

## Readoption Review

### **Retail Food Establishment Sanitation Requirements 410 IAC 7-24**

IC 4-22-2.5-3.1(c) requires an agency to conduct a review to consider whether there are alternative methods of achieving the purpose of the rule that are less costly or less intrusive, or that would minimize the economic impact of the proposed rule on small business.

#### **Description of Rule:**

The Indiana State Department of Health (ISDH) has the responsibility and authority to adopt rules to regulate food establishments in Indiana. IC 16-42-5 provides authority for the department to adopt rules to further regulate food establishments. This rule, as well as previous versions of it, have been based on the U.S. Food and Drug Administration (FDA) Model Food Code that is periodically updated and released for states to use as a guideline in adopting rules to regulate retail food establishments. The current rule is based on the 2005 version.

#### **Readoption Analysis:**

**1) Is there a continued need for this rule?**

Yes, this is the only rule that effectively provides specific requirements for retail food establishments. These establishments include restaurants, grocery stores, convenience stores, concessions, taverns, farmers' markets, temporary events and any other operation where food is sold to the final consumer. The most recent census estimates that there are over 43,000 retail food establishments in Indiana. Due to the large number of facilities, it is imperative that this rule be readopted to provide public health protection. The Center for Disease Control and Prevention (CDC) and the FDA have publicly stated that there continues to be 76 million illnesses, 325,000 hospitalizations and over 5,000 deaths in the United States each year and a financial burden of \$10-\$83 billion relating to medical costs and lost productivity due to these occurrences. Without this rule to regulate the industry, the human and financial costs would be much greater than currently exist.

**2) What is the nature of any complaints or comments received from the public, including small business, concerning the rule or the implementation of the rule by the agency?**

Since the Notice of Intent to Readopt 410 7-24 had been published, there have been no complaints or comments received from the public or small business concerning this rule or the implementation of this rule by the ISDH.

**3) Examine the complexity of the rule, including difficulties encountered by the agency in administering the rule and small businesses in complying with the rule.**

This rule, which is modeled after the U.S. FDA Model Food Code, arises out of a body of work and deliberations from the National Conference for Food Protection. This body has equitable representation from the food industry, regulatory, academia, and consumer advocacy groups and therefore, is evaluated, debated and voted on at a national level with some of the brightest and smartest people in the country. Because this rule is enforced by local health departments, there is some inconsistent application. However, ISDH works with the local health departments for consistent application.

**4) To what extent does the rule overlap, duplicate, or conflict with other federal, state, or local laws, rules, regulations, or ordinances?**

There are no specific FDA laws that regulate retail food establishments, since all they provide is the Model Food Code. The Indiana State Egg Board has requirements for the sale of shell eggs that include retail food establishments. The United States Department of Agriculture (USDA) and the Indiana State Board of Animal Health (BOAH) have compliance authority that extends into retail food establishments where meat and poultry products are sold that originate from one of their “official facilities”, but otherwise this rule does not overlap, duplicate, or conflict with any other federal, state, or local laws, rules, regulations, or ordinances.

**5) When was the last time the rule was reviewed under this section or otherwise evaluated by the agency, and the degree to which technology, economic conditions, or other factors have changed in the area affected by this rule since that time?**

The rule was amended in 2004 to provide updates based on new changes to the U.S. FDA Model Food Code. These changes are usually based in science and emerging technologies. The ISDH does plan to further amend and update this rule.

July 9, 2010