

## Readoption Review

### **WHOLESALE FOOD ESTABLISHMENT SANITATION REQUIREMENTS TITLE 410 IAC 7-21**

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:** This rule establishes minimum sanitary standards for the operation of wholesale food establishments which include manufacturers, processors, repackagers and distributors of food, excluding meat and poultry processors, dairy processors, and shell egg plants which are regulated by other agencies.

#### **Readoption Analysis:**

- 1) **Is there a continued need for this rule? Please explain.**  
Yes, the provisions of this rule provide a system of prevention and safeguards designed to minimize foodborne illness through ensuring employee health requirements are maintained, an adequate level of manager knowledge is demonstrated, safe food is provided to the consuming public, nontoxic and easily cleanable production equipment is provided and acceptable sanitation levels of wholesale food establishment premises are maintained.
- 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?**  
The ISDH Food Protection Program is not aware of any complaints regarding this rule. The Indiana wholesale food industry is accustomed to compliance with the rule and strives to maintain their operations in compliance with its requirements.
- 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.**  
ISDH has not encountered any specific problems or difficulties in the administration of the rule. Likewise, the agency is not aware of any issues dealing with complexity or ability to meet compliance with requirements. The rule is applied to a wide variety of operations with varying degrees of complexity of operations and to our knowledge poses no issues.
- 4) **To what extent does the rule overlap, duplicate, or conflict with other federal, state, or local laws, rules, regulations, or ordinances?**  
This rule was designed to work in harmony with other local, state or federal rules and regulations. Federal laws enforced by the U.S. Food and Drug Administration apply to food products within channels of interstate commerce. Local rules and ordinances enforced by Indiana's local health departments primarily apply to retail food establishments. Therefore, there is still a need for this rule to protect Indiana's wholesale food supply in intrastate commerce and to protect its consumers.

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 current rule has not been fully evaluated since its effective date of April 26, 2002. However, the basic language is still in substantial compliance with federal food regulations. The U.S. Food and Drug Administration is currently in the process of promulgating a series of food protection laws under the Food Safety Modernization Act (FSMA). FSMA was signed into law on January 4, 2011. Upon release of all associated rules under FSMA, ISDH will need to reevaluate 410 IAC 7-21 to assure compliance with said federal regulations.

May 28, 2014