

## SCIENTIFIC OPINION

### Scientific Opinion on the substantiation of health claims related to *Lactobacillus reuteri* ATCC 55730 and decreasing potentially pathogenic intestinal microorganisms (ID 904) pursuant to Article 13(1) of Regulation (EC) No 1924/2006<sup>1</sup>

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

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 in relation to *Lactobacillus reuteri* ATCC 55730 and decreasing potentially pathogenic intestinal microorganisms. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The food constituent that is the subject of the health claim is *Lactobacillus reuteri* ATCC 55730. The Panel considers that *Lactobacillus reuteri* ATCC 55730 is sufficiently characterised.

The claimed effect ‘intestinal flora’ is not sufficiently defined but in the context of the proposed wording, the Panel assumes that the claimed effect refers to aspects of: “probiotic, beneficially affect the intestinal flora, support a healthy intestinal flora, and balance intestinal flora”. The Panel considers that decreasing potentially pathogenic intestinal microorganisms might be beneficial to human health.

In weighing the evidence, the Panel took into account that the results of two human studies which related to *Helicobacter pylori* eradication were only available as poster abstracts, that the evidence from the animal and *in vitro* studies does not predict the effect of *Lactobacillus reuteri* ATCC 55730 consumption on the claimed effect in humans, and that the remaining references dealt with outcomes unrelated to the claimed effect.

On the basis of the data available, the Panel concludes that a cause and effect relationship has not been established between the consumption of *Lactobacillus reuteri* ATCC 55730 and decreasing potentially pathogenic intestinal microorganisms.

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**KEY WORDS**

*Lactobacillus reuteri* ATCC 55730, intestinal flora, potentially pathogenic microorganisms, health claims

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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<sup>3</sup> submitted by Member States contains main entry claims with corresponding conditions of use and literature from similar health claims. The information provided in the consolidated list for the health claims subject to this opinion is given in Table 1.

Table 1. Main entry health claims related to *Lactobacillus reuteri* ATCC 55730, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food component	Health Relationship	Proposed wording
904	Lactobacillus reuteri ATCC 55730	Intestinal flora	probiotic
			beneficially affects the intestinal flora
			supports a healthy intestinal flora
			balances the intestinal flora
<b>Conditions of use</b>			
<ul style="list-style-type: none"> <li>- Food supplement with 100 million <i>Lactobacillus reuteri</i> (ATCC 55730) lactic acid bacteria in the daily dose.</li> <li>- at least 1x10<sup>8</sup> cfu/day daily consumption</li> <li>- Yoghurts, butter milks and juices with a <i>Lactobacillus reuteri</i> lactic acid bacteria content of at least 5*10<sup>5</sup>cells/ml= log cells/ml 5.7, min. 1*10<sup>8</sup>cells/200g or 2 dl, at least 1*10<sup>8</sup>cells/day. According to the respondent, the amount of lactic acid bacteria is a guideline. Furthermore, there is no danger of an “overdose” of <i>L.reuteri</i>, so it is possible to consume the recommended amount of the ingredient that the claim is based upon. Heat treatment may destroy living lactic acid bacteria, but the correct usage is explained in the package.</li> <li>- Tägliche Menge 4x10E8 KbE/Tag</li> </ul>			

## ASSESSMENT

### 1. Characterisation of the food/constituent

The food constituent that is the subject of the health claim is *Lactobacillus reuteri* ATCC 55730 (hereafter *L. reuteri* ATCC 55730). The strain *L. reuteri* ATCC 55730 is also known as *Lactobacillus reuteri* SD2112 (Connolly, 2004). The 16S rRNA sequence of the strain is deposited at Genbank (Accession n° EU394679) and the strain has been characterised by both phenotypic and genotypic methods (Rosander et al., 2008). The sequencing of the genome of the strain is reported (Bath et al., 2005).

The Panel notes that a culture collection number from the American Type Culture Collection (ATCC) is provided.

<sup>3</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

The Panel considers that the food constituent, *L. reuteri* ATCC 55730, which is the subject of the health claim, is sufficiently characterised.

## 2. Relevance of the claimed effect to human health

The claimed effect is ‘intestinal flora’. The Panel assumes that the target population is the general population.

“Intestinal flora” is not sufficiently defined. In the context of the proposed wording, the Panel assumes that the claimed effect refers to aspects of: “probiotic, beneficially affect the intestinal flora, support a healthy intestinal flora, and balance intestinal flora”.

The numbers/proportions of bacterial groups that would constitute a “beneficial/healthy/balanced” intestinal flora have not been established. Increasing the number of any groups of bacteria is not in itself considered as beneficial. The Panel considers that no evidence has been provided that aspects of the claimed effect, “probiotic, beneficially affect the intestinal flora, support a healthy intestinal flora, and balance intestinal flora”, are beneficial to human health.

The Panel considers that decreasing potentially pathogenic intestinal microorganisms might be beneficial to human health.

