Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

An Equal Opportunity Employer

DATE: June 11, 2009

TO: All Local Health Departments and other Interested Parties

FROM: A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

SUBJECT: Guidance for Uniform Use of House Enrolled Act 1309

PURPOSE

This document is provided for the purpose of assisting local health departments (LHD) and other Indiana food regulatory agencies in the uniform use of House Enrolled Act (HEA) 1309. This new law passed in 2009 by the Indiana Legislature has made statutory changes which will allow certain food products to be made in a private residence with limited regulatory oversight and then be legally sold in two (2) specific public places.

BACKGROUND

HEA 1309 consists of a modification of three sections of the Indiana Code (IC):

1. Excludes certain vendors of farmers markets and roadside stands from the statutory definition of the term "food establishment" in IC 16-18-2-137,
2. Adds the term and definition of "potentially hazardous food product" to IC 16-18-2-287.8, and
3. Adds section 29 of IC 16-42-5, also known as the "Sanitary Requirements for Food Establishments".

A copy of HEA 1309 is attached.

DEFINITIONS

"Acid Food" means food which has a natural pH of 4.6 or below.

"Acidified Food" means:
(a) low-acid food to which acid is added; these foods include, but are not limited to: beans, cucumbers, cabbage, artichokes, cauliflower, puddings, peppers, salsa, tropical fruits, and fish singly or in any combination. They have a water activity (Aw) greater than eighty-five hundredths (0.85) and have a finished equilibrium pH of 4.6 or below. These foods may be called pickled, such as "pickled cauliflower".

(b) Excluded from the definition of acidified foods are: carbonated beverages, jams, jellies, preserves, and acid foods.

"Farmers' Market" means a common facility where two or more farmers or growers gather on a regular recurring basis to sell a variety of fruits, vegetables, and other farm products directly to consumers.

"Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low-acid foods, to maintain the commercial sterility of its contents after processing.

"Home-Based Vendor" (HBV) means an individual who:

- *has made a non-potentially hazardous food product in their primary residence;*
- *is selling the food product they made, only at a roadside stand or at a farmers' market; and*
- *complies with IC 16-42-5-29.*

This term is not defined in statute; however, it is suggested that "home-based vendor" should be used to refer to a person who complies with IC 16-42-5-29. The use of "home-based vendor" should help to prevent confusion with terms, such as food establishment, retail food establishment, wholesale food establishment, and bed & breakfast establishment, which are defined in laws, rules and ordinances.

"Low-Acid Food" means any food, other than alcoholic beverages, with a finished equilibrium pH of greater than 4.6 and a water activity (Aw) greater than eighty-five hundredths (0.85).

"Potentially Hazardous Food Product" means:
(a) a food that is natural or synthetic and requires temperature control because it is in a form capable of supporting any of the following:
(1) The rapid and progressive growth of infectious or toxigenic microorganisms.
(2) The growth and toxin production of Clostridium botulinum.
(3) In raw shell eggs, the growth of Salmonella enteritidis.
(b) The term includes the following:
(1) A food of animal origin that is raw or heat treated.
(2) A food of plant origin that is heat treated or consists of raw seed sprouts.
(3) Cut melons.
(4) Garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth described in subsection (a).

It must be noted that this term, while not quite as specific, is essentially the same term and has the same meaning as the commonly recognized term "potentially hazardous food," which is used in other Indiana food laws, rules, and ordinances. It is suggested that, for the purpose of preventing possible confusion over very subtle differences in the two terms, the term "potentially hazardous food" may be used interchangeably with, or substituted for, the term "potentially hazardous food product". Scientifically recognized principles, such as pH, water activity (Aw), and other intrinsic factors, will be used to determine whether or not a food must be time or temperature controlled to be safe within the context of either definition.

"pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution. Values between zero (0) and seven (7) indicate acidity, and values between seven (7) and fourteen (14) indicate alkalinity. The value for pure distilled water is seven (7), which is considered neutral.

"Roadside Stand" means a place, building or structure along, or near, a road, street, lane, avenue, boulevard, or highway where a home-based vendor (HBV) sells their food product(s) to the public.

"Water Activity" means:

a) A measure of the free moisture in a food.
b) The quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.
c) Indicated by the symbol Aw.

DISCUSSION

In IC 16-42-5-29 (c)(1)(A), the words "under section 12(b) of this chapter" seems to refer to language which was present in early legislative drafts of this bill, but was removed before passage of the final version. This appears to be a typographical error and should be disregarded. It is also believed the meaning of the term "misbranded" in subsection 29(c)(1)(A) is relative to the labeling in subsection 29 (b)(5).

