Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

23 November 2017*

(Appeal — Public health — Consumer protection — Regulation (EC) No 1924/2006 — Health claims on foods — Article 13(3) — List of permitted health claims on foods — Botanical substances — Claims on hold — Action for failure to act — Article 265 TFEU — Defined position of the European Commission — Interest in bringing proceedings — *Locus standi*)

In Joined Cases C-596/15 P and C-597/15 P,

TWO APPEALS under Article 56 of the Statute of the Court of Justice of the European Union, brought on 13 November 2015,

Bionorica SE, established in Neumarkt (Germany) (C-596/15 P),

and

Diapharm GmbH & Co. KG, established in Münster (Germany) (C-597/15 P),

represented by M. Weidner, T. Guttau and N. Hußmann, Rechtsanwälte,

appellants,

the other party to the proceedings being:

European Commission, represented by S. Grünheid and M. Wilderspin, acting as Agents,

defendant at first instance,

THE COURT (Third Chamber),

composed of L. Bay Larsen, President of the Chamber, J. Malenovský, M. Safjan (Rapporteur), D. Šváby and M. Vilaras, Judges,

Advocate General: M. Bobek,

Registrar: M. Aleksejev, Administrator,

having regard to the written procedure and further to the hearing on 19 January 2017,

after hearing the Opinion of the Advocate General at the sitting on 25 April 2017,

gives the following

* Language of the case: German.

Judgment

1 By their appeals, Bionorica SE and Diapharm GmbH & Co. KG seek to have set aside the orders of the General Court of the European Union of 16 September 2015, *Bionorica* v *Commission* (T-619/14, not published, EU:T:2015:723) ('the order in Case T-619/14'), and of 16 September 2015, *Diapharm* v *Commission* (T-620/14, not published, EU:T:2015:714) ('the order in Case T-620/14') by which it dismissed their applications seeking a declaration that the Commission's failure to act, in that it unlawfully failed to instruct the European Food Safety Authority (EFSA) to assess the health claims relating to botanical substances for the purposes of adopting, pursuant to Article 13(3) 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, and corrigendum OJ 2007 L 12, p. 3) as amended by Regulation (EC) No 109/2008 of the European Parliament and of the Council of 15 January 2008 (OJ 2008 L 39, p. 14) ('Regulation No 1924/2006'), a definitive list of permitted health claims.

Legal context

Decision 1999/468

2 Article 5a of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ 1999 L 184, p. 23), as amended by Council Decision 2006/512/EC of 17 July 2006 (OJ 2006 L 200, p. 11) ('Decision 1999/468'), governs the regulatory procedure with scrutiny.

3 Decision 1999/468 was repealed by the first paragraph of Article 12 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ 2011 L 55, p. 13). Nevertheless, in accordance with the second paragraph of Article 12 of that regulation, the effects of Article 5a of Decision 1999/468 are maintained for the purposes of existing basic acts making reference thereto.

Regulation (EC) No 178/2002

4 Article 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ 2002 L 31, p. 1), entitled 'Other definitions', provides:

'For the purposes of this Regulation:

…

(2) "food business" means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food;

(3) "food business operator" means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;

…'

Regulation No 1924/2006

5 Recital 23 of Regulation No 1924/2006 states that 'Health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard. In order to ensure harmonised scientific assessment of these claims, the [EFSA] should carry out such assessments'.

6 Article 2 of that regulation, entitled 'Definitions', states in paragraph 1(a) and paragraph 2(5) thereof:

'1. Within the meaning of this Regulation:

(a) the definitions of … "food business operator", … set out in … Article 3(3) … of [Regulation No 178/2002], shall apply;

…

2. The following definitions shall also apply:

…

(5) "health claim" means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;

…'

7 Article 3 of Regulation No 1924/2006, entitled 'General Principles for all claims', provides, in point (a) of its second paragraph, that the nutrition and health claims must not, in particular, 'be false, ambiguous or misleading'.

8 Article 6 of that regulation, entitled 'Scientific substantiation for claims', provides, at paragraph 1:

'Nutrition and health claims shall be based on and substantiated by generally accepted scientific evidence.'

9 Article 10 of the regulation, entitled 'General provisions', provides, at paragraph 1:

'Health claims shall be prohibited unless they comply with the general requirements in Chapter II and the specific requirements in this Chapter and are authorised in accordance with this Regulation and included in the lists of authorised claims provided for in Articles 13 and 14.'

10 Article 13 of the same regulation, entitled 'Health claims other than those referring to the reduction of disease risk and to children's development and health', provides:

'1. Health claims describing or referring to:

(a) the role of a nutrient or other substance in growth, development and the functions of the body; or

(b) psychological and behavioural functions; or

(c) without prejudice to [Commission] Directive 96/8/EC [of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ 1996 L 55, p. 22)], slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet,

which are indicated in the list provided for in paragraph 3 may be made without undergoing the procedures laid down in Articles 15 to 19, if they are:

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

2. Member States shall provide the Commission with lists of claims as referred to in paragraph 1 by 31 January 2008 at the latest accompanied by the conditions applying to them and by references to the relevant scientific justification.

3. After consulting the [EFSA], the Commission shall adopt … a Community list designed to amend non-essential elements of the Regulation by supplementing it, of permitted claims as referred to in paragraph 1, and all necessary conditions for the use of these claims by 31 January 2010 at the latest.

4. Any changes to the list referred to in paragraph 3, based on generally accepted scientific evidence and designed to amend non-essential elements of this Regulation by supplementing it, shall be adopted … after consulting [the EFSA], on the Commission's own initiative or following a request by a Member State.

5. Any additions of claims to the list referred to in paragraph 3 based on newly developed scientific evidence shall be adopted following the procedure laid down in Article 18, except claims referring to children's development and health ...'

11 Article 17 of Regulation No 1924/2006, entitled 'Community authorisation', provides at paragraph 5:

'Health claims included in the lists provided for in Articles 13 and 14 may be used, in conformity with the conditions applying to them, by any food business operator ...'

12 Article 25 of that regulation, entitled 'Committee procedure', provides, at paragraph 3:

'Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision [1999/468] … shall apply, having regard to the provisions of Article 8 thereof.'

