

Reports of Cases

JUDGMENT OF THE GENERAL COURT (Fifth Chamber)

16 March 2016*

(Consumer protection — Regulation (EC) No 1924/2006 — Health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health — Refusal to authorise certain claims in spite of EFSA's positive opinion — Proportionality — Equal treatment — Obligation to state reasons)

In Case T-100/15,

Dextro Energy GmbH & Co. KG, established in Krefeld (Germany), represented by M. Hagenmeyer and T. Teufer, lawyers,

applicant,

v

European Commission, represented by S. Grünheid, acting as Agent,

defendant,

APPLICATION for annulment of Commission Regulation (EU) 2015/8 of 6 January 2015 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (OJ 2015 L 3, p. 6),

THE GENERAL COURT (Fifth Chamber),

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

Registrar: S. Bukšek Tomac, Administrator,

having regard to the written procedure and further to the hearing on 25 November 2015,

gives the following

Judgment

Background to the dispute

- ¹ The applicant, Dextro Energy GmbH & Co. KG, is an undertaking established in Germany which manufactures, under the Dextro Energy brand, products of different formats made almost entirely from glucose for the German and European markets. The 'cube classic' consists of eight glucose tablets, each weighing six grams.
- ² Glucose is a monosaccharide forming part of the group of carbohydrates. According to Article 2(4) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ 2011 L 304, p. 18), read with point 8 of Annex I to that regulation, all monosaccharides and disaccharides present in food, excluding polyols, are sugars.
- ³ Pursuant to Article 13(5) and Article 18 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), the applicant requested the German competent authority, the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (Federal Office for Consumer Protection and Food Safety), to authorise, in particular, the following food health, specifying a target population for each of them:
 - 'Glucose is metabolised within body's normal energy metabolism'; the target population was the general population;
 - 'Glucose supports physical activity'; the target population was healthy active people as well as endurance trained men and women;
 - 'Glucose contributes to normal energy-yielding metabolism'; the target population was the general population;
 - 'Glucose contributes to normal energy-yielding metabolism during exercise'; the target population
 was healthy active people as well as endurance trained men and women;
 - 'Glucose contributes to normal muscle function during exercise'; the target population was healthy active people as well as endurance trained men and women;
- ⁴ In accordance with Article 18(3) of Regulation No 1924/2006, the Bundesamt für Verbraucherschutz und Lebensmittelsicherheit transmitted that request to the European Food Safety Authority (EFSA).
- 5 By letter of 12 March 2012, EFSA asked the applicant to provide further information.
- ⁶ By letter of 26 March 2012 to EFSA, the applicant proposed adding the word 'normal' to the claim 'glucose supports physical activity, before the word 'physical'. In addition, concerning the claim 'glucose contributes to normal muscle function during exercise', it agreed to delete the words 'during exercise'.

- On 25 April 2012, EFSA adopted five scientific opinions relating to the health claims at issue, in accordance with Article 18(3) of Regulation No 1924/2006, read with Article 16(3) of that regulation. In its opinion relating to the claim 'glucose is metabolised within the body's normal energy metabolism', EFSA concluded that, on the basis of the data submitted, a cause to effect relationship had been established between the consumption of glucose and the contribution to energy-yielding metabolism. It also noted that the words 'glucose contributes to energy-yielding metabolism' reflected the scientific evidence and that in order to bear that claim a food should be a significant source of glucose. In that regard, EFSA observed that reference intake values for carbohydrates had been established in Regulation No 1169/2011 and that the target population was the general population.
- 8 As regards the other four health claims, as amended in accordance with the applicant's proposals or accepted by the applicant, EFSA concluded, in its respective scientific opinions, on the basis of the data produced by the applicant, that the effects claimed referred to the contribution of glucose to energy-yielding metabolism, the assessment of which had already led to a favourable outcome.
- ⁹ Following the publication of the five scientific opinions on 11 May 2012, in accordance with Article 16(6) of Regulation No 1924/2006, the British Specialist Nutrition Association ('the BSNA') submitted comments on those opinions to the European Commission on 7 June 2012. By letter of 11 June 2012, the applicant submitted comments on EFSA's scientific opinions concerning the claims 'glucose supports normal physical activity' and 'glucose contributes to normal muscle function'. The Commission forwarded the applicant's comments to EFSA for consideration.
- ¹⁰ On 12 September 2012, EFSA submitted two technical reports in which it examined the applicant's comments on the two scientific opinions concerned.
- On 17 October 2014, the Commission submitted to the representatives of the Member States on the 11 Standing Committee on Plants, Animals, Food and Feed a draft regulation refusing to authorise the health claims applied for by the applicant. That committee was set up under 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), as amended by Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 882/2004, (EC) No 396/2005 and (EC) No 1107/2009 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ 2014 L 189, p. 1). At the meeting of that committee held on 17 October 2014, there was consensus among the Member States on that draft regulation.
- ¹² On 6 January 2015, the Commission adopted Regulation (EU) 2015/8 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (OJ 2015 L 3, p. 6; 'the contested regulation'). Under Article 1(1) of that regulation, read with the annex thereto, the five health claims forming the subject matter of EFSA's scientific opinions referred to in paragraphs 7 and 8 above were not to be included in the EU list of permitted claims, as provided for in Article 13(3) of Regulation No 1924/2006. According to Article 1(2) of the contested regulation, the health claims referred to in paragraph 1 of that article used prior to the entry into force of that regulation could continue to be used for a maximum period of six months after the entry into force of that regulation.

According to recital 14 of the contested regulation, the Commission based its refusal to authorise the five health claims at issue on the following considerations:

'Pursuant to Articles 6(1) and 13(1) of Regulation ... No 1924/2006 health claims need to be based on generally accepted scientific evidence. Authorisation may also legitimately be withheld if health claims do not comply with other general and specific requirements of Regulation ... No 1924/2006, even in the case of a favourable scientific assessment by [EFSA]. Health claims inconsistent with generally accepted nutrition and health principles should not be made. [EFSA] concluded that a cause and effect relationship has been established between the consumption of glucose and contribution to energy-yielding metabolism. However, the use of such a health claim would convey a conflicting and confusing message to consumers, because it would encourage consumption of sugars for which, on the basis of generally accepted scientific advance, national and international authorities inform the consumer that their intake should be reduced. Therefore, such a health claim does not comply with point (a) of the second paragraph of Article 3 of Regulation ... No 1924/2006 which foresees that the use of claims should not be ambiguous or misleading. Furthermore, even if the concerned health claim was to be authorised only under specific conditions of use and/or accompanied by additional statements or warnings, it would not be sufficient to alleviate the confusion of the consumer, and consequently the claim should not be authorised.'

Procedure and forms of order sought

- ¹⁴ By application lodged at the Court Registry on 27 February 2015, the applicant brought the present action.
- ¹⁵ By letter of 24 September 2015, the applicant requested that a hearing be held, in accordance with Article 106(2) of the Rules of Procedure of the General Court.
- ¹⁶ Upon hearing the report of the Judge-Rapporteur, the Court (Fifth Chamber) decided to open the oral procedure.
- ¹⁷ The parties presented oral argument and answered the questions put to them by the Court at the hearing on 25 November 2015.
- ¹⁸ The applicant claims that the Court should:
 - annul the contested regulation;
 - order the Commission to pay the costs.
- ¹⁹ The Commission contends that the Court should:
 - dismiss the action;
 - order the applicant to pay the costs.

Law

In support of its action, the applicant raises four pleas in law, alleging, first, infringement of Article 18(4) of Regulation No 1924/2006; second, breach of the principle of proportionality; third, breach of the principle of equal treatment; and, fourth, breach of the obligation to state reasons.

First plea, alleging infringement of Article 18(4) of Regulation No 1024/2006

- ²¹ The applicant claims that the Commission infringed Article 18(4) of Regulation No 1924/2004 by refusing, in spite of EFSA's positive scientific opinions, to include the five health claims applied for in the EU list of permitted claims referred to in Article 13(3) of that regulation.
- ²² In essence, the first plea consists of five parts. The first alleges failure to comply with the conditions laid down in Article 18(4) of Regulation No 1924/2006 for refusing to include a health claim in the list of permitted claims. The second part relates to the Commission's assessment of the compatibility of the health claims at issue with the generally accepted nutrition and health claims. By the third part, the applicant claims that the Commission was wrong to consider that the use of the health claims at issue would convey a contradictory message to consumers. In the fourth part, the applicant asserts that, contrary to the Commission's findings, the health claims at issue were neither ambiguous nor misleading. Last, the sixth part concerns whether the Commission failed to fulfil its obligation to ascertain whether the health claims at issue could be permitted in specific use conditions or accompanied by additional statements or warnings.