In the newly modified IC 16-18-2-137(b) (5), the statutory definition of food establishment, there is a crossed out "~~the~~" which has no meaning.

Food safety authorities and requirements provided to local health officers under IC 16-42-5-24 and elsewhere in the Indiana Code, when acting on behalf of the state health commissioner, have not changed with HEA 1309. There are some administrative differences between the requirements for a Home-Based Vendor (HBV) when compared to the requirements for a retail or wholesale food establishment.

Home Base Vendor (HBV) (Section 29(b))

- A HBV is **not** a "food establishment" as defined in IC 16-18-2-137. HEA 1309 added a specification into that definition of food establishment which excludes an individual vendor of a farmers' market or roadside stand meeting the requirements of IC 16-42-5-29. Because a **HBV is not a food establishment**, it is not subject to "food establishment" regulatory activities, such as registration, permitting/licensing and routine inspection activities usually conducted by local health departments, Indiana State Department of Health (ISDH), or other Indiana food regulatory authorities, provided the vendor has complied with IC 16-42-5-29(b).
- The production area of a HBV is required to be in the vendor's primary residence, which may include another building or structure on the HBV premises, will not be routinely inspected. The HBV cannot comingle the activities of a HBV food product and those of a food establishment. If a HBV sells food products other than those produced in the home, then it becomes a food establishment. **One is either a HBV or a food establishment, not both**.
- A HBV failing to meet the requirements of Section 29(b) means the vendor's place of production and food product(s) become subject to all of the food safety requirements of a "food establishment". Examples include the operation of a café, restaurant, or grocery store.

Food Product Produced by a HBV (IC 16-18-2-287.8 and Section 29(b)(2))

- Some examples of a traditional HBV food products that could be produced, but are not limited to:
  - Baked items, such as cookies, cakes, fruit pies, cupcakes, bars, yeast breads, fruit breads, baguettes
  - Candy and confections, such as caramels, chocolates, fudge, peanut brittle, chocolate covered fruits, bon bons, buckeyes, chocolate covered nuts
  - Produce, such as unprocessed fruits and vegetables (i.e.) cherries, blackberries, cranberries, grapefruit, strawberries, oranges, blueberries, plums, tomato
  - Tree nuts, legumes
  - Pickles processed in a traditional method
  - Honey, molasses, sorghum, maple syrup
- The above food products may be refrigerated or frozen for quality purposes.

- The above listed items are typical examples of food products that are either high acid and/or low water activity, therefore making them a "non potentially hazardous food".
- Whole, uncut produce is not restricted from sale regardless of the locale of its origin.
- Mushrooms grown as a product of agriculture are not restricted from sale. It is recommended that uncultivated (wild) mushrooms be certified in writing as to their species by a person competent to make such a certification.
- Traditional jams, jellies, preserves made from strawberries, grape, raspberries, etc. are often made from acid foods and have a low Aw in its final form as safety factors. Special recipes of these products, including those which may be called "low sugar" or "no sugar added", as well as some fruit butters (pumpkin, pear) may fall into the category of acidified food or low-acid canned food and may not be allowed to be sold, since they may be considered a potentially hazardous food.
- A HBV's food product in its final form **shall not be a potentially hazardous food**. HBV food products may not contain ingredients in any form which have as a component:
  - meat (domestic or wild),
  - poultry,
  - aquatic animal products,
  - dairy (including cheese, butter, yogurt, but excluding some baked items, i.e. cakes and cookies), or
  - egg products (excluding some baked items, i.e. cakes and cookies, and dried noodles), including fresh shell eggs.
- In addition, a HBV's food product **shall not be:**
  - a "canned" or other "hermitically sealed containers" of acidified food, (i.e. packaged salsas, chutney, chow-chow)
  - a "canned" or other "hermitically sealed containers" of low-acid food, (i.e. packaged cooked vegetables, meats, poultry and raw fish)
  - cut melons
  - raw seed sprouts that have been harvested
  - non-modified garlic-in-oil mixtures
  - cut tomatoes
- Packaging considered to be "canned" or "hermitically sealed" consists of cans, glass jars, plastic containers, laminated pouches, paperboard containers, etc.
- The use of a "reduced oxygen packaging" method, such as the use of a vacuum packaging machine, is not allowed.
- All state or federal laws governing the production and sale of the above listed items are still applicable.
- If the food product of a HBV is found to be or contain any of the above listed items, it should be considered in violation of IC 16-42-5-29, and according to IC 16-42-5-29(d), must not be sold.
- Purdue University or other private consultants may serve as resources to assist in determining if a specific food product is acceptable to be produced and sold as an HBV food product.