13 Article 28 of the regulation, entitled 'Transitional measures', provides in paragraphs 5 and 6:

'5. Health claims as referred to in Article 13(1)(a) may be made from the date of entry into force of this Regulation until the adoption of the list referred to in Article 13(3), under the responsibility of food business operators provided that they comply with this Regulation and with existing national provisions applicable to them, and without prejudice to the adoption of safeguard measures as referred to in Article 24.

6. Health claims other than those referred to in Article 13(1)(a) and in Article 14(1)(a), which have been used in compliance with national provisions before the date of entry into force of this Regulation, shall be subject to the following:

(a) health claims which have been the subject of evaluation and authorisation in a Member State shall be authorised as follows:
   (i) Member States shall communicate to the Commission, by 31 January 2008 at the latest, such claims accompanied by a report evaluating the scientific data in support of the claim;
   (ii) after consulting [the EFSA], the Commission shall adopt … a decision concerning the health claims authorised in this way and designed to amend non-essential elements of this Regulation by supplementing it.

Health claims not authorised under this procedure may continue to be used for six months following the adoption of the Decision;

(b) health claims which have not been the subject of evaluation and authorisation in a Member State: such claims may continue to be used provided an application is made pursuant to this Regulation before 19 January 2008; health claims not authorised under this procedure may continue to be used for six months after a decision is taken pursuant to Article 17(3).'

Regulation (EU) No 432/2012

14 Recitals 10 and 11 of 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), states:

'(10) The Commission has identified a number of claims submitted for evaluation, referring to effects of plant or herbal substances, commonly known as "botanical" substances, for which the [EFSA] has yet to complete a scientific evaluation. In addition, there are a number of health claims for which either a further evaluation is required before the Commission is able to consider their inclusion or otherwise in the list of permitted claims, or which have been evaluated, but due to other legitimate factors consideration cannot be completed by the Commission at this time.

(11) Claims whose evaluation by the [EFSA] or whose consideration by the Commission has not yet been completed will be published on the website of the Commission … and may continue to be used pursuant to Article 28(5) and (6) of Regulation [No 1924/2006].'

15 Article 2 of the regulation, entitled 'Entry into force and application', provides, in the third paragraph, that the regulation is to be binding in its entirety and directly applicable in all Member States.

Background to the disputes

16 The relevant background to the disputes, as set out in the orders in Cases T-619/14 and T-620/14, may be summarised as follows.

17 Bionorica is a company that manufactures and markets pharmaceutical products and food supplements on the European market and which, to that end, uses health claims on those products and in their publicity.

18 Diapharm is a company that provides, at an international level, an integrated range of services for the health industry. A substantial part of its activity consists of advising companies on the subject of health claims made on foods, in particular as regards food supplements.

19 Following the adoption of Regulation No 1924/2006, the Commission received, pursuant to Article 13(2) of that regulation, a total of about 44 000 health claims from the Member States. On the basis of those national lists of health claims, the Commission compiled a consolidated list of health claims.

20 On 24 July 2008, the Commission formally submitted to the EFSA a request for a scientific opinion regarding those claims, in accordance with Article 13(3) of Regulation No 1924/2006. On that occasion, the Commission communicated to the EFSA a first part of the consolidated list of health claims. The remaining parts of that list were provided in November and December 2008, and by

means of an addendum in March 2010, making the final number of health claims to be examined 4 637. Between October 2009 and July 2011, the EFSA carried out the scientific assessment of the health claims submitted by the Commission.

21 On 27 September 2010, the Commission issued a press release on its webpage in which it stated that, given the large number of health claims and the delays in processing them, it was in favour of establishing a process allowing for gradual adoption of the list of claims permitted in the European Union. Furthermore, according to the Commission, that change of priorities in the procedure for the adoption of that list was explained inter alia by tensions reported about the treatment of plant ingredients under the legislation on health claims and under legislation governing traditional herbal medicinal products, and by the need to continue the reflection on the consistent treatment of those ingredients. Consequently, the Commission requested the EFSA to suspend temporarily its assessment of the health claims relating to botanical substances and to concentrate instead on all the other claims submitted with a view to completing the examination of those claims as soon as possible. In that context, the Commission explained that the health claims concerning substances other than botanical substances would be examined in a first stage, whereas claims relating to botanical substances would be examined in a second stage.

22 On 16 May 2012 the Commission adopted Regulation No 432/2012. In that regulation the Commission authorised a partial list of 222 health claims, corresponding to 497 entries in the consolidated list, for which the EFSA had essentially concluded that the information submitted was sufficient to establish a cause-and-effect relationship between a food category, a food or one of its constituents and the claimed effect.

23 On the same date, the Commission identified a list of more than 2 000 claims in respect of which the EFSA had not completed its evaluation or the Commission itself had not yet taken a decision, and published that list on its website. According to the Commission, those health claims, which principally concerned the effects of botanical substances, remained on hold and therefore could continue to be used in accordance with the transitional scheme provided for in Article 28(5) and (6) of Regulation No 1924/2006. Whereas the partial list of permitted claims established by Regulation No 432/2012 was subsequently updated by the Commission, the health claims relating to botanical substances remained on hold.

24 By letters of 22 and 24 April 2014, Bionorica and Diapharm respectively requested the Commission to resume the assessment of the health claims relating to botanical substances and, in particular, instruct the EFSA to proceed immediately with that assessment so that the definitive list of permitted health claims could be adopted, as required by Article 13(3) of Regulation No 1924/2006. They also indicated their intention to bring proceedings before the General Court, if the Commission failed to act.

25 By letters of 19 June 2014 (‘the letters of 19 June 2014’), the Commission replied to those requests to act from Bionorica and Diapharm, by stating inter alia as follows:

‘As you are aware, the Commission initiated a reflection on health claims on so-called “botanicals” after concerns were raised by a number of Member States and stakeholders with regard to the differentiated treatment of products containing such substances under the legislation on health claims and that on the traditional herbal medicinal products.

Pending the outcome of this reflection, the Commission has asked the [EFSA] to discontinue its scientific assessment of health claims on botanicals. The Commission recognises the importance of this complex issue both for consumers and business operators. However, to identify the best course of action needed, the Commission should be allowed the time and context necessary for that purpose.’

