

## SCIENTIFIC OPINION

### Scientific Opinion on the substantiation of health claims related to live yoghurt cultures and improved lactose digestion (ID 1143, 2976) pursuant to Article 13(1) of Regulation (EC) No 1924/2006<sup>1</sup>

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)<sup>2,3</sup>

European Food Safety Authority (EFSA), Parma, Italy

This scientific output, published on 12 January 2011, replaces the earlier version published on 19 October 2010<sup>4</sup>.

#### SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to live yoghurt cultures and improved lactose digestion. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claim is “yoghurt cultures (live)”, which contain the starter micro-organisms “*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*” as specified by Codex Alimentarius Standard No. 243/2003. The Panel considers that live yoghurt cultures, which are the subject of the health claim, are sufficiently characterised in relation to the claimed effect.

The claimed effect is “lactose digestion”. The target population is individuals with lactose maldigestion. The Panel considers that improved lactose digestion is a beneficial physiological effect for individuals with lactose maldigestion.

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<sup>1</sup> On request from the European Commission, Question No EFSA-Q-2008-1882, EFSA-Q-2008-3708, adopted on 09 July 2009. Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Paalasmaa, Maria Agostoni, Rosângela Barreto, Sanaïa Căscăla, Martin, Theodor Moseley, Monica Neuhäuser-Kathod, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. One member of the Panel did not participate in the discussion on the subject referred to above because of potential conflicts of interest identified in accordance with the EFSA policy on declarations of interests. Correspondence: [nda@efsa.europa.eu](mailto:nda@efsa.europa.eu)

<sup>3</sup> Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this scientific opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen. The members of the Claims Sub-Working Group on Gut/Immune: Jean-Louis Bresson, Maria Carmen Collado, Miguel Gueimonde, Daisy Jonkers, Martinus Løvik, Bevan Moseley, Maria Saarela, Seppo Salminen, Yolanda Sanz, Stephan Strobel, Daniel Tomé and Hendrik van Loveren.

<sup>4</sup> After publication of this opinion, it has been identified that the conditions of use and the conclusions needed to be clarified. The opinion has been changed accordingly. Where changes have been made to the text of the opinion footnotes have been included to indicate the changes. In addition, the suggested citation was aligned with the title.

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In weighing the evidence, the Panel took into consideration that thirteen of fourteen human studies showed enhanced digestion of lactose in yoghurt in lactose maldigesters, when live yoghurt starter cultures were ingested in yoghurt, that the one study which did not show such effect reported reduced symptoms and that there was strong evidence for the biological plausibility of the effect.<sup>5</sup>

The Panel concludes that a cause and effect relationship has been established between the consumption of live yoghurt cultures in yoghurt and improved digestion of lactose in yoghurt in individuals with lactose maldigestion.<sup>6</sup>

In order to bear the claim, the yoghurt should contain at least  $10^8$  CFU live starter microorganisms (*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*) per gram.<sup>7</sup> The target population is individuals with lactose maldigestion.

## KEY WORDS

Yoghurt cultures, live, *Lactobacillus delbrueckii* subsp. *bulgaricus*, *Streptococcus thermophilus*, lactose, digestion, maldigestion, health claims.

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<sup>5</sup> "...enhanced lactose digestion in lactose maldigesters..." has been replaced with "... enhanced digestion of lactose in yoghurt in lactose maldigesters..."

<sup>6</sup> "...improved lactose digestion in individuals with lactose maldigestion." has been replaced with "...improved digestion of lactose in yoghurt in individuals with lactose maldigestion."

<sup>7</sup> "In order to bear the claim, the yoghurt should contain at least  $10^8$  CFU per serving live starter microorganisms (i.e. *Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*).“ has been replaced with "In order to bear the claim, the yoghurt should contain at least  $10^8$  CFU live starter microorganisms (*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*) per gram."

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**BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION**

See Appendix A

**TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION**

See Appendix A

**EFSA DISCLAIMER**

See Appendix B

## INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006<sup>8</sup> submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out<sup>9</sup>. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

### 1. Characterisation of the food/constituent (ID 1143, 2976)

The food constituent that is the subject of the health claim is “yoghurt cultures (live)”, which contain the starter micro-organisms “*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*”. These starter cultures “*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*” are well specified for their use in yoghurt manufacture by Codex Alimentarius Standard No. 243/2003.

