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August 12, 2016

Sarah Simpson, JD
Director of Legal Affairs, Licensing and Enforcement
Indiana Board of Animal Health
Discovery Hall, Suite 100
1202 East 38th Street
Indianapolis, IN 46205

Dear Ms. Simpson,

Pursuant to IC 4-22, the Indiana Office of Small Business and Entrepreneurship (OSBE) has reviewed the economic impact analysis for small business associated with rule changes contained in LSA Document 16-222 proposed by the Indiana Board of Animal Health (BOAH). The proposed rule Amends 345 8-2-1.1 to update definitions and align certain definitions with the Grade A Pasteurized Milk Ordinance (PMO). Amends 345 IAC 8-2-1.6 to clarify what treatment of an animal makes milk "contaminated milk" unfit for human consumption. Amends 345 IAC 8-2-1.7 to clarify the pasteurization requirement for ice cream mix. Amends 345 IAC 8-2-1.9 to clarify that manufacturing grade milk products may be sold to final consumers, restaurants, and retail. Amends 345 IAC 8-2-2 to phase out the effective date for these standards in accordance with the compliance dates of 21 CFR 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk Based Preventive Controls for Human Food. Adds 345 IAC 8-2-2.1 to establish the requirements in 21 CFR 117 as the required standards for manufacturing grade milk product plants. Adds 345 IAC 8-2-2.2 to exempt a manufacturing grade milk plant that is a qualified facility from certain requirements of 21 CFR 117. Amends 345 IAC 8-2-2.5 to phase out the effective date for the plant extended run standards in accordance with the compliance dates of 21 CFR 117. Amends 345 IAC 8-2-4 to modify the milk sample container labeling requirements and remove the collection time frame for Grade A milk shipped in cans. Amends 345 IAC 8-2-5 to reference the definition of "adulterated" in IC 15-17 and remove sediment standards. Amends 345 IAC 8-3-1 to update the incorporation by reference of the Grade A PMO and other Food and Drug Administration (FDA) regulations. Amends 345 IAC 8-3-2 to establish a process for a farm to convert a milk house bulk tank into a raw milk storage vessel holding commingled milk for pasteurization. Effective 30 days after filing with the publisher.

The economic impact statement prepared by BOAH states the proposed rule will impose an economic impact on small businesses under IC 4-22-2.1-5. The proposed rule does increase annual reporting, record keeping, and other administrative costs for regulated entities. The proposed rule also increases compliance costs. 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.

In the opinion of BOAH, the proposed rule does not impose a requirement or cost beyond what is expressly required by federal or state law. BOAH states the proposed rule is necessary to comply with state and federal mandates, avoid potential negative economic development consequences, and ensure that state processing standards ease the burden of compliance.

Based upon this analysis, OSBE does not object to the economic impact to small business associated with the proposed rule. If you have any questions about the comments contained herein please contact me at 317.232.5679 or ombudsman@osbe.in.gov.

Regards,

A handwritten signature in black ink, appearing to read "R Warner", written over a horizontal line.

Robert Warner