The proceedings before the General Court and the orders in Cases T-619/14 and T-620/14

26 By applications lodged with the Court Registry on 19 August 2014, Bionorica and Diapharm sought a declaration by the General Court that the Commission had failed to act, in that it had unlawfully failed to instruct EFSA to proceed with the assessment of health claims relating to botanical substances for the purpose of adopting a definitive list of permitted health claims pursuant to the procedure laid down in Article 13(3) of Regulation No 1924/2006.

27 By separate documents, lodged with the Court Registry on 20 November 2014, the Commission raised objections of inadmissibility, on which Bionorica and Diapharm submitted their observations on 19 December 2014 asking the General Court to reject those objections and rule on substance.

28 By the order in Case T-619/14 and by the order in Case T-620/14, the General Court rejected the actions brought by Bionorica and Diapharm respectively and ordered them to pay the costs.

29 In the first place, the General Court examined whether the actions for failure to act brought by Bionorica and Diapharm complied with the conditions laid down in Article 265 TFEU and declared, in paragraph 26 of the order in Case T-619/14 and the order in Case T-620/14 that those actions were inadmissible owing to the failure to comply with those conditions.

30 More specifically, after recalling, in paragraphs 19 and 20 of those orders, that the requirements laid down in Article 265 TFEU for the admissibility of an action for failure to act are not met where the institution called upon to act has defined its position on that request before proceedings are brought, the General Court concluded, in paragraph 23 of those orders, that the letters of 19 June 2014, read in their entirety, to the extent that they set out the reason why it had suspended the procedure for evaluating the health claims at issue and informed Bionorica and Diapharm that, for the examination of the latter question, the Commission needed more time and a more specific context, were sufficiently clear and precise to enable them to know the Commission's position regarding their requests, namely that it would not instruct the EFSA to proceed with the evaluation sought.

31 Consequently, the General Court regarded, in paragraph 24 of those orders, those letters as defining the Commission's position, within the meaning of the second paragraph of Article 265 TFEU, thus bringing an end to its failure to act.

32 The General Court observed on that occasion, in paragraph 25 in the order in Case T-619/14 and the order in Case T-620/14, that the fact that the Commission's reply did not satisfy Bionorica and Diapharm was immaterial in that regard. Article 265 TFEU refers to failure to act in the sense of failure to take a decision or to define a position, not the fact that a measure different from that desired by the persons concerned has been adopted.

33 In the second place, the General Court examined, for the sake of completeness, the objection of inadmissibility raised by the Commission alleging a lack of interest on the part of Bionorica and Diapharm in bringing proceedings and declared, in paragraph 56 of the order in Case T-619/14 and paragraph 55 in the order in Case T-620/14, that their actions for failure to act were also inadmissible for lack of interest to act.

34 In that regard, the General Court arrived at the conclusion, set out in paragraphs 39 and 55 of the order in Case T-619/14 and paragraphs 39 and 54 of the order in Case T-620/14, that neither Bionorica nor Diapharm had produced evidence to establish how the resumption of the evaluations by the EFSA of the health claims relating to botanical substances and the adoption of a definitive list of permitted health claims could procure a certain benefit for them.

35 First, the General Court held, in paragraphs 38, 42 and 43 of the order in Case T-619/14 and paragraphs 38, 41 and 42 of the order in Case T-620/14, that it was clear from the wording of Article 28(5) and (6) of Regulation No 1924/2006 that the application of transitional measures is provided for, since the adoption of that regulation, in respect of health claims that are under evaluation and those in respect of which no decision has been adopted by the Commission. In those circumstances, companies affected by the health claims on hold may continue to make those claims, provided that they comply with the transitional rules laid down in Article 28(5) and (6) of that regulation. Consequently, according to the General Court, Article 17(5) of Regulation No 1924/2006, which allows, in principle, any food business operator to make permitted health claims included in the definitive list, places those health claims in the same situation as health claims on hold, that is to say, in a situation in which they may be used for the marketing of food.

36 Moreover, the General Court held, in paragraphs 44 and 45 of the order in Case T-619/14 and paragraphs 43 and 44 of the order in Case T-620/14, that, in any event, even if it could be established that there were consequences for the legal situation of Bionorica and other food business operators under Article 17(5) of Regulation No 1924/2006 by comparison, inter alia, with its situation under the transitional provisions provided for in Article 28(5) and (6) of the regulation, such a benefit rested, by definition, on the premiss that its health claims on hold would be authorised on conclusion of the EFSA's assessment and in the Commission's final decision. However, the General Court observed that that premiss remained, for the time being, a premiss and, for that reason, could not satisfy the requirements of the case-law, which established that, if the interest pleaded by an applicant concerns a future legal situation, it must demonstrate that the prejudice to that situation is already certain. In that regard, the General Court recalled that, by Regulation No 432/2012, which established a partial list of permitted health claims, the Commission had authorised only 222 health claims out of a total of more than 2 000 claims examined, such that the transitional regime could prove to be more advantageous for the operators than the definitive list of permitted health claims.

37 Secondly, the General Court rejected, in paragraphs 47 and 48 of the order in Case T-619/14 and paragraphs 46 and 47 of the order in Case T-620/14, the arguments advanced by Bionorica and Diapharm that the fact that certain health claims had been the object of an assessment by the EFSA and that other claims remained on hold created unequal terms of competition in the market, holding that such an unequal situation could only affect the interests of producers whose health claims were rejected following the adoption of Regulation No 432/2012 and not those of producers whose health claims remained on hold.

38 Thirdly, the General Court did not accept the assertions made by Bionorica and Diapharma that they were strongly affected by the legal uncertainty governing the market owing to the lack of a definitive and complete decision by the Commission on the authorisation of health claims. In that regard, the General Court noted, in paragraphs 51 and 52 of the order in Case T-619/14 and paragraphs 50 and 51 of the order in Case T-620/14, that the principle of legal certainty required that legal rules be clear and precise, and that their consequences be foreseeable. According to the General Court, both the rules applicable to, on the one hand, authorised or rejected health claims and, on the other hand, health claims on hold, satisfy those requirements. In particular, the rules to which the health claims on hold were subject flowed expressly from Regulation No 1924/2006 and, in particular, Article 28(5) and (6) thereof, which set out the rules applicable, since the adoption of that regulation, to health claims pending an assessment and a final decision.

