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Overview of Home-Based Vendor Law

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Introduction

Food sold to the public typically goes through extensive regulatory and inspection processes. However, Indiana provides exceptions to these rules for home-based vendors (HBV), individuals who produce nonhazardous food products in their homes for sale at farmers markets and roadside stands. Although they are exempt from some regulations, home-based vendors must navigate a complex set of food safety guidelines, production requirements, and packaging instructions for animal and plant products. This article will help farmers and food entrepreneurs to understand home-based vendor law in Indiana by answering the following questions:

- Who qualifies as a home-based vendor?
- How do I identify potentiallyhazardous food products?

- Can I sell animal products as a homebased vendor?
- How do I determine what plant products are safe?
- Is produce ever hazardous?
- What are the packaging regulations?
- Does the location of the market impact my exemptions?
- Are non-potentially hazardous products always safe for consumers?

For complete information regarding Home-Based Vendor operation in Indiana, refer to the Indiana State Department of Health and Indiana General Assembly

www.in.gov/isdh/files/hbv-presentation-3-8-2017.pdf

http://iga.in.gov/legislative/laws/2018/ic/titles/016

Who qualifies as a home-based vendor?

According to the Indiana State Department of Health, a home-based vendor refers to a person 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 [9], which describes Indiana's requirements in terms of sanitary requirements for food establishments [5] (1). A homebased vendor may also be referred to as "Section 29 vendor" [11](4). Non-potentially hazardous foods are defined by NSF International [14]. They often include uncut and uncooked produce, nuts, honey, maple syrup, jam, baked goods and candy.

In 2009, the state of Indiana passed the House Enrolled Act (HEA 1309), which created criteria for home-based vendors. If you qualify as a home-based vendor, then you may sell certain food products made, grown, or raised at your primary residence directly to consumers at farmers markets or roadside stands without having your kitchen inspected by the Indiana State/County Health Department. (HEA 1309 is subject to updates and should be referenced periodically for new information).

To qualify as a home-based vendor, an individual may not sell many types of meat, poultry, dairy, fish, cooked or cut produce, raw seed sprouts and garlicin-oil mixtures (see Figure 1). These products are considered hazardous because they must be stored in a temperature-controlled environment or reduced oxygen packaging in order to prevent the growth of pathogens.

How do I identify potentially-hazardous food products?

While all foods have some level of hazard associated with them, certain foods pose heightened risks because they support the rapid growth of harmful bacteria or are associated with foodborne illness outbreaks [4].

Potentially hazardous food products are defined as "a food that is natural or synthetic and requires temperature control because it is in a form capable of supporting any of the following: rapid and progressive growth of infectious/toxigenic microorganisms, growth and toxin production of *Clostridium botulinum*, and growth of *Salmonella enteritidis* in raw shell eggs" [11]; pH (acidity), water activity (Aw) and other intrinsic factors are considered when making a determination.

Potentially hazardous food products are often referred to as "TCS" foods or foods "that require Time/ Temperature Control for Safety (TCS) to limit pathogenic microorganism growth or toxin formation" [11](4). Table 1 shows common potentially-hazardous food products within three categories: animal products, plant products, and packaging format.

Understand that even products typically regarded as low-risk, such as baked goods or jam, can become hazardous if prepared incorrectly or due to variations in the recipe. This article will later discuss ways to ensure your food products comply with Indiana law and reduce risk of contamination.



Table 1. Examples of common potentially hazardous and food products that may be sold by HBV

Potentially hazardous	Products that may be sold by HBV
Potentially hazardous Animal Products Meat* Poultry* Dairy products Fish Shrimp Jerky Plant Products Cut tomatoes	Products that may be sold by HBV Animal Products Honey Plant Products Whole and uncut produce Cut carrots Cut potatoes Maple syrup Jams, jellies, preserves (only high acid fruit in sugar) Fermented produce using "traditional pickling" (not in oxygen
 Cut tomatoes Cut leafy greens Cut melons Cooked produce Raw seed sprouts Garlic-in-oil mixture Some fruit butters Some "low sugar" or "no sugar added" jams and jellies Packaging Format Use of reduced oxygen packaging 	 Fermented produce using "traditional pickling" (not in oxygen sealed container) Tree nuts and legumes Sorghum Molasses Baked/Prepared Goods Baked goods: cakes, fruit pies, cookies, brownies, dry noodles Candy and confections: caramels, chocolates, fudge, hard candy
Acidified and low-acid foods (canned or in hermetically sealed containers) *Refer to Table 2 for guidance on whether HBV laws apply for selling	

*Refer to Table 2 for guidance on whether HBV laws apply for selling +Adapted from [3].

Can I sell animal products as a homebased vendor?