Labeling/Misbranded of HBV Food Products (Section 29(b)(5))

- There are some very specific labeling requirements for the food product of a HBV. Any food product provided by a HBV **shall** include a label which contains the following:
  - The name and address of the producer of the food product.
  - The common or usual name of the food product.
  - The ingredients of the food product, in descending order by predominance by weight.
  - The net weight and volume of the food product by standard measure or numerical count.
  - The date on which the food product was processed.
  - The following statement in **at least** 10 point type: "This product is home produced and

processed and the production area has not been inspected by the State Department of Health".

- This labeling **must** be present with and/or on the food at the point of sale regardless of whether or not the product is packaged. Unpackaged food, such as some baked items, should be considered "labeled" when there is easily readable signage accompanying the food product stating all of the above listed items. Labeling (or signage) is not required for whole, uncut produce. A HBV food product which is not labeled according to Section 29(b)(5) is misbranded and may not be sold until the label is provided or corrected.
- Food products being provided to consumers as open samples can be considered to be labeled when there is a nearby container of the same product labeled according to section 29(b)(5).
- There is authority for the food safety agency to take action when a product is determined to be misbranded according to Section 29(b)(5), adulterated under IC 16-42-2, or a consumer complaint is received.
- HEA 1309 provides a "buyer beware" responsibility to the consumer of HBV food products. A primary "safety factor" for food products produced and sold under this new law will be the information provided on the required label. Because of this, labeling in **strict accordance** with section 29 (b)(5) is of substantial public health significance. If a HBV food product fails to meet any of the requirements of section 29 (b)(5), it is considered to be misbranded and must be removed from sale until the label can be corrected.
- Sections 29(c), (d), and (e) specify when a vendor is subject to regulatory sample collection, inspection, investigation and other enforcement activities.
- A food product that is found not labeled in compliance with 29(b)(5) does not necessarily mean the product is not approved. It could be a food product that is regulated which does not require the same labeling as an HBV food product.

Roadside Stand or Farmers' Market (Section 29(a))

- To comply with the subsection 29(a) of HEA 1309, a "Home-Based Vendor" may sell their food product(s) only in two places:
  - a farmers' market, and
  - a roadside stand.

  These products **may not** be sold at any other venue, such as a grocery store, restaurant, festival, carnival or any other event.
- A roadside stand or farmers' market should not be operated in violation of other federal, state or local laws and ordinances, such as those related to, but not limited to, highway/traffic, zoning/planning, fire/safety/building codes, or municipal selling laws, sometimes known as "peddlers" ordinances or "itinerant vendor" codes.
- A farmers' market or roadside stand should be located where the land owner has given permission for the HBV to operate at the site.
- For reason of providing better food product safety, security, or quality, the point of sale for a food product sold at a roadside stand may be in a nearby publicly accessible building or structure, such as a tent or shed, on the premises where the food product was made.
- The HBV is not permitted to sell other commercially prepared products that were not produced in the primary residence from a roadside stand or farmer market, such as prepackaged chips, soft drinks, etc. The food product of a HBV must be made by an individual in the individual's primary residence. The production of the product from another nearby building or structure located on the HBV premises is allowed when doing so can be done in a sanitary manner.
- Preordering by telephone, internet, in person, mail order, etc., of a HBV food product is acceptable. However, the consumer must take possession of the HBV food product at the farmers' market and/or roadside stand. The HBV shall not deliver to any other location.

Food Sampling for Consumers (Section 29(b)(3))

- Sampling of a HBV food product being provided to consumers is not prohibited. The individual must "practice proper sanitary procedures". These proper sanitary procedures should include at least:
  - Proper hand washing;
  - Sanitation of the container or other packaging in which the food product is contained; and
  - Safe storage of the food product, which would include protection during display and service, such as single portion service of samples for individual consumers (use of cups, utensils, tongs, and wax papers)
- Sampling at a roadside stand and/or farmers' market does not include the assembling of two (2) or more HBV food products to produce an additional food product. (i.e. HBV food product "strawberries" plus HBV food product "pound cake" cannot be combined at the roadside stand and/or farmers' market to produce another HBV food product, such as "strawberry shortcake").
- If HBV is sampling food and is not in compliance with the proper sanitary procedures listed above, then the sampling must be discontinued until such time as the HBV comes into compliance.