39 Fourthly, in paragraph 54 of the order in Case T-619/14 and paragraph 53 of the order in Case T-620/14, the General Court rejected the claims made by Bionorica and Diapharm that they had suffered financial loss as a result of the Commission's lack of action, observing that they had not explained either how those losses arose or how they would disappear if the Commission were to instruct the EFSA to proceed with the assessment of the health claims on hold.

40 Finally, in the third place, the General Court examined and upheld, in Case T-620/14 only, the plea of inadmissibility, relied on by the Commission, alleging that Bionorica and Diapharm lacked *locus standi*. The General Court found in that regard, in paragraph 56 of the order in Case T-620/14, that Diapharm — which is a company supplying advisory and support services (including in respect of health claims on food) to companies in the health industry — does not manufacture or market those types of products on the European Union market. For that reason, according to the General Court, Diapharm is not sufficiently linked to the latter activities for it to be regarded as being directly concerned by the act to be adopted by the Commission following a possible finding of failure to act on its part.

The forms of order sought and the procedure before the Court

41 By their respective appeals, Bionorica and Diapharm ask the Court to:

– set aside the order in Case T-619/14 and the order in Case T-620/14, and

– order the Commission to pay the costs.

42 The Commission asks the Court to dismiss the appeals as unfounded and to order the appellants to pay the costs.

43 By order of the President of the Court of 21 January 2016, Case C-596/15 P and C-597/15 P were joined for the purposes of the written and oral procedure and the judgment, in accordance with Article 54 of the Rules of Procedure of the Court.

Concerning the appeals

44 In support of their appeals, Bionarica and Diapharm each rely on three grounds, which partially overlap.

The second ground of appeal in Case C-596/15 P and the first ground of appeal in Case C-597/15 P

Arguments of the parties

45 By their second and first grounds of appeal respectively, Bionorica and Diapharm complain that the General Court, in essence, committed an error of law in holding, in paragraph 24 of the order in Case T-619/14 and of the order in Case T-620/14, that the letters of 19 June 2014 constituted a defined position within the meaning of the second paragraph of Article 265 TFEU, bringing an end to the failure to act on the part of the Commission.

46 According to the appellants, the finding made by the General Court, in paragraph 23 of the order in Case T-619/14 and the order in Case T-620/14, that the letters of 19 June 2014, ‘read in [their] entirety, [were] sufficiently clear and precise to enable [Bionorica and Diapharm] to know the Commission’s position as regards [their] requests, in particular, the fact that it would not instruct the EFSA to commence the assessment sought and the reasons justifying that position’, is evidence in particular that the General Court did not carry out a detailed examination of the contents of those letters.

47 In that regard, Bionorica and Diapharm submit that, in the first two sentences of those letters, the Commission merely set out the status quo as it existed with respect to the assessment of the health claims of botantical substances. The appellants themselves had already summarised that situation in their letters requesting the Commission to act. Furthermore, they submit that the process of reflection to which the Commission referred in the letters of 19 June 2014, in the context of which a consultation document on the further assessment of those claims was sent to the Member States, was commenced by that institution in July 2012 and completed at the end of 2012 with the majority of the Member States deciding in favour of the continuation of the assessment in accordance with the scientific approach applied until then, including of the health claims on hold. According to Bionorica and Diapharm, the letters of 19 June 2014 are at the very least ambiguous to the extent that they could refer to a fresh process of reflection.

48 Bionorica and Diapharm also observe that, in the third sentence of the letters of 19 June 2014, the Commission merely acknowledged, as regards the assessment of the health claims relating to botanical substances, the importance 'of this complex problem' both for consumers and for economic operators. In the fourth and final sentence, the Commission simply explained that it required time and context in order to determine the 'best course of action required' without however explaining what it regarded as necessary in the present case.

49 Consequently, it would be impossible to deduce from the letters of 19 June 2014 what position the Commission had adopted on the requests to act that had been sent to it and, in particular, whether it would act, and, if so, when it intended to ask the EFSA to proceed with its assessment of the health claims relating to botanical substances. In accordance with the judgment of the Court of 22 May 1985, *Parliament* v *Council* (13/83, EU:C:1985:220, paragraph 25), such an evasive reply is not capable of constituting a defined position sufficient to bring an end to the failure to act.

50 The Commission submits that the General Court was correct to hold that the letters of 19 June 2014 enabled Bionorica and Diapharm to understand that that institution would not uphold their request to end the suspension of the assessment of the health claims relating to botanical substances. According to the Commission, the context of those letters informed the appellants as to the fact that it had reviewed its priorities and maintained the assessment of the health claims on hold so as to examine first the health claims relating to substances other than botanical substances. Finally, it was clear from the letters of 19 June 2014 and their context that the Commission considered, at the time when it sent those letters to Bionorica and Diapharm, that the circumstances did not justify upholding their requests to act.

Findings of the Court

51 Under the second paragraph of Article 265 TFEU, an action for failure to act is admissible only if the institution concerned has first been called upon to act. If, within two months of being so called upon, the institution, body, office or agency concerned has not defined its position, the action may be brought within a further period of two months.

52 According to the case-law of the Court, a failure to act, for the purposes of Article 265 TFEU, means a failure to take a decision or to define a position (judgments of 13 July 1971, *Deutscher Komponistenverband* v *Commission*, 8/71, EU:C:1971:82, paragraph 2, and of 19 November 2013, *Commission* v *Council*, C-196/12, EU:C:2013:753, paragraph 22 and the case-law cited).

53 In that regard, an action for failure to act may be brought not only against a failure to adopt a measure that is legally binding on, and capable of affecting the interests of the applicant by bringing about a distinct change in its legal position, but also against the failure to adopt a preparatory act, if it is a necessary preliminary act in a procedure leading to an act that has binding legal effects (see, to that effect, judgment of 27 September 1988, *Parliament* v *Council*, 302/87, EU:C:1988:461, paragraph 16).

