Case Report

The Water-Claim Proceedings: Statement of Claim

Tobias Teufer, Moritz Hagenmeyer and Andreas Hahn

Four years ago the second and the third authors submitted an application for authorisation of a health claim (in the shape of a disease risk reduction claim) via the German Federal Office for Consumer Protection and Food Safety. Their application was recently refused in a Commission Regulation relying on a negative opinion of the European Food Safety Authority. As a means of last resort the applicants have decided to challenge this Regulation and have asked the first author to represent them before the General Court of the European Union. As a measure of transparency, in order to assist the current debate of issues caused by the Nutrition and Health Claims Regulation and to give interested parties an opportunity to participate, the authors make a swift convenience translation of the statement of claim dated 13/1/2012 available to the public with this article. The General Court received the pleadings on 16/01/2012 and allocated the case number T-17/12.

Statement of Claim of

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and
Prof. Dr. Andreas Hahn, Leibniz Universität Hannover, Am Kleinen Felde 30, 30167 Hannover, Germany,
– Plaintiffs –
Legal representative: Dr. Tobias Teufer, KROHN Rechtsanwälte, Esplanade 41, 20354 Hamburg, Germany,
The legal representative agrees that documents may be served via telefax to No. +49 40 35610-180 or via EMail to teufer@krohnlegal.de
against
the European Commission, Rue de la Loi 200, B1040 Brussels, Belgium,
– Defendant –
concerning the challenge of a legal Act (Art. 263, 264 TFEU)

In the name of and empowered by the plaintiffs, I file this statement of claim for the voidness of Regulation of the European Commission, attaching
– a certificate pursuant to Art. 44, para. 3 of the procedural rules and
– a power of attorney of the plaintiffs

with the **applications**:
1. The part of Regulation (EU) No. 1170/2011 of the Commission of 16/11/2011 on the non-authorisation of certain health claims on food concerning the reduction of a disease risk (OJ L299, p. 1) which concerns the claim submitted by the plaintiffs "The regular consumption of significant amounts of water can reduce the risk of dehydration and concomitant reduction of performance" is declared void.
2. The defendant bears the costs of the proceedings.

Subject matter of the claim:

1 Subject matter of the claim for voidness is Regulation (EU) No. 1170/2011 of the Commission of 16/11/2011 with the part which refers to the claim submitted by the plaintiffs with the following wording: "The regular consumption of significant amounts of water can reduce the risk of dehydration and concomitant reduction of performance" (Reference No. EFSA opinion Q-2008-05014). Regulation (EU) No. 1170/2011 is based on Art. 17 of Regulation (EC) No. 1924/2006 of the European Parliament and the Council of 20 December 2006 on nutrition and health claims on foodstuffs.

(cf. Regulation (EU) Nr. 1170/2011 of the Commission of 16/11/2011, published in the Official Journal of the European Union L299/1 of 17/11/2011 – attached –).

Legal frame:

2 Regulation (EU) No. 1170/2011 is a registration decision with which the Commission refuses the authorisation of the claim "The regular consumption of significant amounts of water can reduce the risk of dehydration and concomitant reduction of performance" pursuant to Art. 17 of Regulation (EC) No. 1924/2006.

3 Pursuant to Art. 2 para. 1 lit. b) of Directive 2000/13/EC it is unlawful to market foodstuffs in a disease-related manner or to use disease-related claims in the labelling or getup of foodstuffs. This provision has been implemented into German law by way of Section 12 para. 1 No. 1 of the Feed and Food Act (LFGB). Art. 10 para. 1 of Regulation (EC) No. 1924/2006 bans the use of health claims in food advertising if the claims have not been expressly authorised pursuant to the Regulation.

4 "Notwithstanding Article 2 (1) b) of Directive 2000/13/EC", Art. 14 para. 1 lit. a) of Regulation (EC) No. 1924/2006 allows the use of disease risk claims, "where they have been authorised in accordance with the procedure laid down in Articles 15, 16, 17 and 19 of this Regulation for inclusion in a Community list of such permitted claims together with all the necessary conditions for the use of these claims".

5 Pursuant to the definition in Art. 2 para. 2 No. 6 of Regulation (EC) No. 1924/2006, "'reduction of disease risk claim' means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease".

6 Pursuant to the definition in Art. 2 para. 2 No. 1 of Regulation (EC) No. 1924/2006, "'claim' means any message or representation, which is not mandatory under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics ".

7 Pursuant to Art. 15 para. 1 Regulation (EC) No. 1924/2006, an application for authorisation has to be submitted in accordance with the further paragraphs of Art. 15 wherever the Regulation refers to this Article. Pursuant to Art. 15 para. 2 of Regulation (EC) No. 1924/2006, the application for authorisation is submitted to the national competent authority of a Member State which acknowledges receipt of the application within fourteen days of its receipt which has to be documented. The national competent authority informs the European Food Safety Authority without delay and transmits the application to the Authority as well as all supplementary information supplied by the applicant. The European Food Safety Authority informs the Member States and the Commission without delay of the application received and makes the information available to them; furthermore, it makes a summary of the application available to the public.

8 Pursuant to Art. 15 para. 3 of Regulation (EC) No. 1924/2006, an application for authorisation has to include the following:

"(a) the name and address of the applicant;
(b) the nutrient or other substance, or the food or the category of food, in respect of which the health claim is to be made and its particular characteristics;
(c) a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the health claim and any other material which is available to demonstrate that the health claim complies with the criteria provided for in this Regulation;
(d) ...
(e) a copy of other scientific studies which are relevant to that health claim;
(f) a proposal for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use."

9 Pursuant to Art. 15 para. 4 and 5 of Regulation (EC) No. 1924/2006, the Commission establishes implementing rules for this Article and – together with the European Food Safety Authority – appropriate technical guidance and tools.

10 Art. 16 para. 1 and 2 of Regulation (EC) No. 1924/2006 provide that the European Food Safety Authority gives an opinion within a time limit of five months after the date of receipt of a valid application for authorisation. The time limit can be extended by up to two months after the date of receipt of the information submitted

by the applicant if the European Food Safety Authority seeks supplementary information from the applicant.

11 Pursuant to Art. 16 para. 3 of Regulation (EC) No. 1924/2006, the European Food Safety Authority verifies
"(a) that the health claim is substantiated by scientific evidence;
(b) that the wording of the health claim complies with the criteria laid down in this Regulation"

12 Art. 16 para. 5 of Regulation (EC) No. 1924/2006 envisages that the European Food Safety Authority forwards to the Commission, the Member States and the applicant its opinion "including a report describing its assessment of the health claim and stating the reasons for its opinion and the information on which its opinion was based". Furthermore, the opinion is made public pursuant to Art. 38 para. 1 of the Regulation (EC) No. 178/2002. Pursuant to Art. 16 para. 6 2nd sentence of Regulation (EC) No. 1924/2006, the applicant and members of the public may make comments on the opinion of the European Food Safety Authority to the Commission within 30 days from its publication.

13 Pursuant to Art. 17 para. 1 Regulation (EC) No. 1924/2006, the Commission submits to the Standing Committee for the Food Chain and Animal Health, which is competent pursuant to Art. 23 para. 2 of the Regulation, a draft decision on the lists of permitted health claims within two months after receiving the opinion of the European Food Safety Authority, "taking into account the opinion of the Authority, any relevant provisions of Community law and other legitimate factors relevant to the matter". Pursuant to Art. 17 para. 2 of the Regulation, the draft decision to amend the lists has to include the details referred to in Art. 16 para. 4 of the Regulation, also i.a. name and address of the applicant.

14 Art. 17 para. 3 Regulation (EC) No. 1924/2006 demands that the final decision on the authorisation is made pursuant to the comitology proceedings mentioned in Art. 25 para. 3 of the Regulation. According to Art. 25 para. 3, Art. 5a paras. 1–4, Art. 7 and Art. 8 of Decision 1999/468/EC apply. Pursuant to Art. 17 para. 4 of Regulation (EC) No. 1924/2006, the Commission informs the applicant immediately about the decision and publishes details of the decision in the Official Journal of the European Union.

15 Pursuant to Art. 20 para. 1 of Regulation (EC) No. 1924/2006, the Commission establishes a Community Register of nutrition and health claims on food. The register contains "a list of rejected health claims and the reasons for their rejection" pursuant to Art. 20 para. 2 lit. d) of the Regulation. Pursuant to Art. 20 para. 3 of Regulation (EC) No. 1924/2006, the register is made available to the public.

16 The Regulations (EC) No. 353/2008 and No. 1169/2009 of the Commission contain implementation provisions on applications for authorisation of health claims pursuant to Regulation (EC) No. 1924/2006.

Summary of the pleas in law:

17 Regulation (EU) No. 1170/2011 has to be declared void, because the defendant has declared the mentioning of a "risk factor" compulsory for an application for authorisation although such an obligation does not follow from Regulation (EC) No. 1924/2006 (infringement of EU law, first plea in law).

18 Regulation (EU) No. 1170/2011 has to be declared void, because the defendant has overlooked that the plaintiffs have actually mentioned a "risk factor" in their proposal for the wording of the applied health claim (infringement of EU law, second plea in law).

19 Regulation (EU) No. 1170/2011 has to be declared void, because it is in breach of proportionality (infringement of EU law, third plea in law).

20 Regulation (EU) No. 1170/2011 has to be declared void, because it has no sufficient legal basis (infringement of EU law, fourth plea in law).

21 Regulation (EU) No. 1170/2011 has to be declared void, because the defendant has enacted a Regulation instead of the Decision stipulated in Regulation (EC) No. 1924/2006 (infringement of essential procedural requirements, fifth plea in law).

22 Regulation (EU) No. 1170/2011 has to be declared void, because the allocation of competences provided for by Regulation (EC) No. 1924/2006 between the defendant, the European Food Safety Authority and the Federal Office for Consumer Protection and Food Safety has been disregarded by the defendant (infringement of

essential procedural requirements, sixth plea in law).

23 Regulation (EU) No. 1170/2011 has to be declared void, because the compulsory time limits for the forwarding of the application for authorisation, the establishment of the scientific opinion and the adoption of the authorisation decision stipulated in Regulation (EC) No. 1924/2006 have been disregarded (infringement of essential procedural requirements, seventh plea in law).

24 Regulation (EU) No. 1170/2011 has to be declared void, because the defendant has disregarded essential submissions of the plaintiffs and interested third parties in its decision (infringement of essential procedural requirements, eighth plea in law).

25 Regulation (EU) No. 1170/2011 has to be declared void, because the defendant has not sufficiently observed its obligation to give reasons pursuant to Art. 296 para. 2 TFEU (ninth plea in law).

Facts:

26 On 11/2/2008 the plaintiffs applied for the authorisation of a health claim for water through the German Federal Office for Consumer Protection and Food Safety. Basis for the application was Art. 14 para. 1 in conjunction with Art. 15 para. 3 of Regulation (EC) No. 1924/2006. The proposed wording of the health claim in the shape of a disease risk reduction claim was:
"Regular consumption of significant amounts of water can significantly reduce the risk of development of dehydration and of concomitant decrease of performance."

The application expressly extended to any claim likely to have the same meaning for the consumer.

