Formulating with Nutraceuticals

The formulators’ question used to be, what can be taken out of a product to make it good for the consumer? The food industry was taking out the fat, taking out the tropical oils (saturated fats), taking out the carbs, taking out the sugar, and so on. Many of these products with components that have been reduced or taken out have gone by the way because they just did not taste good. No matter what the benefit, short of giving you eternal life, it won’t sell if it doesn’t taste good. The formulators’ challenge now is: What can we put into the product to make it better for the consumer? Then: How do we do that while keeping the consumer safe and, all the while, remaining friends with the FDA?

Some specific components are still being taken out of products or reduced such as trans fats and sodium. The science is pretty clear on the benefits of reducing our intake of these specific components. As for additives that make food healthier, the science is not always that clear, and the answers are not always simple to find. This is when you need to do your research. But, the product still needs to taste good.

Do Your Homework

The list of ingredients claiming health benefits, or nutraceuticals, seems to be growing longer every day. You have ingredients which claim health benefits such as: rich in antioxidants, high in fiber, prebiotic, probiotic, provides enzymes, inhibits enzymes, etc. Several critical questions need to be asked when you look into using them. Is the ingredient recognized as safe for use in food or GRAS? How much of a particular ingredient do you need to use to get an effect? Is the ingredient affected by processing, such as baking? Once you put these ingredients into food, what can you say about them and their effects? How much science supports what the claimed effect is?

First thing’s first, is it GRAS? An ingredient is considered “generally recognized as safe,” or GRAS, if it has been in common use prior to 1958 (experience) or if it has been determined so through scientific means. The GRAS system is voluntary. Interested parties submit ingredients along with supporting safety information to the FDA for determination of whether they are “GRAS.” Interested parties can also do a self-affirmed GRAS. This is where the interested party, person, or company compiles data regarding the use of the product and the opinions of qualified experts to determine if it is GRAS. The FDA can challenge this status; however, if the status is not affirmed by the FDA, it could lead to the product being deemed adulterated and trigger a possible recall.

When determining whether a product is GRAS, its level of use may have a bearing on this determination. You need to do your homework on what level of an ingredient is necessary to get the effect the supplier claims. The old adage, “If some is good, then more must be better,” does not always apply and in some instances this can be dangerous. After all, you are working with ingredients that can have significant medical impacts. To this end, it is important to know what you are dealing with.

An example of a nutraceutical gaining popularity and usage is omega-3. There are three main types of omega-3, the first two, derived from fish, are eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). The third, alpha-linolenic acid (ALA), comes from plants such as flax or chia. All three have different functions in the body. The FDA recommends a daily value (DV) of 160 mg and no more than 3 g of DHA or EPA omega-3 consumed per day due to possible adverse effects on excessive bleeding time and LDL cholesterol levels. For ALA, the DV is 1.6 g because it is not used as effectively by the body.

Claims of Functionality

Most of these FDA-approved claims, daily values, RACC’s (Reference Amount Customarily Consumed), and levels are found in FDA code 21 CFR 101.xx.(-). Besides the regulations, the FDA also has guidelines and responses to petitions for claims and Federal Register documents that contain necessary information. The internet is a good place to start the search, for example www.cfsan.fda.gov or the old reliable Google.com.

The FDA rules on making claims such as “good source,” “excellent source,” or “high in” can be found in 21 CFR 101.12 or 13. Typically, if the food contains 10 percent of the daily value in a RACC, the claim of “good source” can be made. For the claim of “excellent source” or “high in,” the food needs to contain 20 percent of the daily value of the nutrient. Finding the daily value for nutrients not listed on the nutrition facts panel can be challenging, although they can be found in responses to petitions, guidelines from the FDA, and the Federal Register. When making a claim, you also need to consider the RACC for your particular product—21 CFR 101.9 will get you started down this path. In addition, the American Institute of Baking has an excellent labeling department to help you with this.

Finding information directly related to a certain ingredient can be as difficult as tracking down the information from the FDA. For levels of use or for the level of the active component in which you are interested, especially with the newer and more exotic ingredients, information can be hard to come by. Looking for specific information on application, heat stability, tolerance to different pH ranges, and other conditions can be even more difficult to find. For the developer this can cause frustration when trying to stay on the cutting edge of innovation.
We use these special ingredients because of the manufacturer’s claimed functionality. The developer needs to sort out to what degree these claims are valid. With luck, the manufacturer will have compiled the scientific studies to support their claims. If not, start tracking down science to support their claims and find out what claims can be made. This can be very time consuming as the newer the ingredient is to the market, often times, the more difficult it is to find the supporting data for the claimed effects.

**Favorite Nutraceuticals on the Market Today**

Here are a few of the many benefits these new ingredients can bring to your product. Antioxidants have been a popular component for the last few years. Only now are you hearing talk of quantifying the level of antioxidants in a product. Antioxidants can be very sensitive to how they are processed and stored. In baked products, where the finished product is exposed to a significant amount of heat during baking, some antioxidants such as Vitamin C are destroyed. To measure a product’s antioxidant levels the industry is moving toward a test like the ORAC which measures the level of antioxidants by measuring the level of oxygen that the product reacts with. It is probably not 100 percent accurate, but it does give the developer and the consumer a relative number to understand the level of antioxidants in a product.

Another popular nutraceutical being added to products are omega-3s, as mentioned above. They help to keep your joints moving by minimizing stiffness and they also provide heart health benefits. Some sources say they can also help with mental acuity. This is an example of when research is needed to find out what scientific studies have been done to substantiate such a claim. You need to also do research on the different types and sources of omega-3, as well as their functions.

More and more these days you are reading about prebiotics. Prebiotics are food for the good bacteria—bifido bacteria—that live in your digestive track. One benefit of prebiotics is that they often count as fiber on your nutritional facts panel. A common source used for prebiotics is FOS—fructo-oligalsaccharides—which can come from various sources. In baking applications they are easy to use because they function similarly to sugar and can have a nice level of sweetness.

A healthy, well-fed digestive track has many benefits to the individual and thus the increased interest in prebiotics. A healthy digestive track makes a person less susceptible to the bad bacteria accidentally ingested due to the sheer number of good bacteria in the gut. A healthy colony of good bacteria is also thought to lower the pH in the gut, which in turn helps the body absorb more calcium for building stronger bones. Now, again the old adage, If some is good, more must be better. This is not necessarily so for prebiotics, either; too much of a prebiotic can cause an individual to have much more flatulence.

Probiotics are actual living bacteria, similar to those you have in your gut. These are much more tricky to incorporate into a product because they are living. A popular place you will find probiotics is in yogurt. This is because they are the right kind of medium to support the bacteria and are kept refrigerated.

Some other ingredients coming out on the market are those claiming to lower the glycemic index of foods by interfering with the enzymes that break down starch during digestion. Some questions these ingredients raise are: Does the amount of calories the food normally provides decrease as well? Does the lower glycemic index decrease the satiety of the individual? Does the food start to function more like a prebiotic in the gut? These are all exciting questions with potentially significant health implications and, in turn, great marketing potential. Again, claims need to be supported by science. You need to do your due diligence to make sure they are grounded in science and not merely marketing zeal.

Nutraceuticals offer a great opportunity to enhance products and contribute to the health of the consumer although it does go beyond just putting them in your product. You need to know what it is you are adding, how much to add to get a benefit, and then how to communicate that benefit to the consumer.

David F. Busken is manager of research and development for Oak Sate Products, a copacker of cookies and bars. He grew up in a full-line retail bakery and, in all, has more than 30 years of baking and development experience. Busken can be reached at david.busken@oakstate.com.