First part, alleging failure to comply with the conditions laid down in Article 18(4) of Regulation No 1924/2006 for refusing to include a health claim in the list of permitted claims

- ²³ The applicant claims that the Commission infringed Article 18(4) of Regulation No 1924/2006 by refusing to include the health claims at issue in the list of permitted claims in spite of the positive scientific opinion issued by EFSA. In general, a claim in respect of which EFSA has provided a positive opinion should be authorised. In the applicant's submission, it is impossible to infer from Article 18(4) of Regulation No 1924/2006 what legitimate and relevant factors the Commission may take into account when taking a decision on an application for the inclusion of a health claim. In the present case, neither requirements of EU law nor legitimate and relevant factors can justify refusing the health claims at issue contrary to EFSA's positive opinion, *a fortiori* because the Commission authorised the use of those claims during a transitional period of six months. In the applicant's submission, in particular, the reasons set out in recital 14 of the contested regulation are neither relevant nor legitimate reasons that would justify rejecting its requests.
- According to Article 18(4) of Regulation No 1924/2006, where EFSA, following scientific assessment, issues an opinion in favour of the inclusion of the claim in the list provided for in Article 13(3) of that regulation, the Commission is to take a decision on the application, taking into account EFSA's opinion, any relevant provisions of EU law and other legitimate factors relevant to the matter under consideration, after having consulted the Member States and within two months of receiving the EFSA's opinion.
- ²⁵ In the first place, as regards the argument that, in general, a claim in respect of which EFSA has issued a positive opinion must be authorised, it should be observed that it is apparent from Article 18(4) of Regulation No 1924/2006 that, in taking a decision on a health claim application, the Commission must take three factors into account, namely, first, the scientific assessment in EFSA's opinion; second, any relevant provisions of EU law; and, third, other legitimate factors relevant to the matter under consideration. As is apparent from the second subparagraph of Article 18(3) of Regulation No 1924/2006, read with Article 16(3) of that regulation, EFSA's opinion does not include the second and third factors mentioned above. According to those provisions, in order to prepare its opinion, EFSA is required only to verify that the health claim is substantiated by scientific evidence and that the wording of the health claim complies with the criteria laid down in Regulation No 1924/2006. In particular, in practical terms, EFSA must ensure that the health claims are based on and substantiated by generally accepted scientific evidence, in accordance with Article 6(1) of that regulation. Consequently, there is no basis on which to conclude that the Commission was required to include the health claims at issue in the list of permitted claims solely because EFSA had issued positive

opinions. Conversely, although, according to recital 17 of Regulation No 1924/2006, scientific substantiation should be the main aspect to be taken into account for the use of nutrition and health claims, when taking a decision in accordance with Article 18(4) of Regulation No 1924/2006, the Commission was also required to take into account any relevant provisions of EU law and other legitimate factors relevant to the matter under consideration. In addition, the fact that the Commission is not obliged to follow EFSA's decision is confirmed by Article 18(5) of Regulation No 1924/2006, under which a health claim may also be authorised where EFSA issues an opinion that does not support the inclusion of the claim in the list referred to in Article 13(3) of that regulation. The applicant's argument must therefore be rejected.

- ²⁶ Nor can the applicant's assertion that neither the requirements of EU law nor legitimate factors relevant to the matter can substantiate the refusal of the health claims at issue against EFSA's positive opinions, especially when the Commission authorised the use of those claims during a transitional period of six months, be upheld. It is a fact that, under Article 1(2) of the contested regulation, the health claims at issue that were used prior to the entry into force of that regulation could continue to be used for a maximum period of six months after the entry into force of that regulation however, it is apparent from recital 16 of the contested decision that the Commission provided for such a transitional period in order to allow both food business operators and the competent national authorities to adapt to the prohibitions of those claims. The fact that provision was made for a transitional period therefore does not undermine the Commission's decision to refuse to authorise the health claims at issue.
- ²⁷ In the second place, the applicant disputes the relevance and legitimacy of the grounds stated in the contested regulation for refusing to include the applicant's claims in the list. It maintains that it cannot be inferred from Article 18(4) of Regulation No 1924/2006 what legitimate and relevant factors the Commission may take into account when taking a decision on an application for inclusion of a health claim, although such factors are also referred to in recital 30 and Article 17(1) of that regulation. Only recital 19 of Regulation No 178/2002 mentions, inter alia, societal, economic, traditional, ethical and environmental factors and the feasibility of controls. However, those aspects played no part in the refusal decision.
- ²⁸ In that regard, first, it should be pointed out that, although the applicant observes that it is not possible to infer from Article 18(4) of Regulation No 1924/2006 what legitimate and relevant factors the Commission may take into account when taking a decision on an application for inclusion of a health claim, it has not raised a plea of illegality against that provision. In fact, it is clear from its arguments that, in the context of the first plea, it has claimed only that there has been an infringement of Article 18(4) of Regulation No 1924/2006.
- ²⁹ Furthermore, even on the assumption that the applicant did intend to raise a plea of illegality against Article 18(4) of Regulation No 1924/2006, its argument would be inadmissible in the absence of any indication of the rule of law that has allegedly been infringed. It should be borne in mind that, under Article 44(1)(c) of the Rules of Procedure of the General Court of 2 May 1991, an application must contain a summary of the pleas in law on which it is based. The information given must be sufficiently clear and precise to enable the defendant to prepare his defence and the Court to rule on the action. While an applicant is not required to state expressly on what specific rule of law his complaint is based, the fact nonetheless remains that his argument must be sufficiently clear for the opposing party and the Courts of the European Union to able to identify that rule without difficulty (see judgment of 20 February 2013 in *Caventa* v *OHIM Anson's Herrenhaus (BERG)*, T-224/11, EU:T:2013:81, paragraphs 14 and 15 and the case-law cited).
- ³⁰ Second, as regards the argument that the grounds for non-inclusion set out in the contested regulation are not relevant and legitimate, it should be borne in mind that, under Article 18(4) of Regulation No 1924/2006, the Commission is to take a decision on the application, taking into account, in addition to EFSA's opinion, any relevant provisions of EU law and other legitimate factors relevant to

the matter under consideration. As is apparent from recital 30 of Regulation No 1924/2006, set out in recital 3 to the contested decision, in some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and other legitimate factors relevant to the matter under consideration should therefore be taken into account. In the light of the foregoing, the Commission must be recognised as enjoying a broad discretion in an area which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments (see, to that effect, judgments of 12 July 2005 in *Alliance for Natural Health and Others*, C-154/04 and C-155/04, ECR, EU:C:2005:449, paragraph 52 and the case-law cited, and of 12 June 2015 in *Health Food Manufacturers' Association and Others* v *Commission*, T-296/12, ECR, EU:T:2015:375, paragraph 65 and the case-law cited).

- ³¹ In accordance with settled case-law, where the European Union authorities have a broad discretion, in particular as to the assessment of highly complex scientific and technical facts in order to determine the nature and scope of the measures which they adopt, review by the Courts of the European Union is limited to verifying whether there has been a manifest error of assessment or a misuse of powers, or whether those authorities have manifestly exceeded the limits of their discretion. In such a context, the Courts of the European Union cannot substitute their assessment of scientific and technical facts for that of the institutions on which alone the FEU Treaty has conferred that task (judgments of 9 September 2003 in *Monsanto Agricoltura Italia and Others*, C-236/01, ECR, EU:C:2003:431, paragraph 135; of 21 July 2011 in *Etimine*, C-15/10, ECR, EU:C:2011:504, paragraph 60; and in *Health Food Manufacturers' Association and Others* v *Commission*, cited in paragraph 30 above, EU:T:2015:375, paragraph 73).
- ³² It is clear from recital 14 of the contested regulation that the Commission refused to authorise the health claims at issue on the ground that health claims inconsistent with generally accepted nutrition and health principles should not be made. According to the Commission, the use of the health claims at issue would convey a conflicting and confusing message to consumers, because it would encourage consumption of sugars for which, on the basis of generally accepted scientific advice, national and international authorities inform the consumer that their intake should be reduced. The Commission therefore considered that the health claims at issue did not comply with point (a) of the second paragraph of Article 3 of Regulation No 1924/2006, which foresees that the use of claims should not be ambiguous or misleading.
- ³³ The applicant's argument does not show that the factors taken into account by the Commission, according to recital 14 of the contested regulation, are not legitimate and relevant to the matter under consideration. It is true that the EU legislature did not indicate the legitimate and relevant factors referred to in Article 18(4) of Regulation No 1924/2006. Recital 30 and Article 17(1) of that regulation also merely mention the obligation to take into account other legitimate factors relevant to the matter under consideration. As the EU legislature has provided no detailed information concerning those factors, they must be determined in each individual case by reference, in particular, to the objective of Regulation No 1924/2006 stated in recital 36 of that regulation, namely to ensure the effective functioning of the internal market as regards nutrition and health claims whilst providing a high level of consumer protection.
- ³⁴ In the present case, it cannot be properly disputed that the generally accepted nutrition and health principles taken into account by the Commission are a legitimate factor relevant to the determination of whether the health claims at issue could be authorised. The fact that those principles are taken into account provides a high level of consumer protection. The relevance of the generally accepted nutrition and health principles to the examination of whether a health claim may be authorised was also expressly referred to by the EU legislature in recital 18 of Regulation No 1924/2006, where it is stated that a nutrition or health claim should not be made if it is inconsistent with those principles.
- ³⁵ Consequently, the first part of the plea must be rejected.

