



INTRODUCTION TO PROBIOTICS

Definition

Although currently there is no regulated definition of “probiotics”, Attune Foods supports and adheres to the definition put forth by the Food and Agriculture Organization (FAO) of the United Nations, the World Health Organization (WHO), and the International Probiotics Association (IPA) as:

Probiotics are “live microorganisms which when administered in **adequate amounts** confer a **health benefit** on the host”¹

It is important to note that a particular bacterium only qualifies as a “probiotic” to the extent that its effects have been **scientifically substantiated and documented**², preferably through published, peer-reviewed human clinical trials. It is also worthwhile noting that while probiotics are “live cultures”, **the vast majority of live cultures are not probiotics**. An “adequate amount”, as referred to in the FAO/WHO definition, is generally regarded in the academic and scientific communities as the same dose administered at the same interval as in the clinical trials that support the benefits attributed to a probiotic strain.

Nomenclature (Kingdom, Phylum, Class, Order, Family, Genus, Species, **Strain**)

Probiotics are specific **strains** of a particular species of bacteria. This is an important distinction to the extent that many species are commonly mistaken as probiotics, whereas only a very small number of strains of a particular species actually qualify for the definition. For example, there are scores of different strains of the widely known species, *Lactobacillus acidophilus*, but only a handful of strains, including *Lactobacillus acidophilus* NCFM, are defined as probiotics.

*Taxonomy of the probiotic *Lactobacillus acidophilus* NCFM:*

Lactobacillus (genus)
Acidophilus (species)
NCFM (strain)

¹ www.fao.org/es/ESN/Probio/probio.htm

² <http://internationalprobiotics.org/consumers.aspx>



SELECTION OF ATTUNE FOODS' PROBIOTICS

Attune Foods is at the forefront of utilizing the most efficacious, researched, and stable probiotics in products that not only act as efficient delivery mechanisms for daily wellness, but also are healthy, convenient, and great tasting. This requires ongoing research, development, and rigorous evaluation of the efficacy and stability of candidate strains.

Demonstrated Efficacy

The first filter through which a candidate strain is passed is the degree to which its health benefits have been substantiated. In this regard we evaluate 1) the quantity of published, peer-reviewed clinical trials for a strain, 2) the quality of the research and the design of the trials, and 3) the depth of the trial's results and conclusions.



Demonstrated Stability

There are two primary factors that negatively influence the viability of all probiotics: increasing **temperatures** and increasing **water activity** (which can be thought of as the amount of water in a certain volume). As such, it is imperative to understand

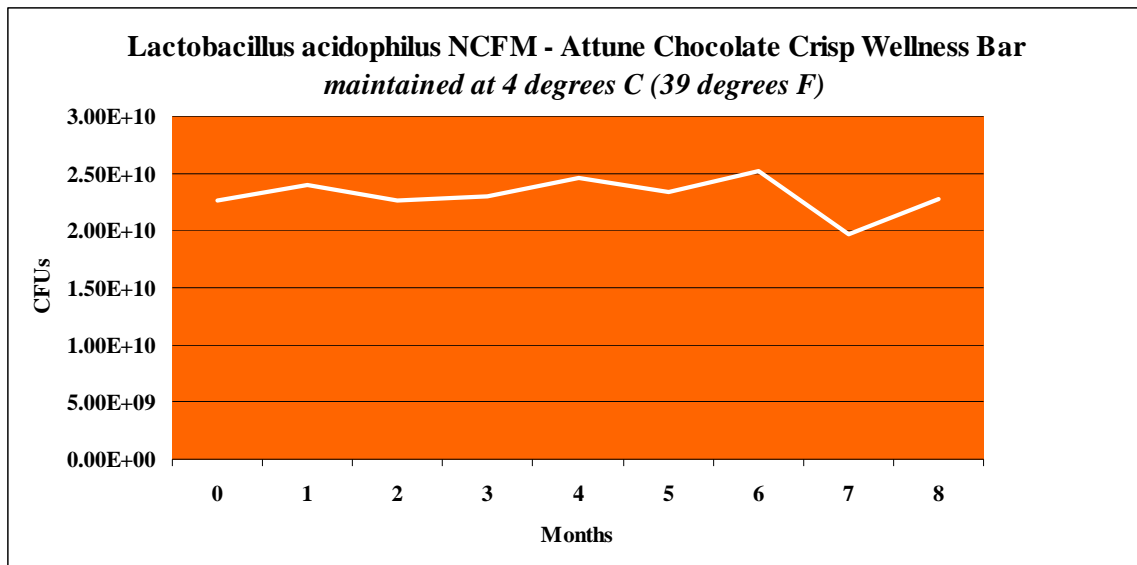


how individual strains react under varying conditions, including the manufacturing environment, the chemistry of the product, and the expected conditions in the supply chain, in order to ensure that an efficacious product can be delivered to the consumer.

Thus, the second filter through which a candidate strain is passed is the degree to which it remains stable in our products over time. This involves a two-part process that begins with inclusion of the candidate strain in sample products manufactured in a laboratory setting. Two batches of the resulting samples are maintained at 4-5 degrees and 23-25 degrees Celsius. Beginning at time zero and monthly thereafter, the sample batches are sent to a laboratory for enumeration of viable cells.

If a candidate strain demonstrates stability over a sufficient period of time (see *Figure 1*) in products manufactured in the laboratory, the candidate strain is then evaluated in real-time manufacturing. The testing process is similar to that for samples manufactured in a laboratory, except that samples are sent to two laboratories that are independent of one another. Only in the event that enumeration results are duplicated within a high degree of confidence does a candidate strain then qualify for inclusion in Attune Foods' products.

Figure 1: Actual Stability Data for Lactobacillus acidophilus NCFM³



³ From enumeration results performed on bench top samples of Attune Chocolate Crisp Probiotic Wellness bars, in conjunction with Danisco USA Inc.



ATTUNE FOODS' PROBIOTIC STRAINS

Our Strains

Attune Foods includes a blend of three different Kosher and GRAS certified probiotic strains that were selected based on their superior clinical efficacy and safety as well as demonstrated stability in our bars. These include:

Lactobacillus acidophilus NCFM
Lactobacillus casei Lc-11
Bifidobacterium lactis HN019

Delivering an Effective Dose

We dose our bars to ensure that every bar delivers a minimum of 8.5 billion colony forming units (CFUs) **throughout the shelf life of the bar** and that each strain is dosed at the **same or greater quantity as they were administered in successful clinical trials**.

To further ensure that our products deliver an efficacious dose of probiotics throughout the shelf life of the bar, we've chosen ingredients (chocolate and yogurt coating) that have relatively low water activities. More importantly, we've chosen to maintain our products in a refrigerated environment (33 to 42 degrees F) throughout the entire supply chain. This affords us better environmental control of the product, eliminates the potentially extreme variances in temperature in a non-refrigerated supply chain, and ultimately allows us to deliver an efficacious dose of probiotics to our consumers.

Efficacy & Benefits

The *Lactobacillus acidophilus NCFM* and *Bifidobacterium lactis HN019* are among the most extensively studied strains of probiotics in the world and were selected for their ability to thrive in our bars and for their supporting clinical data, which is robust in terms of both the quality of the underlying research and the positive effect that they have demonstrated on human health.

Specifically, the NCFM strain has been shown to confer outstanding benefits related **gut health**⁴, given in part to its unique ability to survive passage through the gastrointestinal tract and to adhere to intestinal mucosa. The HN019 strain has been shown to **improve immune function**⁵ and may be linked to a risk reduction of some types of enteritis and non-gastro-intestinal diseases.



⁴Partial list of publications relating to NCFM

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