SCIENTIFIC OPINION

Scientific Opinion on the substantiation of health claims related to non-characterised microorganisms pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2]

European Food Safety Authority (EFSA), Parma, Italy

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 1924/2006. This opinion addresses the scientific substantiation of health claims related to

1 On request from the European Commission, Question No EFSA-Q-2008-3723, EFSA-Q-2008-3705, EFSA-Q-2008-3704, EFSA-Q-2008-3703, EFSA-Q-2008-3702, EFSA-Q-2008-3699, EFSA-Q-2008-3698, EFSA-Q-2008-3695, EFSA-Q-2008-3694, EFSA-Q-2008-3690, EFSA-Q-2008-3689, EFSA-Q-2008-3688, EFSA-Q-2008-3687, EFSA-Q-2008-3686, EFSA-Q-2008-3685, EFSA-Q-2008-3684, EFSA-Q-2008-3683, EFSA-Q-2008-3682, EFSA-Q-2008-3681, EFSA-Q-2008-3680, EFSA-Q-2008-3679, EFSA-Q-2008-3678, EFSA-Q-2008-2331, EFSA-Q-2008-1837, EFSA-Q-2008-1836, EFSA-Q-2008-1835, EFSA-Q-2008-1834, EFSA-Q-2008-1833, EFSA-Q-2008-1832, EFSA-Q-2008-1831, EFSA-Q-2008-1830, EFSA-Q-2008-1829, EFSA-Q-2008-1828, EFSA-Q-2008-1827, EFSA-Q-2008-1826, EFSA-Q-2008-1825, EFSA-Q-2008-1824, EFSA-Q-2008-1819, EFSA-Q-2008-1818, EFSA-Q-2008-1815, EFSA-Q-2008-1814, EFSA-Q-2008-1812, EFSA-Q-2008-1811, EFSA-Q-2008-1810, EFSA-Q-2008-1809, EFSA-Q-2008-1808, EFSA-Q-2008-1807, EFSA-Q-2008-1806, EFSA-Q-2008-1805, EFSA-Q-2008-1804, EFSA-Q-2008-1802, EFSA-Q-2008-1801, EFSA-Q-2008-1799, EFSA-Q-2008-1796, EFSA-Q-2008-1795, EFSA-Q-2008-1794, EFSA-Q-2008-1793, EFSA-Q-2008-1792, EFSA-Q-2008-1791, EFSA-Q-2008-1790, EFSA-Q-2008-1789, EFSA-Q-2008-1788, EFSA-Q-2008-1787, EFSA-Q-2008-1786, EFSA-Q-2008-1785, EFSA-Q-2008-1784, EFSA-Q-2008-1783, EFSA-Q-2008-1782, EFSA-Q-2008-1781, EFSA-Q-2008-1780, EFSA-Q-2008-1779, EFSA-Q-2008-1778, EFSA-Q-2008-1777, EFSA-Q-2008-1776, EFSA-Q-2008-1775, EFSA-Q-2008-1774, EFSA-Q-2008-1773, EFSA-Q-2008-1772, EFSA-Q-2008-1771, EFSA-Q-2008-1765, EFSA-Q-2008-1764, EFSA-Q-2008-1763, EFSA-Q-2008-1762, EFSA-Q-2008-1761, EFSA-Q-2008-1760, EFSA-Q-2008-1759, EFSA-Q-2008-1758, EFSA-Q-2008-1757, EFSA-Q-2008-1756, EFSA-Q-2008-1755, EFSA-Q-2008-1754, EFSA-Q-2008-1753, EFSA-Q-2008-1752, EFSA-Q-2008-1751, EFSA-Q-2008-1750, EFSA-Q-2008-1749, EFSA-Q-2008-1748, EFSA-Q-2008-1747, EFSA-Q-2008-1746, EFSA-Q-2008-1745, EFSA-Q-2008-1744, EFSA-Q-2008-1743, EFSA-Q-2008-1742, EFSA-Q-2008-1741, EFSA-Q-2008-1740, EFSA-Q-2008-1739, EFSA-Q-2008-1738, EFSA-Q-2008-1737, EFSA-Q-2008-1736, EFSA-Q-2008-1735, EFSA-Q-2008-1734, EFSA-Q-2008-1731, EFSA-Q-2008-1730, EFSA-Q-2008-1729, EFSA-Q-2008-1728, EFSA-Q-2008-1727, EFSA-Q-2008-1726, EFSA-Q-2008-1725, EFSA-Q-2008-1723, EFSA-Q-2008-1722, EFSA-Q-2008-1721, EFSA-Q-2008-1720, EFSA-Q-2008-1719, EFSA-Q-2008-1718, EFSA-Q-2008-1716, EFSA-Q-2008-1715, EFSA-Q-2008-1714, EFSA-Q-2008-1713, EFSA-Q-2008-1712, EFSA-Q-2008-1710, EFSA-Q-2008-1709, EFSA-Q-2008-1708, EFSA-Q-2008-1707, EFSA-Q-2008-1706, EFSA-Q-2008-1705, EFSA-Q-2008-1704, EFSA-Q-2008-1702, EFSA-Q-2008-1701, EFSA-Q-2008-1700, EFSA-Q-2008-1699, EFSA-Q-2008-1698, EFSA-Q-2008-1694, EFSA-Q-2008-1690, EFSA-Q-2008-1688, EFSA-Q-2008-1686, EFSA-Q-2008-1685, EFSA-Q-2008-1684, EFSA-Q-2008-1682, EFSA-Q-2008-1678, EFSA-Q-2008-1676, EFSA-Q-2008-1675, EFSA-Q-2008-1674, EFSA-Q-2008-1673, EFSA-Q-2008-1672, EFSA-Q-2008-1670, EFSA-Q-2008-1668, EFSA-Q-2008-1667, EFSA-Q-2008-1666, EFSA-Q-2008-1665, EFSA-Q-2008-1664, EFSA-Q-2008-1663, EFSA-Q-2008-1662, EFSA-Q-2008-1661, EFSA-Q-2008-1660, EFSA-Q-2008-1658, EFSA-Q-2008-1657, EFSA-Q-2008-1656, EFSA-Q-2008-1655, EFSA-Q-2008-1648, EFSA-Q-2008-1647, EFSA-Q-2008-1646 adopted on 02 July 2009.

2 Panel members: Jean-Louis Bresson, Albert Flynn, Marina Heinonen, Karin Hulshof, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Hildegard Przyrembel, Seppo Salminen, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Henk van den Berg, Hendrik van Loveren and Hans Verhagen.
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a number of microorganisms, for which the Panel considers that the data provided are not sufficient to characterise the microorganisms in question. 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.

Microorganisms or microbes (e.g. bacteria) are living organisms, and can change over time depending on culture conditions. Correct identification of the microorganism's species and strain is of critical importance, as the observed effects are species and strain specific.

Species identification and sufficient characterisation (genetic typing) at strain level, by using internationally accepted molecular methods is needed. In addition, strains should be named according to the International Code of Nomenclature. As indicated by the FAO/WHO (FAO, 2006), strains should also be deposited in an internationally recognised culture collection (with access number). In the context of the Regulation (EC) nº 1924/2006, the purposes of characterisation are to confirm the identity of the food/constituent that is the subject of the health claim, and to establish that the studies provided for substantiation of the health claim were performed with the food/constituent in respect of which the health claim is made. Although not required for substantiation of a claim, characterisation should also be sufficient to allow control authorities to verify that the food/constituent which bears a health claim is the same one that was the subject of a community authorisation.

The Panel has decided to use the following criteria for characterisation of food constituents that are microorganisms, which are the subject of health claims:

- Species identification by DNA-DNA hybridization or 16S rRNA sequence analysis.
- Strain identification by DNA macrorestriction followed by PFGE, RAPD, ARDRA or other internationally accepted genetic typing molecular methods.

Only when these two criteria were fulfilled, the microorganism was considered to be sufficiently characterised. In the case of combination of several microorganisms, the Panel considers that if one microorganism used in the combination is not sufficiently characterised, the combination proposed is not sufficiently characterised.

Based on these criteria the Panel considers that the microorganisms/combination of microorganisms covered in this opinion, are not sufficiently characterised.

As the data available are insufficient to characterise the microorganisms/combination of microorganisms addressed in this opinion, and that owing to the strain-specificity of the effects, the evidence obtained for one strain cannot be extrapolated to another, the Panel concludes that a cause and effect relationship has not been established between the consumption of the microorganisms/combination of microorganisms addressed in this opinion and their claimed effects.

KEY WORDS

Microorganisms, species, strain, characterisation, scientific substantiation, Article 13, health claims

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EFSA DISCLAIMER

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation 1924/2006[3] submitted by Member States contains main entry claims with corresponding conditions of use and literature from similar health claims.

ASSESSMENT

This opinion addresses the scientific substantiation of health claims related to a number of **microorganisms**, for which the Panel considers that the data provided are not sufficient to characterise the microorganisms in question.

1. Characterisation of the food/constituent

Introduction on the process used for characterisation of food constituents that are microorganisms:

Microorganisms or microbes (e.g. bacteria) are living organisms, and can change over time depending on culture conditions. Correct identification of the microorganism's species and strain is of critical importance, as the observed effects are species and strain specific.

The appropriate classification, identification and nomenclature of microorganisms constitute the starting point for the assessment of microbial properties. Classification assigns an organism to a known taxonomic group according to its similarity to that group. This allows the prediction of the properties of the microorganism on the basis of what is already known about the taxa. A reliable identification confirms the identity of the strain(s) used in a given process and requires the use of appropriate methods.

Traditional phenotypic identification of bacteria is not always reliable since certain species cannot be distinguished by these methods. Molecular techniques have emerged in recent years as a replacement or complement to traditional phenotypic tests. DNA-DNA hybridization has become the generally accepted standard for determination of bacterial species identification. However this technique is difficult to perform and requires an expertise not normally present in the food industry. For these reasons phylogenetically based approaches such as sequence analysis of the 16S rRNA gene has proven to be a useful tool for bacterial identification. The EU-funded PROSAFE project concluded that biochemical tests should not be used as a stand-alone approach for identification of bacterial cultures (Vankerckhoven et al., 2008). The use of 16S rRNA gene sequence analysis was considered the best tool for routine species identification. Moreover, the use of sequence-based methods, such as 16S rRNA gene sequencing, was encouraged given their high reproducibility and data exchangeability (Vankerckhoven et al., 2008). The FAO/WHO expert group (FAO, 2006) recommends that phenotypic tests should be done first, followed by genetic identification, using methods such as DNA-DNA hybridization or 16S rRNA sequence analysis. Nevertheless, it is important to underline that in some cases 16S rRNA sequencing has a limited resolution and it may not be enough for discrimination of closely related species (Felis and Dellaglio, 2007; Vankerckhoven et al., 2008) being necessary to use other methods.

For the strain identification (characterisation of the strain by genetic typing), the FAO/WHO working group also recommended that strain typing has to be performed with a reproducible genetic method or using a unique phenotypic trait (FAO, 2006). DNA macrorestriction followed by Pulsed Field Gel

[3] 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.

Electrophoresis (PFGE) is considered as the generally accepted standard (FAO, 2006) and it has been extensively used for differentiating commercial microorganism strains. Other discriminatory molecular methods, such as Randomly Amplified Polymorphic DNA (RAPD) or Amplified rDNA restriction analysis (ARDRA) among others, are also available for strain characterisation.

Hence, species identification and sufficient characterisation (genetic typing) at strain level by using internationally accepted molecular methods is needed. In addition, strains should be named according to the International Code of Nomenclature.

Although there is no direct requirement on deposition of the particular strain in an internationally recognised culture collection, the FAO/WHO (FAO, 2006) recommends that strains should also be deposited in an internationally recognised culture collection (with access number). These will assure the tracking and access of scientists and regulatory authorities to the strain and related information in case it is needed.

In the context of the Regulation (EC) nº 1924/2006, the purposes of characterisation are to confirm the identity of the food/constituent that is the subject of the health claim, and to establish that the studies provided for substantiation of the health claim were performed with the food/constituent in respect of which the health claim is made. Although not required for substantiation of a claim, characterisation should also be sufficient to allow control authorities to verify that the food/constituent which bears a health claim is the same one that was the subject of a community authorisation.

The Panel has decided to use the following criteria for characterisation of food constituents that are microorganisms, which are the subject of health claims:

- Species identification by DNA-DNA hybridization or 16S rRNA sequence analysis.
- Strain identification by DNA macrorestriction followed by PFGE, RAPD, ARDRA or other internationally accepted genetic typing molecular methods.

Only when these two criteria were fulfilled, the microorganism was considered to be sufficiently characterised. In case of combination of several microorganisms, the Panel considers that if one microorganism used in the combination is not sufficiently characterised, the combination proposed is not sufficiently characterised.

The characterisation of food constituents that are microorganisms, which are the subject of health claims pursuant to Article 13 of the Regulation (EC) nº 1924/2006, is based on evaluation of available references up to 31 December 2008, including the following:

- 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;
- Generally available data obtained by searching PubMed and Web of Science databases by using the strain name as search term.

1.1. Characterisation of "*Bifidobacterium bifidum* I-3426" (ID 859, 860).

The food constituent that is the subject of the health claim is *Bifidobacterium bifidum* I-3426 (hereafter *B. bifidum* I-3426). The identification/characterisation of the strain *B. bifidum* I-3426 is not included in the studies provided as reference material and no information regarding strain *B. bifidum* I-3426 identification/characterisation was found in the literature. The Panel considers that the strain *B. bifidum* I-3426, which is the subject of the health claims ID 859, 860, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.2. Characterisation of "*Bifidobacterium bifidum* CNCM I-373" (ID 861)

The food constituent that is the subject of the health claim is *Bifidobacterium bifidum* CNCM I-373 (hereafter *B. bifidum* CNCM I-373). The identification/characterisation of the strain *B. bifidum* CNCM I-373 is not included in the studies provided as reference material. The strain is included together with other strains in a patent on acid-resistant bifidobacteria (Sozzi, 1989; Chandan, 1999). However, no other information regarding strain *B. bifidum* CNCM I-373 identification/characterisation was found in the literature. The Panel considers that *B. bifidum* CNCM I-373, which is the subject of the health claim ID 861, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) is provided. The CNCM is a restricted-access non-public collection which has the status of International Depositary Authority under the Budapest Treaty.

1.3. Characterisation of a combination of "*Bifidobacterium animalis* ssp. *lactis* Bb-12®, *Lactobacillus acidophilus* LA-5®" (ID 868, 870)

The food constituent that is the subject of the health claim is a combination of **"***Bifidobacterium animalis* ssp. *lactis* Bb-12® and *Lactobacillus acidophilus* LA-5®".

***Bifidobacterium animalis* ssp. *lactis* Bb-12®** (hereafter *B. animalis* ssp. *lactis* Bb-12®) - The strain *B. animalis ssp. lactis* Bb-12®, previously known as *B. lactis* Bb-12® is subjected to reclassification (Masco et al., 2004). The species identity as well as the strain identity and characteristics have been determined using different genotypic methods (Yimin et al., Unpublished; Garrigues et al., 2005; Mayer et al., 2007; Ventura et al., 2001a). It is important to point out that it may not be possible to differentiate commercially available *B. animalis* ssp. *lactis* strains from each other on the basis of traditional genetic methods (e.g. PFGE) (Engel et al., 2003; Gueimonde et al., 2004) and may be necessary to use multi-locus sequencing or genome-wide approaches. To this regard the genome of *B. animalis* ssp. *lactis* Bb-12® although sequenced (Yimin et al., Unpublished) is not publicly available at the databases. The Panel considers that *B. animalis* ssp. *lactis* Bb-12, which is the subject of the health claims D_868, 870, is sufficiently characterised.

The deposit of the strain at the German culture collection DSMZ under number DSM 15954 was reported in the literature (Kajander et al., 2008). In addition several authors consider the strain Bb-12 to be also equal to the strain DSMZ 10140 (Ventura et al., 2001b). This is due to the fact that although the strain owner did not deposit the strain under Bb-12 name, strain DSMZ 10140 was isolated from a yoghurt containing Bb-12 and deposited by Meile et al. (1997).

***Lactobacillus acidophilus* LA-5®** (hereafter *L. acidophilus* LA-5®) - The identification/characterisation of the strain *L. acidophilus* LA-5® is not included in the studies provided as reference material. No genotypic information regarding identification/characterisation of the strain was found in the literature, only some limited information regarding phenotypic tests was found (Nighswonger et al., 1996). The Panel considers that *L. acidophilus* LA-5®, which is the subject of the health claims D_868, 870, is not sufficiently characterised.

The deposit of the strain in an internationally recognised culture collection was not reported in the information provided or the literature.

The Panel considers that the combination of "*Bifidobacterium animalis* ssp. *lactis* Bb-12® and *Lactobacillus acidophilus* LA-5®", which is the subject of the health claims D_868, 870, is not sufficiently characterised.