## 3. Scientific substantiation of the claimed effect

Thirty references were cited to substantiate the claimed effect. The references included human intervention studies, *in vitro* and animal studies, and reviews.

Three human studies demonstrated the presence of *L. reuteri* ATCC 55730 in faecal samples and gastric, duodenal and ileal mucosa after oral ingestion, and supporting survival and colonisation in the gastrointestinal tract (Valeur et al., 2004; Wolf et al., 1995; Wolf et al., 1998). Two studies investigated the safety aspects of the strain in both healthy males and HIV-infected subjects (Wolf et al., 1995; Wolf et al., 1998). The Panel notes that these references dealt with outcomes unrelated to the claimed effect.

In other studies the effect of the strain on clinical symptoms in different clinical conditions (acute diarrhoea, irritable bowel syndrome, infant colic, constipation, reduction of gingivitis and lowering infections rate) was evaluated (Tubelius et al., 2005; Niv et al., 2005; Ouweland et al., 2002; Ruiz-Palacios et al., 1996; Savino et al., 2005 and al., 2007; Shornikova et al., 1997a and 1997b; Weizman et al., 2003 and 2006; Guerrero et al., 1996; Krasse et al., 2006). The Panel notes that these studies do not address the claimed effect. Studies demonstrating reduced concentrations of salivary streptococci (Caglar et al., 2006; Nikawa et al., 2004) do not evaluate the effect of the bacterial strain on intestinal pathogens. The studies by Lionetti et al. (2005 and 2006) focused on reduction of side-effects of *H. pylori* treatment and reported on outcomes, which are unrelated to the claimed effect. The trial of Jakobsen et al. (2005, abstract of a poster) related to the effect of oral supplementation of *Lactobacillus reuteri* on the immunological composition of breast milk, which is also unrelated to the claimed effect.

In one study, dyspeptic *Helicobacter pylori* (*H. pylori*) positive patients were treated with omeprazole, *L. reuteri* ATCC 55730 ( $8 \times 10^5$  b.i.d.) or placebo (Saggioro, 2005, abstract of a poster). In another study, 40 asymptomatic healthy volunteers with a positive urea breath test for *H. pylori* were divided over 4 groups (Imase et al., 2005, abstract of a poster). Two of the groups received tablets containing *L. reuteri* ATCC 55730 (dose not known) for 4 weeks followed by placebo for 4 weeks or vice versa. The Panel notes that only the abstracts (of posters) were available and the full text of the publications were not retrievable. The abstracts did not provide sufficient information to allow a scientific evaluation.

In several *in vitro* and animal models antibacterial effects, immunomodulatory properties and the adhesion characteristics of *L. reuteri* ATCC 55730 were reviewed together with infection rates, morbidity and mortality caused by bacterial pathogens (Axelsson et al., 1989; Casas and Dobrogosz, 2000; Dobrogosz, 2005). The Panel considers that the evidence provided in the animal and *in vitro* studies does not predict the effect of *L. reuteri* ATCC 55730 consumption on the claimed effect in humans.

In weighing the evidence, the Panel took into account that the results of two human studies which related to *Helicobacter pylori* eradication were only available as poster abstracts, that the evidence in the animal and *in vitro* studies does not predict the effect of *L. reuteri* ATCC 55730 consumption on the claimed effect in humans, and that the remaining references dealt with outcomes unrelated to the claimed effect.

The Panel concludes that a cause and effect relationship has not been established between the consumption of *Lactobacillus reuteri* ATCC 55730 and decreasing potentially pathogenic intestinal microorganisms.

## CONCLUSIONS

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

- The food constituent, *Lactobacillus reuteri* ATCC 55730, which is the subject of the health claim is sufficiently characterised.
- The claimed effect is “intestinal flora”. The target population is assumed to be the general population. Decreasing potentially pathogenic intestinal microorganisms might be beneficial to human health.
- A cause and effect relationship has not been established between the consumption of *Lactobacillus reuteri* ATCC 55730 and decreasing potentially pathogenic intestinal microorganisms.

## DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1691). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

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

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## APPENDICES

### APPENDIX A

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

The Regulation 1924/2006 on nutrition and health claims made on foods<sup>4</sup> (hereinafter "the Regulation") entered into force on 19<sup>th</sup> January 2007.

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

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

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

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

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

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

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

#### ISSUES THAT NEED TO BE CONSIDERED

##### IMPORTANCE AND PERTINENCE OF THE FOOD<sup>5</sup>

Foods are commonly involved in many different functions<sup>6</sup> of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

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

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

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:

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<sup>4</sup> OJ L12, 18/01/2007

<sup>5</sup> The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.

<sup>6</sup> The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

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

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

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

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

#### **WORDING OF HEALTH CLAIMS**

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

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

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

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

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

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

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

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

## TERMS OF REFERENCE

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

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

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

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

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

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

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

## **APPENDIX B**

### **EFSA DISCLAIMER**

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

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