Consumer Complaints (Section 29(c) and (d))

- Consumer complaints received on HBV and/or HBV food products shall be forwarded to the ISDH Food Protection Program.
- Complaint investigation and/or follow-up will be coordinated between ISDH and the affected local health jurisdiction.

Exemptions (Section 29(f))

- A potential HBV wishing to comply with Subsection 29(b) may request guidance from the regulatory authority for the "best safe food handling practices", "disease control measures" and "standards for potable water sources". Examples of this would be:
  - an existing "food establishment" wishing to comply with section 29(b);
  - an individual wishing to become an HBV but not currently in business.

  This would be an opportunity for education to help minimize risk to the public.

CONCLUSION

The creation of HEA 1309 resulted in the exemption of certain food operations from the definition of a food establishment. Since these entities are not food establishments, then the regulations used to regulate food establishments **do not apply**. This is similar to other recent changes to the definition that now allows other food operations, such as those operated by religious organizations and non-public educational organizations, from being regulated as food establishments. Permitting requirements do not apply to a legally operating HBV. The practice of requiring some other form of registration to "track" or "maintain surveillance" of the HBV activities cannot be required; however, the information can be offered voluntarily by the vendor or the market master.

The food product of a HBV **may not be resold** and is subject to the laws of the state and the Federal Food Drug & Cosmetic Act if sold in another state. HBV food products being sold from other states are subject to the Federal Food Drug & Cosmetic Act and legally cannot be sold in Indiana. If a HBV product is found to be resold, the product should be considered "adulterated" under IC 16-42-2 and IC 16-42-5-29 and must be removed from sale.

It should be understood that the regulatory authority may need to inquire and ask questions about a food product. For example, a food product that is found not labeled in compliance with section 29(b)(5) does

not necessarily mean the product is not approved. It could be another regulated food product which does not require the same labeling as an HBV food product.

The regulatory authority may also examine HBV food products and product labeling when being offered for sale to ensure they are in fact in compliance with the new law to maintain their exemption. This may also include the collection of samples for testing to verify that certain characteristics, such as pH and Aw, are measured to confirm the product is a non-potentially hazardous food. The HBV may have confirmatory laboratory analyses that may negate the necessity for any sampling. However, unless there is probable cause that determines the product is adulterated/ misbranded or a complaint is received on the HBV, then no further action, such as an inspection or product embargo can be taken against them.

Under IC 16-42-5-29 (d) of the new law, if an imminent health hazard occurs, such as when the food product of a HBV is determined to be adulterated or epidemiologically linked to a foodborne illness, the regulatory authority may order a HBV to cease production and/or sale of the product until the hazardous situation is determined to have been resolved. Section 29(e) allows the regulatory authority to collect and have food samples analyzed, conduct investigations, examinations, and inspect the HBV's facilities (at reasonable times).

Until the requirements of HEA 1309 become more widely known and understood by vendors & potential vendors, **it is reasonable to expect that Indiana food regulatory authorities should emphasize education on the new requirements over enforcement action**.

In addition, a comprehensive guidance document pertaining to "farmers' markets" is being developed and will be available very soon. Topics covered include permitting options and general inspection guidance.

Food Protection Program representatives are available to assist you with any questions you may have about situations or questionable products that may be encountered. Additional guidance may be developed in the future if warranted.

HOUSE ENROLLED ACT No. 1309

AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

SOURCE: IC 16-18-2-137; (09)HE1309.1.1. -->

SECTION 1. IC 16-18-2-137, AS AMENDED BY P.L.3-2008, SECTION 105, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: Sec. 137. (a) "Food establishment", for purposes of IC 16-42-5 and IC 16-42-5.2, means any building, room, basement, vehicle of transportation, cellar, or open or enclosed area occupied or used for handling food.

(b) The term does not include the following:

(1) A dwelling where food is prepared on the premises by the occupants, free of charge, for their consumption or for consumption by their guests.

(2) A gathering of individuals at a venue of an organization that is organized for educational purposes in a nonpublic educational setting or for religious purposes, if:

(A) the individuals separately or jointly provide or prepare, free of charge, and consume their own food or that of others attending the gathering; and

(B) the gathering is for a purpose of the organization.