1.4. Characterisation of a combination of "*Lactobacillus acidophilus* ATCC SD5221 and *Bifidobacterium lactis* ATCC SD5220" (ID 869)

The food constituent that is the subject of the health claim is a combination of **"***Lactobacillus acidophilus* ATCC SD5221 and *Bifidobacterium lactis* ATCC SD5220".

***Lactobacillus acidophilus* ATCC SD5221** (hereafter *L. acidophilus* ATCC SD5221) - The strain *L. acidophilus* ATCC SD5221, also known as *L. acidophilus* NCFM, species identity as well as the strain identity and characteristics have been clearly established by using both phenotypic and genotypic methods (Sanders and Klaenhammer, 2001). In addition, the genome *L. acidophilus* NCFM (ATCC SD5221) is publicly available at the National Center for Biotechnology Information (NCBI) database (Altermann et al., 2005) (accession nº NC_006814). The Panel considers that *L. acidophilus* ATCC SD5221, which is the subject of the health claim ID 869, is sufficiently characterised.

A culture collection number from the American Type Culture Collection (ATCC) is provided.

***Bifidobacterium lactis* ATCC SD5220** (hereafter *B. lactis* ATCC SD5220) - The identification/characterisation of the strain *B. lactis* ATCC SD5220, also known as *B. lactis* Bi-07, is not included in the studies provided as reference material. Some phenotypic features of the strain are known (Ding and Shah, 2007), but no information regarding genotypic identification/characterisation was found in the literature. The species *B. lactis* has been reclassified as *B. animalis* ssp. *Lactis* (Masco et al. 2004). It is important to point out that it may not be possible to differentiate the commercially available *B. animalis* ssp. *lactis* strains from each other on the basis of traditional genetic methods (e.g. PFGE) (Engel et al. 2003; Gueimonde et al., 2004) and may be necessary to use multi-locus sequencing or genome-wide approaches. The Panel considers that *B. lactis* ATCC SD5220, which is the subject of the health claim ID 869, is not sufficiently characterised.

A culture collection number from the American Type Culture Collection (ATCC) is provided.

The Panel considers that the combination of "*Lactobacillus acidophilus* ATCC SD5221 and *Bifidobacterium lactis* ATCC SD5220", which is the subject of the health claim ID 869, is not sufficiently characterised.

1.5. Characterisation of "*Bifidobacterium breve* I-3425" (ID 871, 873)

The food constituent that is the subject of the health claim is ***Bifidobacterium breve* I-3425** (hereafter *B. breve* I-3425)**.** The identification/characterisation of the strain *B. breve* I-3425 is not included in the studies provided as reference material and no information regarding the strain *B. breve* I-3425 identification/characterisation was found in the literature. The Panel considers that *B. breve* I-3425, which is the subject of the health claims ID 871, 873, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.6. Characterisation of "*Bifidobacterium infantis* I-3424" (ID 874, 876)

The food constituent that is the subject of the health claim is *Bifidobacterium infantis* I-3424 (hereafter *B. infantis* I-3424). The identification/characterisation of the strain *B. infantis* I-3424 is not included in the studies provided as reference material and no information regarding the strain

identification/characterisation was found in the literature. The species *B. infantis* has been reclassified as subspecies of *Bifidobacterium longum*, *B. longum* ssp. *infantis* (Sakata et al., 2002). The Panel considers that *B. infantis* I-3424, which is the subject of the health claims ID 874, 876, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.7. Characterisation of "*Bifidobacterium infantis* UCC35624" (ID 875, 1093, 1094)

The food constituent that is the subject of the health claim is *Bifidobacterium infantis* UCC35624 (hereafter *B. infantis* UCC35624). The identification/characterisation of the strain *B. infantis* UCC35624 is not included in the studies provided as reference material. The strain has been genetically characterised by PFGE (O'Riordan and Fitzgerald, 1997), however this technique may not be appropriate for species identification and no other information regarding the species identification was found in the literature. The species *B. infantis* has been reclassified as subspecies of *Bifidobacterium longum*, *B. longum* ssp. *infantis* (Sakata et al., 2002). The Panel considers that *B. infantis* UCC 35614, which is the subject of the health claims ID 875, 1093, 1094, is not sufficiently characterised.

The deposit of the strain *B. infantis* UCC35624 as NCIMB 41003 at the National Collection of Industrial and Marine Bacteria (UK) collection was found in the literature (Collins et al., 2000. Patent WO2000042499).

1.8. Characterisation of "*Bifidobacterium longum* I-3470" (ID 877, 878)

The food constituent that is the subject of the health claim is *Bifidobacterium longum* I-3470 (hereafter *B. longum* I-3470). The identification/characterisation of the strain *B. longum* I-3470 is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *B. longum* I-3470, which is the subject of the health claims ID 877, 878, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.9. Characterisation of "*Lactobacillus acidophilus* CNCM I-1722" (ID 879)

The food constituent that is the subject of the health claim is *Lactobacillus acidophilus* CNCM I-1722 (hereafter *L. acidophilus* CNCM I-1722). The identification/characterisation of the strain *L. acidophilus* CNCM I-1722 is not included in the studies provided as reference material and no other information regarding the strain identification/characterisation was found in the literature. The Panel considers that *L. acidophilus* CNCM I-1722, which is the subject of the health claim ID 879, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) is provided. The CNCM is a restricted-access non-public collection which has the status of International Depositary Authority under the Budapest Treaty.

1.10. Characterisation of "*Lactobacillus acidophilus* LA-5®" (ID 880)

The food constituent that is the subject of the health claim is *Lactobacillus acidophilus* LA-5® (hereafter *L. acidophilus* LA-5®). The identification/characterisation of the strain *L. acidophilus* LA-5® is not included in the studies provided as reference material. No genotypic information regarding

identification/characterisation of the strain was found in the literature, only some limited information regarding phenotypic tests was found (Nighswonger et al., 1996). The Panel considers that *L. acidophilus* LA-5®, which is the subject of the health claim ID 880, is not sufficiently characterised.

The deposit of the strain in an internationally recognised culture collection was not found in the information provided or the literature.

1.11. Characterisation of "*Lactobacillus acidophilus* Lafti L10 (CBS 116.411)" (ID 881, 883)

The food constituent that is the subject of the health claim is *Lactobacillus acidophilus* Lafti L10 (CBS 116.411) (hereafter *L. acidophilus* Lafti L10 (CBS 116.411)). The identification/characterisation of the strain *L. acidophilus* Lafti L10 (CBS 116.411) is not included in the studies provided as reference material. No information regarding the strain identification/characterisation was found in the literature. The Panel considers that *L. acidophilus* Lafti L10 (CBS 116.411), which is the subject of the health claims ID 881, 883, is not sufficiently characterised.

A culture collection number from the Centraalbureau voor Schimmelcultures (CBS) is provided.

1.12. Characterisation of a combination of "*Lactobacillus acidophilus* CUL21 NCIMB 30156, *Lactobacillus acidophilus* CUL60 NCIMB 30157, *Bifidobacterium adolescentis* CUL20 NCIMB 30153, *Bifidobacterium lactis* (*animalis* ssp. *lactis*) CUL34 NCIMB 30172" (ID 885, 944)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus acidophilus* CUL21 NCIMB 30156, *Lactobacillus acidophilus* CUL60 NCIMB 30157, *Bifidobacterium adolescentis* CUL20 NCIMB 30153, *Bifidobacterium lactis* (*animalis* ssp. *lactis*) CUL34 NCIMB 30172"

***Lactobacillus acidophilus* CUL21 NCIMB 30156** (hereafter *L. acidophilus* CUL21 (NCIMB 30156)) - The identification/characterisation of the strain *L. acidophilus* CUL21 (NCIMB 30156) is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *L. acidophilus* CUL21 (NCIMB 30156), which is the subject of the health claims ID 885, 944, is not sufficiently characterised.

A culture collection number from the National Collection of Industrial and Marine Bacteria (UK) is provided.

***Lactobacillus acidophilus* CUL60 NCIMB 30157** (hereafter *L. acidophilus* CUL60 (NCIMB 30157)) - The identification/characterisation of the strain *L. acidophilus* CUL60 (NCIMB 30157) is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *L. acidophilus* CUL60 (NCIMB 30157), which is the subject of the health claims ID 885, 944, is not sufficiently characterised.

A culture collection number from the National Collection of Industrial and Marine Bacteria (UK) is provided.

***Bifidobacterium adolescentis* CUL20 NCIMB 30153** (hereafter *B. adolescentis* CUL20 (NCIMB 30153)) - The identification/characterisation of the strain *B. adolescentis* CUL20 (NCIMB 30153) is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *B. adolescentis*

CUL20 (NCIMB 30153), which is the subject of the health claims ID 885, 944, is not sufficiently characterised.

A culture collection number from the National Collection of Industrial and Marine Bacteria (UK) is given.

***Bifidobacterium lactis* (*animalis* ssp. *lactis*) CUL34 NCIMB 30172** (hereafter *B. lactis* CUL34 (NCIMB 30172)) - The identification/characterisation of the strain *B. lactis* CUL34 (NCIMB 30172) is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The species *B. lactis* has been reclassified as *B. animalis* ssp. *lactis* (Masco et al., 2004). It is important to point out that it may not be possible to differentiate the commercially available *B. animalis* ssp. *lactis* strains from each other on the basis of traditional genetic methods (e.g. PFGE) (Engel et al., 2003; Gueimonde et al., 2004) and may be necessary to use multi-locus sequencing or genome-wide approaches. The Panel considers that *Bifidobacterium animalis* ssp. *lactis* CUL34 (NCIMB 30172), which is the subject of the health claims ID 885, 944, is not sufficiently characterised.

A culture collection number from the National Collection of Industrial and Marine Bacteria (UK) is given.

The Panel considers that the combination of "*Lactobacillus acidophilus* CUL21 (NCIMB 30156), *Lactobacillus acidophilus* CUL60 (NCIMB 30157), *Bifidobacterium adolescentis* CUL20 (NCIMB 30153), *Bifidobacterium lactis* (*animalis* ssp. *lactis*) CUL34 (NCIMB 30172)", which is the subject of the health claims ID 885, 944, is not sufficiently characterised.

1.13. Characterisation of "*Lactobacillus helveticus* I-1722" (ID 886, 887)

The food constituent that is the subject of the health claim is *Lactobacillus helveticus* I-1722. The identification/characterisation of the strain *Lactobacillus helveticus* I-1722 is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus helveticus* I-1722, which is the subject of the health claims ID 886, 887, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.14. Characterisation of "*Lactobacillus casei* Lafti L26 (CBS 116.412)" (ID 888)

The food constituent that is the subject of the health claim is *Lactobacillus casei* Lafti L26 (CBS 116.412). The only information regarding the strain identification/characterisation found in the references provided refers to the sequence of the 16S-23S rRNA intergenic region (deposited at Genbank, accession nº DQ265738) and the design of a putatively strain specific primer (Su et al., 2007). No information regarding strain characterisation was found in the literature. The Panel considers that *Lactobacillus casei* Lafti L26 (CBS 116.412), which is the subject of the health claim ID 888, is not sufficiently characterised.

A culture collection number from the Centraalbureau voor Schimmelcultures (CBS) is provided.

1.15. Characterisation of "*Lactobacillus casei* I-3429" (ID 889, 891)

The food constituent that is the subject of the health claim is *Lactobacillus casei* I-3429. The identification/characterisation of the strain *Lactobacillus casei* I-3429 is not included in the studies provided as reference material and no information regarding the strain identification/characterisation

was found in the literature. The Panel considers that *Lactobacillus casei* I-3429, which is the subject of the health claims ID 889, 891, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.16. Characterisation of "*Lactobacillus paracasei* NCC2461 (ST11) (CNCM I-2116)" (ID 895, 897, 899)

The food constituent that is the subject of the health claim is *Lactobacillus paracasei* NCC2461 (ST11) (CNCM I-2116) (hereafter *L. paracasei* NCC2461 (ST11) (CNCM I-2116)). The identification/characterisation of the strain *L. paracasei* NCC2461, also known as *L. paracasei* ST11, is not included in the studies provided as reference material. This strain has been identified by sequence analysis of *tuf* genes and subsequent phylogenetic analyses (similar phylogenetic analysis are found between the use of *tuf* and 16 sRNA genes) (Ventura et al., 2003), but no other studies on phenotypic and genotypic identification/characterisation have been found in the literature. The Panel considers that *L. paracasei* NCC2461 (ST11) (CNCM I-2116), which is the subject of the health claims ID 895, 897, 899, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) is provided.

1.17. Characterisation of "*Lactobacillus paracasei* ssp. *paracasei* CRL-431" (ID 898)

The food constituent that is the subject of the health claim is *Lactobacillus paracasei* ssp. *paracasei* CRL-431 (hereafter *L. paracasei* ssp. *paracasei* CRL-431). The identification/characterisation of the strain *L. paracasei* ssp. paracasei CRL-431, previously known as *L. casei* CRL 431, is not included in the studies provided as reference material. No studies on identification/characterisation of the strain have been found in the literature. The Panel considers that *Lactobacillus paracasei* ssp. *paracasei* CRL-431, which is the subject of the health claim ID 898, is not sufficiently characterised.

The Panel notes that a culture collection number from the research institute in which the strain was isolated is given (CERELA, Argentina). A patent application for this strain indicates its deposit at the American Type Culture Collection (ATCC) as ATCC 55544 (Cravero, 1996).

1.18. Characterisation of "*Lactobacillus plantarum* Rosell-1012" (ID 901, 903)

The food constituent that is the subject of the health claim is *Lactobacillus plantarum* Rosell-1012. The identification/characterisation of the strain *Lactobacillus plantarum* Rosell-1012 is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus plantarum* Rosell-1012, which is the subject of the health claims ID 901, 903, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.19. Characterisation of "*Lactobacillus rhamnosus* I-1720" (ID 907, 911)

The food constituent that is the subject of the health claim is *Lactobacillus rhamnosus* I-1720. The identification/characterisation of the strain *Lactobacillus rhamnosus* I-1720 is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus*

rhamnosus I-1720, which is the subject of the health claims ID 907, 911, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found. Although there is a strain deposited as *L. rhamnosus* CNCM I-1720 at Collection Nationale de Cultures de Microorganismes it is not possible to determine whether this refers to the deposited strain.

1.20. Characterisation of "*Saccharomyces boulardii* (trade name PXN68)" (ID 912)

The food constituent that is the subject of the health claim is *Saccharomyces boulardii* (trade name PXN68). The identification/characterisation of the strain *Saccharomyces boulardii* PXN68 is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Saccharomyces boulardii* PXN68, which is the subject of the health claim ID 912, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.21. Characterisation of "Saccharomyces cerevisiae var boulardii" (ID 913)

The food constituent that is the subject of the health claim is *Saccharomyces cerevisiae* var *boulardii*. No strain identification or name is provided. The Panel considers that *Saccharomyces cerevisiae* var *boulardii*, which is the subject of the health claim ID 913, is not characterised.

1.22. Characterisation of "*Streptococcus thermophilus* I-3428" (ID 914, 915)

The food constituent that is the subject of the health claim is *Streptococcus thermophilus* I-3428. The identification/characterisation of the strain *Streptococcus thermophilus* I-3428 is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Streptococcus thermophilus* I-3428, which is the subject of the health claims ID 914, 915, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.23. Characterisation of "*Bacillus subtilis* HU58" (ID 917, 1091, 1092)

The food constituent that is the subject of the health claim is *Bacillus subtilis* HU58. Although the 16S rRNA sequence of *B. subtilis* HU58 is deposited at Genbank (EF101709) and phylogenetic analysis of 16S rRNA sequences had been performed (Tam et al., 2006), no information regarding the strain characterisation was found in the literature. The Panel considers that *Bacillus subtilis* HU58, which is the subject of the health claims ID 917, 1091, 1092, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was reported in the information provided or the literature.

1.24. Characterisation of "*Bacillus subtilis* PB6" (ID 918)

The food constituent that is the subject of the health claim is *Bacillus subtilis* PB6. The strain PB6 has been identified as *Bacillus subtilis* by using biochemical profiles and ribotyping as indicated in the references provided (Teo and Tan, 2005). However, these techniques may not be appropriate for species identification; in fact, using other techniques such as sequentiation of *gyrA* gene and DNA-

DNA hybridization, it has been proposed to reclassify the strain as *Bacillus amyloliquefaciens* (Benedikt et al., 2008). The Panel considers that *Bacillus subtilis* PB6, which is the subject of the health claim ID 918, is not sufficiently characterised.

No indication of the deposit of the strain in a culture collection is given as reference material, but indication of the deposit of this strain at the American Type Culture Collection as ATCC-PTA 6737 was found in the literature (Peys et al., 2007).

