

**Economic Impact Statement**

LSA Document #13-230

**IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses**

The BOAH proposes to amend its rules governing meat and poultry products inspection ([345 IAC 9](#); [345 IAC 10](#)). This amendment will align BOAH's rules to the new United States Department of Agriculture - Food Safety Inspection Service (USDA-FSIS) requirements at 9 CFR 417.4. These requirements govern the validation, verification, and reassessment of the Hazard Analysis and Critical Control Points (HACCP) plan for meat and poultry processing establishments. In addition, in order to comply with state law, BOAH must periodically update the meat and poultry regulations to ensure they are at least equal to 9 CFR Subchapter E, which contains the requirements for federally-inspected facilities. This is largely accomplished by updating the incorporation by reference of the pertinent federal regulations every two years, which is what is being proposed. BOAH is proposing to update the incorporation by reference at [345 IAC 9-2.1-1](#) and [345 IAC 10-2.1-1](#) from January 1, 2012, to January 1, 2013.

The proposed rule also adds a new section to clarify that an establishment that produces non-intact beef products is required to conduct microbiological testing as a component of the ongoing verification activities required by 9 CFR 417.4. BOAH also proposes to amend [345 IAC 9-17-4](#) to require an establishment selected for the USDA-FSIS Cooperative Program for Interstate Shipment of Carcasses, Parts of Carcasses, Meat and Meat Food Products (CIS Program) to comply with the labeling requirements at 9 CFR Part 317.

**1. Description of Affected Industry**

There are currently 85 state-inspected meat and poultry processing plants that will be subject to the proposed rule. These plants sell only in intrastate commerce. All of these plants employ less than one hundred fifty (150) employees and fall within the statutory definition of a "small business" ([IC 5-28-2-6](#)).

**2. Reporting, Record Keeping, and Other Administrative Costs**

The update to the incorporation by reference does change record keeping requirements for state-inspected plants. USDA-FSIS regulations already require plants to reassess the adequacy of their HACCP plan at least annually and whenever changes occur that could affect the hazard analysis (9 CFR 417.4(a)(3)(i)). Beginning June 7, 2012, each establishment must also make a record of the reassessment and document the reason for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment (9 CFR 417.4(a)(3)(ii)). Such changes may include changes in raw materials or source of raw materials, product formulation, slaughter or processing methods or systems, production volume, personnel, packaging, finished product distribution systems, or the intended use or consumers of the finished product. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination. The individual performing this function must have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing.

The new section related to microbiological testing does not change record keeping requirements for state-inspected plants. If an establishment makes a determination pursuant to 9 CFR 417.2 that contamination with Shiga-toxin producing *Escherichia coli* (STEC) is reasonably likely to occur in the hazard analysis, the latest edition of USDA documents interpreting 9 CFR 417.4 state that microbiological testing is an essential component of ongoing verification activities. [345 IAC 9-2.1-1](#) states that the board will utilize the latest edition of these documents when interpreting the federal regulations. Therefore, the proposed rule is simply clarifying what is already a requirement under 9 CFR 417.4 and [345 IAC 9-2.1-1](#).

The amendment related to labeling approval also does not change record keeping requirements for state-inspected plants. It clarifies that an establishment selected for the USDA-FSIS CIS Program must comply with the federal labeling requirements. This amendment is necessary because these products will not be staying within the state. Therefore, these products must bear the official marks, devices, certificates, and labels appropriate for products intended for interstate commerce. It is important to note that this is a voluntary program that permits a state-inspected plant to ship their product interstate. Therefore, an owner can avoid any potential additional costs by choosing not to participate in the program. It is also important to note that this language for CIS participants is required by the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and compliance is mandated by federal law for those that choose to participate.

**3. Estimated Total Annual Economic Impact on Small Business**

As stated above, official establishments are already required to conduct reassessments of their HACCP plan. The proposed rule merely requires that they make a record of each reassessment and document the reasons for either changing or not changing the plan based upon the reassessment. The estimated annual cost for plants to

perform this additional record keeping function is difficult to quantify for several reasons. First, it will depend on the number of changes that could affect the hazard analysis occurring in that plant per year, which varies greatly depending on the plant. It also depends upon the hourly wage paid to the trained individual conducting the reassessment. If an annual reassessment is done, there is no additional cost if the plant determines that no changes are needed to its HACCP plan. Because plants already having trained personnel conducting the reassessments and following these plans on a daily basis, we do not expect the costs of compliance with this additional record keeping requirement to be significant.