Enclosure A1: Application for authorisation of 11/2/2008.

27 After the plaintiffs had not received the statutorily prescribed acknowledgement of receipt from the Federal Office for Consumer Protection and Food Safety, one of the plaintiffs called an official of the Federal Office on 29/2/2008. During the telephone conversation he was advised that the application could not be found in the competent department of the Federal Office for Consumer Protection and Food Safety. Thereupon, the plaintiffs submitted their application for authorisation again on 10/3/2008.

Enclosure A2: Letter of the plaintiffs to the Federal Office for Consumer Protection and Food Safety of 10/3/2008.

28 Via e-mail of 14/3/2008, an official of the Federal Office for Consumer Protection and Food Safety sent a letter to one of the plaintiffs as acknowledgement of receipt of the application for authorisation which showed the date "13 January 2008". This letter was received via surface mail on 17/3/2008 by one of the plaintiffs. As is apparent from its official reference, the acknowledgement of receipt related to: "Your application of 23 November 2007 pursuant to Article 15 para. 1".

Enclosure A3: E-mail of the Federal Office for Consumer Protection and Food Safety of 14/3/2008 and acknowledgement of receipt with date "13 January 2008".

29 In their letter of 26/3/2008, the plaintiffs asked the head of the competent department of the Federal Office for Consumer Protection and Food Safety to send an acknowledgement of receipt which related to their application of 11/2/2008. Thereupon, one of the plaintiffs got an acknowledgement of receipt in advance via e-mail on 11/5/2008 which related to the plaintiffs' application of 11/2/2008 which, as is apparent from the acknowledgement of receipt, was received by the Federal Office for Consumer Protection and Food Safety on 12/2/2008. This confirmation of receipt reached one of the plaintiffs via surface mail on 13/5/2008.

Enclosure A4: Letter of the plaintiffs of 26/3/2008.

Enclosure A5: Acknowledgement of receipt of the Federal Office for Consumer Protection and Food Safety of 8/5/2008.

30 By e-mail of 9/5/2008, the plaintiffs asked the competent official of the Federal Office for Consumer Protection and Food Safety for further

information when the application for authorisation had been received by the European Food Safety Authority.

Enclosure A6: E-mail of the plaintiffs to the Federal Office for Consumer Protection and Food Safety of 9/5/2008.

31 The Federal Office for Consumer Protection and Food Safety referred one of the plaintiffs with a letter of 21/7/2008 to the implementing rules of the Commission in Regulation (EC) No. 353/2008 of 18/4/2008 and requested "to submit the application again, this time using the guidance published by EFSA".

Enclosure A7: Letter of the Federal Office for Consumer Protection and Food Safety of 21/7/2008.

32 Having returned from his holidays, the plaintiff addressed by the Federal Office for Consumer Protection and Food Safety responded with a letter of 21/8/2008 that the plaintiffs saw no reasons for "filing the application again using the guidance published by EFSA". For the purpose of justification they pointed out that Regulation (EC) No. 353/2008 was dated 18/4/2008 and could thus not apply to the application of 11/2/2008 already for reasons of time sequence. In this letter, the plaintiffs also pointed out that pursuant to Art. 15 para. 2 lit. a) Nos. ii) and iii) of Regulation (EC) No. 1924/2006 the Federal Office for Consumer Protection and Food Safety was obliged to inform the European Food Safety Authority "without delay" of the application and to make the application documents available to the Authority.

Enclosure A8: Letter of the plaintiffs to the Federal Office for Consumer Protection and Food Safety of 21/8/2008.

33 After they had not heard anything regarding their letter, the plaintiffs asked the head of the competent department of the Federal Office for Consumer Protection and Food Safety in an e-mail of 15/9/2008 whether their application of 11/2/2008 had already been transmitted to the European Food Safety Authority. Thereupon, the head of the department replied with an e-mail of 15/9/2008 that she had signed a reply to the plaintiffs' letter of 21/8/2011 a couple of days earlier and that the letter should reach the plaintiffs "in the next days".

Enclosure A9: E-mail of the plaintiffs to the Federal Office for Consumer Protection and Food Safety of 15/9/2008.

Enclosure A10: E-mail of the Federal Office for Consumer Protection and Food Safety of 15/9/2008.

34 On 18/9/2008, a letter of the Federal Office for Consumer Protection and Food Safety reached the plaintiffs in which the Federal Office Safety pointed out: "The transmission of your above mentioned application to EFSA was initiated".

Enclosure A11: Letter of the Federal Office for Consumer Protection and Food Safety of 12/9/2008.

35 On 20/10/2008 the plaintiffs asked the Federal Office for Consumer Protection and Food Safety why the submission of their application to the European Food Safety Authority had taken approximately seven months. In a letter of 11/11/2008 the head of the competent department of the Federal Office for Consumer Protection and Food Safety replied that the European Commission had requested the Member States with reference to Art. 18 para. 3 of Regulation (EC) No. 1924/2006 to take care that only valid applications were transmitted to the European Food Safety Authority. Because of the formal requirements of the European Food Safety Authority and several recently published implementing and adopting rules, additional time had been consumed whilst examining the application.

Enclosure A12: Letter of the plaintiffs to the Federal Office for Consumer Protection and Food Safety of 20/10/2008.

Enclosure A13: Letter of the Federal Office for Consumer Protection and Food Safety of 11/11/2008.

36 In a letter of 10/11/2008, which was also received by one of the plaintiffs on 12/11/2008

as the letter of 11/11/2008, the Federal Office for Consumer Protection and Food Safety pointed out that the European Food Safety Authority had "initially conducted a formal examination of your application". This related "in particular" to the "legal classification of the health claim". The European Food Safety Authority had voiced doubt towards the Federal Office for Consumer Protection and Food Safety whether this was in fact a claim pursuant to Art. 14 of Regulation (EC) No. 1924/2006, "since it made neither a direct nor an indirect reference to a disease". The Federal Office for Consumer Protection and Food Safety granted the plaintiffs a time limit until 28/11/2008 for commenting on these issues before advising the European Food Safety Authority of its own legal opinion. Furthermore, the head of the competent department of the Federal Office for Consumer Protection and Food Safety pointed out that pursuant to No. III 2.1 of the "Guidance on the implementation of Regulation No. 1924/2006 on nutrition and health claims made on foods, Conclusions of the Standing Committee on the food chain and animal health" it was sufficient "to adequately refer to the reduction of a risk factor in order to fall into the scope of application of Art. 14 para. 1 lit. a) of the Regulation". For the "appropriate examination of the application by EFSA" it was "necessary that the application documents mentioned the corresponding scientific connection between risk factor, in your case 'dehydration', and one or several disease patterns".

Enclosure A14: Letter of the Federal Office for Consumer Protection and Food Safety of 10/11/2008.

37 The plaintiffs replied to the letter of the Federal Office for Consumer Protection and Food Safety of 10/11/2008 with a letter of 28/11/2008 emphasising that subject matter of the application was the disease "dehydration and concomitant decrease of performance". Furthermore, they pointed out that the application in accordance with the requirements of Regulation (EC) No. 1924/2006 also extended to any claim likely to have the same meaning for the consumer as "dehydration and concomitant decrease of performance". By way of example, they mentioned "dehydration and physiological dysfunctions caused thereby", "physiological dysfunctions as a result of dehydration" and "restrictions of the physiological function through dehydration". Finally, the plaintiffs asked for a copy of the information on the legal opinion of the Federal Office for Consumer Protection and Food Safety to the European Food Safety Authority.

Enclosure A15: Letter of the plaintiffs to the Federal Office for Consumer Protection and Food Safety of 28/11/2008.

38 By e-mail of 29/1/2009 the head of the competent department of the Federal Office for Consumer Protection and Food Safety sent a letter to the plaintiffs, dated 18/12/2008, in which the Federal Office for Consumer Protection and Food Safety shared the opinion that "dehydration can be perceived as a disease". In the letter it also says that for the transmission of the submitted health claim within the meaning of Art. 14 para. 1 in conjunction with Art. 2 para. 2 No. 6 of Regulation (EC) No. 1924/2006 "the mentioning of a risk factor" was necessary in addition to the naming of the disease. Since there were different kinds of dehydration, like for example isotone, hypotone and hypertone dehydration, it was particularly important to exactly define the risk factor. The Federal Office for Consumer Protection and Food Safety asked to supplement the application for authorisation with a risk factor accordingly and suggested to refer to "the water content in tissue" when mentioning the risk factor.

Enclosure A16: Letter of the Federal Office for Consumer Protection and Food Safety to one of the plaintiffs of 18/12/2008.

39 With a letter of 10/2/2009 the plaintiffs answered pointing out that neither Art. 14 para. 1 of Regulation (EC) No. 1924/2006 nor the definition in Art. 2 para. 2 No. 6 of the Regulation expressly demanded the mentioning of a "risk factor". Rather all suggestions and implications regarding the reduction of risk factors were also comprised. The submitted claim at least suggested or implied "that the 'risk for the development of dehydration and concomitant decrease of performance' could be significantly reduced

by the consumption of water". The legislator had not envisaged any difference in definition between a disease risk and a risk factor in the development of a disease. Any risk factor as a contributing circumstance of a risk was thus a risk itself. At the same time, the plaintiffs agreed with the Federal Office for Consumer Protection and Food Safety that the reduction of water content in tissue mentioned in the previous correspondence could also be perceived as a "risk factor" when properly interpreting the submitted claim. Furthermore, they once again emphasised that the application did not only refer to the proposed wording literally, but expressly also to any claim "likely to have the same meaning for the consumer". The plaintiffs suggested the following other wordings:

"Regular consumption of significant amounts of water can positively influence a water loss in tissue (risk factor) and thus reduce the risk for the development of dehydration and concomitant decrease of performance."

or

"Regular consumption of significant amounts of water can significantly reduce the risk of development of dehydration and concomitant decrease of performance because it can positively influence water loss in tissue (risk factor)."

or

"Regular consumption of significant amounts of water can significantly reduce the risk of development of dehydration and concomitant decrease of performance (risk factor 100 %)."

or

"Regular consumption of significant amounts of water can significantly reduce the main risk factor and thus the risk of development of dehydration and concomitant decrease of performance."

Enclosure A17: Letter of the plaintiffs to the Federal Office for Consumer Protection and Food Safety of 10/2/2009.

40 Upon request, the head of the competent department of the Federal Office for Consumer Protection and Food Safety advised one of the plaintiffs on 19/5/2009 that the application and further correspondence had been transmitted to the European Food Safety Authority on 20/3/2009.

Enclosure A18: Letter of the Federal Office for Consumer Protection and Food Safety of 19/5/2009.

41 On 15/6/2009 the plaintiffs wrote to the European Food Safety Authority in order to find out when an opinion of the Authority could be expected regarding the application transmitted by the Federal Office for Consumer Protection and Food Safety on 15/9/2008. The European Food Safety Authority responded to one of the plaintiffs with a letter of 21/7/2009 that – involving the defendant – the question whether the application of the plaintiffs concerned a claim regarding the reduction of a disease risk within the meaning of the Regulation (EC) No. 1924/2006 was still being examined. With a letter of 27/7/2009 the plaintiffs pointed out to the European Food Safety Authority that the International Statistical Classification of diseases and related health problems (10th revision, version 1.3) of the World Health Organisation listed as cause of morbidity and mortality in Chapter XX:

"X54 Lack of water
Incl.: lack of water as the cause of:
– dehydration
– exsiccation
– inanition".