The Panel considers that live yoghurt cultures, which are the subject of the health claim, are sufficiently characterised in relation to the claimed effect.

### 2. Relevance of the claimed effect to human health (ID 1143, 2976)

The claimed effect is “lactose digestion”. The Panel assumes that the target population is individuals with lactose maldigestion.

In the context of the proposed wording, the Panel assumes that the claimed effect refers to improved lactose digestion. Lactose maldigestion is a common condition characterised by reduced levels of intestinal lactase.

The Panel considers that improved lactose digestion is a beneficial physiological effect for individuals with lactose maldigestion.

### 3. Scientific substantiation of the claimed effect (ID 1143, 2976)

Forty-three references were cited to substantiate the claim. Among these references, the non-pertinent references included review articles and text books, or were related to yoghurt and gut functions in general, survival of lactic acid bacteria in the human stomach, “probiotics” and “prebiotics” in promotion of lactose digestion, production of  $\beta$ -galactosidase by *Streptococcus thermophilus*, the effect of *Lactobacillus acidophilus* on lactose maldigestion and survival of starter cultures and lactase in heated and frozen yoghurts. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

The following 14 human intervention studies were considered pertinent to the claim (Kolars et al., 1984; Savaiano et al., 1984; Dewit et al., 1988; Lerebours et al., 1989; Onwulata et al., 1989; Pochart et al., 1989; Marteau et al., 1990; Martini et al., 1991; Rosado et al., 1992; Varela-Moreiras et al., 1992; Shermak et al., 1995; Rizkalla et al., 2000; Labayen et al., 2001; Pelletier et al., 2001).

<sup>8</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

<sup>9</sup> Briefing document for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims: <http://www.efsa.europa.eu/en/ndameetings/docs/nda100601-ax01.pdf>

Many studies have compared the effect of consumption of fresh yoghurt with live cultures to pasteurised yoghurt with reduced or no live cultures on intestinal lactose utilisation in lactose maldigesters (Savaiano et al., 1984; Dewit et al., 1988; Lerebours et al., 1989; Pochart et al., 1989; Varela-Moreiras et al., 1992; Shermak et al., 1995; Rizkalla et al., 2000; Labayen et al., 2001; Pelletier et al., 2001). Also, in some studies pasteurised milk (Kolars et al., 1984; Marteau et al., 1990), milk inoculated with *Lactobacillus acidophilus* (Onwulata et al., 1989), lactose-hydrolysed milk (Onwulata et al., 1989; Rosado et al., 1992) and lactase tablets (Onwulata et al., 1989) were compared with yoghurt (fresh or heated) in order to investigate the effect on lactose digestion.

In most pertinent studies, the breath hydrogen concentration (BHC) method has been applied to measure lactose digestion. This method is based on the measurement of the concentration of hydrogen released into the breath from lactose hydrolysed after ingestion of a certain amount of lactose (usually 18 grams or higher). The method is not specific but is generally applied in clinical practice for the diagnosis of lactose maldigestion.

In most studies, lactose digestion has been investigated upon a single dose of the test product (Kolars et al., 1984; Savaiano et al., 1984; Dewit et al., 1988; Lerebours et al., 1989; Martini et al., 1991; Rosado et al., 1992; Varela-Moreiras et al., 1992; Shermak et al., 1995; Onwulata et al., 1989; Pelletier et al., 2001) whereas in a few studies lactose digestion was studied after prolonged ingestion of fresh or heat-treated yoghurt (Lerebours et al., 1989; Marteau et al., 1990; Rizkalla et al., 2000; Labayen et al., 2001).

All of the 14 studies mentioned above were performed using the yoghurt cultures *Lactobacillus delbrueckii* subsp. *bulgaricus* (*L. bulgaricus*) and *Streptococcus thermophilus* (*S. thermophilus*).

Dewit et al. (1988) investigated breath hydrogen concentration (BHC) after ingestion of lactose in water, milk, fresh or heated yoghurt by 26 healthy, young adults with or without lactose maldigestion. The fresh yoghurt contained  $3 \times 10^8$  CFU/g *S. thermophilus* and  $3 \times 10^8$  CFU/g *L. bulgaricus*. The total amount of lactose ingested with each product was 18 g. Ingestion of fresh yoghurt reduced BHC significantly ( $p < 0.001$ ) compared to lactose or milk, whereas after ingestion of heated yoghurt BHC was higher ( $p < 0.01$ ) compared to fresh yoghurt.

