

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Agriculture

Regulation/Package Title: Division of Food Safety – Juice Products

Rule Number(s): 901:3-23-01.

Date: September 4, 2015

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☐ Rescinded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 Administrative Code 901:3-23-01 and the rules of that chapter regulate the processing of juice products in the state of Ohio. Without proper safeguards, the juice manufacturing process can result in the growth of highly dangerous pathogens such as *Clostridium botulinum*, *E. coli* 0157:H7, *Salmonella*, and *Listeria monocytogenes*. These bacteria can result in human illnesses including respiratory problems, pneumonia, diarrhea, vomiting and in some cases can result in the death of the infected individual. Due to this high level of risk there is significant regulation to monitor the juice production industry which is designed to prevent illness and protect consumers.

901:3-23-01 sets for the criteria and definitions of juice products. This rule outlines the definitions to be used in Ohio Administrative Code Chapter 901:3-23 as well as defines the food processing establishments that are subject to the rules of the chapter. The rule is being amended to clarify the establishments who are exempt from this chapter.

Prior to the proposed amendment, the chapter excluded “a retail food establishment or food service operation defined in section 3717.01 of the Revised Code where the juice produced is only sold or served from that premises.” This allowed companies to produce raw, unpasteurized juice for consumers so long as it was produced at the site where it was sold. The Ohio Department of Agriculture (hereinafter “Department”) was contacted by several raw juice producers looking to expand their business however, were unable to as they were limited by the rule.

In order to accommodate these growing businesses, the Department has proposed to amend the rule to allow these companies to utilize a “central kitchen” model. This model would allow the raw juice companies to produce their product in a central kitchen and deliver it to their own establishments. Prior to the proposed amendment each new establishment was required to possess separate production equipment. This equipment costs thousands of dollars and limited each company’s ability to expand. With the proposed amendment, businesses would now be able to expand without the excessive cost of the additional equipment.

The rule only allows these facilities to deliver their products to either a licensed food service operation or retail food establishment which is licensed under the same name. This ensures that the product is controlled by the company itself which understands and monitors the shelf-life, safety, and quality of the products. This is important due to the food safety risks when dealing with unpasteurized juice. As stated above, without proper safeguards, the juice manufacturing process can result in the growth of potentially deadly bacteria.

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

ORC 3715.02, 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 regulation does not implement a federal requirement. However, 901:3-23-01 and the rules of that chapter allow the Department to participate in the Federal Drug Administration's (FDA) Manufactured Foods Regulatory Program Standards (MFRPS). This allows the Department's manufacture food inspection program to be considered equivalent to the FDA's inspection program.

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)?

Juice products are made of plant material which, due to ordinary growing techniques, may be contaminated with naturally occurring bacteria. These bacteria exist either as spores or as vegetative cells. The spores, which are comparable to plant seeds, can survive harmlessly in soil and water for many years. When ideal conditions exist for growth, the spores produce vegetative cells which multiply rapidly and may produce a deadly toxin within 3 to 4 days. When not properly treated, these bacteria can cause numerous health problems including, but not limited to, death of the infected individual. Through these regulations, the risk for contamination and subsequently human death is dramatically decreased.

This amendment does not relieve the raw juice establishments from monitoring their product and abiding by all other applicable sanitary and health requirements found in the Ohio Uniform Food Code. The amendment eases the regulatory burden on these small companies while preserving the food safety requirements.

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 juice producers. OAC 901:3-23-01 and the rules of that chapter 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.

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 Department reached out to the Ohio Manufacturers' Association (OMA) for review of this rule. OMA is an organization dedicated to the promotion and growth of manufacturing in Ohio. They represent many juice manufacturers and have distributed this rule to their constituents.

In addition the Department worked with raw juice companies to modify the exemption in the rule. In particular, a Columbus based raw juice company, Zest Juice, worked closely with the Department to amend this rule.

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

Zest Juice, as well as other raw juice companies, expressed the desire to expand their business. Under the current rule, raw juice was only allowed to be sold at the place of production. Therefore, each company would have to maintain expensive juice production equipment in each establishment. This would dramatically increase the cost of expanding their business. Zest Juice worked with the Department to create a "central kitchen" model which would simultaneously increase business opportunities as well as protect food safety. Zest Juice, and others like it, are very much in support of the proposed amendment.

The Ohio Manufacturer's Association did not have any negative comments to the rule.

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?

OAC 901:3-23-01 and the rules of that chapter mirror standards set forth by the FDA. The rules were developed over years of scientific research. The rules present the best scientific approach to limiting the spread of harmful bacteria to protect public safety.

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 reviewed how other states were regulating the raw juice industry and found that many states were already allowing this type of production. Upon review, the Department elected to amend the rule to allow this production to occur.

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.

Due to the serious public health risks, the Department did not consider a performance based regulation. The regulations dictate the process in order to ensure safety. Requiring each company to keep their own products within their own establishments dramatically cuts down the associated health risks.

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 among Ohio agencies and acts as the in-state inspector for the FDA.

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.

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

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 juice processors operating within the state of Ohio.

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

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Each juice processor must register as a food processing establishment under Ohio Administrative Code 901:3-21-01.

There are many factors to determining the cost of complying with this regulation. The equipment must be in working order and calibrated correctly and then records must be maintained to demonstrate that the filed process is being followed to produce a safe food. Records must then be reviewed before product is allowed to go into commerce.

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.

Establishments which serve raw, unpasteurized juice are only allowed to move their product to another establishment which is licensed under the same name as the production facility.

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 cost to register as a food processing establishment depends on the square footage of the facility. A majority of Ohio’s juice processors who register as a food processing establishment fall under the smallest category which is below 5000 square feet. The cost of this registration is \$50 annually. The largest facilities, over 100,000 square feet, must pay \$300 annually to register as a food processing establishment.

The adverse impact of these regulations is difficult to quantify as it is hard to separate production practices from regulation. The regulations dictate some equipment specifications; however equipment manufacturers specifically tailor their machinery to meet the regulations. Additionally, there are record keeping requirements which require time for employer compliance however; for the most part the machinery used in this industry automatically records this information.

Prohibiting the transportation of juice to a separate, unaffiliated establishment would limit the market share of the company. The quantified cost of this is unknown

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 rule only allows these facilities to deliver their products to either a licensed food service operation or retail food establishment which is licensed under the same name. This ensures that the product is controlled by the company itself which understands and monitors the shelf-life, safety, and quality of the products. This is important due to the food safety risks when dealing with unpasteurized juice. As stated above, without proper safeguards, juice manufacturing process can result in the growth of potentially deadly bacteria. The regulatory intent of this rule 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 the primary purpose of OAC 901:3-23-01 and the rules of that chapter is public safety, exemptions for small businesses 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. 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.

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.