Enclosure A19: Letter of the plaintiffs to the European Food Safety Authority of 15/6/2009.

Enclosure A20: Letter of the European Food Safety Authority of 21/7/2009.

Enclosure A21: Letter of the plaintiffs to the European Food Safety Authority of 27/7/2009.

42 On 23/9/2009 (in advance via e-mail) the European Food Safety Authority replied that also at this time "the authorisation of this health claim is in fact still being discussed with the European Commission and the Member States. That is why at this time EFSA is not yet responsible. Only recently, on 17/7/2009 in Brussels, this question was examined once again. An answer is still being expected". The plaintiffs responded with a letter of 15/10/2009 and pointed out that

pursuant to Art. 16 para. 1 of Regulation (EC) No. 1924/2006 it was the task of the European Food Safety Authority to give a scientific opinion on the application for authorisation within a time limit of five months. The decision on the authorisation itself remained the task of the defendant pursuant to Art. 17 of the Regulation. Accordingly, it was incomprehensible why the European Food Safety Authority did not perform its task of a scientific assessment of the claim applied for. The European Food Safety Authority replied with a letter of 23/11/2009 that during the course of the application "interpretation questions had arisen regarding the applicable European law" which had to be clarified in advance with the defendant and the Member States. For further information the plaintiffs should turn to the Federal Office for Consumer Protection and Food Safety.

Enclosure A22: Letter of the European Food Safety Authority of 23/9/2009.

Enclosure A23: Letter of the plaintiffs to the European Food Safety Authority of 15/10/2009.

Enclosure A24: Letter of the European Food Safety Authority of 23/11/2009.

43 After the plaintiffs had turned to the Federal Office for Consumer Protection and Food Safety for further information, they were informed that the European Food Safety Authority apparently wanted to get rid of the plaintiffs' application for authorisation arguing that applications for authorisation of claims pursuant to Art. 14 para. 1 of Regulation (EC) No. 1924/2006 could only be filed by food business operators. Thereupon, the plaintiffs made it clear in a letter of 15/1/2010 that pursuant to the wording of the Regulation such applications could of course be filed by other interested parties and once again emphasised that the statutory time limits for the opinion of the European Food Safety Authority had long been exceeded. In its letter of 27/1/2010 to one of the plaintiffs the European Food Safety Authority replied that "answering questions regarding the interpretation of European law was not one of the tasks of the Authority". For this reason, the defendant and the Federal Office for Consumer Protection and Food Safety had been informed.

Enclosure A25: Letter of the European Food Safety Authority to the Federal Office for Consumer Protection and Food Safety of 9/10/2009.

Enclosure A26: Letter of the European Food Safety Authority to the Federal Office for Consumer Protection and Food Safety of 9/10/2009.

Enclosure A27: Letter of the European Food Safety Authority of 27/1/2010.

44 After an approach by the European Food Safety Authority and with a copy to one of the plaintiffs the Federal Office for Consumer Protection and Food Safety advised the European Food Safety Authority on 4/2/2010 that the wording of Regulation (EC) No. 1924/2006 according to the opinion of the Federal Office did not allow an unambiguous interpretation whether applications pursuant to Art. 15 para. 1 of the Regulation could only be filed by food business operators.

Enclosure A28: Letter of the Federal Office for Consumer Protection and Food Safety of 7/9/2010.

45 With a letter of 16/12/2009 the plaintiffs had directly written to the competent official of the defendant regarding the "interpretation questions concerning applicable European law" which according to the European Food Safety Authority had to be discussed with the defendant in order to find out with what kind of potential support the processing of the application which in the meantime had been pending before the European Food Safety Authority for 15 months could be accelerated. In a reply of 19/1/2010 the defendant pointed out that the examination of the "validity of applications filed under the Regulation" was a task of the respective Member State. That is why the European Food Safety Authority had turned to the competent Federal Office for Consumer Protection and Food Safety in its letter of 9/10/2009; an answer was apparently still being expected. After the

Federal Office for Consumer Protection and Food Safety had replied to the European Food Safety Authority that Regulation (EC) No. 1924/2006 according to its opinion allowed potentially different interpretations of the question whether only food business operators could file applications pursuant to Art. 15 para. 1 of the Regulation, the plaintiffs once again wrote to the defendant on 21/4/2010 asking it to persuade the European Food Safety Authority to process the application for authorisation now having been pending there for 19 months.

Enclosure A29: Letter of the plaintiffs to the defendant of 16/12/2009.

Enclosure A30: Answer of the defendant of 19/1/2010.

Enclosure A31: Reply of the plaintiffs of 21/4/2010.

46 In a further letter of the defendant to one of the plaintiffs which was received on 16/7/2010, the defendant advised this plaintiff that the plaintiffs' application for authorisation had been discussed upon an informal meeting of the "Working Group on Nutrition & Health Claims" on 12/4/2010 with the Member States. This had resulted in the view that the application was not complying with the requirements of Regulation (EC) No. 1924/2006 for health claims because the application did not mention a risk factor. In this context, the European Food Safety Authority had once again got in touch with the competent German Office since it was the responsibility of Member States to examine the validity of applications for authorisation. A reply by the Federal Office for Consumer Protection and Food Safety was not known. At the same time the defendant conceded that Regulation (EC) No. 1924/2006 also allowed applications of interested persons who are not food business operators.

Enclosure A32: Letter of the plaintiff of 9/7/2010 (received on 16/7/2010).

47 On 7/10/2010 a letter dated 1/10/2010 of the European Food Safety Authority reached the plaintiffs. The European Food Safety Authority explains therein that it was not in a position to identify a specific risk factor of the disease concerned in the application for authorisation. It prompted the plaintiffs to comment on this issue within 30 days. The scientific examination was to continue subsequently. The European Food Safety Authority argued that the beneficial physiological effect of a disease risk reduction claim was the reduction or beneficial change of a risk factor in the development of a human disease and not the reduction of the disease risk itself. In their reply of 25/10/2010 the plaintiffs pointed out that there were two applicants whilst the defendant as well as the Federal Office for Consumer Protection and Food Safety and the European Food Safety Authority were invariably only writing to one plaintiff. In this letter the plaintiffs emphasised that Regulation (EC) No. 1924/2006 according to their opinion did not demand the mentioning of a "risk factor". Furthermore, an alternative risk factor had been carved out in the letter of 10/2/2009 to the Federal Office for Consumer Protection and Food Safety which had been transmitted to the European Food Safety Authority. Additionally, the plaintiffs listed several generally acknowledged scientific research results on "dietary reference values for water" in their letter which had recently been published by the European Food Safety Authority itself in which the connection between the consumption of water and dehydration as well as circumstances of disease resulting therefrom had been dealt with.

Enclosure A33: Letter of the European Food Safety Authority to one of the plaintiffs of 1/10/2010.

Enclosure A34: Answer of the plaintiffs of 25/10/2010.

Enclosure A35: Scientific opinion on dietary reference values for water, EFSA-Journal 2010; 8(3); 1459.

48 In EFSA-Journal 2011;9(2):1982 [7pp.] of February 2011, the European Food Safety Authority published a scientific opinion of the "Panel on dietetic products, nutrition and allergies (NDA)" with the title "Scientific opinion on the substantiation of a health claim related to water and reduced risk of development of dehydration and

of concomitant decrease of performance pursuant to Article 14 of Regulation (EC) No. 1924/2006". The scientific opinion came to a negative result regarding the claim submitted by the plaintiffs. By way of reasons, the European Food Safety Authority essentially pointed out only that it could not identify a "risk factor" which, however, was necessary for the classification of the claim as a health claim pursuant to Art. 14 para. 1 of Regulation (EC) No. 1924/2006. The opinion was published for comments by interested parties pursuant to Art. 16 para. 6 of Regulation (EC) No. 1924/2006.

Enclosure A36: Scientific opinion on the substantiation of a health claim related to water and reduced risk of development of dehydration and of concomitant decrease of performance pursuant to Article 14 of Regulation (EC) No. 1924/2006, EFSA-Journal 2011; 9(2):1982 [7pp.].

49 In the statutory time limit of 30 days for comments, nine statements by enterprises, lawyers and university professors reached the defendant. All comments were critical of the opinion of the European Food Safety Authority and suggested a review. In another statement towards the defendant the plaintiffs also pointed out with several arguments that the opinion of the European Food Safety Authority was based on an unjustified interpretation of Regulation (EC) No. 1924/2006 and was wrong as regards its content. A reply by the European Food Safety Authority was only made to the statement by Cognis.

Enclosure A37: Public statements and statement of the plaintiffs in the proceedings pursuant to Art. 16 para. 6 of Regulation (EC) No. 1924/2006 to the defendant as well as reply of the European Food Safety Authority to the comments by Cognis (as **enclosure bundle**).

50 In Commission Regulation (EU) No. 1170/2011 of 16/11/2011, published in the Official Journal L299/1 of 17/11/2011 the defendant refused the authorisation of the health submitted claim by the plaintiffs "The regular consumption of significant amounts of water can reduce the risk of development of dehydration and of concomitant decrease of performance" pursuant to Art. 17 para. 4 of Regulation (EC) No. 1924/2006. With a letter of 28/11/2011 which was sent to the plaintiffs on 28/11/2011 via e-mail, the defendant advised the plaintiffs that according to the opinion of the European Food Safety Authority Q-2008-05014 the submitted risk factors were "measures of water depletion and thus are measures of the disease". Risk reduction claims had to refer to the reduction of an identified risk factor for the development of a human disease which was following from Art. 2 para. 6 of Regulation (EC) No. 1924/2006. That is why the missing scientific substantiation of the reduction of a suitable risk factor in the development of dehydration was not complying with the requirements of Regulation (EC) No. 1924/2006; thus the submitted claim could not be authorised. Furthermore, the defendant mentioned that in its decision it and the Member States had considered all statements which the defendant had received pursuant to Art. 16 para. 6 of the Regulation.

Enclosure A38: Letter of the defendant to the plaintiffs of 28/11/2011.

Legal assessment:

51 The statement of claim is admissible and justified pursuant to Art. 263 of the Treaty on the Functioning of the European Union (TFEU)

Admissibility of the claim:

52 The claim is admissible pursuant to Art. 263 para. 4 TFEU. This already follows from the fact that the plaintiffs are addressees of the challenged legal act. Regulation (EU) No. 1170/2011 – in its challenged part – directly concerns the application for authorisation of the plaintiffs of 11/2/2008 to which it refers. With the Regulation the application for authorisation was rejected by the defendant. The plaintiffs were notified in person by the defendant with the letter of 28/11/2011; thus, the Regulation was addressed by the defendant directly to the plaintiffs.

