

**Indiana State Department of Health
Division of Consumer Protection
Food Protection Program**

**Final Guidance on Whole Uncut Fresh Produce
Storage and Distribution – December 12, 2006**

Purpose

The purpose of this Food Protection Program “Guidance Document” is to provide whole uncut fresh produce harvesters and distributors with regulatory information for their operations. This guidance is intended to assist the industry in being able to harvest and prepare their product intended for sale in a safe manner and to assist local health departments in the inspection of these operations.

Background

Locally grown whole, uncut fresh produce is a low risk food product and falls into a group known as “value-added” products. Produce is a raw agricultural commodity that does not undergo any processing other than a “quick cursory” wash to remove field dirt or minor trimming to remove damaged or unsightly leaves, roots or stems, such as on heads of lettuce, cabbage or corn. This guidance is intended only for the harvesting and prewashing of whole uncut fresh produce that is not “ready-to-eat”.

There have been many cases of food borne illness linked directly to fresh produce, especially related to cut or damaged melons (cantaloupe, honeydew, etc.); tomatoes; leafy vegetables, such as lettuce, cabbage and cilantro; and raw seed sprouts. This is why it is imperative that the products covered under this guidance are never promoted or advertised as a “ready-to-eat” food. Consumers must be informed that further washing and cleaning of the product is required before consumption.

There are three categories of food establishments: a retail food establishment operated under 410 IAC 7-24, Retail Food Establishment Sanitation Requirements, pursuant to IC 16-42-5; a wholesale food establishment operated under 410 IAC 7-21, Wholesale Food Establishment Sanitation Requirements, pursuant to IC 16-42-5; and a food processing plant operated solely under IC 16-42-5.

A food establishment selling whole uncut fresh fruits and vegetables is exempt from 410 IAC 7-24 if this produce is sold directly to the final consumer. In addition, a food establishment that does not ordinarily clean, prepare, treat or otherwise process this produce is also exempt from 410 IAC 7-21 if sold to other customers at wholesale.

Therefore, operations that are harvesting, brushing, hosing or spraying off field dirt and then only removing outer leaves or roots and stems of fresh fruits and vegetables would be considered a “food establishment” operated under IC 16-42-5 and do not need to meet the requirements of 410 IAC 7-24 or 410 IAC 7-21. For purposes of this guidance document, the food establishment can be a structure located in or by a crop field, a vehicle used to transport the harvested produce, or a storage building located remotely from the harvest area.

It is recommended that produce growers, who plan to store and distribute their product, contact the local health department for inspection and permitting in each county where they plan to operate. The health department may or may not conduct an inspection since the products covered under this document are a low risk food. In addition, for wholesale distribution, it is required that all produce processors and distributors contact the Food Protection Program of the ISDH to register their operations.

It is also strongly recommended that produce growers use and follow the “**Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables**” published by the U.S. Food and Drug Administration (FDA). This document incorporates “good agricultural practices” as a means of controlling or eliminating potential contamination problems. It is further recommended that distributors, who purchase produce from other harvesters, ensure that these FDA guidelines are being followed as part of a purchase agreement. This document may be found at the following URL address: <http://www.cfsan.fda.gov/~dms/prodguid.html> or on the Food Protection Program website at: <http://www.in.gov/isdh/21054.htm>

Definitions

Pre-cleaning: The practice of using potable water, brushes or other implements to remove soil or dirt to facilitate the handling and storing of produce, but not sufficiently enough that the product could be considered “ready-to-eat”.

Produce: Fresh fruits and vegetables that are sold to consumers in an unprocessed or minimally processed (i.e., raw) form. Fresh produce may be intact, such as whole strawberries, whole carrots, radishes, or tomatoes, or cut during harvesting, such as celery, broccoli, or cauliflower. Absent thorough cleaning, these products are not considered to be “ready-to-eat”.

Grower: A person, such as an individual, corporation, cooperative organization, or municipality that plants, cultivates, and harvests fresh fruits and vegetables.

Processor: A person, such as an individual, corporation, cooperative organization, or municipality that cleans, washes, slices, chops or otherwise comminutes or prepares fresh fruits and vegetables for consumption without the need for further washing by the final consumer.

Guidance

The following is guidance for a food establishment that stores and distributes whole uncut fresh produce. Food establishments must be operated pursuant to Indiana Code 16-42-5. The following guidance states the statutory provision (*in italics*) followed by guidance specific to produce operations.

