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): 901:3-23-02, 03, 04, 05, 06, 07, 08, 09 and 10.

Date: September 4, 2015

Rule Type:

- ☐ New
- ☐ Amended
- X 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- ☐ Rescinded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.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov

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.

   The rules in this package regulate the processing of juice products in the state of Ohio. Without proper safeguards, 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.

   These rules contained in this package mirror federal regulations in order to allow Ohio's juice processors to be able to ship all across the country. The rules below have been reviewed in accordance with Chapter 119 of the Ohio Revised Code and are being proposed as being requiring no changes:

   901:3-23-02 states that all processors shall have and implement a sanitation standard operating procedure. This procedure addresses sanitation controls at all points in the production line including, water sanitation, cross contamination of other insanitary objects (ie. utensils, food packaging material, gloves, and clothing), and control of employee health conditions.

   901:3-23-03 sets forth the requirement that each processor shall have a written hazard analysis to determine at what steps in their juice production are food hazards likely to occur and ways that processors can apply controls to these hazards to limit their likelihood.

   901:3-23-04 requires all juice processors subject to the rules of this chapter to develop a written Hazard Analysis and Critical Control Point plan, otherwise known as a HACCP plan. This is required whenever the hazard analysis as set forth in Ohio Administrative Code rule 901:3-23-03 reveals one or more food hazards are likely to occur during production. This plan outlines critical control points where food hazards are likely to occur and critical limits which, when operating within these limits, allows the processor to decrease the likelihood of product contamination. Additionally, the HACCP plan outlines how processors will monitor these critical control points and requires the development and implementation of corrective action plans should a deviation from the critical limits occur.

   901:3-23-05 outlines the process for taking corrective actions when a deviation from a critical limit occurs. The rule states that all corrective action plans shall ensure that no product which may be injurious to consumer health or otherwise adulterated enter the stream of commerce. The rule also requires that the cause of this deviation be corrected.

901:3-23-06 requires all juice processors to verify and validate that their HACCP plan is being implemented according to its design. A processor verifies and validates their HACCP plan by reviewing any consumer complaints, calibrating instruments, and recording any deviation that may occur. This validation must take place at least once every twelve months.

901:3-23-07 requires that all juice processors maintain records which document the processor's HACCP plan. In particular, the processor must maintain records documenting that the processor continues to monitor the critical control points and their critical limits.

901:3-23-08 states that the original hazard analysis, the development, verification, and validation of the HACCP plan must be performed by an individual who has successfully completed training in the application of HACCP principals as they relate to juice processing.

901:3-23-09 requires that all juice processors subject to these rules must show in their HACCP plan that their processes will consistently produce juice that has undergone a five-log reduction for "pertinent microorganisms." A five-log reduction is a process which achieves at least a 100,000 decrease in the micro-organisms present in the juice. This process is akin to pasteurization however, other methods may be utilized to meet this requirement. These organisms include Clostridium botulinum, E. coli 0157:H7, Salmonella, and Listeria monocytogenes. This process can be obtained through a process whereby the juice is heated to a level that eradicates the bacteria present in the juice.

901:3-23-10 states that the failure of a processor to have and/or implement their HACCP plan shall render the juice that the processor produces adulterated under section 3715.59 of the ORC.

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, the rules contained in this package 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.

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. 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 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 these rules. OMA is an organization dedicated to the promotion and growth of manufacturing in Ohio. They represent many juice manufacturers and have distributed these rules to their constituents.

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

   The stakeholders had no comments to these rules. After a thorough review by the Department, these rules were deemed to require no changes.

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 rules contained in the package 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 is statutorily tasked with developing and establishing standards for this industry. The standards that are contained in this rule are based on scientific research and in are in line with the federal regulations. Stakeholder participation in this rule package has indicated to the Department that this is the best regulatory scheme at this time as it allows Ohio manufacturers to ship their products across the country. 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.**

    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. This process is recognized nationally and allows manufacturer to be able to ship their products across the country. Further, the process allows individual producers the flexibility to create a process based on their own production methods. These processes are based on the size of the food, the ingredients in the finished product and the process time. The critical control points along with the requirements of the regulation must be followed to protect against Clostridium botulinum, E. coli 0157:H7, Salmonella, Listeria monocytogenes, and other organisms.

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.**

    These rules are already implemented within the industry and 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, except for those specifically exempted in Ohio Administrative Code 901:3-23-01(B).

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

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.

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.

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 the primary purpose of these rules 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.