53 The plaintiffs are directly and individually concerned by Regulation (EU) No. 1170/2011 in any event. The direct concern follows from the fact that the plaintiffs may not use the submitted health claim pursuant to Art. 14 para. 1 in conjunction with Art. 10 para. 1 of Regulation (EC) No. 1924/2006 as well as Art. 2 para. 1 lit. b) of Directive 2000/13/EC. This is an absolute advertising ban. The plaintiffs are also individually concerned. Pursuant to the so called Plaumann formula, anyone is individually concerned who is touched by a challenged legal act because of certain personal characteristics in particular respects that distinguish him from all other persons and is thus similarly individualised as an addressee (ECJ, C-25/62 – Plaumann). The plaintiffs as applicants are at least individualised as addressees by the refusal of their application in Regulation No. 1170/2011.

54 The admissibility of the claim also follows from permanent case law of the Court of the European Union, pursuant to which anyone is allowed to claim against a legal act of an institution of the Union who, with individual rights, has been involved into formal proceedings forming the basis for the issue of a legal act (cf. only ECJ, joint matters C-67, 68 and 70/85 – van der Kooy BV and others v. Commission, marginal 20 seq.). In the case at hand, the plaintiffs submitted a proper application for authorisation of the health claim "The regular consumption of significant amounts of water can reduce the risk of dehydration and of concomitant reduction of performance" by the Commission in the proceedings laid down in Art. 15 of Regulation (EC) No. 1924/2006. The defendant has apparently perceived the application as admissible – this is expressly mentioned in its letter of 28/11/2011 (Enclosure A38) – but has refused it with a procedurally terminal decision by way of Regulation (EU) No. 1170/2011. In case of a refusal of their application for authorisation the applicants pursuant to Art. 15 para. 1 of Regulation (EC) No. 1924/2006 – i.e. instantly the plaintiffs – thus must have a chance to file a claim for voidness of the Regulation which terminates the proceedings (thus also Delewski, LMuR 2009, 80, 81 seq. as well as Meisterernst/Haber, Health & Nutrition Claims, Hamburg 2011, Art. 17 marginal 14–14d).

55 Furthermore, Regulation (EU) No. 1170/2011 is a decision directly addressed towards the plaintiffs functionally. The Regulation form cannot disguise that the challenged legal act is a negative registration decision of the defendant which rejects the application of the plaintiffs for authorisation and registration of the health claim "The regular consumption of significant amounts of water can reduce the risk of dehydration and concomitant reduction of performance" in the register of authorised health claims. This already follows from the underlying Regulation (EC) No. 1924/2006 itself. That is because Art. 17 of that Regulation expressly provides that the authorisation of health claims by the defendant has to be performed by way of a Decision within the meaning of ex Art. 249 TEC. By choosing a Regulation as the legal instrument of its authorisation decision the defendant has not complied with this express requirement of the European legislator. It cannot be at the defendant's discretion to obviate the legal protection of the plaintiffs, as envisaged by the European legislator, by choosing a legal instrument contrary to the Regulation. With respect to the legal protection of the plaintiffs, Regulation (EU) No. 1170/2011 thus has to be treated functionally like a Decision – as expressly envisaged by Regulation (EC) No. 1924/2006. This is rather a "hybrid" legal act which can be the basis of a legal right of action (cf. ECJ, C-50/00, Unión de Pequeños Agricultores, marginal 36).

56 The admissibility of the claim finally follows from the requirement of effective legal protection. The plaintiffs have no other alternative of proceeding against the refusal of the application for authorisation. In connection with Art. 14 para. 1 and Art. 10 para. 1 of Regulation (EC) No. 1924/2006 with Art. 2 para. 1 lit. b) of Directive 2000/13/EC, the new Regulation (EU) No. 1170/2011 effectively establishes a ban of the further use of the submitted health claim for marketing food. This is a directly effective ban all over the Union which does not require any national implementation. Effective legal protection can therefore only be achieved by the plaintiffs through the action for voidness against Regulation (EU) No. 1170/2011.

Justification of the claim:

57 The claim is justified pursuant to Art. 263 para. 2 in conjunction with para. 4 TFEU. The

voidness of Regulation (EU) No. 1170/2011 follows from nine pleas of law.

First plea in law: No "risk factor" necessary

58 Regulation (EU) No. 1170/2011 has to be declared void, because the defendant has declared the mentioning of a "risk factor" compulsory for an application for authorisation although such an obligation does not follow from Regulation (EC) No. 1924/2006 (infringement of EU law, first plea in law).

59 Regulation (EU) No. 1170/2011 is in conflict with the requirements of Regulation (EC) No. 1924/2006. The plaintiffs' application for authorisation concerning the claim "The regular consumption of significant amounts of water can reduce the risk of dehydration and of concomitant reduction of performance" could not be refused on the grounds that it did not comply with Regulation (EC) No. 1924/2006. Pursuant to Art. 17 para. 1 in conjunction with Art. 16 para. 3 and Art. 14 para. 1 of Regulation (EC) No. 1924/2006, the defendant had to examine first of all upon the basis of the application particulars and the opinion of the European Food Safety Authority, "that the health claim is substantiated by scientific evidence" and whether "the wording of the health claim complies with the criteria laid down in this Regulation". Furthermore, the defendant had to take into account "any relevant provisions of Community law and other legitimate factors relevant to the matter" pursuant to Art. 17 para. 1 Regulation (EC) No. 1926/2006.

60 It is clear from the recitals of Regulation (EU) No. 1170/2011 and the letter of the defendant with which the applicants were informed about the Regulation that the defendant bases its decision exclusively on the reason that the wording of the health claim – allegedly – does not conform with the formal requirements of Regulation (EC) No. 1924/2006. The instant issue is that pursuant to the defendant's opinion a special risk factor in the development of the human disease dehydration should have been identified. The further reference in Regulation (EU) No. 1170/2011 that the statutorily required scientific substantiation had not been sufficiently established only relates to this issue. The quality of the scientific evidence which the plaintiffs submitted in the application procedure, however, has neither been doubted by the defendant nor the European Food Safety Authority in any way. Furthermore, the defendant has not based its decision on any relevant provisions of Union law or other relevant legitimate factors mentioned in Art. 17 para. 1 of Regulation (EC) No. 1924/2006.

61 Essentially, the case turns around the question whether Regulation (EC) No. 1924/2006 – as purported by the defendant – requires the mentioning of a specific risk factor in the development of a human disease for applications pursuant to Art. 15 in conjunction with Art. 14 para. 1 lit. a) of the Regulation and – if so – whether the plaintiffs have identified such a risk factor and have established sufficient scientific evidence.

62 Already with the letter of 10/2/2009 to the Federal Office for Consumer Protection and Food Safety (Enclosure A17) as well as with their letter of 25/10/2010 towards the European Food Safety Authority (Enclosure A34), the plaintiffs had comprehensively explained that the mentioning of a special disease risk reduction factor was not necessary pursuant to the requirements of Regulation (EC) No. 1924/2006. From the starting point in Art. 14 para. 1 lit. a) of Regulation (EC) No. 1924/2006, the application procedure pursuant to Art. 15 of the Regulation concerns the use of health claims in the shape of "reduction of disease risk claims". The wording of this provision does not contain a reference to a "risk factor". The legal definition in Art. 2 para. 2 No. 6 of Regulation (EC) No. 1924/2006 of a "reduction of disease risk claim" does not expressly demand the mentioning of a "risk factor" either but has intentionally been worded broadly by the European legislator. Accordingly, "any health claim that states, suggests or implies that the consumption of ... a food ... significantly reduces a risk factor in the development of a human disease" is sufficient. Thus – as with the legal definition of health claims in general – any suggestions and implications regarding the reduction of disease risk factors are included.

63 A precise distinction between "disease risk" (thus Art. 14 para. 1 lit. a) of Regulation (EC) No. 1924/2006) and "risk factor in the development of a human disease" (thus Art. 2 para. 2 No. 6 of the Regulation) has therefore not been established by the European legislator

(cf. Meisterernst, ZLR 2002, 589, 578). This is also confirmed by a press release of the defendant itself (MEMO/06/200 of 16/5/2006, **Enclosure A39**), in which the question "What are health and nutrition claims?" is answered i.a. as follows: "Health claims maintain that there is a relationship between a specific food and improved health, or that a food can reduce the risk of a particular disease". Regarding further explanations of a so called "disease reduction claim", the press release expressly refers to the indication "calcium helps reduce the risk of osteoporosis". Academic commentary literature also explains the interpretation of the term "risk factor" mentioning this example and emphasises "the term must therefore be interpreted broadly" (Meisterernst/ Haber, Health & Nutrition Claims, Hamburg 2011, Art. 2 marginal 30).

64 The result of this interpretation is also confirmed by the general rules of German language comprehension. "Risk" (from the Italian word risico = cliff) is a "potentially negative outcome of an undertaking resulting in disadvantage, loss or damage" and "factor" (from the Latin word factor = maker, producer) is "something which has certain effects in a certain context" or a "contributing cause" or a "codetermining, essential circumstance". "Risk factor" therefore means "factor resembling a certain risk" (DUDEN, Deutsches Universalwörterbuch, 2nd edition 1989, 481 and 1254 and DUDEN, Das große Wörterbuch der deutschen Sprache in 6 volumes, 1977, Vol. II, 790 and Vol. V, 2168). Accordingly, any risk factor as a contributing circumstance of a risk is at the same time a risk itself which is why it "presents a particular risk".

65 Furthermore, this interpretation is also confirmed by the use of the risk term in practice. The Federal Agency for Health Information i.a. refers to "malnutrition" as a risk factor (Franzkoviak, "Risikofaktoren", in: BZgA, Leitbegriffe der Gesundheitsförderung, 4th edition 2003, 195, 196). In epidemiology, one does not distinguish clearly either between risk and risk factor.

66 In the "Guidelines for use of nutrition and health claims" of the Codex Alimentarius Commission (CAC/GL 23-1997, **Enclosure A40**) two examples of disease risk reduction claims are mentioned: "A healthful diet low in nutrient or substance A may reduce the risk of disease D. Food X is low in nutrient or substance A" and "A healthful diet rich in nutrient or substance A may reduce the risk of disease D. Food X is high in nutrient or substance A". Both disease risk reduction claim examples do not mention a specific risk factor as such.

67 This is also very clear with a view to the significance of folate for the avoidance of the risk of neural tube defects (NTD). Corresponding risk reduction claims are not only scientifically accepted but are also correctly propagated by official institutions. For example "Health Canada", the "federal department responsible for helping Canadians maintain and improve their health" gives the following advice: "Research has shown that women who take a daily vitamin supplement containing folic acid before conception and in the early weeks of pregnancy can reduce the risk of having a baby with an NTD" (cf. http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/folic-folique-eng.php). The European Food Safety Authority also points out: "the health benefits of folic acid in relation to the reduction in risk of NTDs are well established ..." (cf. http://www.efsa.europa.eu/en/scdocs/doc/3e.pdf). The supply of the nutrient is therefore suitable to reduce the risk of neural tube defects. A special risk factor is not mentioned in this context. It is rather pointed out in this and several other statements that an insufficient supply of folate presents a risk of neural tube defects and the supply of folate accordingly reduces this risk.

