

# CSI - Ohio

The Common Sense Initiative

## Business Impact Analysis

Agency Name: Ohio Department of Agriculture

Regulation/Package Title: Food Safety – Food Coloring & Standards of Identity

Rule Number(s): 901:3-1-(12 & 13)

Date: January 25, 2017

**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☐ Rescinded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.*

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 Department of Agriculture 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 901:3-1-12 sets forth the standards of identity of various food products. 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. These standards are adopted by reference to the particular food standards found in 21 C.F.R. Parts 100 - 169. The rule has been updated to include standards of identity for salt and iodized salt, common or usual name for non-standardized foods, milk, cheese, and frozen desserts. The adoption of these standards allow Ohio producers to ship their products across the United States. The adoption of these rules is not a federal requirement however, by adopting the federal standards of identity, Ohio have producers the flexibility needed to expand their businesses nationwide.

Ohio Administrative Code 901:3-1-13 adopts standards found in Title 21 of the Code of Federal Regulations applicable to the use of color additives in foods. As with standards of identity, the adoption of these standards allow 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 have producers the flexibility needed to expand their businesses nationwide.

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

ORC 3715.021

### **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.*

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.

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

Not applicable.

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**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)?**

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 Ohio manufacturers to ship their products virtually nationwide because many other states have adopted these standards as well. Through this mutual adoption, manufacturers do not have to vary their product to meet the requirements of other standards of identity.

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

All food manufacturers who produce milk and dairy products in the state of Ohio are inspected and any complaints regarding labeling issues are investigated. The rules are judged as being successful when inspections find few violations, and when there is no increase in the number of complaints filed with the Department.

**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.*

On November 1, 2016, the Department reached out to its list of Food Safety stakeholders. The stakeholders had no suggested changes or requests regarding this rule package. The stakeholders are listed below:

Ohio Soft Drink Association	Kimberly McConville
Ohio Manufacturer's Association	Ryan Augsberger
Ohio Association of Food Banks	Lisa Hamler-Fugitt
Ohio Department of Education/Child Nutrition	Andrea Denning
Ohio Farm Bureau	Tony Seegers
Ohio Produce Growers Association	Lisa Schacht
Ohio Dairy Producers	Scott Higgins

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Snack Food Association – Arlington, VA	David Walsh
Maple Producers	Dan Brown
Ohio Bakery Association	Lora Miller
Ohio Council of Retail Merchants	David Raber
Wholesale Beer and Wine Association	Timothy Bechtold
Ohio Wine Producers	Donniella Winchell
	Belinda Jones
Ohio Restaurant Association	Joe Rosato
	John Barker
Mid-America Food Processors Association	Debra Gibson
Ohio Ecological Food and Farm Association	Amalie Lipstreu
Ohio State University (Farmers Markets)	Christie Welch
	Gwen Wolford
Ohio Beef Council	Elizabeth Harsh
Ohio Pork Producers Council	Bryan Humphreys
Ohio Farmers Union	Joe Logan
	Roger Wise
	Ron Sylvester
Ohio Grocers Association	Kristen Mullins
	Joe Ewig
Ohio Poultry Association	Jim Chakeres

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

As stated above, the stakeholders had no suggested changes or requests regarding this rule package.

**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?**

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.

**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?**

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. 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.

**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.*

This rule is a performance based regulation.

**12. 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.

**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.**

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**

**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;**

All food manufacturers operating within the state of Ohio.

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

These rules do not have fines or penalties, however food manufacturers 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.

**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.*

The only adverse impact from these rules would be a situation where a manufacturer wanted to classify their product as a particular product but it did not meet the standard. This impact is difficult to quantify based on a variety of factors including, the type of product, amount potentially produced, and the price of that product.

**15. 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

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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**

**16. 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 would not be applicable.

**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.

**18. 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.