Second part, alleging an error in the assessment of the compatibility of the health claims at issue with the generally accepted nutrition and health principles

- ³⁶ The applicant claims that the Commission infringed Article 18(4) of Regulation No 1924/2006 in that it incorrectly considered that the various health claims at issue were inconsistent with the generally accepted nutrition and health principles. In the applicant's submission, if there was any inconsistency, EFSA would not have delivered positive opinions. The relationships which the applicant establishes in its health claims between a nutritional element, namely glucose, and health are scientifically established. In referring to a scientific opinion delivered by EFSA, relating to the nutritional reference values for the carbohydrate and alimentary fibre content, the applicant claims that the nutritional significance of carbohydrates is generally accepted for scientific purposes, as is the particular importance for human food.
- According to recital 14 of the contested decision, the Commission found that a health claim could not be inconsistent with the generally accepted nutrition and health principles. It observed that, although EFSA concluded that a cause and effect relationship had been established between the consumption of glucose and contribution to energy-yielding metabolism, the use of such a health claim would convey a conflicting and confusing message to consumers, because it would encourage consumption of sugars for which, on the basis of generally accepted scientific advice, national and international authorities inform the consumer that their intake should be reduced.
- ³⁸ In the first place, as regards the applicant's argument that the wording of the different health claims at issue is not inconsistent with generally accepted nutrition and health claims, it must be rejected as ineffective. It follows from recital 14 of the contested regulation that the Commission did not refuse to authorise the different health claims at issue because their wording as such was inconsistent with generally accepted nutrition and health principles. According to the Commission, it is the fact that the use of the health claims at issue would encourage the sugar consumption that is contrary to those principles, because, according to those principles, sugar intake should be reduced.
- ³⁹ In the second place, as regards the applicant's argument that EFSA would not have given positive opinions in relation to the health claims at issue if they had been inconsistent with generally recognised nutrition and health principles, first, it should be observed that EFSA's examination is of only a limited nature. As already stated (see paragraph 25 above), under the second subparagraph of Article 18(3) of Regulation No 1924/2006, read with Article 16(3) of that regulation, in order to prepare its opinion, EFSA is required only to verify that the health claim is substantiated by scientific evidence and that the wording of the health claim complies with the criteria laid down in Regulation No 1924/2006. In particular, in practical terms, EFSA must ensure that the health claims are based on and substantiated by generally accepted scientific evidence, in accordance with Article 6(1) of that regulation. In accordance with Article 2(2)(5) and Article 5(1)(a) of Regulation No 1924/2006, such a scientific risk assessment carried out by EFSA must address the question whether the health claim applied for properly expresses a cause to effect relationship between the consumption of a category of food, a food or one of its components and the beneficial physiological effect stated.
- ⁴⁰ Second, as the Commission asserts, the scientific risk assessment carried out by EFSA must be distinguished from the risk management undertaken by the Commission. Recital 30 of Regulation No 1924/2006 states in that regard that in some cases scientific risk assessment alone cannot provide all the information on which a risk management decision should be based and that other legitimate factors relevant to the matter under consideration should therefore be taken into account.
- ⁴¹ Third, as is apparent from recital 14 of the contested regulation, the Commission has not called into question EFSA's opinions relating to the health claims at issue, according to which a cause to effect relationship had been established between the consumption of glucose and contribution to energy-yielding metabolism. However, in accordance with Article 18(4) of Regulation No 1924/2006, the Commission was required to take into account, in addition to EFSA's scientific assessment, any

relevant provisions of EU law and other legitimate factors relevant to the matter under consideration. The Commission thus took into account, in particular, generally accepted nutrition and health principles which had not formed part of the assessment undertaken by EFSA. The fact that, according to EFSA's opinions, the health claims at issue are scientifically established therefore does not support the conclusion that the Commission erred in finding that the use of a health claim encouraging sugar consumption was inconsistent with generally recognised nutrition and health principles.

- ⁴² In the third place, referring to a scientific opinion delivered by EFSA, relating to the reference nutrition values for carbohydrate and dietary fibre content, the applicant asserts that the health claims at issue are not inconsistent with generally accepted nutrition and health principles, since the nutritional importance of carbohydrates is generally accepted in scientific terms, as is the particular importance of glucose for human food.
- ⁴³ First, it should be stated that, as that EFSA scientific opinion has not been produced before the Court, the applicant's argument cannot show that the Commission was wrong to take the view that a health claim that encouraged the consumption of sugar was inconsistent with generally accepted nutrition and health principles.
- ⁴⁴ Furthermore, while it is true that glucose is important for human food, as the applicant asserts, that cannot undermine the finding in recital 14 of the contested regulation that, on the basis of generally accepted scientific advice, national and international authorities inform the consumer that the consumption of sugars should be reduced and that, consequently, the use of a health claim that encourages the consumption of sugars is inconsistent with generally accepted nutrition and health principles.
- ⁴⁵ Second, in so far as the applicant claims in the reply that the data on which the Commission relied do not permit generalisation as regards glucose, but refer to high levels of added sugars, confectionery and sweetened beverages, the consumption of sweetened beverages by children or foodstuffs with a high content of added sugar and are only partly conclusive, that argument cannot be upheld either.
- ⁴⁶ In fact, when claiming that it is recommended, on the basis of generally accepted scientific opinions, that the consumption of sugars should be reduced, the Commission made clear in its written pleadings that it relied on consensus at international, EU and national level on the need to reduce the consumption of pure sugar and of sugars added to foodstuffs. In that regard, it should be observed that, as the statement of reasons for the contested regulation is sufficient as regards the examination of the consistency of the health claims at issue with generally accepted nutrition and health claims, which, moreover, the applicant does not dispute, the Court may take account of that clarification, provided during the judicial proceedings, of the statement of reasons at issue (see, to that effect, judgment of 3 September 2015 in *Inuit Tapiriit Kanatami and Others* v *Commission*, C-398/13 P, ECR, EU:C:2015:535, paragraph 30 and the case-law cited).
- ⁴⁷ At international level, the Commission referred to a report of a working group of the World Health Organisation (WHO) on Diet, Nutrition and the Prevention of Chronic Diseases, dating from 1989, according to which discussions should be encouraged in order to develop foods low in fat, simple refined sugars and salt. In addition, the Commission referred to a WHO Guideline on sugars intake for adults and children, dating from 2015, which provides recommendation on the intake of free sugars in order to reduce the risk of chronic diseases. According to the definition given in that guideline, 'free sugars' include monosaccharides and disaccharides added to foods and beverages by the manufacturer, cook or consumer, and sugars naturally present in honey, syrups, fruit and fruit juice concentrates. In addition, the Commission referred to the WHO European Food and Nutrition Action Plan 2015-2020, which encourages the adoption of strict measures to limit the global impact on children of any form of marketing of foods high in energy, saturated facts, trans fats, sugar or salt.

- 48 At EU level, the Commission referred, in particular, to the adoption by the High Level Group on Nutrition, Overweight and Obesity of the EU Framework for National Initiatives on Selected Nutrients. That framework seeks to reduce high-calory foods, such as foods containing added sugars. In addition, the Commission referred to the Council conclusions on nutrition and physical activity (OJ 2014 C 213, p. 1), seeking a reduction in the consumption of food containing added sugars.
- ⁴⁹ Last, at national level, the Commission referred, in particular, to the position of the Deutsche Gesellschaft für Ernährung (German Nutrition Society, DGE) on the indicative values of the energy intake of carbohydrates and lipides, dating from 2011, according to which, in Germany, as a significant part of the intake in carbohydrates came from the consumption of monosaccharides and disaccharides used particularly in confectionery and sweetened beverages, a move towards the consumption of products based on whole grain was necessary. In addition, the Commission referred to the national programme 'Nutrition Santé' 2011-2015 of the French Republic, which recommends an increase in the content of complex carbohydrates and a reduction in the intake of sugars, and to the recommendations for the reduction in consumption of sugars, entitled 'Sugar reduction: Responding to the challenge', of the independent executive agency Public Health England, set up by the United Kingdom Ministry of Health, dating from 2014. Last, the Commission referred to the recommendations of the Council of Nordic Ministers, applied in Denmark, Finland and Sweden, which state a maximum value for the consumption of added sugars.
- ⁵⁰ In the light of the foregoing, it cannot be validly argued that there is no consensus at international, EU and national levels on the need to reduce the consumption of sugar. The facts presented by the Commission, referred to in paragraphs 47 to 49 above, show that such consensus exists for the reduction in consumption of both sugars added to food and pure sugar. Since the applicant does not dispute that it is generally recommended that the consumption of added sugars be reduced, it cannot validly assert that such a recommendation does not apply to the consumption of pure sugar. In addition, it is correct that the applicant's products do not constitute either foods with a high hidden added sugar content or sweetened beverages for children. However, it must be borne in mind that the health claims at issue relate specifically to glucose in that it is a sugar (see paragraph 2 above) and that health claims authorised by the Commission may be used, in accordance with Article 17(5) of Regulation No 1924/2006, by any food business operator. In addition, it should be pointed out that the applicant's products are composed almost exclusively of sugar.
- ⁵¹ Consequently, the second part of this plea must be rejected.

Third part, alleging an error relating to the finding of a conflicting and confusing message

The applicant claims that the Commission infringed Article 18(4) of Regulation No 1924/2006 in that 52 it considered that the use of the health claims at issue would convey a conflicting and confusing message to consumers. Contrary to the Commission's assertion, the health claims at issue would not encourage the consumption of sugars. They only describe the effects of glucose in a context of sporting physical activities. In three of the five health claims at issue, well-trained men and women are explicitly mentioned as the target population. For such individuals, sugar consumption has a different significance from that which it has for, for example, groups of particularly sensitive consumers. In the applicant's submission, the mere fact that the authorities have recommended that sugar consumption be reduced does not alter the fact that glucose has the beneficial properties for health referred to by the health claims at issue, irrespective of the fact that, according to the authorities, certain individuals consume too much sugar. In addition, the applicant has been present on the market for around seven decades and the benefits of its products for health are therefore generally accepted. Consumers are not misled as to the meaning of the health claims at issue, nor do they adopt potentially undesirable conduct, such as excessive consumption, because of those claims. In the applicant's submission, an average consumer who is reasonably well informed and reasonably observant and circumspect knows that he must not consume too much sugar. If the Commission's logic is followed, two other claims relating to beverages containing glucose should not have been authorised either.