1.25. Characterisation of a combination of "Bifidobacterium animalis ssp. lactis Bb-12, Lactobacillus acidophilus LA-5, Lactobacillus bulgaricus LBY-27, Streptococcus thermophilus STY-31" (ID 919, 920)

The food constituent that is the subject of the health claim is a combination of "*Bifidobacterium animalis* ssp. *lactis* Bb-12, *Lactobacillus acidophilus* LA-5, *Lactobacillus bulgaricus* LBY-27, *Streptococcus thermophilus* STY-31".

***Bifidobacterium animalis* ssp. *lactis* Bb-12** (hereafter *B. animalis* ssp. *lactis* Bb-12) - The strain *B. animalis* ssp. *lactis* Bb-12, previously known as *B. lactis* Bb-12 is subjected to reclassification (Masco et al., 2004). The species identity as well as the strain identity and characteristics have been determined using different genotypic methods (Yimin et al., Unpublished; Garrigues et al., 2005; Mayer et al., 2007; Ventura et al., 2001a). It is important to point out that it may not be possible to differentiate commercially available *B. animalis* ssp. *lactis* strains from each other on the basis of traditional genetic methods (e.g. PFGE) (Engel et al., 2003; Gueimonde et al., 2004) and it may be necessary to use multi-locus sequencing or genome-wide approaches. To this regard the genome of *B. animalis* ssp. *lactis* Bb-12® although sequenced (Yimin et al., Unpublished) is not publicly available at the databases. The Panel considers that *B. animalis* ssp. *lactis* Bb-12, which is the subject of the health claims ID 919, 920, is sufficiently characterised.

The deposit of the strain in a culture collection, DSM 15954, was reported in the literature (Kajander et al., 2008). In addition several authors consider the strain Bb-12 to be also equal to the strain DSMZ 10140 (Ventura et al., 2001b). This is due to the fact that although the strain owner did not deposit the strain under Bb-12 name, strain DSMZ 10140 was isolated from a yoghurt containing Bb-12 and deposited by Meile et al. (1997).

***Lactobacillus acidophilus* LA-5** - The identification/characterisation of the strain *L. acidophilus* LA-5 is not included in the studies provided as reference material. No genotypic information regarding identification/characterisation of the strain was reported in the literature, only some limited information regarding phenotypic tests was found (Nighswonger et al., 1996). The Panel considers that *L. acidophilus* LA-5, which is the subject of the health claims ID 919, 920, is not sufficiently characterised.

No reference to the deposit of the strain in internationally recognised culture collection was reported in the information provided or the literature.

***Lactobacillus bulgaricus* LBY-27** - The identification/characterisation of the strain *Lactobacillus bulgaricus* LBY-27 is not included in the studies provided as reference material. The strain species identity (using a strain isolated from a product containing *Lactobacillus bulgaricus* LBY-27) has been confirmed by sequentiation of the 16S rRNA (Tabasco et al., 2007) and polymerase chain reaction (PCR) but no information regarding the strain characterisation was found in the literature. The Panel considers that *Lactobacillus bulgaricus* LBY-27, which is the subject of the health claims ID 919, 920, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was reported in the information provided or the literature.

***Streptococcus thermophilus* STY-31 -** The identification/characterisation of the strain *Streptococcus thermophilus* STY-31 is not included in the studies provided as reference material. The strain species identity (using a strain isolated from a product containing *Streptococcus thermophilus* STY-31) has been confirmed by sequentiation of the 16S rRNA (Tabasco et al., 2007) and PCR but no information regarding the strain characterisation was found in the literature. The Panel considers that *Streptococcus thermophilus* STY-31, which is the subject of the health claims ID 919, 920, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was reported in the references provided or the literature.

The Panel considers that the combination of "*Bifidobacterium animalis* ssp. *lactis* Bb-12, *Lactobacillus acidophilus* LA-5, *Lactobacillus bulgaricus* LBY-27, *Streptococcus thermophilus* STY-31", which is the subject of the health claims ID 919, 920, is not sufficiently characterised.

1.26. Characterisation of a combination of "*Lactobacillus paracasei* ssp. *paracasei* CRL-431, *Lactobacillus acidophilus* LA-5" (ID 921, 922)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus paracasei* ssp. *paracasei* CRL-431, *Lactobacillus acidophilus* LA-5".

***Lactobacillus paracasei* ssp. *paracasei* CRL-431** (hereafter *L. paracasei* ssp. *paracasei* CRL-431) **-** The identification/characterisation of the strain *L. paracasei* ssp. *paracasei* CRL-431, previously known as *L. casei* CRL 431, is not included in the studies provided as reference material. No studies on identification/characterisation of the strain have been found in the literature. The Panel considers that *Lactobacillus paracasei* ssp. *paracasei* CRl-431, which is the subject of the health claims ID 921, 922, is not sufficiently characterised.

A culture collection number from the research institute in which the strain was isolated is given (CERELA, Argentina). A patent application for this strain indicates its deposit at the American Type Culture Collection (ATCC) as ATCC 55544 (Cravero, 1996).

***Lactobacillus acidophilus* LA-5 -** The identification/characterisation of the strain *Lactobacillus acidophilus* LA-5 is not included in the studies provided as reference material. No genotypic information regarding identification/characterisation of the strain was found in the literature; only limited information regarding phenotypic tests was found (Nighswonger et al., 1996). The Panel considers that *Lactobacillus acidophilus* LA-5, which is the subject of the health claims ID 921, 922, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was reported in the information provided or the literature.

The Panel considers that the combination of "*Lactobacillus paracasei* ssp. *paracasei* CRL-431, *Lactobacillus acidophilus* LA-5**"**, which is the subject of the health claims ID 921, 922, is not sufficiently characterised.

1.27. Characterisation of the combination of "*Lactobacillus casei* F19, *Bifidobacterium animalis ssp. lactis* Bb-12, *Lactobacillus acidophilus* LA-5" (ID 923, 1085, 1086)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus casei* F19, *Bifidobacterium animalis ssp. lactis* Bb-12, *Lactobacillus acidophilus* LA-5"

***Lactobacillus casei* F19 -** The identification/characterisation of the strain *Lactobacillus casei* F19 is not included in the studies provided as reference material; only reference to the identification by the

use of specific primers is done (Sullivan et al., 2001). Data regarding phenotypic and molecular characterisation of the strain were found in the databases (Charteris et al., 2001; Björneholm et al., 2002). The Panel considers that *Lactobacillus casei* F19, which is the subject of the health claims ID 923, 1085, 1086, is sufficiently characterised.

The deposit of the strain in the LMG culture collection under nº LMG P-17806 (Ljungh-Wadstrom et al., 2004) was reported in the literature. In the LMG, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can also be deposited in a restricted-access collection as Patent deposits.

***Bifidobacterium animalis* ssp. *lactis* Bb-12** (hereafter *B. animalis* ssp. *lactis* Bb-12) - The strain *B. animalis ssp. lactis* Bb-12, previously known as *B. lactis* Bb-12 is subjected to reclassification (Masco et al., 2004). The species identity as well as the strain identity and characteristics have been determined using different genotypic methods (Yimin et al., Unpublished; Garrigues et al., 2005; Mayer et al., 2007; Ventura et al. 2001a). It is important to point out that it may not be possible to differentiate commercially available *B. animalis* ssp. *lactis* strains from each other on the basis of traditional genetic methods (e.g. PFGE) (Engel et al., 2003; Gueimonde et al., 2004) and may be necessary to use multi-locus sequencing or genome-wide approaches. To this regard the genome of *B. animalis* ssp. *lactis* Bb-12 although sequenced (Yimin et al., unpublished) is not publicly available at the databases. The Panel considers that *B. animalis* ssp. *lactis* Bb-12, which is the subject of the health claims ID 923, 1085, 1086, is sufficiently characterised.

The deposit of the strain at the German culture collection DSMZ under number DSM 15954 was reported in the literature (Kajander et al., 2008). In addition several authors consider the strain Bb-12 to be also equal to the strain DSMZ 10140 (Ventura et al., 2001b). This is due to the fact that although the strain owner did not deposit the strain under Bb-12 name, strain DSMZ 10140 was isolated from a yoghurt containing Bb-12 and deposited by Meile et al. (1997).

***Lactobacillus acidophilus* LA-5** - The identification/characterisation of the strain *Lactobacillus acidophilus* LA-5 is not included in the studies provided as reference material. No genotypic information regarding identification/characterisation of the strain was found in the literature, only some limited information regarding phenotypic tests was found (Nighswonger et al., 1996). The Panel considers that the *Lactobacillus acidophilus* LA-5, which is the subject of the health claims ID 923, 1085, 1086, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was reported in the information provided or the literature.

The Panel considers that the combination of "*Lactobacillus casei* F19, *Bifidobacterium animalis ssp. lactis* Bb-12, *Lactobacillus acidophilus* LA-5", which is the subject of the health claims ID 923, 1085, 1086, is not sufficiently characterised.

1.28. Characterisation of a combination of *"Bifidobacterium bifidum* CNCM I-3426, *Lactobacillus casei* CNCM MA 64U, *Lactobacillus acidophilus* CNCM I-1722, *Lactococcus lactis* CNCM MA67/4J" (ID 925)

The food constituent that is the subject of the health claim is a combination of *"Bifidobacterium bifidum* CNCM I-3426, *Lactobacillus casei* CNCM MA 64U, *Lactobacillus acidophilus* CNCM I-1722, *Lactococcus lactis* CNCM MA67/4J"

***Bifidobacterium bifidum* CNCM I-3426** (hereafter *B. bifidum* CNCM I-3426) - The identification/characterisation of the strain *B. bifidum* CNCM I-3426 is not included in the studies provided as reference material and no information regarding strain *B. bifidum* CNCM I-3426 identification/characterisation was found in the literature. The Panel considers that *Bifidobacterium*

bifidum CNCM I-3426, which is the subject of the health claim ID 925, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) is provided. The CNCM is a restricted-access non-public collection which has the status of International Depositary Authority under the Budapest Treaty.

***Lactobacillus casei* CNCM MA 64U** (hereafter *L. casei* CNCM MA 64U) - The identification/characterisation of the strain *L. casei* CNCM MA 64U, also known as *L. casei* EQ 85 (Durand and Panes, 2001), is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *L. casei* CNCM MA 64U, which is the subject of the health claim ID 925, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) is given.

***Lactobacillus acidophilus* CNCM I-1722 -** The identification/characterisation of the strain *Lactobacillus acidophilus* CNCM I-1722 is not included in the studies provided as reference material. The strain is included in a patent on particles coated with microorganisms (Durand and Panes, 2001). However, no other information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus acidophilus* CNCM I-1722, which is the subject of the health claim ID 925, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) is provided.

***Lactococcus lactis* CNCM MA67/4J -** The identification/characterisation of the strain *Lactococcus lactis* CNCM MA67/4J is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactococcus lactis* CNCM MA67/4J, which is the subject of the health claim ID 925, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) is given.

The Panel considers that the combination of *"Bifidobacterium bifidum* CNCM I-3426, *Lactobacillus casei* CNCM MA 64U, *Lactobacillus acidophilus* CNCM I-1722, *Lactococcus lactis* CNCM MA67/4J", which is the subject of the health claim ID 925, is not sufficiently characterised.

1.29. Characterisation of a combination of "*Lactobacillus acidophilus* and *Lactobacillus rhamnosus*" (ID 926).

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus acidophilus* and *Lactobacillus rhamnosus*".

***Lactobacillus acidophilus* -** No strain identification or name is provided. The Panel considers that *Lactobacillus acidophilus*, which is the subject of the health claim ID 926, is not sufficiently characterised.

***Lactobacillus rhamnosus* -** No strain identification or name is provided. The Panel considers that *Lactobacillus rhamnosus*, which is the subject of the health claim ID 926, is not sufficiently characterised.

The Panel considers that the combination of "*Lactobacillus acidophilus* and *Lactobacillus rhamnosus*", which is the subject of the health claim ID 926, is not sufficiently characterised.

1.30. Characterisation of "*Saccharomyces boulardii*" (ID 927).

The food constituent that is the subject of the health claim is *Saccharomyces boulardii.* No strain identification or name is provided. The Panel considers that *Saccharomyces boulardii*, which is the subject of the health claim ID 927, is not sufficiently characterised.

1.31. Characterisation of a combination of "*Saccharomyces boulardii, Lactobacillus acidophilus* (CNCM I-1722)*, Lactobacillus rhamnosus* (CNCM I-1720)*, Bifidobacterium longum* (CNCM I-3470)" (ID 928).

The food constituent that is the subject of the health claim is a combination of "*Saccharomyces boulardii, Lactobacillus acidophilus* (CNCM I-1722), *Lactobacillus rhamnosus* (CNCM I-1720), *Bifidobacterium longum* (CNCM I-3470)".

Saccharomyces boulardii **-** No strain identification or name is provided. The Panel considers that *Saccharomyces boulardii,* which is the subject of the health claim ID 928, is not sufficiently characterised.

Lactobacillus acidophilus **CNCM I-1722 -** The identification/characterisation of the strain *Lactobacillus acidophilus* CNCM I-1722 is not included in the studies provided as reference material. The strain is included in a patent on particles coated with microorganisms (Durand and Panes, 2001). However, no other information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus acidophilus* CNCM I-1722, which is the subject of the health claim ID 928, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) is given.

Lactobacillus rhamnosus **CNCM I-1720 -** The identification/characterisation of the strain *Lactobacillus rhamnosus* CNCM I-1720, also known as *Lactobacillus rhamnosus* R0011 (Mesnage et al., 2007), is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus rhamnosus* CNCM I-1720, which is the subject of the health claim ID 928, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) is provided.

Bifidobacterium longum **CNCM I-3470 -** The identification/characterisation of the strain *Bifidobacterium longum* I-3470 is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Bifidobacterium longum* CNCM I-3470, which is the subject of the health claim ID 928, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) is provided.

The Panel considers that the combination of "*Saccharomyces boulardii, Lactobacillus acidophilus* (CNCM I-1722), *Lactobacillus rhamnosus* (CNCM I-1720), *Bifidobacterium longum* (CNCM I-3470)", which is the subject of the health claim ID 928, is not sufficiently characterised.

1.32. Characterisation of a combination of "*Bifidobacterium infantis* CNCM I-3424, *Bifidobacterium bifidum* CNCM I-3426, *Lactobacillus acidophilus* CNCM I-1722" (ID 929).

The food constituent that is the subject of the health claim is a combination of "*Bifidobacterium infantis* CNCM I-3424; *Bifidobacterium bifidum* CNCM I-3426; *Lactobacillus acidophilus* CNCM I-1722".

***Bifidobacterium infantis* CNCM I-3424 -** The identification/characterisation of the strain *Bifidobacterium infantis* CNCM I-3424 is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The species *Bifidobacterium infantis* has been reclassified as subspecies of *Bifidobacterium longum*, *B. longum* ssp. *Infantis* (Sakata et al., 2002). The Panel considers that *Bifidobacterium infantis* CNCM I-3424, which is the subject of the health claim ID 929, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) is provided.

***Bifidobacterium bifidum* CNCM I-3426 -** The identification/characterisation of the strain *Bifidobacterium bifidum* CNCM I-3426 is not included in the studies provided as reference material and no information regarding strain *B. bifidum* CNCM I-3426 identification/characterisation was found in the literature. The Panel considers that *Bifidobacterium bifidum* CNCM I-3426, which is the subject of the health claim ID 929, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) is provided.

***Lactobacillus acidophilus* CNCM I-1722 -** The identification/characterisation of the strain *Lactobacillus acidophilus* CNCM I-1722 is not included in the studies provided as reference material. The strain is included in a patent on particles coated with microorganisms (Durand and Panes, 2001). However, no other information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus acidophilus* CNCM I-1722, which is the subject of the health claim ID 929, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) is provided.

The Panel considers that the combination of "*Bifidobacterium infantis* CNCM I-3424, *Bifidobacterium bifidum* CNCM I-3426, *Lactobacillus acidophilus* CNCM I-1722", which is the subject of the health claim ID 929, is not sufficiently characterised.

1.33. Characterisation of a combination of "*Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* MF 20/5, *Bifidobacterium longum* SP 07/3" (ID 931, 933)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* MF 20/5, *Bifidobacterium longum* SP 07/3".

***Lactobacillus gasseri* PA 16/8 -** No reference to strain *Lactobacillus gasseri* PA 16/8 species identification/characterisation is indicated in the references provided and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus gasseri* PA 16/8, which is the subject of the health claims ID 931, 933, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was reported in the information provided or the literature.

***Bifidobacterium bifidum* MF 20/5 -** No reference to strain *Bifidobacterium bifidum* MF 20/5 species identification/characterisation is indicated in the references provided and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Bifidobacterium bifidum* MF 20/5, which is the subject of the health claims ID 931, 933, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was reported in the information provided or the literature.

