ECARF Seal of Quality

Criteria for allergy-friendly probiotics (food supplements) for persons with allergic rhinoconjunctivitis and allergic asthma

BACKGROUND

The number of people affected by hay fever is growing from year to year. As much as 30 percent of the population in industrialised countries now suffer from one or more allergic diseases, such as hay fever, asthma or allergic skin problems. Current therapies often have side effects, such as dry mucous membranes in the mouth and drowsiness. Probiotics represent a new approach in the treatment of allergic rhinitis, e.g. hay fever.

"Probiotics are live microorganisms which when administered in adequate amounts confer a health benefit on the host" (WHO/FHO definition 2001).

These live microorganisms are resistant to the stomach's hydrochloric acid and reach the intestine, where they are said to have a positive effect when taken as a dietary supplement. The best-known probiotic food supplements include the genera Lactobacillus, Bifidobacterium, Enterococcus and Enterobacteriaceae or certain yeasts.

It is neither a very high dosage nor a very high number of bacterial strains that determines the effect of a probiotic. What is more important is to select the appropriate bacterial strains for the specific health condition and to take them in the scientifically tested dosage, just like medication. Depending on the amount consumed and taking into account the expiration date, most products require a regular, usually daily dose of 10^8 to 10^9 probiotic microorganisms in order to develop a probiotic effect in the human organism.

The test criteria are based on the question of whether the intake of a probiotic food supplement reduces allergic symptoms in people with allergic rhinitis or allergic asthma when exposed by inhalation in an exposure chamber to pollen, animal hair or mites under precisely defined and repeatable conditions.

1. TEST CRITERIA

1.1. Required product properties

Species:

- Lactobacillus
- Bifidobacterium
- Saccharomyces boulardii yeast fungus
- Escherichia coli Nissle 1917

Probiotic food supplements contain both individual strains of one species and mixtures of several strains and species.

The above-mentioned species represent a selection of the species described in research to date. However, the award of the ECARF seal is not limited to the presence of these species. The latest scientific studies and tests are taken into account on an ongoing basis.

The following procedure must be followed when producing probiotics:

- **Fermentation** begins with the careful selection of a specific probiotic strain that has been documented with regard to its genetic identification, viability and stability prior to the development process. This should include the correct scientific name, the population density of the probiotic strain and specific activities relevant to the effects they are claimed to have. These specifications are used to define the products and product categories which are claimed to have certain effects. The proof must be based on scientific evidence obtained from human studies.
- Various methods can be used in the next step, **freezing**, such as filling the cryoprotective concentrate into cans, pelletising the concentrate or **freeze-drying (lyophilisation)**. The cells are processed at low temperatures, which limits possible damage to their structure and metabolites. The dried material is then processed into a powder of a specific particle size and density, depending on the user's requirements. Finally, additives or fillers can be added to the pulverised material.
- In **bioprocessing**, a specific procedure is developed for the propagation and extraction of each strain before it is submitted for scaled production. Each batch is produced and tested to the highest quality standards to ensure compliance with the strictest regulatory requirements.

1.2. Testing the efficacy in a subject test in the exposure chamber

Subjects with a history of allergic respiratory disease (rhinoconjunctivitis or rhinitis, allergic asthma) who have had the condition for at least two years are tested - as far as possible - outside the clinically relevant exposure period (pollen drift) or in the case of year-round exposure (mites, animal hair, certain moulds) throughout the year in an allergen exposure chamber **under the following conditions:**

- Double-blind treatment with probiotic or placebo under standardised conditions

A provocation with the relevant allergens is carried out before and after using the probiotic in a double-blind manner in an exposure chamber. The probiotics must bring about a reliable decrease in symptoms (nasal, conjunctival and bronchial symptoms, summarised in the so-called Total Symptom Score) when tested on persons with confirmed respiratory allergy (allergic rhinoconjunctivitis or rhinitis and allergic asthma). This is compared to exposure at the same exposure level (e.g. same amount of pollen/m³ air) at the same temperature and humidity level over a period of at least two hours.

The ECARF Seal of Quality is awarded if, in controlled tests in an exposure chamber, the symptoms (Total Symptom Score) are statistically significantly reduced when using the probiotic compared to exposure without taking a probiotic.

2. QUALITY CONTROL AND COMPLAINTS MANAGEMENT

The manufacturer has established a functional system of quality control that effectively documents, processes and follows up complaints. The following is also ensured:

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- The manufacturer's contact details, such as the address, telephone number and/or email address, are clearly visible on the product packaging;
- Consumer complaints are handled and followed up in an appropriate manner by qualified and experienced personnel of the manufacturer;
- The assessment of consumer complaints and, if applicable, any inferred areas of improvement are reapplied to product quality and safety. The manufacturer agrees to make this data available to ECARF on an ongoing basis.