

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Agriculture

Regulation/Package Title: Food Safety – Maple Syrup, Honey, Sorghum

Rule Number(s): 901:3-44-01; 901:3-45-(01-05); and 901:3-46-(01-09)

Date: May 9, 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☒ Rescinded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.

Generally, any food production operation is required to be licensed as a food processing establishment and inspected regularly by the Ohio Department of Agriculture or their local department of health. However, pursuant to Ohio Revised Code 3715.021, this general rule does not apply to processors of maple syrup, sorghum, and honey who meet certain criteria. Regardless, certain provisions of Chapter 3715 of the ORC do apply to maple syrup, sorghum, and honey. The rules of this package contain the regulations and standards of maple syrup, sorghum, and honey as allowed under the ORC.

OAC 901:3-44-01 outlines the mandatory food sampling tolerance levels for maple syrup, sorghum, and honey. As stated above, maple syrup, sorghum, and honey producers are not regulated in the same manner as other food production operations. However, ORC 3715.022 states that *all food products*, including maple syrup, sorghum, and honey, shall be sampled and tested to determine if the food product is misbranded and/or adulterated. The rules establish lead tolerance levels in maple syrup and sorghum. Maple syrup and sorghum products which are found to contain lead in greater than 500 parts per billion are considered adulterated. Further, the rule is being amended to state that all honey products sampled which detect antibiotics are adulterated. Beekeepers who apply antibiotics to their hives must withhold from drawing honey until the withdrawal period of the antibiotics has lapsed.

Pursuant to ORC 3715.24, the Department shall adopt rules which establish voluntary grades, authorized optional ingredients, standards for fill of containers, and standards of weight for the sale of maple products in this state and that specify the analytical tests to be used for determining compliance with those voluntary grade requirements. The rules in Division 901:3-45 of the Administrative Code fulfill this requirement.

OAC 901:3-45-01 replaces the existing rule, which is to be rescinded in this package. The new rule is established to mirror the grading system used to classify maple syrup utilized by the United States Department of Agriculture. The rule adopts color classifications of maple syrup which are verified by measuring light transmission of the syrup.

OAC 901:3-45-02 sets out the optional ingredients which are allowed in maple products. These optional ingredients match those ingredients allowed in federal law (See 21 C.F.R. 168.140). There are no substantive changes to this rule, rather, the rule is being amended to comply with LSC's drafting manual.

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OAC 901:3-45-03 outlines the labeling requirements for maple syrup. The rule is being amended to modify the grading labeling requirements to reflect U.S. versus Ohio. This change will allow manufacturer's to comply with federal labeling requirements should producers wish to ship their products across state lines. Further, a code reference has been updated within the rule.

OAC 901:3-45-04 sets forth the packing and fill requirements for maple syrup. The rule is being amended to make formatting changes which should help with comprehension. Further, the rule has added a requirement that all containers must be made of food grade materials.

OAC 901:3-45-05 sets forth the bulk packaging requirements for maple syrup. The rule has added a requirement that all containers must be made of food grade materials.

Ohio Revised Code 3715.024 permits maple syrup, sorghum, and honey producers to be voluntarily inspected by the Department. Upon successfully passing inspection, the producers will receive a seal of conformity and inspection by the Department. The rules below identify the requirement of these processors necessary to pass inspection.

OAC 901:3-46-01 outlines the definitions as used in the Chapter. The rule is being amended to replace "ODA" with "Department."

OAC 901:3-46-02 reiterates the option that maple syrup, sorghum, and honey processors may seek voluntary inspection. A stylistic change, which does not impact the substance of the rule, has been made.

OAC 901:3-46-03 states that maple syrup, sorghum, and honey processors who elect to be voluntarily inspected must register with the Department. A stylistic change, which does not impact the substance of the rule, has been made.

OAC 901:3-46-04 outlines the seal of conformity and inspection pursuant to ORC 3715.024. The rule is being amended for clarity and comprehension. No substantive changes to the rule have been made.

OAC 901:3-46-05 outlines the collection equipment which may be utilized in production. The rule has been amended for clarity and comprehension. No substantive changes to the rule have been made.

OAC 901:3-46-06 sets forth the packing and fill requirements for maple syrup, sorghum, and honey. The rule is being amended to make formatting changes which should help with comprehension. Further, the rule has added a requirement that all containers must be made of food grade materials.

OAC 901:3-46-07 sets forth the bulk packaging requirements for maple syrup, sorghum, and honey. The rule has added a requirement that all containers must be made of food grade materials.

OAC 901:3-46-08 outlines the good manufacturing practices which are required under the rule. The rule has been amended for clarity and comprehension. No substantive changes to the rule have been made.

OAC 901:3-46-09 establishes water supply requirement for production. The rule is being amended to comply with the incorporation by reference standards.

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

ORC 3715.021, 3715.022, 3715.023, and 3715.024.

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 rule does not implement a federal requirement however, the rule mirrors the current federal standards.

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

Not applicable.

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)?

