Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fifth Chamber)

30 April 2014*

(Consumer protection — Regulation (EC) No 1924/2006 — Food health claims — Refusal to authorise a reduction of disease risk claim — Designation of a risk factor — Lawfulness of the procedure for the authorisation of reduction of disease risk claims — Action for annulment — Interest in bringing proceedings — Direct and individual concern — Admissibility — Proportionality — Obligation to state reasons)

In Case T-17/12,

Moritz Hagenmeyer, residing in Hamburg (Germany),

Andreas Hahn, residing in Hanover (Germany),

represented by T. Teufer, lawyer,

applicants,

v

European Commission, represented by L. Pignataro-Nolin and S. Grünheid, acting as Agents,

defendant,

supported by

Council of the European Union, represented by I. Šulce, Z. Kupčová and M. Simm, acting as Agents,

intervener,

APPLICATION for annulment in part of Commission Regulation (EU) No 1170/2011 of 16 November 2011 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk (OJ 2011 L 299, p. 1),

THE GENERAL COURT (Fifth Chamber),

composed of A. Dittrich (Rapporteur), President, J. Schwarcz and V. Tomljenović, Judges,

Registrar: K. Andová, Administrator,

having regard to the written procedure and further to the hearing on 15 January 2014,

gives the following

* Language of the case: German.

Judgment

Background to the dispute

1 The applicants, Mr Moritz Hagenmeyer and Mr Andreas Hahn, are, respectively, a lawyer responsible for teaching food law at Leibniz Universität (Leibniz University), Hanover (Germany) and Professor of Food and Human Nutrition Sciences at that university.

2 Under Article 14(1)(a) and Article 15 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ 2006 L 404, p. 9), most recently amended by Commission Regulation (EU) No 116/2010 of 9 February 2010 (OJ 2010 L 37, p. 16) ('Regulation No 1924/2006'), the applicants on 11 February 2008 applied to the competent German authority, the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (Federal German Office for Consumer Protection and Food Safety, 'the Bundesamt'), for authorisation of the following reduction of disease risk claim: 'Regular consumption of significant amounts of water can reduce the development of dehydration and of concomitant decrease of performance' ('the claim at issue'). The application extended to any other claim to which consumers would in all likelihood ascribe the same meaning.

3 On 10 March 2008, the applicants re-sent their application for authorisation to the Bundesamt, after it had informed them on 29 February 2008, in answer to a question concerning the state of the file, that the application sent on 11 February 2008 could not be found in the competent department of the Bundesamt.

4 By letter of 8 May 2008, the Bundesamt acknowledged receipt of the application sent on 11 February 2008.

5 By letter of 21 July 2008, the Bundesamt drew the first applicant's attention to the fact that on 18 April 2008 the Commission of the European Communities had adopted Regulation (EC) No 353/2008 establishing implementing rules for applications for authorisation of health claims as provided for in Article 15 of Regulation No 1924/2006 (OJ 2008 L 109, p. 11) and asked him to re-submit the application for authorisation of the claim at issue using the forms published by the European Food Safety Agency (EFSA).

6 By letter to the Bundesamt of 21 August 2008, the applicants refused to re-submit their application using the forms published by EFSA and asked that their application be forwarded to EFSA forthwith.

7 By letter of 15 September 2008, the Bundesamt forwarded the application for authorisation of the claim at issue to EFSA so that it might give its opinion on the application, pursuant to Article 16 of Regulation No 1924/2006.

8 In answer to a letter of 20 October 2008 from the applicants concerning the reasons for the time that had elapsed between the submission of the application at issue and its being forwarded to EFSA, the Bundesamt informed the first applicant, by letter of 11 November 2008, that it was required to forward to EFSA only complete and valid applications and that procedural requirements and the adoption of implementing measures in the meantime had meant that it had taken longer to check the applications.

9 By letter of 10 November 2008, the Bundesamt explained to the first applicant that EFSA had expressed doubts as to whether the application for authorisation of the claim at issue came under Article 14 of Regulation No 1924/2006, since it was neither directly nor indirectly linked to a disease.

In addition, the Bundesamt stated that, in order that the claim at issue might be properly examined by EFSA, it was necessary to designate, in the documents submitted with the claim, the scientific relation between a risk factor and one or more diseases.

10 After the applicants informed the Bundesamt, by letter of 28 November 2008, that the application for authorisation of the claim at issue concerned a disease, namely 'dehydration and [the] concomitant decrease of performance', the Bundesamt informed them, by letter of 18 December 2008, that a risk factor needed to be indicated before the claim at issue could be forwarded to EFSA.

11 By letter of 10 February 2009, the applicants informed the Bundesamt that there was no need to designate a risk factor, but that reduced water content in tissues might be taken to be a risk factor, on a proper interpretation of the claim at issue. In addition, observing that the application for authorisation of the claim at issue extended to any other claim to which consumers would in all likelihood ascribe the same meaning, the applicants proposed other forms of wording of the claim at issue in which water loss in tissues was mentioned as a risk factor.

12 By letter of 20 March 2009, the Bundesamt sent EFSA the applicants' letters of 28 November 2008 and 10 February 2009.

13 In answer to the questions relating to the state of the file and the applicants' letters of 15 June, 27 July and 15 October 2009 and 15 January 2010, EFSA informed them, by letters of 21 July, 23 September and 23 November 2009 and 27 January 2010, that before a scientific evaluation of the claim at issue could be carried out, a number of questions relating to the interpretation of the applicable provisions must be clarified by the Commission and the Member States.

14 By letter of 9 July 2010, the Commission informed the first applicant that it followed from the discussions of the informal working group on nutrition and health claims on 12 April 2010 that the application for authorisation of the claim at issue did not meet the requirements of Regulation No 1924/2006 because it did not designate a risk factor.

15 In answer to EFSA's letter of 1 October 2010 requesting the applicants to identify the risk factor on which they proposed to act in order to reduce the risk of disease, the applicants, by letter of 25 October 2010, maintained the position expressed in their letter of 10 February 2009.

16 On 28 January 2011, EFSA adopted its scientific opinion on the basis of the claim at issue, pursuant to Article 16 of Regulation No 1924/2006. In that opinion, EFSA concluded that the risk factors proposed by the applicants were measures of water depletion and, accordingly, measures of disease. Consequently, the claim at issue did not in its view satisfy the requirements of a reduction of disease risk claim, pursuant to Article 14 of Regulation No 1924/2006.

17 On 16 February 2011, EFSA's scientific opinion was made public, in accordance with the first subparagraph of Article 16(6) of Regulation No 1924/2006. During the 30 days following its publication, the applicants and a number of interested third parties made comments to the Commission concerning EFSA's opinion, in accordance with the second subparagraph of Article 16(6) of that regulation.

18 On 28 April 2011, the Commission submitted to the Standing Committee on the Food Chain and Animal Health ('the Committee') instituted by Article 58(1) 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 EFSA and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1) a proposal for a regulation refusing to authorise certain health claims made on foods and referring to the reduction of disease risk, and in particular the claim at issue.

19 On 30 June 2011, at the Commission's request, EFSA produced a technical report responding to certain comments submitted by interested third parties pursuant to the second subparagraph of Article 16(6) of Regulation No 1924/2006.

20 On 11 July 2011, in accordance with the regulatory procedure with scrutiny provided for in Article 17(3) and Article 25(3) of Regulation No 1924/2006, the Committee decided unanimously in favour of the adoption of the Commission's proposal for a regulation and, on 26 July 2011, that proposal was submitted for review to the European Parliament and to the Council of the European Union, which raised no objections.

21 On 16 November 2011, the Commission adopted Regulation (EU) No 1170/2011 refusing to authorise certain health claims made on foods and referring to the reduction of disease risk (OJ 2011 L 299, p. 1; 'the contested regulation'). Under Article 1, read with the annex to that regulation, the claim at issue is not to be included in the European Union list referred to in Article 14(1) of Regulation No 1924/2006. As a ground for that refusal of authorisation, the Commission concluded, in particular, at recital 6 in the preamble to the contested regulation, referring to Article 2(2)(6) of Regulation No 1924/2006 and to EFSA's scientific opinion, that, as a risk factor in the development of a disease had not been shown to be reduced, the claim at issue did not comply with the requirements of Regulation No 1924/2006 and could not be authorised.

22 By letter of 28 November 2011, the Commission informed the applicants of its definitive decision on the application for authorisation of the claim at issue, set out in the contested regulation.

Procedure and forms of order sought

23 By application lodged at the Court Registry on 16 January 2012, the applicants brought the present action.

24 By separate document, lodged at the Court Registry on 30 March 2012, the Commission raised an objection of inadmissibility pursuant to Article 114(1) of the Rules of Procedure of the General Court. On 14 May 2012, the applicants lodged their observations on the objection of inadmissibility.

25 By letter lodged at the Court Registry on 16 April 2012, the Council requested leave to intervene in support of the form of order sought by the Commission. On 16 May 2012, the President of the Seventh Chamber of the Court decided to suspend consideration of the application to intervene pending a decision on the objection of inadmissibility.

26 By order of the Court (Seventh Chamber) of 23 November 2012, the objection of inadmissibility was joined to the substance of the case and costs were reserved.

27 By order of the President of the Seventh Chamber of the Court of 4 February 2013, the Council's request for leave to intervene was granted, the views of the main parties having been heard. The Council lodged its statement in intervention on 15 March 2013. By document lodged at the Court Registry on 17 May 2013, the applicants submitted their observations on that statement in intervention. The Commission did not submit observations on the statement in intervention.

28 The composition of the Chambers of the Court was altered and the Judge-Rapporteur was assigned to the Fifth Chamber, to which the present case was therefore assigned.

29 On hearing the report of the Judge-Rapporteur, the Court (Fifth Chamber) decided to open the oral procedure.

30 The parties presented oral argument and answered the questions put to them by the Court at the hearing on 15 January 2014. During the hearing, the Commission withdrew its claim that there was no need to adjudicate, this being noted in the minutes of the hearing.

31 The applicants claim that the Court should:

— annul the contested regulation in so far as it relates to the claim at issue;

— order the Commission to pay the costs.

32 The Commission contends that the Court should:

— dismiss the action as inadmissible or, in the alternative, as unfounded;

— order the applicants to pay the costs.

33 The Council contends that the Court should:

— dismiss the action;

— make an appropriate order as to costs.

Law

34 Before examining the parties' substantive pleas and arguments, it is appropriate to examine the Commission's objection of inadmissibility.

Admissibility

35 In support of its objection of inadmissibility, the Commission raises two pleas of inadmissibility. The first plea alleges that the applicants lack an interest in bringing proceedings, while the second alleges that the applicants lack *locus standi*, on the ground that the contested regulation does not concern them either directly or individually.