***Bifidobacterium longum* SP 07/3 -** No reference to strain *Bifidobacterium longum* SP 07/3 species identification/characterisation is indicated in the references provided and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Bifidobacterium longum SP* 07/3, which is the subject of the health claims ID 931, 933, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was reported in the references provided or the literature.

The Panel considers that the combination of "*Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* MF 20/5, *Bifidobacterium longum* SP 07/3", which is the subject of the health claims ID 931, 933, is not sufficiently characterised.

1.34. Characterisation of a combination of "*Lactobacillus johnsonii* La-19/CLbA5 and *Bifidobacterium animalis ssp. lactis* Bf-6/Bif-6/CB111" (ID 932, 940)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus johnsonii* La-19/CLbA5 and *Bifidobacterium animalis ssp. lactis* Bf-6/Bif-6/CB111".

***Lactobacillus johnsonii* La-19/CLbA5 -** No reference to strain *Lactobacillus johnsonii* La-19 or CLbA5 species identification/characterisation is indicated in the references provided and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus johnsonii* La-19/CLbA5, which is the subject of the health claims ID 932, 940, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection is reported. However, the strain was found at the open catalogue of the LMG culture collection as *Lactobacillus johnsonii* LMG 24393 (available also in the Prosafe project collection; PRSF-L313).

***Bifidobacterium animalis* ssp. *lactis* Bf-6/Bif-6/CB111 -** No reference to strain *Bifidobacterium animalis* ssp. *lactis* Bf-6, Bif-6 or CB111 species identification/characterisation is indicated in the references provided. However, reference to *Bifidobacterium animalis* Bf-6 strain identification/characterisation by different genotypic methods was found in the literature (Mayer et al., 2007). It is important to point out that it may not be possible to differentiate commercially available *B. animalis* ssp. *lactis* strains from each other on the basis of traditional genetic methods (e.g. PFGE) (Mayer et al., 2007; Engel et al., 2003; Gueimonde et al., 2004) and may be necessary to use multi-locus sequencing or genome-wide approaches. To this regard the genome of *B. animalis* ssp. *lactis* Bf-6/Bif-6/CB111 is not available. The Panel considers that *Bifidobacterium animalis* ssp. *lactis* Bf-6/Bif-6/CB111, which is the subject of the health claims ID 932, 940, is sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection is given as reference material. However, according to Mayer et al. (2007) the strain is deposited at the open catalogue of the DSMZ culture collection as DSMZ 20105 (available also at the ATCC; ATCC 27536).

The Panel considers that the combination of "*Lactobacillus johnsonii* La-19/CLbA5 and *Bifidobacterium animalis ssp. lactis* Bf-6/Bif-6/CB111", which is the subject of the health claims ID 932, 940, is not sufficiently characterised. .

1.35. Characterisation of a combination of "Lactobacillus gasseri 57C, Lactobacillus fermentum 57A, Lactobacillus plantarum 57B" (ID 934)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus gasseri* 57C, *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B**"**.

***Lactobacillus gasseri* 57C** - The only reference to strain *Lactobacillus gasseri* 57C species identification/characterisation found in the studies provided refers to the use of phenotypic tests and species identification by 16S-23S rDNA sequence analysis (IBSS Biomed Report). No reference regarding the strain characterisation was found in the studies provided or in the literature. The Panel considers that *Lactobacillus gasseri* 57C, which is the subject of the health claim ID 934, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

***Lactobacillus fermentum* 57A** - The only reference to strain *Lactobacillus fermentum* 57A species identification/characterisation found in the studies provided refers to the use of phenotypic tests and species identification by 16S-23S rDNA sequence analysis (IBSS Biomed Report). No reference regarding the strain characterisation was found in the studies provided or in the literature. The Panel considers that *Lactobacillus fermentum* 57A, which is the subject of the health claim ID 934, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

***Lactobacillus plantarum* 57B** - The only reference to strain *Lactobacillus plantarum* 57B species identification/characterisation found in the studies provided refers to the use of phenotypic tests and species identification by 16S-23S rDNA sequence analysis (IBSS Biomed Report). No reference regarding the strain characterisation was found in the studies provided or in the literature. The Panel considers that *Lactobacillus plantarum* 57B, which is the subject of the health claim ID 934, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

The Panel considers that the combination of "*Lactobacillus gasseri* 57C, *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B", which is the subject of the health claim ID 934, is not sufficiently characterised.

1.36. Characterisation of a combination of "*Bifidobacterium animalis* ssp. *lactis* Bb-12 and *Lactobacillus paracasei* ssp. *paracasei* CRL-431" (ID 935)

The food constituent that is the subject of the health claim is a combination of "*Bifidobacterium animalis* ssp. *lactis* Bb-12 and *Lactobacillus paracasei* ssp. *paracasei* CRL-431".

***Bifidobacterium animalis* ssp. *lactis* Bb-12** (hereafter *B. animalis* ssp. *lactis* Bb-12) - The strain *B. animalis ssp. lactis* Bb-12 (previously known as *B. lactis* Bb-12 but subjected to reclassification (Masco et al., 2004)) species identity as well as the strain identity and characteristics have been determined using different genotypic methods (Yimin et al., Unpublished; Garrigues et al., 2005;

Mayer et al., 2007; Ventura et al., 2001a). It is important to point out that it may not be possible to differentiate commercially available *B. animalis* ssp. *lactis* strains from each other on the basis of traditional genetic methods (e.g. PFGE) (Engel et al., 2003; Gueimonde et al., 2004) and may be necessary to use multi-locus sequencing or genome-wide approaches. To this regard the genome of *B. animalis* ssp. *lactis* Bb-12 although sequenced (Yimin et al., unpublished) is not publicly available at the databases. The Panel considers that *B. animalis* ssp. *lactis* Bb-12, which is the subject of the health claim ID 935, is sufficiently characterised.

The references provided do not give a culture collection number for the strain, but reference to the deposit of the strain at the German culture collection DSMZ under number DSM 15954 was reported in the literature (Kajander et al., 2008). In addition several authors consider the strain Bb-12 to be also equal to the strain DSMZ 10140 (Ventura et al., 2001b). This is due to the fact that although the strain owner did not deposit the strain under Bb-12 name, strain DSMZ 10140 was isolated from a yoghurt containing Bb-12 and deposited by Meile et al. (1997).

***Lactobacillus paracasei* ssp. *paracasei* CRL-431 -** The identification/characterisation of the strain *Lactobacillus paracasei* ssp. paracasei CRL-431, previously known as *Lactobacillus casei* CRL 431, is not included in the studies provided as reference material. No studies on identification/characterisation have been found in the literature. The Panel considers that *Lactobacillus paracasei* ssp. *paracasei* CRl-431, which is the subject of the health claim ID 935, is not sufficiently characterised.

A culture collection number from the collection of the research institute in which the strain was isolated (CERELA, Argentina). A patent application for this strain indicates its deposit at the American Type Culture Collection (ATCC) as ATCC 55544 (Cravero, 1996).

The Panel considers that the combination of "*Bifidobacterium animalis* ssp. *lactis* Bb-12 and *Lactobacillus paracasei* ssp. *paracasei* CRL-431", which is the subject of the health claim ID 935, is not sufficiently characterised.

1.37. Characterisation of a combination of "*Lactobacillus gasseri* PA 16/8 and *Bifidobacterium bifidum* MF 20/5" (ID 936)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus gasseri* PA 16/8 and *Bifidobacterium bifidum* MF 20/5".

***Lactobacillus gasseri* PA 16/8 -** No reference to strain *Lactobacillus gasseri* PA 16/8 species identification/characterisation is indicated in the references provided and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus gasseri* PA 16/8, which is the subject of the health claim ID 936, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

***Bifidobacterium bifidum* MF 20/5 -** No reference to strain *Bifidobacterium bifidum* MF 20/5 species identification/characterisation is indicated in the references provided and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Bifidobacterium bifidum* MF 20/5, which is the subject of the health claim ID 936, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

The Panel considers that the combination of "*Lactobacillus gasseri* PA 16/8 and *Bifidobacterium bifidum* MF 20/5", which is the subject of the health claim ID 936, is not sufficiently characterised.

1.38. Characterisation of a combination of "*Lactobacillus helveticus* CNCM I-1722 and *Bifidobacterium longum* CNCM I-3470" (ID 938, 939)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus helveticus* CNCM I-1722 and *Bifidobacterium longum* CNCM I-3470".

***Lactobacillus helveticus* CNCM I-1722 -** The identification/characterisation of the strain *Lactobacillus helveticus* CNCM I-1722 is not included in the studies used as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus helveticus* CNCM I-1722, which is the subject of the health claims ID 938, 939, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) was provided, but instead referring to another strain, *Lactobacillus acidophilus*, under the same collection number (CNCM I-1722) which is included in a patent (Durand and Panes, 2001). This indicates problems or a mistake in identification of the strain.

***Bifidobacterium longum* CNCM I-3470 -** The identification/characterisation of the strain *Bifidobacterium longum* CNCM I-3470 is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Bifidobacterium longum* CNCM I-3470, which is the subject of the health claims ID 938, 939, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) was provided. The CNCM is a restricted-access non-public collection which has the status of International Depositary Authority under the Budapest Treaty.

The Panel considers that the combination of "*Lactobacillus helveticus* CNCM I-1722 and *Bifidobacterium longum* CNCM I-3470", which is the subject of the health claims ID 938, 939, is not sufficiently characterised.

1.39. Characterisation of a combination of "*Propionibacterium freudenreichii* SI 41 and *Propionibacterium freudenreichii* SI 26" (ID 941)

The food constituent that is the subject of the health claim is a combination of "*Propionibacterium freudenreichii* SI 41 and *Propionibacterium freudenreichii* SI 26".

***Propionibacterium freudenreichii* SI 41 -** The strain *Propionibacterium freudenreichii* SI 41 species identification/characterisation is indicated in the references provided (Jan et. al., 2002; Jan et al., 2000). In addition the strain has been further characterised in different published reports on stress response or transcarboxylase gen characterisation (Jan et al., 2000; Herve et al., 2007). The Panel considers that *Propionibacterium freudenreichii* SI 41, which is the subject of the health claim ID 941, is sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the references provided or the literature.

***Propionibacterium freudenreichii* SI 26 -** The strain *Propionibacterium freudenreichii* SI 26 species identification/characterisation is not indicated in the references provided and no information was found in the literature. The Panel considers that *Propionibacterium freudenreichii* SI 26, which is the subject of the health claim ID 941, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

The Panel considers that the combination of "*Propionibacterium freudenreichii* SI 41 and *Propionibacterium freudenreichii* SI 26", which is the subject of the health claim ID 941, is not sufficiently characterised.

1.40. Characterisation of a combination of "*Bifidobacterium animalis ssp. lactis* Bb-12 and *Lactobacillus acidophilus* LA-5" (ID 942)

The food constituent that is the subject of the health claim is of a combination of "*Bifidobacterium animalis ssp. lactis* Bb-12 and *Lactobacillus acidophilus* LA-5".

***Bifidobacterium animalis* ssp. *lactis* Bb-12** (hereafter *B. animalis* ssp. *lactis* Bb-12) - The strain *B. animalis ssp. lactis* Bb-12, previously known as *B. lactis* Bb-12 is subjected to reclassification (Masco et al., 2004). The species identity as well as the strain identity and characteristics have been determined using different genotypic methods (Yimin et al., Unpublished; Garrigues et al., 2005; Mayer et al., 2007; Ventura et al., 2001a). It is important to point out that it may not be possible to differentiate commercially available *B. animalis* ssp. *lactis* strains from each other on the basis of traditional genetic methods (e.g. PFGE) (Engel et al., 2003; Gueimonde et al., 2004) and may be necessary to use multi-locus sequencing or genome-wide approaches. To this regard the genome of *B. animalis* ssp. *lactis* Bb-12 although sequenced (Yimin et al., unpublished) is not publicly available at the databases. The Panel considers that *B. animalis* ssp. *lactis* Bb-12, which is the subject of the health claim ID 942, is sufficiently characterised.

A culture collection number for the strain referencing to the deposit of the strain at the German culture collection DSMZ under number DSM 15954 was found in the literature (Kajander et al., 2008). In addition several authors consider the strain Bb-12 to be also equal to the strain DSMZ 10140 (Ventura et al., 2001b). This is due to the fact that although the strain owner did not deposit the strain under Bb-12 name, strain DSMZ 10140 was isolated from a yoghurt containing Bb-12 and deposited by Meile et al. (1997).

***Lactobacillus acidophilus* LA-5** - The identification/characterisation of the strain *Lactobacillus acidophilus* LA-5 is not included in the studies used as reference material. No genotypic information regarding identification/characterisation of the strain was found in the literature, only some limited information regarding phenotypic tests was found (Nighswonger et al., 1996). The Panel considers that *Lactobacillus acidophilus* LA-5, which is the subject of the health claim ID 942, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

The Panel considers that the combination of "*Bifidobacterium animalis ssp. lactis* Bb-12 and *Lactobacillus acidophilus* LA-5", which is the subject of the health claim ID 942, is not sufficiently characterised.

1.41. Characterisation of a combination of "*Bacillus mesentericus* TO-A, *Clostridium butyricum* TO-A and *Streptococcus faecalis* T-110" (ID 943)

The food constituent that is the subject of the health claim is a combination of "*Bacillus mesentericus* TO-A, *Clostridium butyricum* TO-A and *Streptococcus faecalis* T-110".

***Bacillus mesentericus* TO-A** - The strain *Bacillus mesentericus* TO-A species identification/characterisation is not indicated in the references provided and no information was

found in the literature. The Panel considers that *Bacillus mesentericus* TO-A, which is the subject of the health claim ID 943, is not sufficiently characterised.

No indication of the deposit of the strain in a culture collection was found in the information provided or the literature.

***Clostridium butyricum* TO-A** - The strain *Clostridium butyricum* TO-A species identification/characterisation is not indicated in the references provided and no information was found in the literature. The Panel considers that *Clostridium butyricum* TO-A, which is the subject of the health claim ID 943, is not sufficiently characterised.

No indication of the deposit of the strain in a culture collection was found in the information provided or the literature.

***Streptococcus faecalis* T-110** - The strain *Streptococcus faecalis* T-110 species identification/characterisation is not indicated in the references provided and no information was found in the literature. To this regard this species was reclassified as member of the genus *Enterococcus* (*Enterococcus faecalis* would be the correct name). The Panel considers that *Streptococcus faecalis* T-110, which is the subject of the health claim ID 943, is not sufficiently characterised.

No indication of the deposit of the strain in a culture collection was found in the information provided or the literature.

The Panel considers that the combination of "*Bacillus mesentericus* TO-A, *Clostridium butyricum* TO-A and *Streptococcus faecalis* T-110", which is the subject of the health claims ID 943, is not sufficiently characterised.

1.42. Characterisation of "*Lactobacillus rhamnosus* LR(3)" (ID 947)

The food constituent that is the subject of the health claim is *Lactobacillus rhamnosus* LR(3)**.** The identification/characterisation of the strain *Lactobacillus rhamnosus* LR(3) is not included in the studies used as reference material and no information regarding strain *L. rhamnosus* LR(3) identification/characterisation was found in the literature. The Panel considers that *Lactobacillus rhamnosus* LR(3), which is the subject of the health claim ID 947, is not sufficiently characterised.

No indication of the deposit of the strain in a culture collection was found in the information provided or the literature.

