



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Joseph Baker, Director

Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Agriculture

Rule Contact Name and Contact Information: Renee Schmauch
Renee.Schmauch@agri.ohio.gov 614-728-6295

Regulation/Package Title (a general description of the rules' substantive content):

Federal Food Safety Regulations

Rule Number(s): 901:3-17-01, 02, 03, 04

Date of Submission for CSI Review: 11/27/2023

Public Comment Period End Date: 12/15/2023

Rule Type/Number of Rules:

New/___ rules

No Change/ 3 rules (FYR? 3)

Amended/ 1 rules (FYR? 1)

Rescinded/___ rules (FYR? ___)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

- a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- c. ☐ **Requires specific expenditures or the report of information as a condition of compliance.**
- d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

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

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

901:3-17-01 incorporates by reference all the food safety regulations housed in 21 CFR 117. This rule is being amended to update the revision of 21 CFR 117 from 2017 to 2022.

901:3-17-02 amends the code of federal regulations adopted in OAC 901:3-17-01 to ensure that the proper terminology is used statewide. Specifically, we amend terminology used in the CFR to ensure that the terminology matches what is used in relevant Ohio Revised Code sections. This rule is being submitted as a no change.

901:3-17-03 sets forth the regulations housed in 21 C.F.R. part 17 which are deleted under the rules. The deleted portions relate to enforcement procedures which only apply to FDA and do not apply to the Department. This rule is being submitted as a no change.

901:3-17-04 sets forth the regulations which are amended under the rules. Many of the amendments have been made to ensure that the correct terminology is accurate for the state of Ohio. This rule is being submitted as a no change.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

ORC 3715.02, 3715.021

- 4. 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, these are federal requirements for all food processing establishments in the country. This chapter incorporates by reference the food safety regulations housed in 21 CFR 117. A few amendments have been made to ensure definitions and terminology in the CFR matches what is used in ORC. Also, the rule deletes portions that related to enforcement procedures which only apply to FDA and do not apply to the Department.

- 5. If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

Not Applicable

- 6. 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)?**

The Ohio Department of Agriculture is tasked with ensuring that all food products manufactured in the state of Ohio are produced and stored in a safe, sanitary establishment. Without these regulations food could be produced or stored in a facility that is filthy, unclean, with a high potential of food borne illnesses.

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

The Department inspects and investigates complaints regarding food manufacturers. The rules are judged as being successful when inspections and investigations find few violations, when there is no increase in the number of complaints filed with the Department, and when there are minimal health related outbreaks attributed to juice products.

- 8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No

Development of the Regulation

- 9. 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.

The following stakeholders were contacted via email on September 18, 2023, for a public comment period which remained open until October 2, 2023.