First plea of inadmissibility, alleging lack of interest in bringing proceedings

36 The Commission claims that the applicants have no interest in bringing proceedings, since the claim at issue was dictated by only a theoretical interest in Regulation No 1924/2006. That follows, first, from the fact that the applicants initiated the administrative procedure relating to the claim in question in reliance on their potential activity as food business operators or potential representatives of those operators and, second, from the fact that when that administrative procedure was publicly presented in a specialist journal, the applicants maintained that the possibility of seeking an authorisation had been offered by Regulation No 1924/2006 in the interest of all mankind. According to the Commission, although it is possible for any individual to initiate a procedure for authorisation of a claim within the meaning of Article 14(1)(a) of Regulation No 1924/2006, it does not follow that everyone also has an interest in securing the annulment of a regulation whereby an application to enter a claim on the list of claims authorised in accordance with that provision is rejected. In particular, the interest in bringing an action does not arise from the fact that the applicants sought authorisation to use the claim at issue and that the administrative procedure ended with the adoption of the contested regulation.

37 The applicants claim that they have a right to bring proceedings by virtue of their right to seek authorisation of the claim at issue, referred to in Article 14(1)(a) of Regulation No 1924/2006. They maintain that they have their own direct legal interest that might also be used for economic purposes. In their submission, they have no other judicial means of securing annulment of the contested regulation whereby their application for authorisation was rejected after a substantive examination of that application by the Commission. The question whether the applicants are food business operators or whether they represent such operators is irrelevant. In their submission, once authorisation of their health claim has been obtained, they could at any time become such operators or work with such operators in order to use that claim commercially. They maintain that their interest lies in obtaining authorisation of the claim at issue, using it themselves and thereby making it available for use by others.

38 According to consistent case-law, an applicant's interest in bringing proceedings must, in the light of the purpose of the action, exist at the stage of lodging the action, failing which the action will be inadmissible. That purpose of the action, like the interest in bringing proceedings, must continue until the decision of the court, failing which there will be no need to adjudicate, which presupposes that the action must be liable, if successful, to procure an advantage to the party bringing it (see Joined Cases C-373/06 P, C-379/06 P and C-382/06 P *Flaherty and Others* v *Commission* [2008] ECR I-2649, paragraph 25 and the case-law cited) and that that party has a vested and present interest in the annulment of the contested act (see judgment of 19 June 2009 in Case T-269/03 *Socratec* v *Commission*, not published in the ECR, paragraph 36 and the case-law cited). That requirement ensures, in procedural terms, that the Courts of the European Union are not required to deal with requests for opinions or purely theoretical questions (*Socratec* v *Commission*, paragraph 38).

39 It is also settled case-law that it is the applicant that must prove that it has an interest in bringing proceedings, which is an essential and fundamental prerequisite for any legal proceedings (order of the President of the Second Chamber of the Court of Justice in Case C-206/89 R *S.* v *Commission* [1989] ECR 2841, paragraph 8, and judgment in Case T-141/03 *Sniace* v *Commission* [2005] ECR II-1197, paragraph 31). Moreover, if the interest pleaded by an applicant concerns a future legal situation, it must demonstrate that the prejudice to that situation is already certain. Accordingly, an applicant cannot rely on future and uncertain situations to justify its interest in applying for annulment of the contested act (Case T-138/89 *NBV and NVB* v *Commission* [1992] ECR II-2181, paragraph 33, and *Sniace* v *Commission*, paragraph 26).

40 It should be observed that, as the applicants claim, the contested regulation is a hybrid measure: it constitutes a normative measure vis-à-vis all food business operators and at the same time a decision vis-à-vis applicants for authorisation.

41 First, in providing that the claim at issue is not to be included in the list of authorised European Union claims referred to in Article 14(1) of Regulation No 1924/2006, the contested regulation is intended to prohibit all food business operators from using that claim. As may be seen from the first subparagraph of Article 1(2) of Regulation No 1924/2006, that regulation is to apply to claims made in commercial communications. Furthermore, Article 6(2) of that regulation refers to a food business operator who, when making a health claim, must justify the use of the claim. In addition, according to Article 17(5) of that regulation, health claims included in the list provided for in Article 14 of that regulation may, in principle, be used by any food business operator.

42 Second, it should be observed that, in the present dispute, it is an authorisation procedure concerning a reduction of disease risk claim, referred to in Article 14(1)(a) of Regulation No 1924/2006, that is at issue. The definitive decision on the application for authorisation, submitted by the applicants in accordance with Article 15 of that regulation, was taken by the Commission in the contested regulation, pursuant to Article 17(3) of Regulation No 1924/2006, as is apparent from Article 1 of,

and the annex to, the contested regulation. By the latter regulation, which is the final point of the authorisation procedure referred to in Articles 14 to 17 of Regulation No 1924/2006, the application was therefore rejected, as confirmed in the Commission's letter of 28 November 2011 to the applicants.

43 That is also apparent from recitals 5, 6 and 9 in the preamble to the contested regulation, which make express reference to the applicants' application. Recital 5 to the contested regulation states in that regard that, following that application, EFSA was required to deliver an opinion on a health claim related to the effects of water and reduction of the risk of development of dehydration and of concomitant decrease of performance. That recital also contains the wording of the claim at issue. Recital 6 summarises the authorisation procedure concerning the claim at issue. According to recital 9, the comments from the applicants and the members of the public received by the Commission pursuant to Article 16(6) of Regulation No 1924/2006 have been considered when setting the measures provided for in the contested regulation.

44 It follows from Article 15 of Regulation No 1924/2006 that it was the legislature's intention that any natural or legal person could submit an application for authorisation and that the legislature did not restrict the circle of applicants for authorisation, which, moreover, the Commission expressly accepted at the hearing. The procedural rules laid down in Articles 15 to 17 and 19 of Regulation No 1924/2006, unlike the procedural rules laid down in Article 18 of that regulation, do not provide that only a food business operator may apply for authorisation of such a claim. They merely make a general reference to applicants. Furthermore, it should be observed that the Commission did not reject the applicants' application on the ground that they were not entitled to apply for authorisation of the claim at issue.

45 In those circumstances, a person who, in compliance with the applicable rules, has applied for authorisation of a reduction of disease risk claim clearly has an interest in seeking annulment of a decision refusing the corresponding authorisation. The annulment of a Commission decision refusing to grant the authorisation applied for has the consequence, for all persons whose applications have been rejected, that authorisation becomes possible again after the Commission has re-examined those applications, as it is required to do (see, to that effect, *Flaherty and Others* v *Commission*, paragraph 38 above, paragraphs 32 and 33, and judgment of 3 December 2009 in Case T-245/08 *Iranian Tobacco* v *OHIM — AD Bulgartabac (TIR 20 FILTER CIGARETTES)*, not published in the ECR, paragraphs 17 to 22).

46 That conclusion is not called into question by the Commission's argument that the applicants have only a theoretical interest with respect to Regulation No 1924/2006. While it is the case that the Courts of the European Union cannot be required to adjudicate on purely theoretical questions, the fact none the less remains that the present case does not concern such questions. The present action concerns the rejection of the individual application for authorisation submitted by the applicants in accordance with the procedure laid down in Articles 14 to 17 of Regulation No 1924/2006.

47 Consequently, the first plea of inadmissibility must be rejected.

Second plea of inadmissibility, alleging lack of *locus standi*

48 The Commission claims that the applicants lack *locus standi*, since the contested regulation is not of direct or individual concern to them.

– Direct concern to the applicants

49 The Commission contends that the contested regulation is not of direct concern to the applicants, since the characterisation of the claim in the contested regulation is of direct concern only to food business operators within the meaning of Regulation No 1924/2006, whom the contested regulation

prohibits from using that claim in the context of their economic activities. It maintains that the applicants have neither asserted that they themselves pursued the activity of food business operator at the time when they brought their action nor stated whether, how, in what context or in respect of which products they themselves, as concerned persons, used the claim at issue. A purely intellectual interest in the structure of Regulation No 1924/2006 and the claim at issue is not sufficient for direct concern to be recognised.

50 Under the fourth paragraph of Article 263 TFEU, any natural or legal person may, under the conditions laid down in the first and second paragraphs of that article, institute proceedings against an act addressed to that person or which is of direct and individual concern to them, and against a regulatory act which is of direct concern to them and does not entail implementing measures.

51 In the present case, the contested regulation was not addressed to the applicants, who are therefore not addressees of that measure. While it is true that the Commission, by letter of 28 November 2011, informed the applicants, pursuant to Article 17(4) of Regulation No 1924/2006, of its definitive decision on the application for authorisation set out in the contested regulation, the fact that it did so does not support the conclusion that the contested regulation was addressed to the applicants. As a regulation has general application and is binding in its entirety and directly applicable in all Member States, pursuant to the second paragraph of Article 288 TFEU, it is not addressed to a particular addressee, but is published in the *Official Journal of the European Union*, in accordance with the second subparagraph of Article 297(2) TFEU. Thus, the contested regulation was published in the Official Journal on 17 November 2011, in accordance with Article 2 of that regulation.

52 In those circumstances, in accordance with the fourth paragraph of Article 263 TFEU, the applicants were entitled to institute proceedings for annulment of the contested regulation only if it was of direct concern to them.

53 As regards direct concern, it has consistently been held that that condition requires, first, that the impugned measure directly affect the individual's legal situation and, second, that it leave no discretion to the addressees of that measure who are entrusted with the task of implementing it, such implementation being purely automatic and resulting from the EU rules alone without the application of other intermediate rules (Case C-386/96 P *Dreyfus* v *Commission* [1998] ECR I-2309, paragraph 43; Case C-486/01 P *Front national* v *Parliament* [2004] ECR I-6289, paragraph 34; and Joined Cases C-445/07 P and C-455/07 P *Commission* v *Ente per le Ville vesuviane* and *Ente per le Ville vesuviane* v *Commission* [2009] ECR I-7993, paragraph 45).

54 It is therefore appropriate to consider whether the contested regulation directly affects the applicants' legal situation.

55 In that regard, it should be borne in mind that the contested regulation is hybrid in nature (see paragraphs 40 to 43 above).

56 First, since it was the legislature's intention that any natural or legal person should be able to submit an application for authorisation under Article 15 of Regulation No 1924/2006 and since the definitive decision rejecting the applicants' application for authorisation is set out in the contested regulation, which constitutes the final point in the authorisation procedure referred to in Articles 14 to 17 of Regulation No 1924/2006, it must be held that the contested regulation has direct effects on the applicants' legal situation. Second, it should be observed that that refusal decision is purely automatic and results from the contested regulation alone without the application of other intermediate rules.

57 Consequently, the contested regulation is of direct concern to the applicants for the purposes of the fourth paragraph of Article 263 TFEU.

