

Date: August 23, 2018

To: All Local Health Departments & Other Indiana Food Regulatory Agencies

From: Krista Click, Director *KC*
Food Protection Program

Subject: Home-based Vendor PHF Products

Purpose

This memorandum is provided to answer questions and promote consistency among regulators at local health departments and other Indiana food regulatory agencies regarding “home-based vendor” (HBV) potentially hazardous food products.

Background

Indiana Code 16-42-5-29 was initially passed into law by the State Legislature in 2009 as, then named, HEA 1309. There have been several modifications of the law since then. That same year, the Indiana State Department of Health (ISDH), Food Protection Program released a guidance document to assist in regulatory consistency in applying the new law. The term “home-based vendor” was developed there and continues to be used along with the term “Section 29 Vendor” to quickly describe a vendor making and selling products under that section of law.

Prior to the 2009 law, the term “potentially hazardous food” (PHF) was used in the Retail Food Establishment Sanitation Requirements, 410 IAC 7-24. Upon initial passage of IC 16-42-5-29, a very similar term, “potentially hazardous food product” (PHF Product) was created in IC 16-18-2-287.7. These terms were described in the ISDH HEA 1309 guidance document as equivalent.

The term “potentially hazardous food product,” while not quite as specific, is essentially the same term and has the same meaning as the commonly recognized term “potentially hazardous food” used in other Indiana food laws, rules, and ordinances. More specific is the term “time/temperature control for safety food” (TCS) defined and used in the 2017 FDA Model Food Code and planned for inclusion in future revisions of the Indiana retail food establishment rule. For the purpose of preventing possible confusion over very subtle differences in the terms, the term “potentially hazardous food” has been used interchangeably with, or substituted for, the term “potentially hazardous food product,” and now are considered equivalent to the term “Time/Temperature Control for Safety Food” used in the 2017 FDA Model Food Code.

The use of the term “Time/Temperature Control for Safety Food” will be announced for retail food establishments during the future rule making process for the updated retail food establishment rule.

Scientifically recognized principles, such as pH, water activity (A_w), 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 any of these definitions.

Potentially Hazardous Food Product

As defined in IC 16-18-2-287.8, the term “*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).

“Time/Temperature Control for Safety Food” (TCS)...From 2017 FDA Model Food Code

(1) “**Time/temperature control for safety food**” means a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation.

(2) “**Time/temperature control for safety food**” includes:

(a) An animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth or toxin formation; and

(b) Except as specified in Subparagraph (3)(d) of this definition, a food that because of the interaction of its A_w and pH values is designated as Product Assessment Required (PA) in Table A or B of this definition:

Table A. Interaction of pH and a_w for control of spores in food heat-treated to destroy vegetative cells and subsequently packaged			
a_w values	pH values		
	4.6 or less	> 4.6 - 5.6	> 5.6
≤0.92	non-TCS food*	non-TCS food	non-TCS food
>0.92 - .95	non-TCS food	non-TCS food	PA**
>0.95	non-TCS food	PA	PA

* TCS food means Time/Temperature Control for Safety Food ** PA means Product Assessment required

Table B. Interaction of pH and a_w for control of vegetative cells and spores in food not heat-treated or heat-treated but not packaged				
a_w values	pH 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 means Time/Temperature Control for Safety food ** PA means Product Assessment required				

(3) “Time/temperature control for safety food” does not include:

- (a) an air-cooled hard-boiled egg with shell intact, or an egg with shell intact that is not hard-boiled, but has been pasteurized to destroy all viable salmonellae;
- (b) a food in an unopened hermetically sealed container that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;
- (c) a food that because of its pH or a_w value, or interaction of a_w and pH values, is designated as a non-TCS food in Table A or B of this definition;
- (d) a food that is designated as Product Assessment Required in Table A or B of this definition and has undergone a Product Assessment showing that the growth or toxin formation of pathogenic microorganisms that are reasonably likely to occur in that food is precluded due to:
 - (i) intrinsic factors including added or natural characteristics of the food such as preservatives, antimicrobials, humectants, acidulants, or nutrients;
 - (ii) extrinsic factors including environmental or operational factors that affect the food such as packaging, modified atmosphere such as reduced oxygen packaging, shelf life and use, or temperature range of storage and use; or
 - (iii) a combination of intrinsic and extrinsic factors; or
- (e) a food that does not support the growth or toxin formation of pathogenic microorganisms in accordance with one of the subparagraphs (3)(a) - (3)(d) of this definition even though the food may contain a pathogenic microorganism or chemical or physical contaminant at a level sufficient to cause illness or injury.

Cut, Leafy Greens as a PHF Product

ISDH and the 2017 FDA Model Food Code define the term “cut, leafy greens” to mean fresh leafy greens whose leaves have been cut, shredded, sliced, chopped, or torn. The term “leafy greens” includes iceberg lettuce, romaine lettuce, leaf lettuce, butter lettuce, baby leaf lettuce (i.e., immature lettuce or leafy greens), escarole, endive, spring mix, spinach, cabbage, kale, arugula and chard. The term does not include herbs such as cilantro or parsley or produce known as “microgreens”, which are immature plants bearing first “true” leaves and which are cut leaving some stem and a root. This also excludes from the definition the “harvest cut” or “field cut” of leafy green vegetables made during their harvest.

In ISDH guidances provided since the original law was passed, cut tomatoes were considered to be phf products and could not be sold by a HBV. Cut, leafy greens are now included as phf products and cannot be sold by a HBV; however, if a cut tomato or cut, leafy green bearing product:

- has been acidified by adding acid or by the action of a culture (fermented);
- is not put into an oxygen sealed container;** and
- can be measured by the vendor to show the product has a pH of 4.6 or less:
 - by use of a calibrated pH meter,
 - in the presence of a regulatory official,

the food would not be considered a phf product and could continue to be sold by a HBV.

A HBV may not use pH papers to measure their product since these measurements compare a color on a paper strip to a chart that is often misread. Otherwise, cut tomatoes and cut, leafy greens which have not been acidified are still considered to be a phf product.

Local regulatory officials would not need to purchase pH meters or measure pH. If the vendor can't measure the product the regulator must assume the product is a phf product.

Conclusion

Indiana Code 16-42-5-29, passed by the legislature in 2009, has since then resulted in the ISDH development of guidance to aid in consistent application of the law across all Indiana food safety agencies.

For HBV food products, cut tomatoes and cut, leafy greens are considered potentially hazardous food products by ISDH, except that, acidified foods containing cut tomatoes and cut, leafy greens that are **not put into an oxygen sealed container**, and can be measured by a vendor to have a sufficiently low pH in the presence of a regulatory official are not considered to be a phf product.

Questions related to this document or topic may be directed to dmiller@isdh.in.gov, your ISDH Food Protection Program Field Staff, or to 317-234-8569.