54 The request for an institution to act must be sufficiently clear and precise to enable that institution to ascertain in specific terms the content of the decision that it is being asked to adopt and must also show what matters are understood to require the institution to define its position (see, by analogy, judgment of 10 June 1986, *Usinor* v *Commission*, 81/85 and 119/85, EU:C:1986:234, paragraph 15, and order of 18 November 1999, *Pescados Congelados Jogamar* v *Commission*, C-249/99 P, EU:C:1999:571, paragraph 18).

55 In addition, it should be recalled that the classification for legal purposes of an act or a measure, such as a letter, by the General Court is a question of law which may be raised in an appeal (see, to that effect judgment of 1 June 2006, *P & O European Ferries (Vizcaya) and Diputación Foral de Vizcaya* v *Commission*, C-442/03 P and C-471/03 P, EU:C:2006:356, paragraph 90, and the case-law cited). Hence, the question of whether a letter sent by an institution in response to a request to act brings an end, or not, to the failure to act alleged against that institution is a question of law which is capable of being examined on appeal.

56 In the present case, it is common ground that, under Article 13(3) of Regulation No 1924/2006, the Commission was required to consult the EFSA with a view to adopting thereafter a definitive list of permitted health claims within the time limit prescribed, namely by 31 January 2010 at the latest, and that that list had only partially been adopted by Regulation No 432/2012, on 16 May 2012. Moreover, it is not contested that Bionorica and Diapharm, by their letters of 22 and 24 April 2014 respectively (referred to in paragraph 24 above) duly requested the Commission to act, namely to ask the EFSA to resume immediately the assessment of the health claims relating to botanical substances with a view to the adoption of a definitive list of permitted claims and, in reply to those letters, the Commission restricted itself to concluding, in the letters of 19 June 2014 (referred to in paragraph 25 above) that 'to identify the best course of action needed, [it] should be allowed the time and context necessary for that purpose.'

57 In that regard, it must be observed that, by describing, first of all, the status quo as it existed with regard to the assessment of the health claims relating to botanical substances since its press release of 27 September 2010 (referred to in paragraph 21 above) and by referring, next, to the time and context necessary, without however clarifying what it regarded as necessary to proceed with the assessment process in question, the Commission had not unambiguously stated its intention as to whether it would, or would not, instruct EFSA to proceed with that assessment.

58 In other words, the Commission had neither proceeded with the consultation of the EFSA, as Bionorica and Diapharm asked it to do, nor stated unambiguously in its letters of 19 June 2014, whether and when it would proceed to such a consultation, which is consistent with the hypotheses set out in paragraph 52 above.

59 It follows from the foregoing that the General Court committed an error of law in holding, in paragraph 24 of the order in Case T-619/14 and the order in Case T-620/14, that the letters of 19 June 2014 had brought an end to the failure to act on the part of the Commission.

60 Consequently, the second ground of appeal in Case C-596/15 P and the third ground of appeal in Case C-597/15 P must be upheld.

61 However, it must be recalled that the General Court assessed, for the sake of completeness, whether Bionorica and Diapharm had an interest in bringing proceedings and having found that those two companies lacked such an interest, it concluded that their respective actions must be dismissed as inadmissible on that ground also. Thus, before it is possible to proceed to set aside, if appropriate, the orders in Cases T-619/14 and T-620/14, it is necessary to examine the grounds in Cases C-596/15 P and C-597/15 P covering the parts of those orders dealing with the interest to bring proceedings.

The first and third grounds of appeal in Case C-596/15 P and the second ground of appeal in Case C-597/15 P

62 To the extent that the first and third grounds of appeal in Case C-596/15 P and the second ground of appeal in Case C-597/15 P target, in essence, the finding made by the General Court of a lack of interest in bringing proceedings on the part of Bionorica and Diapharm, those grounds should be examined together.

Arguments of the parties

– The first plea in Case C-596/15 P

63 By its first ground of appeal, Bionorica complains that the General Court committed a procedural error in that it partly based its decision on incorrect facts and that it therefore wrongly classified it, in paragraphs 1 and 48 of the order in Case T-619/14, as a company that manufactured and marketed food supplements or food on the European market. As a consequence, according to Bionorica, the General Court reached an erroneous decision against it in deciding that it was not concerned by the health claims on hold and that the existence of unequal terms of competition could not therefore be the basis of its interest in bringing proceedings in the present case.

64 It is clear from its application before the General Court that it was one of the first global manufacturers of herbal medicinal products, amongst which those cited as examples in the application contained substances with therapeutic effects in respect of which the health claims on hold were sought.

65 The Commission disputes Bionorica's arguments.

66 As is clear from a comparison of the documents on the case file with the order in Case T-619/14, the findings of facts made in paragraphs 1 and 48 of the order under appeal, which are challenged by Bionorica, are not erroneous in any way and could even be more favourable to it since the General Court upheld, without casting any doubt on it, that company's statement that it had the intention of using the health claims relating to botanical substances as an operator in the food sector. The Commission states that that finding is consistent with the statements made in the application.

– The third ground of appeal in Case C-596/15 P and the second ground of appeal in Case C-597/15 P

67 By their third and second grounds of appeal respectively, Bionorica and Diapharm complain that the General Court committed an error of law in finding, for the sake of completeness, in paragraphs 55 and 56 of the order in Case T-619/14 and in paragraphs 54 and 55 of the order in Case T-620/14, that their actions for failure to act were inadmissible for lack of interest to bring proceedings on the ground that they would not obtain any certain advantage from the adoption of a definitive list of permitted health claims.

68 Bionorica and Diapharm submit, in the first place, that the use of permitted health claims and the use of health claims on hold are subject to different requirements and, therefore, cannot be placed in the same situation. They state, in that regard, that paragraphs 5 and 6 of Article 28 of Regulation No 1924/2006 do not allow the unconditional use of health claims on hold, but subject their use to conditions, including, in particular, that those claims 'comply with this regulation and with existing national provisions applicable to them'.