- ⁵³ It should be borne in mind that the Commission stated, in recital 14 of the contested regulation, that the use of the health claims at issue would convey a conflicting and confusing message to consumers, because it would encourage consumption of sugars for which, on the basis of generally accepted scientific advice, national and international authorities inform the consumer that their intake should be reduced.
- ⁵⁴ The applicant's argument does not show that that consideration is vitiated by an error.
- First, the Commission did not err in taking the view that the use of the health claims at issue would 55 encourage the consumption of sugar. It should be pointed out that, under Article 1(2) of Regulation No 1924/2006, that regulation is to apply to nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer. As stated in recital 10 of Regulation No 1924/2006, foods promoted with claims may be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products to which such nutrients and other substances are not added. This may encourage consumers to make choices which directly influence their total intake of individual nutrients or other substances in a way which run counter to scientific advice (judgment of 6 September 2012 in Deutsches Weintor, C-544/10, ECR, EU:C:2012:526, paragraph 37). As is apparent from recital 19 of Regulation No 1924/2006, the grant of a nutrition or health claim confers a positive image on the foods concerned. Since the use of the health allegations at issue by a food business operator would confer a positive connotation on his products by presenting an advantage and creating a positive image, it cannot be concluded that that image would not encourage the consumption of those products which, according to EFSA's scientific opinions (see paragraphs 7 and 8 above), must be a significant source of glucose to be able to bear those claims.
- As regards, in that respect, the applicant's argument that it has used specific health claims on glucose for years without any noticeable impact on its sales figures, it should be observed that that argument is not substantiated by any evidence. Furthermore, as the Commission asserts, the fact that the applicant's market shares have, according to the applicant, increased continuously indicates rather that the applicant's claims relating to the effect of glucose may have had effects on the sales of its glucose-based products.
- As regards the applicant's argument that it is the target group that matters for the purpose of assessing the health claims at issue, in so far as three of the five claims expressly mention well-trained men and women as the target group, it cannot be accepted either. It is apparent from EFSA's scientific opinions relating to the three claims in question that the alleged effects refer without distinction to the contribution of glucose to the energy-yielding metabolism of all physically active individuals. According to those opinions, energy-yielding metabolism is essential to all functions of the body and to physical activities, including physical exercise and the normal muscular function. The health claims at issue may therefore also be used for glucose-based products intended for the population in general, especially since it has already been noted that health claims authorised by the Commission may be used, in accordance with Article 17(5) of Regulation No 1924/2006, by any food business operator (see paragraph 50 above).
- Second, it is clear on examining the second part of the present plea (see paragraphs 36 to 51 above) that the applicant has not shown that the Commission had been wrong to state, in recital 14 of the contested regulation, that on the basis of generally accepted scientific advice, national and international authorities inform the consumer that their sugar intake should be reduced and that, consequently, the use of a health claim that would encourage consumption of sugars is inconsistent with generally accepted nutrition and health principles. It should therefore be observed that the

Commission did not err in taking the view that the use of the health claims at issue, which would encourage consumption of sugars, although such encouragement is inconsistent with generally accepted nutrition and health principles, would convey a conflicting and confusing message to consumers. That applies *a fortiori* because, according to EFSA's scientific opinions, in order to be able to bear health claims, the products concerned must be a significant source of glucose (see paragraph 55 above). In that regard, it should also be borne in mind that, under Article 5(1)(b)(i) of Regulation No 1924/2006, the use of nutrition and health claims is to be permitted only if the nutrient or other substance for which the claim is made is contained in the final product in a significant quantity as defined in the EU legislation or, where such rules do not exist, in a quantity that will produce the nutritional or physiological effect claimed as established by generally accepted scientific evidence.

- ⁵⁹ As regards, in that respect, the applicant's argument that the average consumer who is reasonably well informed and reasonably observant and circumspect would not consume more sugar by reason of the health claims, because he knows that he must not consume too much sugar, it must be rejected as well.
- Even on the assumption that that were so, it would not deprive the messages conveyed by the health 60 claims at issue of their conflicting and confusing nature as described in paragraph 58 above. Furthermore, it is indeed correct, as the applicant asserts, that under Article 9(1)(l) and Article 30(1)(b) of Regulation No 1169/2011, foods must, in principle, contain a nutrition declaration which must include, in particular, the amount of sugars, under Article 32(4) of that regulation the quantity of sugars may also be expressed as a percentage of the reference intakes referred to in Part B of Annex XIII to that regulation, which states, for sugars, 90 grams for adults (8 400 kilojoules/2 000 kilocalories). However, as the applicant acknowledges, not all foods are required to contain a nutrition declaration. The omission of such a declaration for certain foods is provided for, in particular, in Article 16 of Regulation No 1169/2011. In addition, in accordance with Article 32(2) and (4) of that regulation, it is not compulsory to express the quantity of sugars as a percentage of the reference intakes; it may also be expressed per 100 grams. Even if the average consumer who is reasonably well informed and reasonably observant and circumspect to whom the applicant refers (see, to that effect, judgment of 4 June in Teekanne, C-195/14, ECR, EU:C:2015:361, paragraph 36 and the case-law cited), knew that he must not consume too much sugar, he might therefore be induced to consume more sugar by reason of the health claims, especially since, according EFSA's scientific opinions, in order to bear the health claims at issue, the products concerned must be a significant source of glucose (see paragraphs 55 and 58 above). Furthermore, as regards the applicant's products, it should be pointed out that the consumption of a 'cube classic' consisting of eight tablets, with a unitary weight of 48 grams (see paragraph 1 above), already supplies more than half of the quantity of sugars fixed as the reference intake in Part B of Annex XIII to Regulation No 1169/2011 for adults.
- ⁶¹ Third, in so far as the applicant refers to the authorisation of two other health claims relating to beverages containing glucose, its argument concerns, in essence, an alleged breach of the principle of equal treatment and will therefore be examined in the context of the third plea (see paragraphs 113 and 114 below).
- ⁶² Consequently, the third part must be rejected.

Fourth part, alleging an error relating to the assessment of the health claims at issue as being ambiguous or misleading

⁶³ The applicant claims that the Commission infringed Article 18(4) of Regulation No 1924/2006, in that it considered that the health claims at issue were ambiguous or misleading within the meaning of point (a) of the second paragraph of Article 3 of Regulation No 1924/2006. It maintains that the objective of that provision is to prevent consumers from being the victims of misleading health claims. The only question to arise in connection with the application of that provision is whether the specific reference to health in the health claim in question would mislead consumers. The alleged contradiction to which the Commission refers is therefore irrelevant in the context of the application of point (a) of the second paragraph of Article 3 of Regulation No 1924/2006. In addition, the applicant claims that it is not required to point out unknown recommendations issued by authorities. The failure to mention a recommendation cannot therefore be misleading either.

- ⁶⁴ It should be borne in mind that, according to recital 14 of the contested regulation, the Commission stated that a health claim that would encourage consumption of sugars for which, on the basis of generally accepted scientific advice, national and international authorities inform the consumer that their intake should be reduced, does not comply with point (a) of the second paragraph of Article 3 of Regulation No 1924/2006, which foresees that the use of claims should not be ambiguous or misleading.
- ⁶⁵ In the words of point (a) of the second paragraph of Article 3 of Regulation No 1924/2006, which is in Chapter II of that regulation, on general principles, without prejudice to 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 2006 L 109, p. 29) and to Council Directive 84/540/EEC of 10 September 1094 relating to the approximation of the laws, regulations and administrative provisions of the Member States concerning misleading advertising (OJ 1984 L 250, p. 17), the use of nutrition and health claims is not to be false, ambiguous or misleading.
- ⁶⁶ As regards the interpretation of the words 'ambiguous or misleading' within the meaning of point (a) of the second paragraph of Article 3 of Regulation No 1924/2006, it has already been held that a claim relating to an alcoholic beverage, even if it can be regarded as being substantively inherently correct, which is incomplete and highlights only a certain quality of the product in question, but is silent as to the dangers inherent in the consumption of that product, is ambiguous or even misleading (judgment in *Deutsches Weintor*, cited in paragraph 55 above, EU:C:2012:526, paragraphs 50 to 52). As is apparent from recital 16 of Regulation No 1924/2006, in order to resolve the question whether a claim is misleading or not, it is necessary to refer to the presumed expectations in relation to that claim which an average consumer who is reasonably well informed, and reasonably observant and circumspect, would have (see, to that effect, judgment in *Teekanne*, cited in paragraph 60 above, EU:C:2015:361, paragraph 36 and the case-law cited).
- ⁶⁷ In the present case, it is common ground that the beneficial effect on energy-yielding metabolism is correctly described by the health claims at issue, as the Commission stated in recital 14 of the contested regulation. However, it is clear on examining the second part of the present plea (see paragraphs 36 to 51 above) that the applicant has not shown that the Commission had been wrong to find that the national and international authorities recommended reducing consumption of sugars, on the basis of generally accepted scientific opinions, and that, consequently, the use of a health claim that would encourage glucose intake does not comply with the generally accepted nutrition and health principles. In addition, it has already been pointed out (see paragraph 60 above) that the use of the health claims at issue could encourage the average consumer who is reasonably well informed, and reasonably observant and circumspect, to consume more sugar, in spite of the fact that, on the basis of generally accepted scientific opinions, it is recommended that consumption of sugars be reduced.
- ⁶⁸ Consequently, the health claims at issue highlight a certain quality of such a kind as to enhance energy-yielding metabolism, but are silent as to the fact that, irrespective of the proper functioning of the energy-yielding metabolism, dangers inherent in the consumption of more sugar are neither ruled out nor limited. By highlighting only the beneficial effects for energy-yielding metabolism, the health claims at issue are likely to encourage consumption of sugars and, in fact, to increase the risks for consumer health inherent in the excessive consumption of sugars. In the light of the foregoing, it must be considered that the health claims at issue are incomplete and therefore ambiguous and

misleading, even though the information provided is correct (see, to that effect, Opinions of Advocate General Mischo in *Gut Springenheide and Tusky*, C-210/96, ECR, EU:C:1998:102, points 86 to 90, and of Advocate General Jääskinen in *Neptune Distribution*, C-157/14, ECR, EU:C:2015:460, point 52).