1.43. Characterisation of "*Bifidobacterium animalis spp. animalis* THT 010401" (ID 958, 959)

The food constituent that is the subject of the health claim is *Bifidobacterium animalis* spp. *animalis* THT 010401**.** No information regarding the identification/characterisation of the strain *Bifidobacterium animalis* ssp. *animalis* THT 010401 was found in the reference material provided or the literature. The Panel considers that *Bifidobacterium animalis* ssp. *animalis* THT 010401, which is the subject of the health claims ID 958, 959, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.44. Characterisation of "*Bifidobacterium animalis spp. lactis* THT 010801" (ID 960, 961, 962)

The food constituent that is the subject of the health claim is *Bifidobacterium animalis* spp. *lactis* THT 010801. No information regarding the identification/characterisation of the strain *Bifidobacterium animalis* ssp. *lactis* THT 010801 was found in the reference material provided or in the literature. It is important to point out that it may not be possible to differentiate the commercially available *B. animalis* ssp. *lactis* strains from each other on the basis of traditional genetic methods (e.g. PFGE) (Engel et al., 2003; Gueimonde et al., 2004) and may be necessary to use multi-locus sequencing or genome-wide approaches. The Panel considers that *Bifidobacterium animalis* ssp. *lactis* THT 010801, which is the subject of the health claims ID 960, 961, 962, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.45. Characterisation of "*Bifidobacterium bifidum* THT 010101" (ID 963, 964)

The food constituent that is the subject of the health claim is *Bifidobacterium bifidum* THT 010101. Although the sequences of the 16S rRNA and the 16S-23S regions of this strain were found to be available at Genbank (Accession nº EF370998 and EF370995) no other information regarding the identification/characterisation of the strain *Bifidobacterium bifidum* THT 010101 was found in the references provided or the literature. The Panel considers that *Bifidobacterium bifidum* THT 010101, which is the subject of the health claims ID 963, 964, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.46. Characterisation of "*Bifidobacterium breve* THT 010601" (ID 965, 966)

The food constituent that is the subject of the health claim is *Bifidobacterium breve* THT 010601. No information regarding the identification/characterisation of the strain *Bifidobacterium breve* THT 010601 was found in the references provided or in the literature. The Panel considers that *Bifidobacterium breve* THT 010601, which is the subject of the health claims ID 965, 966, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.47. Characterisation of "*Bifidobacterium longum bv infantis* THT 010201" (ID 967, 968)

The food constituent that is the subject of the health claim is *Bifidobacterium longum* bv *infantis* THT 010201. Although the sequences of the 16S rRNA and the 16S-23S regions of this strain were found to be available at Genbank (Accession nº EF370999 and EF370996) no other information regarding the identification/characterisation of the strain *Bifidobacterium longum* bv *infantis* THT 010201 was found in the literature. The Panel considers that *Bifidobacterium longum* bv *infantis* THT 010201, which is the subject of the health claims ID 967, 968, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.48. Characterisation of "*Bifidobacterium longum* THT 010301" (ID 969, 970)

The food constituent that is the subject of the health claim is *Bifidobacterium longum* THT 010301. Although the sequences of the 16S rRNA and the 16S-23S regions of this strain were found to be available at Genbank (Accession nº EF370991 and EF370997) no other information regarding the identification/characterisation of the strain *Bifidobacterium longum* THT 010301 was found in the literature. The Panel considers that *Bifidobacterium longum* THT 010301, which is the subject of the health claims ID 969, 970, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.49. Characterisation of "*Bifidobacterium pseudolongum ssp pseudolongum* THT 010501" (ID 971, 972)

The food constituent that is the subject of the health claim is *Bifidobacterium pseudolongum* ssp *pseudolongum* THT 010501. No information regarding the identification/characterisation of the strain *Bifidobacterium pseudolongum* ssp. *pseudolongum* THT 010501 was found in the literature. The Panel considers that *Bifidobacterium pseudolongum* ssp. *pseudolongum* THT 010501, which is the subject of the health claims ID 971, 972, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.50. Characterisation of "*Lactobacillus acidophilus* THT 030102" (ID 973, 974)

The food constituent that is the subject of the health claim is *Lactobacillus acidophilus* THT 030102. No information regarding the identification/characterisation of the strain *Lactobacillus acidophilus* THT 030102 was found in the literature. The Panel considers that *Lactobacillus acidophilus* THT 030102, which is the subject of the health claims ID 973, 974, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.51. Characterisation of "*Lactobacillus casei* THT 030401"(ID 975, 976)

The food constituent that is the subject of the health claim is *Lactobacillus casei* THT 030401**.** No information regarding the identification/characterisation of the strain *Lactobacillus casei* THT 030401 was found in the literature. The Panel considers that *Lactobacillus casei* THT 030401, which is the subject of the health claims ID 975, 976, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.52. Characterisation of "*Lactobacillus delbrueckii bulgaricus* THT 030301" (ID 977, 978)

The food constituent that is the subject of the health claim is *Lactobacillus delbruckii bulgaricus* THT 030301. The Panel notes that the species name provided is incorrect; the right scientific name is *Lactobacillus delbrueckii* ssp. *bulgaricus.* No information regarding the identification/characterisation of the strain *Lactobacillus delbrueckii* ssp. *bulgaricus* THT 030301 was found in the literature. The Panel considers that *Lactobacillus delbrueckii* ssp. *bulgaricus* THT 030301, which is the subject of the health claims ID 977, 978, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.53. Characterisation of "*Lactobacillus delbrueckii bulgaricus* THT 030302" (ID 979, 980)

The food constituent that is the subject of the health claim is *Lactobacillus delbrueckii bulgaricus* THT 030302. The Panel notes that the species name provided is incorrect; the right scientific name is *Lactobacillus delbrueckii* ssp. *bulgaricus.* No information regarding the identification/characterisation of the strain *Lactobacillus delbrueckii* ssp. *bulgaricus* THT 030302 was found in the literature. The Panel considers that *Lactobacillus delbrueckii* ssp. *bulgaricus* THT 030302, which is the subject of the health claims ID 979, 980, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.54. Characterisation of "*Lactobacillus delbrueckii bulgaricus* THT 030303" (ID 981, 982)

The food constituent that is the subject of the health claim is *Lactobacillus delbrueckii bulgaricus* THT 030303. The Panel notes that the species name provided is incorrect; the right scientific name is *Lactobacillus delbrueckii* ssp. *bulgaricus.* No information regarding the identification/characterisation of the strain *Lactobacillus delbrueckii* ssp. *bulgaricus* THT 030303 was found in the literature. The Panel considers that *Lactobacillus delbrueckii* ssp. *bulgaricus* THT 030303, which is the subject of the health claims ID 981, 982, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.55. Characterisation of "*Lactobacillus gasseri* THT 031301" (ID 983, 984)

The food constituent that is the subject of the health claim is *Lactobacillus gasseri* THT 031301. No information regarding the identification/characterisation of the strain *Lactobacillus gasseri* THT 031301 was found in the literature. The Panel considers that *Lactobacillus gasseri* THT 031301, which is the subject of the health claims ID 983, 984, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.56. Characterisation of "*Lactobacillus helveticus* THT 031102" (ID 985, 986)

The food constituent that is the subject of the health claim is *Lactobacillus helveticus* THT 031102. No information regarding the identification/characterisation of the strain *Lactobacillus helveticus* THT 031102 was found in the literature. The Panel considers that *Lactobacillus helveticus* THT 031102, which is the subject of the health claims ID 985, 986, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.57. Characterisation of "*Lactobacillus helveticus* THT 031101" (ID 987, 988)

The food constituent that is the subject of the health claim is *Lactobacillus helveticus* THT 031101. No information regarding the identification/characterisation of the strain *Lactobacillus helveticus* THT 031101 was found in the literature. The Panel considers that *Lactobacillus helveticus* THT 031101, which is the subject of the health claims ID 987, 988, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.58. Characterisation of "*Lactobacillus plantarum* THT 030701" (ID 994, 995)

The food constituent that is the subject of the health claim is *Lactobacillus plantarum* THT 030701. No information regarding the identification/characterisation of the strain *Lactobacillus plantarum* THT 030701 was found in the literature. The Panel considers that *Lactobacillus plantarum* THT 030701, which is the subject of the health claims ID 994, 995, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.59. Characterisation of "*Lactobacillus plantarum* THT 030707" (ID 996, 997)

The food constituent that is the subject of the health claim is *Lactobacillus plantarum* THT 030707. No information regarding the identification/characterisation of the strain *Lactobacillus plantarum* THT 030707 was found in the literature. The Panel considers that *Lactobacillus plantarum* THT 030707, which is the subject of the health claims ID 996, 997, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.60. Characterisation of "*Lactobacillus reuteri* THT 030802" (ID 998, 999)

The food constituent that is the subject of the health claim is *Lactobacillus reuteri* THT 030802. No information regarding the identification/characterisation of the strain *Lactobacillus reuteri* THT 030802 was found in the literature. The Panel considers that *Lactobacillus reuteri* THT 030802, which is the subject of the health claims ID 998, 999, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.61. Characterisation of " *Lactobacillus reuteri* THT 030803" (ID 1000, 1001)

The food constituent that is the subject of the health claim is *Lactobacillus reuteri* THT 030803. No information regarding the identification/characterisation of the strain *Lactobacillus reuteri* THT 030803 was found in the literature. The Panel considers that *Lactobacillus reuteri* THT 030803, which is the subject of the health claims ID 1000, 1001, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.62. Characterisation of "*Lactobacillus rhamnosus* THT 030901" (ID 1002, 1003)

The food constituent that is the subject of the health claim is *Lactobacillus rhamnosus* THT 030901. No information regarding the identification/characterisation of the strain *Lactobacillus rhamnosus* THT 030901 was found in the literature. The Panel considers that *Lactobacillus rhamnosus* THT 030901, which is the subject of the health claims ID 1002, 1003, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.63. Characterisation of "*Lactobacillus rhamnosus* THT" (ID 1004, 1005)

The food constituent that is the subject of the health claim is *Lactobacillus rhamnosus* THT 030902. No information regarding the identification/characterisation of the strain *Lactobacillus rhamnosus* THT 030902 was found in the literature. The Panel considers that *Lactobacillus rhamnosus* THT 030902, which is the subject of the health claims ID 1004, 1005, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.64. Characterisation of "*Lactobacillus salivarius* THT 031001" (ID 1006, 1007)

The food constituent that is the subject of the health claim is *Lactobacillus salivarius* THT 031001. No information regarding the identification/characterisation of the strain *Lactobacillus salivarius* THT 031001 was found in the literature. The Panel considers that *Lactobacillus salivarius* THT 031001, which is the subject of the health claims ID 1006, 1007, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.65. Characterisation of "*Lactococcus lactis* THT 090101" (ID 1008, 1009)

The food constituent that is the subject of the health claim is *Lactococcus lactis* THT 090101. No information regarding the identification/characterisation of the strain *Lactococcus lactis* THT 090101 was found in the literature. The Panel considers that *Lactococcus lactis* THT 090101, which is the subject of the health claims ID 1008, 1009, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.66. Characterisation of "*Saccharomyces boulardii* ATY-SB-101" (ID 1010, 1011)

The food constituent that is the subject of the health claim is *Saccharomyces boulardii* ATY-SB-101. No information regarding the species identification or characterisation of the strain *Saccharomyces boulardii* ATY-SB-101 was found in the studies provided as reference material or in the literature. The Panel considers that *Saccharomyces boulardii* ATY-SB-101, which is the subject of the health claims ID 1010, 1011, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.67. Characterisation of "*Streptococcus thermophilus* THT 070101" (ID 1012, 1013)

The food constituent that is the subject of the health claim is *Streptococcus thermophilus* THT 070101. No information regarding the identification/characterisation of the strain *Streptococcus thermophilus* THT 070101 was found in the literature. The Panel considers that *Streptococcus thermophilus* THT 070101, which is the subject of the health claims ID 1012, 1013, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.68. Characterisation of "*Streptococcus thermophilus* THT 070102" (ID 1014, 1015)

The food constituent that is the subject of the health claim is *Streptococcus thermophilus* THT 070102. No information regarding the identification/characterisation of the strain *Streptococcus thermophilus* THT 070102 was found in the literature. The Panel considers that *Streptococcus thermophilus* THT 070102, which is the subject of the health claims ID 1014, 1015, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

1.69. Characterisation of "*Lactobacillus crispatus* P 17631" (ID 1030, 2950)

The food constituent that is the subject of the health claim is *Lactobacillus crispatus* P 17631. Reference to phenotypic (API 50Ch and SDS-PAGE) identification of the strain (BCCM/LMG Report 29/01/97) and plasmidic profiles (Dondi and Morelli, 1999; Morelli, 1997) was found in the studies provided as reference material. However no other information regarding the strain identification/characterisation was found. The Panel considers that *Lactobacillus crispatus* P 17631, which is the subject of the health claim ID 1030, 2950, is not sufficiently characterised.

According to the patent application by Dondi and Morelli (1999), the strain is deposited in the LMG under nº LMG P-17631. In the LMG, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

1.70. Characterisation of a combination of "*Lactobacillus acidophilus* R0052 (I-1722), *Lactobacillus paracasei* 8.16b, *Lactobacillus rhamnosus* I-1720, *Bifidobacterium animalis* ssp. *lactis* Bb-12" (ID 1055, 1056)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus acidophilus* R0052 (I-1722), *Lactobacillus paracasei* 8.16b, *Lactobacillus rhamnosus* I-1720, *Bifidobacterium animalis* ssp. *lactis* Bb-12".

***Lactobacillus acidophilus* R0052 (I-1722) -** The identification/characterisation of the strain *Lactobacillus acidophilus* R0052 (I-1722) is not included in the studies provided as reference material. The strain is included in a patent on particles coated with microorganisms (Durand and Panes, 2001). However, no other information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus acidophilus* R0052 (I-1722), which is the subject of the health claims ID 1055, 1056, is not sufficiently characterised.

A culture collection number from an internationally recognised culture collection is not provided. *Lactobacillus acidophilus* strain is deposited at the Collection Nationale de Cultures de Microorganismes under restricted access as CNCM I-1722.

***Lactobacillus paracasei* 8.16b -** The identification/characterisation of the strain *Lactobacillus Paracasei* 8.16b is not included in the studies provided as reference material. No other information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus paracasei* 8.16b, which is the subject of the health claims ID 1055, 1056, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

***Lactobacillus rhamnosus* I-1720 -** The identification/characterisation of the strain *Lactobacillus rhamnosus* I-1720 is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers

that *Lactobacillus rhamnosus* I-1720, which is the subject of the health claims ID 1055, 1056, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature. There is a strain deposited as *Lactobacillus rhamnosus* CNCM I-1720 at Collection Nationale de Cultures de Microorganismes (the CNCM is a restricted-access non-public collection which has the status of International Depositary Authority under the Budapest Treaty).

***Bifidobacterium animalis* ssp. *lactis* Bb-12** (hereafter *B. animalis* ssp. *lactis* Bb-12) - The strain *B. animalis ssp. lactis* Bb-12, previously known as *B. lactis* Bb-12 is subjected to reclassification (Masco et al., 2004). The species identity as well as the strain identity and characteristics have been determined using different genotypic methods (Yimin et al., unpublished; Garrigues et al., 2005; Mayer et al., 2007; Ventura et al., 2001a). It is important to point out that it may not be possible to differentiate commercially available *B. animalis* ssp. *lactis* strains from each other on the basis of traditional genetic methods (e.g. PFGE) (Engel et al., 2003; Gueimonde et al., 2004.) and may be necessary to use multi-locus sequencing or genome-wide approaches. To this regard the genome of *B. animalis* ssp. *lactis* Bb-12 although sequenced (Yimin et al., unpublished) is not publicly available at the databases. The Panel considers that *B. animalis* ssp. *lactis* Bb-12, which is the subject of the health claims ID 1055, 1056, is sufficiently characterised.

A culture collection number for this strain is not provided but reference to the deposit of the strain at the German culture collection DSMZ under number DSM 15954 was found in the literature (Kajander et al., 2008). In addition several authors consider the strain Bb-12 to be also equal to the strain DSMZ 10140 (Ventura et al., 2001b). This is due to the fact that although the strain owner did not deposit the strain under Bb-12 name, strain DSMZ 10140 was isolated from a yoghurt containing Bb-12 and deposited by Meile et al. (1997).

The Panel considers that the combination of "*Lactobacillus acidophilus* R0052 (I-1722), *Lactobacillus paracasei* 8.16b, *Lactobacillus rhamnosus* I-1720, *Bifidobacterium animalis* ssp. *lactis* Bb-12", which is the subject of the health claims ID 1055, 1056, is not sufficiently characterised.

1.71. Characterisation of "*Lactobacillus reuteri* lactic acid bacteria" (ID 1057)

The food constituent that is the subject of the health claim is "*Lactobacillus reuteri* lactic acid bacteria". No strain identification or name is provided. The Panel considers that "*Lactobacillus reuteri* lactic acid bacteria", which is the subject of the health claim ID 1057, is not sufficiently characterised.

1.72. Characterisation of "Lactococcus *lactis* L1A NCIMB 40157" (ID 1060, 1062)

The food constituent that is the subject of the health claim is *Lactococcus lactis* L1A NCIMB 40157. The identification/characterisation of the strain *Lactococcus lactis* L1A is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactococcus lactis* L1A (NCIMB 40157), which is the subject of the health claims ID 1060, 1062, is not sufficiently characterised.

A culture collection number from the National Collection of Industrial and Marine Bacteria (UK), NCIMB 40157, is reported in the references provided.

1.73. Characterisation of "*Lactobacillus plantarum* LB931 DSM 11918" (ID 1063)

The food constituent that is the subject of the health claim is *Lactobacillus plantarum* LB931 DSM 11918. The identification of *Lactobacillus plantarum* LB931 (DSM 11918) by phenotypic methods, sugars fermentation profiles (API 50CH) and SDS-page (identified not un-ambiguously as *Lactobacillus plantarum-pentosus-paraplantarum* by this method) was reported in a patent application and the literature provided (Hakansson et al., 2004; Rönnqvist et al., 2005; Rönnqvist et al., 2006). Reference to strain genetic characterisation by PFGE was also found (Rönnqvist et al., 2006). Although the strain is characterised at strain level (PFGE), the identification data are not un-ambiguous. No other references about the strain identification/characterisation were found in the literature. The Panel considers that *Lactobacillus plantarum* LB931 (DSM 11918), which is the subject of the health claim ID 1063, is not sufficiently characterised.