68 Other than maintained by the defendant and the European Food Safety Authority, the necessity of a clear distinction between "risk" and "risk factor" and a resulting statutory obligation to mention a specific risk factor in the application for authorisation in issue does not follow from the applicable provision of EU law. Obviously, such a distinction, as the example of folate and neural tube defect shows, is often neither possible nor commonly accepted. It is – as has been shown – neither demanded by Regulation (EC) No. 1924/2006 itself nor by the implementing Regulation (EC) No. 353/2008 or publications of the European Food Safety Authority itself, for example "EFSA Presubmission guidance" or "EFSA Scientific and technical guidance". On the contrary: Pursuant to Art. 15 para. 3 lit. f) of Regulation (EC) No. 1924/2006, the applicant

has only got to submit the "proposal for the wording of the health claim". There is no mention of the identification or the mentioning of a "risk factor".

69 The authorisation decision of the defendant which is completely based on the scientific opinion of the European Food Safety Authority is also infringing law with a view to the principle of uniform and transparent assessment proceedings. It is in clear conflict with scientific assessments of the European Food Safety Authority in comparable cases of applications which were authorised by the defendant on the basis of those scientific opinions.

70 The opinion on an application pursuant to Art. 14 of Regulation (EC) No. 1924/2006 regarding xylitol chewing gum/pastilles and the reduction of the risk of tooth decay (EFSA Journal 2008, 852, 1-15, **Enclosure A41**) dealt with the application for authorisation of a claim on the reduction of a disease risk concerning tooth decay in the form of caries. The applicant had proposed as the wording of the health claim applied for: "Xylitol chewing gum/pastilles reduces the risk of caries". In this context the European Food Safety Authority commented the following i.a.:

"The claimed effect ‚reduces the risk of tooth decay' relates to a reduction of dental caries development. ... The applicant states that the application focuses on studies with dental caries as primary end point, and that although studies on the risk factors ‚number of mutans streptococci' and ‚amount of plaque' are also presented, these are not the primary outcome.

...

The Panel considers that the claimed effect i.e., reducing the risk of tooth decay, is beneficial to health."

71 Subsequently, the European Food Safety Authority changed the wording of the proposed claim and suggested its own wording of a claim on the reduction of a disease risk. The scientists in Parma explained this as follows:

"The Panel considers that the following wording reflects the scientific evidence: ‚Xylitol chewing gum reduces the risk of caries in children'.

The specific risk factor(s) for tooth decay affected by xylitol chewing gum is unclear."

72 The defendant authorised a corresponding disease risk reduction claim with the wording suggested by the European Food Safety Authority in Regulation (EC) No. 1024/2009 with express reference to the scientific opinion and the proposal by the European Authority. The European Food Safety Authority itself had made it clear at the time in the passage quoted that the "risk factor" of the health claim was unclear to it. The defendant made no further mention of a "risk factor" at the time. In other words: The defendant authorised a disease risk reduction claim for xylitol with Regulation (EC) No. 1024/2009 without perceiving the mentioning of a "risk factor" as necessary whilst in Regulation (EU) No. 1170/2011 it determined the mentioning of a "risk factor" to be compulsory pursuant to Regulation (EC) No. 1924/2006 and refused the claim submitted by the plaintiffs for this reason alone. That is legally unjustified.

Second plea in law: A risk factor is part of the application for authorisation

73 Regulation (EU) No. 1170/2011 has to be declared void, because the defendant has overlooked that the plaintiffs have actually mentioned a "risk factor" in their wording proposals for the applied health claim (infringement of EU law, second plea in law).

74 Regulation (EU) No. 1170/2011 breaches the requirements of Regulation (EC) No. 1924/2006 because the application of the plaintiffs in fact contained a "risk factor". For this reason alone, the defendant was not allowed to refuse the plaintiffs' application for authorisation.

75 Already with its letter of 18/12/2008 (Enclosure A16), the Federal Office for Consumer Protection and Food Safety, after conferring with the European Food Safety Authority, had pointed out to the plaintiffs that they could "refer to the water content in tissue for the mentioning of the risk factor". This was because the plaintiffs had already raised this context in their letter of 28/11/2008 under item 3 c) (Enclosure A15). As early as in the year 2008, there was thus a mentioning of a risk factor by the plaintiffs in the opinion of the Federal Office for Consumer Protection and Food Safety, even if this was not expressly included in the proposed wording of the health claim in the application for authorisation.

76 In their letter of 10/2/2009, the plaintiffs explained their application for authorisation in

detail by way of carving out the risk factor which – albeit not expressly mentioned – was already contained in the originally proposed wording. Thus, they complemented their wording with the following variations:

"Regular consumption of significant amounts of water can positively influence a water loss in tissue (risk factor) and thus reduce the risk for the development of dehydration and concomitant decrease of performance."

or

"Regular consumption of significant amounts of water can significantly reduce the risk of development of dehydration and concomitant decrease of performance because it can positively influence water loss in tissue (risk factor)."

or

"Regular consumption of significant amounts of water can significantly reduce the risk of development of dehydration and concomitant decrease of performance (risk factor 100%)."

or

"Regular consumption of significant amounts of water can significantly reduce the main risk factor and thus the risk of development of dehydration and concomitant decrease of performance."

77 The risk factor "water loss in tissue" identified by the plaintiffs is labelled as "measure of the disease" by the European Food Safety Authority in its scientific opinion (Enclosure A36). This has been adopted by the defendant in Regulation (EU) No. 1170/2011. However, it remains completely unclear what the difference between a "risk factor" and a "measure of the disease" should be. In any event, the terms "risk factor", "risk" and "disease" are – as explained before – permeating one another. A "measure of the disease" is not mentioned in Regulation (EC) No. 1924/2006.

78 The "water loss in tissue" is described in the opinion of the European Food Safety Authority (Enclosure A36) as a "measure of the disease dehydration". However, the plaintiffs have not mentioned a disease called "dehydration" in their originally proposed wording but rather "dehydration and concomitant decrease of performance". The second part "and concomitant decrease of performance" has been completely ignored by the European Food Safety Authority and subsequently by the defendant. Even the German wording of the original application is falsely quoted in Regulation (EU) No. 1170/2011 where the German word "Dehydratation" is shortened to "Dehydration".

79 The European Food Safety Authority itself has portrayed the connection between "water loss in tissue", "dehydration" and "decrease of performance" as scientifically undisputed and has published a corresponding statement as "Scientific opinion on dietary reference values for water" (EFSA-Journal 2010, 8(3):1459, Enclosure A35). This is where the European Food Safety Authority explains in detail that water loss in tissue can lead to a loss of performance via dehydration. The European Authority, obliged to strict scientific criteria pursuant to Art. 29 of Regulation (EC) No. 178/2002, has thus made a connection between water loss in tissue, dehydration and decrease of performance in the year 2010, which it has ignored in its scientific assessment of the plaintiffs' application and denied with unjustified formal arguments in the year 2011 (Enclosure A36). The defendant has adopted this without critical examination and has not put forward any further arguments for the refusal of the application for authorisation.

80 Furthermore, it can be concluded from the statement of the European Food Safety Authority "Scientific opinion on dietary reference values for water" (Enclosure A35) that the European Authority itself perceives dehydration as the "risk factor" of the disease "decrease of performance". Then, "water loss in tissue" may consequentially be a "measure of the disease ". The plaintiffs, however, have explained this connection already in their application (Enclosure A1) and several times in the subsequent correspondence with the Federal Office for Consumer Protection and Food Safety, the defendant and the European Food Safety Authority. The risk factor "dehydration" is even expressly mentioned in the proposed wording of the health claim in the application for authorisation – there also in the context with the disease "decrease of performance". The "risk factor" demanded by the European Food Safety Authority and the defendant was thus contained in the application for authorisation from the outset – the defendant and the European Food Safety Authority, however, obviously did not want to acknowledge it.

81 In this context, it has to be pointed out that the application for authorisation of a health claim

pursuant to Art. 15 para. 3 lit. f) of Regulation (EC) No. 1924/2006 merely needs to contain:
*"a **proposal** for the wording of the health claim for which authorisation is sought including, as the case may be, specific conditions for use ".* [Emphasis by us]"

82 Pursuant to the requirements of Regulation (EC) No. 1924/2006, the wording of the health claim is therefore merely a proposal by the applicants. It is clear from Art. 16 of Regulation (EC) No. 1924/2006 that the European Food Safety Authority has discretion in the examination and can therefore change the proposed wording if necessary. In the past, the European Food Safety Authority has indeed adjusted the wording of claims when scientifically assessing applications for authorisation in several instances. Especially with a view to its own publication of a "Scientific opinion on dietary reference values for water" (Enclosure A35), the European Food Safety Authority could and should thus have been able to change the wording of the health claim proposed by the plaintiffs. The same applies to the defendant who, pursuant to Art. 17 of Regulation (EC) No. 1924/2006, has to make its own decision on the wording of the health claim to be authorised – it can thereby deviate from the scientific opinion of the European Food Safety Authority. However, neither the defendant nor the European Food Safety Authority have even made use of their discretion. On the contrary, they obviously wanted to get rid of an unwelcome application for authorisation with formal arguments, although the European legislator obliges them to use their discretion upon the basis of scientific evidence. The scientific evidence for the health claim applied for by the plaintiffs is undisputed; this is shown by the "Scientific opinion" of the European Food Safety Authority submitted as Enclosure A36.

83 But even if one wanted to formally restrict the plaintiffs to the wording of the proposed health claim, they have established sufficient evidence for the "risk factor" which is mistakenly demanded by the defendant. The legal definitions of the European legislator regarding "claim", "health claim" and "reduction of disease risk claim" pursuant to Art. 2 para. 2 Nos. 1, 5 and 6 of Regulation (EC) No. 1924/2006 have to be taken into account. There it always says "which states, suggests or implies". In other words: The European legislator defines the terms mentioned broadly. A health claim within the scope of application of Regulation (EC) No. 1924/2006 is not confined to a specific wording but comprises any wording which from the perspective of the average consumer has the same meaning. What is applicable in one direction must also be true in the other direction. The proposed wording of the plaintiffs' health claim has thus got to be interpreted broadly and to comprise any wordings having the same meaning. This interpretation also follows unambiguously from the authorisation practice of the defendant itself. For example, recital 12 of the above mentioned authorisation Regulation (EC) No. 1024/2009 (Enclosure A41) expressly reads as follows:
"One of the objectives of the Regulation (EC) No 1924/2006 is to ensure that health claims are truthful, clear and reliable and useful to the consumer, and that wording and presentation have to be taken into account in that respect; that therefore where the wording of claims has the same meaning for consumers as that of an authorised health claim as they demonstrate the same relationship that exists between a food category, a food or one of its constituents and health, included in Annex I to the present Regulation, they should be subject to the same conditions of use indicated therein."

