



Position Paper on Probiotics

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Abstract

Probiotics are live microorganisms which when administered in adequate amounts confer a health benefit on the host. Probiotics, used to supplement normal daily nutrition, are therefore an important element in consumer health and should be made available as widely as possible. The regulatory status of probiotics has yet to be established on an international level. That is also the finding of a report by the Food and Agriculture Organization of the United Nations and the World Health Organization (FAO/WHO) evaluating the health and nutritional properties of probiotics. Different European countries currently have differing national regulations for probiotics. This position paper asks for harmonized legislation on the use of probiotics as food supplements, so as to promote free trade in probiotics between European countries. In a draft proposal on the regulation of food health claims, the European Commission has already recognized probiotic bacteria as having the status of nutrients. In addition, probiotics in powder, capsule or tablet form fall within the definition of 'food supplements' found in the European Food Supplements Directive (2002/46/EC). So far, this legislation has only been elaborated for vitamins and minerals. This position paper asks for this legislation to be expanded to include probiotics. Given that the Food Supplements Directive specifies safety and quality requirements for food supplements, it is these aspects of probiotics that this position paper particularly discusses.

Introduction

NPN (Natuur- & gezondheidsproducten Nederland) is the Dutch sector association for producers, wholesalers, importers and distributors of natural food and health products, such as vitamins, minerals, herbal preparations and natural cosmetics. NPN has approximately 100 members and, as regards sales revenue, represents at least 80% of the companies that put health products onto the Dutch market. The aim of this position paper is to achieve greater clarity regarding the status of probiotics as food supplements and to arrive at a harmonized set of European regulations so that probiotics clearly fall within the scope of the Food Supplement Directive in terms of safety and quality.

Current situation

Different European countries have differing national regulations for probiotics. This interferes with free trade and distorts competition and thus directly affects the workings of the internal market. In the Netherlands, probiotics in capsule, tablet or powder form are regarded as food

supplements and therefore fall within the scope of the Warenwet (Commodities Act); no notification or registration is required for these products. In Germany, however, the same probiotic products can have the status of pharmaceutical products. There is therefore a considerable need for harmonization of European legislation on probiotics considered as food supplements.

Considering the significant rise in the annual consumption of probiotic products worldwide, it is important that such products are correctly labeled and that the probiotic strains are well-documented regarding safety and functionality. Studies on the quality of commercial available probiotic products clearly indicate the need of such regulations¹.

NPN's position

The opinion of NPN is that probiotics, both as a part of the diet and in the form of food supplements, have to be regarded as food. As food supplements, probiotics should be freely marketable and obtainable in all countries of the EU without any form of obligation to register them. The European Commission must therefore create legal frameworks to harmonize the legislation on probiotics as food supplements. The current EU Food Supplements Directive 2002/46/EC already states that specific regulations must be laid down for nutrients other than vitamins and minerals. Given that probiotics fall within the definition of food supplements as used in this Directive, an expansion of this legislation to include probiotic food supplements would be the next logical step. Regulation of this kind can help to guarantee the safety and quality of these products.

What are probiotics?

Intestinal flora

The human intestines contain an average of approximately 10^{14} microorganisms, made up of more than 400 different species. This microflora has a symbiotic relationship with the host organism and protects the body against infections, assists digestion, produces nutrients, and plays an important role in the immune system. A good microfloral balance in the intestines is essential for these functions and for the health of the host. When the intestinal flora is in balance, both beneficial and harmful microorganisms (pathogens) are present. This balance can be disturbed by factors such as the use of antibiotics, stress or an unbalanced diet. Disturbing the balance creates a risk that the beneficial intestinal bacteria will be suppressed and that the pathogenic bacteria will become dominant.

Probiotics

According to the definition contained in the report by the Food and Agriculture Organization of the United Nations and the World Health Organization (FAO/WHO), probiotics are: *Live microorganisms which when administered in adequate amounts confer a health benefit on the host*².