A culture collection number from the DSMZ (DSM 11918) is provided. In the DSMZ, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

1.74. Characterisation of "*Lactobacillus plantarum* LB7c DSM 17853" (ID 1065)

The food constituent that is the subject of the health claim is *Lactobacillus plantarum* LB7c DSM 17853. The identification/characterisation of the strain *Lactobacillus plantarum* LB7c is not included in the studies provided as reference material. The phenotypic and genotypic identification of the strain *Lactobacillus plantarum* LB7c (DSM 17853) was reported (Grahn Hakansson and Ekbeck, 2007). However, no reference about the characterisation at strain level was found in the literature. The Panel considers that *Lactobacillus plantarum* LB7c (DSM 17853), which is the subject of the health claim ID 1065, is not sufficiently characterised.

A culture collection number from the DSMZ (DSM17853) is provided. In the DSMZ, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

1.75. Characterisation of "*Lactobacillus plantarum* LB3e DSM 17852" (ID 1066)

The food constituent that is the subject of the health claim is *Lactobacillus plantarum* LB3e DSM 17852. The identification/characterisation of the strain *Lactobacillus plantarum* LB3e is not included in the studies provided as reference material. The identification of the strain *L. plantarum* LB3e (DSM 17853) was reported (Grahn Hakansson and Ekbeck, 2007). However, no references about the characterisation at strain level were found in the literature. The Panel considers that *Lactobacillus plantarum* LB3e (DSM 17852), which is the subject of the health claim ID 1066, is not sufficiently characterised.

A culture collection number from the DSMZ (DSM 17852) is provided. In the DSMZ, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

1.76. Characterisation of "*Streptococcus sanguis* NCIMB 40104" (ID 1067)

The food constituent that is the subject of the health claim is *Streptococcus sanguis* NCIMB 40104. The phenotypic identification of the strain *Streptococcus sanguis* NCIMB 40104 by sugars fermentation profiles (API 20 Strep) was reported in the literature (Grahn Hakansson et al., 1999; Grahn and Holm, 1990). No other references to the species identification were found. With regard to characterisation of the specific strain among the references provided there is one containing genotypic characterisation by PFGE, but no reference to the specific strain NCIMB40104 is done in the study

(Tano et al., 1999). The Panel considers that *Streptococcus sanguis* NCIMB 40104, which is the subject of the health claim ID 1067, is not sufficiently characterised.

A culture collection number from the National Collection of Industrial and Marine Bacteria (UK), NCIMB 40104, is provided.

1.77. Characterisation of "*Streptococcus sanguis* NCIMB 40873" (ID 1068)

The food constituent that is the subject of the health claim is *Streptococcus sanguis* NCIMB 40873. The phenotypic identification of the strain *Streptococcus sanguis* NCIMB 40873 by sugars fermentation profiles (API 20 Strep) was found in the literature (Grahn Hakansson et al., 1999; Grahn and Holm., 1990). No other reference to the species identification was found in the literature. With regard to characterisation of the specific strain among the references provided there is one regarding genotypic characterisation by PFGE, but no reference to the specific strain NCIMB40873 is done in the study (Tano et al., 1999). The Panel considers that *Streptococcus sanguis* NCIMB 40873, which is the subject of the health claim ID 1068, is not sufficiently characterised.

A culture collection number from the National Collection of Industrial and Marine Bacteria (UK), NCIMB 40873, is provided.

1.78. Characterisation of "*Streptococcus oralis* NCIMB 40875" (ID 1069)

The food constituent that is the subject of the health claim is *Streptococcus oralis* NCIMB 40875. The phenotypic identification of the strain *Streptococcus oralis* NCIMB 40875 by sugars fermentation profiles (API 20 Strep) was reported in the literature (Grahn Hakansson et al., 1999; Grahn and Holm., 1990). Among the reference provided there is a reference regarding genotypic characterisation of *Streptococcus* strains by PFGE, but no reference to the specific strain NCIMB40875 is done in the study (Tano et al., 1999). No other references to the species identification and strain characterisation were found in the literature. The Panel considers that *Streptococcus sanguis* NCIMB 40875, which is the subject of the health claim ID 1069, is not sufficiently characterised.

A culture collection number from the National Collection of Industrial and Marine Bacteria (UK), NCIMB 40875, is provided.

1.79. Characterisation of "*Streptococcus oralis* NCIMB 40876" (ID 1070)

The food constituent that is the subject of the health claim is *Streptococcus oralis* NCIMB 40876. The phenotypic identification of the strain *Streptococcus oralis* NCIMB 40876 by sugars fermentation profiles (API 20 Strep) was reported in the literature (Grahn Hakansson et al., 1999; Grahn and Holm., 1990). Among the reference provided there is a reference regarding genotypic characterisation of *Streptococcus* strains by PFGE, but no reference to the specific strain NCIMB40876 is done in the study (Tano et al., 1999). No other reference to the species identification and strain characterisation was found in the literature. The Panel considers that *Streptococcus sanguis* NCIMB 40876, which is the subject of the health claim ID 1070, is not sufficiently characterised.

A culture collection number from the National Collection of Industrial and Marine Bacteria (UK), NCIMB 40876, is provided.

1.80. Characterisation of "*Lactobacillus plantarum* HEAL 9 (DSM 15312=39D)" (ID 1071)

The food constituent that is the subject of the health claim is *Lactobacillus plantarum* HEAL 9 (DSM 15312=39D). The only information found in the literature about the identification/characterisation of the strain *Lactobacillus plantarum* HEAL 9 (DSM 15312) regards to the use of chromosomic DNA

restriction analysis (REA) (Molin et al., 2004; Vasquez et al., 2005a). REA is not considered a stand-alone method; for reliable species identification this technique (REA) requires phylogenetic analysis with an appropriate number of strains from different species and controls. However, this data were not shown. No other information regarding strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus plantarum* HEAL 9 (DSM 15312=39D), which is the subject of the health claim ID 1071, is not sufficiently characterised.

A culture collection number from the DSMZ, DSM 15312, is provided. In the DSMZ, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

1.81. Characterisation of "*Lactobacillus plantarum* HEAL 19 (DSM 15313=52A)" (ID 1072)

The food constituent that is the subject of the health claim is *Lactobacillus plantarum* HEAL 19 (DSM 15313=52A). The only information found in the literature about the identification/characterisation of the strain *Lactobacillus plantarum* HEAL 19 (DSM 15313) regards the use of chromosomic DNA restriction analysis (REA) (Molin et al., 2004; Vasquez et al., 2005a). REA is not considered a stand-alone method; for reliable species identification this technique (REA) requires phylogenetic analysis with an appropriate number of strains from different species and controls. However, this data were not found. No other information regarding strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus plantarum* HEAL 19 (DSM 15313=52A), which is the subject of the health claim ID 1072, is not sufficiently characterised.

A culture collection number from the DSMZ, DSM 15313, is provided. In the DSMZ, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

1.82. Characterisation of "*Lactobacillus plantarum* HEAL 99 (DSM 15316=61A)" (ID 1073)

The food constituent that is the subject of the health claim is *Lactobacillus plantarum* HEAL 99 (DSM 15316=61A). The identification/characterisation of the strain *Lactobacillus plantarum* HEAL 99 (DSM 15316) by chromosomic DNA restriction analysis (REA) was reported in the literature (Molin et al., 2004; Vasquez et al., 2005a). REA is not considered a stand-alone method; for reliable species identification this technique (REA) requires phylogenetic analysis with an appropriate number of strains from different species and controls. However, this data were not found. No other information regarding strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus plantarum* HEAL 99 (DSM 15316=61A), which is the subject of the health claim ID 1073, is not sufficiently characterised.

A culture collection number from the DSMZ, DSM 15316, is provided. In the DSMZ, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

1.83. Characterisation of "*Lactobacillus paracasei* 02A (DSM 13432)" (ID 1075)

The food constituent that is the subject of the health claim is *Lactobacillus paracasei* 02A (DSM 13432). The genotypic identification and characterisation of the strain *Lactobacillus paracasei* 02A (DSM 13432) by chromosomic DNA restriction analysis (REA) and RAPD was reported in the literature (Antonsson and Molin, 2002; Vasquez et al., 2005b). REA is not considered a stand-alone method; for reliable species identification this technique (REA) requires phylogenetic analysis with an appropriate number of strains from different species and controls. However, this data were not

found. The Panel considers that *Lactobacillus paracasei* 02A (DSM 13432), which is the subject of the health claim ID 1075, is not sufficiently characterised.

A culture collection number from the DSMZ, DSM 13432, is provided. In the DSMZ, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

1.84. Characterisation of "*Lactobacillus rhamnosus* 271 (DSM 6594)" (ID 1076)

The food constituent that is the subject of the health claim is *Lactobacillus rhamnosus* 271 (DSM 6594). The phenotypic (API 20 Strep) and genotypic identification and characterisation of the strain *Lactobacillus rhamnosus* 271 (DSM 6594) by chromosomic DNA restriction analysis (REA) and RAPD was reported in the references provided and in the literature (Molin et al., 2006; Vasquez et al. 2005b; Adawi et al. 1997; Molin et al., 1993). REA is not considered a stand-alone method; for reliable species identification this technique (REA) requires phylogenetic analysis with an appropriate number of strains from different species and controls. However, this data were not found. The Panel considers that *Lactobacillus rhamnosus* 271 (DSM 6594), which is the subject of the health claim ID 1076, is not sufficiently characterised.

A culture collection number from the DSMZ, DSM 6594, is provided. In the DSMZ, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

1.85. Characterisation of "*Lactobacillus crispatus* VPC111 (DSM 16741)" (ID 1079)

The food constituent that is the subject of the health claim is *Lactobacillus crispatus* VPC111 (DSM 16741). The genotypic identification and characterisation of the strain *Lactobacillus crispatus* VPC111 (DSM 16741) by chromosomic DNA restriction analysis (REA) and RAPD was reported in the literature (Molin et al., 2006). REA is not considered a stand-alone method; for reliable species identification this technique (REA) requires phylogenetic analysis with an appropriate number of strains from different species and controls. However, this data were not found. The Panel considers that *Lactobacillus crispatus* VPC111 (DSM 16741), which is the subject of the health claim ID 1079, is not sufficiently characterised.

A culture collection number from the DSMZ, DSM 16741, is provided. In the DSMZ, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

1.86. Characterisation of "*Lactobacillus crispatus* VPC177 (DSM 16743)" (ID 1080)

The food constituent that is the subject of the health claim is *Lactobacillus crispatus* VPC177 (DSM 16743). The genotypic identification and characterisation of the strain *Lactobacillus crispatus* VPC177 (DSM 16743) by chromosomic DNA restriction analysis (REA) and RAPD was reported in the literature (Molin et al., 2006). REA is not considered a stand-alone method; for reliable species identification this technique (REA) requires phylogenetic analysis with an appropriate number of strains from different species and controls. However, this data were not found. The Panel considers that *Lactobacillus crispatus* VPC177 (DSM 16743), which is the subject of the health claim ID 1080, is not sufficiently characterised.

A culture collection number from the DSMZ, DSM 16743, is provided. In the DSMZ, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

1.87. Characterisation of "*Lactobacillus reuteri*" (ID 1087, 1088, 1089)

The food constituent that is the subject of the health claim is *Lactobacillus reuteri*. No strain identification or name is provided. The Panel considers that *Lactobacillus reuteri*, which is the subject of the health claims ID 1087, 1088, 1089, is not sufficiently characterised.

1.88. Characterisation of a combination of "Lactobacillus casei F19, Lactobacillus plantarum 2592, Leuconostoc mesenteriodes 77:1, Pediococcus pentosaceus 16:1" (ID 1090)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus casei* F19, *Lactobacillus plantarum* 2592, *Leuconostoc mesenteriodes* 77:1, *Pediococcus pentosaceus* 16:1".

***Lactobacillus casei* F19** - The identification/characterisation of the strain *Lactobacillus casei* F19 is not included in the studies provided as reference material; only reference to the identification by the use of specific primers is reported (Sullivan et al., 2001). Data regarding phenotypic and molecular characterisation of the strain were found in the databases (Charteris et al., 2001; Björneholm et al. 2002). The Panel considers that *Lactobacillus casei* F19, which is the subject of the health claim ID 1090, is sufficiently characterised.

Information regarding the deposit of the strain in the LMG culture collection under nº LMG P-17806 (Ljungh-Wadstrom et al., 2004) was found in the literature. In the LMG, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can also be deposited in a restricted-access collection as Patent deposits.

***Lactobacillus plantarum* 2592** - The identification/characterisation of the strain *Lactobacillus plantarum* 2592 is not included in the studies provided as reference material. Data regarding the identification of the strain by phenotypic (API 50CH) and genotypic (Ribotyping) methods were found in the literature (Ljungh-Wadstrom et al., 2004). However the results are not shown and the ribotyping method not sufficiently explained (for a reliable identification this technique requires phylogenetic analysis with an appropriate number of strains from different species and controls). The Panel considers that *Lactobacillus plantarum* 2592, which is the subject of the health claim ID 1090, is not sufficiently characterised.

Information regarding the deposit of the strain in the LMG culture collection under nº LMG P-20606 (Ljungh-Wadstrom et al., 2004) was found in the literature.

***Leuconostoc mesenteriodes* 77:1** - The identification/characterisation of the strain *Leuconostoc mesenteroides* 77:1 is not included in the studies provided as reference material. Data regarding the identification of the strain by phenotypic (API 50CH) and genotypic (Ribotyping) methods were found in the literature (Ljungh-Wadstrom et al., 2004). However the results are not shown and the ribotyping method not sufficiently explained (for a reliable identification this technique requires phylogenetic analysis with an appropriate number of strains from different species and controls). The Panel considers that *Leuconostoc mesenteroides* 77:1, which is the subject of the health claim ID 1090, is not sufficiently characterised.

Information regarding the deposit of the strain in the LMG culture collection under nº LMG P-20607 (Ljungh-Wadstrom et al., 2004) was found in the literature.

***Pediococcus pentosaceus* 16:1** - The identification/characterisation of the strain *Pediococcus pentosaceus* 16:1 is not included in the studies provided as reference material. Data regarding the identification of the strain by phenotypic (API 50CH) and genotypic (Ribotyping) methods were found in the literature (Ljungh-Wadstrom et al., 2004). However the results are not shown and the ribotyping method not sufficiently explained (for a reliable identification this technique requires

phylogenetic analysis with an appropriate number of strains from different species and controls). The Panel considers that *Pediococcus pentosaceus* 16:1, which is the subject of the health claim ID 1090, is not sufficiently characterised.

Information regarding the deposit of the strain in the LMG culture collection under nº LMG P-20608 (Ljungh-Wadstrom et al., 2004) was found in the literature.

The Panel considers that the combination of "*Lactobacillus casei* F19, *Lactobacillus plantarum* 2592, *Leuconostoc mesenteriodes* 77:1, *Pediococcus pentosaceus* 16:1", which is the subject of the health claim ID 1090, is not sufficiently characterised.

1.89. Characterisation of a combination of "*Lactobacillus paracasei* CUL08 NCIMB 30154, *Lactobacillus salivarius* CUL61, *Bifidobacterium adolescentis* (bifidum) CUL20 NCIMB 30153, *Bifidobacterium lactis* CUL34 NCIMB 30172" (ID 1095)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus paracasei* CUL08 NCIMB 30154, *Lactobacillus salivarius* CUL61, *Bifidobacterium adolescentis* (bifidum) CUL20 NCIMB 30153, *Bifidobacterium lactis* CUL34 NCIMB 30172".

***Lactobacillus paracasei* CUL08 NCIMB 30154 -** The identification/characterisation of the strain *L. paracasei* CUL08 is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus paracasei* CUL08 (NCIMB 30154), which is the subject of the health claim ID 1095, is not sufficiently characterised.

A culture collection number from the National Collection of Industrial and Marine Bacteria (UK), NCIMB 30154, is provided.

***Lactobacillus salivarius* CUL61 -** The identification/characterisation of the strain *Lactobacillus salivarius* CUL61 is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus salivarius* CUL61, which is the subject of the health claim ID 1095, is not sufficiently characterised.

No reference to the deposit of the strain was reported in the information provided as reference material or in the literature.

***Bifidobacterium adolescentis* (bifidum) CUL20 NCIMB 30153 -** The identification/characterisation of the strain *Bifidobacterium adolescentis* CUL20 is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Bifidobacterium adolescentis* CUL20 (NCIMB 30153), which is the subject of the health claim ID 1095, is not sufficiently characterised.

A culture collection number from the National Collection of Industrial and Marine Bacteria (UK), NCIMB 30153, is provided.

