



Regulations for Specific Products

Selling Herbal and Dietary Supplements

30

Herbal and dietary supplements are products that are ingested and include dried herbs, teas, tinctures, capsules, and tablets. These supplements have a specific federal and state definition and must meet the same regulatory requirements for any processed food as well as additional requirements listed below.

This fact sheet includes:

- Dietary supplements definition;
- Food safety regulations for dietary supplements;
- Making dietary supplement health claims; and
- Labeling requirements for dietary supplements.

Fresh culinary herbs are exempt from the regulations for selling herbal and dietary supplements. Information on selling fresh herbs can be found in the “Selling Herbs” fact sheet.

Definition of Dietary Supplements

The State of Washington follows the Food and Drug Administration (FDA) definition of “dietary supplements.” This means that in Washington State, dietary supplements are considered products (other than tobacco) that are:

1. *Intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin, a mineral, an herb or other botanical, an amino acid, a dietary substance used by humans to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combination of these ingredients; and is*
2. *Intended for ingestion in pill, capsule, tablet, or liquid form.*

Food Safety Regulations for Dietary Supplements

To manufacture a dietary supplement you are required to be licensed as a WSDA Food Processor. As the “manufacturer,” you are responsible for ensuring that the supplement is safe before it is marketed. This is required by the Federal Dietary Supplement Health and Education Act of 1994. Private businesses offer testing services as do some public universities.

Making Dietary Supplements Health Claims

Washington State law abides by the federal legislation, *The Food, Drug, and Cosmetic Act* and *Trade Commission Act*, that expressly outlaws the false advertisement of food, drugs, devices, and cosmetics. For more information, please see the Washington State Food, Drug, and Cosmetic Act

(RCW 69.04) which outlines the regulations governing the sale of dietary supplements at <http://apps.leg.wa.gov/RCW/default.aspx?cite=69.04>.

This means that producers need to be very careful about making any health claims. Specifically, Washington State does not allow any claims to be made about the use of herbal and dietary supplements to diagnose, prevent, mitigate, treat, or cure a specific disease. For instance, statements such as "cures cancer" or "treats arthritis" may not be used.

However, appropriate health claims that are authorized by the FDA may be used if the supplement qualifies to bear that claim. For example, "calcium reduces the risk of osteoporosis." The manufacturer may also describe a supplement's effects on the structure or function of the body or the "well-being" achieved by consuming the dietary supplement. Visit www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm064919.htm for a table of FDA's model health claims statements. For additional support, contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2371.

Labeling Requirements for Dietary Supplements

Dietary supplements must meet the same labeling requirements as processed foods. See the "WSDA Food Processor License and Facilities" fact sheet. In addition, dietary supplements need to be identified as a "dietary supplement" on the product label as well as identifying "serving size," "calories," "dietary ingredients," and "supplement facts." The FDA's specific labeling requirements, guidelines, and examples are available online at:

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=101&showFR=1&subpartNode=21:2.0.1.1.2.3

Dietary supplements regulations are found under *FDA Title 21 CFR Part 111* Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements at:

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=111&showFR=1

For more information, please call (360) 902-1876, email foodsafety@agr.wa.gov or visit www.agr.wa.gov/FoodAnimal/FoodProcessors to reach the WSDA Food Safety Program.

Recommended Fact Sheets

- 19. WSDA Food Processor License and Facilities
- 29. Selling Herbs

For further information, to provide comments, or suggest a resource to add to this fact sheet, please email smallfarms@agr.wa.gov or call (360) 902-2888.