– Individual concern to the applicants

58 The Commission claims that the applicants are not individually concerned by the contested regulation, since that regulation, as a legislative measure focusing on substantive rules and not on persons, prohibits all persons from using the claim at issue. In addition, the mere fact of having submitted an application for authorisation to use a claim and having subsequently been involved in an exchange of correspondence with the responsible authorities cannot suffice to confer *locus standi* on an applicant.

59 Under the fourth paragraph of Article 263 TFEU, the present action for annulment is admissible only if the contested regulation is of individual concern to them or if it is a regulatory act which does not entail implementing measures.

60 According to settled case-law, persons other than the addressees of an act cannot claim to be individually concerned unless they are affected by that act by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons and, by virtue of these factors, distinguished individually just as in the case of the person to whom the act is addressed (Case 25/62 *Plaumann* v *Commission* [1963] ECR 95, 107, and *Flaherty and Others* v *Commission*, paragraph 38 above, paragraph 36 and the case-law cited).

61 For the same reasons as those set out at paragraphs 38 to 45 above concerning the interest in bringing proceedings, it must be held that the contested regulation is of individual concern to the applicants. Since they submitted an individual application for authorisation of the claim at issue, it is sufficient to observe that that is a circumstance capable, according to the case-law cited at paragraph 60 above, of differentiating them from all other persons and distinguishing them individually just as in the case of the persons to whom an act is addressed (see, to that effect, *Flaherty and Others* v *Commission*, paragraph 38 above, paragraph 41, and Joined Cases C-463/10 P and C-475/10 P *Deutsche Post and Germany* v *Commission* [2011] ECR I-9639, paragraph 74).

62 It follows from the foregoing that the Commission's argument relating to individual concern to the applicants must be rejected.

63 It follows that the second plea of inadmissibility and, accordingly, the Commission's objection of inadmissibility must be rejected.

Substance

64 In support of their action, the applicants put forward nine pleas in law. The first four pleas allege infringement of EU law owing, first, to the lack of necessity to designate a risk factor; second, to the fact that the Commission did not take the actual designation of a risk factor into account; third, to the fact that the contested regulation is disproportionate; and, fourth, to the lack of sufficient legal basis. The next four pleas allege breach of essential procedural requirements in that the Commission adopted a regulation instead of a decision (fifth plea); failure to have regard to the distribution of powers (sixth plea); failure to adopt a decision within the prescribed period (seventh plea); and failure to take fully into account the comments of the applicants and interested third parties (eighth plea). Last, the ninth plea alleges breach of the obligation to state reasons.

First plea, alleging an error of law owing to the lack of necessity to designate a risk factor

65 The applicants claim that the Commission infringed EU law in that it considered that the designation of a risk factor in the application for authorisation was mandatory, when such a requirement does not result from Regulation No 1924/2006.

66 It follows from recital 6 in the preamble to the contested regulation that the Commission refused to authorise the claim at issue on the ground that it did not comply with the requirements of Regulation No 1924/2006, since a risk factor in the development of a disease was not shown to be reduced. It follows that, in the Commission's submission, authorisation of the claim at issue required the designation by the applicant of a risk factor in the development of a disease. The Commission maintains that such a designation could have been made either in the proposal for the wording of the claim at issue or in the documents accompanying the application for authorisation.

67 The Court must therefore consider whether, when applying for authorisation of the claim at issue, the applicants ought to have designated, in the proposed wording of that claim or in the documents accompanying the application for authorisation, a risk factor in the development of a disease.

68 Under Article 14(1)(a) of Regulation No 1924/2006, reduction of disease risk claims may be made where they have been authorised in accordance with the procedure laid down in Articles 15 to 17 and 19 of that regulation for inclusion in a Union list of permitted claims, together with all the necessary conditions for the use of those claims. Article 15(3) of Regulation No 1924/2006 lists the items that the applicant must include in the application.

69 While it is true that, as the applicants claim, the wording of Article 14(1)(a) and the wording of Article 15(3) of Regulation No 1924/2006 do not mention the words 'risk factor', the fact none the less remains that the concept of 'reduction of disease risk claim' is defined in Article 2(2)(6) of that regulation. According to that definition, that concept includes any risk claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.

70 In that regard, the applicants claim that the concept of 'reduction of disease risk claim', within the meaning of Article 2(2)(6) of Regulation No 1924/2006, must be given a broad interpretation and include any reduction of disease risk suggested or implied, since the legislature did not draw a distinction between that concept and the concept of 'disease risk' within the meaning of Article 14(1)(a) of that regulation, as is also apparent from a Commission press release and from the judgment in Case C-299/12 *Green Swan* [2013] ECR, paragraph 25. In addition, the applicants stress that, according to the general rules of linguistic comprehension and in keeping with practical usage, there is no significant distinction between a risk and a risk factor.

71 That argument must be rejected. The Courts of the European Union have, admittedly, held that a certain element of the concept of health claim, within the meaning of Article 2(2)(5) of Regulation No 1924/2006, namely the 'relationship' that must exist between a food or one of its constituents, on the one hand, and health, on the other, must be given a broad interpretation (Case C-544/10 *Deutsches Weintor* [2012] ECR, paragraph 34). However, it should be observed that, even on the assumption that the legislature did envisage that the concept of 'reduction of disease risk claim', within the meaning of Article 2(2)(6) of Regulation No 1924/2006, should be given a broad interpretation, that would not allow the 'risk factor' element of that concept to be ignored. In addition, if the legislature had envisaged any reduction of a disease risk without relying on the need for a risk factor, it would not have needed to define that concept, which expressly refers to the requirement of a risk factor in the development of a disease. Furthermore, in so far as the applicants refer, in that context, to a Commission press release, it should be observed that such a press release has no legal value in the context of the examination of the present case.

72 As regards the applicants' argument relating to *Green Swan*, paragraph 70 above, it should be observed that, in the part of that judgment to which the applicants refer, the Court of Justice interpreted Article 2(2)(6) of Regulation No 1924/2006 as meaning that, in order to be characterised as a 'reduction of disease risk claim', a health claim need not necessarily state expressly that the

consumption of a category of food, a food or one of its constituents 'significantly' reduces a risk factor in the development of a human disease. As that question is not relevant in the present case, however, the applicants' argument must be rejected.

73 The authorisation of a reduction of disease risk claim, within the meaning of Article 2(2)(6) of Regulation No 1924/2006, therefore requires, first, in addition to the designation of a disease, the designation of a risk factor in the development of that disease and, second, a finding that the consumption of a category of food, a food or one of its constituents significantly reduces that factor.

74 It follows that, in order that the Commission should be able to examine the application for authorisation of the claim at issue, it was necessary for the applicants to designate, in addition to a disease, a risk factor in the development of that disease.

75 Even if it was sufficient for such a designation to emerge, at least implicitly, from the proposed wording of that claim or from the documents accompanying the application for authorisation, the applicants were none the less required to designate a disease and a specific risk factor in the development of that disease which in their view would be significantly reduced. The legislature recognised, in Article 14(2) of Regulation No 1924/2006, that a disease has multiple risk factors. According to that provision, the labelling or, if no such labelling exists, the presentation or advertising is also to bear a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect. Consequently, without a designation of a disease and a specific risk factor by the applicants, the Commission was not in a position to assess what risk factor in the development of what disease would be significantly reduced by the regular consumption of significant quantities of water.

76 Furthermore, it should be observed that, as the Commission claims, such an interpretation of the concept of reduction of disease risk claim ensures compliance with the principle, referred to in Article 14(1) of Regulation No 1924/2006 and Article 2(1)(b) 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), that the labelling and methods used must not attribute to any foodstuff the property of preventing a human disease.

77 The applicants' argument that the Commission was wrong to consider that the designation of a risk factor in the development of a disease was mandatory must therefore be rejected.

78 That conclusion is not affected by the other arguments put forward by the applicants.

79 First, the applicants claim that it was not possible to reject their application for authorisation on the ground that it did not satisfy the requirements of Regulation No 1924/2006 because, under the combined provisions of Article 17(1), Article 16(3) and Article 14(1) of Regulation No 1924/2006, it was for the Commission to ascertain, on the basis of the file relating to the application and EFSA's opinion, whether the claim at issue was based on scientific evidence and whether the wording of the claim at issue satisfied the criteria laid down in that regulation. However, the Commission and EFSA failed to examine the scientific evidence submitted by the applicants during the authorisation procedure. In addition, contrary to the requirements of Article 17(1) of Regulation No 1924/2006, the Commission did not base its decision on either the applicable provisions of the EU legislation or on other legitimate and relevant factors.

80 In that regard, it is sufficient to observe that, in order to be able, on the basis of the application file and EFSA's opinion, to examine the scientific evidence produced by the applicants and then to adopt a definitive decision on that application, taking account of all the applicable provisions of EU legislation and also of other legitimate factors of relevance to the question to be examined, the Commission had to have received an application for authorisation of a reduction of disease risk claim within the

meaning of Article 2(2)(6) and Article 14(1)(a) of Regulation No 1924/2006. As already stated (see paragraph 75 above), such an application required the designation by the applicants of, as well as the disease in question, a specific risk factor in the development of that disease that in their view would be significantly reduced.

81 In so far as the applicants assert in that regard, maintaining that the claim at issue is not misleading, that there is a scientific consensus relating to that claim, so that scientific evidence was not necessary, and that, in order to protect consumers, the Commission was not required to adopt the restriction provided for in the contested regulation, it should be borne in mind that the Commission did not refuse to authorise the claim at issue on the basis of the absence of scientific evidence relating to the relationship between dehydration and the concomitant reduction of performance. Authorisation was refused because a risk factor in the development of a disease was not shown to be reduced, as required according to the system established by Regulation No 1924/2006. In addition, as is apparent from Article 13 of Regulation No 1924/2006, the system established by that regulation permits the authorisation of health claims other than those referring to the reduction of a risk of disease, which do not require the designation of a risk factor. However, that does not apply to the claim at issue. The applicants' argument cannot therefore be accepted.

82 Second, the applicants claim that paragraph 2.2.3 of the Guidelines for use of nutrition and health claims, adopted by the Codex Alimentarius Commission of the United Nations Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) in 1997, as revised in 2004 and most recently amended in 2008 (CAC/GL 23-1997), contains two examples of reduction of disease risk claims that do not expressly refer to a specific risk factor.

83 In that regard, first, it should be observed that it does admittedly follow from recital 7 to Regulation No 1924/2006 that the legislature properly took into account the definitions and conditions set out in those guidelines. However, in order to define the concept of reduction of disease risk claim, the legislature did not merely refer to the definition set out in those guidelines, but included its own definition in Article 2(2)(6) of that regulation. Second, it should be observed that, in defining reduction of disease risk claim, paragraph 2.2.3 of those guidelines refers to the existence of a risk factor. According to that definition, the reduction of the risk means the substantial reduction of one or more significant risk factors in the development of a disease or a specific state. That definition states that diseases have multiple risk factors and that the modification of one of these factors may or may not have a beneficial effect. Consequently, the applicants'' argument must be rejected.

