfully manufactured and marketed in other Member States, can be adopted only if the real risk alleged for public health appears sufficiently established

on the basis of the latest scientific data available at the date of the adoption of such decision. In such a context, the object of the risk assessment to be carried out by the Member State is to appraise the degree of probability of harmful effects on human health from the addition of certain nutrients to foodstuffs and the seriousness of those potential effects (*Commission* v *Denmark*, paragraph 48; Case C-24/00 *Commission* v *France*, paragraph 55; and *Commission* v *Netherlands*, paragraph 49).

90 In exercising their discretion relating to the protection of public health, the Member States must comply with the principle of proportionality. The means which they choose must therefore be confined to what is actually necessary to ensure the safeguarding of public health; they must be proportional to the objective thus pursued, which could not have been attained by measures which are less restrictive of intra-Community trade (*Commission* v *Denmark*, paragraph 45, and Case C-24/00 *Commission* v *France*, paragraph 52).

91 It is true that the assessment which a Member State is required to make may reveal a high degree of scientific and practical uncertainty in that regard. Such uncertainty, which is inseparable from the concept of precaution, influences the extent of the discretion of the Member State and thus has an impact on the means of applying the proportionality principle. In such circumstances, it must be acknowledged that a Member State may, under the precautionary principle, take protective measures without having to wait for the reality and the seriousness of those risks to be fully demonstrated (see, to that effect, Case C-157/96 *National Farmers' Union and Others* [1998] ECR I-2211, paragraph 63, and *Commission* v *Netherlands*, paragraphs 51 and 52). However, the assessment of the risk cannot be based on purely hypothetical considerations (see, to that effect, Case C-236/01 *Monsanto Agricoltura Italia and Others* [2003] ECR I-8105, paragraph 106; *Commission* v *Denmark*, paragraph 49; and *Commission* v *Netherlands*, paragraph 52).

92 A correct application of the precautionary principle presupposes, first, identification of the potentially negative consequences for health of the proposed use of processing aids, and, secondly, a comprehensive assessment of the risk to health based on the most

reliable scientific data available and the most recent results of international research (*Monsanto Agricoltura Italia and Others*, paragraph 113; *Commission* v *Denmark*, paragraph 51; and *Commission* v *Netherlands*, paragraph 53).

93 Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures, provided they are non-discriminatory and objective (*Commission* v *Denmark*, paragraph 52, and *Commission* v *Netherlands*, paragraph 54).

94 In this case, the French Republic justifies the prior authorisation scheme laid down by its legislation by reference to the potential health risks of certain categories of processing aids.

95 However, if there are risks concerning certain categories of processing aids, the national legislation must be targeted and clearly justified in relation to those categories and must not envisage all processing aids or all foodstuffs in the preparation of which processing aids not entering into those dangerous or suspect categories have been used. It is not sufficient to base justification on potential risks posed by the substances or products subject to authorisation.

96 It is true that a Member State may base justification on the precautionary principle where it proves impossible to determine with certainty the existence or the scope of the alleged risk. However, a correct application of that principle presupposes that the Member State demonstrates the existence of the conditions, referred to in paragraph 92 of this judgment, required for the latter to apply.

97 As regards the prior authorisation scheme laid down by the 1912 Decree, there is no demonstration of the existence of those conditions. Even if, as the French Republic claims, in accordance with the precautionary principle the Member State merely has to establish the risk which the use of processing aids may pose, the fact remains that the generalised presumption of a health risk put forward by that Member State in this case is not supported by evidence to explain why the marketing of any foodstuff, in the preparation of which processing aids have been used which have been lawfully manufactured and/or marketed in other Member States, must depend on the entry of the processing aid in question on a positive list established by French legislation, which in turn depends on the conformity of the foodstuff in question with purity criteria, requirements concerning maximum residual doses or conditions for using processing aids laid down by that legislation.

98 Moreover, as regards the evidence put forward by the French Republic to demonstrate that the choice of schemes at issue is based on a comprehensive risk analysis in accordance with Articles 28 EC and 30 EC, it should be noted that the AFFSA note of 13 August 2008 and its study report of April 2007 to demonstrate that the legislation in question complied with Articles 28 EC and 30 EC substantially post-date the 1912 Decree. Furthermore, following the publication, on 2 December 2006, of the ministerial order referred to in Article 2 of the 2001 Decree, the 1912 Decree was no longer in force at the time those documents were drawn up.

99 As is apparent from paragraph 90 of this judgment, in order to comply with the principle of proportionality, the means which the Member States choose must be limited to what is actually necessary in order to safeguard health.

