Department of Food Science

Food Safety

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Herbal Foods

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Botanicals as Foods

What makes a plant a food anyway? Botanicals are materials of plant origin, often referred to as herbs. Many are reputed to impart special benefits to the user. Often the plant is obscure to the food industry. The 60's saw the growth of herbal teas produced by many entrepreneurs. The trend continues with rose petals used in a sorbet, kudzu blossoms added to jelly, or even an attempt to use mistletoe juice. By the way, the mistletoe juice is toxic! Where does one turn to know if the material is fit for human food use?

A botanical is a medicine or preparation made from a plant. Many botanicals have a history of medicinal use, but little or no history of food use. One visiting a market in China or Hong Kong is struck by the array of botanicals, dried or pickled, carefully preserved. The folk healers of Africa also have large stocks for sale.

FDA takes a couple of approaches to dealing with these products. First, those products for therapeutic use fall under drug provisions of the law. However, just removing the therapeutic claims may not automatically convert these products to foods. FDA has tried to take the approach that the botanicals must have a history of "common use in food" in the U.S. This standard, however, was struck down by a court in 1983 which said that FDA could

not limit the food's common use to consumption in this country alone.

A botanical is generally recognized as safe (GRAS) if it has a history of use in food that predates 1958. FDA will determine if there are reported adverse effects associated with consumption of the substance, including long-term toxicity or carcinogenicity. This history of use in food must show that it was used as a food ingredient, not as a drug, tonic, or folk remedy. Essentially, the burden of determination of safety for GRAS foods is on FDA.

A person wishing to use this type of product in food should be able to provide proper botanical identification of the plant by genus and species with information concerning the specific part of the plant used, the amount and method of consumption and documentation of the history of consumption prior to 1958. A GRAS affirmation can be requested of FDA. Choosing to proceed on the basis of an independent GRAS determination without FDA concurrence runs the risk that the substance may be found not to be GRAS and thus be an illegal food additive. A botanical with no history of common use in food prior to 1958 requires a food additive petition to FDA.

The method of consumption of botanicals is important. An old adage says that "the dose makes the poison." Consumption of small amounts of these products may reveal no public health concerns. However, greatly increasing consumption, making an extract or using another part of the plant may change the safety of the product. Assessing this hazard is expensive and time consuming. It can be assumed that a change in form or method of use would require filing a food additive petition to FDA.

Speciality Products

There has been an increase in specialty products made with herbs. These include:

- 1. Herbs in vinegar
- 2. Herbs in oil

The popularity of these products is based on changes in the diet toward pasta and low cholesterol alternatives.

Herbs in Vinegar

Vinegar is considered to be an acid food. The definition becomes muddied as herbs are added to it. As long as a sprig or two are added to the vinegar, and (1) they become fully acidified throughout, and (2) the herb did not contribute to a change in the acidity of the vinegar solution, the product may be considered an acid food. However, as the amount of low-acid food (the plant material) increases, it begins to have an effect on the acidity of the vinegar. At this point, the product is no longer a "vinegar" but an acidified herb.

This is an important distinction for several reasons:

1. The public health implications of acidifying a low acid food (acidified herb) are greater than simply packaging an acid food. A mistake in the proper acidification of the herb could cause botulism, a deadly disease.

- 2. Full compliance with 21CFR 114, the regulation governing acidified food is more costly than packaging an acid food. The product will require a scheduled process to be submitted to FDA and it will have to be processed under the supervision of a certified supervisor who has successfully completed a course at an FDA-approved school. As an alternative, the product can be refrigerated or frozen.
- 3. The acidity of the product may require monitoring using an electronic pH meter to assure safety.

Either way, it is necessary to make sure the plant material is submerged in the vinegar long enough to become acidified to the point that its internal pH is 4.6 or below.

Herbs in Oil

Another popular product category is oils which are flavored with herbs. Many of these products, which may be described as being of ethnic origin, have appeared over the years. Common ones have been garlic or pepper materials packaged in oil. FDA has found botulism-causing toxins could be produced in these products. In order to produce these products safely, herbs should be dehydrated; alternatively, they must be properly acidified prior to the addition of oil. This renders them as acidified foods. A recognized process authority must establish the process conditions. This should not be done without adequate controls in place established by knowledgeable individuals.

Probably due to the increase in pasta in the diet, pesto, a blend of herbs in oil, is becoming more popular. These products have similar hazards to those above and must be processed using the same guidelines. A possible process alternative for fresh pesto is freezing. Another

solution is the use of dried herbs for which a low-water activity has been established.

From a food safety point of view, it is necessary to make the consumer aware of the hazards of refrigerated or frozen pesto. Botulism is a hazard in oil-coated low acid foods. There should be a warning label reminding the user to "Thaw in the refrigerator, keep refrigerated, discard after (5 days or some reasonable time)." The concern increases as the product is held for a longer time under fluctuating temperature conditions.

Shelf life may be a problem due to active enzymes in the herbs which break down the tissues. Blanching will destroy the enzymes, but it changes the character of the herbs.

There are several applicable rules for these types of products. The primary

requirements are contained in 21CFR 110 which describes the "Good Manufacturing Practices" (GMP's) for production, storage, and distribution of human food. These include the requirements for preparation facilities, sanitation, and protection of food. The other major regulation deals with the GMP's for producing acidified foods (21CFR 114). In that regulation, certain foods are excluded because they are naturally acid foods. Even though acid foods are exempted from 21CFR 114, we advocate following its recommendations anyway.

Nationally, most processed and packaged foods are regulated by the Food and Drug Administration. In North Carolina, these rules are enforced by the Food and Drug Protection Division of NCDA&CS. Contact this agency for further information and copies of the rules.