Gatherings for the purpose of the organization include funerals, wedding receptions, christenings, bar or bat mitzvahs, baptisms, communions, and other events or celebrations sponsored by the organization.

(3) A vehicle used to transport food solely for distribution to the needy, either free of charge or for a nominal donation.

(4) A private gathering of individuals who separately or jointly provide or prepare and consume their own food or that of others attending the gathering, regardless of whether the gathering is held on public or private property.

(5) Except for food prepared by a for-profit entity, a venue of the sale of food prepared **for** an ~~the~~ organization:

(A) that is organized for:

(i) religious purposes; or

(ii) educational purposes in a nonpublic educational setting;

(B) that is exempt from taxation under Section 501 of the Internal Revenue Code; and

(C) that offers the food for sale to the final consumer at an event held for the benefit of the organization;

unless the food is being provided in a restaurant or a cafeteria with an extensive menu of prepared foods.

(6) Except for food prepared by a for-profit entity, an Indiana nonprofit organization that:

(A) is organized for civic, fraternal, veterans, or charitable purposes;

(B) is exempt from taxation under Section 501 of the Internal Revenue Code; and

(C) offers food for sale to the final consumer at an event held for the benefit of the organization;

if the events conducted by the organization take place for not more than fifteen (15) days in a calendar year.

(7) An individual vendor of a farmer's market or roadside stand if the individual meets the requirements of IC 16-42-5-29.

SOURCE: IC 16-18-2-287.8; (09)HE1309.1.2. --> SECTION 2. IC 16-18-2-287.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2009]: **Sec. 287.8. (a) "Potentially hazardous food product", for purposes of IC 16-42-5-29, means a food that is natural or synthetic and requires temperature control because it is in a form capable of supporting any of the following:**

(1) The rapid and progressive growth of infectious or toxigenic microorganisms.

(2) The growth and toxin production of Clostridium botulinum.

(3) In raw shell eggs, the growth of Salmonella enteritidis.

(b) The term includes the following:

(1) A food of animal origin that is raw or heat treated.

(2) A food of plant origin that is heat treated or consists of raw seed sprouts.

(3) Cut melons.

(4) Garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth described in subsection (a).

SOURCE: IC 16-42-5-29; (09)HE1309.1.3. --> SECTION 3. IC 16-42-5-29 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE UPON PASSAGE]: **Sec. 29. (a) This section applies to an individual vendor of a farmer's market or roadside stand.**

(b) An individual vendor of a farmer's market or roadside stand is not considered to be a food establishment and is exempt from the requirements of this title that apply to food establishments if the individual vendor's food product:

(1) is made by an individual in the individual's primary residence;

(2) is not a potentially hazardous food product;

(3) is prepared by an individual who practices proper sanitary procedures, including:

(A) proper hand washing;

(B) sanitation of the container or other packaging in which the food product is contained; and

(C) safe storage of the food product;

(4) is not resold; and

(5) includes a label that contains the following information:

(A) The name and address of the producer of the food product.

(B) The common or usual name of the food product.

(C) The ingredients of the food product, in descending order by predominance by weight.

(D) The net weight and volume of the food product by standard measure or numerical count.

(E) The date on which the food product was processed.

(F) The following statement in at least 10 point type: "This product is home produced and processed and the production area has not been inspected by the state department of health.".

(c) An individual vendor who meets the requirements in subsection (b) is subject to food sampling and inspection if:

(1) the state department determines that the individual vendor's food product is:

(A) misbranded under section 12(b) of this chapter; or

(B) adulterated; or

(2) a consumer complaint has been received by the state department.

(d) If the state department has reason to believe that an imminent health hazard exists with respect to an individual vendor's food product, the state department may order cessation of production and sale of the food product until the state department determines that the hazardous situation has been addressed.

(e) For purposes of this section, the state health commissioner or the commissioner's authorized representatives may take samples for analysis and conduct examinations and investigations through any officers or employees under the state health commissioner's supervision. Those officers and employees may enter, at reasonable times, the facilities of an individual vendor and inspect any food products in those places and all pertinent equipment, materials, containers, and labeling.

(f) The state health commissioner may develop guidelines for an individual vendor who seeks an exemption from regulation as a food establishment as described in subsection (b). The guidelines may include:

(1) standards for best safe food handling practices;

(2) disease control measures; and

(3) standards for potable water sources.

SOURCE: ; (09)HE1309.1.4. --> SECTION 4. **An emergency is declared for this act.**