

# CSI - Ohio

The Common Sense Initiative

## Business Impact Analysis

Agency Name: Ohio Dept. of Agriculture

Regulation/Package Title: Food Processing Manufacturing Practices, Standards of Identity and Labeling Requirements

Rule Number(s): 901:3-1-01 through 901:3-1-12

Date: April 30, 2013

**Rule Type:**

☒ New

☐ Amended

☒ 5-Year Review

☐ Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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## **Regulatory Intent**

**1. Please briefly describe the draft regulation in plain language.**

**Please include the key provisions of the regulation as well as any proposed amendments.**

These rules cover the sanitation and safe handling of food during manufacturing and the storing of food. All rules, except 901:3-1-05 and 11, have been reviewed and found to need no change at this time. Rules 901:3-1-05 and 901:3-1-11 are being amended to correct references to other statutes and rules, however no substantive changes are being made at this time.

**2. Please list the Ohio statute authorizing the Agency to adopt this regulation.**

ORC 3715.021(B)

**3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

**If yes, please briefly explain the source and substance of the federal requirement.**

Yes and no. The department of Agriculture has had this rule in place for a while. All food manufacturers and warehouses that fall under our jurisdiction are inspected for compliance to these rules. Since 2012, the Division of Food Safety has received a grant from the FDA which provides money to allow the division to become standardized with the FDA. As part of the standardization program, ODA's rules must be equivalent to those of the FDA. As it is written currently 901:3-1 is equivalent and it needs to stay that way.

**4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

NA

**5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

These rules are the first set of regulations food manufacturers must comply with to assure the food they produce or warehouse is safe, wholesome and labeled correctly for the citizens of Ohio.

**6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

This regulation has been in effect since 2005, the safety of Ohio's food supply demonstrates the success of the rule.

## **Development of the Regulation**

- 7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

**If applicable, please include the date and medium by which the stakeholders were initially contacted.**

These rules went into effect in 2005. Before we began the rule making process various food organizations were contacted to review the proposed rule. These organizations included The Ohio Manufacturers' Association and the Grocery Manufacturers' Association.

- 8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

There was no opposition to the rule.

- 9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

NA, Used Food and Drug Administration rule.

- 10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

None, it would have done a disservice to Ohio's industry to have a regulation not in line with federal regulations.

- 11. Did the Agency specifically consider a performance-based regulation? Please explain.**

***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

For the most part these rules are performance based. There are parameters for producing safe food but they allow for facilities to how to produce the food in a safe manner.

- 12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

NA

- 13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

NA

### **Adverse Impact to Business**

**14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:**

**a. Identify the scope of the impacted business community;**

The rule applies to all food processing establishments, which by definition include all food processing facilities and food warehouses. All food to be considered safe must be manufactured using this rule. It provides the parameters good manufacturing practices. It covers everything from building design, equipment design, sanitation, food processing constraints, personnel, grounds outside the facility and labeling. Safe food cannot be manufactured unless it follows the applicable sections of OAC 901:3-1.

**b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**

The rule does not contain any provisions for license fees or fines. It is difficult to qualify employer time since all applicable portions of the rule must be followed to produce safe food. If the facility is not kept clean the food can be contaminated; if the food is not processed in a safe manner it is adulterated. Equipment must be cleaned and sanitized, floors, walls and ceiling must be cleaned, food must be cooked or held cold to keep the food safe, employees must be free from illness and use good hygiene practices to keep food safe. Everything a firm does with respect to food is controlled by this rule; therefore most of the employer time is in response to this rule.

**c. Quantify the expected adverse impact from the regulation.**

**The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a “representative business.” Please include the source for your information/estimated impact.**

There is no adverse impact from this rule; it contains science based parameters for safe food production. Industry follows this rule not only because they must also because that is how to produce safe food. It is impossible to determine a cost, be it the entire population or a representative business. The Division of Food Safety regulates everything from the largest cannery in the United States to the small independently owned business that may be producing a small amount of some food such as spice blends. This rule is how safe food is produced; safe food cannot be produced without following this rule.

**15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

To protect the citizens of Ohio.

### **Regulatory Flexibility**

**16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

No, the production of safe food is not dependent on the size of the facility.

**17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

There are no penalties for paperwork violations. When violations are found during an inspection a facility is given time to come into compliance (a minimum of 10 days) before legal remedy is sought.

**18. What resources are available to assist small businesses with compliance of the regulation?**

The Division of Food Safety provide assistance and guidance to all facilities in Ohio, it is not dependent on size.