84 Third, the Court must reject the applicants' argument that, in Regulation (EC) No 1024/2009 of 29 October 2009 on the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children's development and health (OJ 2009 L 283, p. 22), the Commission authorised a claim relating to the reduction of a risk of disease concerning the effects of xylitol chewing gum/pastilles on the risk of tooth decay, without considering that the designation of a risk factor was necessary. The claim authorised by the Commission in Regulation No 1024/2009 states clearly that dental plaque was the risk factor taken into account. Furthermore, as the concept of 'reduction of disease risk claim', within the meaning of Article 2(2)(6) of Regulation No 1924/2006, is a legal concept and must be interpreted on the basis of objective factors, it cannot depend on a subjective assessment by the Commission and must be determined independently of any previous practice of the Commission (see, to that effect, Case C-138/09 *Todaro Nunziatina & C.* [2010] ECR I-4561, paragraph 21, and Case T-303/10 *Wam Industriale* v *Commission* [2012] ECR, paragraph 82). Furthermore, it must be borne in mind that the principle of equal treatment cannot be relied upon in order to justify the repetition of an incorrect interpretation of a measure (Case C-313/90 *CIRFS and Others* v *Commission* [1993] ECR I-1125, paragraph 45).

85 The first plea must therefore be rejected.

Second plea, alleging infringement of the law, owing to the Commission's failure to take the actual designation of a risk factor into account

86 The applicants claim that the Commission infringed EU law by failing to take account of the actual designation of a risk factor in the proposals for the wording of the claim at issue. In their letter of 28 November 2008, the applicants already referred to water content in tissues and, following the advice of the Bundesamt in its letter of 18 December 2008, they referred, in their letter of 10 February 2009, to water loss in tissues as a risk factor. Furthermore, the risk factor 'dehydration' already appeared in the proposed wording of the claim at issue in the context of the disease 'lowered performance'. In any event, EFSA and the Commission could have altered the wording of the proposal for the claim at issue, in the exercise of their discretion, or have given that proposal a broad interpretation.

87 First, as regards the applicants' argument that the Commission did not take account of the fact that they had relied on water loss in tissues as a risk factor, it should be observed that EFSA and the Commission did take that designation into account. First, in its scientific opinion of 28 January 2011, EFSA concluded that the risk factors proposed by the applicants, namely water loss in tissues or reduced water content in tissues, were measures of water depletion and thus measures of the disease 'dehydration' referred to by the applicants. Second, according to recital 6 to the contested regulation, following a request for clarification, the applicants proposed water loss in tissues or reduced water content in tissues as risk factors of dehydration. On the basis of EFSA's scientific opinion, the Commission then concluded that a risk factor in the development of a disease had not been shown to be reduced.

88 In that regard, it should be observed that, as the Commission claims and as is also apparent from EFSA's scientific opinion of 28 January 2011, water loss in tissues is not a risk factor for the disease 'dehydration', but describes, rather, the state of dehydration and the existence of that state according to the loss of water found. The Commission was therefore entitled to conclude, at recital 6 to the contested regulation, on the basis of EFSA's scientific opinion, that a risk factor in the development of a disease had not been shown to be reduced because water loss in tissues is a measure of water depletion and, accordingly, a measure of the disease 'dehydration'.

89 As regards, in that context, the applicants' argument that EFSA and the Commission were wrong to take 'dehydration' into consideration as a disease and did not take 'dehydration and [the] concomitant decrease of performance' into consideration as a disease, as indicated in their letter of 28 November 2008, it should be observed that, as the Commission states, a concomitant decrease of performance is not in itself a disease but the consequence or symptom of a disease. Furthermore, in their letter of 28 November 2008, the applicants acknowledged that a decrease of performance was a classic concomitant symptom and a consequence of dehydration. Likewise, in their letter of 25 October 2010, the applicants considered that dehydration constituted a pathological state which was accompanied by a decrease of performance and that the regular consumption of significant amounts of water reduced the risk of development of dehydration, without mentioning the concomitant decrease of performance.

90 As regards the applicants' argument that they designated water loss in tissues as a risk factor on the advice of the Bundesamt, it must be held that the Bundesamt merely indicated, in its letter of 18 December 2008, that it was foreseeable that the applicants would take water loss in tissues into account in order to designate a risk factor. The Bundesamt therefore did not indicate water loss in tissues as a risk factor of the disease 'dehydration'.

91 Second, as regards the applicants' argument that the Commission was wrong not to take the risk factor 'dehydration' into account as a risk factor for the disease 'decrease of performance', which was expressly stated in the proposed wording of the claim at issue, it is sufficient to observe that the applicants, at the request of the Bundesamt in its letter of 10 November 2008, expressly stated, in

their letter of 28 November 2008, that they were referring to the disease 'dehydration and concomitant decrease of performance'. Apart from the fact that decrease of performance cannot be regarded as a disease (see paragraph 89 above), EFSA and the Commission could not therefore regard dehydration as a risk factor within the meaning of Article 2(2)(6) and Article 14(1)(a) of Regulation No 1924/2006.

92 Third, as regards the applicants' argument that EFSA and the Commission ought, in the exercise of their discretion, to have re-worded the proposal for the claim at issue, given that wording a broad interpretation or made the use of the claim at issue conditional on the indication of other factors, it has already been held (see paragraph 75 above) that the applicant is required to designate, at least implicitly, a disease and a specific risk factor in the development of that disease which in its view would be significantly reduced. In the absence of such a designation, independently of the actual wording of the claim at issue, neither EFSA nor the Commission was in a position to assess what risk factor in the development of what disease would be significantly reduced by the consumption of a certain food or one of its constituents. Furthermore, as is apparent from the file, the Bundesamt, EFSA and the Commission drew the applicants' attention on a number of occasions to the requirement to designate a risk factor for the development of a disease (see paragraphs 9, 10, 14 and 15 above).

93 Fourth, in so far as the applicants refer in their reply to insufficient water content as a risk factor, it is sufficient to observe that it follows from a submission made by the applicants in the defence that insufficient water content constitutes, in their view, an additional risk factor that was not referred to in the application for authorisation of the claim at issue.

94 Consequently, the second plea must be rejected.

Third plea, alleging breach of the principle of proportionality

95 The applicants claim that the Commission breached the principle of proportionality in adopting the contested regulation. They maintain that the rejection of the application for authorisation of the claim at issue was neither appropriate nor necessary in order to achieve the aim pursued by Regulation No 1924/2006, namely to ensure the use of health claims having sufficient scientific support. The Commission could have altered the proposed wording of the claim at issue while complying with its essential content. Thus, the Commission could have shown sufficiently clearly in the wording the risk factor which it required. More specifically, the rejection of the application is not appropriate in so far as it was not the purpose of Regulation No 1924/2006 to prohibit communication using health claims that have sufficient scientific support. In addition, the rejection was unnecessary because the relationship described in support of the application for authorisation undeniably had a sufficient scientific basis. Furthermore, the rejection of the application is disproportionate, since it prevents consumers from being provided with information that is substantially incontestable. In the applicants' submission, the contested regulation also adversely affects their freedoms as recognised by Articles 6 and 16 of the Charter of Fundamental Rights of the European Union. Furthermore, the Commission breached the principle of equal treatment, since in the past it has authorised comparable reduction of disease risk claims where no risk factor has been designated.

96 In the first place, as regards the applicants' argument that the Commission breached the principle of proportionality in adopting the contested regulation, it should be observed that the Commission refused to authorise the claim at issue because it failed to satisfy a mandatory requirement of the authorisation procedure laid down in Regulation No 1924/2006. According to recital 6 to the contested regulation, the Commission did not authorise the claim at issue because the applicants had not shown that a risk factor in the development of a disease would be reduced, as the risk factors proposed by them were measures of the disease. As already stated (see paragraph 75 above), an application for authorisation of such a claim required the designation of, as well as the disease in question, a specific risk factor in the development of that disease which in the applicants' view would be significantly

reduced. Furthermore, it follows from the examination of the second plea that the applicants did not designate such a risk factor. In such a case, the Commission was therefore not in a position to assess what risk factor in the development of the disease in question would be significantly reduced by the regular consumption of significant quantities of water. Contrary to the applicants' assertion, the refusal to authorise the claim at issue was therefore not linked to the specific formulation of the proposed wording of the claim at issue. In the absence of a designation of a risk factor by the applicants, any change in the proposed wording of the claim at issue could not in any event have led to the authorisation applied for. Consequently, the applicants' argument that, in adopting the contested regulation, the Commission breached the principle of proportionality must be rejected.

97 That conclusion is not affected by the applicants' assertion that, in the light of Case C-239/02 *Douwe Egberts* [2004] ECR I-7007, an absolute prohibition on publicity exceeds what is necessary to achieve the objective of protecting consumers against fraud. The present case specifically does not concern an absolute prohibition of the claim at issue, but compliance with the requirements of the authorisation procedure referred to in Articles 14 to 17 of Regulation No 1924/2006.

98 Furthermore, in so far as the applicants claim that the rejection of their application was disproportionate because it prevented consumers from being provided with information which was substantially incontestable, it should be borne in mind that Regulation No 1924/2006 also provides, under Article 13, for the authorisation of health claims other than those referring to the reduction of disease risk, which do not require designation of a risk factor and whereby it is possible to draw attention to the positive effect of sufficient consumption of water on the human body and its functions.

99 In the second place, as regards the applicants' argument that the contested regulation breaches the freedoms recognised by Articles 6 and 16 of the Charter of Fundamental Rights, on the right to liberty and security and also to freedom to conduct a business, it should be observed that the applicants merely refer to a breach of those provisions in the abstract in the context of the present plea. A breach of Articles 6 and 16 of the Charter of Fundamental Rights constitutes a separate plea, independent of the present plea, which alleges a breach of the principle of proportionality. In accordance with the first paragraph of Article 21 of the Statute of the Court of Justice of the European Union, applicable to proceedings before the General Court pursuant to the first paragraph of Article 53 of that Statute, and Article 44(1)(c) of the Rules of Procedure, the application is to contain, in particular, a summary of the pleas in law on which it is based. It must thus specify the nature of the plea in law on which the action is based, so that a mere abstract reference to that plea does not satisfy the requirements of the Statute of the Court of Justice or the Rules of Procedure (see, to that effect, Case T-351/05 *Provincia di Imperia* v *Commission* [2008] ECR II-241, paragraph 87 and the case-law cited). It follows that the applicants' argument relating to a breach of Articles 6 and 16 of the Charter of Fundamental Rights must be rejected as inadmissible.