The double-blind study by Lerebours et al. (1989) evaluated lactose digestion (using BHC) after short-term (24 h) or prolonged (8 day) ingestion of yoghurt and fermented-then-pasteurised milk (FPM) by 16 lactase-deficient subjects. Consumption of yoghurt (125 g three times per day) enhanced lactose digestion (18 g lactose in yoghurt) and this effect was destroyed by pasteurisation. Similar results were obtained in both study periods and no adaptation of lactase activity was observed in long-term ingestion of yoghurt.

Marteau et al. (1990) measured BHC in eight lactase-deficient volunteers who ingested 18 g of lactose in the form of milk (400 mL whole milk per day), yoghurt (450 g per day) and heated yoghurt (450 g per day) for three consecutive days. Total BHC was significantly lower after consumption of yoghurt and heated yoghurt compared with milk consumption ( $p < 0.001$ ). Significantly less lactose was recovered from the terminal ileum after yoghurt than after heated yoghurt meals ( $p < 0.05$ ), and approximately one-fifth of the lactase activity contained in yoghurt reached the terminal ileum.

Varela-Moreiras et al. (1992) evaluated lactose maldigestion after ingestion of three dairy products by 53 healthy institutionalised elderly people; 36 % of them were found to be lactose maldigesters using the BHC test. The effect of consuming an equivalent amount of lactose (11 g lactose in 200 mL of product) contained in yoghurt and fermented-then-pasteurised milk (FPM) was assessed in these subjects. BHC was significantly higher after ingestion of milk than after ingestion of yoghurt ( $p < 0.05$ ). This effect was partially eliminated when FPM was tested. Moreover, BHC was significantly higher three hours after ingestion of FPM compared to normal yoghurt ( $p < 0.05$ ).

In the study of Rizkalla et al. (2000), two groups of 12 healthy men with or without lactose maldigestion were recruited using the BHC test with a 30 g lactose load. Subjects were randomly



assigned in a cross-over design to 500 g per day of either fresh or heat-treated yoghurt for two periods of 15 days each, separated by a 15 days washout interval. In subjects with lactose maldigestion, BHC values were significantly lower after consumption of fresh compared to heat-treated yoghurt consumption ( $p < 0.01$ ).

In the double-blind, cross-over designed study of Labayen et al. (2001), 22 lactose maldigesters received daily 25 g of lactose in fresh yoghurt (live yoghurt bacteria  $> 10^8$  CFU/g) or heat-treated yoghurt ( $< 10^2$  CFU/g) for 15 days, followed by a cross-over (15 days) after a wash-out period (14 days). The test dose was 500 mL per day for both products. The BHC test indicated more effective lactose digestion after fresh yoghurt intake as compared to heat-treated yoghurt. The oro-caecal transit time (OCTT) was shorter after heated yoghurt ingestion as compared with fresh yoghurt and there were less severe gastrointestinal symptoms ( $p < 0.05$ ) after fresh yoghurt intake.

Pelletier et al. (2001) assessed in a double-blind, randomised cross-over study the effects of ingestion of milk, yoghurt ( $10^8$  CFU/mL), heat-treated ( $70^\circ\text{C}$ , 30 sec) yoghurt ( $< 15$  CFU/mL) and two products obtained by dilution of yoghurt with heat-treated product ( $10^6$  and  $10^5$  CFU/mL) on hydrogen production and symptoms of lactose intolerance in 24 male lactose maldigesters. Hydrogen production and adverse events were followed during eight hours after ingestion of a single dose of each test product. The volume of each serving was not indicated. At each test, subjects received 25 g lactose in one of the products. Ingestion of yoghurt with  $10^8$  CFU/mL led to significantly lower BHC values ( $p < 0.001$  for AUCi (incremental area under curve,  $p = 0.036$  for Cmax maximal hydrogen concentration variation)) and a reduced number of complaints compared to the other products.

