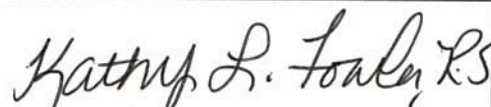
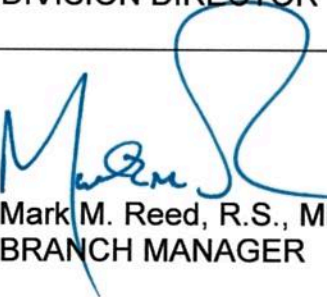


KENTUCKY DEPARTMENT FOR PUBLIC HEALTH DIVISION OF PUBLIC HEALTH PROTECTION & SAFETY—FOOD SAFETY BRANCH EXTERNAL LHD ADMINISTRATIVE POLICY DOCUMENT	NO: 2014-06-01	REV:
	EFFECTIVE: June 16, 2014	
TITLE: Exemptions for Establishments Offering Only Commercially Prepackaged, Shelf-Stable, Non- Potentially Hazardous, Non- Time/Temperature Control for Safety Foods ASSOCIATED SOPs: N/A ASSOCIATED DOCUMENTS: N/A RELATES TO: Kentucky Food, Drug & Cosmetic Act (KRS 217.002-217.998); Kentucky Food Code (902 KAR 45:005); 2005 FDA Food Code	APPROVED BY:	DATE
	 Kathy L. Fowler, R.S. DIVISION DIRECTOR	June 9, 2014
	 Mark M. Reed, R.S., MPA, MPH BRANCH MANAGER	June 9, 2014

SUBJECT: Permitting and Inspection Requirements for Establishments Handling Only Commercially Prepackaged, Shelf-Stable, Non-Potentially Hazardous, Non-Time/Temperature Control for Safety Foods.

STATEMENT OF PURPOSE: To Establish a Uniform, Statewide Policy Clarifying Local Health Department Permitting and Inspection Requirements for Retail-Level Establishments Handling Only Commercially Prepackaged, Shelf-Stable, Non-Potentially Hazardous, Non-Time/Temperature Control for Safety (TCS) Foods in Alignment with the 2005 FDA Food Code.

BACKGROUND:

The Food Safety Branch has received a number of inquiries regarding permit/inspection requirements for food items being marketed in a number of retail-level, non-traditional grocery store operations, including but not limited to department stores, home-improvement stores, and farm-supply stores that only offer “commercially” prepackaged, shelf-stable, non-potentially hazardous, non-time/temperature control for safety foods.

The purpose of this Policy Statement is to clarify our agency’s current interpretation of those definitions found in Kentucky’s Food Drug & Cosmetic Act (KRS 217.002 to 217.998, available at: <http://www.lrc.ky.gov/statutes/chapter.aspx?id=38245>) as well as the Kentucky Food Code (902 KAR 45:005, available at: <http://www.lrc.state.ky.us/kar/902/045/005.htm>) which adopts, by reference, the 2005

FDA Food Code (available at: <http://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm2016793.htm>).

HISTORY:

Kentucky's Food, Drug & Cosmetic Act defines a "Retail Food Store" as follows:

"Retail food store" means any fixed or mobile establishment where food or food products, including prepackaged, labeled sandwiches or other foods to be heated in a microwave or infrared oven at the time of purchase, are offered for sale to the consumer, and intended for off-premises consumption, but does not include establishments which handle **only prepackaged, snack-type, nonpotentially hazardous foods** (emphasis added), markets that offer only fresh fruits and vegetables for sale, food service establishments, food and beverage vending machines, vending machine commissaries, or food processing establishments;

Historically, previous interpretations/policy statements have considered "commercially" prepared, ready to eat foods that are packaged in **individual portion sizes** (emphasis added), including but not limited to candy bars, candy suckers, chewing gum, snack crackers, cupcakes, chips, nuts and similar items, and non-potentially hazardous beverages to be exempt from the classification of "retail food market." However, past guidance from the Food Safety Branch emphasized that where these items were offered in bulk packages—including candy and other non-potentially hazardous/TCS (time/temperature control for safety) foods—a "retail market permit" would be in order.

CURRENT GUIDANCE:

The 2005 FDA Food Code provides a number of examples of operations that fall under the definition of "Food Establishment." The document also provides in its definitions section, as follows, that a "Food Establishment" does not include:

*An establishment that offers only **prePACKAGED FOODS that are not POTENTIALLY HAZARDOUS** (emphasis added) (TIME/TEMPERATURE CONTROL FOR SAFETY) FOODS;*

In May 2010, Kentucky modernized its Retail Food Code with the formal implementation of the 2005 FDA Food Code which emphasizes risk-based inspections and inspection frequencies. After re-examining the existing statutory definition of "Retail Food Store" in light of the above 2005 FDA Food Code exemption for prepackaged non-potentially hazardous foods, it is the determination of this office that establishments engaged solely in the retail level, direct-to-consumer sales/marketing of exclusively **commercially** prepackaged, non-potentially hazardous, non-time/temperature control for safety (TCS) foods will not require permitting or routine inspections as a "Retail Food Store." This exemption includes those retail-level facilities such as department stores, home-

improvement stores, and farm-supply stores that only offer “commercially” prepackaged, non-TCS foods, regardless of package size.

Where necessary, however, these facilities may still be inspected for cause (including consumer complaints, insect/rodent contamination, fires, floods, and other occurrences that may have compromised food product safety) under the authority of the Kentucky Food, Drug, & Cosmetic Act. Additionally, in terms of enforcement actions for non-permitted establishments, the Cabinet and its Local Health Department Agents still retain quarantine authority for any food that is adulterated or misbranded under the provisions of Kentucky’s Food, Drug & Cosmetic Act.

Those retail-level establishments that exceed the operational exemptions noted above, shall continue to be permitted as a “Retail Food Store.” This exemption shall not apply to retail-level salvage foods grocery stores that are engaged in the culling and sorting of product. Instead, these types of operations should be permitted and inspected as a 610 with processing.

It is the recommendation of this office that our Local Health Department Partners closely evaluate the operational status of currently permitted 610 prepackaged establishments to ensure that only those meeting the exemptions in this policy statement are released from permitting and routine inspection requirements. “Exempt” establishments that currently have a permit to operate that is set to expire on December 31, 2014 should retain their permit to operate until it expires, and have received at least one inspection during the year, prior to the permit expiration date. Please ensure that 2015 permit renewal notices are not forwarded to those establishments verified to have met the “exempt” status as defined in this policy statement.

Please be advised that it is the opinion of DPH that those facilities identified as having met the newly clarified parameters for “exempt” status that wish to retain their permit to operate, or obtain a permit to operate, be allowed to do so.

This policy document shall supersede all previous interpretations/policy statements issued prior to the effective date noted above.

REFERENCES

2005 FDA Food Code, available at <http://www.fda.gov/food/guidanceregulation/retailfoodprotection/foodcode/ucm2016793.htm>



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