The term 'probiotics' should only be used for products if:

1. The bacteria strains in the product are able to survive the stomach acid and bile, so that they reach the intestines alive in adequate numbers.
2. The bacteria strains have health improving features.
3. The probiotic activity is guaranteed throughout the entire production process, storage period and shelf life of the product.

Most probiotics consist of lactic acid bacteria, such as Lactobacilli, Lactococci and Bifidobacteria. These bacteria are also found in large quantities in the human intestines. However, several strains of Streptococci, Enterococci, Pediococci, Bacilli and some yeasts are also regarded as probiotic strains.

Why probiotics?

Due to improvements in hygiene, human beings today are exposed to bacteria much less frequently than was formerly the case. This is certainly true for the undesirable (pathogenic) bacteria, but it also holds for useful, protective bacteria. Bacteria have been consumed by humans for many years, not only because they are used in traditional preparations such as yogurt, cheese, sauerkraut, sausage, etc., but also because they occur naturally in various foodstuffs. These foodstuffs contain bacteria that are now classified as beneficial to health. At present there are strict rules governing food safety. These products are therefore fermented under stringently controlled, hygienic conditions. Only a limited number of selected bacteria are as yet used to produce these products and in some instances products are no longer fermented but acidulated. In addition, more and more products are pasteurized or sterilized at the end of the production process, or are subjected to other purification steps, which destroy these beneficial bacteria. As a result of all these changes the human body comes into contact with far fewer bacteria (both in terms of quantities and variety of species) than formerly. This has the advantage, of course, that many diseases caused by pathogenic bacteria can be avoided, but it also means that the human being comes into natural contact with beneficial and useful bacteria to a much lesser extent than was formerly the case.

Probiotics support the microbial balance in the intestines of the host and are therefore recommended as supplements to normal everyday nutrition. In addition, they are also used for their health benefits and are attracting a great deal of interest from scientists, as is apparent from a report of a FAO/WHO expert group in which the various potential health and nutritional benefits of probiotics are evaluated³.

In principle, the situation with regard to bacteria is the same as that of vitamins, minerals and fibres: as the human being doesn't consume enough of them from food and while the body cannot produce these substances itself, supplements are a desirable addition to normal nutrition.

Food Supplements Directive

Probiotics can occur as either mono- or multispecies of various bacterial strains in powder, capsule or tablet form or in food (e.g. in dairy products). The last of these forms (i.e. as an ingredient of food) is not covered by this position paper. The other variants fall within the definition of food supplements to be found in the Food Supplements Directive 2002/46/EC (article 2a): *'food supplements' means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities*⁴.

To date, the Food Supplements Directive has only been elaborated for vitamins and minerals: the intention is to guarantee and harmonize the safety and quality of these supplements at European level. In Consideration 6 of the Directive it says: *'There is a wide range of nutrients and other ingredients that might be present in food supplements including, but not limited to, vitamins, minerals, amino acids, essential fatty acids, fibre and various plants and herbal extracts.'* In Consideration 8 it says that specific regulations should be laid down concerning nutrients other than vitamins and minerals or other substances with a nutritional or physiological effect used as ingredients of food supplements, on condition that adequate and appropriate scientific data on these nutrients becomes available. An expansion of this legislation to include probiotics is therefore an important logical step which will ensure the required quality and safety standards to the benefit of the consumer. Besides it will stimulate the free trade of these products in Europe to the benefit of the industry.

Probiotics are already recognized as nutrients by the European Commission in the proposal for the regulation of nutrition and health claims made on foods. The definition of nutrients used

therein shows that the proposal is intended to cover not only traditional nutrients such as proteins, carbohydrates, fat, etc., but also other substances with a nutritional or physiological effect, for example antioxidants and *probiotic bacteria*⁵.