Kolars et al. (1984) used the BHC test to determine in 10 lactose-intolerant subjects (20 to 28 years of age) whether lactase-deficient subjects digested lactose better in yoghurt than in milk. Breath samples were obtained in the fasting state and hourly for eight hours after ingestion of the following test meals: lactulose (10 g in 200 mL of water), lactose (20 g in 400 mL of water), milk (400 mL containing 18 g of lactose) and commercial unflavoured yoghurt (440 g containing 18 g of lactose, and 270 g containing 11 g of lactose, respectively). Ingestion of 440 g of test yoghurt resulted in only about one third as much hydrogen excretion as a similar load of lactose in milk or water. This difference was statistically significant ( $p < 0.01$ ). In case of lactulose, the increase in breath hydrogen was comparable to that obtained with lactose. The symptoms reported by the subjects after ingestion of test meals supported the perception that lactose was digested better in yoghurt than in milk; 80 per cent of the subjects ingesting milk versus 20 per cent of those ingesting yoghurt reported diarrhoea or flatulence.

Onwulata et al. (1989) evaluated lactose digestion after intake of commercial plain yoghurt, sweet acidophilus milk, hydrolysed-lactose milk, a lactase tablet, and whole milk by 10 lactose-intolerant subjects. In a  $5 \times 5$  Latin square design, BHC was measured for five hours after the subjects had consumed one of the products (totally 18 g lactose in each except lactose-hydrolysed milk, which provided 5 g). The products were consumed in a single dose (volume was not indicated) in five periods at five weekly intervals. Mean BHC values (ppm) were significantly ( $p < 0.05$ ) lower for yoghurt than for sweet acidophilus milk and whole milk. With regard to alleviating symptoms of lactose maldigestion, yoghurt was as effective as lactose-hydrolysed milk, but was significantly ( $p < 0.05$ ) more effective than commercial lactase consumed along with milk.

Shermak et al. (1995) compared symptoms of lactose maldigestion and breath hydrogen production after typical servings of milk, heat-treated yoghurt ( $85^\circ\text{C}$ , 30 min), and yoghurt containing live bacteria ingested by 14 lactose-maldigesting children (mean age 9.5 years). Symptoms and BHC values were recorded for eight hours after ingestion of 12 g lactose served in milk and yoghurts. Live yoghurt contained  $1.6 \times 10^8$  CFU/g of both yoghurt cultures and the pasteurised yoghurt contained  $2.5 \times 10^3$  CFU/g of both cultures. Lactose-maldigesting children experienced significantly fewer symptoms after consuming yoghurt with live cultures than after intake of milk ( $p < 0.005$ ). Pasteurised yoghurt showed an intermediate effect. Lactose from yoghurt was not better digested than lactose from milk, as indicated by similar areas under the hydrogen curve in the BHC test. However, yoghurt was

associated with a delayed time to rise and lower rate of rise of the hydrogen concentration in the breath.

Rosado et al. (1992) compared the efficiency of lactose digestion after consumption of two unmodified plain yoghurts, a low-fat yoghurt and a yoghurt produced from lactose-hydrolysed milk by assessing BHC in 14 lactose-maldigesters. Compared to whole milk, the hydrogen breath response to two varieties of unmodified yoghurt and the lactose-hydrolysed yoghurt was significantly ( $p < 0.05$ ) attenuated while the hydrogen response to low-fat yoghurt was intermediate. Intolerance symptoms were significantly ( $p < 0.05$ ) and equally reduced (50 %,  $p < 0.05$ ) with all four yoghurt products compared to whole milk.

The results from human studies carried out by Savaiano et al. (1984), Pochart et al. (1989) and Martini et al. (1991) are consistent with those from the above studies and can be considered as supportive although the number of subjects enrolled in those studies was relatively small (less than 12 per study).

In addition, Drouault et al. (2002) applied a bacterial luciferase to monitor gene expression of *Streptococcus thermophilus* in the digestive tract of germ-free mice. The main result was that the bacterium was able to produce active  $\beta$ -galactosidase enzyme in the digestive tract, although the bacterium did not multiply during gastrointestinal transit. The enzyme production was enhanced when lactose (the inducer) was added to the diet.