***Bifidobacterium lactis* CUL34 NCIMB 30172 -** The identification/characterisation of the strain *Bifidobacterium lactis* CUL34 is not reported in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The species *Bifidobacterium lactis* has been reclassified as *Bifidobacterium animalis* ssp. *Lactis* (Masco et al., 2004). It is important to point out that it may not be possible to differentiate the commercially available *Bifidobacterium animalis* ssp. *lactis* strains from each other on the basis of traditional genetic methods (e.g. PFGE) (Engel et al., 2003; Gueimonde et al., 2004) and may be necessary to use multi-locus sequencing or genome-wide approaches. The Panel considers that *Bifidobacterium*

animalis ssp. *lactis* CUL34 (NCIMB 30172), which is the subject of the health claim ID 1095, is not sufficiently characterised.

A culture collection number from the National Collection of Industrial and Marine Bacteria (UK), NCIMB 30172, is provided.

The Panel considers that the combination of "*Lactobacillus paracasei* CUL08 NCIMB 30154, *Lactobacillus salivarius* CUL61, *Bifidobacterium adolescentis* (bifidum) CUL20 NCIMB 30153, *Bifidobacterium lactis* CUL34 NCIMB 30172", which is the subject of the health claim ID 1095, is not sufficiently characterised.

1.90. Characterisation of a combination of "Lactobacillus acidophilus, Bifidobacterium breve, Bifidobacterium longum, Bifidobacterium infantis" (ID 1096)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus acidophilus, Bifidobacterium breve, Bifidobacterium longum, Bifidobacterium infantis* & Vitamin C, Green Tea Extract, Grape Seed Extract, Pine Bark Extract".

For the microorganisms included in the combination, no strains name or identification is provided. The Panel considers that the strains included in the product, i.e. *Lactobacillus acidophilus, Bifidobacterium breve, Bifidobacterium longum, Bifidobacterium infantis,* which is the subject of the health claim ID 1096, are not sufficiently characterised.

1.91. Characterisation of a combination of "*Lactobacillus acidophilus* CUL60, *Lactobacillus casei* LC11, *Bifidobacterium lactis* CUL34" (ID 1097)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus acidophilus* CUL60, *Lactobacillus casei* LC11, *Bifidobacterium lactis* CUL34".

***Lactobacillus acidophilus* CUL60 -** The identification/characterisation of the strain *Lactobacillus acidophilus* CUL60 is not reported in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus acidophilus* CUL60 (NCIMB 30157), which is the subject of the health claim ID 1097, is not sufficiently characterised.

A culture collection number is not provided.

***Lactobacillus casei* LC11 -** The identification/characterisation of the strain *Lactobacillus casei* LC11 is not included in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus casei* LC11, which is the subject of the health claim ID 1097, is not sufficiently characterised.

No reference to the deposit of the strain in an internationally recognised culture collection was found in the studies provided as reference material or the literature.

***Bifidobacterium lactis* CUL34** - The identification/characterisation of the strain *Bifidobacterium lactis* CUL34 is not reported in the studies provided as reference material and no information regarding the strain identification/characterisation was found in the literature. The species *Bifidobacterium lactis* has been reclassified as *Bifidobacterium animalis* ssp. *Lacti (*Masco et al., 2004). It is important to point out that it may not be possible to differentiate the commercially available *Bifidobacterium animalis* ssp. *lactis* strains from each other on the basis of traditional genetic methods (e.g. PFGE) (Engel et al., 2003; Gueimonde et al., 2004) and may be necessary to use multi-locus sequencing or genome-wide approaches. The Panel considers that *Bifidobacterium*

animalis ssp. *lactis* CUL34 (NCIMB 30172), which is the subject of the health claim ID 1097, is not sufficiently characterised.

A culture collection number is not provided.

The Panel considers that the combination of "*Lactobacillus acidophilus* CUL60, *Lactobacillus casei* LC11, *Bifidobacterium lactis* CUL34", which is the subject of the health claim ID 1097, is not sufficiently characterised.

1.92. Characterisation of "*Lactobacillus* LA-5" (ID 1098)

The food constituent that is the subject of the health claim is *Lactobacillus* LA-5. No species name is provided. The Panel considers that *Lactobacillus* LA-5, which is the subject of the health claim ID 1098, is not sufficiently characterised.

1.93. Characterisation of "Lactic acid bacteria/ *Enterococcus faecium*" (ID 1595)

The food constituent that is the subject of the health claim is "Lactic acid bacteria/ *Enterococcus faecium*". The lactic acid bacteria (LAB) constitute a wide group of microorganisms with diverse metabolic capacities. Among the LAB, the *Enterococcus* genum comprises more than thirty different species. No information is provided about the name or the strain that is the subject of the health claim.

The Panel considers that the food constituent "Lactic acid bacteria/*Enterococcus faecium*", which is the subject of the health claim ID 1595, is not sufficiently characterised".

1.94. Characterisation of "*Lactobacillus acidophilus* P 18806" (ID 2946, 2947)

The food constituent that is the subject of the health claim is *Lactobacillus acidophilus* P 18806**.** The phenotypic identification of the strain by sugar fermentation profiles and SDS-PAGE analyses as member of the *Lactobacillus acidophilus* complex is reported in the references provided (Dondi, 2000; BCCM/LMG Report 04/02/99). However no other information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus acidophilus* P 18806, which is the subject of the health claims ID 2946, 2947, is not sufficiently characterised.

According to the patent application by Dondi (Dondi, 2000) the strain is deposited in the LMG under nº LMG P-18806. LMG is a non-public International Depositary Authority under the Budapest Treaty.

1.95. Characterisation of a combination of "Lactobacillus acidophilus, Bifidobacterium (BB46), Bifidobacterium (BB02), Bifidobacterium breve Bbr8 (LMG P-17501), Lactobacillus rhamnosus ATCC53103 (LGG), Lactobacillus casei 101/37 (LMG P-17504), Lactobacillus delbrueckii ssp. bulgaricus AY/CSL (LMG P-17224)" (ID 2948)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus acidophilus*, *Bifidobacterium* (BB46), *Bifidobacterium* (BB02), *Bifidobacterium breve* Bbr8 (LMG P-17501), *Lactobacillus rhamnosus* ATCC53103 (LGG), *Lactobacillus casei* 101/37 (LMG P-17504), *Lactobacillus delbrueckii* ssp. *bulgaricus* AY/CSL (LMG P-17224)".

Lactobacillus acidophilus - No strain identification or name is provided. The Panel considers that *Lactobacillus acidophilus*, which is the subject of the health claim ID 2948, is not sufficiently characterised.

***Bifidobacterium* (BB46) -** No species name is provided. The Panel considers that *Bifidobacterium* (BB46), which is the subject of the health claim ID 2948, is not sufficiently characterised.

***Bifidobacterium* (BB02) -** No species name is provided. The Panel considers that *Bifidobacterium* (BB02)**,** which is the subject of the health claim ID 2948, is not sufficiently characterised.

***Bifidobacterium breve* Bbr8 (LMG P-17501) -** The only information found on identification/characterisation of the strain regarded identification by PCR (Bianchi et al., 2004); no other information regarding identification/characterisation was found in the literature. The Panel considers that *Bifidobacterium breve* Bbr8 (LMG P-17501), which is the subject of the health claim ID 2948, is not sufficiently characterised.

A culture collection number from the LMG culture collection is provided. LMG is a non-public International Depositary Authority under the Budapest Treaty.

***Lactobacillus rhamnosus* ATCC53103 (LGG) -** The strain *Lactobacillus rhamnosus* GG species identity as well as the strain identity and characteristics have been clearly established by using both phenotypic and genotypic methods (Tynkkynen et al., 1999; Charteris et al., 2001; Janoir et al., unpublished). The Panel considers that *Lactobacillus rhamnosus* ATCC53103 (LGG), which is the subject of the health claim ID 2948, is sufficiently characterised.

This strain is deposited in a recognised international culture collection (ATCC under nº 53103, also available at LMG under nº 18243).

***Lactobacillus casei* 101/37 (LMG P-17504) -** The identification/characterisation of the strain *Lactobacillus casei* 101/37 is not reported in the references provided and no information regarding identification/characterisation was found in the literature. The Panel considers that *Lactobacillus casei* 101/37 (LMG P-17504), which is the subject of the health claim ID 2948, is not sufficiently characterised.

A culture collection number from the LMG culture collection is provided. In the LMG, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

***Lactobacillus delbrueckii* ssp. *bulgaricus* AY/CSL (LMG P-17224) -** The only reference to the identification/characterisation of the strain *Lactobacillus delbrueckii* ssp. *bulgaricus* AY/CSL found in the studies provided as reference material is the identification by sugar fermentation profiles (Bianchi-Salvadori et al., 1984). No other information regarding identification/characterisation was found in the literature. The Panel considers that *Lactobacillus delbrueckii* ssp. *bulgaricus* AY/CSL (LMG P-17224), which is the subject of the health claim ID 2948, is not sufficiently characterised.

A culture collection number from the LMG culture collection is provided. In the LMG, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

The Panel considers that the combination of "*Lactobacillus acidophilus*, *Bifidobacterium* (BB46), *Bifidobacterium* (BB02), *Bifidobacterium breve* Bbr8 (LMG P-17501), *Lactobacillus rhamnosus* ATCC53103 (LGG), *Lactobacillus casei* 101/37 (LMG P-17504), *Lactobacillus delbrueckii* ssp. *bulgaricus* AY/CSL (LMG P-17224)", which is the subject of the health claim ID 2948, is no sufficiently characterised.

1.96. Characterisation of "*Lactobacillus casei* CNCM I-1572 DG" (ID 2949)

The food constituent that is the subject of the health claim is *Lactobacillus casei* CNCM I-1572 DG. The only information found in the references provided regarding the identification of the strain *Lactobacillus casei* CNCM I-1572 DG, also known as *Lactobacillus casei* DG, related to the use of phenotypic tests (API 50CH) (Drago et al., 2002). No other information was found in the studies provided or in the literature. The Panel considers that *Lactobacillus casei* CNCM I-1572 DG, which is the subject of the health claim ID 2949, is not sufficiently characterised.

A culture collection number from the Collection Nationale de Cultures de Microorganismes (CNCM) is provided. CNCM is a restricted-access non-public collection which has the status of International Depositary Authority under the Budapest Treaty.

1.97. Characterisation of "*Lactobacillus delbrueckii* P 18805" (ID 2951, 2952)

The food constituent that is the subject of the health claim is *Lactobacillus delbrueckii* P 18805. The phenotypic identification of the strain is reported in the references provided (Dondi, 2000; BCCM/LMG Report 04/02/99). However no other information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus delbrueckii* P 18805, which is the subject of the health claims ID 2951, 2952, is not sufficiently characterised.

According to the patent application by Dondi (Dondi, 2000) the strain is deposited at the LMG under nº LMG P-18805. In the LMG, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

1.98. Characterisation of a combination of "*Lactobacillus delbrueckii* ssp. *bulgaricus* AY/CSL (LMG P-17224), *Streptococcus thermophilus* 9Y/CSL (LMG P-17225)" (ID 2953, 2954, 2955)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus delbrueckii* ssp. *bulgaricus* AY/CSL (LMG P-17224), *Streptococcus thermophilus* 9Y/CSL (LMG P-17225)".

***Lactobacillus delbrueckii* ssp. *bulgaricus* AY/CSL (LMG P-17224) -** The only reference to the identification/characterisation of the strain *Lactobacillus delbrueckii* ssp. *bulgaricus* AY/CSL reported in the references provided is the identification by sugar fermentation profiles (Bianchi-Salvadori et al., 1984). No other information regarding identification/characterisation was found in the literature. The Panel considers that *Lactobacillus delbrueckii* ssp. *bulgaricus* AY/CSL (LMG P-17224), which is the subject of the health claims ID 2953, 2954, 2955, is not sufficiently characterised.

A culture collection number from the LMG culture collection is provided. In the LMG, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

***Streptococcus thermophilus* 9Y/CSL (LMG P-17225) -** The identification/characterisation of the strain *Streptococcus thermophilus* 9Y/CSL is not included in the studies provided as reference material and no information regarding identification/characterisation was found in the literature. The Panel considers that *Streptococcus thermophilus* 9Y/CSL (LMG P-17225), which is the subject of the health claims ID 2953, 2954, 2955, is not sufficiently characterised.

Indication of the deposit of the strain at the LMG is provided. In the LMG, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in a restricted-access collection as Patent deposits.

The Panel considers that the combination of "*Lactobacillus delbrueckii* ssp. *bulgaricus* AY/CSL (LMG P-17224), *Streptococcus thermophilus* 9Y/CSL (LMG P-17225)", which is the subject of the health claims ID 2953, 2954, 2955, is not sufficiently characterised.

1.99. Characterisation of "*Lactobacillus gasseri* P 17632" (ID 2956)

The food constituent that is the subject of the health claim is *Lactobacillus gasseri* P 17632. Reference to phenotypic identification of the strain was found in studies provided (Dondi and Morelli, 1999; BCCM/LMG Report 29/01/97; Morelli, 1997). However no other information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus gasseri* P 17632, which is the subject of the health claim ID 2956, is not sufficiently characterised.

According to the patent application by Dondi and Morelli (1999) the strain is deposited in the LMG under nº LMG P-17632. In the LMG, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited at in restricted-access collection as Patent deposits.

1.100. Characterisation of "*Lactobacillus gasseri* P 18137" (ID 2957, 2958)

The food constituent that is the subject of the health claim is *Lactobacillus gasseri* P 18137. Reference to phenotypic identification of the strain was found (Dondi and Morelli, 1999; BCCM/LMG Report 04/09/98). However no other information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus gasseri* P 18137, which is the subject of the health claims ID 2957, 2958, is not sufficiently characterised.

According to the patent application by Dondi and Morelli (1999) the strain is deposited at the LMG under nº LMG P-18137. In the LMG, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in restricted-access collection as Patent deposits.

1.101. Characterisation of "*Lactobacillus paracasei* I1688" (ID 2962, 2963)

The food constituent that is the subject of the health claim is *Lactobacillus paracasei* I1688. Information on the strain identification/characterisation by sugar fermentation and plasmidic profile of the strain was found in the references provided (Pedraglio, 2004; Morelli, 1996). RAPD and ARDRA for this strain were also performed in a study (Bonetti et al., 2002). No other information regarding the identification/characterisation of the strain *Lactobacillus paracasei* I1688 was found in the literature. The Panel considers that *Lactobacillus paracasei* I1688, which is the subject of the health claims ID 2962, 2963, is not sufficiently characterised.

According to a patent cited in the references provided as reference the strains is deposited at the Collection Nationale de Cultures de Microorganismes (CNCM), as *Lactobacillus paracasei* CNCM I-1688 (Pedraglio, 2004). The CNCM is a restricted-access non-public collection which has the status of International Depositary Authority under the Budapest Treaty.

1.102. Characterisation of "*Lactobacillus plantarum* P 17630" (ID 2966, 2967)

The food constituent that is the subject of the health claim is *Lactobacillus plantarum* P 17630. The phenotypic identification of the strain and plasmidic profile was reported in the reference provided

(Dondi, 2000; BCCM/LMG Report 29/01/97; Morelli, 1997). However no other information regarding the strain identification/characterisation was found in the literature. The Panel considers that *Lactobacillus plantarum* P 17630, which is the subject of the health claims ID 2966, 2967, is not sufficiently characterised.

According to the patent application by Dondi (2000) the strain is deposited in the LMG under nº LMG P-17630. In the LMG, which is a non-public International Depositary Authority under the Budapest Treaty, cultures can be deposited in restricted-access collection as Patent deposits.

1.103. Characterisation of "*Lactobacillus salivarius* I1794" (ID 2970, 2971)

The food constituent that is the subject of the health claim is *Lactobacillus salivarius* I1794. Information on the strain identification/characterisation by sugar fermentation and plasmidic profile of the strain was found in the references provided (Pedraglio, 2004; Morelli, 1996). RAPD and ARDRA for this strain were also performed in a study (Bonetti et al., 2002). No other information regarding the identification/characterisation of the strain *Lactobacillus salivarius* I1794 was found in the literature. The Panel considers that *Lactobacillus salivarius* I1794, which is the subject of the health claims ID 2970, 2971, is not sufficiently characterised.

According to a patent cited in the references provided as reference the strains is deposited at the Collection Nationale de Cultures de Microorganismes (CNCM), as *Lactobacillus salivarius* CNCM I-1794 (Pedraglio, 2004). The CNCM is a restricted-access non-public collection which has the status of International Depositary Authority under the Budapest Treaty.

1.104. Characterisation of a combination of "*Lactobacillus paracasei* I1688, *Lactobacillus salivarius* I1794" (ID 2972, 2973)

The food constituent that is the subject of the health claim is a combination of "*Lactobacillus paracasei* I1688, *Lactobacillus salivarius* I1794".

