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## Sterilizing Raw Material – Pros/Cons of Popular Methods

2007/02/15 - Darlene Pickell, Quality Control Manager, BI Nutraceuticals

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Whether due to the environment in which the plant is grown, or the manner in which it is collected and processed, all wildcrafted and cultivated herbs carry a certain degree of microbial load. Implementation of Good Agricultural and Collection Practices (GACP) helps in assuring that herbal raw materials are accurately identified and are not adulterated with contaminants that may present a public health risk. Because all agricultural commodities carry microbes that can originate from a variety of both non-pathogenic and potentially harmful bacteria, molds and yeasts, certain pathogens must be reduced to acceptable levels in order to provide a product that is safe for human consumption. Therefore, when microbial loads are found to exceed established specifications, or if pathogens are present, herbs will generally require some form of sterilization, preferably by a method that minimally impacts the quality and efficacy of a product. Commercial viability, governmental regulations and consumer acceptance all influence the sterilization method chosen.

### Types of Sterilization Methods

#### Ethylene Oxide (ETO)

Treatment with ethylene oxide (ETO) has been shown to be very effective in reducing microbial load in herb products, but due to environmental concerns, it has been banned throughout Europe. In the United States, ETO is not legally allowed to be used on dietary supplements, and doing so renders the product adulterated under the Federal Food, Drug and Cosmetic Act (FDCA). Additionally, California Proposition 65 identified ETO as a carcinogen and reproductive toxin as far back as 1987. It also is not permitted for treatment of all certified organic products.

Beyond these considerations, treated materials must be well aerated in order to reduce residuals, and ETO may have a significant detrimental effect on the organoleptic qualities of an herb. Due to its strong residual odor, use of ETO in the production of teas and other such products that are dependent on the retention of the herb's sensory qualities may be impacted; therefore, it may not be an appropriate treatment method.

#### Gamma-Irradiation

Gamma-irradiation is also highly effective at reducing microbial loads; like ETO, it is prohibited in Europe, and in the United States it is restricted to use on very few crops. Also like ETO, treatment of herb products with gamma-irradiation renders the material adulterated under the FDCA. Additionally, this treatment method is not permitted on certified organic products, and there is increasing concern with the processes of such treatment and long-term environmental impacts.

#### Ozone Gas

The use of ozone gas (O<sub>3</sub>) reduces microbial loads through an oxidation process, leaving no residuals. It has a long history of use in disinfection of municipal water and bottled drinking water. Due to its strong oxidizing activity, however, ozone may cause organoleptic quality changes in various products, and may also cause corrosion of metals and other materials in processing equipment. Appropriate safeguards must be in place when using ozone as a sanitizing agent, and adequate ventilation is necessary.

#### Steam Sterilization

Dry steam sterilization is an alternative method of treatment that provides the log reduction required for herb products. This 20-minute process involves treating herbal materials and

spices with steam at a temperature of approximately 112°C under high pressure. The resulting steam vapor is 3 percent moisture and 97 percent gas, without any condensate remaining. This method of sterilization has shown to be effective in reducing microbial loads sufficiently (2-to-3 fold log reduction on TPC, yeast and mold), without increasing moisture or impacting assay, solubility or volatile oil content of the herbal material. There may be minor color changes to sensitive products. Steam sterilization does not have any residual impact on herbal materials, and the process is acceptable for the treatment of certified organic products.

In considering various methods of treatment available for microbial load reduction, not only cost and efficacy are of concern. Limitations or restrictions on such sterilization methods as irradiation and ethylene oxide, along with changes in consumer trends, may lead companies to seek alternative means of supplying product that meets these criteria. Acceptance by consumers of different treatment methods is evolving to a point where there is a greater demand for products that fulfill their increasing requirement for “healthy and natural foods”, and herbs that are considered “safe” without compromising quality or efficacy.