69 That implies, in particular, that, in accordance with Regulation No 1924/2006, the health claims on hold must not be misleading and must be based on generally accepted scientific data. In that regard, the question of whether the conditions are complied with or whether purchasers are wrongly induced would be subject, in addition to the review carried out by the national authorities responsible for the supervision of food, to an examination on a case by case basis by the national courts before which other market operators may bring actions. In German practice such court supervision, which can lead to an immediate suspension of sales on German territory, would involve a summary examination that does not systematically give rise to outcomes that are materially justifiable and which, moreover, may differ radically from one court to another in respect of the same health claim, above all given the imprecise legal criterion of generally accepted scientific evidence which leaves scope for widely diverging interpretations.

70 Consequently, there is never any legal certainty whatsoever at any time, either for Bionorica and Diapharm or for the other companies, as to whether the health claims on hold may lawfully be used. By contrast, it would be different if permitted health claims were included in a positive and exhaustive list which would bring an end to case by case assessments. In addition, Bionorica and Diapharm submit in that regard that the EU legislature has not expressly laid down transitional measures for the period after 31 January 2010, namely after the deadline set in Article 13(3) of Regulation No 1924/2006 for the adoption of the list of permitted health claims.

71 In response to the General Court's finding in paragraph 45 of the order in Case T-619/14 and in paragraph 44 of the order in Case T-620/14, that the application of transitional measure may be more advantageous than a rejection of health claims, Bionorica and Diapharm submit that, in terms of the legal certainty to which they aspire when using health claims and, hence, to their benefit, health claims that are permitted definitively are just as reliable as those that are definitively rejected.

72 In the second place, Bionorica and Diapharm submit that, in having considered, in paragraphs 47 and 48 of the order in Case T-619/14 and in paragraphs 46 and 47 of the order in Case T-620/14, that unequal competition conditions could only be created in respect of manufacturers whose health claims were rejected after the adoption of Regulation No 432/2012 compared with those whose health claims were permitted under that regulation and not compared with manufacturers whose health claims remained on hold, the General Court relied on the false interpretation that permitted health claims and those on hold must benefit from the same treatment. Whereas it would be clear, in the case of those health claims that are authorised and those that are rejected, that they may or may not be used, the same legal certainty does not exist for the health claims on hold.

73 Finally, in the third place, Bionorica and Diapharm observe, referring to paragraphs 51 to 53 of the order in Case T-619/14 and in paragraphs 50 to 52 of the order in Case T-620/14, that the General Court was wrong to hold that the rules applicable both to permitted or rejected health claims and to those on hold are sufficiently clear and precise and that the consequences resulting from them are sufficiently foreseeable. The transitional measures that apply to the health claims on hold, which, first, mean that for each case a new assessment in which there is, as regards the assessment of scientific evidence, a wide margin of discretion, and which, second, can lead to widely diverging — even contradictory — outcomes, in particular in German judicial practice, would not produce sufficiently foreseeable legal consequences.

74 The Commission submits that since neither Bionorica nor Diapharm were manufacturers operating as food businesses at the time when the applications were lodged, neither of those companies can obtain a certain benefit from the definitive authorisation of health claims on foods relating to botanical substances given that they themselves are not engaged in the manufacture or marketing of foods capable of being promoted by claims of that type.

75 First of all, to the argument advanced by Bionorica and Diapharm that the General Court had wrongly placed permitted health claims and those that remained on hold in the same situation, the Commission counters that the General Court merely observed, in paragraphs 43 and 42 of the orders in Case T-619/14 and Case T-620/14 respectively, that the use of health claims was permitted in both cases. According to the Commission, that finding is correct in law in the light of the provisions of Article 28(5) and (6) of Regulation No 1924/2006. By contrast, it goes without saying, according to the Commission, that the use of lawful health claims, whether they are authorised or on hold, presupposes that the conditions laid down for that purpose by the European Union are satisfied in each case. In addition, the appellants' observations as regards the alleged negative effects of the application of national law in force should be directed, regarding their substance, not against the General Court but, first, against the German legislature and the German courts and, second, against the EU legislature that adopted the transitional provisions concerned.

76 Next, in response to the argument that the General Court wrongly found that they could only draw a future and uncertain benefit from the authorisation of the health claims on hold, the Commission observes that the appellants do not dispute, in that context, that the General Court correctly held that the authorisation of health claims concerning botanical substances was not yet a confirmed fact and could not therefore satisfy the criteria, established by settled case-law, according to which it is for the appellant, if the interest that it claims to have concerns a future legal situation, to demonstrate that the prejudice to that situation is already certain.

77 However, Bionorica and Diapharm consider that even a refusal to authorise the health claims relating to botanical substances could confer an advantage on them. According to the Commission, that argument, which could never in any case emanate from a company in the food sector wishing to use a health claim, shows that the appellants attach importance not to the authorisation of health claims relating to botanical substances but only to the existence of any list whatsoever, which could certainly have effects for the legal situation of other businesses but which, with regard to the appellants' commercial activities, can only concern their factual situation.

78 In Bionorica's case, such a refusal would mean that food businesses would no longer have the right to use those claims, which would allow Bionorica, as a manufacturer of herbal medicinal products, to keep unwanted competitors in the food sector at a distance. As to Diapharm, the rejection or authorisation or even the continued suspension of the health claims relating to botanical substances would also have no effect on its legal situation, given that that company could carry on its advisory activities in all those situations.

79 Finally, the Commission submits that the appellants' arguments alleging legal uncertainty arising from the application of transitional measures must be rejected on the ground that the validity of the General Court's findings in respect of legal certainty, which are challenged by the appellants, is fully confirmed by the case-law on that subject.

Findings of the Court

– *The first plea in Case C-596/15 P*

80 It is clear from the order in Case T-619/14 that although, in its assessment of Bionorica's interest in bringing proceedings, the General Court started from the premiss that it was a food manufacturer, it did not rely on that alleged characteristic in order to conclude that Bionorica did not have an interest in bringing proceedings.

81 In those circumstances, it must be held that, to the extent that the consequences that Bionorica draws from the distortion, by the General Court, of the facts concerning it arise from a misreading of the order in Case T-619/14, the arguments advanced by the latter in that regard must be rejected as

ineffective in that they could not lead to the setting aside of that order (see, to that effect, judgments of 9 September 2015, *Lito Maieftiko Gynaikologiko kai Cheirourgiko Kentro* v *Commission*, C-506/13 P, EU:C:2015:562, paragraphs 87 and 88, and of 26 July 2017, *AGC Glass Europe and Others* v *Commission*, C-517/15 P, not published, EU:C:2017:598, paragraphs 63 to 65).