***Lactobacillus paracasei* I1688 -** Information on the strain identification/characterisation by sugar fermentation and plasmidic profile of the strain was found in the references provided (Pedraglio, 2004; Morelli, 1996). RAPD and ARDRA for this strain were also performed in a study (Bonetti et al., 2002). No other information regarding the identification/characterisation of the strain *Lactobacillus paracasei* I1688 was found in the literature. The Panel considers that *Lactobacillus paracasei* I1688, which is the subject of the health claims ID 2972, 2973, is not sufficiently characterised.

According to a patent cited in the references provided as reference the strains is deposited at the Collection Nationale de Cultures de Microorganismes (CNCM), as *Lactobacillus paracasei* CNCM I-1688 (Pedraglio, 2004). The CNCM is a restricted-access non-public collection which has the status of International Depositary Authority under the Budapest Treaty.

***Lactobacillus salivarius* I1794 -** Information on the strain identification/characterisation by sugar fermentation and plasmidic profile of the strain was found in the references provided (Pedraglio, 2004; Morelli, 1996). RAPD and ARDRA for this strain were also performed in a study (Bonetti et al., 2002). No other information regarding the identification/characterisation of the strain *Lactobacillus salivarius* I1794 was found in the literature. The Panel considers that *Lactobacillus salivarius* I1794, which is the subject of the health claims ID 2972, 2973, is not sufficiently characterised.

According to a patent cited in the references provided as reference the strains is deposited at the Collection Nationale de Cultures de Microorganismes (CNCM), as *Lactobacillus salivarius* CNCM I-

1794 (Pedraglio, 2004). The CNCM is a restricted-access non-public collection which has the status of International Depositary Authority under the Budapest Treaty.

The Panel considers that the combination of "*Lactobacillus paracasei* I1688, *Lactobacillus salivarius* I1794", which is the subject of the health claims ID 2972, 2973, is not sufficiently characterised.

1.105. Characterisation of "*Lactobacillus salivarius* LS-33" (ID 2991)

The food constituent that is the subject of the health claim is *Lactobacillus salivarius* LS-33. The only information reported on the identification/characterisation of the strain *Lactobacillus salivarius* LS-33 in the references provided relates to the use of Rep-PCR (Daniel et al., 2006). No other information regarding identification/characterisation was found in the literature. The Panel considers that *Lactobacillus salivarius* LS-33, which is the subject of the health claim ID 2991, is not sufficiently characterised.

No indication of the deposit of the strain in an internationally recognised culture collection was found in the information provided or the literature.

CONCLUSIONS

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

- The following food constituents that are microorganisms/combination of microorganisms (addressed in this opinion and listed in the table below), which are subject of health claims are not sufficiently characterised.
- As the data available is insufficient to characterise the microorganisms/combination of microorganisms addressed in this opinion, and that owing to the strain-specificity of the effects, evidence obtained for one strain cannot be extrapolated to another, a cause and effect relationship has not been established between the consumption of the microorganisms/combination of microorganisms addressed in this opinion and their claimed effects.

ID number	Strain / combination of strains	Section in the opinion
859, 860	*Bifidobacterium bifidum* I-3426	2.1
861	*Bifidobacterium bifidum* CNCM I-373	2.2
868, 870	*Bifidobacterium animalis ssp.* lactis Bb-12®, *Lactobacillus acidophilus* LA-5®	2.3
869	*Lactobacillus acidophilus* ATCC SD5221, *Bifidobacterium lactis* ATCC SD5220	2.4
871, 873	*Bifidobacterium breve* I-3425	2.5
874, 876	*Bifidobacterium infantis* I-3424	2.6
875, 1093, 1094	*Bifidobacterium infantis* UCC35624	2.7
877, 878	*Bifidobacterium longum* I-3470	2.8
879	*Lactobacillus acidophilus* CNCM I-1722	2.9
880	*Lactobacillus acidophilus* LA-5®	2.10

ID number	Strain / combination of strains	Section in the opinion
881, 883	*Lactobacillus acidophilus* Lafti L10 (CBS 116.411)	2.11
885, 944	*Lactobacillus acidophilus* CUL21 NCIMB 30156, *Lactobacillus acidophilus* CUL60 NCIMB 30157, *Bifidobacterium adolescentis* CUL20 NCIMB 30153, *Bifidobacterium lactis* (*animalis* ssp. *lactis*) CUL34 NCIMB 30172	2.12
886, 887	*Lactobacillus helveticus* I-1722	2.13
888	*Lactobacillus casei* Lafti L26 (CBS 116.412)	2.14
889, 891	*Lactobacillus casei* I-3429	2.15
895, 897, 899	*Lactobacillus paracasei* NCC2461 (ST11) (CNCM I-2116)	2.16
898	*Lactobacillus paracasei* ssp. *paracasei* CRL-431	2.17
901, 903	*Lactobacillus plantarum* Rosell-1012	2.18
907, 911	*Lactobacillus rhamnosus* I-1720	2.19
912	*Saccharomyces boulardii* (trade name PXN68)	2.20
913	*Saccharomyces cerevisiae* var *boulardii*	2.21
914, 915	*Streptococcus thermophilus* I-3428	2.22
917, 1091, 1092	*Bacillus subtilis* HU58	2.23
918	*Bacillus subtilis* PB6	2.24
919, 920	*Bifidobacterium animalis* ssp. *lactis* Bb-12, *Lactobacillus acidophilus* LA-5, *Lactobacillus bulgaricus* LBY-27, *Streptococcus thermophilus* STY-31	2.25
921, 922	*Lactobacillus paracasei* ssp. *paracasei* CRL-431, *Lactobacillus acidophilus* LA-5	2.26
923, 1085, 1086	*Lactobacillus casei* F19, *Bifidobacterium animalis* ssp. *lactis* Bb-12, *Lactobacillus acidophilus* LA-5	2.27
925	*Bifidobacterium bifidum* CNCM I-3426, *Lactobacillus casei* CNCM MA 64U, *Lactobacillus acidophilus* CNCM I-1722, *Lactococcus lactis* CNCM MA67/4J	2.28
926	*Lactobacillus acidophilus, Lactobacillus rhamnosus*	2.29
927	*Saccharomyces boulardii*.	2.30
928	*Saccharomyces boulardii, Lactobacillus acidophilus* CNCM I-1722, *Lactobacillus rhamnosus* CNCM I-1720, *Bifidobacterium longum* CNCM I-3470	2.31
929	*Bifidobacterium infantis* CNCM I-3424, *Bifidobacterium bifidum* CNCM I-3426, *Lactobacillus acidophilus* CNCM I-1722	2.32
931, 933	*Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* MF 20/5, *Bifidobacterium longum* SP 07/3	2.33
932, 940	*Lactobacillus johnsonii* La-19/CLbA5, *Bifidobacterium*	2.34

ID number	Strain / combination of strains	Section in the opinion
	animalis ssp. *lactis* Bf-6/Bif-6/CB111	
934	*Lactobacillus gasseri* 57C, *Lactobacillus fermentum* 57A, *Lactobacillus plantarum* 57B	2.35
935	*Bifidobacterium animalis* ssp. *lactis* Bb-12, *Lactobacillus paracasei* ssp. *paracasei* CRL-431	2.36
936	*Lactobacillus gasseri* PA 16/8, *Bifidobacterium bifidum* MF 20/5	2.37
938, 939	*Lactobacillus helveticus* CNCM I-1722, *Bifidobacterium longum* CNCM I-3470	2.38
941	*Propionibacterium freudenreichii* SI 41, *Propionibacterium freudenreichii* SI 26	2.39
942	*Bifidobacterium animalis* ssp. *lactis* Bb-12, *Lactobacillus acidophilus* LA-5	2.40
943	*Bacillus mesentericus* TO-A, *Clostridium butyricum* TO-A, *Streptococcus faecalis* T-110	2.41
947	*Lactobacillus rhamnosus* LR(3)	2.42
958, 959	*Bifidobacterium animalis* spp. *animalis* THT 010401	2.43
960, 961, 962	*Bifidobacterium animalis* spp. *lactis* THT 010801	2.44
963, 964	*Bifidobacterium bifidum* THT 010101	2.45
965, 966	*Bifidobacterium breve* THT 010601	2.46
967, 968	*Bifidobacterium longum* bv *infantis* THT 010201	2.47
969, 970	*Bifidobacterium longum* THT 010301	2.48
971, 972	*Bifidobacterium pseudolongum* ssp *pseudolongum* THT 010501	2.49
973, 974	*Lactobacillus acidophilus* THT 030102	2.50
975, 976	*Lactobacillus casei* THT 030401	2.51
977, 978	*Lactobacillus delbrueckii bulgaricus* THT 030301	2.52
979, 980	*Lactobacillus delbrueckii bulgaricus* THT 030302	2.53
981, 982	*Lactobacillus delbrueckii bulgaricus* THT 030303	2.54
983, 984	*Lactobacillus gasseri* THT 031301	2.55
985, 986	*Lactobacillus helveticus* THT 031102	2.56
987, 988	*Lactobacillus helveticus* THT 031101	2.57
994, 995	*Lactobacillus plantarum* THT 030701	2.58
996, 997	*Lactobacillus plantarum* THT 030707	2.59
998, 999	*Lactobacillus reuteri* THT 030802	2.60

ID number	Strain / combination of strains	Section in the opinion
1000, 1001	*Lactobacillus reuteri* THT 030803	2.61
1002, 1003	*Lactobacillus rhamnosus* THT 030901	2.62
1004, 1005	*Lactobacillus rhamnosus* THT 030902	2.63
1006, 1007	*Lactobacillus salivarius* THT 031001	2.64
1008, 1009	*Lactococcus lactis* THT 090101	2.65
1010, 1011	*Saccharomyces boulardii* ATY-SB-101	2.66
1012, 1013	*Streptococcus thermophilus* THT 070101	2.67
1014, 1015	*Streptococcus thermophilus* THT 070102	2.68
1030, 2950	*Lactobacillus crispatus* P 17631	2.69
1055, 1056	*Lactobacillus acidophilus* R0052 (I-1722), *Lactobacillus paracasei* 8.16b, *Lactobacillus rhamnosus* I-1720, *Bifidobacterium animalis* ssp. *lactis* Bb-12	2.70
1057	*Lactobacillus reuteri* lactic acid bacteria	2.71
1060, 1062	*Lactococcus lactis* L1A NCIMB 40157	2.72
1063	*Lactobacillus plantarum* LB931 DSM 11918	2.73
1065	*Lactobacillus plantarum* LB7c DSM 17853	2.74
1066	*Lactobacillus plantarum* LB3e DSM 17852	2.75
1067	*Streptococcus sanguis* NCIMB 40104	2.76
1068	*Streptococcus sanguis* NCIMB 40873	2.77
1069	*Streptococcus oralis* NCIMB 40875	2.78
1070	*Streptococcus oralis* NCIMB 40876	2.79
1071	*Lactobacillus plantarum* HEAL 9 (DSM 15312=39D)	2.80
1072	*Lactobacillus plantarum* HEAL 19 (DSM 15313=52A)	2.81
1073	*Lactobacillus plantarum* HEAL 99 (DSM 15316=61A)	2.82
1075	*Lactobacillus paracasei* 02A (DSM 13432)	2.83
1076	*Lactobacillus rhamnosus* 271 (DSM 6594)	2.84
1079	*Lactobacillus crispatus* VPC111 (DSM 16741)	2.85
1080	*Lactobacillus crispatus* VPC177 (DSM 16743)	2.86
1087, 1088, 1089	*Lactobacillus reuteri*	2.87
1090	*Lactobacillus casei* F19, *Lactobacillus plantarum* 2592, *Leuconostoc mesenteriodes* 77:1, *Pediococcus pentosaceus* 16:1	2.88
1095	*Lactobacillus paracasei* CUL08 NCIMB 30154, *Lactobacillus salivarius* CUL61, *Bifidobacterium adolescentis* (bifidum)	2.89

ID number	Strain / combination of strains	Section in the opinion
	CUL20 NCIMB 30153, *Bifidobacterium lactis* CUL34 NCIMB 30172	
1096	*Lactobacillus acidophilus, Bifidobacterium breve, Bifidobacterium longum, Bifidobacterium infantis*	2.90
1097	*Lactobacillus acidophilus* CUL60, *Lactobacillus casei* LC11, *Bifidobacterium lactis* CUL34	2.91
1098	*Lactobacillus* LA-5	2.92
1595	*Lactic acid bacteria/ Enterococcus faecium*	2.93
2946, 2947	*Lactobacillus acidophilus* P 18806	2.94
2948	*Lactobacillus acidophilus, Bifidobacterium* (BB46), *Bifidobacterium* (BB02), *Bifidobacterium breve* Bbr8 (LMG P-17501), *Lactobacillus rhamnosus* ATCC53103 (LGG), *Lactobacillus casei* 101/37 (LMG P-17504), *Lactobacillus delbrueckii* ssp. *bulgaricus* AY/CSL (LMG P-17224)	2.95
2949	*Lactobacillus casei* CNCM I-1572 DG	2.96
2951, 2952	*Lactobacillus delbrueckii* P 18805	2.97
2953, 2954, 2955	*Lactobacillus delbrueckii* ssp. *bulgaricus* AY/CSL (LMG P-17224), *Streptococcus thermophilus* 9Y/CSL (LMG P-17225)	2.98
2956	*Lactobacillus gasseri* P 17632	2.99
2957, 2958	*Lactobacillus gasseri* P 18137	2.100
2962, 2963	*Lactobacillus paracasei* I1688	2.101
2966, 2967	*Lactobacillus plantarum* P 17630	2.102
2970, 2971	*Lactobacillus salivarius* I1794	2.103
2972, 2973	*Lactobacillus paracasei* I1688, *Lactobacillus salivarius* I1794	2.104
2991	*Lactobacillus salivarius* LS-33	2.105

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-3723, EFSA-Q-2008-3705, EFSA-Q-2008-3704, EFSA-Q-2008-3703, EFSA-Q-2008-3702, EFSA-Q-2008-3699, EFSA-Q-2008-3698, EFSA-Q-2008-3695, EFSA-Q-2008-3694, EFSA-Q-2008-3690, EFSA-Q-2008-3689, EFSA-Q-2008-3688, EFSA-Q-2008-3687, EFSA-Q-2008-3686, EFSA-Q-2008-3685, EFSA-Q-2008-3684, EFSA-Q-2008-3683, EFSA-Q-2008-3682, EFSA-Q-2008-3681, EFSA-Q-2008-3680, EFSA-Q-2008-3679, EFSA-Q-2008-3678, EFSA-Q-2008-2331, EFSA-Q-2008-1837, EFSA-Q-2008-1836, EFSA-Q-2008-1835, EFSA-Q-2008-1834, EFSA-Q-2008-1833, EFSA-Q-2008-1832, EFSA-Q-2008-1831, EFSA-Q-2008-1830, EFSA-Q-2008-1829, EFSA-Q-2008-1828, EFSA-Q-2008-1827, EFSA-Q-2008-1826, EFSA-Q-2008-1825, EFSA-Q-2008-1824, EFSA-Q-2008-1819, EFSA-Q-2008-1818, EFSA-Q-2008-1815, EFSA-Q-2008-1814, EFSA-Q-2008-1812, EFSA-Q-2008-1811, EFSA-Q-2008-1810, EFSA-Q-2008-1809, EFSA-Q-2008-1808, EFSA-Q-2008-1807, EFSA-Q-2008-1806, EFSA-Q-2008-1805, EFSA-Q-2008-1804, EFSA-Q-2008-1802, EFSA-Q-2008-1801, EFSA-Q-

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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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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[4] (hereinafter "the Regulation") entered into force on 19th 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[5]

Foods are commonly involved in many different functions[6] 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.

[4] OJ L12, 18/01/2007
[5] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[6] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

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

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 DISCAIMER

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.

GLOSSARY AND ABBREVIATIONS

rRNA	Ribosomal RNA
AGAL	Australian Government Analytical Laboratories. Australia
ARDRA	Amplified rDNA restriction analysis
ATCC	American Type Culture Collection. USA
BCCM/LMG	Belgian Co-ordinated Collections of Microorganisms. Belgium
CBS	Centraalbureau voor Schimmelcultures. The Netherlands
CECT	Colección Española de Cultivos Tipo. Spain
CERELA	Centro de Referencia para Lactobacilos. Argentina
CNCM	Collection Nationale de Cultures de Microorganismes. France
DSMZ	Deutsche Sammlung von Mikroorganismen und Zellkulturen. Germany
FERM	Fermentation Research Institute. Japan
IBSS	Institute of Biotechnology Sera and vaccines BIOMED SA. Poland.
NCBI	National Center for Biotechnology Information
NCIMB	National Collection of Industrial and Marine Bacteria. UK
PCR	Polymerase chain reaction
PFGE	Pulsed Field Gel Electrophoresis
RAPD	Randomly Amplified Polymorphic DNA
REA	Chromosomic DNA Restriction Analysis
SDS-PAGE	Sodium Dodecyl Sulfate Polyacrylamide Gel Electrophoresis