In weighing the evidence, the Panel took into consideration that thirteen of fourteen human studies showed enhanced digestion of lactose in yoghurt in lactose maldigesters, when live yoghurt starter cultures were ingested in yoghurt, that the one study which did not show such an effect reported reduced symptoms and that there was strong evidence for the biological plausibility of the effect.<sup>10</sup>

The Panel concludes that a cause and effect relationship has been established between the consumption of live yoghurt cultures in yoghurt and improved digestion of lactose in yoghurt in individuals with lactose maldigestion.<sup>11</sup>

#### 4. Panel's comments on the proposed wording (ID 1143, 2976)

The Panel considers that the following wording reflects the scientific evidence: "Live yoghurt cultures in yoghurt improve digestion of lactose in yoghurt in individuals with lactose maldigestion".<sup>12</sup>

#### 5. Conditions and possible restrictions of use (ID 1143, 2976)

In order to bear the claim, the yoghurt should contain at least  $10^8$  CFU live starter microorganisms (*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*) per gram.<sup>13</sup> The target population is individuals with lactose maldigestion.

### CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- Live yoghurt cultures, which are the subject of the health claim, are sufficiently characterised in relation to the claimed effect.

<sup>10</sup> "...enhanced lactose digestion in lactose maldigesters..." has been replaced with "... enhanced digestion of lactose in yoghurt in lactose maldigesters..."

<sup>11</sup> "...improved lactose digestion in individuals with lactose maldigestion." has been replaced with "...improved digestion of lactose in yoghurt in individuals with lactose maldigestion."

<sup>12</sup> "Live yoghurt cultures in yoghurt improve lactose digestion in individuals with lactose maldigestion." has been replaced with "Live yoghurt cultures in yoghurt improve digestion of lactose in yoghurt in individuals with lactose maldigestion."

<sup>13</sup> "In order to bear the claim, the yoghurt should contain at least  $10^8$  CFU per serving live starter microorganisms (i.e. *Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*)." has been replaced with "In order to bear the claim, the yoghurt should contain at least  $10^8$  CFU live starter microorganisms (*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*) per gram."



- The claimed effect is “lactose digestion”. The target population is individuals with lactose maldigestion. Improved lactose digestion is a beneficial physiological effect for individuals with lactose maldigestion.
- A cause and effect relationship has been established between the consumption of live yoghurt cultures in yoghurt and improved digestion of lactose in yoghurt in individuals with lactose maldigestion.<sup>14</sup>
- The following wording reflects the scientific evidence: “Live yoghurt cultures in yoghurt improve digestion of lactose in yoghurt in individuals with lactose maldigestion”.<sup>15</sup>
- In order to bear the claim, the yoghurt should contain at least 10<sup>8</sup> CFU live starter microorganisms (*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*) per gram.<sup>16</sup> The target population is individuals with lactose maldigestion.

## DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1882, EFSA-Q-2008-3708). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: <http://www.efsa.europa.eu/panels/nda/claims/article13.htm>.

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<sup>14</sup> “...improved lactose digestion in individuals with lactose maldigestion.” has been replaced with “...improved digestion of lactose in yoghurt in individuals with lactose maldigestion.”

<sup>15</sup> “Live yoghurt cultures in yoghurt improve lactose digestion in individuals with lactose maldigestion.” has been replaced with “Live yoghurt cultures in yoghurt improve digestion of lactose in yoghurt in individuals with lactose maldigestion.”

<sup>16</sup> “In order to bear the claim, the yoghurt should contain at least 10<sup>8</sup> CFU per serving live starter microorganisms (i.e. *Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*).” has been replaced with “In order to bear the claim, the yoghurt should contain at least 10<sup>8</sup> CFU live starter microorganisms (*Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*) per gram.”

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## APPENDICES

### APPENDIX A

#### BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods<sup>17</sup> (hereinafter "the Regulation") entered into force on 19<sup>th</sup> January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

- a) the role of a nutrient or other substance in growth, development and the functions of the body; or
- b) psychological and behavioural functions; or
- c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

- (i) based on generally accepted scientific evidence; and
- (ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

#### ISSUES THAT NEED TO BE CONSIDERED

##### IMPORTANCE AND PERTINENCE OF THE FOOD<sup>18</sup>

Foods are commonly involved in many different functions<sup>19</sup> of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

##### SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

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<sup>17</sup> OJ L12, 18/01/2007

<sup>18</sup> The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

<sup>19</sup> The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

- (a) the claimed effect of the food is beneficial for human health,
- (b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),
- (c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,
- (d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

### WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

## **TERMS OF REFERENCE**

### **HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH**

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity consumed.
- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.