100 In the third place, the applicants' argument that the Commission breached the principles of proportionality and equal treatment in that it has in the past authorised health claims in the absence of designation of any risk factor must be rejected. It is sufficient to observe, first, that the applicants refer to health claims other than those referring to the reduction of disease risk, authorised by the Commission under Article 13 of Regulation No 1924/2006; and it has already been stated (see paragraphs 81 and 98 above) that the authorisation of those claims does not require designation of a risk factor. Second, the applicants refer to the authorisation, in Regulation No 1024/2009, of a claim relating to the reduction of a health risk concerning the effect of xylitol chewing gum/pastilles on the risk of tooth decay. That argument has already been rejected in the context of the first plea (see paragraph 84 above).

101 Consequently the third plea must be rejected.

Fourth plea, alleging lack of sufficient legal basis

102 The applicants claim that the contested regulation must be annulled because it does not have a sufficient legal basis. The contested regulation is based on Article 17(1), read with Article 14(1)(a) and Article 10(1), of Regulation No 1924/2006. In the applicants' submission, those provisions are contrary to EU law in that they constitute a breach of the principle of proportionality, referred to in Article 5(4) TFEU. By the present plea, the applicants therefore raise an objection of illegality against Article 17(1), read with Article 14(1)(a) and Article 10(1), of Regulation No 1924/2006.

103 It should be borne in mind that the principle of proportionality requires that measures adopted by EU institutions should not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question, and where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued (see Case C-174/05 *Zuid-Hollandse Milieufederatie and Natuur en Milieu* [2006] ECR I-2443, paragraph 28 and the case-law cited).

104 As regards judicial review of the conditions referred to in the preceding paragraph, it should be borne in mind that the legal basis of Regulation No 1924/2006 is Article 95 EC, which provides that the legislature is to adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market. Under Article 95(3) EC, the legislature is, in particular in relation to health and consumer protection, to take as a base a high level of protection, taking account in particular of any new development based on scientific facts. In that context, in order to be able to pursue effectively the objective assigned to it, the EU legislature must be allowed a broad discretion in an area such as that involved in the present case, which entails political, economic and social choices on its part and in which it is called upon to undertake complex assessments. Consequently, the legality of a measure adopted in that area can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institution is seeking to pursue (see, to that effect, Case C-491/01 *British American Tobacco (Investments) and Imperial Tobacco* [2002] ECR I-11453, paragraph 123; Case C-210/03 *Swedish Match* [2004] ECR I-11893, paragraph 48; Joined Cases C-453/03, C-11/04, C-12/04 and C-194/04 *ABNA and Others* [2005] ECR I-10423, paragraph 69; Case C-380/03 *Germany* v *Parliament and Council* [2006] ECR I-11573, paragraph 145; and Case T-475/07 *Dow AgroSciences and Others* v *Commission* [2011] ECR II-5937, paragraph 150).

105 As regards the objectives pursued by Regulation No 1924/2006, it should be borne in mind that it is clear from Article 1(1) of that regulation, and from recitals 1 and 36 in the preamble thereto, that the objective of that regulation is to ensure the effective functioning of the internal market as regards nutrition and health claims whilst providing a high level of consumer protection. As stated in recitals 1 and 18 in the preamble to Regulation No 1924/2006, health protection is among the principal aims of that regulation (*Deutsches Weintor*, paragraph 71 above, paragraph 45). Recital 1 in the preamble to Regulation No 1924/2006 states in that regard that products put on the market, including imported products, should be safe and adequately labelled. According to recital 9, the principles established by Regulation No 1924/2006 should ensure a high level of consumer protection, give the consumer the necessary information to make choices in full knowledge of the facts, as well as creating equal conditions of competition for the food industry. In that regard, recital 23 in the preamble to Regulation No 1924/2006 states that health claims should be authorised for use in the European Union only after a scientific assessment of the highest possible standard and that, in order to ensure harmonised scientific assessment of those claims, EFSA should carry out such assessments.

106 In the first place, the applicants claim that the procedure for the authorisation of a reduction of disease risk claim referred to in Article 10(1), Article 14(1)(a) and Article 17(1) of Regulation No 1924/2006, is not a suitable means of enabling the objective of harmonisation of the use of health claims to be achieved whilst ensuring a high level of consumer protection. In the applicants' submission, the EFSA scientific assessment procedure is wholly lacking in transparency and gives inconsistent results.

107 First, in support of that assertion, the applicants emphasise that claims of the type of that at issue cannot be used in the communication intended for consumers, although EFSA has already accepted, in a separate scientific opinion, that the scientific links underlying the claim at issue might be regarded as having sufficient scientific support. Furthermore, in the present case EFSA required the designation of a risk factor, although it did not consider that the designation of such a factor was necessary in another case concerning the effects of xylitol chewing gums/pastilles on the risk of tooth decay, which was approved by the Commission.

108 In that regard, first, it should be observed that the applicants' criticisms relate, in essence, to the way in which the authorisation procedure in question was applied by EFSA. Such factors are not, as such, capable of affecting the legality of the procedure (see, to that effect, Joined Case C-154/04 and C-155/04 *Alliance for Natural Health and Others* [2005] ECR I-6451, paragraphs 87 and 88). Second, it must be stated that the scientific opinion taken into account by the applicants generally relates to the reference dietary values relating to water and that it therefore does not deal with the effects of regular consumption of significant quantities on a disease development risk factor. As regards the argument relating to the alleged inconsistency with the case concerning the effects of xylitol chewing gum/pastilles on the risk of tooth decay, that argument has already been rejected (see paragraph 84 above).

109 Second, in so far as the applicants claim, without providing further details, that the legal framework governing the authorisation procedure in question is inappropriate, since specific provisions relating to the scientific assessment carried out by EFSA are lacking, it is sufficient to observe that Chapter III of Regulation No 178/2002 governs EFSA's working method in detail. In addition, Article 16 of Regulation No 1924/2006 contains provisions relating to EFSA's opinion and, in adopting Regulation No 353/2008, the Commission established rules on the implementation of Article 15 of Regulation No 1924/2006, including rules on the preparation and presentation of an application for authorisation of a reduction of disease risk claim. This argument must therefore be rejected.

110 Consequently, in the light of the applicants' argument, it does not appear that the authorisation procedure for a reduction of disease risk claim, referred to in Article 10(1), Article 14(1)(a) and Article 17(1) of Regulation No 1924/2006, is not a suitable means of enabling the objectives of that regulation to be achieved.

111 In the second place, the applicants claim that the authorisation procedure at issue is not necessary in order to achieve the objectives of Regulation No 1924/2006. That procedure places an absolute prohibition on advertising together with a possibility of authorisation. The freedom of advertising and communication of the persons concerned would be less limited if the principle of the prohibition of abuse, laid down in Article 2 of Directive 2000/13, which was in force until Regulation No 1924/2006 was adopted, were maintained. In the applicants' submission, the legislature could have made use of Article 2(2) of Directive 2000/13, according to which the prohibition of advertising by means of claims linked with a disease could be limited. The provisions of that directive, which enable the use of health claims to be controlled a posteriori at national level, on a case-by-case basis, would have been sufficient. Furthermore, since the scientific criterion remained the same, it is unclear why the objectives of Regulation No 1924/2006 could be better achieved by the examination carried out by EFSA than by that carried out by the national authorities.

112 In that regard, it should be observed that the legislature stated the reasons for the need for Regulation No 1924/2006, and more specifically for the authorisation procedure for health risk reduction claims, in the light of the objectives of that regulation, by the following considerations. At recital 2 in the preamble to Regulation No 1924/2006, the legislature stated that differences between national provisions relating to such claims, which might impede the free movement of foods and create unequal conditions of competition, had a direct impact on the functioning of the internal market. According to recital 10, the use, at national level, of criteria for determining whether a product could be subject to claims was likely to result in barriers to trade within the Union and should therefore be

harmonised. That is further clarified at recital 14 to that regulation, which states that there was a wide variety of claims currently used in the labelling and advertising of foods in some Member States relating to substances that had not been shown to be beneficial or for which there was not sufficient scientific agreement. In that regard, recital 17 to Regulation No 1924/2006 states, first, that scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims and, second, that the food business operators using such claims should justify them. According to that recital, a claim should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence. Furthermore, recital 28 states that, as diet is only one of the many factors influencing the onset of certain human diseases and as other factors may all influence the onset of those diseases, specific labelling requirements should apply in respect of reduction of disease risk claims.

113 Having regard to the applicants' arguments, it does not seem that those considerations are not capable of constituting a ground for the need for the provisions in question relating to the authorisation procedure for reduction of disease risk claims by reference to the objectives of Regulation No 1924/2006. Admittedly, the applicants' freedom of promotion and communication would perhaps have been less limited if the arrangements provided for in Directive 2000/13, which were in force until the adoption of Regulation No 1924/2006, had been maintained. However, having regard to the reasons stated in the recitals referred to at paragraph 112 above, it does not appear that measures adopted on the basis of the arrangements provided for in Directive 2000/13 in the area of reduction of disease risk claims would, by comparison with the objectives referred to at paragraph 105 above, be just as appropriate as the provisions at issue of Regulation No 1924/2006. That is attributable, in particular, to the fact that, owing to the introduction by Regulation No 1924/2006 of the principle of the prohibition of health claims, together with the possibility of authorisation, controls must be carried out before authorisation is given.

114 As regards the fact that the examination of the health claims at issue has been transferred from the national authorities to EFSA, the consideration set out at recital 23 in the preamble to Regulation No 1924/2006, according to which, in order to ensure harmonised scientific assessment, the scientific assessment of the health claims in question should be carried out by EFSA, does not appear to be flawed. Even though the national authorities must apply the same criteria for the purposes of assessing those claims, the fact that the scientific assessments are carried out by a single entity is an additional factor that can ensure harmonisation. Furthermore, as is apparent from Article 22(2), (3) and (6) of Regulation No 178/2002, EFSA's mission is, in particular, to provide scientific advice which constitutes the scientific basis to be taken into account for the drafting and adoption of European Union measures in the fields having a direct or indirect impact on food safety and it is to contribute to a high level of protection of health.

115 The applicants' argument that the procedure for the authorisation of reduction of disease risk claims is unnecessary must therefore be rejected.

116 In the third place, the applicants claim that the authorisation procedure at issue, established by Regulation No 1924/2006, is not appropriate because it imposes on those concerned a long and costly procedure which is also lacking in transparency. The question of a different interpretation by the competent national authorities of the 'sufficient scientific basis' criterion, under the arrangements provided for in Directive 2000/13, could, in their submission, have been addressed by means of the procedure for a reference to the Court of Justice for a preliminary ruling.