100 Examination of the file concerning the prior authorisation scheme laid down by the 1912 Decree shows the latter to be disproportionate in that it systematically prohibits, without prior authorisation, the marketing of any processing aids or of any foodstuffs in the preparation of which processing aids lawfully manufactured and/or marketed in other Member States were used, without making any distinction according to the various processing aids or according to the level of risk which their use might potentially pose for health.

101 By its systematic nature, the 1912 Decree does not permit compliance with Community law as regards prior identification of the harmful effects of processing aids and the assessment of the actual risk which they pose for health, both of which require an in-depth, case-by-case assessment of the effects which use of the processing aids in question might produce.

102 Moreover, that scheme systematically hinders the marketing of foodstuffs in the preparation of which processing aids were used if the method of using the latter does not correspond to the method of use prescribed by the French legislation, even in the absence of detectable residues of those processing aids in the final foodstuffs.

103 A Member State cannot justify a systematic and untargeted prior authorisation scheme such as that laid down by the 1912 Decree by pleading the impossibility of carrying out more exhaustive prior examinations by reason of the considerable quantity of processing aids which may be used or by reason of the fact that manufacturing processes are constantly changing. As is apparent from Articles 6 and 7 of Regulation No 178/2002, concerning the analysis of risks and the application of the precautionary principle, such an approach does not correspond to the requirements laid down by the Community legislature as regards both Community and national food legislation and designed to achieve the general objective of a high level of health protection.

104 It is true that, as the French Republic has argued, one of the alternative methods less restrictive of free movement suggested by the Commission, namely the mentioning of the processing aids used in the manufacturing process of a foodstuff, is not capable of achieving the objective of protection envisaged by the French legislation concerning processing aids in relation to which a genuine risk to health has been established. However, this Court must reject the argument of that Member State that such a mention would in any event constitute an infringement of Directive 2000/13. Although Article 6(4)(c)(ii) of that directive shows that processing aids do not constitute ingredients which must compulsorily be mentioned on labelling, in accordance with

Article 3(1) of that directive, the Member States may, in accordance with Article 18(1) of that directive, lay down measures on labelling which are justified for reasons of protecting public health.

105 It should also be noted, as the French Republic has pointed out, that the mere fact that one Member State imposes less strict rules than those applicable in another Member State does not mean that the latter are incompatible with Articles 28 EC and 30 EC (see, to that effect, Case C-514/03 *Commission* v *Spain* [2006] ECR I-963, paragraph 49). However, the absence of a prior authorisation scheme with regard to the use of processing aids in the preparation of foodstuffs in all or nearly all of the other Member States may be relevant when assessing the objective justification put forward in relation to the French legislation, and, particularly, with regard to the assessment of its proportionality.

106 As for the Commission's arguments concerning the nature of the mutual recognition clauses which each Member State must incorporate into its national legislation in relation to a prior authorisation scheme such as that at issue in this case, it should be noted, as is apparent from paragraph 80 of this judgment, that national legislation subjecting to prior authorisation foodstuffs in the preparation of which processing aids have been used which are lawfully manufactured and/or marketed in other Member States is not in principle contrary to Community law provided the conditions set out in paragraphs 81 and 82 of this judgment are met.

107 The Commission's argument in paragraph 64 of this judgment concerning the nature of the mutual recognition clause necessary in order to comply with Community law cannot be accepted.

108 It is true that a Member State which establishes a prior authorisation scheme must provide for a simplified registration procedure and justify the scheme by demonstrating the existence of a genuine health risk. That State must demonstrate that the scheme which it has chosen in order to attain the legitimate objective of the protection of health

does not go beyond what is necessary to attain that objective, which the French Republic has not succeeded in doing in this case as regards the scheme laid down by the 1912 Decree.

109 However, to require in national legislation establishing a prior authorisation scheme that a mutual recognition clause be included such as that contemplated by the Commission in paragraph 64 of this judgment would go against the very rationale of such a scheme, since the Member State concerned would be obliged to allow the marketing on its territory of processing aids and foodstuffs benefiting from that clause without being able to verify the absence of genuine risks for public health.

110 Having regard to the above, the Commission's first head of claim must be regarded as being well founded as regards the 1912 Decree.

The second head of claim, alleging the existence of an obstacle to Article 28 EC arising from the legal uncertainty created by the 2001 Decree

111 During the pre-litigation procedure and before the Court, the Commission has argued that the adoption of the 2001 Decree, which only entered into force on 2 December 2006 following the publication of the ministerial order referred to in Article 2 thereof, the publication, in 2002, of the notice to undertakings, and the publication, in 2003, of guidelines for the constitution of a file concerning the use of a processing aid applicable to categories of processing aids listed in the annex to the 2001 Decree (the guidelines) have created a situation of legal uncertainty which itself constitutes an unjustified obstacle to Article 28 EC.