Ohio Veterinary Medical Board	ohiovma@ohiovma.org
Samuel Porter	samuel.porter@icemiller.com
Capitol Advocates	reshenbaugh@capitoladvocates.net
CIFT	twildermuth@ciftinnovation.org
Maple Producers	dnbrown33@gmail.com
Mid-Ohio Growers	midohiogrowersmtg@gmail.com
Midwest Foods Association - Ohio group	Patricia.Anderson@midwestfoodsassociation.com
Ohio Ag Council	info@ohioagcouncil.org
Ohio Apples	ohioapplemarketingprogram@gmail.com
Ohio Association of Food Banks	Lisa@ohiofoodbanks.org
Ohio Aquaculture Association	smith.11460@osu.edu
Ohio Bakery Association	loram@ohioretailmerchants.com
Ohio Beef Council/Ohio Cattlemen's Association	eharsh@ohiobeef.org
Ohio Council of Retail Merchants	info@ohioretailmerchants.com
Ohio Craft Brewer's Association	mary@ohiocraftbeer.org
Ohio Craft Brewer's Association	ashley@ohiocraftbeer.org
Ohio Dairy Producers	scott.higgins@odpa.org
Ohio Ecological Food and Farm Association	amalie@oeffa.org
Ohio Ecological Food and Farm Association	Alisha@oeffa.org
Ohio Ecological Food and Farm Association	Amber@oeffa.org
Ohio Farm Bureau	asharp@ofbf.org
Ohio Farm Bureau	jirvin@ofbf.org
Ohio Farm Bureau	lcurtis@ofbf.org
Ohio Farm Bureau	rhigh@ofbf.org
Ohio Farm Bureau	lantosch@ofbf.org
Ohio Farmers Union	joelogan.jl@gmail.com
Ohio Manufacturer's Association	raugsburger@ohiomfg.com
Ohio Pork Producers Council	cday@ohiopork.org
Ohio Poultry Association	jchakeres@ohiopoultry.org
Ohio Produce Growers Association	schachtfarmmarket@gmail.com
Ohio Restaurant Association	jbarker@ohiorestaurant.org
Ohio Restaurant Association	lmorrison@ohiorestaurant.org
Ohio Restaurant Association	tbowen@ohiorestaurant.org
Ohio Soybean Association	bkern@soyohio.org
Ohio State University	ward.311@osu.edu
Ohio State University (Farmers Markets)	welch.183@osu.edu
Ohio Wine Producers Association	dwinchell@ohiowines.org
Snack Food Association – Arlington, VA	dwalsh@sfa.org
The Ohio State University	hall.673@osu.edu
Wholesale Beer and Wine Association	tjbechtold@vorys.com
Great Lakes Community Action Partnership	rrichter@glcap.org

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

PACA Inc.
Wood County Committee on Aging
Ohio Greater Showmen Association
President/CEO- Ohio Grocers
Ohio Farmers Market Network
Ohio Farmers Market Network

dpc@pacainc.com
abradford@wccoa.net
greaterohiosa@gmail.com
kristin@ohiogrocers.org
hello@ohiofarmersmarketnetwork.org
ohiofarmersmarketnetwork@gmail.com

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

The Department did not receive any stakeholder comments during the open comment period.

11. 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?

The rules contained in the package mirror standards that are nationally accepted. The rules were developed over years of research by the FDA utilizing the industry and other public entities. The rules present the best approach to address protecting the food supply from intentional adulteration.

12. 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?
Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.

The department is statutorily tasked with developing and establishing standards for this industry. The standards that are contained in this rule are based on scientific research and are in line with the federal regulations. Lack of stakeholder participation in this rule package has indicated to the Department that this is the best regulatory scheme at this time as it allows Ohio manufacturers to ship their products across the country. For those reasons, no other regulatory alternatives were considered.

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

The Department has sole regulatory authority among Ohio agencies and acts as the in-state inspector for the FDA.

14. 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.

These rules are already implemented within the industry and the Department works with all manufacturers to educate and inform them on the requirements and regulations. The staff members of the Division of Food Safety ensure that all manufacturers in Ohio are treated in a

similar manner. The Department has online resources and has field staff available to provide assistance. Training and seminars are also available.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

All food manufacturers operating within the state of Ohio, except for those specifically exempted in the rules.

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

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.

The adverse impact from these rules is difficult to quantify. The amount of work required depends greatly on the product, the amount of product produced, and the size and layout of the facility. Many manufacturer's already have a food safety plan in place. Smaller manufacturers may choose to draft the food safety plan themselves and thereby reduce costs – or – hire an outside company to complete the necessary plan.

Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls. Current GMPs have been updated and clarified. There are no fines associated with this regulation. However, failure to comply with the requirements may result in the adulteration and eventual embargo or destruction of products.

16. Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify. (*Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors*).

No

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

The prevention of food borne illnesses and the protection of consumers is outweighed by the adverse impact of these regulations. The regulatory intent of these rules is considered justified due to the public safety risk.

Regulatory Flexibility

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

No, all food processing establishments must comply with the rule to ensure they are producing safe food.

19. 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.

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

The staff members of the Division of Food Safety ensure that all manufacturers in Ohio are treated in a similar manner. The Department has online resources and has field staff available to provide assistance. Training and seminars are also available.