Some requirements for the use of probiotics have already been formulated in legislation. Firstly, the regulation on animal nutrition (directive 93/113/EC) has set down requirements for the use of microorganisms⁶. Secondly, the Scientific Committee on Food has recognized the necessity to come to a decision on the use of probiotics in infant formulae and follow-on formulae, but has no reason to object to the addition of probiotic bacteria to follow-on formulae, provided requirements on safety and quality are fulfilled⁷. From these developments it can be concluded that probiotics are already recognized as being part of the food-chain and this increases the need of such regulation for every-day consumed food supplements even more. Expansion of the Food Supplements Directive with probiotics would guarantee a high level of consumer protection, since this directive lays down requirements for the safety and quality of food supplements. The remainder of this position paper therefore deals with the safety and quality aspects of probiotics.

Safety and Quality

A probiotic must first and foremost be safe. The long history of safe use of probiotic bacteria is the best evidence for the safety of probiotic products. The probiotic bacteria used do naturally occur in the human intestines. Besides these bacteria have been consumed in enormous quantities, primarily through consumption of fermented foods, already for many centuries. A list of microorganisms used in the production of various foodstuffs has been drawn up by the International Dairy Federation and the European Food and Feed Cultures Association. This list shows the year (with reference) since which the microorganisms have been used without safety problems. This list includes the most commonly used probiotic bacteria^{8,9}. In case a documented history of safe use is not available for a probiotic bacterium, safety studies as laid down by the Novel Foods Regulation (97/258/EC) are applicable within the EU¹⁰.

Also the report by the FAO/WHO expert group cites the best evidence for the safety of Lactobacilli to be their long history of safe use, without established risk to humans³. It states that no pathogenic and virulence properties have been found for Lactobacilli, Bifidobacteria and Lactococci. The report does, however, recognize the need to lay down criteria for the safety of probiotics, and in a follow-up report several such criteria are mentioned². Even the Scientific Committee on Food considers the use of probiotics as safe by having no objection to the addition of these bacteria to follow-on formulae, provided safety requirements are fulfilled⁷. A document of the European Commission describes the possibility of introducing a system for microorganisms similar in concept and purpose to the GRAS (Generally Recognized as Safe) status used in the USA¹¹.

Considering the reports of the FAO/WHO^{2,3}, the European Commission¹¹ and the Scientific Committee on Food⁷ we come to the following quality and safety requirements for probiotic food supplements (see table 1).

Table 1: Requirements for the safety and quality of probiotic food supplements

	Requirements
Food safety	Produced conform relevant hygiene and quality control rules (HACCP) Probiotic bacteria should have: <ul style="list-style-type: none"> - a long history of safe use - no pathogenic properties - no virulence properties - no toxin production - no acquired antibiotic resistance
Labeling	Conform European regulations Should contain the identity of each bacteria strain Should contain the quantity of the living bacteria in total, guaranteed until the 'best before' date.
Health claims	Conform national regulations (in future European regulations)

In the great majority of controlled studies with probiotics performed with children and adults, no adverse effects have been observed, not even in studies in which probiotics were administered to humans suffering from a severely compromised immune system^{12,13,14,15}. In addition, probiotics were not found to have any toxic effects in animal tests¹⁶. Most probiotic supplements contain approximately $1-5 \times 10^9$ viable bacteria per daily portion. If this figure is compared with the number of bacteria in the intestines (10^{14}), it is clear that there is no risk of overdose. A small portion of yogurt can also contain a similar number of bacteria.

In spite of the fact that probiotics generally make a positive contribution to the health of the host, a few cases of adverse effects are known^{17,18,19}, although it is unlikely that the probiotic bacteria were the causative agents in these cases^{19,20}. Also the FAO/WHO report quotes a study that found no increase in the risk of adverse effects with probiotics²¹. Nevertheless the safety of probiotic organisms is an important criterion for the use of these strains into food products. It is the responsibility of the manufacturer to demonstrate the safety of the strains used. Given the large amount of probiotic bacteria that have already been consumed for many years without any problems and the many studies that have demonstrated their health benefits, it can be confidently stated that the advantages of consuming probiotics far outweigh any risks.

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