The current state of maple syrup, sorghum, and honey regulations is an example of a food safety conscious, business friendly approach of allowing individuals to sell safe, wholesome food products without the burden of regulation. For example, these rules would allow an individual with a hobby for maple syrup, sorghum, or honey production to sell their food items as a side business or may allow a company thinking about starting a full time operation

to test the water by selling a small number of maple syrup, sorghum, and honey items without investing thousands of dollars into a full production line.

This flexibility is not without food safety restraints. The rules require mandatory food sampling and allow for voluntary inspection of their operations. The seal of conformity and inspection gives consumers the confidence that the product they are purchase is safe and wholesome.

In the end, the rule removes general licensure requirements in a safe, flexible manner to allow individuals to produce and sell wholesome, non-potentially hazardous foods.

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

The Department inspects and investigates complaints regarding maple syrup, sorghum, and honey production operations. 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 maple syrup, sorghum, and honey food products.

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.

The following stakeholders were sent the proposed rules via email on April 19, 2017:

Ohio Ecological Food and Farm Association	Amalie Lipstreu
Ohio Department of Education/Child Nutrition	Andrea Denning
Environmental Law & Policy Center	Madeline Fleisher
Ohio Beef Council/Ohio Cattlemen's Association	Elizabeth Harsh
Ohio State University (Farmers Markets)	Christie Welch
Maple Producers	Dan Brown
Ohio Council of Retail Merchants	David Raber
Snack Food Association – Arlington, VA	David Walsh
Mid-America Food Processors Association	Debra Gibson
Ohio Dairy Producers	Scott Higgins
Ohio State University (Farmers Markets)	Gwen Wolford
Ohio Farm Bureau	Jack Irvin
Ohio Produce Growers Association	Jennifer Kennedy
Ohio Farm Bureau	Tony Seegers

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Ohio Grocers Association	Joe Ewig
Ohio Farm Bureau	Yvonne Lesicko
Ohio Restaurant Association	Joe Rosato
Ohio Farmers Union	Joe Logan
Ohio Restaurant Association	John Barker
Ohio Farmers Union	Linda Borton
Ohio Farmers Union	Roger Wise
Ohio Soft Drink Association	Kimberly McConville
Ohio Grocers Association	Kristen Mullins
Ohio Pork Producers Council	Bryan Humphreys
Ohio Poultry Association	Jim Chakeres
Ohio Association of Food Banks	Lisa Hamler-Fugitt
Ohio Produce Growers Association	Lisa Schacht
Ohio Bakery Association	Lora Miller
Ohio Lawn Care Association	Mark Bennett
Ohio Manufacturer's Association	Ryan Augsburg
Wholesale Beer and Wine Association	Timothy Bechtold
Ohio State University, Extension	Dr. Gary Graham
State Apiarist	Barb Bloetscher

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

Ms. Barbara Bloetscher, the state apiarist of Ohio, provided comments with regards to the mandatory tolerance levels of honey products. Current rule specifically lists out three antibiotics whose presence in honey would render the product adulterated. Due to continual changes in the pharmaceutical industry, Mr. Bloetscher indicated that it would be impractical to specifically list out the unapproved antibiotics rather, all antibiotics should not be present in the final product. The Department incorporated this change.

Dr. Gary Graham, Ohio Maple Syrup Program leader, Ohio State University Extension, provided comments on the maple syrup side of the rules. Dr. Graham strongly agreed to the inclusion of “food grade materials” as a requirement. Further, Dr. Graham provided other comments which were unable to be included in the rule due to statutory requirements.

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?

The majority of these rules are administrative having been derived from statute. However, some of the rules have been developed through years of scientific research and data.

Specifically, the mandatory tolerances have been established to ensure that food products are safe for consumption. Further, OAC 901:3-46-08 mirror the basic good manufacturing practices established by years of experience and research.

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 obligated to promulgate the rules listed in this package.

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.*

The rules in this chapter are performance-based regulations. The rules do not define how the product is produced, rather it defines the standards which the product must meet.

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 to regulate c maple syrup, sorghum, and honey production operations in the state of Ohio.

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 maple syrup, sorghum, and honey food production operations to educate and inform them on the requirements and regulations. The staff members of the Division of Food Safety ensure that all maple syrup, sorghum, and honey production operations 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 maple syrup, sorghum, and honey production operations operating within the state of Ohio.

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

All maple syrup, sorghum, and honey production operations are prohibited from producing adulterated products. Further, maple syrup, sorghum, and honey production operations may subject themselves to voluntary inspection. Pursuant to the rules, these processors must register with the Department. There is no cost for this registration however; through voluntary registration individuals subject themselves to additional requirements.

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. Maple syrup, sorghum, and honey production operations which produce foods that are misbranded or adulterated 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.

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

The prevention of the food borne illness 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

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

As stated above, generally any food production operation is required to be licensed as a food processing establishment and inspected regularly by the Ohio Department of Agriculture or their local department of health. However, pursuant to Ohio Revised Code 3715.021, this general rule does not apply to processors of maple syrup, sorghum, and honey who meet certain criteria. Ohio Revised Code 3715.024 permits maple syrup, sorghum, and honey producers to be voluntarily inspected by the Department. Upon successfully passing inspection, the producers will receive a seal of conformity and inspection by the Department.

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 processors of maple syrup, sorghum, and honey 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.