It is also important to note that plants are already operating under the new HACCP requirements pursuant to [345 IAC 9-2.1-1](#)(d), which states that the board will utilize the latest edition of FSIS Regulatory Directives and Notices when interpreting and implementing the provisions of this article and [IC 15-17](#). This rule plays an important role in ensuring that plants are subject to current FSIS requirements when there are changes to those requirements subsequent to the most recent incorporation by reference.

The new section related to microbiological testing does not change the current annual cost of compliance for state-inspected plants subject to the rule. The vast majority of establishments producing non-intact beef products have made a determination in their hazard analysis that contamination with Shiga-toxin producing Escherichia coli (STEC) is reasonably likely to occur. Therefore, they are already conducting microbiological testing as a component of ongoing verification of their HACCP plan. If a plant producing non-intact beef products determines that contamination with Shiga-toxin producing Escherichia coli (STEC) is not reasonably likely to occur, they are subject to a different set of requirements related to purchase specifications. Again, it is important to emphasize that microbiological testing in these circumstances is already the expectation of the USDA based on federal rules and policies. The purpose of the proposed rule is merely to clarify this existing requirement.

The amendment related to labeling approval also does not change the current annual cost of compliance for state inspected plants subject to the rule. A state inspected plant is already complying with the state program's requirements for official marks, devices, certificates, and labels. This amendment clarifies that, when a plant in the CIS program is processing a product for interstate shipment, the federal labeling standards apply in place of the state's labeling requirement. As stated above, this is a voluntary program that permits a state-inspected plant to ship their product interstate. Therefore, any potential additional costs are at the discretion of the plant owner. In addition, compliance with the federal labeling requirements that are referenced in the proposed rule is mandated by federal law for CIS participants to be able to ship their products in interstate commerce.

#### **4. Justification for Costs**

This proposed rule is expressly required by state and federal law. The proposed rule does not impose a requirement beyond what is required by state and federal law.

##### **a. Compliance with State Law**

State law requires the Board of Animal Health to enforce requirements with respect to intrastate operations that are at least equal to those imposed and enforced under the federal Meat Inspection Act (21 U.S.C. 601 et seq.) and the federal Poultry Products Inspection Act (21 U.S.C. 451 et seq.). See [IC 15-17-5-1](#)(4). In order to comply with this statutory mandate, BOAH must periodically update the meat and poultry regulations to ensure they are at least equal to 9 CFR Subchapter E, which contains the requirements for federally-inspected facilities.

##### **b. Federal Cooperative Agreement**

State law authorizes the BOAH to cooperate with USDA-FSIS to effectuate the purpose of the Meat and Poultry Inspection Law, to accept federal assistance for that purpose, and spend public funds appropriate for the administration of the law to pay not more than 50% of the total cost of the cooperative program ([IC 15-17-5-5](#)(11)). Pursuant to this power, the BOAH has entered into a state-federal cooperative agreement with USDA-FSIS in order to receive 50% of the annual operating costs of the Meat and Poultry Inspection program. BOAH's program is subject to regular audits by USDA-FSIS to ensure that the state standards are at least equal to federal requirements. If the BOAH does not update the incorporation by reference, it would jeopardize the funding we receive under the state-federal agreement.

Loss of this funding would have negative consequences for the state-inspected plants, producers that sell animals to these plants, and consumers of the meat and poultry products. Indiana relies on the federal funding to support an adequate number of inspectors for our 85 official plants and 41 custom exempt plants. If BOAH cannot fund an adequate number of inspectors, the 85 official plants will not be able to operate at full capacity because an inspector must be on site continually during the slaughtering process and inspect the processing area once per day.

#### **5. Regulatory Flexibility Analysis**

Because state law and the USDA-FSIS Cooperative Agreement require that the BOAH rule be at least equal to federal standards, BOAH did not consider any less costly alternative methods to achieving the purpose of the proposed rule. If the proposed rule did not incorporate the federal standards, Indiana would be in violation of the Agreement.

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