84 Then, the express mentioning of a specific "risk factor" cannot be decisive, if the "risk factor" is patent from the application as a whole and can be found in the proposed wording. This was clearly the case here because the plaintiffs mentioned "dehydration" as well as "concomitant decrease of performance" in their proposed wording. Even the "water loss in tissue" was already contained in the application – as the Federal Office for Consumer Protection and Food Safety correctly determined (cf. Enclosure A16). Furthermore, the plaintiffs have unambiguously carved out the connection between "water loss in tissue", "dehydration" and "concomitant decrease of performance" in the further correspondence with the defendant and the European Food Safety Authority as well as the Federal Office for Consumer Protection and Food Safety. The publication of the European Food Safety Authority on water (Enclosure A35)

shows that the European Authority has also clearly acknowledged this connection and recognises it as sufficiently scientifically substantiated. The defendant has therefore not raised any doubts as to this scientific connection in its authorisation decision pursuant to Art. 17 of Regulation (EC) No. 1924/2006.

Third plea in law: Lack of proportionality

85 Regulation (EU) No. 1170/2011 has to be declared void, because it is in breach of proportionality (infringement of EU law, third plea in law).

86 Pursuant to Art. 5 para. 1 and 4 of the EU Treaty, the defendant has to observe the principle of proportionality when making use of its powers of regulation (cf. ECJ, joint cases C-36/97 and C-37/97 – Kellinghusen, marginal 33 seq.). Measures of institutions of the Union are only proportional if they are suitable and necessary for the achievement of the lawfully pursued goals (cf. ECJ, C-8/55 – Fédération Charbonnière de Belgique). Pursuant to the case law of the European Court of Justice, absolute advertising bans like Art. 14 para. 1 in conjunction with Art. 10 para. 1 of Regulation (EC) No. 1924/2006 and Art. 2 para. 1 lit. b) of Directive 2000/13/EC are subject to particularly strict examinations of proportionality (cf. ECJ, C-239/02, ZLR 2004, 600 – Douwe Egberts). This is because the plaintiffs are banned from using the submitted health claim through the refusal of their application for authorisation – and that includes any claim which declares, suggests or implies the subject matter of the proposed wording.

87 Goal of Regulation (EC) No. 1924/2006 is to restrict health claims in food advertising to those which are scientifically sufficiently substantiated. For this purpose, the European legislator has stipulated the authorisation of such claims by the defendant taking into account the European Food Safety Authority as specialised body and engaging the Standing Committee for the Food Chain and Animal Health as well as the European Parliament. Core of the authorisation proceedings is the scientific basis of the claim to be potentially authorised. As explained before, within the scope of its authorisation decision the defendant has the discretion to modify or supplement the proposed wording of the submitted claims. In several cases the defendant has done this conferring with the European Food Safety Authority. It is decisive alone in this context that the health related core of the submitted claim is maintained with a view to its scientific foundation. As a consequence, the legal definitions of "claim", "health claim" and "reduction of disease risk claim" in Art. 2 para. 2 of Regulation (EC) No. 1924/2006 are very broad. As another consequence, the European legislator has stipulated that the wording of a submitted health claim is merely proposed by the applicant.

88 Against this background, the negative decision of the defendant by way of Regulation (EU) No. 1170/2011 was neither suitable nor necessary to reach the goal of Regulation (EC) No. 1924/2006, namely the use of scientifically sufficiently substantiated health claims. The defendant would have had an opportunity to modify or supplement the wording of the plaintiffs' proposed health claim pursuant to Art. 17 of Regulation (EC) No. 1924/2006 in such a way that – maintaining its core content – the "risk factor" demanded by the defendant could have become sufficiently clear in the wording even according to the ideas of the defendant. An intensive exchange of views has taken place between the plaintiffs and the defendant as well as the Federal Office for Consumer Protection and Food Safety and the European Food Safety Authority. The European Food Safety Authority's "Scientific opinion on dietary reference values for water" of the year 2010 (cf. Enclosure A35) proves that the defendant after conferring with the European Food Safety Authority had all necessary information concerning the undisputed scientifically substantiated connection between "water loss in tissue", "dehydration" and "concomitant decrease of performance". The negative decision in Regulation (EU) No. 1170/2011 was thus not necessary to reach the goals of Regulation (EC) No. 1924/2006 because undisputedly there is sufficient scientific evidence for the health relation described by the plaintiffs in the application. However, it was also unsuitable to reach the goals mentioned from the outset because Regulation (EC) No. 1926/2006 does not pursue the purpose of restricting communication with scientifically sufficiently substantiated health claims. This also violates the fundamental freedom rights of the plaintiffs entrenched in Art. 6 and 16 of the EU-Charta.

89 Therefore, the defendant's decision conflicts with the purpose of Regulation (EC) No. 1924/2006 pursuant to which consumers shall be protected against misleading claims by restricting health claims exclusively to those which are scientifically sufficiently substantiated. The refusal of authorisation of the claim by the defendant is thus also disproportional because it restricts the information of consumers with uncontested information. This is contrary to the legislator's intention since dehydration and concomitant decrease of performance as a consequence of insufficient water intake is widely spread amongst the population, especially regarding older persons. With its negative decision in Regulation (EU) No. 1170/2011, the defendant thus prohibits appropriate consumer information and thereby increases the risk of the development of dehydration and concomitant decrease of performance in the population.

90 Furthermore, the defendant obviously knows very well that regular supply of water decreases the risk of dehydration and of concomitant decrease of performance. This is exactly what the defendant itself points out in its European school milk programme:
"*You may not have known, but a large part of milk is actually water. So if you regularly drink milk, you can stay hydrated at the same time. When people do not get enough water, a condition called ‚dehydration', they can become tired, irritable and have a hard time concentrating. Drinking milk can help put the necessary water back into the body, while providing carbohydrates, proteins and other nutrients to give you energy.*" (cf. http://ec.europa.eu/agriculture/drinkitup/for_kids_en.htm).

91 Accordingly, the defendant has refused the authorisation of a scientifically undisputed health claim against its own better knowledge. At the same time, it violates the principle of equality. Upon the basis of the corresponding EFSA opinion (EFSA-Journal 2011;9 (4): 2075), the defendant has put forward as scientifically sufficiently substantiated for authorisation the claim: "Water, via a good hydration, contributes to the maintenance of normal physical and cognitive functions" (cf. excerpt from Art. 13 list, **Enclosure A42**) in its final draft of a list of authorised health claims pursuant to Art. 13 of Regulation (EC) No. 1924/2006.

92 The missing proportionality and an additional violation of the principle of equality furthermore follow from the fact that the defendant has authorised comparable claims on the reduction of a disease risk without mentioning a risk factor (cf. marginals 69-72).

Fourth plea in law: Regulation without sufficient legal basis

93 Regulation (EU) No. 1170/2011 has to be declared void, because it has no sufficient legal basis (infringement of EU law, fourth plea in law).

94 The challenged Regulation has no sufficient legal basis. It is based on Art. 17 in conjunction with Art. 14 para. 1 lit. a) and Art. 10 para. 1 of Regulation (EC) No. 1924/2006. These provisions, however, violate EU law themselves, especially the principle of proportionality of Art. 5 para. 4 of the EU Treaty.

95 Pursuant to Art. 5 para. 4 of the EU treaty, measures of the Union must not exceed the extent necessary for reaching the goals of the treaty. That is to say they have to be suitable, necessary and appropriate or proportional in a true sense with a view to the goals mentioned (cf. only ECJ, joint matters C-36/97 and C-37/97 – Kellinghusen, marginals 33 seq.).

96 The European Parliament and the Council of the European Union have based Regulation (EC) No. 1924/2006 especially on Art. 95 ECT and thus on their harmonisation competences of the Treaty. Art. 1 para. 1 of the Regulation mentions as goals the harmonisation of law, regulation and administrative action in Member States which relate to nutrition and health claims, the effective functioning of the internal market and the provision of a high level of consumer protection. Regarding the health claims relevant here, recital 23 of Regulation (EC) No. 1924/2006 says that they shall "only be authorised ... after a scientific assessment of the highest possible standard". In other words: The European legislator wishes to harmonise the use of health claims for the purpose of a functioning internal market with the stipulations of the Regulation and guarantee by way of he scientific authorisation procedures that for the purpose of consumer protection only such health claims are used which withstand a scientific assessment "at the highest possible standard".

97 Measured against these goals, the stipulations in Art. 10 para. 1, 14 para. 1 lit. a) and Art. 17 of Regulation (EC) No. 1924/2006 are neither suitable nor necessary nor appropriate.

98 Especially the authorisation proceedings, upon which the challenged authorisation decision of the defendant pursuant to Art. 17 of Regulation (EC) No. 1924/2006 is based, is not suitable to reach the goal of harmonisation of the use of health claims whilst providing a high level of consumer protection at the same time. The goal of harmonisation is not reached because the scientific assessment process of the European Food Safety Authority amounts to a "black box", i.e. is completely intransparent and leads to inconsistent outcomes. This also results in a patchy consumer protection level: Claims like the one submitted by the plaintiffs may not be used in consumer communication although the European Food Safety Authority has already perceived the underlying scientific connections as sufficiently substantiated in a different "scientific opinion" (cf. Enclosure A35).

99 The main reason for the inconsistent results of the authorisation proceedings is the lacking transparency of the criteria pursuant to which the European Food Safety Authority examines health claims. Thus, the defendant has demanded the mentioning of a special "risk factor" in the instant case referring to the scientific opinion of the European Food Safety Authority although such an express identification is not stipulated in Regulation No. 1924/2006 at all. At the same time the European Food Safety Authority did not consider the mentioning of a "risk factor" as necessary in its scientific opinion on xylitol chewing gum/pastilles and the reduction of the risk of tooth decay (EFSA-Journal 2008, 852, 1–15, Enclosure A41). This was adopted by the defendant in Regulation (EC) No. 1024/2009 without further discussion. The European food Safety Authority had even expressly realised: *"The specific risk factor(s) for tooth decay affected by xylitol chewing gum is unclear"*. Why the European Food Safety Authority demands a special "risk factor" without justification in the instant proceedings, which it did not demand in comparable proceedings with justification, remains completely unclear.

100 The European Food Safety Authority has apparently entangled itself in its internal scientific criteria because of the lack of specific requirements for the scientific examination by the Authority itself. That is why the authorisation procedure currently framed by Art. 14 para. 1 lit. a), Art. 15–17 Regulation (EC) No. 1924/2006 as well as the implementing provisions based on Art. 15 para. 4 of Regulation (EC) No. 1924/2006 and the published guidelines of the European Food Safety Authority are unsuitable to reach the goal of harmonisation whilst providing a high level of consumer protection at the same time.

101 The authorisation proceedings envisaged in Regulation (EC) No. 1924/2006 on health claims within the meaning of Art. 14 para. 1 lit. a) of the Regulation are not even necessary to reach the above mentioned goals of the European legislator. These goals can be reached to the same extent – or even better – with more lenient measures which do not constrain the rights of liberty of the enterprises concerned and interested third parties so severely. It has to be remembered in this context that the European legislator provided an absolute advertising ban subject to authorisation pursuant to Art. 10 para. 1 in conjunction with Art. 1 of Regulation (EC) No. 1924/2006. The advertising and communication freedom of those concerned, however, would be less restricted if the abuse principle existing prior to the enactment of Regulation (EC) No. 1924/2006 had remained which the European legislator had especially stipulated in Art. 2 of Directive 2000/13/EC. Those rules implemented by the Member States in their respective national laws, which are still subsisting next to Regulation (EC) No. 1924/2006, ban the advertising with effects which are insufficiently scientifically substantiated. The European legislator has thus specified the general ban on misleading food advertising by way of the yardstick of a sufficient scientific substantiation of claims on effects. That, however, is exactly the same yardstick envisaged programmatically by Art. 6 para. 1 for the scope of application of Regulation (EC) No. 1924/2006.