117 As regards the assertion that the authorisation procedure at issue is long and non-transparent, it is sufficient to observe that that procedure lays down time-limits and is regulated, in detail, in Articles 14 to 17 of Regulation No 1924/2006. In particular, it is apparent from Article 15(2) of that regulation that an application is to be sent to the national competent authority of a Member State, which is to acknowledge receipt of that application within 14 days of its receipt and is to inform EFSA without delay. Under Article 16(1) of that regulation, EFSA is to give its opinion within five

months of the date of receipt of a valid application and that period may be extended by up to two months whenever EFSA seeks further information from the applicant. Last, in accordance with Article 17(1) of Regulation No 1924/2006, the Commission is to submit to the Committee, within two months after receiving EFSA's opinion, a draft decision on the lists of permitted health claims. Article 17(3) of that regulation provides that the decision on the application is to be adopted in accordance with the regulatory procedure with scrutiny.

118 As regards the applicants' argument that the procedure in question is costly, it should be observed that neither EFSA nor the Commission is reimbursed for the costs of the procedure. Nor have the applicants established that the procedure at issue is excessively costly by reference to the objectives of Regulation No 1924/2006.

119 In the light of the foregoing, the applicants' argument relating to harmonisation by means of the procedure for a reference to the Court of Justice for a preliminary ruling cannot be accepted.

120 Consequently, in the light of the applicants' argument, it is not apparent that the procedure for the authorisation of a health risk reduction claim is inappropriate by reference to the objectives of Regulation No 1924/2006.

121 It follows from the foregoing considerations that Article 10(1), Article 14(1)(a) and Article 17(1) of Regulation No 1924/2006 are not manifestly inappropriate within the meaning of the case-law referred to at paragraph 104 by reference to the objectives that the institutions intend to pursue and that, consequently, those provisions are not unlawful on account of a breach of the principle of proportionality.

122 In so far as the applicants assert in the reply, without providing further details, that there has been an infringement of Article 14(1), Article 15(1) and Article 16 of the Charter of Fundamental Rights, on the right to education and freedom to choose an occupation and to conduct a business, that argument must be rejected as inadmissible. First, the mere abstract reference to such an infringement does not satisfy the requirements of the Statute of the Court of Justice and the Rules of Procedure (see paragraph 99 above). Second, in accordance with the first subparagraph of Article 48(2) of the Rules of Procedure, no new plea in law may be introduced in the course of proceedings unless it is based on matters of law or of fact which come to light in the course of the procedure, which is manifestly not the case here. In addition, the assertion that there has been an infringement of the provisions of the Charter of Fundamental Rights does not constitute an expansion of a plea stated beforehand, directly or implicitly, in the application initiating the proceedings. In any event, it should be observed that the prohibition of a reduction of disease risk claim resulting from the completion of the procedure provided for in Articles 14 to 17 of Regulation No 1924/2006 does not breach the principles of freedom to choose an occupation or the freedom to conduct a business (see, to that effect, *Deutsches Weintor*, paragraph 71 above, paragraphs 42 to 59).

123 The fourth plea must therefore be rejected.

Fifth plea, alleging breach of essential procedural requirements owing to the adoption of a regulation

124 The applicants claim that the Commission has committed a breach of essential procedural requirements by adopting a regulation instead of a decision in order to refuse authorisation of the claim at issue. Under Article 17(1) to (4) of Regulation No 1924/2006, the Commission is required to authorise or reject health claims by means of a decision within the meaning of the first paragraph of Article 288 TFEU. The applicants maintain that the adoption of a regulation is contrary to the structure of the procedure laid down in Article 15 et seq. of Regulation No 1924/2006, because the legislature conceived that procedure as an individual application procedure.

125 The Commission disputes the applicants' arguments. As regards the admissibility of this plea, the Commission claims that it is inadmissible since the applicants did not sustain harm as a result of the legal form of the measure rejecting their application. The applicants also claim that a regulation is also of direct concern to them.

126 The Commission's argument is inconsistent. It cannot, on the one hand, assert that the action is inadmissible and, on the other, rely, in order to demonstrate that the present plea is inadmissible, on the applicants' argument that the action is admissible.

127 However, the present plea is unfounded, as the Commission asserts. It does not follow from Article 17(1) to (4) of Regulation No 1924/2006 that the Commission was required to adopt a decision within the meaning of Article 288 TFEU in order to refuse authorisation of the claim at issue. The use of the word 'decision' in Article 17 of Regulation No 1924/2006 means only that the Commission must make a positive or negative determination of the claim at issue.

128 According to settled case-law, it is necessary, in order to interpret a provision of EU law, to take account of its wording, its context and its aims (see Case C-151/98 P *Pharos* v *Commission* [1999] ECR I-8157, paragraph 19 and the case-law cited). In the present case, while it is true that Article 17(1) to (4) of Regulation No 1924/2006 contains the same word as Article 288 TFEU, the fact none the less remains that the word 'decision' in Article 17 of Regulation No 1924/2006 must be interpreted by reference to the context in which the word is used and the aim pursued by that provision.

129 In that regard, it should be observed that Article 17 of Regulation No 1924/2006 contains provisions relating to the end of the procedure for authorisation of the health claims referred to in Article 14 of that regulation, when EFSA has given its scientific opinion, pursuant to Article 16 of that regulation. Thus, Article 17(1) of Regulation No 1924/2006 provides that, within two months after receiving EFSA's opinion, the Commission is to submit to the Committee a 'draft decision' on the lists of permitted health clams and that, where the 'draft decision' is not in accordance with the opinion, it is to provide an explanation. Paragraph 2 of that article defines the content of the 'draft decision'. Paragraph 3 determines the procedure for the adoption of the 'final decision', including, the 'decision' authorising or not authorising the claim, where, upon a request for the protection of the applicant's proprietary data, the Commission proposes to restrict the use of the claim in favour of the applicant. Article 17(4) of Regulation No 1924/2006 contains the obligation to inform the applicant of the 'decision taken' and the obligation to publish the 'decision' in the Official Journal.

130 It follows from the use of the word 'decision' and, in particular, from the use of the words 'draft', 'final' and 'taken' in the context of the concept of 'decision' that Article 17 of Regulation No 1924/2006 envisages the various stages of the procedure which the Commission must follow in order to deliver a final decision on an application pursuant to Article 14 of that regulation. On the other hand, the regulation is silent as to the legal form of that decision. The choice of the legal form of the measure to be adopted is, rather, left by the legislature to the Commission's discretion. While it is true that it does not follow from Article 17 of Regulation No 1924/2006 that the legislature envisaged that the Commission would adopt a regulation, there is no reason to consider that that provision precludes the adoption of such a measure.

131 Last, the applicants' argument that the adoption of a regulation is contrary to the structure of the procedure provided for in Article 15 et seq. of Regulation No 1924/2006 because the legislature conceived that procedure as an individual application procedure must be rejected. While it is true that the authorisation procedure in question has as its subject-matter an individual application, the fact none the less remains that, in accordance with Article 17(5) of that regulation, the health claims authorised by the Commission may be used by any food business operator. Since that provision produces effects *erga omnes*, the authorisation procedure in question therefore has a dual nature, namely an individual nature and a general nature. It follows that the adoption of a regulation, which is of general application, is not contrary to the structure of the procedure in question.

132 Furthermore, in so far as the applicants claim, in that context, that the Commission was wrong not to mention their address in the contested regulation, it should be observed that such an obligation exists, under Article 17(2), read with Article 16(4)(a) of Regulation No 1924/2006, only in the case of a decision designed to amend the lists of permitted health claims, in accordance with Article 19 of that regulation. That is not the case here.

133 The fifth plea must therefore be rejected.

Sixth plea, alleging failure to have regard to the distribution of powers

134 The applicants claim that the Commission committed a breach of essential procedural requirements in that the distribution of powers between it, EFSA and the Bundesamt was not observed by the Commission during the administrative procedure. In the applicants' submission, under Regulation No 1924/2006 the power to resolve the legal questions of interpretation concerning the scope of that regulation is solely a matter for the Commission, as the Bundesamt is only a 'postbox' for the purpose of lodging an application and EFSA is responsible only for carrying out the scientific analysis of the data provided and the proposal for the wording in the light of the criteria laid down in that regulation. During the administrative procedure EFSA and the Bundesamt ruled on two legal questions, namely the question of the requirement to designate a risk factor and the question of capacity as food business operative in order to be able to submit an application for authorisation of a reduction of disease risk claim, which led to a significant delay in the procedure.

135 In the first place, as regards the argument that the Bundesamt exceeded its powers, it should be observed that, contrary to the applicants' contention, the role of the national competent authority is not merely that of a 'postbox' for the purpose of lodging an application. It is true that the application for authorisation of a reduction of disease risk claim must be lodged with the competent national authority, in accordance with Article 15(2)(a) of Regulation No 1924/2006, which provides that the application is to be sent to the competent national authority of a Member State, which is to acknowledge receipt of that application in writing within 14 days of its receipt, inform EFSA without delay and make the application and any supplementary information supplied by the applicant available to EFSA.

136 However, it follows from the first sentence of Article 16(1) of Regulation No 1924/2006 that responsibility for the existence of a valid application is to be borne, at least equally, by the competent national authority. Under that provision, EFSA is to give its opinion within five months from the date of receipt of a valid application. That assumes that the application forwarded to EFSA by the competent national authority is valid in order to proceed to the next stage in the procedure, namely the drafting of a scientific opinion by EFSA. The application must therefore satisfy the procedural and substantive requirements laid down in Regulation No 1924/2006, and in particular the requirement to designate a risk factor, without which EFSA is unable to give its opinion (see the first plea in that respect).

137 Contrary to the applicants' assertion, that consideration is not contradicted by the second sentence of Article 16(1) of Regulation No 1924/2006, which provides that whenever EFSA asks the applicant to supply supplementary information, as provided for in paragraph 2 of that article, the five-month time-limit is to be extended by up to two months following the date of receipt of the requested information from the applicant. That sentence does not affect the requirement that a valid application must be forwarded by the competent national authority, when the five-month period during which EFSA is then required to give its scientific opinion begins to run.

138 Consequently, the fact that the Bundesamt ruled, during the administrative procedure, on the requirements relating to the validity of the application for authorisation of the claim at issue does not constitute a procedural irregularity.

139 In the second place, as regards the argument that EFSA exceeded its powers in ruling on questions of legal interpretation of the provisions of Regulation No 1924/2006, it should be observed that, in its letters to the first applicant of 23 November 2009 and 27 January 2010, EFSA made clear that it was not competent to interpret the provisions of EU law. It referred in that regard to the Commission and the Member States. Furthermore, in so far as EFSA proceeded, in its scientific opinion, from the principle that the applicants were required to designate a risk factor, it should be observed that it was already apparent from the discussions of the informal working group on nutrition and health claims on 12 April 2010 that the application for authorisation of the claim at issue did not comply with the requirements of Regulation No 1924/2006 because it did not designate a risk factor (see paragraph 14 above). The applicants' argument must therefore be rejected.

