

**VIA EMAIL**

November 15, 2024

Kian Hoss  
Staff Attorney  
Office of Legal Affairs  
Indiana Department of Health  
2 N Meridian Street  
Indianapolis, IN 46204

Re: LSA Document #24-375/Regulatory Analysis-Small Business Economic Impact Statement

Dear Mr. Hoss,

Pursuant to Indiana Code 4-22-2.1-5(c)(2), as the Small Business Ombudsman for the state of Indiana, I have reviewed the proposed rule and regulatory analysis associated with the rule changes contained in LSA Document #24-375 (proposed rule) submitted to the Indiana Small Business Ombudsman by the Indiana Department of Health (IDOH). I have found the following to be true.

Proposed rule LSA #24-375 amends 410 Indiana Administrative Code (IAC) 7-24 in order to adopt modernized U.S. Food and Drug Administration (FDA) Model Food Code, effectively serving as a repeal and replacement of current 410 IAC 7-24. The basis of this repeal and replacement stems from the need to implement updated food safety standards, trainings, and best practices, which have not been updated in Indiana since adoption of the 2001 FDA Model Food Code in 2002. The proposed rule contains several provisions, as expected, which include reference to civil penalties for violations, as set forth in 410 IAC 7-23 and a newly proposed 410 IAC 7-26 which will serve as a new code cite in an assumed separate proposed rule, updated definitions, trainings, and framework for regulation of this extensive industry.

The IDOH's provided analysis displays an above and beyond due diligence and understanding of how implementation must be carried out to ensure compliance while minimizing burdens to businesses. Thousands of entities within Indiana's food industry may be considered small businesses, the direct and indirect impact to small businesses by the proposed rule appears to be minimal as it is estimated that actual costs to businesses will range from \$15 to \$41.17 per business. Much of any impact to businesses regulated within this industry is mitigated thanks to free and regular trainings, free guiding documents, and a free electronic food inspection system for local jurisdictions' adoption. The most apparent impact to a regulated industry would be because of a violation occurrence and ensuing civil penalty, however the IDOH's proposed rule does not appear to create any new fines beyond the current structure and an estimated 90+% of establishments will already be in compliance with the various new requirements. The proposed 410 IAC 7-26 will provide a tiered structure to violations based on potential food safety risks for further clarity to how a fine may be imposed for violations of 410 IAC 7-24.

Additionally, IDOH has conducted extensive industry and local jurisdiction outreach and coordination to ensure a reasonable approach is taken to this significant overhaul of the current regulatory landscape. A supporting factor will be an increase in certainty on the regulatory framework of this industry and Indiana will be aligned with national FDA standards, as opposed to the currently two-decades outdated model, and some compliance mechanisms may result in reduced costs to entities. Based upon this statement and review, the Indiana Small Business Ombudsman supports the proposed rule related to the economic impact on small business if the IDOH's conclusion reflects the actual result after promulgation. If there are any questions about these comments, please contact me at [ombudsman@iedc.in.gov](mailto:ombudsman@iedc.in.gov).

Sincerely,  
Matt Jaworowski  
Small Business Ombudsman  
Indiana Economic Development Corporation