- It is true that, in the judgment in *Deutsches Weintor*, cited in paragraph 55 above, (EU:C:2012:526, 69 paragraphs 50 to 52), the Court examined the ambiguous and misleading nature of a health claim relating to an alcoholic beverage the consumption of which had in itself inherent dangers for everyone, while the consumption of a certain quantity of sugar is not capable of entailing risks for each individual person. As already noted (see paragraph 44 above), glucose is important for human food. However, it should be borne in mind that, if the health claims at issue were authorised, they might be used, in accordance with the conditions applicable to them, by any food sector operator if there use were not restricted in accordance with the provisions of Article 21 of Regulation No 1924/2006, on data protection (see paragraph 50 above). As is apparent from EFSA's scientific opinions on the applications at issue, the claimed effects refer without distinction to the contribution of glucose to the energy-yielding metabolism of all physically active human beings (see paragraph 57 above). While it is true that, for three of the five health claims applied for by the applicant, the target population consists of endurance-trained healthy active men and women (see paragraph 3 above), the fact nonetheless remains that health claims relating to glucose as such may also be used for glucose-based products intended for the population in general. When examining the ambiguous and misleading nature of the health claims at issue, it is therefore appropriate to refer to the average consumer, as is also clear from recital 16 of Regulation No 1924/2006. As the average consumer should, according to generally accepted nutrition and health principles, reduce his consumption of sugars, the Commission did not err in finding that the health claims at issue, which highlight only the beneficial effects for the energy-yielding metabolism, but are silent as to the dangers inherent in the consumption of more sugar, were ambiguous and misleading.
- ⁷⁰ It must also be stated, in the interest of completeness, that, in the light of the legislature's observations in recital 10 of regulation No 1924/2006 (see paragraph 55 above), the use of the health claims at issue might lead consumers to believe that there is a cause to effect relationship only between the consumption of glucose and the proper functioning of the energy-yielding metabolism, whereas such a relationship also exists between other carbohydrates and the proper functioning of the energy-yielding metabolism.
- ⁷¹ Last, as regards the applicant's argument that it was not aware of the recommendations of the national and international authorities relating to the reduction in the consumption of sugars, on the basis of generally accepted scientific opinions, it should be observed that, for the purpose of establishing that the health claims at issue are ambiguous and misleading, the question whether the applicant was aware of the recommendations concerned is irrelevant (see, to that effect, judgment of 10 September 2009 in *Severi*, C-446/07, ECR, EU:C:2009:530, paragraph 62). As already stated (see paragraph 66 above), it is necessary to refer to the presumed expectations in relation to that claim which an average consumer who is reasonably well informed, and reasonably observant and circumspect, would have. The finding that a claim is misleading, within the meaning of point (a) of the second paragraph of Article 3 of Regulation No 1924/2006, does not depend on whether the applicant acted with knowledge of that misleading nature or even intentionally.
- ⁷² Consequently, the fourth part of the plea must be rejected.

Fifth part, alleging failure to examine specific conditions of use or additional statements or warnings

⁷³ The applicant claims that the Commission infringed Article 18(4) of Regulation No 1924/2006, in that it failed to fulfil its obligation to ascertain whether the health claims at issue might be authorised under specific conditions of use or accompanied by additional statements or warnings. The contested regulation does not reveal what specific conditions of use may have been taken into account, or what additional statements or warnings might have made the message less confusing for consumers. In the applicant's submission, the addition of compulsory information designed to draw attention to the international authorities' recommendation that the consumption of sugars should be reduced or controlled might have been sufficient to prevent the message being confusing for consumers, in accordance with the principle of proportionality. As in the case of other health claims, the Commission could also have required the applicant to add information to the effect that an increase in the consumption of sugars could present risks to health, in order to avoid the alleged risk of confusion.

- ⁷⁴ In the first place, as regards the argument that the Commission failed to fulfil its obligation to ascertain whether the health claims at issue might be authorised under specific conditions of use or accompanied by additional statements or warnings, it cannot be accepted. The Commission stated, in recital 14 of the contested regulation, that even if the health claims at issue were to be authorised only under specific conditions of use or accompanied by additional statements or warnings, it would not be sufficient to alleviate the confusion of the consumer, and consequently the claims should not be authorised. Thus, the Commission did examine the possibility of examining the health claims at issue under specific conditions of use or accompanied by additional statements or warnings.
- As regards, in that respect, the applicant's argument that the contested regulation does not reveal what specific conditions of use might have been taken into account, or what additional statements or warnings might have made the message less confusing for consumers, it is sufficient to observe that it is apparent to the requisite legal standard from recital 14 of the contested regulation that, according to the Commission, it was not possible to formulate specific conditions of use or additional statements or warnings in such a way to ensure to a sufficient degree that consumers would not be misled.
- ⁷⁶ In the second place, as regards the applicant's argument that the Commission was wrong to consider that the health claims at issue could not be authorised under specific conditions of use and/or accompanied by additional statements or warnings, it relates, in essence, to the principle of proportionality and will be examined in the context of the second plea (see paragraphs 87 to 91 below). In so far as the applicant claims that in numerous cases the Commission has provided that the authorisation of health claims relating to food products should be subject to certain conditions, such as compulsory advertising, it should be pointed out that that fact is not disputed by the Commission, but that it is of no relevance to the examination of whether the Commission was wrong to consider that the health claims at issue, relating specifically to glucose, could not be authorised under specific conditions of use and/or accompanied by additional statements or warnings.
- ⁷⁷ In light of the foregoing, the fifth part and, consequently, the first plea in its entirety must be rejected.

Second plea, alleging breach of the principle of proportionality

The applicant claims that the Commission breached the principle of proportionality in adopting the contested regulation. It maintains that the refusal decision was neither appropriate nor necessary in order to achieve the objective of Regulation No 1924/2006, namely the use of sufficiently scientifically established health claims. Where there is an absolute prohibition on advertising, it is necessary to undertake a strict review of proportionality, taking account of the fact that Regulation No 1924/2006 provides that applications are to be rejected for non-scientific reasons only exceptionally and for solid reasons. The rule is to align the authorisation decision to the outcome of the extremely long and expensive scientific control procedure. In the applicant's submission, the health claims at issue should have been authorised, at least together with restrictive conditions or references, as a less severe method. In addition, the Commission could have amended or supplemented the wording of the health claims was retained, the alleged deception would have been avoided. In addition, the applicant claims that there has been a breach of its rights as set out in Articles 6 and 16 of the Charter of Fundamental Rights of

the European Union. In the applicant's submission, the refusal decision is also contrary to the objective of Regulation No 1924/2006, under which the protection of consumers against misleading claims must be ensured by the exclusive use of sufficiently scientifically substantiated claims. Last, the Commission's decision is disproportionate, because it prevents consumers from receiving factually indisputable information.

- ⁷⁹ It should be borne in mind that the principle of proportionality requires that acts adopted by EU institutions do not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question; 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 judgment of 9 March 2006 in *Zuid-Hollandse Milieufederatie and Natuur en Milieu*, C-174/05, ECR, EU:C:2006:170, paragraph 28 and the case-law cited).
- ⁸⁰ In the first place, as regards judicial review of the conditions referred to in the preceding paragraph, it should be borne in mind that, pursuant to Article 18(4) of Regulation No 1924/2006, the Commission was to take a decision on the applicant's applications, taking into account, in addition to EFSA's opinion, any relevant provisions of EU law and other legitimate factors relevant to the matter under consideration. As already stated (see paragraph 30 above), the Commission must be recognised as enjoying a broad discretion in an area which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments. 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, judgments in *Alliance for Natural Health and Others*, cited in paragraph 30 above, EU:C:2005:449, paragraph 52 and the case-law cited, and in *Health Food Manufacturers' Association and Others* v *Commission*, cited in paragraph 30 above, EU:T:2015:375, paragraph 65 and the case-law cited).
- It has also been held that the discretion enjoyed by the competent authorities in determining the balance to be struck between freedom of expression and the objective of protecting health varies for each of the goals justifying restrictions on that freedom and depends on the nature of the activities in question (judgment of 12 December 2006 in *Germany v Parliament and Council*, C-380/03, ECR, EU:C:2006:772, paragraph 155; see also judgment of 2 April 2009 in *Damgaard*, C-421/07, ECR, EU:C:2009:222, paragraph 27 and the case-law cited). In application of that case-law, it should also be recognised that the Commission enjoys a broad discretion in relation, specifically, to the commercial use of freedom of expression, especially in advertising messages (see, to that effect, Opinion of Advocate General Jääskinen in *Neptune Distribution*, cited in paragraph 68 above, EU:C:2015:460, point 55).
- As regards, in that respect, the applicant's argument that it is appropriate to undertake a strict control 82 of proportionality where there is an absolute prohibition on advertising, it is indeed true that, under Article 10(1) of Regulation No 1924/2006, health claims are to be prohibited unless they comply with the general requirements in Chapter II of that regulation and the specific requirements in Chapter IV of that regulation and are authorised in accordance with that regulation and included in the lists of authorised claims provided for in Articles 13 and 14 of that regulation. Contrary to the applicant's assertion, however, the introduction by Regulation No 1924/2006 of the principle of the prohibition of those health claims, together with the possibility of authorisation, is not an absolute prohibition of advertising. Furthermore, there are already health claims in existence which the applicant may use. In particular, Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (OJ 2012 L 136, p. 1), as amended by Commission Regulation (EU) No 2015/7 of 6 January 2015 (OJ 2015 L 3, p. 3), provides for authorised health claims for carbohydrate-electrolyte solutions and the effects of carbohydrates on recovery of normal muscle function after strenuous exercise.