140 Even on the assumption that the Bundesamt or EFSA did exceed their powers in ruling on questions of the legal interpretation of Regulation No 1924/2006, it should be borne in mind that a procedural irregularity entails the annulment in whole or in part of a measure only if it is established that in the absence of that irregularity the content of that measure might have been different (see, to that effect, Joined Cases 209/78 to 215/78 and 218/78 *van Landewyck and Others* v *Commission* [1980] ECR 3125, paragraph 47; Case C-142/87 *Belgium* v *Commission* [1990] ECR I-959, paragraph 48; and Joined Cases C-465/02 and C-466/02 *Germany and Denmark* v *Commission* [2005] ECR I-9115, paragraph 37).

141 In the applicants' submission, the Commission failed to exercise its power relating to the legal interpretation concerning the requirement to designate a risk factor, but merely adopted the interpretation set out in EFSA's scientific opinion. They maintain that the Commission would in all likelihood have delivered a positive decision on their application if EFSA had confined itself to exercising its powers.

142 In that regard, first, it should be observed that it is already apparent from the Commission's letter of 9 July 2010 that, according to the discussions of the informal working group on nutrition and health claims on 12 April 2010, it was necessary to designate a risk factor (see paragraph 14 above). Second, there is no indication in the file that the Commission merely adopted EFSA's scientific opinion and failed to interpret itself the requirements laid down in Articles 14 to 17 of Regulation No 1924/2006. On the contrary, the procedure for the authorisation of the reduction of disease risk claim concerning the effects of xylitol chewing gum/pastilles on the risk of tooth decay, to which the applicants refer as an example of the Commission's practice, indicates, rather, that the Commission does not adopt EFSA's scientific opinion in every case. It is apparent from recitals 7 and 8 in the preamble to Regulation No 1024/2009, whereby the Commission authorised that claim, that it revised the wording of that claim after EFSA had given its opinion.

143 Consequently, the applicants have not succeeded in showing that, had the Bundesamt and EFSA not exceeded their powers, as the applicants allege, the content of the contested regulation might have been different.

144 The sixth plea must therefore be rejected.

Seventh plea, alleging failure to comply with the time-limits

145 The applicants claim that the Commission breached essential procedural requirements by failing to comply with the time-limits laid down in Regulation No 1924/2006 for the forwarding of their application for authorisation, the drafting of the scientific opinion and the adoption of the decision relating to their application for authorisation.

146 In the first place, the applicants maintain that, contrary to Article 15(2)(a)(i) and (ii) of Regulation No 1924/2006, the Bundesamt failed to acknowledge receipt of their application for authorisation in writing within 14 days of its receipt and, following the Commission's instruction that it was for the Bundesamt to examine any legal question of interpretation concerning the scope of that regulation, the Bundesamt did not pass that application on to EFSA without delay.

147 In that regard, first, it should be observed that it is apparent from the file that, by letter of 8 May 2008, the Bundesamt acknowledged receipt of the applicants' application submitted on 11 February 2008 (see paragraph 4 above). Even if the starting point of the period in question should be taken to be the re-submission of the application, by letter of 10 March 2008, which was done because, according to the Bundesamt, the application initially submitted could not be found, it must be held that the Bundesamt did not comply with the time-limit of 14 days from receipt of the application within which it was to acknowledge receipt of the application, pursuant to Article 15(2)(a)(i) of Regulation No 1924/2006.

148 Second, as regards the Bundesamt's obligation to forward the applicants' application to EFSA, it should be observed that, pursuant to Article 15(2)(a)(ii) and (iii) of Regulation No 1924/2006, the Bundesamt is, first, to inform EFSA without delay and, second, to make the application and any supplementary information supplied by the applicant available to EFSA. In that regard, it must be held that, unlike the situation concerning the obligation to inform EFSA laid down in Article 15(2)(a)(ii) of Regulation No 1924/2006, no specific time-limit is imposed for forwarding the application and any supplementary information to EFSA pursuant to Article 15(2)(a)(iii) of that regulation.

149 That being the case, it should be borne in mind that, under a general principle of EU law, in the context of EU administrative procedures, a reasonable time must be observed (see, to that effect, Joined Cases T-213/95 and T-18/96 *SCK and FNK* v *Commission* [1997] ECR II-1739, paragraph 56 and the case-law cited). The reasonableness of a period must be assessed in the light of the circumstances specific to each case and, in particular, the importance of the case for the person concerned, its complexity and the conduct of the parties (see, to that effect and by analogy, Joined Cases C-403/04 P and C-405/04 P *Sumitomo Metal Industries and Nippon Steel* v *Commission* [2007] ECR I-729, paragraph 116 and the case-law cited).

150 In the present case, a period of around seven months elapsed between the date on which the application for authorisation of the claim at issue was submitted, namely 11 February 2008, and the date on which it was forwarded to EFSA, namely 15 September 2008. As is apparent from the file and, in particular, from the Bundesamt's letter of 11 November 2008, that period was attributable, first, to the fact that the applicants' application could not initially be found in the competent department of the Bundesamt and, second, to the fact that the Bundesamt, at the Commission's request, examined the validity of the application in question before forwarding it to EFSA.

151 In the circumstances of the present case, that period seems to be excessive. While it is not apparent from the file that the importance of the case for the applicants, who are not food business operators (see paragraph 1 above), was very great, the fact none the less remains that, after the applicants enquired on 29 February 2008 about the state of their application and after the application had been re-sent by letter of 10 March 2008, the Bundesamt, after acknowledging receipt by letter of 8 May 2008, merely drew the applicants' attention to the adoption of Regulation No 353/2008 and asked them to re-submit their application using the forms published by EFSA, by letter of 21 July 2008 (see paragraphs 3 to 7 above). Furthermore, although it is appropriate to take account of the fact that the Commission asked the Bundesamt to forward only valid applications to EFSA and of the fact that responsibility for the existence of a valid application is borne at least equally by the Bundesamt under Regulation No 1924/2006, as already stated (see paragraph 136 above), it must be borne in mind that Article 15(2)(a)(i) and (ii), Article 16(1) and Article 17(1) of that regulation prescribe time-limits for the stages in the authorisation procedure in question. Thus, the national authority must acknowledge receipt of an application within 14 days of its receipt and inform EFSA without delay; EFSA must, in principle, give its opinion within five months; and the Commission must submit to the Committee a

draft decision on the lists of permitted health claims within two months after receiving EFSA's opinion. It follows from the structure of those provisions that examination of the validity of an application by the national authority cannot in any event last seven months. Consequently, the period necessary for the Bundesamt to forward the applicants' application to EFSA does not seem reasonable.

152 In the light of the foregoing, the applicants' argument that the Bundesamt did not comply with the time-limit for acknowledging receipt of their application, or with the time-limit for forwarding the application to EFSA, must be accepted.

153 In the second place, the applicants claim that, contrary to Article 16(1) of Regulation No 1924/2006, EFSA did not comply with the time-limit of five months within which it was to give its opinion, but took 29 months to do so.

154 In that regard, it should be observed that, pursuant to Article 16(1) of Regulation No 1924/2006, EFSA is to give its opinion within a time-limit of five months from the date of receipt of a valid application. In order to be valid, an application must satisfy the procedural and substantive requirements laid down in Regulation No 1924/2006, including the requirement to designate a risk factor, without which EFSA cannot give its opinion (see the first plea in that regard and paragraph 136 above).

155 In the present case, it is apparent from the file that, after forwarding the application to EFSA on 15 September 2008, the Bundesamt asked the applicants, by letters of 10 November 2008 and 18 December 2008, to designate a risk factor. By letter of 10 February 2009, the applicants informed the Bundesamt that there was no need to designate a risk factor, but that reduced water content in tissues could be taken to be a risk factor. In addition, the applicants proposed other forms of wording for the claim at issue, in which water loss in tissues was mentioned as a risk factor (see paragraph 11 above). It follows that in their letter of 10 February 2009 the applicants presented reduced water content in tissues or water loss in tissues as risk factors, which is also apparent from recital 6 to the contested regulation. As other procedural or substantive requirements relating to the validity of the applicants' application are not at issue in the present case, it must be held that the applicants'' application became valid after they had designated risk factors in the letter of 10 February 2009.

156 That consideration is not called into question by the Commission's argument that it was only after the applicants' letter of 25 October 2010 in reply to EFSA's letter of 1 October 2010 that the application became valid and complete. It is apparent from the file that the questions which, during the period between March 2009 and September 2010, prevented EFSA from giving its opinion concerned the legal interpretation of the provisions of Regulation No 1924/2006 and, in particular, the requirement to designate a risk factor (see paragraphs 13 and 14 above). Furthermore, it should be stated that, in answer to EFSA's request, by letter of 1 October 2010, that they specify the risk factor, the applicants merely maintained the position expressed in their letter of 10 February 2009, which, however, did not prevent EFSA from giving its scientific opinion.

157 As is apparent from the file, the applicants' letter of 10 February 2009 was forwarded to EFSA by the Bundesamt by letter of 20 March 2009 (see paragraph 12 above). Consequently, the time-limit of five months laid down in Article 16(1) of Regulation No 1924/2006 began to run on the date of receipt of the Bundesamt's letter of 20 March 2009. As EFSA gave its scientific opinion on 28 January 2011, it did not therefore comply with the time-limit of five months.

158 The applicants' argument relating to failure to comply with the time-limit of five months laid down in Article 16(1) of Regulation No 1924/2006 must therefore be accepted.

159 In the third place, the applicants claim that the Commission did not comply with the time-limit laid down in Article 17(1) of Regulation No 1924/2006 within which it was to adopt the decision relating to the application for authorisation. In that regard, it should be observed that that provision states that the Commission is to submit to the Committee a draft decision on the lists of permitted health

claims within two months after receiving EFSA's opinion. In the present case, EFSA gave its opinion on 28 January 2011 and that opinion was published on 16 February 2011. The submission of a draft decision to the Committee on 28 April 2011 therefore did not comply with the time-limit laid down in Article 17(1) of Regulation No 1924/2006. Consequently, the applicants' argument must be accepted.

160 In the fourth place, as regards the legal consequences of the failure to comply with the time-limits laid down in Article 15(2)(a)(i), Article 16(1) and Article 17(1) of Regulation No 1924/2006, it must be stated that that regulation does not provide for any sanction where the time-limits in question are exceeded. In such a case, it is appropriate to have regard to the case-law according to which, in the absence of a provision setting out either expressly or implicitly the consequences of failure to comply with procedural time-limits such as those in the present case, such a failure can entail the annulment, in whole or in part, of the measure to be adopted within the period in question only if it is shown that, had it not been for such an irregularity, the content of the measure might have been substantively different (see *Dow AgroSciences and Others* v *Commission*, paragraph 104 above, paragraph 203 and the case-law cited).