112 In that regard, it should be noted that the lapse of time between the adoption of the 2001 Decree and the publication, on 2 December 2006, of the ministerial order permitting the entry of that decree into force and the coexistence during that period of the said decree and the 1912 Decree have given rise to an ambiguous factual situation by maintaining, for economic operators, a state of uncertainty as regards the possibilities

for marketing in France processing aids or foodstuffs in the preparation of which processing aids were used which are lawfully manufactured and/or marketed in other Member States.

113 That legal uncertainty has been reinforced, first, by the notice to undertakings which indicated to economic operators that there was no obstacle, as from the publication date of that notice, to the application of certain provisions of the 2001 Decree and, second, by the guidelines published by AFFSA on 2 July 2003 which were, in its own words, applicable to categories of processing aids listed in the annex to the 2001 Decree.

114 Even if those guidelines were in conformity with the requirements arising from the case-law of the Court concerning the existence of a simplified registration procedure, an economic operator would not have been able to constitute a file concerning the use of a processing aid and seeking to enter the latter on a positive list referred to in Article 2 of the 2001 Decree at a time when that list had not been established, the ministerial order intended to make provision for that list having not yet been either adopted or published.

115 In those circumstances, the Commission's second head of claim concerning the 2001 Decree must be regarded as well founded.

The third head of claim, concerning the lack of a simplified procedure for registering processing aids

116 The Commission takes the view that the registration procedure laid down by the 1912 Decree does not comply with the requirements arising from the case-law of the Court and referred to in paragraph 81 of this judgment. The 1912 Decree does not contain any

indication as to the duration of the procedure, the right of economic operators to initiate it, or their opportunities to appeal in the event of refusal. Nor was any indication given to those operators as to the body to which they should address their applications or the documents which they should place on file.

117 In that respect, it should be noted that, as is apparent from paragraph 81 of this judgment, national legislation making the addition of a substance such as a processing aid to a foodstuff subject to prior authorisation must be accompanied by a procedure allowing economic operators to obtain the entry of that substance in the national list of authorised substances. That procedure must be easily accessible, must be capable of being concluded within a reasonable time, and, if it leads to a refusal, the refusal decision must be capable of review before the courts (see, to that effect, Case C-344/90 *Commission* v *France*, paragraph 9, and Case C-24/00 *Commission* v *France*, paragraph 26).

118 In paragraph 40 of its judgment in Case C-24/00 *Commission* v *France*, the Court held, having regard to the examples provided by the Commission concerning the registration procedure laid down by the 1912 Decree, that applications for authorisation submitted by economic operators were not dealt with either within a reasonable period or according to a procedure which was sufficiently transparent as regards the possibility of challenging refusal to authorise before the courts.

119 In the present case, the documents before the Court show that the registration procedure applicable to nutritive substances such as the vitamins at issue in Case C-24/00 *Commission* v *France* is similar or identical to that laid down by the 1912 Decree for the entry of processing aids onto the list of substances authorised in France. The French Republic has not provided any evidence to demonstrate that that is not the case.

120 In those circumstances, the conclusions which the Court reached in Case C-24/00 *Commission* v *France*, concerning the registration procedure laid down by the 1912 Decree, may be transposed to the registration procedure applicable, by virtue of the same decree, to processing aids.

121 It must therefore be concluded that, as regards the 1912 Decree, the Commission's third head of claim, concerning the lack of a simplified registration procedure, must be regarded as well founded.

122 Having regard to the above, this Court finds that, by laying down, for processing aids and foodstuffs whose preparation involved the use of processing aids from other Member States where they are lawfully manufactured and/or marketed, a prior authorisation scheme not complying with the principle of proportionality, the French Republic has failed to fulfil its obligations under Article 28 EC.

Costs

123 Under Article 69(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the Commission has applied for a costs order against the French Republic, and the latter has been unsuccessful, the French Republic must be ordered to pay the costs.

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

1. **By laying down, for processing aids and foodstuffs whose preparation involved the use of processing aids from other Member States where they are lawfully manufactured and/or marketed, a prior authorisation scheme not complying with the principle of proportionality, the French Republic has failed to fulfil its obligations under Article 28 EC.**

2. **The French Republic is ordered to pay the costs.**

[Signatures]