

Economic Impact Statement

LSA Document #17-566

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](#)). The primary purpose of the changes is to conform BOAH rules to the 2017 Grade A Pasteurized Milk Ordinance (PMO). BOAH is proposing to update the current incorporation by reference of the 2015 PMO to the 2017 revision. BOAH is also proposing to update the current incorporation by reference of certain Food and Drug Administration (FDA) food standards from April 1, 2016, to April 1, 2017. In addition, the proposed rule will amend the drug residues section to align records retention standards with the PMO and clarify the actions that must be taken by the state veterinarian when milk is found to test as a confirmed positive for drug residues.

In order to comply with federal law, BOAH recently aligned standards for manufacturing grade milk plants with 9 CFR 117, Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (see LSA Document #16-222). In order to align with the new Food Safety Modernization Act (FSMA) regulations at 9 CFR 117, BOAH structured a phase in schedule for the new FSMA regulations incorporated at [345 IAC 8-2-2.1](#). In order to complete this transition, it was also necessary to establish a phase out schedule for the preexisting state standards for these facilities. This rule will repeal the preexisting state standards that are no longer in effect now that all facilities are subject to the FSMA standards. The rule will also amend the above-described new section governing manufacturing grade processing plants to clarify that milk received by a plant must be from a permitted source.

1. Description of Affected Industry

BOAH currently inspects 1,025 Grade A dairy farms and 24 Grade A dairy plants. These are dairies producing Grade A milk that is processed for use in products such as fluid milk and yogurt. BOAH currently inspects 27 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, proposed rule changes of the BOAH are presented at the BOAH dairy industry meeting and the annual Indiana Milk Quality Conference. 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. The state is operating under a federally mandated deadline to have all facilities operating under the FSMA standards by September 18, 2018.

As described above, these requirements have already been put in place for manufacturing grade facilities in 2016 (see LSA Document #16-222). The effect of this proposed rule is to also make these applicable to Grade A facilities through the incorporation by reference of the 2017 revision of the PMO, which integrates the key components of 9 CFR 117. Because of the wide disparity of the personnel costs for each plant to develop these plans, the costs for each plant will be highly variable and therefore the cumulative cost is difficult to quantify.

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. The rule also updates the incorporation by reference of certain FDA food standards that also apply to manufacturing grade milk products, such as cheese and ice cream. 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.

It is also important to note that the proposed rule potentially reduces compliance costs for regulated entities by eliminating a state requirement that is absent from the federal regulations. The current version of the state drug residue rule mandates that the state veterinarian suspend a farm permit whenever milk tests positive for drug residues and is confirmed. [345 IAC 8-4-1\(d\)](#). The proposed rule will align this section with the PMO, which allows other equally effective measures to be taken to prevent the sale of milk containing drug residues. This change will continue to prevent this milk from entering human food channels, but provides BOAH the discretion to avoid

requiring a dairy farmer to undergo a burdensome permit suspension and reinstatement process in appropriate circumstances.

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 1,025 Grade A farms and 24 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.

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. As discussed above, this rule will amend the new section governing manufacturing grade processing plants to clarify that milk received by a plant must be from a permitted source. [345 IAC 8-2-2.1](#). However, this will merely align the BOAH rule with the state dairy products law versus impose a new requirement. [IC 15-18-1-3](#); [IC 15-18-1-15](#). It is already a longstanding and integral part of the dairy plant receiving process to verify that milk received for processing is coming from a permitted source.

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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