82 Consequently, the first ground of appeal in Case C-596/15 P must be rejected.

– The third ground of appeal in Case C-596/15 P and the second ground of appeal in Case C-597/15 P

83 First of all, it must be recalled that it is for the applicant to prove its interest in bringing proceedings, which is an essential and fundamental prerequisite for any legal proceedings (see, to that effect, order of 31 July 1989, *S.* v *Commission*, 206/89 R, EU:C:1989:333, paragraph 8, and judgment of 4 June 2015, *Andechser Molkerei Scheitz* v *Commission*, C-682/13 P, not published, EU:C:2015:356, paragraph 27).

84 An applicant's interest in bringing proceedings must be vested and current, and may not concern a future and hypothetical situation. That interest must, in the light of the purpose of the action, exist at the stage of lodging the action, failing which the action will be inadmissible, and continue until the final decision, failing which there will be no need to adjudicate (judgment of 17 September 2015, *Mory and Others* v *Commission*, C-33/14 P, EU:C:2015:609, paragraphs 56 and 57 and the case-law cited).

85 The applicant's interest in bringing proceedings presupposes that the action must be liable, by its outcome, to procure an advantage to the party bringing it (judgments of 7 June 2007, *Wunenburger* v *Commission*, C-362/05 P, EU:C:2007:322, paragraph 42 and the case-law cited; of 17 April 2008, *Flaherty and Others* v *Commission*, C-373/06 P, C-379/06 P and C-382/06 P, EU:C:2008:230, paragraph 25; and of 4 June 2015, *Andechser Molkerei Scheitz* v *Commission*, C-682/13 P, not published, EU:C:2015:356, paragraph 25). By contrast, there is no interest in bringing proceedings when the favourable outcome of an action could not, in any event, give the applicant satisfaction (see, by analogy, judgment of 9 June 2011, *Evropaïki Dynamiki* v *ECB*, C-401/09 P, EU:C:2011:370, paragraph 49 and the case-law cited).

86 In the present case, in the first place, in paragraphs 38 to 43 and 45 of the order in Case T-619/14 and in paragraphs 38 to 42 and 44 of the order in Case T-620/14, the General Court upheld the Commission's argument that Bionorica and Diapharm could not procure any certain benefit from the adoption of a definitive list of permitted health claims because, in essence, the applicable transitional regime already placed the health claims on hold in a situation that was just as beneficial as that of permitted health claims.

87 However, such a finding of equivalence of the transitional and definitive regimes cannot be confirmed. In that regard, while it is true, as the General Court held in paragraph 43 of the order in Case T-619/14 and in paragraph 42 of the order in Case T-620/14, that the permitted health claims and the health claims on hold could, in principle, be used in the marketing of food, it remains the case that the two categories of claims are subject to different requirements and do not benefit from the same conditions.

88 Whereas Article 17(5) of Regulation No 1924/2006 authorises, in principle, any food business operator to use the permitted health claims, included in the single definitive list for the European Union, the health claims on hold which are subject to the transitional regime must, inter alia, pursuant to Article 28(5) and (6) of that regulation, comply with that regulation and also the applicable national provisions.

89 That means, in particular, first, that in accordance with the second paragraph of Article 3, point (a), and Article 6(1) of Regulation No 1924/2006, all health claims must not be false, ambiguous or misleading and must be based on generally accepted scientific evidence. Second, the health claims on hold must also meet, in each Member State, the requirements of its own national regime. Consequently, their examination on a case by case basis entails a risk of giving rise to diverging outcomes at the end of national administrative and judicial proceedings for the authorisation of such claims, not only as between one Member State and another, but also within the same Member State.

90 In that regard, the Commission stated at the hearing before the Court that the national provisions of the Member States differed in particular on the question of whether a botanical substance is safe.

91 It is important to note that such a transitional situation, prolonged indefinitely beyond the period that ended, pursuant to Article 13(3) of Regulation No 1924/2006, at the latest on 31 January 2010, does not meet the requirements of that regulation, formulated in recital 23 thereof, according to which, in order to ensure a scientific assessment of the claims that is harmonised and of the highest possible standard, such assessments should be carried out by the EFSA (see, to that effect, judgment of 14 July 2016, V*erband Sozialer Wettbewerb*, C-19/15, EU:C:2016:563, paragraph 41).

92 Having regard to the considerations set out in paragraphs 87 to 91 above, it must be held that, in paragraphs 47 and 48 of the order in Case T-619/14 and in paragraphs 46 and 47 of the order in Case T-620/14, the General Court based its reasoning on the erroneous premiss that the transitional and definitive regimes were equivalent, and wrongly reached the conclusion that the unequal competition conditions could only be created as regards manufacturers whose health claims were rejected following the adoption of Regulation No 432/2012 compared with those whose health claims were authorised under that regulation, and not as regards the manufacturers whose health claims remained on hold.

93 As regards the finding made by the General Court, in paragraph 45 of the order in Case T-619/14 and in paragraph 44 of the order in Case T-620/14, that weighing against recognising Bionorica and Diapharm as having an interest in bringing proceedings was the fact that the transitional regime could be more advantageous than the definitive rejection of a health claim having regard to the fact that, by Regulation No 432/2012, which established a partial list of permitted health claims, the Commission had authorised only 222 claims out of a total of more than 2 000 claims assessed, it must be observed that that finding is vitiated by errors.

94 To uphold such an approach would mean accepting, as the Advocate General observed in point 67 of his opinion, that an applicant would only have an interest in bringing proceedings for failure to act if the worst possible outcome of that action would be better than the status quo.

95 It must be recalled that, in accordance with the case-law cited in paragraph 85 of this judgment, an interest in bringing proceedings is only lacking where the favourable outcome of an action could not, in any event, give the applicant satisfaction.

96 In that regard, even the rejection of a health claim could procure a benefit, in terms of legal certainty, for an economic operator that is planning its entry into the market for food or food supplements. An unequivocal determination of the legal status of health claims on hold until now would thus allow such an operator to adapt its commercial strategy.

