QUALITY AND SAFETY STANDARDS

1995 EDITION

NPQAA

NATURAL PRODUCTS
QUALITY ASSURANCE
ALLIANCE

Probiotics

An initial quality assurance survey was answered by only one manufacturer. This document is being re-submitted to industry members in an ongoing attempt to increase communication and awareness with regard to safety standards and quality in manufacturing and labeling.

All comments and suggestions can be written or faxed to NPQAA. If a copy of this document and a package of information should be sent to anyone, please let us know.

Definition and Range of Products

Probiotics is a dietary supplement category which describes products delivering beneficial microorganisms into the human body, where they inhibit the growth of dangerous microbes by competitive exclusion. These dried or liquid microbial concentrates are available as freeze-dried powders, capsules and fermented liquids.

The application of germ management in systems other than the human body is gaining recognition and popularity, as well, particularly in the realm of organic agriculture. Microbial management is relevant to fertilization, insect control, silage inoculation and bioremediation. There is increasing use of microorganisms in systems of waste management and environmental protection.

Good Manufacturing Practices and Certification Standards

All organisms should be proven to be safe for use in humans. The trade group is working to establish an "approved list" of safe microorganisms.

Certification that products are free from pathogens and harmful chemical contaminants is essential.

Label and Claims Standards

Human oral probiotics have established standards (see National Nutritional Foods Association Probiotic Labeling Standard, July 1989). General NNFA labeling standards have also been adopted, and participation in the NNFA TruLabel program is mandatory for NNFA members.

Trade Associations

Twenty companies and laboratories have been represented at numerous meetings of a Probiotic Interest Group within the National Nutritional Foods Association. As members of the NNFA, members of the Probiotic group are obligated to uphold the NNFA's Code of Ethics, to participate in the TruLabel program, and to conform with the NNFA's ComPLI program.

National Nutritional Food Association Probiotic Labeling Standard, July, 1989

1. Introduction

The Committee for Product and Label Integrity of the National Nutritional Food Association (NNFA) has adopted this labeling standard for probiotics to assure retailers and consumers of the quality of the products sold in our stores. The standard requires that distributors of probiotics provide information on the label giving the quantity and identity of living microorganisms present, a suggested final date for use (or *"Better If Used Before"* date), a statement of storage requirements and a listing of additional ingredients.

2. Viable Cell Count

2.1 The label shall contain a statement of the minimum number of viable cells or colony-forming units (CFU's) per unit of measure such as capsule, tablespoon, gram, etc.

2.2 In mixed cultures, the label statement shall include minimum numbers for each species present over the guaranteed shelf life of the product. The method used for this enumeration shall preferably be a published method; if not published, it shall be made available to NNFA upon request.

2.2.1 If a manufacturer wants to protect a proprietary mixture, a label statement guaranteeing potency of all species to a final date will be acceptable, provided that actual numbers for each species are submitted to NNFA when required for testing purposes. All species shall be listed on the label in decreasing order of numbers present.

2.3 An expiration date or a suggested final date for use shall be provided on the label. The manufacturer/distributor shall assure minimum viable cell numbers for each species present up to this date when proper storage conditions are provided.

2.4 Laboratory data of cell numbers and species for each lot of product shall be maintained by the manufacturer/distributor and shall be made available upon request.

3. Species Identification

3.1 Microorganisms included in any probiotic shall be identified to the genus and species level, using a method of identification which conforms to Bergey's Manual of Systematic Bacteriology. Such terms as *lactic acid bacteria* or *lactobacillus species* shall not be used.

3.2 The manufacturer shall certify the absence of pathogens in 500 mg. of product, a total yeast and mold count of not more than 100 mg.per gram and a maximum non-claimed bacterial count of 10,000 mg./gram.

3.3 The long-term constancy of the culture organism(s) shall be guaranteed to the distributor by the actual manufacturer of the materialAny mutation or other change in the strain must be detected and reported. Distributors or private labelers shall require proof of genetic constancy at least annually from their suppliers.

To ensure proper labeling of products, the Probiotic Interest Group is developing procedures for species identification. The first species to be considered is Lactobacillus acidophilus. The methods to be used include DNA analysis, API and lactic acid enantiomer determination. Procedures will be adopted to implement product testing by these methods.

4. Storage Requirements

4.1 The required storage conditions for reaching the guaranteed shelf life shall be listed on the label.

4.2 If refrigeration is not required, a statement to that effect should be present on the label.

5. Other Ingredients

Additional materials present, such as lactose, milk powder, starch or modified starches, etc., shall be included on the label in descending order of quantity present. A dried product shall contain no more than 7% moisture.

TruLabel/NNFA

NNFA's Probiotic Interest Group, under the direction of the Committee for Product and Label Integrity, has adopted a method for the enumeration of lactic acid bacteria.

The protocol is the **International Dairy Federation Method 117A:1988** with the following modifications:

1) Use a non-acidified MRS medium with 0.05% cysteine.

2) Prepare a 1:10 suspension of the sample with peptone diluent at 35 C; stomach for 2 minutes.

3) Preincubate 30 minutes at 23 C; restomach.

The International Dairy Federation

Square Vergote 41, B-1040 Brussels
Belgium

The International Dairy Federation Standards were developed by a joint IDF/ISO/AOAC Group of Experts (Group E44) and was aproved for publication as a final standard at the IDF Annual Sessions in Helsinki, Finland, in September 1987.