## APPENDIX B

### EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

## APPENDIX C

Table 1. Main entry health claims related to Yoghurt cultures (live), including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
1143	<p>Yoghurt cultures (live)</p> <p><u>Clarification provided</u></p> <p>Yoghurt and any fermented milk containing live yoghurt cultures<sup>1</sup> (i.e. any strain of <i>Streptococcus thermophilus</i> and <i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i>). Since any strain of <i>Streptococcus thermophilus</i> and <i>Lactobacillus bulgaricus</i> expresses the enzyme (lactase) which degrades lactose, all yoghurts and other fermented milks fermented with both species are eligible for the claim. This effect is dependent on the dose of bacteria: only products containing at least 10<sup>7</sup> cfu of live yoghurt cultures / per g of product improve the lactose digestion of the population with digestive discomfort related to lactose digestion.</p> <p>1: the term "yoghurt" here refers to the definition of the Codex Standard for Fermented Milks, (Codex Stan 243-2003), i.e. a product obtained from fermentation of milk by cultures of <i>Streptococcus thermophilus</i> and <i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i>, in which starter microorganisms must be viable, active and abundant to the date of minimum durability. The population of bacteria in the product should contain at least 10<sup>7</sup> CFU per g of product at the end of the shelf life (Table 3; section 3.3 "Composition" of codex stan 243-2003).</p>	Lactose digestion	<p>-live cultures of yoghurt improve lactose digestion;</p> <p>-fermented milks containing live cultures of yoghurt improve lactose digestion.</p>
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Average daily serving to be consumed to produce the claimed effect is 100 grams of yoghurt containing live yoghurt cultures. There are no known factors that could interfere with bioavailability. The claimed effect is expected to become apparent in habitual intake of the above product. There is no limit to the amount of yoghurt which should be consumed in order to avoid adverse health effects.</li> <li>- Live cultures of <i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i> and <i>Streptococcus thermophilus</i> contained in "yoghurt" as defined by Codex Standard for Fermented Milks (Codex Stan 243-2003).</li> </ul>		
	<p><b>Comments from Member States</b></p> <p>German Claims in the second level: DE 23403 belongs to main entry 668; DE 23408 is a downstream effect of the circumstances covered by main entry 1143; DE 23407 describes the laxative properties of lactose not covered by any other main entry of the consolidated list</p>		

ID	Food or Food constituent	Health Relationship	Proposed wording
2976	<p>Yoghurt cultures (live)</p> <p><u>Clarification provided</u></p> <p>Yoghurt and any fermented milk containing live yoghurt cultures<sup>1</sup> (i.e. any strain of <i>Streptococcus thermophilus</i> and <i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i>). Since any strain of <i>Streptococcus thermophilus</i> and <i>Lactobacillus bulgaricus</i> expresses the enzyme (lactase) which degrades lactose, all yoghurts and other fermented milks fermented with both species are eligible for the claim. This effect is dependent on the dose of bacteria: only products containing at least 10<sup>7</sup> cfu of live yoghurt cultures / per g of product improve the lactose digestion of the population with digestive discomfort related to lactose digestion.</p> <p>1: the term "yoghurt" here refers to the definition of the Codex Standard for Fermented Milks, (Codex Stan 243-2003), i.e. a product obtained from fermentation of milk by cultures of <i>Streptococcus thermophilus</i> and <i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i>, in which starter microorganisms must be viable, active and abundant to the date of minimum durability. The population of bacteria in the product should contain at least 10<sup>7</sup> CFU per g of product at the end of the shelf life (Table 3; section 3.3 "Composition" of codex stan 243-2003).</p>	Lactose digestion	<p>-live cultures of yoghurt improve lactose digestion;</p> <p>-fermented milks containing live cultures of yoghurt improve lactose digestion.</p>
	<p><b>Conditions of use</b></p> <ul style="list-style-type: none"> <li>- Live cultures of <i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i> and <i>Streptococcus thermophilus</i>, with "yoghurt" as defined by Codex Standard for Fermented Milks (Codex Stan 243-2003)</li> </ul>		
	<p><b>Comments from Member States</b></p> <p>Claim 2976 is the same as claim 1143 provided by Germany and UK. List of references available in EFSA database is incomplete compared to the list of references originally provided by the stakeholder (EDA in August/September 2008).</p>		

**GLOSSARY AND ABBREVIATIONS**

AUCi	Incremental area under the curve
BHC	Breath hydrogen concentration
CFU	Colony forming unit
FPM	Fermented-then-pasteurised milk
OCTT	Orocaecal transit time