The sale of animal products is highly regulated and in most cases requires inspection by the USDA Food Safety Inspection Service or the Indiana Board of Animal Health. Indiana home-based vendor law allows for some exceptions. Raw poultry, raw rabbits, and in-shell chicken eggs are examples of non-ready-to-eat animal products that can be sold by home-based vendors if the criteria described in Table 1 and 2 are met under certain conditions.

The temperature of animal products during packaging, storage, transportation and sale is crucial to whether or not it qualifies as potentially hazardous. Poultry and rabbits that are sold at farmers markets or roadside stands must have labels indicating that they were not inspected and must remain frozen until delivery to the consumer according to IC 16-42-5-29 Section (g) [5]. Poultry that are sold at the farm where they were produced must be refrigerated at the point of sale [5]. Rabbits sold from the farm must be refrigerated or frozen, whereas rabbits sold at a farmers market or roadside stand must be frozen [5]. Depending on the size of the farm and the type of processing that occurs, the product may need to be sold directly at the farm rather than at a roadside stand or a farmers market. More information about these animal products and the criteria for poultry and rabbits covered by home-based vendor law are explained in Table 2 [7].

Selling eggs from animals other than domestic chickens requires a permit from the local health department. Chicken eggs are not discussed in this HBV overview document. Please contact the Indiana State Egg Board (http://www.ansc.purdue.edu/iseb/) or your local health department for more information.

Table 2. Home-Based Vendor Law for Poultry and Rabbits

	Sell as HBV at farmers market, roadside stand, on farm	If any are met, HBV does NOT apply
Poultry**	Slaughter or process less than 1,000 annually OR Slaughter or process more than 1,000 and up to 20,000 birds annually with a BOAH limited permit - Household Consumer (HC) Sell only to end consumer*	Slaughter or process more than 1 and up to 20,000 birds annually with a BOAH limited permit - Retail-HRI Sell to end consumer AND retail stores, restaurants, hotels, or institutions that resell or serve the product
Rabbits***	Slaughtered and processed on the farm	Not slaughtered and processed on the farm

*End consumer is defined as: "a person who is the last person to purchase any food product and who does not resell the food product" [12].

**Poultry—Meat and Poultry Division of the Indiana State Board of Animal Health (BOAH). Refer to [6] for more information.

***Rabbits—Meat and Poultry Division of the Indiana State Board of Animal Health (BOAH). Refer to [8] for more information.

How do I determine what plant products are safe?

Some plant products (such as raw seed sprouts and garlic-in-oil mixtures) require a controlled temperature to be safe (TCS), so they are *always* considered potentially-hazardous foods that cannot be sold by home-based vendors. The final composition of a food product impacts its pH level and water activity, both of which influence the growth of bacteria. While pH and water activity can be adjusted during food processing to create a hostile environment for bacteria, the only way to be certain that your plant products are outside of the "danger zone" is to have them professionally tested. It is important that home-based vendors recognize why this is necessary and understand how water activity and pH level affect bacterial growth.

Loosely defined, "water activity" refers to water available in a food product. Water interacts with components like salt and sugar contained within food, making that water less available to be used by bacteria [2], which inhibits their growth. There are many factors that can influence water activity and pH, and most of them are a result of processing. For example, "no sugar added" or "low sugar" jams and jellies are often considered potentially hazardous food products due to high water activity. Adding sugar to these products, however, can significantly reduce the water activity and prevent bacterial growth.

Bacteria also require certain pH ranges to grow. The pH of a food refers to whether the food is acidic (low pH), basic (high pH), or neutral (pH ~7.0). Many foods classified as "products that may be sold by HBV" have

low water activity and/or low pH (high acid) since this environment does not support the growth of pathogenic microorganisms. In general, bacteria tend to grow best when a food has high water activity and a close to neutral pH. Pathogens typically do not grow in highly acidic foods such as citrus fruits or vinegar. Low acid (high pH) fruits such as bananas, however, can support the rapid growth of dangerous bacteria.

Water activity and pH can also be used in combination or separately to control the growth of pathogenic microorganisms in food. In general, pH levels less than or equal to 4.6 will inhibit the growth of pathogens, regardless of the water activity. Similarly, water activity levels of 0.85 and below will inhibit pathogenic growth independently of pH. Therefore, if a home-based vendor does not want to add sugar to their jam in order to reduce water activity, they can still sell "no sugar added" jams and jellies if the pH of the product is lowered (acidified). This can be accomplished by adding highly acidic (low pH) foods such as citrus juices or by adding food additives like citric acid, which make the product too acidic for bacterial growth. As Table 3 and Table 4 demonstrate, various combinations of pH and water activity levels can inhibit bacteria and toxin growth, even if the pH and water activity levels are above 4.6 and 0.85, respectively.

