



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

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

Food Safety- Food Coloring

Rule Number(s): 901:3-1-13

Date of Submission for CSI Review: 11/26/2024

Public Comment Period End Date: 12/18/2024

Rule Type/Number of Rules:

New/___ rules

No Change/___ rules (FYR? ___)

Amended/ 1 rules (FYR? yes)

Rescinded/___ rules (FYR?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):

- 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.

Ohio Revised Code 3715.021 states that the director of agriculture shall adopt rules to conform with or be equivalent to the standards for foods established by the United States food and drug administration found in Title 21 of the Code of Federal Regulations. These rules adhere to the standards and good manufacturing practices for food processing establishments.

Ohio Administrative Code 901:3-1-13 adopts standards found in Title 21 of the Code of Federal Regulations (C.F.R.) applicable to the use of color additives in foods. The adoption of these standards allows Ohio producers to ship their products across the United States. The adoption of these standards is not a federal requirement however, by adopting the federal standards of identity, Ohio producers have the flexibility needed to expand their businesses nationwide. ODA is proposing amendments to this rule which update the effective dates of the referenced C.F.R. parts.

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.

3715.02, 3715.021, 3715.59, 3715.60

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. The adoption of these rules is not a federal requirement however, by doing so, it gives Ohio producers the flexibility needed to expand their businesses nationwide.

- 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)?**

Standards of identity are legal definitions of food products which outline what a food must contain, often in terms of ingredients and measurements, in order to be marketed as that product. This allows a consumer to be confident in purchasing this type of product by ensuring that the label accurately reflects what the product actually is.

Further, by adopting the federal standard it allows food processing establishments in Ohio to ship their products virtually nationwide because many other states have adopted these standards as well. Through this mutual adoption, food manufacturers do not have to vary their product to meet the requirements of other standards of identity.

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

The Department inspects food processing establishments and investigates complaints involving manufactured foods. The rules are judged as being successful when inspections and investigations find few violations and when there is no increase in the number of complaints.

- 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 October 11, 2024, for a public comment period which remained open until October 25, 2024.

Organization	Contact
Buckeye Quality Beef Association	David Hyde
Capital Advocates	Kurt Leib
Capitol Advocates	Rob Eshenbaugh

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CIFT	Troy Wildermuth
Government Advantage Group	Amanda Sines
Great Lakes Community Action Partnership	Robin Richter
Greater Ohio Showmen Association	general email
Greater Ohio Showmen Association	David Drake
Greater Ohio Showmen Association	Randy Kissel
Greater Ohio Showmen Association	Russell Clements
Ice Miller	Samuel Porter
Maple Producers	Dan Brown
Mid-Ohio Growers	general email
Midwest Foods Association - Ohio group	Pat Anderson
Nation Farmers Organization	Alva Heiss
Nation Farmers Organization	Tony Bensman
Nation Farmers Organization	Bill Stachler
Ohio Agribusiness Association	Aaron Heilers
Ohio Agribusiness Association	Janice Welsheimer
Ohio Agribusiness Association	Lauren Prettyman
Ohio Agribusiness Association	Melinda Witten
Ohio Apples	general email
Ohio Association of Food Banks	Joree Novotny
Ohio Bakery Association	Lora Miller
Ohio Beef Council/Ohio Cattlemen's Association	Elizabeth Harsh
Ohio Council of Retail Merchants	David Raber
Ohio Craft Brewer's Association	Ashley Rose
Ohio Craft Brewer's Association	Mary MacDonald
Ohio Dairy Producers	Scott Higgins
Ohio Ecological Food and Farm Association	Alisha Schleining
Ohio Ecological Food and Farm Association	Amber Mitchell
Ohio Farm Bureau	Adam Sharp
Ohio Farm Bureau	Jack Irvin
Ohio Farm Bureau	Leah Curtis
Ohio Farm Bureau	Roger High
Ohio Farm Bureau	Tony Seegers
Ohio Farmers Market Network	general email
Ohio Farmers Market Network	general email
Ohio Farmers Union	Joe Logan
Ohio Grocers	Kristin Mullins
Ohio Lawn Care Association	Mark Bennett
Ohio Manufacturer's Association	Ryan Augsberger

Ohio Pork Producers Council	Cheryl Day
Ohio Poultry Association	Jim Chakeres
Ohio Produce Growers Association	Lisa Schacht
Ohio Restaurant Association	John Barker
Ohio Restaurant Association	Tod Bowen
Ohio Soil and Water Conservation Commission	Jen Bowman
Ohio Soybean Association	Brandon Kern
Ohio State Grange	Mike Russell
Ohio State University	Adam Ward
Ohio State University (Farmers Markets)	Christie Welch
Ohio Veterinarian Medical Association	general email
Ohio Wine Producers	Donniella Winchell
PACA Inc.	David P. Corey
Snack Food Association – Arlington, VA	David Walsh
The Ohio State University	Peggy Hall
Wholesale Beer and Wine Association	Timothy Bechtold
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?

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?

Standards of identity were first adopted by Congress in the 1938 Food, Drug and Cosmetic Act. At the time of their enactment, Congress recognized the need to promote food safety and consumer protection by establishing consistent standards in commercial food products. Many of these standards were recognized based on the longstanding history of food safety for a particular product, the customary use of the food, and the information generally available to scientists at the time.

Since then, these standards have been updated to protect consumers from contaminated products, economic fraud, and to promote nutrition. These changes are vetted on a Federal level by the Food and Drug Administration and the United States Department of Agriculture – Food Safety Inspection Service. These two agencies utilize sixteen broad principles, many of which concentrate on the most current scientific information, to make a determination on whether or not to amend the standard of identity for any given product.

The scientific data used in developing these standards has been critical as there has been a dramatic decrease of food borne outbreaks and illnesses in the United States since that time.

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 regulating the manufacturing of food. The standards that are contained in these rules are based on scientific research and in most cases are nationally accepted. Lack of stakeholder participation in this rule package has indicated to the Department that this is the best regulatory approach at this time. 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 pursuant to ORC 3715.021.

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 food manufacturers, processors, and packagers to educate and inform them on the requirements and regulations. The staff members of the Division of Food Safety ensure that all entities 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 processing establishments operating within the state of Ohio.

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.

These rules do not have fines or penalties; however, food processing establishments must ensure that their products are produced in accordance with the rule. Failure to do so may result in the possible embargo of products and eventual destruction of the food.

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 regulatory intent of the statute and rules is to give consumers the confidence to know what kind of product they are purchasing. These rules adopt the federal standard for food products. In doing so, it gives consistency across Ohio and the country on the type of product that it contains. Proper labeling also gives consumers a clear understanding of what ingredients are included in products. This promotes public safety by warning individuals that may be sensitive to certain types of ingredients and products. Due to the nature of the risk, the adverse impact is considered to be justified.

Regulatory Flexibility

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

As the primary purpose of these rules is public safety and consumer confidence, exemptions for smaller operations are not applicable.

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 members of the Division of Food Safety ensure that all food processing establishments in Ohio are treated in a similar manner. The Department has online resources and has field staff available through a 24-hour helpline to provide assistance. Training and seminars are also available.