102 It is true that Art. 2 para. 1 lit. b) of Directive 2000/13/EC also contains an advertising ban on disease related claims. However, the Euro-

pean legislator has expressly envisaged in Art. 2 of the Directive that this advertising ban may be restricted. This follows from the empowerment in Art. 2 para. 2 of Directive 2000/13/EC. The fact that a part of the ban in Art. 2 para. 1 lit. b) of Directive 2000/13/EC, namely disease risk reduction claims, can be released from this ban is thus already stipulated in Art. 2 of the Directive. The European legislator could have made use of this rule in order to reach the goals determined by Regulation (EC) No. 1924/2006 easily.

103 The difference of the legislative approach between Art. 2 of Directive 2000/13/EC and Regulation (EC) No. 1924/2006 is therefore that pursuant to the stipulations of the Regulation a scientific assessment by the European Food Safety Authority and an authorisation decision of the defendant is necessary prior the use of a health claim, whilst pursuant to the stipulations of the Directive the use of the health claim can be challenged nationally by food supervisory authorities or courts individually. Essentially, this is a shift of the examination of the scientific substantiation of a health claim from the national authorities and courts to the European Food Safety Authority. However, it is not apparent why the goals of Regulation (EC) No. 1924/2006 mentioned by the legislator can be reached better through an examination by the European Food Safety Authority. The scientific yardstick to be used for the respective examination is the same. Furthermore, the European Food Safety Authority has shown i.a. in the present proceedings that it cannot guarantee reaching consistent results or even consistently applying the statutorily envisaged scientific yardstick.

104 Finally, the authorisation proceedings pursuant to Art. 10 para. 1, 14 para. 1 lit. a) and 15–17 Regulation (EC) No. 1924/2006 are not appropriate or proportionate in the true sense. This also applies with regard to the two main goals of Regulation (EC) No. 1924/2006 mentioned by the European legislator, namely harmonising the use of health claims in the internal market and providing a high level of consumer protection.

105 The stipulations of Regulation (EC) No. 1924/2006 subject those concerned to long and expensive authorisation proceedings the result of which can hardly be predicted because of the intransparent examination process of the European Food Safety Authority. The reason for the demand of harmonising of the use of health claims in the internal market was the realisation that authorities in some Member States applied the statutory yardstick of sufficient scientific substantiation in a stricter manner than in other Member States. This, however, always only seemed to be a problem. That is because of course the stipulation of the decisive scientific standard in Art. 2 of Directive 2000/13/EC in each Member State of the European Union presents the opportunity to have measures of supervisory authorities subjected to judicial review and to demand a harmonised interpretation within the internal market by way of referring the proceedings to the European Court of Justice. A harmonisation effect would thus be achievable via reference proceedings to the European Court of Justice. The general ban subject to authorisation pursuant to Regulation (EC) No. 1924/2006 thus only presents the chance of a very minute further harmonisation through a central assessment by the European Food Safety Authority. This is contrasted by the severe restrictions as to time, money and resources which the requirement of authorisation pursuant to Art. 10 para. 1 in conjunction with Art. 14 para. 1 lit. a) of Regulation (EC) No. 1924/2006 establishes. Against this background, the stipulation of authorisation proceedings in the Regulation is inappropriate.

106 The same applies with a view to the second main goal, the provision of a high level of consumer protection. A centralisation of the scientific examination of health claims can only achieve a marginally higher level of consumer protection compared to the subsisting abuse principle of Art. 2 of Directive 2000/13/EC – as the case may be in its modified shape (see above, marginal 102). This is not only outweighed by the further restrictions of advertising and communication already mentioned in marginal 101, but also the restrictions of the freedom of information of consumers themselves. The present proceedings present a good example in this context. The importance and accuracy of the scientific connection between the consumption of sufficient amounts of

water and the protection against dehydration as well as concomitant decrease of performance has been assessed as scientifically substantiated by the European Food Safety Authority itself in its "Scientific opinion" submitted as Enclosure A35. Still, the submitted claim may no longer be used in the communication with the consumer because of formal considerations of the defendant and the European Food Safety Authority caused by the completely misguided authorisation proceedings of Regulation (EC) No. 1924/2006.

Fifth plea in law: Regulation as inadmissible legislatory instrument

107 Regulation (EU) No. 1170/2011 has to be declared void, because the defendant has enacted a Regulation instead of the Decision stipulated in Regulation (EC) No. 1924/2006 (infringement of essential procedural requirements, fifth plea in law).

108 Pursuant to Art. 17 of Regulation No. 1924/2006, the defendant has to decide about the Community authorisation of health claims by way of a Decision. This is unambiguously clear from the wording of paras. 1-4 of Art. 17. The European legislator uses the term "Decision" there. Nowhere is there any reference with a view to the Community authorisation that the defendant could make use of a "Regulation" in this respect.

109 Union law, however, clearly distinguishes between Decisions and Regulations as measures of the institutions of the EU. This was expressly clear from Art. 249 para. 1 of the EC Treaty, the legal basis at the time of the enactment of Regulation (EC) No. 1924/2006. In the meantime, Art. 288 para. 1 TFEU also uses the term "Decision". Hence, references of secondary European law to Decisions now refer to Decisions pursuant to Art. 288 para. 1 TFEU.

110 The distinction between a Regulation and a Decision is not a mere formality. That is because pursuant to the stipulations of Art. 288 para. 2 and 3 TFEU, Decisions are distinct from Regulations in that they are directed towards certain addressees and are only binding on them. This essential difference has only been recently portrayed by the European Court of Justice in a food law matter (cf. ECJ, C-327/09, ZLR 2011, 339, 346 – Mensch und Natur). The distinction between Regulations and Decisions also has drastic effects on the legal protection of those concerned. Addressees of Decisions can challenge them without major problems pursuant to Art. 263 para. 4 TFEU, whereas Regulations can only be reviewed by citizens of the European Union before the General Court under certain conditions which are restrictively interpreted by the European Court of Justice. This also applies in the other direction: EU citizens are covered by a Regulation, who would not be concerned by the statutorily envisaged Decision.

111 Accordingly, if the European legislator has expressly and exclusively stipulated pursuant to Art. 17 of Regulation (EC) No. 1924/2006 that the defendant grants the Community authorisation as Decision, the defendant cannot deviate therefrom at its own discretion. In the end, this is a consequence of principle of the limited individual empowerment of Art. 5 of the EU Treaty. The defendant derives its competence from Regulation (EC) No. 1924/2006 and thus from Art. 95 of the EC Treaty. This competence has been transferred to the European Union by the Member States to the precisely limited extent. Thus, if the European legislator derives its own competence to constrict health claims in food advertising by way of Regulation (EC) No. 1924/2006, the defendant can only implement this to the extent provided by the European legislator in Regulation (EC) No. 1924/2006. Then the defendant is confined to grant Community authorisations and the refusals of Community authorisations of health claims by Decision.

112 Furthermore, the shape of the defendant's authorisation decision as Regulation is also systematically unlawful. The European legislator has intentionally shaped the proceedings pursuant to Art. 15 seq. of Regulation (EC) No. 1924/2006 on disease risk reduction claims pursuant to Art. 14 para. 1 lit. a) of the Regulation as an individual application procedure. If an EU citizen files an application, pursuant to the principles of European law and the law of the Member States this citizen is entitled to a direct decision as an addressee. Of course, this is not possible on the basis of a Regulation which pursuant to Art. 288 para. 2 TFEU has general application. As a consequence, the de-

fendant had to hide the plaintiffs as applicants – without the statutorily demanded mentioning of an address – in the recitals of Regulation (EU) No. 1170/2011. In the legally binding part of the Regulation the plaintiffs are not mentioned. This is complemented by the consequential restrictions of legal protection of the plaintiffs, namely the limited possibilities to claim pursuant to Art. 263 para. 4 TFEU.

Sixth plea in law: Violation of the allocation of competences

113 Regulation (EU) No. 1170/2011 has to be declared void, because the allocation of competences provided for by Regulation (EC) No. 1924/2006 between the defendant, the European Food Safety Authority and the German Federal Office for Consumer Protection and Food Safety has been disregarded by the defendant (infringement of essential procedural requirements, sixth plea in law).

114 The allocation of competences between the national authority (in this case the Federal Office for Consumer Protection and Food Safety), the European Food Safety Authority and the defendant is clearly stipulated by Regulation (EC) No. 1924/2006. However, in the enactment proceedings of Regulation (EU) No. 1170/2011 the defendant deviated therefrom. Pursuant to Art. 15 para. 2 of Regulation (EC) No. 1924/2006, the application for authorisation has to be filed with the national competent authority of a Member State, i.e. in Germany the Federal Office for Consumer Protection and Food Safety. The national authority merely sends an acknowledgement of receipt to the applicant and furthermore transmits the application and all supplementary information as well as correspondence with the applicants to the European Food Safety Authority. Regulation (EC) No. 1924/2006 does not stipulate an examination of the validity of the application by the national authority. One can only assume that, according to the sense and purpose of the stipulations, the national authority is not required to transmit applications which are obviously inadmissible. It follows from Art. 15 para. 2 lit. b) of the Regulation that the European Food Safety Authority in turn has to inform the Member States and the defendant without delay about the application for authorisation. Furthermore, it is the task of the European Food Safety Authority to give a scientific opinion. For this purpose, it examines the scientific evidence for the proposed health claim and its wording pursuant to Art. 16 para. 3 of Regulation (EC) No. 1924/2006. Finally, it is the task of the defendant pursuant to Art. 17 of Regulation (EC) No. 1924/2006 to adopt an authorisation decision upon the basis of a scientific opinion of the European Food Safety Authority in coordination with the Standing Committee and the European Parliament. The defendant has to examine the scientific opinion of the authority as well as "any relevant provisions of Community law" pursuant to Art. 17 para. 1 of the Regulation.

115 Questions of legal interpretation regarding the scope of application of Regulation (EC) No. 1924/2006 have thus been exclusively allocated to the defendant by the European legislator. The national authority, however, according to the intentions of the European legislator is merely a "letter box authority". The European Food Safety Authority is exclusively confined to the scientific examination of the submitted data and the proposed wording pursuant to the criteria provided by Regulation (EC) No. 1924/2006. This is even pointed out by the European Food Safety Authority itself in its letter of 27/1/2010 (cf. Enclosure A27). Still, this did not stop the European Food Safety Authority from actually undertaking a legal interpretation according to which the plaintiffs' application – allegedly – did not correspond with the legal requirements of Regulation (EC) No. 1924/2006. Moreover, this allocation of competences cannot be changed by implementing provisions of the defendant which can be made pursuant to Art. 15 para. 4 of Regulation (EC) No. 1924/2006. That is because according to the wording of the stipulation such implementing provisions merely relate to "this Article". The European legislator therefore has expressly provided that the allocation of competences pursuant to Art. 15 of Regulation (EC) No. 1924/2006 has to remain; implementing provisions can only substantiate this allocation of competences but not change it.