Table 3 discusses the water activity and pH interactions needed to control spores in heat-treated packaged products. Spores are formed by bacteria when environmental conditions are not favorable for growth. They can then regenerate bacteria once conditions again become favorable to bacterial growth. Bacterial cells that are active are known as vegetative cells [1]. Unlike spores, vegetative cells can be destroyed by heat treatment. As Table 3 demonstrates, spores can be destroyed and prevented from regenerating vegetative cells in heat-treated, packaged food products such as canned tomatoes, green beans, and salsa by adjusting the water activity and pH levels. If adjusted properly, these products no longer need to be temperature controlled for safety (TCS) and can be sold by homebased vendors.

Table 4 outlines the water activity and pH interactions needed to control both spores and vegetative cells for unpackaged products, whether the food is heat treated or not. Home-based vendors can submit product samples for water activity and pH testing to university labs; nutritional analysis labs; or third-party labs that conduct shelf-life testing, such as Silliker Laboratories. Once your products are tested, use the water activities and pH levels given in Tables 3 and 4 to determine if the food is potentially hazardous, which corresponds to "PA." Products that may be sold by HBV correspond to "non-TCS foods."

Make sure your samples are tested with a pH meter, since the color of pH papers can be misinterpreted [11]. If you are unable to measure the pH of a food product that has been identified as potentially-hazardous, then the food must be considered unsafe and it cannot be sold by a home-based vendor.

Table 3. Water activity and pH interactions to control spores in food heat-treated to destroy vegetative cells and then packaged

Water Activity Values	pH Values			
water Activity values	≤ 4.6	> 4.6 - 5.6	> 5.6	
≤0.92	non-TCS food*	non-TCS food	non-TCS food	
>0.92 - 0.95	non-TCS food	non-TCS food	PA**	
>0.95	non-TCS food	PA	PA	

*TCS food — Time/Temperature control for safety food **PA — Product assessment required +Adapted from [11]

Table 4. Water activity and pH interactions to control spores and vegetative cells in food either heat-treated or not heat-treated and not packaged

Water Activity Values	pH Values			
water Activity values	< 4.2	4.2 - 4.6	> 4.6 - 5.0	> 5.0
< 0.88	non-TCS food*	non-TCS food	non-TCS food	non-TCS food
0.88 - 0.90	non-TCS food	non-TCS food	non-TCS food	PA**
> 0.90 - 0.92	non-TCS food	non-TCS food	PA	PA
> 0.92	non-TCS food	PA	PA	PA

*TCS food – Time/Temperature control for safety food **PA – Product assessment required +Adapted from (4) [11]

Is produce ever hazardous?

Cut and cooked produce may be considered potentially hazardous and therefore cannot be sold by home-based vendors. Cooking produce can release nutrients, which can increase the growth of pathogens, particularly in vegetables. For example, raw potatoes could be sold by home-based vendors because consumers will cook the potatoes before eating them, thus eliminating the pathogens by heat treatment. However, cooked potatoes, like baked potatoes, cannot be sold by homebased vendors, especially if they are foil-wrapped. The foil can create an anaerobic (low oxygen) environment in which pathogens such as Clostridium botulinum can grow. Cooked fruit with no sugar added may still have enough acidity to inhibit bacteria growth, but it must be 4.6 pH or lower at the point of sale to qualify as a legal product for home-based vendors

Cut produce, especially tomatoes, leafy greens, and melons, can pose a food safety risk by making nutrients available to certain pathogens that can use these nutrients to grow [13]. In recent years, many foodborne illnesses have been associated with fresh produce. One example of an outbreak associated with cut produce occurred when *Salmonella* grew on the cut surface of tomatoes at room temperature, which resulted in a salmonellosis outbreak [13]. Microorganisms such as *Clostridium botulinum, E. coli, Salmonella spp., Listeria monocytogenes*, and *Staphylococcus aureus* can contaminate cut produce as well. A complete list of the possible microorganisms that can contaminate fresh cut produce is provided by the Food and Drug Administration [3].

One way to make these products non-hazardous for home-based vendors is to acidify the produce. Acidified foods are "low-acid foods to which acid or acid food is added" (3) [10]. Fresh cut produce, such as cut tomatoes or cut leafy greens, can be acidified by adding low pH foods such as vinegar or citrus juice or food additives like citric acid. This decreases their pH and creates an acidic environment inhospitable to bacterial growth. If these acidified products were not packaged in an oxygen sealed container and their pH values are measured as safe for a Regulatory Official using a pH meter, these foods would be considered safe for a home-based vendor to sell [11].

What are the packaging regulations?

Packaged foods prepared at home and sold by homebased vendors should be limited to jams, jellies, and high-acid fruits canned in sugar. All food products packaged in oxygen sealed containers (vacuum or hermetically sealed, for example), are considered potentially hazardous food products, with the exception of products that are high acid fruit in sugar, such as strawberry jam. Anaerobic pathogens, such as *Clostridium botulinum*, do not need oxygen to grow and therefore sealing these products does not guarantee safety without refrigeration.