161 The applicants have not established that if the time-limits in question had not been exceeded the Commission would have adopted a regulation having a different content. They merely claim that the failure to respect the time-limits in question is, in essence, attributable to the improper allocation of powers between the Commission, EFSA and the Bundesamt. In their submission, if the procedure had been conducted correctly, resources would have been available to examine sufficiently the reasons on which their application was based and the Commission would therefore have authorised the claim at issue. In that regard, it should be observed that the questions that prevented EFSA, during the period between March 2009 and September 2010, from giving its opinion concerned the legal interpretation of the provisions of Regulation No 1924/2006, and in particular the requirement to designate a risk factor. However, the designation of a risk factor had already been considered necessary before EFSA's scientific opinion was adopted (see paragraph 155 above).

162 In the light of the foregoing, the seventh plea must be rejected.

Eighth plea, alleging failure to take the comments of the applicants and interested third parties fully into account

163 The applicants claim that the Commission breached essential procedural requirements in that it did not take account, in its decision relating to the authorisation of the allegation at issue, of a significant part of their comments and the comments of interested third parties, in accordance with the second subparagraph of Article 16(6) of Regulation No 1924/2006. In the applicants' submission, the Commission did not respond to the arguments in those comments and the contested regulation does not reveal whether the Commission considered those comments.

164 It should be observed that the applicants claim, generally, that the Commission did not take account of the comments submitted pursuant to the second subparagraph of Article 16(6) of Regulation No 1924/2006. They do not refer, in the context of the present plea, to any particular comment that was not taken into account by the Commission.

165 Under the second subparagraph of Article 16(6) of Regulation No 1924/2006, the applicant or any other person may make comments to the Commission within 30 days from publication of EFSA's scientific opinion. This right implies that the comments will be taken into account in the process leading to the adoption of the final decision on the claim at issue, but does not impose on the Commission an obligation to implement the proposals made in those comments (see, to that effect, order of 5 May 2009 in Case C-355/08 P *WWF-UK* v *Council*, not published in the ECR, paragraph 45).

166 It is apparent from the file that, in addition to the applicants' comments, the Commission received eight comments from interested third parties. As may be seen from the Commission's letters in reply to the persons who submitted those comments, confirming receipt thereof, the Commission informed them of the way in which their comments would be dealt with in the authorisation procedure. Thus, according to those letters, the Commission forwarded the comments relating to matters of risk management and to EFSA's scientific opinion to the competent authorities of the Member States in order to facilitate examination of those questions in the context of the authorisation procedure, in accordance with Article 17 of Regulation No 1924/2006. Furthermore, it is apparent from one of those letters that the Commission responded directly to certain questions raised by an interested third party and from another of those letters that, in so far as the comments related to EFSA's scientific opinion, they were also forwarded to EFSA, which on 30 June 2011 produced a technical report in response to those comments.

167 As shown in the minutes of the meeting of the Committee of 11 July 2011, the comments submitted pursuant to the second subparagraph of Article 16(6) of Regulation No 1924/2006 were examined by the Committee, which unanimously approved the proposal for the contested regulation.

168 In the light of the foregoing, the Commission was entitled to state, at recital 9 in the preamble to the contested regulation and in its letter of 28 November 2011 informing the applicants of its final decision on their application for authorisation, that their comments and the comments of any other person forwarded to the Commission pursuant to the second subparagraph of Article 16(6) of Regulation No 1924/2006 had been considered when it set the measures provided for in the contested regulation during the authorisation procedure.

169 Furthermore, in so far as the applicants claim that the Commission did not forward their comments to EFSA, it is sufficient to state, first, that they provide no evidence on which it might be concluded that it was necessary to forward their comments and, second, that the applicants did not suggest in their comments that their comments should be forwarded to EFSA.

170 It follows that the applicants' argument that the Commission, in its decision relating to the authorisation of the claim at issue, did not take account of a significant part of their comments and the comments of the interested third parties who had intervened in the procedure before the Commission, pursuant to the second subparagraph of Article 16(6) of Regulation No 1924/2006, cannot be accepted.

171 The eighth plea must therefore be rejected.

Ninth plea, alleging breach of the obligation to state reasons

172 The applicants claim that the Commission has breached its obligation to state reasons by failing to address in the contested regulation either their argument that the designation of a risk factor was unnecessary, or the designation of risk factors other than water loss in tissues or reduced water content in tissues, or their comments and the comments of interested of third parties submitted on the basis of the second subparagraph of Article 16(6) of Regulation No 1924/2006.

173 It should be borne in mind that, according to settled case-law, the statement of reasons required by the second paragraph of Article 296 TFEU must be appropriate to the nature of the measure at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in question in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the competent Court to exercise its power of review. The requirement to state reasons must be assessed according to the circumstances of the case. It is not necessary for the reasoning to go into all the relevant facts and points of law, since the question whether the statement of reasons for a measure meets the requirements of the second paragraph of

Article 296 TFEU must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question. In particular, the Commission is not obliged to adopt a position on all the arguments relied on by the parties concerned, but it is sufficient if it sets out the facts and the legal considerations having decisive importance in the context of the decision (See *Dow AgroSciences and Others* v *Commission*, paragraph 104 above, paragraph 246 and the case-law cited).

174 In the present case, recitals 5 and 6 to the contested regulation set out the grounds on which the applicants' application for authorisation of the claim at issue was rejected. Recital 5 states the applicants' names and the proposed wording of the claim at issue. Recital 6 mentions water loss in tissues or reduced water content in tissues as risk factors proposed by the applicants, following a reference to the concept of reduction of disease risk claims set out in Article 2(2)(6) of Regulation No 1924/2006. The Commission also refers in that recital to EFSA's scientific opinion, which states that those factors are measures of water depletion and are thus measures of the disease, and states that as a risk factor in the development of a disease had not been shown to be reduced, the claim at issue did not comply with the requirements of Regulation No 1924/2006 and could not be authorised.

175 That statement of reasons enabled the applicants to ascertain the reasons for the measure that had been adopted and enabled the Court to exercise its power of review. The proposed wording of the claim at issue, the legal rule applied by the Commission and the risk factors proposed by the applicants are clear from those recitals. In addition, it is clearly stated that, according to EFSA's opinion, the risk factors proposed by the applicants were not risk factors within the meaning of Regulation No 1924/2006 and that, consequently, in the absence of evidence that a risk factor in the development of a disease would be reduced, the claim at issue did not comply with the requirements of Regulation No 1924/2006 and could not therefore be authorised.

176 That conclusion is not affected by the applicants' arguments.

177 First, as regards the argument that the statement of reasons did not address the applicants' argument that the designation of a risk factor was not necessary, it is sufficient to observe that, in setting out in recital 6 to the contested regulation the wording of Article 2(2)6) of Regulation No 1924/2006, the Commission sufficiently stated the reason why the designation of a risk factor was required in the present case.

178 Second, as regards the argument that the statement of reasons did not address the other risk factors proposed by the applicants, it has already been held that the only other risk factor which, in the applicants' submission, was also to be found in the proposed wording of the claim at issue was dehydration, as insufficient water content was not mentioned by the applicants as a risk factor in the application for authorisation of the claim at issue (see paragraphs 91 and 93 above). As dehydration was expressly designated by the applicants as the disease in question, EFSA and the Commission could not consider that it constituted a risk factor for the purposes of Article 2(2)(6) and Article 14(1)(a) of Regulation No 1924/2006 (see paragraph 91 above). There was thus no need to provide a specific reason for not qualifying dehydration as a risk factor. The applicants' argument must therefore be rejected.

179 Third, the argument that the statement of reasons did not address the comments submitted by the applicants and interested third parties pursuant to the second subparagraph of Article 16(6) of Regulation No 1924/2006 must be rejected. It is clear from the case-law referred to at paragraph 173 above that the Commission was not required to adopt a position on all the arguments relied on by the persons concerned, but that it was sufficient if it set out the facts and legal considerations having decisive importance in the context of the decision. Accordingly, the Commission was entitled merely to indicate, in recital 9 to the contested regulation, that the comments from the applicants and any other

person received by the Commission pursuant to the second subparagraph of Article 16(6) of Regulation No 1924/2006 had been considered when the measures provided for in the contested regulation were set.

180 That consideration is not affected by the applicants' assertion that the Commission ought to have addressed at least two factors submitted in those comments, namely EFSA's scientific opinion on dietary reference values in relation to water and the Commission's practice in taking decisions. First, as regards that EFSA scientific opinion, it has already been held (see paragraph 108 above) that that opinion did not deal with the effects of the regular consumption of significant quantities of water on a disease development risk factor. Second, as regards the Commission's practice in taking decisions, the applicants refer to authorisations relating to health claims other than reduction of disease risk claims and to a reduction of disease risk claim concerning the effects of xylitol chewing gum/pastilles on the risk of tooth decay. As has already been held (see paragraphs 84 and 100 above), while health claims other than reduction of disease risk claims do not require the designation of a risk factor, in the case of the claim relating to the effects of xylitol chewing gum/pastilles, dental plaque was the risk factor taken into account. It was therefore not necessary for the Commission to address those factors when stating the reasons on which the contested regulation was based.

181 Fourth, the applicants claim that it follows from the preamble to the contested regulation that the Commission did not examine their comments and the comments of interested third parties, but applied globally the considerations set out in EFSA's opinion without undertaking its own examination. In that regard, it should be observed that the obligation to state reasons is a separate issue from that of the merits of the grounds of the contested measure (see *Dow AgroSciences and Others* v *Commission*, paragraph 104 above, paragraph 245 and the case-law cited). The argument relating to the failure to consider the comments submitted by the applicants and interested third parties goes to the substantive legality of the contested regulation and cannot therefore substantiate a breach of the Commission's obligation to state reasons. In any event, it should be observed that that argument has already been rejected when the Court considered the sixth and eighth pleas (see paragraphs 141 and 142 and also paragraphs 163 to 171 above).

182 Last, in so far as the applicants claim that the Commission ought to have stated their address, pursuant to Article 17(2), read with Article 16(4) of Regulation No 1924/2006, it has already been stated (see paragraph 132 above) that no such obligation existed in the present case.

183 The ninth plea must therefore be rejected and, accordingly, the action in its entirety must be dismissed.

Costs

184 Under Article 87(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. In accordance with Article 87(4) of those Rules, the institutions which have intervened in the proceedings are to bear their own costs.

185 As the applicants have been unsuccessful, they must be ordered to bear their own costs and to pay the costs incurred by the Commission, in accordance with the form of order sought by the Commission. The Council must bear its own costs.

On those grounds,

THE GENERAL COURT (Fifth Chamber)

hereby:

1. **Dismisses the action;**

2. **Orders Mr Moritz Hagenmeyer and Mr Andreas Hahn to bear their own costs and to pay the costs incurred by the European Commission;**

3. **Orders the Council of the European Union to bear its own costs.**

Dittrich Schwarcz Tomljenović

Delivered in open court in Luxembourg on 30 April 2014.

[Signatures]