

Economic Impact Statement

LSA Document #16-222

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

The Indiana State Board of Animal Health (BOAH) is requesting approval to amend its rules governing dairy products inspection ([345 IAC 8-3-1](#)). The primary purpose of the changes is to conform BOAH rules to the 2015 Grade A Pasteurized Milk Ordinance (PMO). BOAH is proposing to update the current incorporation by reference of the 2013 PMO to the 2015 revision. BOAH is also proposing to update the current incorporation by reference of certain Food and Drug Administration (FDA) food standards from April 1, 2014, to April 1, 2016. In order to comply with federal law, BOAH must also align standards for Grade A and manufacturing grade milk plants with 9 CFR 117, Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, which was published on September 17, 2015.

1. Description of Affected Industry

BOAH currently inspects 1,089 Grade A dairies and 21 Grade A processing plants. These are dairies producing Grade A milk that is processed for use in products such as fluid milk and yogurt. BOAH currently inspects 29 manufacturing grade plants, which are facilities using manufacturing grade milk as an ingredient in products such as ice cream and cheese. BOAH has worked to involve regulated entities in the development of the rule. For example, the proposed changes were presented at the BOAH dairy industry meeting and the Indiana Milk Quality Conference in April 2016. The affected industry includes small businesses under the definition at [IC 4-22-2.1-4](#).

2. Estimated Annual Reporting, Record Keeping, and Other Administrative Costs

The proposed rule does increase annual reporting, record keeping, or other administrative costs for milk processing plants. However, any increased administrative costs are federally mandated by the requirements in 9 CFR 117 for the processing plants to have a preventive control plan, recall plan, allergen control plan, supplier verification plan, and environmental monitoring plan. It is also important to emphasize that the proposed rule is critical to ensuring that the plants are not subject to inconsistent or more stringent administrative requirements at the state level upon the Food Safety Modernization Act (FSMA) effective dates. The effective dates for FSMA are dependent on the size of the plant and the type of products they produce.

3. Estimated Total Annual Economic Impact on Small Businesses

A primary purpose of the proposed rule is to update existing dairy product rules to align with federal standards for Grade A products, which are regulated by the FDA under the PMO. It also aligns existing dairy products rules for manufacturing grade dairy products with federal regulations. Similar to the above-described administrative costs, this rule does increase compliance costs for regulated entities. However, any increased compliance costs are federally mandated by the requirements in 9 CFR 117. Many plants already have these plans in place and there is a wide disparity in personnel costs for the remaining plants to develop and maintain the plans required by FSMA. Therefore, the compliance costs for each plant will be highly variable and the cumulative cost is difficult to quantify. BOAH estimates that the total estimated impact (cost) will be less than \$500,000.

4. Justification of Requirements**a. Compliance with Federal and State Law**

This proposed rule is necessary to comply with a state mandate. State law requires the board to adopt rules that are the same as, or at least as effective in protecting health, as the federal standards for Grade A milk adopted by the National Conference on Interstate Milk Shipments (NCIMS) in accordance with their Memorandum of Understanding (MOU) with the FDA. [IC 15-18-1-14](#). The PMO is the document that is accepted by the FDA as the federal standards for the interstate shipment of milk. Therefore, in order to comply with this statutory mandate, the agency must ensure that the most recent revision of the PMO is being referenced in the state dairy products rule.

The proposed rule is also necessary to comply with a federal mandate. BOAH is a voting member of the NCIMS. As a member of this entity, each state has agreed to enforce the sanitation standards set forth in the PMO. The FDA audits state program implementation by conducting check ratings. The check rating process involves the FDA inspecting all farms and plants in Indiana every six years. If BOAH does not update the incorporation by reference, Indiana would not be able to enforce the most current federal requirements to ship milk in interstate commerce. Therefore, Indiana would be in violation of its agreement with FDA.

If the BOAH does not comply with the MOU, it would have negative consequences with regard to economic

development. Indiana's 1,089 Grade A farms and 21 Grade A plants rely on the board to adopt and enforce the most current version of the PMO. If the board does not incorporate the most recent version of the federal standards, it could jeopardize their ability to ship their product in interstate commerce. This could occur due to a plant or farm failing their milk rating survey, which occurs every two years. A failed survey could result in a plant or a Bulk Tank Unit (BTU), which is comprised of several farms, being delisted from the interstate shippers list. A delisting prohibits a plant or BTU from shipping their milk across state lines. Alternatively, this could occur due to Indiana ultimately failing the FDA check rating process, which would jeopardize the ability for all plants and farms to access out of state markets for their products. If the BOAH does not update its rule, it could also have negative consequences for our state's 29 manufacturing grade plants. These plants must comply with BOAH's processing standards for manufacturing grade milk products, such as cheese and ice cream. However, under the new FDA Preventive Controls for Human Foods Rule, these facilities must also have a written preventive control plan, recall plan, allergen control plan, supplier verification plan, and environmental monitoring plan that meets federal standards. A primary purpose of this rulemaking is to ensure that the state processing standards align with the requirements of 21 CFR 117 in order to ease the burden of compliance for these plants.

b. Justification of Requirements not Mandated by Federal or State Law

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

5. Regulatory Flexibility Analysis

Because the proposed rule does not impose requirements above the federal standards, BOAH did not examine alternative methods with regard to the requirements for dairy farms and processors.

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