



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

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Business Impact Analysis

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

Rule Contact Name and Contact Information:

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

Food Safety – Chapter 20

Rule Number(s): 901:3-20-01 to 901:3-20-05

Date of Submission for CSI Review: December 22, 2021

Public Comment Period End Date: January 17, 2022

Rule Type/Number of Rules:

New/___ rules

No Change/_5_ rules (FYR? _5_)

Amended/___ rules (FYR? ___)

Rescinded/___ rules (FYR?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.

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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):

- Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- Requires specific expenditures or the report of information as a condition of compliance.**
- 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.

The rules in chapter 901:3-20 regulate cottage food production operations in the state of Ohio. Cottage food productions operations are defined as, “a person who, in the person’s home, produces food items that are not potentially hazardous foods.” The rules act as an exemption to the general rule which requires any food production operation to be licensed and inspected regularly. The rules are as follows:

Rule 901:3-20-01 outlines the definitions as used in the Chapter.

Rule 901:3-20-02 outlines the labeling requirements for a cottage food production operation.

Rule 901:3-20-03 states that all cottage food products are subject to sampling conducted by the Department in order to ensure that the products are not adulterated or misbranded.

Rule 901:3-20-04 sets forth the cottage food products which are allowed to be produced under this chapter.

Rule 901:3-20-05 sets forth the prohibitions under the chapter.

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- 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.**

Section 3715.025 of the Revised Code.

- 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.***

No.

- 5. If the regulation 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)?**

Allowing cottage food production operations is a food conscious, business friendly approach of allowing individuals to sell safe, wholesome food products without the burden of regulation. This flexibility is not without food safety restraints. The rule is tailored in a way to only allow some low-risk food products to be sold. If an individual wants to produce products that are not on the list, they must be properly licensed to do so. Overall, the rules remove the general licensure requirements in a safe, flexible manner to allow individuals to produce and sell wholesome, non-potentially hazardous foods.

- 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 cottage food production operations. The rules are considered successful when inspections and investigations find few violations, there is no increase in the number of complaints filed with the Department, and there are minimal health related outbreaks attributed to cottage food 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.**

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

The following stakeholders were contacted via email on September 3, 2021 for a public comment period open until September 17, 2021:

Capitol Advocates – Rob Eshenbaugh

Maple Producers – Dan Brown

Ohio Association of Food Banks – Lisa Hamler-Fugit

Ohio Bakery Association- Lora Miller

Ohio Beef Council / Ohio Cattlemen’s Association – Elizabeth Harsh

Ohio Council of Retail Merchants – David Raber

Ohio Dairy Producers – Scott Higgins

Ohio Ecological Food and Farm Association – Amalie Lipstreu

Ohio Farm Bureau – Adam Sharp, Jack Irvin, Leah Curtis, Roger High, and Tony Seegers

Ohio Farmers Union – Joe Logan

Ohio Lawn Care Association – Mark Bennett

Ohio Manufacturer’s Association – Ryan Augsberger

Ohio Pork Producer’s Council – Bryan Humphreys

Ohio Poultry Association – Jim Chakeres

Ohio Produce Growers Association – Lisa Schacht

Ohio State University – Peggy Hall, Adam Ward, Christie Welch, and Gwen Wolford

Snack Food Association (Arlington, VA) – David Walsh

Wholesale Beer and Wine Association – Timothy Bechtold

Great Lakes Community Action Partnership – Robin Richter

PACA Inc. – David P. Corey

Wood County Committee on Aging – Angie Bradford

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

During the public comment period, no comments were received.

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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?

Through scientific research and experience, the cottage food products listed in rule 901:3-20-04 of the Administrative Code have been deemed low risk.

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?

The Department is statutorily obligated to produce a list of food items that a cottage food operation may produce. Based on the specific statutory requirement, no other regulatory alternatives were considered.

13. 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.*

The rules in this chapter are performance-based regulations. The rules define the food that are able to be produced in a cottage food production operation, but do not describe how that food is to be produced.

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

The Department has sole regulatory authority to regulate cottage food production operations in the state of Ohio.

15. 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.

The rules are already implemented within the industry and the Department works with all cottage food production operations to educate and inform them on the requirements and regulations.

Adverse Impact to Business

16. 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; and

All cottage food production operations operating within the state of Ohio.

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

All cottage food production operations are permitted to only produce the products listed in rule 901:3-20-04 of the Administrative Code. Individuals wishing to produce other

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foods must obtain a license from the Ohio Department of Agriculture. There are no fines, licenses, or fees associated with the regulations; however, failure to comply with the requirements may result in adulteration and eventual embargo or destruction of products.

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 quantifiable adverse impact from this regulation. There is a prohibition on producing food not on the list without a license. Cottage food production operations which produce foods not on the list, misbranded, or adulterated food would be subject to embargo and destruction of their products. The quantified loss for this cannot be calculated due to the variables of the food product.

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

The prevention of food borne illness and the protection of consumers is outweighed by the adverse impact of the regulations. The regulatory intent of the 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.

In general, these rules are an exemption for small businesses. Any further exemptions from the requirements contained in the rules would not be appropriate as the primary purpose of the rules is public safety.

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.

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

The staff of the Division of Food Safety ensure that all cottage food production operations in Ohio are treated in a similar manner. The Department has online resources and field staff available to provide assistance.