Modified packaging includes modified atmospheric packaging and vacuum packaging. Vacuum packaging occurs when "air is removed from a package of food and the package is hermetically sealed so that a vacuum remains inside the package" [10]. Modified atmospheric packaging is when "the atmosphere of the package of food is modified so that its composition is different from air but the atmosphere may change over time due to the permeability of the packaging material or the respiration of the food. Modified atmospheric packaging includes any of the following: reduction in the proportion of oxygen, total replacement of oxygen, and an increase in the proportion of other gases, such as carbon dioxide or nitrogen" [10]. Because foods packaged in this manner can contain anaerobic pathogens, they cannot be sold by home-based vendors. In addition, acidified and low-acid foods (pH of 4.6 or below) that are canned or packaged in hermetically sealed containers are dangerous due to the severe risk that the process is done incorrectly at home. Home-based vendors cannot sell foods that have been professionally packaged.

Exceptions may be made to these packaging regulations if the home-based vendor can prove, through documented testing by a credible lab or university that the product being sold is not a potentially-hazardous food because the product meets pH and water activity requirements as outlined in Table 3.

Does the location of the market impact HBV exemptions?

Whether or not the home-based vendor rule applies is based on the characteristics of the product, how it is processed, and where and to whom it is sold. To be covered by the home-based vendor law, the vendor must meet the criteria in the left column of Table 5. If the vendor meets any of the criteria described in the right side of Table 5, the home-based vendor law does not apply.



Table 5. Home-Based Vendor Law for Produce

All are met = HBV	If any are met = HBV Does NOT apply
Sell inside of Indiana	Sell outside of Indianamust follow the laws of that state
Sell only at farmers market, roadside stand, or on farm	Sell at food establishment or other locations
Sell to end consumer directly	Sell to end consumer indirectly

Are non-potentially hazardous products always safe for consumers?

Foods that are not categorized as potentially hazardous can still pose health risks if not properly handled. For example, dried egg noodles are shelf-stable and not categorized as a potentially-hazardous food product in the context of home-based vendor law. However, it is possible that pathogenic microorganisms such as Salmonella spp., which is commonly associated with egg and flour, could survive on and contaminate dried egg noodles if not processed or stored carefully. Product contamination from pathogenic microorganisms can come from many sources, including contaminated ingredients used to make the product or crosscontamination. For example, cut potatoes are categorized as "products that may be sold by HBV," but if the knife used to cut the potatoes was previously used to cut meat, chicken, or other produce contaminated with pathogens, the pathogens can be transferred from the knife to the potatoes. It is therefore essential that as a home-based vendor you practice safe food handling practices at all times, in addition to ensuring that the products you sell qualify as non-hazardous under Indiana law.

Additional Resources

For more information about the home-based vendor law, you can contact the following resources.

County Department of Health Refer to <u>https://www.in.gov/isdh/24822.htm</u> Indiana State Department of Health Food Protection Program Phone: (317) 234-8569 Email: <u>food@isdh.in.gov</u> 100 North Senate Avenue, N855 Indianapolis, IN 46204

Indiana State Board of Animal Health Refer to <u>https://secure.in.gov/boah/index.htm</u> Meat and Poultry Phone: (317) 544-2400 or (877) 747-3038 Email: <u>animalhealth@boah.in.gov</u> 1202 East 38th Street, Indianapolis, IN 46205

Indiana State Egg Board

Refer to <u>http://www.ansc.purdue.edu/ISEB</u> Rules and Regulation, Farm Market Info, Egg Law Phone: (765) 494-8510 Email: <u>straw@purdue.edu</u> 270 South Russel Street, West Lafayette, IN 47907

For more information related to highlighted terms, potential hazards, and safe food handling practices, please refer to the following resources.

Additional Definitions of Terms Related to Food Processing

Indiana State Department of Health Refer to <u>https://www.in.gov/isdh/21116.htm</u> 410 IAC 7-21 DEFINITIONS

Potential Hazards

Food and Drug Administration Refer to <u>https://www.fda.gov/downloads/Food/</u> <u>GuidanceRegulation/FSMA/UCM517402.pdf</u> Appendix 1, Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry

Safe Food Handling Practices

FightBAC! The Partnership for Food Safety Education

Refer to http://www.fightbac.org/food-safety-basics/the-core-four-practices/

The Core Four Practices

United States Department of Agriculture Refer to <u>https://www.fsis.usda.gov/wps/portal/fsis/</u> <u>topics/food-safety-education/get-answers/food-safety-</u> <u>fact-sheets/safe-food-handling</u>. Safe Food Handling Fact Sheet

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