97 In those circumstances, in view of the errors of law committed by the General Court, set out in paragraphs 87 to 96 above, it must be declared that the third ground of appeal in case C-596/15 P is well founded. Consequently, the appeal in Case C-596/15 P must be allowed.

98 As regards the second ground of appeal in Case C-597/15 P, and as follows from the documents lodged by Diapharm in the course of the proceedings before the General Court, the latter is a company that provides advice, including on the subject of health claims relating to food supplements or food. In its appeal, it submits that it acts as early as the conception and creation stage of the products concerned, and provides its clients with, inter alia, product recipes that are ready to be used, proposals for packaging and labelling, assistance relating to questions of intellectual property law and complete commercial and promotional strategies.

99 On the other hand, as Diapharm confirmed before the Court, its activities do not include either the manufacture or the marketing of food supplements or food.

100 In its appeal, Diapharm argues that the Commission's failure to adopt a definitive list of health claims relating to botanical substances negatively affects it by reducing demand for its services, resulting in significant loss of revenue. Without that list, Diapharm would not be able to provide reliable advice on the potential possibilities of marketing food supplements or food.

101 In the present case, it cannot be accepted that Diapharm has demonstrated its interest in bringing proceedings because it cannot procure, in accordance with the case-law cited in paragraph 85 above, any personal benefit from the resumption, by the EFSA, of the assessment of health claims relating to botanical substances and the subsequent adoption of a definitive list of permitted health claims.

102 In its capacity as an economic operator that is situated upstream of the manufacture or marketing process for food supplements or food, Diapharm will not be able to use the claims concerned itself, any more than it will be in direct competition with operators using those claims.

103 Having regard to the foregoing considerations, it must be held that, by ruling, in paragraph 55 of the order in Case T-620/14, that Diapharm's action for failure to act must be rejected for lack of interest in bringing proceedings, the General Court did not err in law.

104 In those circumstances, the second ground of appeal in Case C-597/15 P must be declared to be unfounded.

The third ground of appeal in Case C-597/15 P

105 By its third ground of appeal, Diapharm complains that the General Court wrongly held that its activity as an advisory company was insufficiently linked with the manufacture of the food concerned such that it did not satisfy the condition of direct concern, which determined its standing to bring proceedings.

106 In that regard, it must be recalled that, according to the case-law of the Court, an interest in bringing proceedings and *locus standi* are distinct conditions for admissibility which must be satisfied by a natural or legal person cumulatively in order to be admissible to bring an action for failure to act under the third paragraph of Article 265 TFEU (see, by analogy, judgment of 17 September 2015, *Mory and Others* v *Commission*, C-33/14 P, EU:C:2015:609, paragraph 62).

107 In view of the answer given to the second ground of appeal in Case C-597/15 P, that the General Court had not erred in law in finding that Diapharm did not have an interest in bringing proceedings, it is unnecessary to examine the third ground of appeal.

108 Consequently, the appeal in Case C-597/15 P must be dismissed.

The action before the General Court

109 In accordance with the first paragraph of Article 61 of the Statute of the Court of Justice of the European Union, if the appeal is well founded, the Court of Justice is to quash the decision of the General Court. It may itself give final judgment in the matter, where the state of the proceedings so permits, or refer the case back to the General Court for judgment.

110 In this case, the Court considers that it has the information necessary to rule definitively on the objection of inadmissibility raised by the Commission during the proceedings at first instance in Case T-619/14.

111 The Commission raised, in essence, three pleas of inadmissibility, alleging that the action did not have a proper purpose, lack of interest in bringing proceedings and lack of standing on the part of Bionorica.

112 It is necessary to examine, in the first place, the Commission's plea of inadmissibility alleging Bionorica's lack of interest in bringing proceedings.

113 In that regard, as is clear from the elements submitted by Bionorica before the General Court, in particular paragraphs 13 to 29 of its application and Annexes 8 and 9 thereto, and as it asserted before the Court at the time its application was lodged, it did not carry on business as a manufacturer of food or food supplements on the European market. Bionorica was a manufacturer of herbal medicinal products, which are not covered by the provisions of Regulation No 1924/2006, which only covers health claims relating to food.

114 It is true that Bionorica submits that, given its presence on the market for herbal medicinal products containing the same botanical substances as those covered by the health claims on hold, it is ready to enter into the market for food supplements if the health claims in question are authorised.

115 However, a mere statement of intention, given that it refers to a future and uncertain situation, cannot suffice, in accordance with the case-law cited in paragraph 84 above, to establish Bionarica's current and vested interest in bringing proceedings (see also, to that effect, judgment of 20 June 2013, *Cañas* v *Commission*, C-269/12 P, not published, EU:C:2013:415, paragraphs 16 and 17).

116 Consequently, without it being necessary to examine the other pleas of inadmissibility raised by the Commission, Bionorica's appeal in Case T-619/14 must be dismissed as inadmissible.

Costs

117 Under Article 184(2) of the Rules of Procedure, where the appeal is well founded and the Court itself gives final judgment in the case, the Court is to make a decision as to costs. Under Article 138(2) of the Rules of Procedure, which is applicable to appeal proceedings by virtue of Article 184(1) thereof, where there is more than one unsuccessful party, the Court is to decide how the costs are to be shared.

118 Bionorica's appeal having been allowed but its action for failure to act rejected, Bionorica and the Commission shall each bear their own costs incurred both at first instance and on appeal.

119 Since the Commission has applied for costs against Diapharm and the latter has been unsuccessful, Diapharm must be ordered to pay the costs relating to the appeal.

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

1. **Sets aside the order of the General Court of the European Union of 16 September 2015, *Bionorica* v *Commission* (T-619/14, not published, EU:T:2015:723);**

2. **Dismisses the action for failure to act lodged by Bionorica SE in Case T-619/14 as inadmissible;**

3. **Dismisses the appeal in Case C-597/15 P;**

4. **Orders Bionorica and the Commission each to bear their own costs incurred both at first instance in Case T-619/14 and on appeal in Case C-596/15 P;**

5. **Orders Diapharm GmbH & Co. KG to pay the costs incurred on appeal in Case C-597/15 P.**

[Signatures]