116 In the enactment proceedings of Regulation (EU) No. 1170/2011 a legal interpretation of Regulation (EC) No. 1924/2006 was necessary.

The European Food Safety Authority had argued that an application pursuant to Art. 14 para. 1 lit. a) in conjunction with Art. 15 para. 1 Regulation (EC) No. 1924/2006 required the mentioning of a "risk factor" (cf. Enclosure A33). Furthermore, the European Food Safety Authority later raised the question whether the plaintiffs were in fact entitled to file the application or whether applications pursuant to Art. 14 para. 1 lit. a) in conjunction with Art. 15 of Regulation (EC) No. 1924/2006 could exclusively be filed by food business operators (Enclosure A25). However, according to the intention of the European legislator, the European Food Safety Authority is not competent for either of the interpretation questions – which apparently significantly protracted the enactment proceedings. This was acknowledged by the Authority itself initially (cf. Enclosure A27). It is only competent for the scientific assessment of the data submitted for a health claim. Questions of legal interpretation have to be answered by the defendant alone in its authorisation decision – that is after receipt of the scientific opinion of the European Food Safety Authority. In the enactment proceedings of Regulation (EU) No. 1170/2011, questions of legal interpretation, however, were first discussed amongst the European Food Safety Authority and the Federal Office for Consumer Protection and Food Safety, later the defendant also participated, however, without deciding on its own legal interpretation. The defendant rather argued instead that both questions of interpretation were part of the admissibility examination of the application for authorisation and thus had to be dealt with by the Federal Office for Consumer Protection and Food Safety (Enclosures A30 and 32). However, this Office's competence for an in-depth legal examination of questions regarding the scope of application of Regulation (EC) No. 1924/2006 is not stipulated by the Regulation itself at all.

117 As a consequence of the false allocation of competences by the defendant in the enactment proceedings of Regulation (EU) No. 1170/2011, the plaintiffs were referred, regarding the examination of their application and the discussion of open questions, in a jolly interplay from the Federal Office for Consumer Protection and Food Safety to the European Food Safety Authority, therefrom to the defendant as well as back to the Federal Office for Consumer Protection and Food Safety. On the one hand, this led to significant delays in the enactment proceedings. Furthermore, the European Food Safety Authority made a legal interpretation decision in its scientific opinion on the plaintiffs' application for authorisation regarding the necessity of the mentioning of a "risk factor" (cf. Enclosure A36) which pursuant to the stipulations of Regulation (EC) No. 1924/2006 was outside the scope of competence of the European Food Safety Authority. The defendant merely adopted this interpretation of the European Food Safety Authority in its authorisation decision and thus did not meet its own responsibility under the allocation of competences of Regulation (EC) No. 1924/2006. It is likely that the defendant would have made a positive authorisation decision if the European Food Safety Authority had confined itself to its scope of competence and had confirmed the scientific evidence – parallel to the other "Scientific opinion" (cf. Enclosure A35). Then it would presumably have become clear to the defendant that no "risk factor" was necessary in the plaintiffs' application for authorisation.

Seventh plea in law: No timely decision

118 Regulation (EU) No. 1170/2011 has to be declared void, because the cogent time limits for the submission of the application for authorisation, the establishment of the scientific opinion and the grant of the authorisation decision stipulated in Regulation (EC) No. 1924/2006 have been disregarded (infringement of essential procedural requirements, seventh plea in law).

119 Art. 15 to 17 of Regulation (EC) No. 1924/2006 also contain clear requirements regarding time limits in the enactment proceedings of the Community authorisation of health claims which were not observed in the enactment proceedings of Regulation (EU) No. 1170/2011. Pursuant to Art. 15 para. 2 lit. a) Nos. i) and ii) the national authority acknowledges receipt of an application in writing "within 14 days of its receipt" and informs the European Food Safety Authority "without dealy". Pursuant to Art. 16

para. 1 of Regulation (EC) No. 1924/2006, the European Food Safety Authority has "a time limit of five months from the date of receipt of a valid application" for its scientific opinion. Only if the European Food Safety Authority seeks supplementary information from the applicant, this time limit can be extended "by up to two months". Finally, the defendant has to present its draft decision on a Community authorisation pursuant to Art. 17 para. 1 of Regulation (EC) No. 1924/2006 "within two months after receiving the opinion".

120 In the enactment proceedings of Regulation (EU) No. 1170/2011, there was already no timely acknowledgement of receipt by the Federal Office for Consumer Protection and Food Safety. Undisputedly, the Federal Office for Consumer Protection and Food Safety did not transmit the application for authorisation to the European Food Safety Authority "without delay". The reason for this – according to the Federal Office for Consumer Protection and Food Safety's own information – was an instruction by the defendant according to which difficult legal interpretation questions regarding the scope of application of Regulation (EC) No. 1924/2006 had to be examined in advance by the national authority (cf. Enclosures A30 and 32). However, this instruction was in breach of competence (cf. above marginals 113-117).

121 Subsequently, the European Food Safety Authority did not observe its time limit pursuant to Art. 16 para. 1 of Regulation (EC) No. 1924/2006. Between receipt of the application for authorisation and submission of the scientific opinion to the defendant, there were almost 29(!) months. The reason for this unlawful delay were not difficulties regarding the scientific examination of the application. The scientific connection between "water loss in tissue", "dehydration" and "concomitant decrease of performance" had already been identified as generally accepted by the European Food Safety Authority in its "Scientific opinion" (cf. Enclosure A35) in 2010. The apparently in fact time consuming questions of the legal application of Regulation (EC) No. 1924/2006 on the plaintiffs' application for authorisation, however, were exclusively in the defendant's scope of competence so that they cannot justify the delay in the establishment of the scientific opinion. In any event, Regulation (EC) No. 1924/2006 stipulates a formal deadline in Art. 16 para. 1 which can only be extended pursuant to Art. 16 para. 1 2nd sentence of the Regulation. But this can only be done within the original five months period. In the enactment proceedings of Regulation (EU) No. 1170/2011, the scientific opinion had thus got to be completed five months after receipt of the application for authorisation by the European Food Safety Authority, i.e. already in the year 2008, at the latest, however, in the year 2009. But this did not happen.

122 According to general principles of law, Regulation (EU) No. 1170/2011 has thus been enacted upon the basis of faulty proceedings and must therefore be declared void. Only this sanction allows the applicants concerned to urge the defendant to observe the time limits provided by Regulation (EC) No. 1924/2006 and to effect that they are also observed by the national and European authorities involved.

Eighth plea in law: Missing observance of the submissions

123 Regulation (EU) No. 1170/2011 has to be declared void, because the defendant has disregarded essential submissions of the plaintiffs and interested third parties in its decision (infringement of essential procedural requirements, eighth plea in law).

124 Within the 30 day period stipulated by Art. 16 para. 6 2nd subpara. of Regulation (EC) No. 1924/2006, the defendant received at least nine statements by interested third parties and comments by the plaintiffs on the scientific opinion of the European Food Safety Authority (cf. Enclosure A37). However, it can only be drawn from Regulation (EU) No. 1170/2011 that the statements "have been considered when setting the measures provided for in this Regulation". A discussion of the arguments of the cited comments is missing completely. It is not apparent from Regulation (EU) No. 1170/2011 and its recitals whether the defendant has even dealt with the submitted arguments during the course of its authorisation decision. Furthermore, only the statement of the company Cognis as an interested third party was submitted to the European Food Safety Authority for fur-

ther comments (Enclosure A37). There was no scientific discussion by the European Food Safety Authority regarding the arguments put forward by the plaintiffs in their comments on the European Food Safety Authority's scientific opinion. The rather stereotype "reasons" in the defendant's cover letter to the plaintiffs (Enclosure A38) also show that the defendant has in fact not sufficiently discussed the arguments of the plaintiffs and third parties.

125 Thus, the defendant has obviously not exhausted the plaintiffs' submissions and the comments of third parties. It can therefore not be excluded that the defendant could have correctly reached a different authorisation decision if it had properly examined the plaintiffs' and other interested third parties' arguments and submitted them again to the European Food Safety Authority and taken care of a proper discussion by the European Food Safety Authority. This is also a violation of the substantive participation rights of the plaintiffs as well as of the interested third parties concerned.

Ninth plea in law: No sufficient reasons

126 Regulation (EU) No. 1170/2011 has to be declared void, because the defendant has not sufficiently observed its obligation to give reasons pursuant to Art. 296 para. 2 TFEU (ninth plea in law).

127 Pursuant to Art. 296 para. 2 TFEU, the defendant has to give reasons of legal acts and refer to proposals and comments. According to case law of the European Court of Justice, the defendant has to especially justify Decisions so that it becomes apparent how it has come to its decision (cf. also ECJ, joint matters C-260/91 and 261/91 – Diversinte SA and others, marginal 12 seq.). The same applies to a measure which is in fact a Decision towards the plaintiffs, although it is – unlawfully – disguised in the shape of a Regulation. Furthermore, the defendant has also got to give sufficient reasons for a Regulation according to case law of the European Court of Justice (ECJ, C-87/78, – Welding, marginal 11).

128 Such sufficient reasons are absent in Regulation (EU) No. 1170/2011. It is true that the defendant mentions the plaintiffs' application and the plaintiffs themselves as applicants, however, without the addresses necessary pursuant to Art. 17 para. 2 in conjunction with Art. 16 para. 4 of Regulation (EC) No. 1924/2006. In recital 6 the defendant merely mentions that the plaintiffs had quoted "water loss in tissue" and a "reduced water content in tissue" as risk factors for dehydration. In fact, the plaintiffs had argued that the mentioning of a risk factor was not necessary at all. Furthermore, they had carved out further risk factors which are not even mentioned by the defendant in the recital. Moreover, the plaintiffs and nine further interested parties' arguments pursuant to Art. 16 para. 6 of Regulation (EC) No. 1924/2006 (Enclosure A37) are not mentioned either. In recital 9 of Regulation (EU) No. 1170/2011 the defendant merely generally says that the "comments ... have been considered when setting the measures provided for in this Regulation". However it cannot be drawn from the Regulation which arguments these are and in what manner the defendant has taken them into account.

129 In fact, the recitals of Regulation (EU) No. 1170/2011 make it very clear that the defendant has either not independently examined the arguments submitted by the plaintiffs and interested third parties at all or at least not sufficiently. Apparently, the defendant has merely adopted the – partly unlawfully derived – arguments of the European Food Safety Authority from its scientific opinion and has made them the basis of its authorisation decision without further examination of the comments reacting to the scientific opinion. At least it does not follow from the incomplete reasons of the defendant in Regulation (EU) No. 1170/2011 how the defendant has dealt with the arguments of the comments. However, it would have been obliged to do this already because of the deviating EFSA opinion submitted as Enclosure A35 as well as its own other authorisation decisions (cf. Enclosures A41 and 42). Thus, the defendant has not observed its obligation of giving reasons pursuant to Art. 296 para. 2 TFEU. As a consequence also for this reason, the challenged Regulation has to be declared void.