- As regards, in that context, the applicant's reference to Article 2(1)(b) of Directive 2000/13 and to the 83 judgment of July 2004 in Douwe Egberts (C-239/02, ECR, EU:C:2004:445) it should be pointed out that, in paragraph 36 of that judgment, the Court of Justice stated that Article 2(1)(a) and (b) of Directive 2000/13 prohibited all statements relating to human diseases, regardless of whether or not they are liable to mislead the consumer, as well as statements which, although not containing any reference to diseases but referring rather to health, prove to be misleading. The Court of Justice also held, in the judgment in *Douwe Egberts* (EU:C:2004:445, paragraph 43), that an absolute prohibition on particulars appearing on the labelling of certain foodstuffs relating to slimming or medical recommendations without an examination on a case-by-case basis of whether they are in fact apt to mislead the buyer would mean that foodstuffs bearing those indications would not be able to be freely marketed in a particular Member State even where those statements are not fraudulent. Since in the present case it was correctly found that the health claims at issue were ambiguous and misleading, the applicant's argument relating to Article 2(1)(b) of Directive 2000/13 and to the judgment in Douwe Egberts (EU:C:2004:445) does not permit the conclusion that a more extensive review of proportionality than that referred to in paragraph 80 above ought to have been carried out.
- ⁸⁴ In addition, contrary to the applicant's assertion, while it is the case that scientific justification should, according to recital 17 of Regulation No 1924/2006, be the main aspect to be taken into account for the use of nutrition and health claims, the fact nonetheless remains that that regulation does not provide that claims are to be rejected on non-scientific grounds only rarely and exceptionally, as is clear from, in particular, Article 18(4) of that regulation. It has already been stated (see paragraph 25 above) that it follows from that provision that, in taking a decision on a health claim application, the Commission must take three factors into account, namely, first, the scientific assessment in EFSA's opinion; second, any relevant provisions of EU law; and, third, other legitimate factors relevant to the matter under consideration.
- ⁸⁵ In the second place, as regards the objectives pursued by the contested regulation, it should be pointed out that the legal basis for that regulation is Article 18(4) of Regulation No 1924/2006. It follows from Article 1(1) and recitals 1 and 36 of Regulation No 1924/2006 that the objective of that regulation is to ensure the effective functioning of the internal market with respect to nutrition and health claims whilst providing a high level of protection for consumers. As stated in recitals 1 and 18 of Regulation No 1924/2006, health protection is among the principal aims of that regulation (judgment in *Deutsches Weintor*, cited in paragraph 55 above, EU:C:2012:526, paragraph 45). According to recital 9 of that regulation, the principles established by that regulation 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. Recital 16 of Regulation No 1924/2006 states that it is important that claims on foods can be understood by the consumer and that it is appropriate to protect all consumers from misleading claims. In that context, it is precisely in order to protect consumers against ambiguous or misleading claims that the Commission refused to authorise the health claims at issue, as is clear from recital 14 of the contested regulation.
- ⁸⁶ In the third place, it should be observed that the applicant's argument does not demonstrate that the contested regulation is manifestly inappropriate by reference to those objectives.
- As regards the applicant's argument that the health claims at issue ought at least to have been authorised accompanied by restrictive conditions or statements, as a less severe method, it should be observed that the applicant has not shown that the Commission was wrong to take the view, in recital 14 of the contested regulation, that that was not possible, because it would not be sufficient to alleviate the confusion of the consumer and, consequently, those claims should not be authorised. As the Commission submits, authorisation of the health claims at issue encouraging the consumption of sugars, accompanied by a compulsory statement inviting, in essence, the consumer to reduce the consumption of sugars or to monitor the quantities of sugar consumed, would convey a contradictory and ambiguous message to consumers. A reference to maximum amounts or to warnings on a product that is a significant source of sugar, and the same time bears a health claim conferring a positive image

on that product, and is therefore seen by consumers as presenting a nutritional or physiological advantage or another health-related advantage, would in itself be contradictory and would not be apt to ensure compliance with generally accepted nutrition and health principles aimed at reducing the consumption of sugars.

- As regards, in particular, the applicant's argument that it was for the Commission to establish that, in the present case, no condition, statement or warning was capable of ensuring sufficient consumer protection, it should be observed, in addition, that in accordance with the third sentence of Article 18(2) of Regulation No 1924/2006, read with Article 15(3)(f) of that regulation, the applicant could have included in its application a proposal for specific conditions for use, which, however, it failed to do.
- Second, in so far as the applicant refers to the case-law of the Court of Justice (judgments of 24 November 1993 in *Keck and Mithouard*, C-267/91 and C-268/91, ECR, EU:C:1993:905; of 9 February 1999 in *van der Laan*, C-383/97, ECR, EU:C:1999:64; and in *Douwe Egberts*, cited in paragraph 83 above, EU:C:2004:445), which states that, where there is a national prohibition on advertising, consumer protection might be sufficiently guaranteed by an appropriate labelling requirement, such as a label ensuring the transparency of offers to consumers, that argument, too, cannot be accepted.
- ⁹⁰ In fact, that case-law concerns national non-harmonised measures. In the present case, it should be borne in mind that the contested regulation has as its legal basis Article 18(4) of Regulation No 1924/2006. The latter regulation is itself based on Article 95 EC, according to which 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. It should be pointed out in that regard that the first subparagraph of Article 168(1) TFEU provides that a high level of human health protection is to be ensured in the definition and implementation of all European Union policies and activities, and that Article 95(3) EC and Article 114(3) TFEU explicitly require that, in achieving harmonisation, a high level of protection of human health should be guaranteed (see judgment in *Alliance for Natural Health and Others*, cited in paragraph 30 above, EU:C:2005:449, paragraph 31 and the case-law cited).
- ⁹¹ Third, the applicant claims that the Commission ought, in the exercise of its discretion, to have reformulated the wording of the proposal for the health claims at issue. According to the applicant, it would only have been necessary to maintain the core of the health claim in the light of its scientific basis. In that regard, it should be pointed out that the applicant does not mention any formulation of the wording of the health claims at issue that the Commission ought to have examined. Furthermore, according to recital 14 of the contested regulation, it was specifically the intrinsic content of the health claims at issue that did not comply with generally accepted nutrition and health principles. The applicant's argument must therefore be rejected.
- ⁹² Fourth, as regards the applicant's argument that the contested regulation undermines the freedoms recognised by Article 6 and 16 of the Charter of Fundamental Rights, on the right to liberty and security and freedom to conduct a business, it should be observed that the applicant merely mentions the breach of those provisions in an abstract manner in the context of the present plea. In fact, 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. Under the first paragraph of Article 21 of the Statute of the Court of Justice of the European Union, which applies to the procedure before the General Court by virtue of the first paragraph of Article 53 of that statute, and Article 44(1)(c) of the Rules of Procedure of the General Court of 2 May 1991, an application is to contain, in particular, a summary of the pleas in law on which the application 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 is a statute of the Statute of the Statute of the Court of Justice or the Rules of Procedure (see judgment of 30 April 2014 in *Hagenmeyer and Hahn* v *Commission*,

T-17/12, ECR, EU:T:2014:234, paragraph 99 and the case-law cited). It follows that the applicant's argument relating to a breach of Articles 6 and 16 of the Charter of Fundamental Rights must be rejected as inadmissible.