IC 16-42-5-6 Conditions of health and comfort

Sec. 6. A food establishment must meet the following conditions:

- (1) Be adequately lighted, heated, drained, and ventilated.*
- (2) Be supplied with uncontaminated running water.*
- (3) Have adequate sanitary facilities.*

The storage facility, which may be located remotely or in any other place used as a food establishment, must meet the following requirements:

1. Adequately lighted, heated, drained and ventilated
 - Lighting may be electrical, natural light coming through windows, or gas lanterns. Lighting must be placed as to avoid contamination of produce if a fixture should break.
 - Light bulbs shall be shielded, coated, or otherwise shatter resistant over the storage and staging areas.
 - Heated only if necessary to protect equipment and the produce.
 - Ventilation should be such as to minimize odors and vapors. Fans, screened windows or other effective means may be used to achieve adequate ventilation.

2. Supplied with uncontaminated running water.

Water used for cleaning and hand washing in the physical structure must be potable and under pressure. If water is used for the washing of fresh produce it must also be potable. Care should be taken to avoid using cold wash water on certain types of produce, such as apples, tomatoes and celery, to remove field heat. Any water used for cleaning of these types of produce should be at least 10° F warmer than the temperature of the produce, otherwise the produce must be air cooled prior to washing. This is to prevent the migration of contaminants into the produce due to the temperature variation. Denser types of produce, such as carrots, are not affected by water temperature variables.

- If well water is used, a sample must be taken annually to determine that it is potable. A copy of the sample results shall be kept on site and available for review.

3. Adequate sanitary facilities

- Toilet facilities must be conveniently available and used within the confines of the physical facility or in a next door farmstead or business.
- If manual harvesting of fruits and vegetables, rather than mechanical, is conducted, then temporary toilet and hand washing facilities must be

provided near the field to reduce the chances that workers harvesting the produce will contaminate it during the harvest process.

IC 16-42-5-7 Construction to facilitate cleanliness

Sec. 7. Each food establishment and the machinery used in each food establishment must be constructed so as to be easily and thoroughly cleaned.

Each food establishment and the machinery used must be constructed so as to be easily and thoroughly cleaned. This includes any warehouse space, mechanical harvesters, transport vehicles, storage bins, shelves or racks.

IC 16-42-5-8 Cleanliness and sanitation of premises and vehicles

Sec. 8. The floors, sidewalls, ceiling, furniture, receptacles, implements, and machinery of a food establishment and a vehicle used to transport food products must at all times be clean and sanitary.

The floors, sidewalls, ceiling, furniture, receptacles, implements, and machinery of a food establishment and a vehicle used to transport produce must at all times be clean and sanitary.

- Non-food contact surfaces, such as floors, sidewalls, ceiling and vehicles, including mechanical harvesters and tractors, shall be cleaned prior to the start of the season and as needed thereafter.
- All food contact equipment shall be stored off the floor.
- Food contact surfaces shall be in good repair, easily cleanable, food grade quality and not contain any toxic chemicals or other hazardous materials. This includes storage boxes, shelves, buckets, baskets, bags, bins and any other type of container used to store the produce.
- Equipment shall not contain any deleterious substances, such as lead, lead solder or lead paint.
- Food contact equipment and surfaces shall be cleaned prior to and after use, and whenever it becomes contaminated

IC 16-42-5-9 & 10 Walls, ceilings, floors; construction; washing

Sec. 9. (a) The sidewalls, woodwork, and ceiling of a food establishment must be made of an impervious material with a finish that is washable.

(b) The sidewalls, woodwork, and ceiling must be kept washed clean with detergent and water.

Sec. 10. (a) The floor of a food establishment must be made of nonabsorbent material that can be flushed with water.

(b) The floor of a food establishment must be kept washed clean with detergent and water.

The sidewalls, woodwork, ceiling and floor of a food establishment must be made of impervious/nonabsorbent material that can be washed clean with detergent and water.

- Walls and ceilings may be constructed of wood or other impervious material, but must be free from unnecessary dust or soil accumulations.

- The floor should be sealed concrete, treated or sealed wood or other material that is nonabsorbent and can be easily cleaned.

IC 16-42-5-11 Domestic animals; rodents; insects

Sec. 11. A food establishment must be protected by all reasonable means against the presence of and entrance of domestic animals, rodents, flies, and other insects.