- ⁹³ In any event, it should be observed that, while it is true that the prohibition of the health claims at issue imposes certain restrictions on the applicant's business activity in one specific respect, compliance with those freedoms is nonetheless assured in the essential respects. Far from prohibiting the production and marketing of the applicant's products or the advertising of those products, the contested regulation merely controls, pursuant to Article 1(2) of Regulation No 1924/2006, the presentation of the foods in question and the advertising of those products, with the aim of protecting public health, which constitutes an objective of general interest justifying a restriction of a fundamental freedom (see judgment in *Deutsches Weintor*, cited in paragraph 55 above, EU:C:2012:526, paragraph 49 and the case-law cited). Thus, the refusal to authorise the health claims at issue does not in any way affect the actual substance of the freedoms recognised by Articles 6 and 16 of the Charter of Fundamental Rights and must be regarded as complying with the requirement that is intended to reconcile the various fundamental rights involved and to strike a fair balance between them (see, to that effect, judgment in *Deutsches Weintor*, cited in paragraph 55 above, EU:C:2012:526, paragraphs 56 to 59).
- ⁹⁴ Fifth, in so far as the applicant claims that the rejection of its application was disproportionate, because it was prevented from imparting to consumers indisputable factual information relating to physical and muscular activity, it should be borne in mind that, according to recital 9 of Regulation No 1924/2006, the principles established by that regulation were to 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. It has already been stated that the health claims at issue give only incomplete information, and specifically do not allow an average consumer who is reasonably well informed and reasonably observant and circumspect to make choices in full knowledge of the facts, and, moreover, a health claim relating to the effects of carbohydrates on recovery of normal muscle function after strenuous exercise has already been authorised (see paragraph 82 above). The applicant's argument must therefore be rejected.
- ⁹⁵ In so far as, in the reply, the applicant refers to the freedom of information recognised by Article 11 of the Charter of Fundamental Rights, it should be observed that a breach of that provision was not claimed in the application and that a plea alleging such a breach must therefore, in the absence of any justification for submitting it at the stage of the reply, be rejected as inadmissible, in application of Article 48(2) of the Rules of Procedure of 2 May 1991. Furthermore, the possibility for the consumer to obtain information on the effects of glucose does not depend on the use of the health claims forming the subject matter of the present action.
- ⁹⁶ Sixth, as regards the applicant's argument that the refusal to authorise the health claims at issue was not appropriate, because it did not contribute to reducing the consumption of sugars, it has already been stated (see paragraph 55 above) that foods promoted with claims might be perceived by consumers as having a nutritional, physiological or other health advantage over similar or other products to which such nutrients and other substances had not been added. Consumers may thus be induced to make choices that have a direct impact on the total quantities of the different nutrients or other substances which they absorb, in a manner that runs counter to the relevant scientific opinions. That argument cannot therefore be accepted.
- 97 Consequently, the second plea must be rejected.

Third plea, alleging breach of the principle of equal treatment

- ⁹⁸ The applicant claims that, in refusing to authorise the health claims at issue, the Commission breached the principle of equal treatment. According to the applicant, the Commission has already authorised comparable claims relating to the contribution of vitamins and mineral salts to energy-yielding metabolism without indicating maximum amounts or warnings. In addition, the Commission has authorised different claims relating to foods the excessive consumption of which is not recommended, such as meat and fish, fructose, lactulose and olive oil polyphenols. In addition, the Commission included in the list of authorised health claims two health claims relating to carbohydrate and electrolyte solutions and also another claim relating to carbohydrates. Last, the applicant claims that the Commission has authorised two health claims for glucomannan (konjac mannan), although the consumption of that food is liable to cause choking followed by sudden death.
- ⁹⁹ It has consistently been held that the principle of equal treatment requires that comparable situations are not treated differently and that different situations are not treated in the same way, unless such treatment is objectively justified (see judgments in *Alliance for Natural Health and Others*, cited in paragraph 30 above, EU:C:2005:449, paragraph 115 and the case-law cited, and in *Health Food Manufacturers' Association and Others* v *Commission*, cited in paragraph 30 above, EU:T:2015:375, paragraph 113 and the case-law cited).
- ¹⁰⁰ In the first place, as regards the claims relating to the contribution of vitamins and mineral salts to energy-yielding metabolism, it is true that, as the applicant claims, according to the annex to Regulation No 432/2012 containing the list of authorised health claims, the Commission authorised, without determining conditions for the use of the food or restrictions on that use, or requiring additional statements or warnings, health claims relating to the fact that pantothenic acid, biotin, calcium, copper, iron, iodine, magnesium, magnesium, niacin, phosphorus, riboflavin (vitamin B2), thiamine, vitamin B6, vitamin B12 and vitamin C contribute to normal energy-yielding metabolism.
- ¹⁰¹ However, the applicant does not show to what extent the authorisation of the health claims relating to those vitamins and minerals is comparable with the present case. The mere fact that in both cases the health claim concerns the contribution of a substance to normal energy-yielding metabolism is not sufficient in that respect. As the Commission asserts, glucose is a different nutrient from vitamins and minerals. While it is permissible to consider that a normal balanced food supplies vitamins and minerals in only a limited quantity, glucose is by its nature a basic substance contained in a large number of foodstuffs and is absorbed by the body following the breakdown of the carbohydrates. In so far as the applicant asserts that excessive consumption of vitamins and minerals may in certain cases have harmful effects for health, it has not provided clarification of those cases and has therefore not shown that a comparable situation exists in the present case.
- ¹⁰² Furthermore, as regards the applicant's argument that the health claims authorised in relation to vitamins and minerals are also used for foods containing sugar, it is sufficient to observe that those claims do not concern effects of sugar, and there is thus no comparable situation in the present case.
- ¹⁰³ In the second place, as regards its arguments relating to the authorisation of various claims referring to foods the excessive consumption of which is discouraged, first, the applicant claims that the Commission has authorised a health claim relating to fish and meat, although it is generally accepted that consumers in the European Union consume too much meat and that they should not eat it on a daily basis.
- ¹⁰⁴ In that regard, it should be observed that, according to the annex to Regulation No 432/2012, the Commission has authorised the health claim that meat and fish contribute to improving the absorption of iron where they are consumed with other foods containing iron. That claim can be used

only for a food containing at least 50 grams of meat or fish in a single quantified portion. The claim may be used if the consumer is informed that the beneficial effect is obtained by consuming 50 grams of meat or fish together with food(s) containing non-haem iron.

- ¹⁰⁵ By its arguments, the applicant does not show that the Commission breached the principle of equal treatment. First, the applicant does not substantiate its assertion concerning the existence of recommendations generally advising against the consumption of too much meat or fish. Although it refers in the reply to certain studies, it should be pointed out that those studies have not been produced. In addition, it must be stated that, while glucose is a nutrient, the meat and fish to which the authorised health claim relates are, as the Commission confirms, foods rich in nutrients and, consequently, completely different from glucose. In the light of the foregoing, there is no comparable situation in this instance.
- ¹⁰⁶ Second, as regards the applicant's argument relating to fructose, it should be stated that, according to the annex to Regulation No 432/2012, the Commission has authorised the health claim that the consumption of foods containing fructose causes a rise in blood glucose lower than that caused by the consumption of foods containing sucrose or glucose. That claim may be used for foods or sweetened beverages in which the glucose and/or sucrose are replaced by fructose, so that the glucose and/or sucrose content of those foods or beverages is reduced by at least 30%.
- ¹⁰⁷ That argument does not demonstrate a breach of the principle of equal treatment. As the Commission asserts, the health claim relating to fructose refers to the replacement of glucose and/or sucrose by fructose in order to reduce the increase in blood glucose. Since that entails the replacement of one sugar by another, the effect of which is to limit the increase of blood glucose, there is no risk of an overall increase in the consumption of sugars as a result of the authorisation of that claim. There is thus no comparable situation in this instance.
- ¹⁰⁸ Third, as regards the applicant's argument relating to lactulose, it should be stated that, according to the annex to Regulation No 432/2012, the Commission authorised the health claim that lactulose contributes to an acceleration of intestinal transit. That claim may be used only for food which contains 10 grams of lactulose in a single quantified portion. The claim may be used if the consumer is informed that the beneficial effect is obtained with a single serving of 10 grams of lactulose per day.
- ¹⁰⁹ That argument, too, does not show that the Commission breached the principle of equal treatment. As the Commission asserts, the health claim authorised in relation to lactulose refers to the laxative effect of that synthetic disaccharide consumed in limited quantities. That claim is authorised only for a precise dose of lactulose necessary to obtain that effect, of which consumers must also be informed. Given that laxative effect obtained when even a limited quantity of lactulose is consumed, there is no comparable situation in this instance.
- ¹¹⁰ Fourth, as regards the applicant's argument relating to olive oil polyphenols, it should be stated that, according to the annex to Regulation No 432/2012, the Commission authorised the health claim that olive oil polyphenols contribute to the protection of blood lipids from oxidative stress. That claim may be used only for olive oil which contains at least 5 milligrams of hydroxytyrosol and its derivatives (for example, oleuropein complex and tyrosol) per 20 grams of olive oil. The claim may be used if the consumer is informed that the beneficial effect is obtained with a daily intake of 20 grams of olive oil.
- ¹¹¹ The applicant's argument does not show that the Commission breached the principle of equal treatment by treating comparable situations differently without objective justification. The applicant does not show that it is recommended, on the basis of generally accepted scientific opinions, that the intake of olive oil polyphenols should be reduced, as is the case for the consumption of sugars. Furthermore, it is true, as the applicant asserts, that the quantity of 20 grams of olive oil represents

around 30% of the reference quantity for total intake of fat referred to in Part B of Annex XIII of Regulation No 1169/2011, which is 70 grams. However, such an argument does not demonstrate the existence of comparable situations in this instance.