A food establishment must be protected by all reasonable means against the presence of, and entrance of domestic animals, rodents, flies, and other insects.

- Openings should be protected as necessary against rodents, birds, squirrels and other vermin. The presence of these pests shall be minimized. Domestic animals are not allowed in a food establishment.

IC 16-42-5-13 & 14 Toilet room; washrooms

Sec. 13. (a) A food establishment must have a convenient toilet room separate and apart from and not opening directly into a room that is used for food handling.

(b) The floor of the toilet room must be made of a nonabsorbent material.

(c) The floor of the toilet room shall be washed and scoured daily.

(d) Each toilet fixture and each toilet room must be adequately ventilated.

Sec. 14. (a) A food establishment must have a washroom adjacent to each toilet room.

(b) The washroom shall be supplied with adequate lavatories, soap, hot and cold running water, and clean individual towels.

(c) The washroom shall be kept clean by washing with detergent and water.

A food establishment must have a convenient toilet room separate and apart from, and not opening directly into, a room that is used for food handling. A washroom must be adjacent to each toilet room.

- If the food establishment does not have a toilet room, then a restroom in a nearby home, farmstead or business can be utilized. The restroom must have a toilet with a handsink, soap, potable hot and cold running water, and clean individual towels.

IC 16-42-5-15 & 18 Food handling room; exclusive use

Sleeping in food handling rooms

Sec. 15. A room that is used for food handling or that is equipped for use for food handling may not be used for any other purpose.

Sec. 18. A person may not live or sleep in a room used for food handling or in a room opening directly into a food establishment.

Whatever facility is used, it cannot be used for any other purpose other than for produce storage and distribution during the time it is in operation. If a home kitchen is used as a food establishment for a seasonal operation, then no other rooms can open directly into the kitchen that are used for living or sleeping purposes without at least a door that minimizes unauthorized entry.

- A separate room that meets all requirements of IC 16-42-5 and 410 IAC 7-24 must be used for processing secondary products of fresh produce, such as jams, jellies, preserves or salsas.
- In a food establishment, there shall be no storage or handling of gasoline, oil, pesticides, or other hazardous materials.
- Equipment may be stored in the warehouse or storage area in the off season, however, the warehouse or storage area must be thoroughly cleaned and vacated of all items not related to the storage and distribution of fresh produce prior to the beginning of the season.

IC 16-42-5-16 Dressing rooms

Sec. 16. (a) Rooms separate and apart from rooms used for food handling must be provided for the changing and hanging of wearing apparel.

(b) The rooms for changing and hanging wearing apparel must be kept clean.

Clothing and apparel must be stored in other rooms that are not used for any part of the food establishment. The changing of clothing and apparel must also be conducted in areas that are not part of the food establishment.

IC 16-42-5-21 Washing; employees

Sec. 21. A person who works in a food establishment shall wash the person's hands and arms thoroughly with soap and clean water before beginning work, before resuming work after a rest period, and before resuming work after visiting a toilet room.

Persons working in a food establishment must be able to wash their hands and arms with soap and clean water before beginning work, before resuming work after breaks, and after visiting a toilet room.

- It is recommended that if a restroom is not located nearby and convenient to the food establishment that hand washing facilities be provided at the harvesting, storage and distribution areas. Soap, disposable paper towels, and a method to adequately wash hands shall be provided and used. A portable water dispenser may be used as part of a hand washing facility if an adequate supply of potable warm running water is provided as well as a means to collect the waste water.

IC 16-42-1 and IC 16-42-2; Food, Drug & Cosmetic Act

This statute is provided to ensure that foods are safe, wholesome and not adulterated. Among other things it requires any produce in packaged form be labeled with the name and address of the producer or distributor, name of the product and an accurate statement of the quantity of the contents in terms of weight, measure or numerical count.

Additionally, 21 Code of Federal Regulations (CFR), Part 131-169, prohibits final product from containing ingredients that are deceptive or fraudulent to the consumer. Products cannot have added ingredients, such as coloring or

preservative, if they are to maintain the common name of the product. Furthermore, the use of sulfite agents is expressly prohibited in fresh produce as a means to preserve a fresh appearance.

It is imperative that good agricultural practices, as specified in the FDA **“Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables”** document, be followed to minimize the risk of contaminating the produce due to improper application of manure, compost or contaminated irrigation water at or near the time of harvest. Such contamination is considered adulteration, which would be grounds to prohibit the sale of the product under IC 16-42-2-2.