- ¹¹² In the third place, the applicant claims that the Commission breached the principle of equal treatment by including in the list of authorised health claims two health claims relating to carbohydrate-electrolyte solutions and another claim relating to carbohydrates.
- ¹¹³ First, as regards the two health claims relating to carbohydrate-electrolyte solutions, it should be stated that, according to the annex to Regulation No 432/2012, the Commission authorised the health claim that carbohydrate-electrolyte solutions contribute to the maintenance of endurance performance during prolonged exercise and the health claim that those solutions enhance the absorption of water during physical exercise. In order to bear those claims, the carbohydrate-electrolyte solutions must contain 80 to 350 kilocalories per litre from carbohydrates and at least 75% of the energy should be derived from carbohydrates which induce a high glycaemic response, such as glucose, glucose polymers and sucrose. In addition, those beverages should contain between 20 milliosmols per litre (460 milligrams per litre) and 50 milliosmols per litre (1 150 milligrams per litre) of sodium, and have an osmolality between 200 and 330 milliosmols per kilogram of water.
- In that regard, it should be stated that the two authorised health claims do not relate to glucose as such, but to carbohydrate-electrolyte solutions, which are products specifically used in a context of prolonged endurance exercise and physical exercise. Furthermore, while it is true that, for three of the five health claims applied for by the applicant, the target populations is healthy endurance trained men and women (see paragraph 3 above), the fact nonetheless remains that health claims relating to glucose as such, which are authorised by the Commission, may also be used by any food business operator for glucose-based products intended for the population in general, in accordance with Article 17(5) of Regulation No 1924/2006. In that regard, it must be stated that it is apparent from the applicant's advertising of its products, submitted by the Commission, that children and schoolchildren are also part of the target population. Furthermore, it should be observed that the applicant may use the two health claims authorised for its products, if the conditions of use are satisfied. In the light of the foregoing, there is no different treatment of comparable situations. The applicant's argument must therefore be rejected.
- ¹¹⁵ Second, as regards the health claim relating to carbohydrates, it should be observed that, according to the annex to Regulation No 432/2012, the Commission authorised the health claim that carbohydrates contribute to the recovery of normal muscular function (contraction) after highly intensive and/or long-lasting physical exercise causing muscular fatigue and the depletion of homocysteine stores in skeletal muscle. The claim may be used only for food which provides carbohydrates which are metabolised by humans (excluding polyols). Information is to be given to the consumer that the beneficial effect is obtained with the consumption of carbohydrates, from all sources, at a total intake of 4 grams per kilogram of body weight, at doses, within the first 4 hours following highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle, and no later than 6 hours after that exercise. The claim may be used only for foods intended for adults who have performed highly intensive and/or long-lasting physical exercise leading to muscle fatigue and the depletion of glycogen stores in skeletal muscle.
- ¹¹⁶ While it is true, as the applicant asserts, that glucose is a carbohydrate, the fact nonetheless remains that the health claims applied for by the applicant refer to normal energy-yielding metabolism during physical exercise, without specifying the intensity or the duration of that exercise or describing the particular physiological processes of the metabolism of sportspeople, unlike the case for the health claim authorised for carbohydrates. As already stated (see paragraph 88 above), in its application for authorisation, the applicant could have proposed specific usage conditions for the health claims applied for, but failed to do so. Furthermore, it should be observed that the applicant may use that authorised

health claim for its products, if the conditions for use are satisfied. Consequently, in the absence of comparable situations, it cannot be concluded that the Commission has breached the principle of equal treatment.

- ¹¹⁷ In the fourth place, the applicant claims that the Commission has authorised two health claims for glucomannan (konjac mannan), although the consumption of that food may cause choking followed by sudden death.
- 118 It should be stated that, according to the annex to Regulation No 432/2012, the Commission authorised the health claim that glucomannan (konjan mannan) contributes to the maintenance of normal blood cholesterol levels and the claim that glucomannan (konjan mannan) in the context of an energy restricted diet contributes to weight loss. It is true that the use of those health claims was authorised by the Commission only with a warning of the risk of choking for people with swallowing difficulties or when ingested with inadequate fluid intake. Consumption with plenty of water is advised in order to ensure that the substance reaches the stomach. However, since it is apparent from an EFSA opinion on that substance that the substance is not found naturally in foods, but is a food additive used as an emulsifier and thickener and that it is also consumed in the form of food supplements, which the applicant does not dispute, it is impossible to establish different treatment of comparable situations.
- ¹¹⁹ In the fifth place, the Court must reject the applicant's argument, put forward at the hearing, relating to a draft regulation concerning a claim for caffeine must be rejected. The applicant has not established that the draft regulation has been adopted by the Commission; and, as it failed to produce that document, the applicant has not in any way demonstrated the existence of a comparable situation in this instance.
- Last, it should be observed that it is clear from recital 12 of Regulation No 432/2012 that the Commission refused to authorise a claim on the effect of fats on the normal absorption of fat soluble vitamins and another claim on the effect of sodium on the maintenance of normal muscle function, essentially for the same reasons as those stated in recital 14 of the contested regulation for the health claims applied for by the applicant. Furthermore, as regards the Commission's treatment of sugars, it should be stated that it is clear from the annex to Regulation No 432/2012 that a health claim relating to carbohydrates was authorised only accompanied by specific conditions of use limiting its use to foods that comply with the nutrition claims 'low in sugars' or 'with no added sugars' defined in the annex to Regulation No 432/2012, the measures provided for in that regulation were not opposed by either the European Parliament or the Council, namely the institutions that adopted Regulation No 1924/2006.
- ¹²¹ Consequently the third plea must be rejected.

Fourth plea, alleging breach of the obligation to state reasons

The applicant claims that the Commission has not sufficiently complied with its obligation to state reasons. The contested regulation does not make clear the arguments contained in the comments submitted by the applicant and the BSNA or the form in which the Commission took those arguments into consideration. The purely formal refusal gives the impression that the Commission did not take them into account. Nor is it apparent from the contested regulation that the Commission differentiated between the different target groups of persons. In the applicant's submission, the contested regulation shows, rather, that the Commission did not sufficiently check the comments submitted by the applicant and by the BSNA. The incomplete reasoning in the contested decision does not disclose how the Commission addressed the arguments put forward in those comments. Nor did the Commission explain the reason why the authorisation of the health claims at issue, accompanied either by special conditions or by additional explanations or warnings, could not constitute a less strict measure.

- 123 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 act 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 required 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 judgment in *Hagenmeyer and Hahn* v *Commission*, cited in paragraph 92 above, EU:T:2014:234, paragraph 173 and the case-law cited).
- 124 First, as regards the applicant's argument that the statement of reasons for the contested regulation does not make clear the arguments contained in the comments submitted by the applicant and by the BSNA or the form in which the Commission took those arguments into consideration, it should be observed that recital 17 of the contested regulation states that the comments from the applicant and the members of the public received by the Commission pursuant to Article 16(6) of Regulation No 1924/2006 were considered when setting the measures provided for in the contested regulation. Those reasons satisfy the requirements laid down in the case-law referred to in paragraph 123 above. In fact, it follows from that case-law that the Commission was not required to adopt a position on all the arguments relied on by the parties concerned, but that it was sufficient for it to set out the facts and the legal considerations having decisive importance in the context of the decision (see, to that effect, judgment in Hagenmeyer and Hahn v Commission, cited in paragraph 92 above, EU:T:2014:234, paragraph 179). In the present case, the reasons for rejecting the applications for authorisation of the health claims at issue are stated in recitals 4 to 14 of the contested regulation, which set out the applicant's applications, EFSA's conclusions on the different health claims at issue and the different risk management considerations, on the basis of which the authorisations were ultimately not granted, in spite of EFSA's favourable positions. That statement of reasons enabled the applicant to ascertain the reasons for the measure that had been adopted and enabled the Court to exercise its power of review.
- ¹²⁵ Second, as regards the applicant's argument that the Commission did not sufficiently ascertain, in an independent fashion, the comments submitted by the applicant and by the BSNA, 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 act. The argument relating to the failure sufficiently to consider the comments submitted by the applicant and interested third parties goes to the substantive legality of the contested regulation and cannot therefore substantiate a breach of the obligation to state reasons (see, to that effect, judgment in *Hagenmeyer and Hahn* v *Commission*, cited in paragraph 92 above, EU:T:2014:234, paragraph 181 and the case-law cited). In any event, the fact that the Commission considered that the applicant's comments were of a scientific nature and the fact that it thus forwarded them to EFSA so that the latter could adopt a position (see paragraph 9 above), although it did not forward to EFSA the comments submitted by the BSNA, support the conclusion, in the absence of any factor capable of substantiating the applicant's argument, that the Commission sufficiently examined all the comments received pursuant to Article 16(6) of Regulation No 1924/2006.

- Third, in so far as the applicant claims that there has been a breach of the obligation to state reasons in that it is not apparent from the contested regulation that the Commission differentiated between the various target groups of persons, its argument must also be rejected. Recitals 5, 7, 9, 11 and 13 of the contested regulation refer to EFSA's scientific opinions relating to the health claims at issue, which take into account the target population, indicated by the applicant, of each health claim applied for. Furthermore, it follows from recital 14 of the contested regulation that the different target populations to which the applicant refers in its applications for authorisation of the health claims at issue were not of decisive importance in the context of the Commission's refusal decision.
- ¹²⁷ Fourth, the applicant claims that the Commission did not explain the reason why the authorisation of the health claims at issue, accompanied by special conditions or additional statements or warnings, could not constitute a less strict measure. That argument, too, must be rejected. It is clear to the requisite legal standard from recital 14 of the contested regulation that, according to the Commission, authorising the health claims applied for by the applicant would have conveyed a conflicting and confusing message to consumers.
- ¹²⁸ Consequently, the fourth plea must be rejected.
- 129 In the light of all of the foregoing, the action must be dismissed in its entirety.

Costs

¹³⁰ Under Article 134(1) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. Since the applicant has been unsuccessful, it must be ordered to pay the costs, in accordance with the form of order sought by the Commission.

On those grounds,

THE GENERAL COURT (Fifth Chamber)

hereby:

1. Dismisses the action;

2. Orders Dextro Energy GmbH & Co. KG to pay the costs.

Dittrich

Schwarcz

Tomljenović

Delivered in open court in Luxembourg on 16 March 2016.

[Signatures]